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Standard Terminology Relating to Medical and Surgical Materials and Devices[1]

This standard is issued under the fixed designation F2809; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This terminology standard is a repository for the terms, and their standardized definitions, as relates to the technical standards generated by ASTM Committee F04 on Medical and Surgical Materials and Devices. The meanings and explanations of the technical terms have been written for both the non-expert and the expert user.

1.2 The terms are listed in alphabetical sequence; in Appendix X1 they are listed by the subcommittee of origin.

1.3 At a minimum, this standard is updated annually (at a time corresponding to the publication of the Annual Book of ASTM Standards containing this terminology standard) to editorially include any terms approved in the Committee's technical standards.

1.4 The originating standard of each term is included for informational purposes, following each listing of a term and its associated definition.

2. Referenced Documents

2.1 *Historical ASTM Standards:*[2]

F921 Terminology Relating to Hemostatic Forceps

F1078 Terminology for Surgical Scissors—Inserted and Non-Inserted Blades

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]

F1582 Terminology Relating to Spinal Implants

F1638 Terminology for Surgical Tissue/Dressing/Pick-Up Forceps (Thumb-Type)

F1840 Terminology for Surgical Suture Needles

F2005 Terminology for Nickel-Titanium Shape Memory Alloys

F2312 Terminology Relating to Tissue Engineered Medical Products

NOTE 1—The definition for each term is accompanied by a reference to the standard from which it originated. All active standards of the Committee may therefore be considered references, and are not reproduced here.

3. Significance and Use

3.1 All approved F04 standards have their terms reproduced in this terminology document, per section 1.3. The terms are listed both alphabetically, and by subcommittee of origin, per section 1.2.

3.1.1 This standard maintains a single source for terminology reference for ASTM Committee F04.

3.1.2 This standard assists in the authoring of new ASTM standards, and standard revisions, where authors can find and utilize existing terms to avoid generation of extraneous, duplicative, or contradicting terms.

3.2 Some terms may appear more than once.

3.2.1 In some cases, multiple definitions of a term are needed, based on the variety of applications and sectors to which it applies.

3.2.2 Because this terminology standard is a repository for all approved terms of Committee F04, it may become evident that multiple definitions for a term have been developed, but need coordination.

3.2.2.1 An objective of this document is to make duplication evident, and to facilitate harmonization of terms by Committee F04 as appropriate.

3.3 Appendix X2 provides background on the history and objectives of this terminology standard.

4. Terminology

accelerator, *n*—additive used to increase the rate of cure. An accelerator may also be a catalyst, or it may actually change composition and, therefore, not qualify as a catalyst. **F602**

acetal plastic, *n*—plastic based on polymers having a predominance of acetal linkages in the main chain. (See also **polyoxymethylene**.) **F1251**

acousto-electric transfer function, H_{SE}, *n*—electrical input to the IMEHD output transducer *E* produced by a sound field,

[1] This terminology is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.97 on Editorial and Terminology.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

divided by the input sound field pressure p_S: $H_{SE} = E/p_S$. **F2504**

DISCUSSION—H_{SE} will depend on the particular gain settings used, for example, full-on gain or minimal gain. The gain should be reported whenever that transfer function is used.

acousto-vibrational transfer function (IMEHD aided), H_{SVA}, *n*—stapes velocity (IMEHD aided) divided by the input sound field pressure: $H_{SVA} = v_A/p_S$. **F2504**

DISCUSSION—This quantity can be measured directly or computed from the product of the electro-vibrational transfer function, H_{EV}, and the acousto-electric transfer function, H_{SE}, measured in the IMEHD-aided condition: $H_{SVA} = v_A/p_S$.

acousto-vibrational transfer function (unimplanted), H_{SVU}, *n*—stapes velocity (unimplanted) when driven by the input sound field, divided by the input sound field pressure: $H_{SVU} = v_U/p_S$. **F2504**

DISCUSSION—This quantity can be measured directly or computed from the product of the middle-ear transfer function, H_{TV}, and the ear-canal transfer function, H_{ST}, measured in the unimplanted condition: $H_{SVU} = v_U/p_S = H_{ST} \cdot H_{TV}$.

acrylic plastic, *n*—plastic based on polymers made with acrylic acid or a structural derivative of acrylic acid. **F1251**

activator, *n*—medical material that demonstrates a shortened clotting time; an initiator of the intrinsic coagulation pathway. **F2382**

active austenite finish temperature, *n*—(in nitinol), term used to denote austenite finish temperature of a finished wire, tube, or component as determined by a bend and free recovery method rather than by DSC. **F2005**

addition polymerization, *n*—polymerization in which monomers are linked together without the splitting off of water or other simple molecules and involves the opening of a double bond. **F1251**

additive, *n*—chemical added to epoxy resins or hardeners to modify the handling characteristics or cured properties, or both, of the epoxy-hardener combination. **F602**

diluent, n—chemical used in admixture to modify or enhance the properties of either or both the uncured or cured formulations. A primary use is to reduce the viscosity of the mixed system although other properties such as exotherm rate, stiffness, moisture absorption, and so forth, may be modified or enhanced also. **F602**

filler, n—a relatively inert solid particulate material added to an epoxy formulation to modify its strength, permanence, working properties, or other qualities, or to lower costs. **F602**

nonreactive diluent, n—a diluent not containing chemically reactive functional groups. **F602**

reactive diluent, n—a diluent that reacts chemically with the epoxy resin or hardener, or both, during cure. **F602**

additives, *n*—component of a silicone elastomer used in relatively small amounts to perform functions such as marking, coloring, or providing opacity to the elastomer. **F2038**

adhesion, *n*—physiochemical state by which a cell is coupled to a non-cell surface by interfacial forces, which may consist of covalent or ionic forces. **F2664**

adhesive failure, *n*—failure of the adhesive/substrate bond. **F2548**

adhesive strength, *n*—strength of the tissue adhesive/substrate interface. **F2548**

adventitious agents, *n*—unintentionally introduced microbiological or other infectious contaminant. In the production of TEMPs, these agents may be unintentionally introduced into the process stream or the final product, or both. **F2212, F2312**

adventitious agents, *n*—unintentionally introduced microbiological or other infectious contaminant. In the production of TEMPs, these agents may be unintentionally introduced into the manufacturing process or into the final product or both. (See Terminology F2312.) **F2383**

DISCUSSION—In this guide, adventitious agents also include microbiological or other infectious contaminants that may be endogenous to the starting cells or tissue.

aging, *n*—the process of exposing materials to an environment for an interval of time. **F1251**

aging effect, *n*—change in a material brought about by exposure of the material to an environment for an interval of time. **F1251**

alginate, *n*—polysaccharide obtained from some of the more common species of marine algae, consisting of an insoluble mix of calcium, magnesium, sodium, and potassium salts.

DISCUSSION—Alginate exists in brown algae as its most abundant polysaccharide, mainly occurring in the cell walls and intercellular spaces of brown seaweed and kelp. Alginate's main function is to contribute to the strength and flexibility of the seaweed plant. Alginate is classified as a hydrocolloid. The most commonly used alginate is sodium alginate. Sodium alginate and, in particular, calcium crosslinked alginate gels are used in Tissue Engineered Medical Products (TEMPs) as biomedical matrices, controlled drug delivery systems, and for immobilizing living cells. **F2259, F2312, F2315**

alkyd resin, *n*—polyester convertible into a crosslinked form; requiring a reactant of functionality higher than two, or having double bonds. **F1251**

allogeneic or allogenic, *adj*—cells, tissues, and organs in which the donor and recipient are genetically different individuals of the same species. Synonyms: *allograft* and *homograft*. **F2312**

allogeneic, *adj*—derived from different individuals of the same species. **F1581**

allograft, *n*—graft of tissue between individuals of the same species but of disparate genotype. Called also *allogeneic graft* and *homograft*. **Dorland's,[4] F2311, F2312**

alloy phase, *n*—*in a shape memory alloy*, the crystal structure stable at a particular temperature and stress. **F2005**

amorphous calcium phosphate, *n*—noncrystalline calcium phosphate. **F1609**

anchor, *n*—bioabsorbable device or a component of a bioabsorbable device that provides the attachment to the bone. **F2502**

anchor, *n*—components that are directly attached to the bony elements of the spine (sacrum, lamina, pedicle, vertebral body, spinous process, transverse process, the pelvis, or ribs). **F1582**

angle, *n*—defined at either the barrel/sideplate or blade/sideplate junction (see Fig. 1 and Fig. 2 of Specification F384). **F384**

angled device, *n*—class of orthopedic devices for the fixation of fractures in the methaphyseal areas of long bones that has a component aligned at an angle to the bone's long axis. **F384**

anneal, *v*—to heat treat in order to remove the effect of cold-working. **F2005**

anorganic, *adj*—denoting tissue (for example, bone) from which the organic material has been totally removed. Also referred to as *deorganified*, *deproteinized* or *deproteinated*. **F1581**

anterior curvature, *n*—condylar design which is generally planar except for a concave—upward region anteriorly on the tibial component. **F1223**

anterior posterior (AP), *n*—any geometrical length aligned with the AP orientation. **F1223**

antigens, *n*—these are substances that stimulate the host to produce an immune response. **F1905**

AOO, *n*—acetone olive oil solution (4:1 v/v) is a suitable nonpolar solvent. **F2148**

AP displacement, *n*—relative linear translation between components in the AP direction. **F1223**

AP draw load, *n*—force applied to the movable component with its vector aligned in the AP direction causing or intending to cause an AP displacement. **F1223**

APA bead, *n*—alginate-poly-L-lysine-alginate bead. **F2312, F2315**

apatite, *n*—mineral substance having the molecular formula $Ca_{10}(X)_2(PO_4)_6$ where X=OH (hydroxyapatite or hydroxylapatite), CO_3 (carbonated apatite), F or C1 (**8**). **F1581**

apparent density, *n*—*see* **density, apparent**. **F1251**

aqueous solvent, *n*—in this assay refers to the polar solvent, saline. **F2148**

articular insert, *n*—polymeric prosthetic portion of a multiple piece glenoid component that articulates with the humeral head. **F1829**

artifact width, *n*—maximum distance (mm) from the edge of the implant to the fringe of the resulting image artifact found in the entire set of images acquired using this test method. **F2119**

artificial intervertebral disc, *n*—synthetic structure that is permanently implanted in the disc space between two adjacent vertebral bodies to provide spinal column support and allow intervertebral motion. **F2346**

artificial weathering, *n*—exposure of a material to laboratory conditions that simulate outdoor weathering.

DISCUSSION—Exposure conditions may be cyclic, involving changes in temperature, relative humidity, radiant energy, and many other elements found in the atmosphere in various geographical areas. The laboratory exposure conditions are usually intensified beyond those encountered in actual out-door exposure to accelerate the effect. **F1251**

assembly, *n*—complete implant configuration (not including spine, pelvis, ribs, or substitute material) as intended for surgical use. **F1582**

atraumatic, *adv*—teeth that would interdigitate except for being spaced apart a predesigned distance so they will not stress, crush, or otherwise traumatize the tissue being grasped. **F1638**

attachment area, *n*—portion of the needle where the attachment of the suture takes place. For example, eyed, drilled, and channel. **F1840**

austenite, *n*—high temperature parent phase in Ni-Ti shape memory alloys with a B2 crystal structure. This phase transforms to R-phase or martensite, or both, on cooling. **F2005**

austenite finish temperature (A_f), *n*—(in nitinol), temperature at which the martensite to austenite transformation is completed on heating in a single-stage transformation (Fig. 1) or the temperature at which the R-phase to austenite transformation is completed on heating in a two-stage transformation (Fig. 2). **F2005**

austenite peak temperature (A_p), *n*—(in nitinol), temperature of the endothermic peak position on the differential scanning calorimeter (DSC) curve upon heating for the martensite to austenite transformation in a single-stage transformation (Fig. 1) or the temperature of the endothermic peak position on the DSC curve upon heating for the R-phase to austenite transformation in a two-stage transformation (Fig. 2). **F2005**

austenite start temperature (A_s), *n*—(in nitinol), temperature at which the martensite to austenite transformation begins on heating in a single-stage transformation (Fig. 1) or the temperature at which the R-phase to austenite transformation

[4] Dorland, WAN, Dorland's Illustrated Medical Dictionary, 29th Ed., W.B. Saunders Company, Philadelphia, 2000.

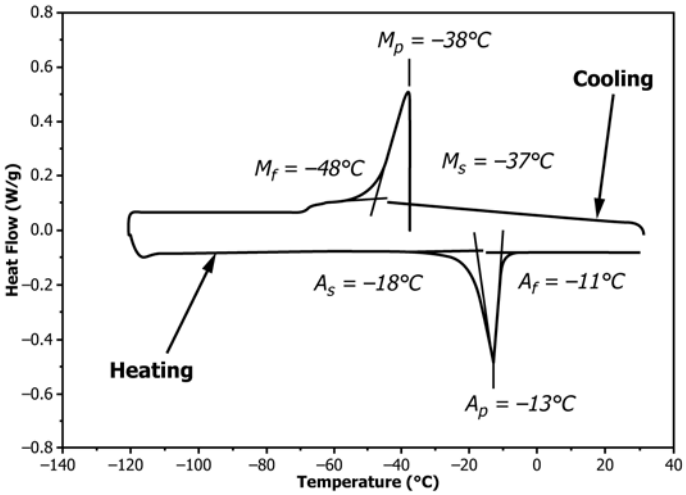

FIG. 1 DSC Graph for a Single-Stage Transformation (Source F2005)

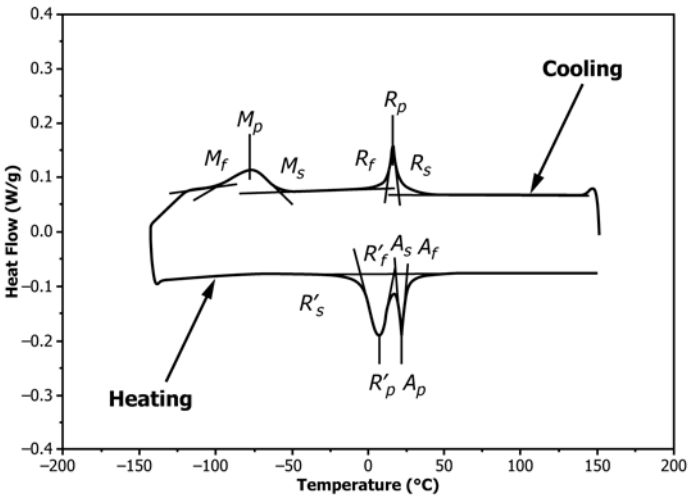

FIG. 2 DSC Graph for a Two-Stage Transformation (Source F2005)

begins on heating in a two-stage transformation (Fig. 2). **F2005**

auto compression, *n*—type of bone plate that by its design can generate a compressive force between adjacent unconnected bone fragments through the use of one or more ramped holes or another type of slot geometry. This ramp or slot geometry contacts the underside of the screw head, and induces compressive force as the screw is inserted and tightened to the bone plate. **F382**

autograft, *n*—graft of tissue derived from another site in or on the body of the organism receiving it.
Dorland's, F2311, F2312

autologous, *adj*—cells, tissues, and organs in which the donor and recipient is the same individual. Synonyms: *autogenous*, *autograft*, or *autotransfusion*, a *self-to-self graft*. **F2312**

axial load; axial translation, *n*—force and displacement, respectively, perpendicular to the glenoid plane; the axial load simulates the net compressive external and muscle forces (see Fig. 1 of Test Methods F2028). **F2028**

axial pull-out load (N), *n*—tensile force in N required to fail or remove a screw from a material into which the screw has been inserted when tested in accordance with Specification and Test Methods F543, Annex A3. **F2193**

axial pullout strength, *n*—tensile force required to fail or remove a bone screw from a material into which the screw has been inserted. **F543**

balloon expandable stent, *n*—stent that is expanded at the treatment site by a balloon catheter. The stent material is plastically deformed by the balloon expansion such that the stent remains expanded after deflation of the balloon. **F2394**

balloon (Foley) catheter, *n*—indwelling catheter retained in the bladder by a balloon that is inflated with liquid. **F623**

DISCUSSION—A two-way balloon catheter has a drainage lumen and inflation lumen (see Fig. 1). Common balloon inflation sizes are 5 cm^3 with the 5-cm^3 balloon being used to hold the catheter in place for normal usage, and 30 cm^3 where so designated when a larger balloon is used. A three-way balloon catheter is used for continuous bladder irrigation and features both a drainage lumen and an irrigation lumen (but as noted above is excluded from consideration in this specification).

balloon integrity (resistance to rupture), *n*—volume of liquid that corresponds with balloon failure, or bursting. **F2528**

band, *n*—flexible anchor component with a noncircular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components using a knot or similar tying mechanism, forming a locked, closed loop. **F1582**

barrel, *n*—portion of an angled device which captures the lag screw (see Fig. 1 of Specification F384). **F384**

barrel length, L_{BR}, *n*—distance from the free end of the barrel to the interior vertex of the barrel/sideplate junction (see Fig. 1 of Specification F384). **F384**

barrier coat, *n*—silicone elastomer layer that is part of the shell of a silicone gel implantable breast prosthesis that retards silicone bleed. **F703**

bearing element, *n*—articulating surface element between the femoral head and shell or bonding agent (bone cement). **F2091**

bearing surface, *n*—those regions of the component which are intended to contact its counterpart for load transmission. **F1223**

bend and free recovery (BFR), *n*—(in nitinol), test method for determining austenite transformation temperatures on heating.

DISCUSSION—The test involves cooling a wire or tube specimen below the M_f temperature, deforming the specimen in a controlled fashion, then heating through the austenite transformation. By measuring the shape memory response of the specimen A_s and A_f, temperatures can be determined. This test method is covered in Test Method F2082. **F2005**

bending compliance, *n*—reciprocal of the stiffness of the IMFD under a bending load in a specified plane as defined and determined in the static four-point bend test described in Annex A1 in Specification Test Methods F1264. **F1264**

bending fatigue runout moment (N·m), *n*—value in N-m of the maximum moment that can be applied to a spinal component where all of the tested samples have experienced 2 500 000 loading cycles without a failure at a specific *R*-ratio. **F2193**

bending moment arm, *L* (mm), *n*—distance in mm between the point where the test sample is gripped (typically the axis of the longitudinal element) and the line-of-action for the applied force prior to any deformation of of the assembly. (See dimension L of Fig. A4.2 of Specifications and Test Methods F2193). **F2193**

bending stiffness, K (N/mm), *n—of a bone plate*, the maximum slope of the linear elastic portion of the load versus load-point displacement curve for a bone plate when tested according to the test method of Annex A1 of Specification F382. **F382**

bending stiffness, *S* (N/mm), *n*—slope in N/mm of the initial linear elastic portion of the load versus total displacement curve (slope of line *0m* in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

bending strength (N-m), *n—of a bone plate*, the bending moment necessary to produce a 0.2 % offset displacement in the bone plate when tested as described in Annex A1 of Specification F382. **F382**

bending strength, *n—of the sideplate*, the bending moment necessary to produce a 0.2 % offset displacement in the sideplate when tested as described in Annex A1 of Specification and Test Methods F382. **F384**

bending structural stiffness, EI (N-m^2), *n—of a bone plate*, the bone plate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration when tested according to the method described in Annex A1 of Specification F382. **F382**

bending structural stiffness, EI_e, *n—of the sideplate*, the sideplate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration when tested according to the method described in Annex A1 of Specification and Test Methods F382. **F384**

bending ultimate moment (N·m), *n*—maximum bending moment in N-m that can be applied to a test sample. This would correspond to the bending moment at Point *E* in Fig. A4.1 of Specifications and Test Methods F2193. **F2193**

bending yield moment (N·m), *n*—bending moment in N-m necessary to produce a 0.2 % offset displacement in the spinal component. If the specimen fractures before the test reaches the 0.2 % offset displacement point, the bending yield moment shall be defined as the bending moment at fracture (point *D* in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

beta tricalcium phosphate, *n*—calcium phosphate substance of empirical chemical formula, $Ca_3(PO_4)_2$ (see Specification F1088). **F1609**

bioabsorbable device, *n*—class of implants that are designed to deteriorate by means of biological resorption once they are implanted into the body. **F2502**

bioactive agents, *n*—any molecular component in, on, or with the interstices of a device that is intended to elicit a desired tissue or cell response.

DISCUSSION—Growth factors, antibiotics, and antimicrobials are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included. **F2312, F2450**

bioactive agents, *n*—any molecular component in, on, or within the interstices of a device that elicits a desired tissue or cell response. Growth factors, antibiotics, and antimicrobials are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included. **F2150**

biconcave, *n*—condylar design with pronounced AP and ML condylar radii seen as a "dish" in the tibial component or a "toroid" in the femoral component. **F1223**

biological product, *n*—"any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man."[5]

DISCUSSION—The term analogous product is interpreted to encompass somatic cell and gene therapy.[6] A biological product may be used as a component of a TEMP. For the purposes of TEMPs, these biological products may be of any origin (that is, organism), tissue type, developmental stage, and may be living, non-living, and genetically or otherwise modified. **F2312**

biological resorption, *n*—process by which degraded biomaterials (that is, products of degradation) are eliminated or incorporated, or both, by means of physiological metabolic routes. **F2502**

biomarker, *n*—biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment. **F2664**

biomaterial, *n*—any substance (other than a drug), synthetic or natural, that can be used as a system or part of a system that treats, augments, or replaces any tissue, organ, or function of the body. **Dorland's, F2311, F2312, F2664**

biomolecule, *n*—biologically active peptide, protein, carbohydrate, vitamin, lipid, or nucleic acid produced by and purified from naturally occurring or recombinant organisms, tissues or cell lines or synthetic analogs of such molecules. A biomolecule may be used as a component of a TEMP. **F2312**

[5] Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a).

[6] FDA, CFR, Title 21, Volume 7, Part 600.3(h), Biological Products: General, Definitions, Revised 04/01/03.

biomolecule therapy, *n*—use of biomolecules to repair, modify, or regenerate the recipient's cells, tissues, or organs or their structure and function, or both. Biomolecule therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

blade, *n*—portion of an angled device which transmits the off axis loading of the anatomical loading condition to the sideplate portion of the angled device (see Fig. 2 of Specification F384). **F384**

blade, *n*—segment that contains the cutting edge which may be with or without serrations. **F1078**

blade alignment, *n*—positioning of the blades with respect to tip match-up and blade setting. **F1078**

blade length, L_{BD}, *n*—distance from the free end of the blade to the interior vertex of the blade/sideplate junction (see Fig. 2 of Specification F384). **F384**

blank, *n*—extraction vehicle not containing the specimen under test which is used for comparison with the extract liquid. **F619**

blank time, *n*—period at the beginning of an assay when no data is taken. This is done to eliminate interference from premixing reagents, bubbles, and so forth. **F2382**

blind (end)-pore, *n*—pore that is in contact with an exposed internal or external surface through a single orifice smaller than the pore's depth. **F2450**

blister, *n*—in sheet plastics, an imperfection, a rounded elevation of the surface, with boundaries that may be more or less sharply defined, somewhat resembling in shape a blister on the human skin. **F1251**

block copolymer, *n*—essentially linear copolymer in which there are repeated sequences of polymeric segments of different chemical structure. **F1251**

bloom, *n*—visible exudation or efflorescence of a performance additive on the surface of a material. **F1251**

body, *n*—central portion of the needle intended to be grasped by the needle holder. **F1840**

bolt, *n*—anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads with the lead threads accomodating a nut thus sandwiching the bony element or implant component between the nut or washer and bolt head or other fixed stop. **F1582**

bolt interconnection, *n*—interconnection having an implant component sandwiched between two nuts or between a nut and fixed stop. **F1582**

bone anchor, *n*—bioabsorbable device that provides a means to attach soft tissue to bone with a suture. **F2502**

bone plate, *n*—device with two or more holes or slots, or both, and a cross section that consists of at least two dimensions (width and thickness), which generally are not the same in magnitude. The device is intended to provide alignment and fixation of two or more bone sections, primarily by spanning the fracture or defect. **F2502**

bone plate, *n*—metallic device with two or more holes or slot(s), or both, and a cross section that consists of at least two dimensions (width and thickness) which generally are not the same in magnitude. The device is intended to provide alignment and fixation of two or more bone sections, primarily by spanning the fracture or defect. The device is typically fixed to the bone through the use of bone screws or cerclage wire. A partial list of general types of bone plates is given in 4.1 of Specification F382. **F382**

bone plate length, *L* (mm), *n*—linear dimension of the bone plate measured along the longitudinal axis as illustrated in Fig. A4.2 of Specification and Test Methods F2502. **F2502**

bone plate length, *L* (mm), *n*—linear dimension of the bone plate measured along the longitudinal axis as illustrated in Fig. 2 of Specification F382. **F382**

bone plate thickness, *b* (mm), *n*—linear dimension of the bone plate measured parallel to the screw hole axis as shown in Fig. A4.2 of Specification and Test Methods F2502. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section. **F2502**

bone plate thickness, *b* (mm), *n*—linear dimension of the bone plate measured parallel to the screw hole axis as shown in Fig. 1a, 1b, and Fig. 2 of Specification F382. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section. **F382**

bone plate width, *w* (mm), *n*—linear dimension of the bone plate measured perpendicular to both the length and thickness axes as shown in Fig. A4.2 of Specification and Test Methods F2502. **F2502**

bone plate width, *w* (mm), *n*—linear dimension of the bone plate measured perpendicular to both the length and thickness axes as shown in Fig. 2 of Specification F382. **F382**

bottom scissor half, *n*—component which contains the threaded end of the screw. **F1078**

box lock, *n*—junction where the female member and the male member are secured forming the pivoting feature. **F921**

breaking angle, *n*—angle of rotation when the screw fails in torsion as demonstrated by a rapid decrease in the indicated torque. **F543**

bulk density, *n*—weight per unit volume of a material including voids inherent in the material as tested.

DISCUSSION—This term is sometimes used synonymously with apparent density. **F1251**

bulk factor, *n*—ratio of the volume of a given mass of molding material to its volume in the molded form.

DISCUSSION—The bulk factor is also equal to the ratio of the density of the material to its apparent density in the unmolded form. **F1251**

bulk oxidation index (BOI), *n*—sample's bulk oxidation index (BOI) is the average of the oxidation indices collected over a 500-mm section at the center of the sample. **F2102**

DISCUSSION—Typically, this is a plateau region with the smallest oxidation indices.

DISCUSSION—For samples less than about 8 to 10 mm thick, this central region may display the sample's highest oxidation indices, depending on its state of oxidation.

buttress thread, *n*—asymmetrical thread profile characterized by a pressure flank which is nearly perpendicular to the screw axis. **F543**

butylene plastic, *n*—plastic based on resins made by the polymerization of butene or copolymerization of butene with one or more unsaturated compounds, the butene being in greatest amount by weight. **F1251**

cable, *n*—group of strands helically twisted together. **F2180**

cable, *n*—multi-strand, flexible longitudinal element designed primarily to resist axial tension loading. **F1582**

calcium phosphate, *n*—any one of a number of inorganic chemical compounds containing calcium and phosphate ions as its principal constituents. **F1609**

calcium sulfate anhydrite, *n*—chemical substance having approximate molecular formula of $CaSO_4$. **F2224**

calcium sulfate dihydrate, *n*—chemical having the approximate molecular formula of $CaSO_4 \cdot 2H_2O$. This substance is also known as gypsum. **F2224**

calcium sulfate hemihydrate, *n*—chemical substance having approximate molecular formula of $CaSO_4 \cdot 1/2H_2O$ or $CaSO_4 \cdot H_2O \cdot CaSO_4$. The mineral name of this substance is bassanite and the substance is also known as Plaster of Paris in the clinical literature **F2224**

calibrated range, *n*—distance over which the linear displacement sensor system is calibrated. **F2537**

calibration certificate, *n*—certification that the sensor meets indicated specifications for its particular grade or model and whose accuracy is traceable to the National Institute of Standards and Technology or another international standard. **F2537**

cancellous screw, *n*—screw designed primarily to gain purchase into cancellous bone. Cancellous screws typically have a HB thread and may or may not be fully threaded. **F543**

cantilever plane, *n*—plane perpendicular to the line of load application at the level on the stem where the stem becomes unsupported. **F1440**

carpal component, *n*—articulating member inserted into or through the carpal bones. **F1357**

cartilage regeneration, *n*—formation of articular-like cartilage that has histologic, biochemical, and mechanical properties similar to that of native articular cartilage.[7] **F2451**

cartilage repair, *n*—process of healing injured cartilage or its replacement through cell proliferation and synthesis of new extracellular matrix.[7] **F2451**

cast film, *n*—film made by depositing a layer of plastic, either molten, in solution, or in a dispersion, onto a surface, solidifying the deposit and removing the film from the surface. **F1251**

catalyst, *n*—component of a silicone elastomer formulation that initiates the crosslinking reaction when the material is vulcanized. **F2038**

cavity, *n*—any slot, cut, hole, or other feature within the shell intended to accommodate modular adjunct fixation elements; instruments for insertion, extraction, and so forth; or for manufacturing purposes. **F2091**

cell, *n*—a small partially or completely enclosed cavity. **F1251**

cell, closed, *n*—*see* **closed cell**.

cell, open, *n*—*see* **open cell**.

cell, *n*—"the smallest structural unit of an organism that is capable of independent functioning, consisting of one or more nuclei, cytoplasm, and various organelles, all surrounded by a semipermeable cell membrane."[8]

DISCUSSION—Cells are highly variable and specialized in both structure and function, though all must at some stage synthesize proteins and nucleic acids, use energy, and reproduce. A cell or cells may be of any origin (that is, organism), tissue type, developmental stage, and may be living, non-living, and genetically or otherwise modified. Cells may be used as a component of a TEMP. **F2312**

cell culture, *n*—*in vitro* growth or maintenance of cells. **F2312**

cell mediated immunity (CMI), *n*—some antigens stimulate the production of lymphocytes that react specifically with the antigen. These cells do not circulate widely in the host and are generally located at the site of antigen deposition. The use of living lymphocytes is required to test for CMI to an antigen. **F1905**

cell therapy, *n*—administration of cells (any kind and form) to repair, modify or regenerate the recipient's cells, tissues, and organs or their structure and function, or both. Cell therapy

[7] Billings, E. J., von Schroeder, H., Mai, M., Aratow, M., Amiel, D., Woo, S. Y., and Coutts, R., "Cartilage Resurfacing of the Rabbit Knee," *Acta Orthopaedic Scandinavia*, 61, 1990, pp. 201-203 and Eyre, D., Brickley-Parsons, D., and Glimcher, M., "Predominance of Type I Collagen at the Surface of Avian Articular Cartilage," *FEBS Letters*, 85, 1978, pp. 259-263.

[8] American Heritage Dictionary of the English Language, Fourth Edition, Houghton Mifflin, 2000.

technologies can be applied in tissue engineering to generate TEMPs. **F2312**

chain extender, *n*—*(1)* active hydrogen containing compound such as a diol or diamine used to increase the molecular weight of an isocyanate-terminated prepolymer by chemical reaction; *(2)* diisocyanate used to extend a polyol-terminated polyurethane by chemical reaction. **F624**

chain terminating agent, *n*—active hydrogen containing a compound such as a monofunctional alcohol, amine, or acid that reacts with the isocyanate group of a prepolymer to prevent further chain growth. **F624**

chamfer, *n*—broken edge of the jaw serrations and the external edges of the box lock surfaces. **F921**

chamfer, *n*—broken external edges of the instrument. **F1078**

channelyzer, *n*—pulse height analyzer; places voltage pulses into appropriate size bins for the size distribution data. **F2149, F2312**

chemically foamed polymeric material, *n*—cellular material in which the cells are formed by gases generated by thermal decomposition or other chemical reaction. **F1251**

chitosan, *n*—linear polysaccharide consisting of β(1→4) linked 2-acetamido-2-deoxy-D-glucopyranose (GlcNAc) and 2-amino-2-deoxy-D-glucopyranose (GlcN). Chitosan is a polysaccharide derived by *N*-deacetylation of chitin. **F2260, F2312**

chitosan, *n*—linear polysaccharide consisting of β(1→4) linked 2-acetamido-2-deoxy-D-glucopyranose (GlcNAc) and 2-amino-2-deoxy-D-glucopyranose (GlcN). **F2103**

DISCUSSION—Chitosan is a polysaccharide derived by N-deacetylation of chitin.

chlorofluorocarbon plastic, *n*—plastic based on polymers made with monomers composed of chlorine, fluorine, and carbon only. **F1251**

chlorofluorohydrocarbon plastic, *n*—plastic based on polymers made with monomers composed of chlorine, fluorine, hydrogen, and carbon only. **F1251**

chord length, *n*—straight line distance between the two ends of a curved needle. **F1840**

circularity, *n*—deviations of taper cross section from a perfect circle. **F2345**

clamp, *n*—interconnection component whose mechanism to secure the longitudinal element is through a squeezing action.

DISCUSSION—For example, crimps, wedges, set screws. **F1582**

clastogen, *n*—any agent that is capable of inducing chromosome breaks. **E1280**

clip applier, *n*—any clip holder designed specifically for a particular type clip used during surgical procedures involving the implantation of intracranial aneurysm clips. This device is referred to in this practice as a clip applier **F700**

closed cell, *n*—cell totally enclosed by its walls and hence not interconnecting with other cells. (See also **cell** and **open cell**.) **F1251**

closed cell, *n*—void isolated within a solid, lacking any connectivity with an external surface. Synonym: *closed pore*. **F2450**

closed-cell foamed plastic, *n*—plastic in which almost all the cells are noninterconnecting. **F1251**

closed cryotip, *n*—hollow, closed end usually shaped to fit a particular anatomical site where the cryogen cools the external surface which is applied to the target tissue. **F882**

closed cryotip reference temperature, *n*—average of the minimum/maximum cycle temperature variation at the end of the freeze cycle. **F882**

closed section, *n*—any cross section perpendicular to the longitudinal axis of a solid IMFD or hollow IMFD in which there is no discontinuity of the outer wall. To orient the IMFD for testing and for insertion, the desired relationship of any irregularities, asymetries, and so forth, to the sagittal and coronal planes should be described for the intended applications. **F1264**

coating, *n*—layer of mechanically or chemically attached material covering a substrate material. **F1609**

cohesive failure, *n*—failure of the internal adhesive bond. **F2458**

cohesive strength, *n*—internal strength of the adhesive. **F2458**

coincidence, *n*—more than one cell transversing the aperture at the same time. **F2149, F2312**

cold flow, *n*—*see* preferred term **creep**. **F1251**

collagen, *n*—Type I collagen is a member of a family of structural proteins found in animals.

DISCUSSION—Type I collagen is part of the fibrillar group of collagens. It derives from the COL1A1 and COL1A2 genes, which express the alpha chains of the collagen. All collagens have a unique triple helical structure configuration of three polypeptide units known as alpha-chains. Proper alignment of the alpha chains of the collagen molecule requires a highly complex enzymatic and chemical interaction *in vivo*. As such, preparation of the collagen by alternate methods may result in improperly aligned alpha chains and, putatively, increase the immunogenicity of the collagen. Collagen is high in glycine, L-alanine, L-proline, and 4-hydroxyproline, low in sulfur, and contains no L-tryptophan. Natural, fibrillar Type I collagen is normally soluble in dilute acids and alkalis. When heated (for example, above approximately 40°C), collagen is denatured to single alpha chains (gelatin). At each end of the chains are short non-helical domains called telopeptides, which are removed in some collagen preparations. Through non-covalent interactions with sites on adjacent helixes, fibrillogenesis is achieved. Subsequently, non-reducible cross-links are formed. Type I collagen can be associated with Type III and Type V collagen and also with the other non-collagenous proteins like elastin and other structural molecules like glycosaminoglycans and complex lipoproteins and glycoproteins. **F2212, F2312**

combination product, *n*—as defined in 21 CFR § 3.2(e), the term combination product includes: *(1)* A product comprised of two or more regulated components, that is, drug/device,

biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; *(2)* Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; *(3)* A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, for example, to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or *(4)* Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect." Furthermore, "many somatic cell products administered to patients will be combinations of a biological product and a device or of a drug, a biological product, and a device."[9] The term "combination product" may apply to TEMPs. **F2312**

compact bone, *n*—classification of ossified boney connective tissue characterized by the presence of osteons containing lamellar bone. **F2451**

comparative hemolysis, *n*—comparison of the hemolytic index produced by a test material compared with that produced by a standard reference material such as polyethylene at the same test conditions. **F756**

complement, *n*—this is a complex system of circulating proteins (enzymes, pro-enzymes, and co-factors) found in the blood. This system is usually activated by antigen-antibody reactions and is a reflection of humoral immunity. However, it is apparent that other factors can activate the complement system. These include large polysaccharides and various materials and tissues. Activation of complement can affect the immune system, inflammation, and vascular activity with fever and shock as a consequence of complement activation in the host. **F1905**

component, *n*—any single element used in an assembly. **F1582**

compressed gas cylinder, *n*—container that is specifically designed to store a gas or liquid under elevated pressure conditions. **F882**

compressed gas cylinder connector, *n*—device specifically designed to attach to a cylinder for proper and safe removal of its contents. **F882**

compression bending stiffness, (K), *n—of a device*, the maximum slope of the linear elastic portion of the load versus displacement curve, when tested as described in Annex A1 of Specification F384. **F384**

compression bending strength, *n—of a device*, the bending moment necessary to produce a 0.2 % offset displacement in the device when tested as described in Annex A1 of Specification F384. **F384**

compression molding, *n*—process for molding a material in a confined cavity by applying pressure and usually heat. **F1251**

condensation polymer, *n*—polymerization in which during an acid/base reaction a small molecule is often split out. **F1251**

condyles, *n*—entity designed to emulate the joint anatomy and used as a bearing surface primarily for transmission of the joint reaction force with geometrical properties which tend to govern the general kinematics of the TKR. **F1223**

cone, *n*—proximal end of the femoral component fabricated as a truncated right cone and used to engage with a mating conical bore of the modular femoral head. **F2345**

cone angle, *n*—included angle of cone (Fig. 1 of Test Methods F2345). **F2345**

construct, *n*—a complete implant configuration attached to and including the spine, pelvis, ribs or substitute material as intended for surgical use. **F1582**

container, *n*—product used for the containment of discarded medical needles and other sharps. **F2132**

continuous flow blood pump, *n*—blood pump that produces continuous blood flow due to its rotary motion. **F1841**

contouring, *v*—manipulation and bending of a bone plate, either pre-operatively or intra-operatively, to match the anatomic geometry of the intended fixation location. **F382**

cooling rate, *n*—absolute value of the instantaneous rate of change of temperature during cooling. **F2386**

coordinate system/axes, *n*—global *XYZ* orthogonal axes are defined following a right-handed Cartesian coordinate system in which the *XY* plane is to bisect the sagittal plane angle between superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The global axes are stationary relative to the IVD prostheses' inferior end plate fixture, which, in this guide, is also considered to be stationary with respect to the test machine's frame. Lower case letters, *xyz*, denote a local, moving orthogonal coordinate system attached to the superior end plate fixturing with directions initially coincident with those of the global *XYZ* axes, respectively. The 3-D motion of the superior relative to inferior end plate fixture is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z*, axial rotation; *x*, lateral bending; and *y*, flexion-extension). **F2423**

origin, n—center of the global coordinate system is located at the initial position of the total disc replacement's instantaneous center of rotation (COR). **F1582**

[9] FDA Regulation, Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, October 14, 1993, (58 FR 53248).

X-axis, n—positive *X*-axis is a global fixed axis relative to the testing machine's stationary base and is to be directed anteriorly relative to the specimen's initial unloaded position.

Y-axis, n—positive *Y*-axis is a global fixed axis relative to the testing machine's stationary base and is directed laterally relative to the specimen's initial unloaded position.

Z-axis, n—positive *Z*-axis is a global fixed axis relative to the testing machine's stationary base and is to be directed superiorly relative to the specimen's initial unloaded position.

x-axis, n—positive *x*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed anteriorly relative to the prosthesis.

y-axis, n—positive *y*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed laterally relative to the prosthesis.

z-axis, n—positive *z*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed superiorly relative to the prosthesis.

coordinate system/axes, *n*—three orthogonal axes are defined as follows: **F2385**

origin, n—center of the coordinate system is located at either the geometric center of the acetabular component segment or the center of a circle defined using the edge of the acetabular component.

X-axis, n—positive *X*-axis is to be directed in the medial direction independent of which hip is to be studied. Some software programs correct the sign of this value but the user must insure that the protocol maintains the convention, (that is, which way is the patient facing).

Y-axis, n—positive *Y*-axis is to be fixed in the superior direction.

Z-axis, n—positive *Z*-axis is to be fixed in the posterior direction.

coordinate system/axes, *n*—three orthogonal axes are defined by Terminology F1582. The center of the coordinate system is located at the geometric center of the artificial intervertebral disc. Alternative coordinate systems may be used with justification. The *XY*-plane is to bisect the superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The positive *Z*-axis is to be directed perpendicular to the bisector of the disc space, oriented in the superior direction. The positive *X*-axis is parallel to the intervertebral space, oriented in the anterior direction and the positive *Y*-axis is parallel to the disc space, oriented in the left direction. Force components parallel to the *XY*-plane are shear components of loading. The compressive axial force is defined to be the component in the negative *Z* direction. Torsional load is defined to be the component of moment parallel to the *Z*-axis. **F2346**

copolymer, *n*—polymer consisting of molecules characterized by the repetition (neglecting ends, branch junctions and other irregularities) of two or more different types of monomeric units. See **polymer**. **F1251**

copolymerization, *n*—*see* **polymerization** and **copolymer**. **F1251**

core, *n*—central rod that moves in and out of the sensor. **F2537**

DISCUSSION—It is preferable that the sensors prevent the core from exiting the sensor housing.

core diameter, *n*—smallest diameter of the threaded portion of the screw measured at the thread root. This is also known as the minor diameter or root diameter. **F543**

corrected count, *n*—cell count corrected for coincidence. **F2149, F2312**

corrosion, *n*—formation of rust. **F921, F1078**

corrosive wear, *n*—wear in which chemical or electrochemical reaction with the environment is significant. **F1875**

cortical screw, *n*—screw designed primarily to gain biocortical purchase into cortical bone. Cortical screws typically have a HA thread and are fully threaded. **F543**

coupling, *n*—points and methods of attachment. **F2504**

coverage, *n*—length, parallel to the taper surface, that the bore and cone interfaces are in contact. **F1875**

cranioplasty plate, *n*—implanted prosthetic device used to repair or cover a skull defect or hole. **F622**

crazing, *n*—apparent fine cracks at or under the surface of a plastic.

DISCUSSION—The crazed areas are composed of polymeric material of lower density than the surrounding matrix. **F1251**

creep, *n*—time-dependent part of strain resulting from stress. **F1251**

crescent section, *n*—bone plate cross-section shape (perpendicular to the long axis of the bone plate) where the thickness is not constant along the section. Typically the section is thickest along the bone plate's centerline and tapers to a smaller thickness at the bone plate's edges (see Fig. 1b of Specification F382.) **F382**

crevice corrosion, *n*—localized corrosion of a metal surface at, or immediately adjacent to, an area that is shielded from full exposure to the environment because of close proximity between the metal and the surface of another material. **F1875**

crimp, *v*—to secure the stent on the delivery system by radially compressing and plastically deforming the stent onto the balloon. **F2394**

cross-contamination, *n*—unintended presence of a cell or a material with another cell or material. **F2312**

crosslinker or cross-linking agent, *n*—component of a silicone elastomer that is a reactant in the crosslinking reaction that occurs when an elastomer is vulcanized. **F2038**

cryoadhesion, *n*—cryotip attachment to target tissue. **F882**

cryogen, *n*—substance used to obtain reduced temperatures. Cryogens are usually classed by their boiling points. The

most common cryogens and their respective boiling points are as follows: **F882**

Cryogen	Boiling Point at S.T.P., °C
Freon 12	-29.8
Freon 22	-49.8
Carbon Dioxide (CO_2)	-78.6
Nitrous Oxide (N_2O)	-88.5
Liquid Nitrogen (LN_2)	-195.8

cryometer, *n*—device for measuring low temperature(s) when used with a temperature sensor such as a thermocouple. **F882**

cryonecrosis, *n*—destruction of tissue cells using a cryosystem. **F882**

cryopreservation solution, *n*—preservation medium to which has been added one or more cryoprotectants. **F2386**

cryoprobe, *n*—instrument used to deliver the cryogen to the cryotip or open tip. For a cryotip, a cryoprobe also directs the cryogen away from the target tissue. **F882**

cryoprotectant, *n*—chemical or biological substance or mixture of substances used to protect cells or matrix, or both, during cryopreservation and rewarming. In general usage, a cryoprotectant is added to a preservation medium to form a cryopreservation solution. **F2386**

cryosystem, *n*—all parts of a system excluding the cryogen and its container, unless supplied by the manufacturer, that is designed to apply or use a cryogen. **F882**

crystalline phases:— **F2024**

Chemical and Mineral Names	Formula	PDF Card No. 3
whitlockite beta-tricalcium phosphate	β-$Ca_3(PO_4)_2$	9-169
calcium phosphate alpha-tricalcium phosphate	α-$Ca_3(PO_4)_2$	9-348
lime calcium oxide	CaO	37-1497
hydroxyapatite (hydroxylapatite)	$Ca_5(PO_4)_3OH$	9-432

cumulative moisture content, M_t (%), *n*—amount of absorbed moisture in a material at a given time t, expressed as a percentage of the weight of absorbed moisture divided by the initial specimen weight, as follows: **F1634**

$$M_t\% = \frac{W_i - W_b}{W_b} \times 100$$

where:

W_i = current specimen weight, g, and
W_b = initial (baseline) specimen weight at $t = 0$ and standard laboratory atmosphere, g.

cure, *v*—to change the properties of a polymeric system into a more stable, usable condition by the use of heat, radiation, or reaction with chemical additives.

DISCUSSION—Cure may be accomplished, for example, by removal of solvent or crosslinking. **F1251**

cure, *v*—to change the properties of a polymeric system into a final, more stable, usable condition by the use of heat, radiation, or reaction with chemical additives. **F602**

cure cycle, n—schedule of time periods at specified conditions to which a reacting thermosetting material is subjected to reach a specified property level. **F602**

cure time, n—interval of time from the start of reaction to the time at which specified properties of the reacting thermosetting composition are reached. For materials that react under the conditions of mixing, the start of reaction is the time of initial exposure to the conditions necessary for reaction to occur. **F602**

functionally cured, v—term used to denote an epoxy plastic that has attained sufficient cure to achieve stable properties. **F602**

fully cured, v—term used to denote total disappearance of epoxy groups as detected by infrared spectroscopy, or other equally sensitive physicochemical methods. **F602**

one-component system, n—a formulation based on an epoxy resin preblended with a heat, moisture, or otherwise activated curing agent or catalyst. The mixture is storable but cures under the appropriate activation conditions. **F602**

postcure, n—additional and separate curing operations to which a "hardened" thermosetting plastic composition is subjected in order to enhance one or more properties. Also used to ensure stabilization of physical properties under use conditions. **F602**

two-component system, n—formulation based on an epoxy resin to which a curing agent or catalyst is added just prior to use. **F602**

curing agent or hardener, *n*—compound normally used in a predetermined concentration to react chemically (copolymerize) by means of several different mechanisms (for example, condensation or addition polymerization) with or without heat or pressure in order to change its form from a liquid or fusible, friable, soluble solid to an infusible, insoluble solid having useful and desirable application or end-use properties. **F602**

initiator, n—additive used to cause a thermosetting resin to react with itself (polymerize). Usually, these additives—used in relatively very small amounts—initiate homopolymerization of the epoxy resin resulting in ether linkages. **F602**

DISCUSSION—The term "catalyst" is frequently misused to denote any material added to a resin to cause a reaction to occur. This usage should be discouraged. The Society of Plastics Industries defines a catalyst as "a compound which alters the speed of a reaction without changing its original composition."

curvature, *n*—shape of the needle viewed in profile. Some common shapes include, but are not limited to: straight, ½

curve or "ski", ⅛ circle, ¼ circle, ⅜ circle, ½ circle, ⅝ circle, and compound curvature. **F1840**

cutoff length, *n*—cutoff length defines the maximal value of the mean twist of profile irregularities that shall be considered in the roughness measurement, that is, with a cutoff length of 0.8 mm, the profile irregularities with a mean twist higher than 0.8 mm shall not be considered.

DISCUSSION—Precise definitions of roughness parameters, cutoff length, and roundness are given in ISO 4287/1, ISO 5436, ISO 4291, and ISO 6318:1985.

cutting edge, *n*—cutting edges are made of various goemetric shapes, that is, triangular, diamond, and hexagonal. The various edges may be sharpened by the manufacturer depending on the user performance. **F1840**

cyanmethemoglobin reagent, *n*—reagent to which whole blood, plasma, or test supernatant is added that quickly converts most of the forms of hemoglobin to the single cyanmethemoglobin form for quantification at its 540-nm spectrophotometric peak. The reagent (based on that by van Kampen and Zijlstra **(1)**, pH 7.0-7.4), is made with 0.14-g potassium phosphate, 0.05-g potassium cyanide, 0.2-g potassium ferricyanide, and 0.5 to 1 mL of nonionic detergent diluted to 1 L with distilled water. The conversion time of this reagent is 3 to 5 min. This reagent is recommended by the National Commission for Clinical Laboratory Studies (NCCLS) and may be made from the chemicals or purchased from supply houses. The first cyanmethemoglobin reagent used to measure total blood hemoglobin concentration was Drabkin's Reagent (1 g of sodium bicarbonate, 0.05 g of potassium cyanide, 0.2 g of potassium ferricyanide, and diluted with distilled water to 1 L). The disadvantages of using the Drabkin's reagent versus the NCCLS cyanmethemoglobin reagent are that it has a conversion time of 15 min and pH of 8.6 which may cause turbidity. However, it is still available as individual chemicals or kits such as Sigma 525-A. The Drabkin's and cyanmethemoglobin reagents were developed to quantify the high hemoglobin concentration normally found in whole blood (for example, 15 000 mg/dL). By modifying the sample dilution volumes and accounting for background interference, these reagents can also be used to measure much lower plasma or supenatant hemoglobin concentrations as well (Moore et al, Malinauskas **(2)**, **(3)**). **F756**

cyclics and linears, *n*—low molecular weight volatile cyclic siloxane species are referred to using the "D" nomenclature which designates the number of Si-O linkages in the material (usually D_4-D_{20}); species from D_7 to D_{40} (or more) may be called "macrocyclics". Linears are straight chain oligomers that may be volatile or of higher molecular weight, depending on chain length; they are designated by "M" and "D" combinations, where "M" is R_3Si-O, and D is as explained above; "R" is usually methyl. (For example, MDM is $(CH_3)_3SiOSiOSi(CH_3)_3$). Low molecular weight species are present in silicone components to varying degrees depending on process and storage. The levels of macrocyclics that can be removed from silicone polymers by vacuum, high temperature stripping, or oven post-cure is dependent on the conditions used. **F2038**

cytocrit, *n*—ratio of cell volume to the total volume of solution and cells for a cell suspension. **F2386**

data acquisition device, *n*—data recorder shall be suitable to continuously record torque versus angle of rotation, as well as linear displacement, calibrated in units of Newton-metres for torque and degrees for angle of rotation. The value of torque shall have a resolution of 5 % of torsional yield strength. The angular displacement scale shall have a minimum sensitivity so as to enable an accurate offset measurement capability for a 2° angular displacement (see A1.5.3 of Specification and Test Methods F2502). **F2502**

data acquisition system, *n*—system generally consisting of a terminal block, data acquisition card, and computer that acquire electrical signals and allows them to be captured by a computer. **F2537**

decomposition, *n*—structural changes of chitosans as a result of exposure to environmental, chemical, or thermal factors, such as temperatures greater than 200°C. **F2103**

DISCUSSION—Decomposition can result in deleterious changes to the chitosan.

decomposition, *n*—structural changes of hyaluronan due to exposure to environmental, chemical, or thermal factors. Decomposition may occur at temperatures as low as 121°C during autoclaving. Decomposition can result in deleterious changes to the hyaluronan. **F2347**

defrost, *v*—ability to return the cryotip to ambient temperature. **F882**

degradation, *n*—change in chemical, physical, or molecular structure or appearance (that is, gross morphology) of material. **F2212**

degradation, *n*—change in the chemical structure, physical properties, or appearance of a material. **F2103**

DISCUSSION—Degradation of polysaccharides occurs by means of cleavage of the glycosidic bonds, usually by acid —catalyzed hydrolysis. Degradation can also occur thermally. Note that degradation is not synonymous with decomposition. Degradation is often used as a synonym for depolymerization when referring to polymers.

degradation, *n*—change in the chemical structure, physical properties, or appearance of a material. Degradation of polysaccharides occurs via cleavage of the glycosidic bonds. It is important to note that degradation is not synonymous with decomposition. Degradation is often used as a synonym for depolymerization when referring to polymers. **F2259, F2260**

degradation, *n*—change in the chemical structure, physical properties or appearance of a material. Degradation of polysaccharides occurs via cleavage of the glycosidic bonds, usually by acid catalyzed hydrolysis. Degradation can also occur thermally and by alkali. It is important to note that degradation is not synonymous with decomposition. Degradation is often used as a synonym for depolymerization when referring to polymers. Degradation (depolymerization)

of hyaluronan may also occur enzymatically by the action of hyaluronidases. **F2347**

degradation, *n*—deleterious change in the chemical structure, physical properties, or appearance of a plastic. **F1251**

degradation, *n*—loss of material or function or material properties as a result of causes other than that associated with wear. **F2423**

degree of deacetylation, *n*—fraction or percentage of glucosamine units (GlcN: deacetylated monomers) in a chitosan polymer molecule. **F2260, F2312**

degree of deacetylation, *n*—fraction or percentage of glucosamine units (deacetylated monomers) in a chitosan polymer molecule. **F2103**

delivery system, *n*—system similar to a balloon dilatation catheter that is used to deliver and deploy a stent at the target site and then removed. **F2394**

density, apparent, *n*—weight in air of a unit of volume of a material.

DISCUSSION—This term is sometimes used synonymously with bulk density. **F1251**

density, bulk, *n*—weight in air of a unit of volume of a material.

DISCUSSION—This term is commonly used synonymously with apparent density. **F1251**

depolymerization, *n*—reduction in the length of a polymer chain to form shorter polymeric units. **F2259, F2260**

depolymerization, *n*—reduction in length of a polymer chain to form shorter polymeric units. Depolymerization may reduce the polymer chain to oligomeric or monomeric units, or both. **F2312**

depolymerization, *n*—reduction in length of a polymer chain to form shorter polymeric units. **F2103**

DISCUSSION—Depolymerization may reduce the polymer chain to oligomeric or monomeric units, or both. In chitosan, hydrolysis of the glycosidic bonds is the primary mechanism.

depolymerization, *n*—reduction in length of a polymer chain to form shorter polymeric units. Depolymerization may reduce the polymer chain to smaller molecular weight polymers, oligomeric, or monomeric units, or combination thereof. In hyaluronan, acid hydrolysis of the glycosidic bonds is the primary mechanism. **F2347**

depth locator (DL), *n*—measurement of the distance from the articular surface, or surface of interest, that a spectrum was collected and a corresponding OI calculated. **F2102**

depth locator (DL), *n*—measurement of the distance from the articular surface, or surface of interest, that a spectrum was collected and a corresponding TVI calculated. **F2381**

dermal autograft, *n*—skin [autograft] from which epidermis and subcutaneous fat have been removed; used instead of fascia[10] in various plastic [surgery] procedures. **Dorland's F2311, F2312**

detachment, *n*—process whereby an adhered cell or group of cells is actively detached from a surface. **F2664**

deterioration (of a bioabsorbable device), *n*—action or process that results in a reduction of mass or mechanical performance properties, or both. **F2502**

device, *n*—"an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,...which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Devices are "intended to affect the structure or any function of the body." (Section 201(h)(1)).[11]

DISCUSSION—Device criteria: "A liquid, powder, or other similar formulation intended only to serve as a component, part or accessory to a device with a primary mode of action that is physical in nature."[12] A device may be used as a component of a TEMP. **F2312**

Dewar, *n*—vacuum-insulated container that is specifically designed to store a liquid cryogen. **F882**

Dewar withdrawal device, *n*—device specifically designed to attach to a dewar for proper and safe removal of its contents. **F882**

diamagnetic material, *n*—material whose relative permeability is less than unity. **F2052, F2213**

diameter, *n*—distance between opposing points across the circle circumscribing either the strand or cable as illustrated in Figs. 1 and 2 of Specification F2180 (see MIL-DTL-83420J, MIL-DTL-83420/1B and MIL-DTL-83420/2B). **F2180**

differential scanning calorimeter (DSC), *n*—device that is capable of heating a test specimen and a reference at a controlled rate and of automatically measuring the difference in heat flow between the specimen and the reference both to the required sensitivity and precision. **F2005**

differential scanning calorimetry (DSC), *n*—technique in which the difference in heat flow into or out of a substance and an inert reference is measured as a function of temperature while the substance and the reference material are subjected to a controlled temperature program. This test method, as it applies to Ni-Ti shape memory alloys, is covered in Test Method F2004. **F2005**

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[10] "a sheet or band of fibrous tissue such as lies deep to the skin..." (Dorland's).

[11] Federal Food Drug and Cosmetic Act (21 U.S.C. 321(g)(1)); Portions revised or new—As Amended by the FDA Modernization Act of 1997, definitions revised/posted November 17, 1998.

[12] Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, 1991.

differential variable reluctance transducer (DVRT), *n*—linear displacement sensor made of a sensor housing and a core. The sensor housing contains a primary coil and a secondary coil. Core position is detected by measuring the coils' differential reluctance. **F2537**

direct contact test, *n*—test for the hemolytic property performed with the test material in direct contact with the blood. **F756**

disinfection, *n*—destruction or reduction of pathogenic and other kinds of microorganisms by thermal or chemical means (for example, alcohol, antibiotics, germicides). **F2312**

dislodgment force, peak, *n*—stent securement test endpoint characterizing the peak or maximum force required to completely dislodge the stent from the delivery system balloon. During a test, this force will occur after or coincide with the initial displacement force. (See Fig. X2.1 of Guide F2394.) **F2394**

dispersion, *n*—uncured silicone elastomer dispersed in a suitable solvent to allow application of a thin layer of elastomer to a substrate by either dipping or spraying. **F2038**

displacement, *n*—integral of velocity measured in nanometres. **F2504**

displacement force, critical distance peak, *n*—stent securement test endpoint characterizing the maximum force required to displace the stent with respect to the balloon a critical distance. This critical distance is the minimum of the following two distances. The first is the distance at which the undamaged stent could overhang the balloon body resulting in a clinically significant, incomplete end deployment. The second is the length (distance) of stent compression or buckling that could result in a clinically significant incomplete deployment of the stent against the vessel walls. (See Fig. X2.1 of Guide F2394.) **F2394**

displacement force, initial, *n*—stent securement test endpoint characterizing the initial force required to displace the stent with respect to the balloon such that the displacement is a non-recoverable movement (see 3.1.15). (See Fig. X2.1 of Guide F2394.) **F2394**

displacement force, initial peak, *n*—stent securement test endpoint characterizing the first peak in force that occurs during or after stent displacement with respect to the balloon. (See Fig. X2.1 of Guide F2394.) **F2394**

disposable, *adj*—any device that is designated to be discarded after use. **F882**

distal, *adj*—refers to the balloon end of the enteral feeding device. **F2528**

distal end, *n*—working end, comprised of two jaws, that is furthest from the surgeon when in use. **F921**

distal end, *n*—working end, comprised of two blades, that is furthest from the surgeon when in use. **F1078**

distal stem axis, *n*—centerline in the anterior/posterior projection of the most distal 50 mm of the stem. **F1440**

distraction, *n*—separation of the femoral component(s) from the tibial component(s) in the *z*-direction. **F1223**

DMSO, *n*—dimethylsulfoxide (nonaqueous, suitable organic solvent). **F2148**

DNCB, *n*—2,4-dinitrochlorobenzene. **F2148**

donor, *n*—living or deceased organism who is the source of cells or tissues, or both, for research or further processing for transplantation in accordance with established medical criteria and procedures. **F2312**

dressing, *n*—any of various materials utilized for covering and protecting a wound. **Dorland's, F2311, F2312**

drug, *n*—"articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Drugs are "intended to affect the structure or any function of the body of man or other animals." (Section 201(g)(1)).

DISCUSSION—Drug criteria: "A liquid, powder, tablet or other similar formulation that achieves its primary intended purpose through chemical action within or on the body, or by being metabolized." A drug may be used as a component of a TEMP. **F2312**

drug therapy, *n*—is the delivery of drug(s) that stimulate a specific physiologic (metabolic) response. Drug therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

dry shipper, *n*—storage and transportation device for frozen products that contains a liquid nitrogen (LN) absorbent material in the walls of the container. This device is designed to maintain cryogenic temperature for several days. **F2386**

duplicate flag, *n*—agreement between the results of duplicate samples in percent. For example, if set to "15," the difference between the two channels must be less than or equal to 15 %. If the variance in clot times exceeds this percentage, an asterisk "*" will be printed by the average results on the report. **F2382**

ear-canal pressure transfer function, H_{ST}, *n*—ear canal sound pressure, p_T, produced by the input sound field pressure, p_S, in the unimplanted case, divided by that input sound field pressure: $H_{ST} = p_T/p_S$; this quantity is unitless. **F2504**

ear-canal sound pressure, p_T, *n*—sound pressure produced in the ear canal, at the tympanic membrane, by a sound field stimulus, specified in units of pascals. **F2504**

edge detection, *n*—method of image analysis used to determine the two dimensional or three dimensional center point of a curved surface. Many computational methods of edge detection exist. **F2385**

edge displacements, *n*—translation, perpendicular to the glenoid plane, of a specific point on the outside edge of the glenoid, when subjected to loading (see Fig. 3 of Test Methods F2028). **F2028**

elasticity, *n*—capacity of the instrument to undergo induced stress without permanent distortion or breakage of any component. **F921**

elastomer, *n*—macromolecular material that at room temperature returns rapidly to approximately its initial dimensions and shape after substantial deformation by a weak stress and release of the stress. **F1251**

electro-vibrational transfer function, H_{EV}, *n*—stapes velocity (IMEHD-aided) when driven by the IMEHD output transducer, divided by the transducer input: $H_{EV} = v_A/E$. **F2504**

electrolyte, *n*—diluent, offering slight conductivity, in which cells are suspended. **F2149, F2312**

encapsulation, *n*—procedure by which biological materials, such as cells, tissues, or proteins, are enclosed within a microscopic or macroscopic semipermeable barrier. **F2312, F2315**

end flaring, *n*—distal or proximal outward conical opening of the diameter of the stent on the balloon. End flaring is a contributing factor to the probability that the stent may become caught during withdrawal into a guide catheter while tracking through a lesion. **F2394**

endotoxin, *n*—high molecular weight lipopolysaccharide (LPS) complex associated with the cell wall of gram-negative bacteria that is pyrogenic in humans. Though endotoxins are pyrogens, not all pyrogens are endotoxins. **F2312, F2347, F2383**

endotoxin, *n*—high-molecular-weight lipopolysaccharide (LPS) complex associated with the cell wall of gram-negative bacteria that is pyrogenic in humans. **F2103, F2212**

DISCUSSION—Though endotoxins are pyrogens, not all pyrogens are endotoxins.

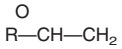
endotoxin, *n*—pyrogenic lipopolysaccharides derived from bacterial cell walls, usually associated with membrane protein unless purified. Though endotoxins are pyrogens, not all pyrogens are endotoxins. **F2315**

engraftment, *n*—incorporation of grafted tissue into the body of the host. **Dorland's, F2311, F2312**

enteral feeding device with retention balloon, *n*—two-way medical device intended to provide a means of nutrition or administration of medication, or both, to patients by means of natural orifice (nasal, oral, transluminal) or a surgically created stoma, or both, consisting of a drainage lumen and inflation lumen (see Fig. 1 of Test Methods F2528). Common balloon inflation sizes are 5, 15, and 20 cm^3. **F2528**

epidermal autograft, *n*—autograft consisting primarily of epidermal tissue, including keratinocyte stem cells, but with little dermal tissue.[13] **F2312**

epoxy, *n*—oxirane ring structures. **F602**



epoxy plastic, n—thermoplastic or thermosetting plastics containing ether or hydroxyalkyl repeating units or both, resulting from the ring-opening reactions of lower molecular weight polyfunctional oxirane resins or compounds, with catalysts or with various polyfunctional acidic or basic coreactants. **F602**

epoxy resin, n—generally, any resin (liquid or solid) with a chemical structure at least difunctional in oxirane. Specifically for this standard, the diglycidyl ethers of bisphenol A or the equivalent. These compounds are defined as Grade 1 in Specification D1763. **F602**

epoxy plastic, *n*—thermoplastic or thermosetting plastic containing ether or hydroxyalkyl repeating units, or both, resulting from the ring-opening reactions of lower-molecular weight polyfunctional oxirane resins, or compounds, with catalysts or with various polyfunctional acidic or basic coreactants.

DISCUSSION—Epoxy plastics often are modified by the incorporation of diluents, plasticizers, fillers, thixotropic agents, or other materials. **F1251**

equator of the articulating surface, *n*—equator of the articulating surface is the circle normal to the revolution axis of the component, the center of which is the center of the spherical articulating surface. **F2033**

equilibration time, *n*—time allowed for the plasma samples to warm to 37°C. The fibrometer can be set to zero if samples are pre-warmed to this temperature. **F2382**

equilibrium freezing temperature, *n*—temperature at which an aqueous solution of a given composition is in equilibrium with ice. **F2386**

equivalent hearing level, L_H, *n*—ratio of an equivalent sound pressure, p_Q, relative to the sound field pressure, p_{RETSPL}, at 0° incidence that is just detectable monaurally by a normally hearing individual, as defined in ANSI S3.6, Table 9, expressed in decibels: $L_H = 20 \cdot \log_{10}(p_Q/p_{RETSPL})$. **F2504**

equivalent sound pressure, p_Q, *n*—unimplanted input sound field pressure needed to produce a stapes velocity equal to that produced by a specified IMEHD input in the IMEHD-aided condition: $p_Q = E \cdot H_{ES}$. **F2504**

DISCUSSION—The equivalent sound pressure is the product of the equivalent sound pressure transfer function, H_{ES}, and the IMEHD output transducer electrical input *E:* $p_Q = E \cdot H_{ES}$. The equivalent sound pressure can be expressed as equivalent sound pressure level in units of decibels, SPL_{eq}, calculated as $20 \cdot \log_{10}(p_Q/2 \cdot 10^{-5}$ Pa).

equivalent sound pressure level, L_Q, *n*—logarithmic representation of equivalent sound pressure, $L_Q = 20 \cdot \log_{10}(p_Q)$. **F2504**

equivalent sound pressure transfer function, H_{ES}, *n*—unimplanted sound field pressure needed to produce a stapes velocity equivalent to that produced by an electrical IMEHD input in the IMEHD-aided condition, divided by the IMEHD input. **F2504**

[13] For practical details, see Fang, P., Engrav, L. H., Gibran, N. S., Horani, S., Kiriluk, D. B., Cole, J. K., Fleckman, P., Heimbach, D. M., Gauer, G. J., Matsumura, H., and Warner, P., "Dermatome Steeing for Autografts to Cover Integra®," J Burn Care Rehabil, 23, 2002, pp. 327-332; and Kagan, R. J., Invited editorial, J Burn Care Rehibil, 23, 2002, p. 326.

DISCUSSION—If the electrical IMEHD input produces a linear change in stapes velocity with a change in input electrical stimulus, the equivalent sound pressure transfer function, H_{ES}, can be computed as the quotient between the vibro-electric transfer function (IMEHD-aided), H_{EV}, and the vibro-acoustic transfer function (unimplanted), H_{SVU}: $H_{ES} = (v/E)/(v/p_S) = H_{EV}/H_{SVU}$.

estimated maximum bending moment, *n*—maximum load times the unloaded moment arm. **F1440**

ethylene plastic, *n*—plastic based on polymers of ethylene or copolymers of ethylene with other monomers, the ethylene being in greatest amount by mass. **F1251**

eutectic point, *n*—temperature(s) at which the solute(s) in a solution become saturated due to freeze-concentration and precipitate from the solution, causing the unfrozen liquid water to simultaneously freeze. **F2386**

expansion anchor, *n*—component that forms a connection to bony element by means of a mechanism which enlarges once the component is inserted into the bony elements. **F1582**

expansion head screw, *n*—threaded anchor that is designed so that the head can be elastically deformed, through mechanical means, to establish an interconnection with another spinal construct element. **F2193**

exposed length (mm), *n*—linear distance measured in mm between the surface of the test block that the screw is embedded in during the test and the location where the screw is anchored (typically the axis of the longitudinal element) in the test fixture (see Fig. A4.2 of Specifications and Test Methods F2193). **F2193**

external circuit, *n*—wires, connectors, measuring devices, current sources, and so forth that are used to bring about or measure the desired electrical conditions within the test cell. **F1875**

extracellular matrix, *n*—"(ECM), any material produced by cells and excreted to the extracellular space within the tissues. It takes the form of both ground substance and fibers and is composed chiefly of fibrous elements, proteins involved in cell adhesion, and glycosaminoglycans and other space-filling molecules. It serves as a scaffolding holding tissues together and its form and composition help determine tissue characteristics."[4] Extracellular matrix, a biological material or tissue derivative, may be used as a component of a TEMP. **F2312**

extract liquid, *n*—that liquid which, after extraction of the specimen, is used in tests. **F619**

extract test, *n*—test for the hemolytic property performed with an isotonic extract of the test material, as described in F619, in contact with the blood. **F756**

extraction vehicle, *n*—liquid specified for use in testing the plastic. **F619**

fabrication, *n*—process by which the uncured elastomer is converted into a fully vulcanized elastomer of the desired size and shape. This process may occur in the same facility as the manufacture of the uncured elastomer but is more typically performed at the facility of a customer of the silicone manufacturer. **F2042**

calendaring, v—the process of forming an uncured, mixed elastomer into a thin sheet or film by passing it between two rolls. **F2042**

compression molding, v—process in which the uncured elastomer is placed in an open mold. The mold is closed and pressure applied to the mold to fill the cavity. Heat is applied to vulcanize the elstomer, the mold is than opened and the fabricated part is removed. **F2042**

dispersion, n—the process of placing an uncured elastomer in a solvent. This lowers the viscosity of the material and is usually done to allow the fabrication of thinner films that can be obtained by calendaring or to form coatings. Following dispersion use, the solvent must be removed either before or during the vulcanization process. Care must be taken to assure that the solvent is compatible with the elastomer, to prevent preferential settling of the components of the formulation by excessive dilution of the elastomer. **F2042**

extrusion, n—a continuous process in which the mixed, uncured elastomer is forced through an orifice having the desired cross-sectional profile. The elastomer is then vulcanized by passing it through either a hot air or radiant heat oven. The most common application of extrusion processing is the fabrication of tubing but it can be used to produce other items as well. **F2042**

freshening, v—because of the interaction that can occur between the fumed silica and silicone polymers, thick uncured high consistency elastomers can become so stiff over time that they are very difficult to process. To overcome this problem, a two–roll mill is used to disrupt this interaction, resulting in a material which is easier to fabricate. This process is called freshening and is typically done immediately before catalyzation. **F2042**

injection molding, v—fabrication of elastomers into forms defined by molds constructed so that the uncured elastomer can be transferred by pumping into the closed mold. This method requires venting of the mold in some manner. The elastomer may be vulcanized by heating the mold after it is filled but more typically the molding conditions (temperature and filling rate) are adjusted so that uncured elastomer can be added to a pre-heated mold in which it will then cure. The mold is than opened and the part removed and post-cured, if necessary. **F2042**

post-cure, n—the process of subjecting a vulcanized elastomer to elevated temperature, usually in a hot-air oven, after its initial fabrication. This process step is done to complete cross-linking of the object, remove peroxide by-products, and eliminate changes in its physical properties. Post-cure is often necessary when the component is only partially cross-liked by molding; it is performed in an attempt to accelerate molding process, and increase its output. **F2042**

transfer molding, v—process in which the mixed, uncured elastomer is placed in a compartment connected to the mold. The compartment is then closed, pressure is applied to transfer the uncured elastomer to the mold, filling the cavity. Heat and

pressure are applied to the mold to vulcanize the elastomer, the mold is then opened, and the fabricated part is removed. **F2042**

failure mode effect analysis (FMEA), *n*—analytical approach to methodically determine and address all possible product failure modes, their associated causes, and their criticality. Used to evaluate designs, prioritize testing, and track risk reducing improvements to the product. **F2394**

failure strength, *n*—force parameter (for example, load, moment, torque, stress, and so forth) required to meet the failure criteria defined and measured according to the test conducted.[14] **F1264**

fatigue, *n*—process of progressive localized permanent structural change occurring in a material subjected to conditions that produce fluctuating stresses and strains at some point or points and that may culminate in cracks or complete fracture after a sufficient number of fluctuations.

DISCUSSION—See Definitions E1150. **F1582**

fatigue life, *n*—number of cycles, *N*, that the artificial intervertebral disc can sustain at a particular load or moment before functional failure occurs. **F2346**

fatigue life, *n*—number of loading cycles, *N*, of a specified character that a given specimen sustains before failure of a specified nature occurs. **F1582**

DISCUSSION—See Definitions E1150.

fatigue life, *n*—number of loading cycles of a specified character that a given specimen sustains before failure of a specified nature occurs. **F382, F384**

fatigue strength at *N* cycles, *n*—estimate of the cyclic forcing parameter (for example, load, moment, torque, stress, and so on) at a given load ratio, for which 50 % of the specimens within a given sample population would be expected to survive *N* loading cycles. **F382, F384**

fatigue strength at N cycles, *n*—maximum cyclic force parameter (for example, load, moment, torque, stress, and so forth) for a given load ratio, which produces device structural damage or meets some other failure criterion in no less than *N* cycles as defined and measured according to the test conducted. **F1264**

fatigue strength at N Cycles, S_n [FL^{-2}], *n*—value of stress for failure at exactly *N* cycles as determined from an *S-N* diagram. The value S_n thus determined is subject to the same conditions as those that apply to the *S-N* diagram.

DISCUSSION—The value of S_n which is commonly found in the literature is the value of *S* max (maximum stress) or S_a (stress amplitude) at which 50 % of the specimens of a given sample could survive *N* stress cycles in which S_{nm} (mean stress) = 0. This is also known as the median fatigue strength for *N* cycles (see Definitions E1150). **F1582**

fatigue test, *n*—test designed to evaluate the cyclic load properties of a material, component, interconnection, subconstruct, construct, subassembly, or assembly. **F1582**

female member, *n*—component that accommodates and encloses the male member at the box lock junction. **F921**

femoral condyles, *n*—anatomic site corresponding to the distal end of the femur characterized by medial and lateral convex surfaces that are lined by cartilage and articulate with the proximal tibia and medial and lateral menisci. **F2451**

femoral head neck extension, *n*—distance parallel to the taper axis, from the nominal neck offset length (*k*), as defined in Specification F1636, and the center of the head. Such variants from the nominal length are used to adjust for resection level, leg length, and so forth. A positive neck extension equates to the center of the head being located further away from the stem. **F1875**

femoral neck-axis, *n*—centerline or axis of symmetry of the femoral cone. **F2345**

femtolitre, *n*—cubic micron; a measurement of cell volume. **F2149, F2312**

ferromagnetic material, *n*—material whose magnetic moments are ordered and parallel producing magnetization in one direction. **F2052, F2213**

fibrocartilage, *n*—disorganized cartilagenous tissue having an abnormally high content of type I collagen. **F2451**

field, *n*—image of a portion of the working surface upon which measurements are performed. **F1854**

filler, *n*—relatively inert material added to a plastic to modify its strength, performance, working properties, or other qualities, or to lower costs. (See also **reinforced plastic**.) **F1251, F665**

filler, *n*—finely divided solid that is intimately mixed with silicone polymers during manufacture to achieve specific properties. The fillers used in silicone elastomers are one of two types:

extending fillers, n—typically have lower surface area and lower cost than reinforcing fillers. They include crystalline forms of silica and diatomaceous earths. While they provide some reinforcement, because they are relatively inexpensive, they are used primarily to extend the bulk of the silicone. **F2038**

reinforcing fillers, n—usually have high surface areas and are amorphous in nature such as fumed or precipitated silica. Such fillers impart high strength and elastomeric physical properties to the elastomer. **F2038**

film, *n*—in plastics, term for sheeting having a nominal thickness not greater than 0.25 mm (0.01 in.). (See also **sheeting**.) **F1251**

final form, *n*—condition of the foam product when used by the end user to perform tests of orthopaedic devices or instruments. The condition of the foam product of which all physical and mechanical tests required by this specification are performed. **F1839**

solid—foam is in a uniform solid form, such as a slab, plate, or block. **F1839**

[14] No present testing standard exists related to this term for IMFDs.

finger rings, *n*—feature of both the female and the male members that forms the gripping surface for the surgeon (commonly classified as the ring-handled feature in ISO 7151). **F921**

finger rings, *n*—feature of the scissors that forms the gripping surface for the surgeon (commonly classified as the ring-handled feature). **F1078**

finish, *n*—final surface visual appearance classified as follows:

bright or mirror finish, n—highly reflective surface.

satin, matte, or black finish, n—reduced reflective surface (as compared to bright or mirror finish) varying from a dull appearance to a blackened surface. **F921, F1078, F1840**

fixation element, *n*—any peg, spike, threadform, or other protrusion from the exterior surface of the shell intended to increase the surface contact or mechanical interlock between the component, the bonding agent, or the natural acetabulum or a combination thereof. **F2091**

fixation site, *n*—area of the shell of an implantable breast prosthesis containing material that allows tissue ingrowth. **F703**

fixation site, *n*—area on the surface of the implant which has material on it that allows tissue ingrowth. **F881**

flange, *n*—rim extending from the entry diameter of bearing element. **F2091**

flexion angle, *n*—angulation of the femoral component (about an axis parallel to the y-axis) from the fully extended knee position to a position in which a "local" vertical axis on the component now points posteriorly. **F1223**

DISCUSSION—For many implants, 0° of flexion can be defined as when the undersurface of the tibial component is parallel to the femoral component surface that *in vivo* contacts the most distal surface of the femur. This technique may not be possible for some implants that are designed to have a posterior tilt of the tibial component. In these cases, the user shall specify how the 0° of flexion position was defined.

fluid absorption, *n*—fluid absorbed by the device material during testing or while implanted *in vivo*. **F2423**

fluorocarbon plastic, *n*—plastic based on polymers made with monomers composed of fluorine and carbon only. **F1251**

DISCUSSION—When the monomer is essentially tetrafluoro-ethylene, the prefix TFE may be used to designate these materials. When the resins are copolymers of tetrafluoro-ethylene and hexafluoropropylene, the resins may be designated with the prefix FEP. Other prefixes may be adopted to designate other fluorocarbon plastics.

fluorohydrocarbon plastic, *n*—plastic based on polymers made with monomers composed of fluorine, hydrogen, and carbon only. **F1251**

fluoroplastic, *n*—plastic based on polymers with monomers containing one or more atoms of fluorine or copolymers of such monomers with other monomers, the fluorine-containing monomer(s) being in greatest amount by mass. (See also **fluorocarbon plastic**, **chlorofluorocarbon plastic**, **fluorohydrocarbon plastic**, and **chlorofluorohydrocarbon plastic**.) **F1251**

foam, *n*—cross-linked material that has a component added to it which generates a volatile gas as the material is being vulcanized. This vulcanization process results in a material with a relatively low density. Foams are usually two-part formulations utilizing a platinum catalyzed addition cure system. They conform as they expand to irregular surfaces just as gels do to provide intimate contact and protection from the environment but are more rigid and provide more strength than gels. Since foams are expanded elastomers, on a weight basis, they are highly crosslinked relative to gels. Most cure conditions will result in a closed cell foam. **F2042**

foam rise direction, *n*—nominal direction that the foam rises during the polymerization ("foaming") process, either at the suppliers production facilities for the solid supplied foam, or at the end-users facilities for foam produced from the liquid supplied form. The foam rise direction shall be marked on the foam block or indicated in the shipping documentation for foam that is supplied in the solid form. **F1839**

formalin, *n*—1⁄10 dilution of 37 to 39 % formaldehyde solution (formaldehyde) in PBS. **F2148**

free plasma hemoglobin, *n*—amount of hemoglobin (iron or heme-containing protein) in plasma. **F1841**

free recovery, *n*—unconstrained motion of a shape memory alloy upon heating and transformation to austenite after deformation below the austenite phase. **F2005, F2082**

French size (Fr), *n*—scale used for denoting the size of catheters and other tubular instruments. The French size value is three times the outer diameter of the tube as measured in millimetres. For example, a diameter of 18 Fr indicates a diameter of 6 mm. **F2528**

French size, *n*—scale used for denoting the size of other tubular instruments and devices, each unit being roughly equivalent to 0.33 mm in diameter. Label French sizes are as follows: **F623**

French Size	Outside Diameter, in. (mm)
12	0.157 (4.0)
13	0.171 (4.3)
14	0.184 (4.7)
15	0.197 (5.0)
16	0.210 (5.3)
17	0.223 (5.7)
18	0.236 (6.0)
19	0.249 (6.3)
20	0.262 (6.7)
21	0.276 (7.0)
22	0.289 (7.3)
23	0.302 (7.7)
24	0.315 (8.0)
25	0.328 (8.3)
26	0.341 (8.7)

fretting, *n*—small amplitude oscillatory motion, usually tangential, between two solid surfaces in contact. **F1875**

fretting corrosion, *n*—deterioration at the interface between contacting surfaces as the result of corrosion and slight oscillatory slip between the two surfaces. **F1875**

fretting wear, *n*—wear arising as a result of fretting. **F1875**

Freund's Complete Adjuvant (FCA), *n*—commercially-available mixture of oil and Mycobacterium that is known to elicit an immune response. **F2147**

full thickness skin autograft, *n*—skin [auto]graft consisting of the epidermis and the full thickness of the dermis. **Dorland's, F2311, F2312**

full-thickness skin wound, *n*—skin wound with the loss of epidermis, and all of the dermis or at least the depth of dermis that includes most or all sources of epidermal cells from epidermal adnexae (glands and follicles). **F2311, F2312**

functional failure, *n*—permanent deformation or wear that renders the IVD prosthesis assembly ineffective or unable to resist load/motion or any secondary effects that result in a reduction of clinically relevant motions or the motions intended by the design of the device. **F2423**

functional failure, *n*—permanent deformation that renders the artificial intervertebral disc ineffective or unable to adequately resist load. **F2346**

fused or adhered joints, *n*—all junctures of dissimilar materials; and all junctures of fully or partly formed or preformed materials bonded or fused together to form a single implant unit. **F881**

DISCUSSION—Implants made from one material by a single charge of unvulcanized elastomer by one-step compression, transfer, or reactive injection molding are not considered to have fused or adhered joints.

fused or adhered joints (seams), *n*—sites in the shell or other parts of an implantable breast prosthesis where materials have been joined (fused or bonded) together, with or without an adhesive, as part of the manufacturing process. **F703, F2051**

fused or adhered joints (seams), *n*—sites in the shell or other parts of the tissue expander device where materials have been joined (fused or bonded) together, with or without adhesive, as part of the manufacturing process. **F1441**

gage length, *n*—distance between the holding device, for example, a split collet, and the underside of the screw head. **F543**

gauge length, *n*—initial unstressed length of catheter tubing between the proximal end of the stent to the grips which engage the catheter tubing. **F2394**

GDF, *n*—growth and differentiation factor. **F2312**

gel, *n—in polymer*, a semisolid system consisting of a network of solid aggregates in which liquid is held.

DISCUSSION—Gels have very low strengths and do not flow like a liquid. They are soft, flexible, and may rupture under their own weight unless supported externally. **F1251**

gel, *n—in polymerization*, the initial jelly-like solid phase that develops during the formation of a resin from a liquid. **F1251**

gel, *n*—lightly crosslinked material having no or relatively low levels of reinforcement beyond that provided by the crosslinked polymer. Gels are usually two-part formulations utilizing a platinum catalyzed addition cure system. The hardness of the gel can be adjusted within wide limits. The material is not usually designed to bear a heavy load but rather to conform to an irregular surface providing intimate contact. As a result, loads are distributed over a wider area. These materials may also be used to provide protection from environmental contaminants. **F2042**

gel, *n*—three-dimensional network structure arising from intermolecular polymer chain interactions.

DISCUSSION—Such chain interactions may be covalent, ionic, hydrogen bond, or hydrophobic in nature. See also Terminology F1251. **F2312**

gel, *n*—three-dimensional network structure arising from intermolecular polymer chain interactions. Such chain interactions may be covalent, ionic, hydrogen bond, or hydrophobic in nature. See also Terminology F1251. **F2315**

gel, *n—with vinyl plastisols*, a state between liquid and solid that occurs in the initial stages of heating, or upon prolonged storage. **F1251**

gel bleed, *n*—diffusion of liquid silicone components of silicone gel through the shell of an implantable breast prosthesis. **F703**

gel-filled breast prosthesis, *n*—implantable breast prosthesis designed and provided with a prefilled, fixed volume of silicone gel. **F703**

Type I breast prosthesis, n—implantable breast prosthesis containing a single lumen containing a fixed amount of silicone gel.

DISCUSSION—The lumen of a Type I breast prostheses is not accessible for volume adjustments of any kind.

Type II breast prosthesis, n—implantable breast prosthesis comprised of two complete lumens, one inside the other.

DISCUSSION—The inner lumen of a Type II implantable breast prosthesis contains a fixed amount of silicone gel and is not accessible for volume adjustments of any kind. The outer lumen is provided with a valve to facilitate filling the void between the inner and outer lumens with saline to adjust the total volume of the prosthesis, at the time of use. The valve system may also be designed to facilitate post-operative saline volume adjustment by following the instructions provided in the product literature.

Type III breast prosthesis, n—implantable breast prosthesis comprised of two complete lumens, one inside the other.

DISCUSSION—The area between the inner and outer lumens contains a fixed amount of silicone gel and is not accessible for volume adjustments of any kind. The inner lumen is contained within the silicone gel contained in the outer lumen and has a valve system to facilitate filling the inner lumen with saline to increase the volume of the prosthesis at the time of use. The valve system may also be designed to facilitate post-operative saline volume adjustment by following the instructions provided in product literature.

gene mutation, *n*—any heritable change whose physical extent is restricted to the limits of a single gene. **E1280**

gene therapy, *n*—"is a medical intervention based on modification of the genetic material of living cells. Cells may be modified *ex vivo* for subsequent administration or may be

altered *in vivo* by gene therapy products given directly to the subject. When the genetic manipulation is performed *ex vivo* on cells that are then administered to the patient, this is also a type of somatic cell therapy. The genetic manipulation may be intended to prevent, treat, cure, diagnose, or mitigate disease or injuries in humans." Gene therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

gene therapy products, *n*—"are defined for the purpose of this statement as products containing genetic material administered to modify or manipulate the expression of genetic material or to alter the biological properties of living cells." **F2312**

genetically modified, *vt*—referring to cells, tissues, and organs of any origin that have an altered or modified genetic content. **F2312**

genetic material, *n*—is nucleic acid (either deoxyribonucleic acid or ribonucleic acid).

DISCUSSION—Genetic material is also known as DNA, RNA, genetic element, gene, factor, allele, operon, structural gene, regulator gene, operator gene, gene complement, genome, genetic code, codon, anticodon, messenger RNA (mRNA), transfer RNA (tRNA), ribosomal extrachromosomal genetic element, plasmagene, plasmid, transposon, gene mutation, gene sequence, exon, intron (modified version).[15] Genetic material may be used as a component of a TEMP. **F2312**

geometric centroid (cantilever plane), *n*—point in a cross-sectional area of the cantilever plane whose coordinates are the mean values of the coordinates of all the points in the area. **F1440**

glass transition temperature, *n*—temperature at which the heat capacity associated with translational molecular motions vanishes during cooling or appears during warming. The glass transition temperature is the formal transition point between the glassy state and the liquid state. **F2386**

glenoid, *n*—prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a prosthetic replacement of the humeral head. It may consist of one or more components from one or more materials, for example, either all-polyethylene or a metal baseplate with a polymeric insert. **F2028**

glenoid backing, *n*—metallic or composite material prosthetic portion of a multiple piece glenoid component that attaches to the scapula. **F1829**

glenoid component, *n*—prosthetic portion that replaces the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement. **F1829**

glenoid plane, *n*—in symmetric glenoids, the plane is defined by joining the two articular edges; in planar and asymmetric glenoids, it is defined by the back surface. **F2028**

grades, *n*—grade designation refers to the nominal density of the foam, in its solid final form, expressed in units of kg/m^3 (lbm/ft^3). Five grades of foam have been defined in Specification F1839. Their nominal densities are: **F1839**

Grade 10:	160.2 kg/m^3 (10.0 lbm/ft^3)
Grade 12:	192.2 kg/m^3 (12.0 lbm/ft^3)
Grade 15:	240.3 kg/m^3 (15.0 lbm/ft^3)
Grade 20:	320.4 kg/m^3 (20.0 lbm/ft^3)
Grade 40:	640.7 kg/m^3 (40.0 lbm/ft^3)

graft, *n*—any tissue or organ for implantation or transplantation. **Dorland's, F2311, F2312**

graft take, *n*—engraftment. **F2311, F2312**

granulations, *n*—granulation tissue. **F2311, F2312**

granulation tissue, *n*—newly formed vascular tissue normally produced in the healing of wounds of soft tissue and ultimately forming the cicatrix [scar]; it consists of small, translucent, red, nodular masses or granulations that have a velvety appearance. **Dorland's, F2311, F2312**

grip length, *n*—length of threads held fast in the split collet or other holding mechanism. **F543**

grips, *n*—means of applying force to the stent and balloon catheter to displace or dislodge the stent relative to the balloon. In particular, grips refer to the end of a device which makes the contact with the stent. Typical grips used to apply force to the stent include shims (as used in Figs. X2.5–X2.8 of Guide F2394); tape which sticks to the stent but not the balloon; an iris which can be narrowed down to allow the balloon to slip by but not the stent; or nubs which contact the stent but not the balloon. **F2394**

gross failure, *n*—permanent displacement resulting from fracture or plastic deformation in excess of the yield displacement that renders the spinal component ineffective in fulfilling its intended function. **F2193**

growth plate, *n*—anatomic location within the epiphyseal region of long bones corresponding to the site of growth of bone through endochondral bone formation. The growth plate in skeletally mature animals is fused. **F2451**

guide catheter, *n*—tube designed to transport the guide-wire and the stent delivery system into the target vessel. **F2394**

guide pin, *n*—pin affixed to the inside of one of the forceps halves that aligns with a hole on the other tweezer half without protruding through when closed. **F1638**

guide pin hole, *n*—hole in one forceps half into which the guide pin fits without passing through when closed. **F1638**

guide-wire, *n*—wire designed to aid in balloon, ultrasound, atherectomy, or stent placement during endovascular procedures. **F2394**

Guinea Pig Maximization Test (GPMT), *n*—procedure described in Practice F720 accepted as a "worst case" assay for allergenic potential. **F2147**

***H*$_1$—**articulating surface superior-inferior height in the frontal plane. **F1672**

***H*$_2$—**metal back superior-inferior height in the frontal plane. **F1672**

[15] *Bloomsbury Thesaurus*, Bloomsbury, 1997.

hardness, *n*—measurement of the resistance to indentation **F921, F1078**

hazard, *n*—potential source of harm. **ISO/IEC Guide 51, F2503**

haze, *n*—*in plastics*, the cloudy or turbid aspect or appearance of an otherwise transparent material caused by light scattered from within the specimen or from its surfaces.

DISCUSSION—For the purpose of Test Method D1003, haze is the percentage of transmitted light which, in passing through the specimen, deviates from the incident beam through forward scatter more than 2.5° on the average. **F1251**

head size, *n*—nominal spherical diameter of the head (generally standardized, but not limited to 22, 26, 28, 32, and 36 mm for total hips.) **F2345**

heal, *v*—to restore wounded parts or to make healthy. **Dorland's, F2311, F2312**

healing, *n*—restoration of integrity to injured tissue. **Dorland's, F2311, F2312**

DISCUSSION—In the surgical wound closure, an important distinction is made according to whether the surgeon expects the healing to be accomplished by granulation tissue. This distinction is made because in the normal physiology of wound healing, granulation tissue matures into scar with wound contracture, which is an undesirable outcome. Wound closure "by approximating the wound edges or performing a skin autograft" is called "healing by first intention," and wound closure by "allowing spontaneous healing from the edges" is called "healing by second intention."

healing by first intention, *n*—healing in which union or restoration of continuity occurs directly without intervention of granulations. **Dorland's, F2311, F2312**

healing by second intention, *n*—union by closure of a wound with granulations which form from the base and both sides toward the surface of the wound. **Dorland's, F2311, F2312**

hearing level (HL), *L*, *n*—ratio of the input sound field pressure, p_S, relative to the sound field pressure p_{RETSPL} at 0° incidence that is just detectable monaurally by a normally hearing individual, as defined in ANSI S3.6, Table 9, expressed in decibels as: $L = 20 \cdot \log_{10}(p_S/p_{RETSPL})$. **F2504**

hemolysis, *n*—damage to erythrocytes resulting in the liberation of hemoglobin into the plasma. **F1841**

hemolysis, *n*—destruction of erythrocytes resulting in the liberation of hemoglobin into the plasma or suspension medium. **F756**

hemostatic forceps, *n*—instrument, available in various sizes and configurations, used in surgical procedures for the compression of blood vessels and the grasping of tissue. **F921**

high consistency rubber (HCR), *n*—elastomer having a viscosity such that it cannot be moved or transferred by readily available pumping equipment. These elastomers are fabricated using high shear equipment such as a two-roll mill and cannot be injection molded. They are typically used in compression or transfer molding and extrusion processes. **F2042**

hinge, *n*—mechanical physical coupling between femoral and tibial components which provides a singular axis about which flexion occurs. **F1223**

hook, *n*—anchoring component that fastens to the spine by means of a curved blade passed under or over lamina, transverse or spinous processes or into an anatomic or surgically created notch or opening. **F1582**

hook blade, *n*—that portion of a spinal hook that is placed under, over, or into a bony structure to provide attachment. **F1582**

hook body, *n*—that portion of a spinal hook that connects the hook blade to the longitudinal element. **F1582**

humeral head, *n*—prosthetic portion that replaces the proximal humerus or humeral head and articulates with the natural glenoid fossa or a prosthetic replacement. **F2028**

humoral immunity, *n*—some antigens stimulate the host to produce antibodies (immunoglobulins) that are specific for the antigen and react with the antigen. Antibodies circulate in the blood and tissue fluids. The antibodies produced can be detected using blood from the host. **F1905**

hyaline articular cartilage, *n*—cartilagenous connective tissue located in diarthrodial joints and characterized by its localization to articulating surfaces. **F2451**

hyaluronan, *n*—polysaccharide with a disaccharide repeating unit composed of D-glucuronic acid and *N*-acetyl-D-glucosamine in β-(1→3) linkage. Each disaccharide unit is attached to the next by β-(1→4) bonds. Hyaluronan is a linear polymer. Other common names are hyaluronic acid and sodium hyaluronate. **F2347**

hybrid longitudinal element, *n*—longitudinal element consisting of two or more types of longitudinal elements of different size or cross-section manufactured into a single element. **F1582**

hydrocolloid, *n*—water-soluble polymer of colloidal nature when hydrated. **F2312, F2347**

hydrogel, *n*—water-based open network of polymer chains that are cross-linked either chemically or through crystalline junctions or by specific ionic interactions. **F2450**

hydrolytically degradable polymer (HDP), *n*—any polymeric material in which the primary mechanism of chemical degradation in the body is by hydrolysis (water reacting with the polymer resulting in cleavage of the chain). **F1635, F2502**

hydrophilic, *adj*—having a strong affinity for water, wettable. **F22, F2664**

hydroxylapatite, *n*—calcium phosphate crystalline compound of empirical chemical formula, $Ca_5(PO_4)_3OH$ (see Specification F1185). **F1609**

hyperextension stop, *n*—geometrical feature which arrests further progress of flexion angles of negative value. **F1223**

ICCVAM, *n*—Interagency Coordinating Committee on the Validation of Alternative Methods. **F2148**

ideal insertion location, *n*—location of the artificial disc in the intervertebral space that is suggested in the manufacturer's surgical installation instructions. The ideal insertion location is to be described with respect to the simulated inferior and superior vertebral bodies (polyacetal or metal blocks) and will be dictated by the device design. **F2346**

image artifact, *n*—pixel in an image is considered to be part of an image artifact if the intensity is changed by at least 30 % when the device is present compared to a reference image in which the device is absent. **F2119**

IMEHD electrical input at threshold $E_{threshold}$, *n*—electrical input to the IMEHD output transducer at threshold of audibility. **F2504**

IMEHD harmonic distortion, *n*—harmonic distortion of the stapes velocity IMEHD-aided analogous to ANSI S3.22, Section 6.11S, from sinusoidal inputs of the frequencies 500, 800, and 1600 Hz; input levels shall be E_{max} – 20 dB. **F2504**

IMEHD output transducer, *n*—electromechanical output transducer of the IMEHD. **F2504**

IMEHD output transducer frequency range, *n*—using the equivalent sound pressure transfer function, HES, draw a horizontal line at the average for 1000, 1600, and 2500 Hz, then subtract 20 dB, or divide by 10; the lower and the upper bounds of the frequency response range are where the average line crosses the transfer function curve. **F2504**

IMEHD output transducer input, *E*, *n*—electrical input to the IMEHD output transducer, specified in volts or amperes, as appropriate for the particular device. **F2504**

IMEHD system frequency range, *n*—using the insertion gain transfer function (velocity), H_{VV}, draw a horizontal line at the average for 1000, 1600, and 2500 Hz, then subtract 20 dB, or divide by 10; the lower and the upper bounds of the frequency response range are where the average line crosses the transfer function curve. **F2504**

IMFD curvature, *n*—dimensions of size and locations of arcs of the curvature, or mathematical description of the curvature, or other quantitative descriptions to which the curvature is manufactured along with tolerances. To orient the IMFD for testing and for insertion, the desired relationship of the curvature to the sagittal and coronal planes should be described for the intended applications. **F1264**

IMFD diameter, *n*—diameter of the circumscribed circle, which envelops the IMFDs' cross section when measured along the IMFDs' working length. If the diameter is not constant along the working length, then the site of measurement should be indicated. **F1264**

IMFD length, *n*—length of a straight line between the most proximal and distal ends of the IMFD. **F1264**

immobilization, *n*—entrapment of materials, such as cells, tissues, or proteins within, or bound to, a matrix. **F2312, F2315**

implant, *n*—substance or object that is put in the body as a prosthesis, or for treatment or diagnosis. **F2664**

implantation, *n*—procedure of inserting materials such as a cell(s), tissue(s), or organ(s) for therapeutic purposes. Synonym: *graft* or *grafting*. TEMPs may be applied to a recipient by implantation or grafting. **F2312**

Index of Hemolysis:— **F1841**

modified index of hemolysis, n—mass of hemoglobin released into plasma normalized by the total amount of hemoglobin pumped through the loop.

normalized index of hemolysis, n—added grams of plasma free hemoglobin per 100 l of blood pumped, corrected for plasma volume using hematocrit and normalized by flow rate and circulation time.

normalized milligram index of hemolysis, n—normalized index of hemolysis expressed by milligram value of free plasma hemoglobin.

inflammatory factors, *n*—various soluble substances may be produced by lymphocytes in response to an antigen. This may occur in humoral immune responses or in CMI. These substances may influence the function of other cells and are called cytokines. Many of these act on various white cells and are called interleukins. They are reflection of antigenic stimulation of the host. **F1905**

inflammatory response, *n*—irritation of tissue cells as a result of using a cryosystem. **F882**

inflatable breast prosthesis, *n*—implantable breast prostheses not containing silicone gel—implantable breast prostheses designed and provided prefilled with saline or empty and to be filled with saline at the time of use to adjust the volume of the prosthesis. **F2051**

Type 1, n—fixed volume inflatable breast prosthesis—an implantable breast prosthesis composed of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with saline at the time of use.

Type 2, n—variable volume inflatable breast prosthesis—an implantable breast prosthesis composed of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with a portion of the volume of saline at the time of use. The valve system is designed to facilitate further post-operative adjustment with saline as instructed in product literature.

Type 3, n—fixed volume inflatable breast prosthesis—an implantable breast prosthesis composed of a single lumen, prefilled with saline by the manufacturer prior to time of use.

inflation volume, *n*—volume of liquid used to inflate the retention balloon of the enteral feeding device for proposed testing in this standard. **F2528**

inhibitor, *n*—component of a silicone elastomer added to moderate the rate of the crosslinking reaction. **F2038**

injection port, *n*—port through which an injection to inflate or deflate the variable volume device is made. **F1441**

remote port, n—port that is remote from the shell and attached to the shell by means of tubing.

self-contained (integrated) port, n—port that is integral to the device shell.

injection surface, *n*—area of the injection port recommended by the manufacturer for needle insertion to inflate or deflate the device. **F1441**

in-process control, *n*—monitoring and, if necessary, adjustments performed to ensure that the process conforms to its specification. The control of the environment or equipment may be part of in-process control. **F2312**

input sound field pressure, p_S, *n*—sound stimulus measured in the free field and presented to the listener in either the IMEHD-aided or unimplanted condition, specified in units of pascals. **F2504**

insertion depth (mm), *n*—linear advancement of the bioabsorbable device into the test block measured relative to its seated position at the test block's surface prior to testing. **F2502**

insertion depth (mm), *n*—linear advancement in mm of the screw into the test block measured relative to its seated position at the test block's surface prior to testing. **F2193**

insertion depth, *n*—threaded length as inserted into the test block. **F543**

insertion gain transfer function (sound field), H_{SS}, *n*—ratio of the equivalent sound pressure produced in the IMEHD-aided case with a given electrical input to the IMEHD output transducer and the input sound field pressure used as input in the IMEHD-aided case required to produce the same IMEHD output transducer electrical input: $H_{SS} = p_E/p_S$; this ratio is unitless. **F2504**

DISCUSSION—With a linear sound signal processor, the insertion gain (sound field) can be computed from the product of the equivalent sound pressure transfer function, H_{ES}, and the electro-acoustic transfer function, H_{SE}: $H_{SS} = p_E/p_S = H_{SE} \cdot H_{ES}$. H_{SS} will depend on the particular gain settings used, for example, full-on gain or minimal gain. The gain should be reported whenever that transfer function is used

insertion gain transfer function (velocity), H_{V_v}, *n*—ratio of the stapes velocity (IMEHD-aided) and the stapes velocity (unimplanted) produced by a given input sound field: $H_{V_v} = v_A/v_U$; the ratio is unitless and can be expressed in decibels as $20 \cdot \log_{10}(H_{V_v})$. **F2504**

DISCUSSION—With a linear sound signal processor and IMEHD, that is, a processor whose electrical output E is proportional to the input sound field pressure, p_S, and an IMEHD whose vibrational output is proportional to its electrical output, the insertion gain (sound field), H_{SS}, will equal the insertion gain transfer function (velocity), H_{VV}.

insertion torque, *n*—amount of torque required to overcome the frictional force between the screw and the material used for testing while driving the screw into the material. **F543**

installation load, *n*—force, applied at 0° from femoral neck axis, used to settle the head on the cone before testing. **F2345**

intended method of application, *n*—artificial intervertebral discs may contain different types of features to stabilize the implant-tissue interface such as threads, spikes, and textured surfaces. Each type of feature has an intended method of application or attachment to the spine. **F2346**

intended spinal location, *n*—anatomic region of the spine intended for the artificial intervertebral disc. Artificial intervertebral discs may be designed and developed for specific regions of the spine such as the cervical, thoracic, and lumbar spine. Also, since different surgical approaches may exist, the description of the intended spinal location should include both the indicated spinal levels and the ideal insertion locations within the intervertebral space allowed at each level. **F2346**

interbody spacer, *n*—structure (biologic or synthetic) to replace (partially or totally) the vertebral body or intervertebral disk(s), or both. **F1582**

intercept, *n*—point on a measurement grid line projected on a field where the line crosses from solid to void or vice versa. **F1854**

interconnection, *n*—mechanical interface or connection mechanism between at least two components or between components and bony elements of the spine, pelvis, or ribs. **F1582**

interdigitation, *n*—interlocking or meshing of the female and male jaw serrations. **F921**

interface, *n*—one of the two mating surfaces, lines or points of contact within an interconnection between two components, between any component and bone, or between two bony elements. **F1582**

internal-external rotation, *n*—relative angulation of the moveable component about an axis parallel to the *z*-axis. **F1223**

interval net volumetric wear rate VR_i during cycle interval i (mm^3/million cycles), *n*—$VR_i = WR_i/\rho$, where ρ = mass density (for example, units of g/mm^3) of the wear material. **F2423**

interval net wear rate WR_i during cycle interval i (g/million cycles), *n*—$WR_i = ((NW_i - NW_{i-1})/(\text{number of cycles in interval } i)) * 10^6$. **F2423**

DISCUSSION—For $i = 1$, $NW_{i-1} = 0$.

intervertebral body fusion devices, *n*—structure that is placed in the disc space between two adjacent vertebral bodies to provide support for eventual arthrodeses of the two adjacent vertebral bodies. **F1582**

intervertebral body fusion cage, *n*—hollow device that contains graft material. **F1582**

intervertebral disc (IVD) prosthesis, *n*—nonbiologic structure intended to restore the support and motion or a portion thereof between adjacent vertebral bodies. **F2423**

intervertebral height, *n*—minimum distance parallel to the Z-axis in the YZ-plane between the unaltered simulated

vertebral bodies: minimum height of 2 mm and maximum height of 16.5 mm.[16,17] See Fig. 1 of Test Methods F2346. **F2346**

intracranial aneurysm clip, *n*—device introduced surgically to occlude the blood inlet into an intracranial aneurysm with the intention that it remain within the body following the surgery. This device is referred to in this practice as an "implant," specifically as an intracranial aneurysm clip. **F700**

ionic compounds/water soluble residue, *n*—residue that is soluble in water, including surfactants and salts. **F2459**

isocenter, *n*—geometric center of the gradient coil system, which generally is the geometric center of a scanner with a cylindrical bore. **F2182**

isotactic, *adj*—pertaining to a type of polymeric molecular structure containing a sequence of regularly spaced asymmetric atoms arranged in like configuration in a polymer chain. **F1251**

item, *n*—medical device or other object that may be brought into the MR environment. **F2503**

jaw alignment, *n*—positioning of the female and male jaws with respect to interdigitation (related to box lock function and ratchet performance). **F921**

jaws, *n*—parts that contain serrations to interrupt the flow of blood through any vessel. **F921**

joint, *n*—junction where the scissor blades are secured by a screw allowing the instrument to pivot. **F1078**

joint reaction force, *n*—applied load whose vector is directed parallel to the z-axis, generally considered parallel to tibial longitudinal axis. **F1223**

kinematic profile, *n*—relative motion between adjacent vertebral bodies that the IVD prosthesis is subjected to while being tested. **F2423**

labeled diameter, *n*—nominal deployed size of a stent as indicated on its manufacturer's label. **F2079**

lag screw, *n*—that component of a compression hip screw angled device which is threaded into the metaphyses and transmits the off axis load to the sideplate through the barrel (see Fig. 1 of Specification F384). **F384**

lag screw length, *n*—straight line distance measured between the proximal and distal ends of the lag screw (see Fig. 1 of Specification F384). **F384**

laminar flow, *n*—well-ordered, patterned flow of fluid layers assumed to slide over one another.[18] **F2664**

laminate, *n*—product made by bonding together two or more layers of material or materials.

DISCUSSION—A single resin-impregnated sheet of paper, fabric, or glass mat, for example, is not considered a laminate. Such a single-sheet construction may be called a "lamina." **F1251**

laminate, cross-plied, *n*—nonparallel laminate. **F1251**

laminate, parallel, *n*—laminate in which all layers or plies are oriented with their principal direction (grain or strongest direction in tension) parallel with the principal direction of the laminate. **F1251**

lay, *n*—direction of the predominant surface pattern. **ISO 13565-1, F2664**

lay (or twist), *n*—helical form taken by the wires in a strand and by the strands in a cable (see MIL-DTL-83420J). **F2180**

DISCUSSION—In a "Right Lay" situation, the wires of the strand (or the strands in a cable) are oriented in the same direction as the thread on a right-hand screw.

length of lay (or pitch), *n*—distance parallel to the axis of the strand (or cable) in which a wire (or strand) makes one complete turn about the axis. **F2180**

lesion, *n*—any pathological or traumatic discontinuity of tissue or loss of function of a part. In this guide, "skin lesion" is intended to encompass skin wounds and skin ulcers. **F2311, F2312**

line of load application, *n*—loading axis of the test machine. **F1440**

linear displacement sensor, *n*—electrical sensor that converts linear displacement to electrical output. **F2537**

linear displacement sensor system, *n*—system consisting of a linear displacement sensor, power supply, signal conditioner, and data acquisition system. **F2537**

linear elasticity, *n*—linear recoverable deformation behavior.

DISCUSSION—No significant phase transformation event occurs while straining the material and the tensile load-extension or stress-strain plot is linear upon loading and unloading. **F2005**

linear polyurethane, *n*—polymer whose backbone consists of urethane groups joined by hydrocarbon chains with little or no cross linking. **F624**

linear variable differential transformer (LVDT), *n*—linear displacement sensor made of a sensor housing and a core. The sensor housing contains a primary coil and two secondary coils. When an ac excitation signal is applied to the primary coil, voltages are induced in the secondary coils. The magnetic core provides the magnetic flux path linking the primary and secondary coils. Since the two voltages are of opposite polarity, the secondary coils are connected in series opposing in the center, or null position. When the core is displaced from the null position, an electromagnetic imbalance occurs. This imbalance generates a differential ac output voltage across the secondary coils, which is linearly proportional to the direction and magnitude of the displacement. When the core is moved from the null position, the induced voltage in the secondary coil, toward which the core

[16] Nissan, M., Gilad, I., "The Cervical and Lumbar Vertebrae—An Anthropometric Model," *Engineering In Medicine*, 13:3, 1984, pp. 111-114.

[17] Lu, J., Ebraheim, N.A., Yang, H., Rollins, J., and Yeasting, R. A., "Anatomic Bases for Anterior Spinal Surgery: Surgical Anatomy of the Cervical Vertebral Body and Disc Space," *Surg Radiol Anat*, 21:4, 1999, pp. 235-239.

[18] *Studying Cell Adhesion*, (hardcover) by P. Bongrand, P. M. Claesson, A.S.G. Curtis (Editor), Springer-Verlag Telos, 1995.

is moved, increases while the induced voltage in the opposite secondary coil decreases. **F2537**

liquid, *n*—water, saline solution, calf serum, or any other liquid solution that is used to condition PMC specimens. **F1634**

liquid silicone rubber or low consistency silicone rubber (LSR), *n*—elastomer having a viscosity such that it can be moved or transferred by readily available pumping equipment. LSRs are typically used in injection molding operations. **F2042**

load axis, *n*—line of action of the compressive force applied to the head. **F2345**

load axis angle, *n*—measured angle "L" between the line of action of the applied force and femoral neck axis (see Fig. 5 of Test Methods F2345). **F2345**

load magnitude, *n*—peak (absolute value) compressive force of the applied constant amplitude cyclic force. **F2345**

load point, *n*—point through which the resultant force on the intervertebral device passes; that is, the geometric center of the superior fixture's sphere (see Figs. 2–4 of Test Methods F2346). **F2346**

load profile, *n*—loading that the device experiences while being tested under a defined kinematic profile or the loading that the IVD prosthesis is subject to if tested in load control. **F2423**

load rate, *n*—rate of applied compressive force. **F2345**

load ratio, R, A, *n*—in fatigue loading, the algebraic ratio of the two loading parameters of a cycle.

DISCUSSION—The most widely used ratios are:

$$R = \frac{\text{Minimum Load}}{\text{Maximum Load}} = \frac{P_{min}}{P_{max}}$$

or

$$\frac{S_{min}}{S_{max}}$$

or

$$R = \frac{\text{Valley Load}}{\text{Peak Load}}$$

and

$$A = \frac{\text{Loading Amplitude}}{\text{Mean Load}} = \frac{Pa}{Pm}$$

or

$$\frac{Sa}{Sm}$$

or

$$A = \frac{(\text{Maximum Load} - \text{Minimum Load})}{(\text{Maxium Load} + \text{Minimum Load})} = \frac{(P_{max} - P_{min})}{(P_{max} + P_{min})}$$

F1528

locking screw, *n*—threaded anchor that is rigidly connected to the longitudinal element of the spinal construct. **F2193**

longitudinal element, *n*—component whose long axis is parallel, or nearly so, to the long axis of the spine. **F1582**

lot or batch, *n*—quantity of material made with a fixed, specified formulation in a single, manufacturing run carried out under specific processing techniques and conditions. **F2038**

low bleed, *n*—silicone gel implantable breast prostheses designed to have minimal silicone bleed when tested using the test method in 9.2.1 in Specification F703. **F703**

lower plateau strength (LPS), *n*—(in nitinol), stress at 2.5 % strain during tensile unloading of the sample, after loading to 6 % strain. **F2005**

lower plateau strength (LPS), *n*—stress at 2.5 % strain during unloading of the sample, after loading to 6 % strain. **F2516**

lumen, *n*—cavity within a shell and patch or base, accessible by an injection port, to facilitate the addition of saline to adjust the volume of the soft tissue expander. **F1441**

lumen, *n*—cavity within a shell of an implantable breast prosthesis. **F703**

DISCUSSION—A lumen may contain either a fixed, nonadjustable volume of silicone gel, or it may be entirely or partly empty and intended to be inflated (filled) with saline. Inflatable lumens are accessible by valve to facilitate the addition of saline to adjust the volume of the prosthesis at the time of use. More than one lumen may be formed within a shell by silicone elastomer membrane partitions.

lumen, *n*—cavity within a shell of an implantable breast prosthesis. Inflatable lumens are accessible by valve to facilitate the addition of saline to adjust the volume of the prosthesis at the time of use. **F2051**

lumen, *n*—channel within a tube. **F623**

***M*×*N*,** *n*—construction designation for strands and cables. In this construction designation M represents the number of strands in the cable and N represents the number of wires in each strand. **F2180**

DISCUSSION—Some examples of strand constructions are 1×7 and 1×3. Similar examples of cable constructions are 7×7 and 7×19.

magnetic field strength (*H* in A/m), *n*—strength of the applied magnetic field. **F2052, F2213**

magnetic induction or magnetic flux density (*B* in *T*), *n*—that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_o is the static field in an MR system. Plain type indicates a scalar (for example, *B*) and bold type indicates a vector (for example, *B*). **F2052, F2213, F2503**

magnetic resonance (MR), *n*—resonant absorption of electromagnetic energy by an ensemble of atomic particles situated in a magnetic field. **F2052, F2213, F2503**

magnetic resonance diagnostic device, *n*—device intended for general diagnostic use to present images which reflect the

spatial distribution or magnetic resonance spectra, or both, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images or spectra, or both, may also be produced. **F2052, F2213**

magnetic resonance (MR) environment, *n*—volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire three dimensional volume of space surrounding the MR scanner. For cases in which the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment. **F2052, F2119, F2213, F2503**

magnetic resonance (MR) environment, *n*—area within the 5 G line of an MR system. **F2182**

magnetic resonance equipment (MR equipment), *n*—medical electrical equipment which is intended for *in-vivo* magnetic resonance examination of a patient. The MR equipment comprises all parts in hardware and software from the supply mains to the display monitor. The MR equipment is a Programmable Electrical Medical System (PEMS). **F2052, F2213**

magnetic resonance examination (MR examination), *n*—process of acquiring data by magnetic resonance from a patient. **F2052, F2213**

magnetic resonance imaging (MRI), *n*—diagnostic imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei. **F2182**

magnetic resonance imaging (MRI), *n*—imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei. **F2119, F2213**

magnetic resonance system (MR system), *n*—ensemble of MR equipment, accessories, including means for display, control, energy supplies, and the MR environment. **IEC 60601-2-33, F2052, F2182, F2213**

magnetically induced displacement force, *n*—force produced when a magnetic object is exposed to the spatial gradient of a magnetic field. This force will tend to cause the object to translate in the gradient field. **F2052, F2213, F2503**

magnetically induced torque, *n*—torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque. **F2213, F2503**

magnetization (M in T), *n*—magnetic moment per unit volume. **F2213**

maintenance therapy, *n*—therapy of chronically ill patients that is aimed at keeping the pathology at its present level and preventing exacerbation. **F2311, F2312**

male member, *n*—component that is inserted through the female member and secured to the female member at the box lock junction. **F921**

mandrel, *n*—wire that may be used as an alternative to the intended guide-wire to provide support for the catheter guide-wire lumen for some test procedures. **F2394**

manufacture, *v*—"any or all steps in the recovery, screening, testing, processing, storage, labeling, packaging or distribution of any human cellular or tissue-based product."[19]

DISCUSSION—For TEMPs, manufacture is expanded to include production of products *in vitro* or *in vivo*. TEMPs may also include the use of non-human cellular or tissue-based materials in any manufacturing steps. **F2312**

manufacture, *v*—process which occurs in the supplier's facility in which the various components of the elastomer are brought together, allowed to interact, and are packaged to provide the uncured elastomer for sale. **F2042**

markers, *n*—tantalum beads 1.0 mm, 0.8 mm, or 0.5 mm in diameter. **F2385**

cage markers, n—tantalum beads held in an external reference frame used to create a three dimensional coordinate system for measuring relative displacements.

implant markers, n—in vivo markers placed on the implant to define the implant as a rigid body.

segment, n—three-dimensional rigid body defined by a minimum of three markers.

marrow, *n*—also called *myeloid tissue*; soft, gelatinous tissue that fills the cavities of the bones. It is either red or yellow, depending upon the preponderance of vascular (red) or fatty (yellow) tissue. **F2451**

martensite, *n*—lowest temperature phase in Ni-Ti shape memory alloys with a B19' (B19 prime) monoclinic crystal structure. **F2005**

martensite deformation temperature (M_d), *n*—(in nitinol), highest temperature at which martensite will form from the austenite phase in response to an applied stress. **F2005**

martensite finish temperature (M_f), *n*—(in nitinol), temperature at which the transformation from austenite to martensite is completed on cooling in a single-stage transformation (Fig. 1) or the temperature at which the transformation from R-phase to martensite is completed on cooling in a two-stage transformation (Fig. 2). **F2005**

martensite peak temperature (M_p), *n*—(in nitinol), temperature of the exothermic peak position on the DSC curve upon cooling for the austenite to martensite transformation (Fig. 1) or the R-phase to martensite transformation (Fig. 2). **F2005**

martensite start temperature (M_s), *n*—(in nitinol), temperature at which the transformation from austenite to martensite begins on cooling in a single-stage transformation (Fig. 1) or the temperature at which the transformation from R-phase to martensite begins on cooling in a two-stage transformation (Fig. 2). **F2005**

[19] FDA, CFR, Title 21, Volume 8, Part 1271.3(f), Human Cells, Tissues, and Cellular and Tissue-Based Products, Revised 04/01/03.

material, *n*—substance(s) used in the construction of a sharps container. **F2132**

matrix, *n*—term applied to either the exogenous implanted scaffold or the endogenous extracelluar substance (otherwise known as extracellular matrix) derived from the host. **F2451**

maximum bend moment, *n*—greatest moment applied to a needle during a bend test. **F1840**

maximum electrical transducer input, E_{max}, *n*—maximum electrical output of the sound signal processor, specified as peak-to-peak or root mean square value, specified in volts or amperes, as appropriate for the particular device. **F2504**

maximum equivalent sound pressure, $p_{E,max}$, *n*—equivalent sound pressure that corresponds to the maximum electrical output E_{max} of the implant electronics, $p_{E,max} = E_{max} \cdot H_{ES}$. **F2504**

maximum equivalent sound pressure level, $L_{E,max}$, *n*—logarithmic representation of the maximum equivalent sound pressure $L_{E,max} = 20 \cdot \log_{10}(p_{E,max}/2 \cdot 10^{-5}$ Pa). **F2504**

maximum insertion gain transfer function (sound field), $H_{SS,max}$, *n*—maximum insertion gain transfer function (sound field) that can be achieved with the implant electronics. **F2504**

maximum run-out load or moment, *n*—maximum load or moment for a given test that can be applied to an artificial intervertebral disc where all of the tested constructs have withstood 10 000 000 cycles without functional failure. **F2346**

maximum torque (N-m), *n*—largest value of torque recorded during the period of rotation before screw failure in torsional shear when tested in accordance with Annex A1 of Specification F543. **F543**

measurement grid lines, *n*—evenly spaced grid of parallel lines all of the same length. **F1854**

mechanical deterioration, *n*—deterioration that is visible to the naked eye and is associated with mechanical damage to the device under test (for example, initiation of fatigue crack or surface wear). **F2346**

mechanical failure, *n*—failure associated with a defect in the material (for example, fatigue crack) or of the bonding between materials that may or may not produce functional failure. **F2423**

mechanical integrity, *n*—ability of all components of a cryosystem to withstand the pressures and temperatures that may be encountered during use as recommended by the manufacturer. **F882**

median bending fatigue moment at *N* cycles (N·m), *n*—value in N-m of the maximum moment that can be applied to a spinal component for which 50 % of the test specimens of a given sample can be expected to survive *N* loading cycles at a specific *R*-ratio. **F2193**

median fatigue strength at N cycles, *n*—maximum stress at which 50 % of the specimens of a given sample would be expected to survive *N* loading cycles. For the purposes of this test method, the fatigue strength will be determined at 5 million load cycles. A rationale for this is provided in the Appendix X1.4 of F2118. **F2118**

medical device, *n*—any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

(1) diagnosis, prevention, monitoring, treatment, or alleviation of disease,
(2) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury,
(3) investigation, replacement, modification, or support of the anatomy or of a physiological process,
(4) supporting or sustaining life,
(5) control of conception,
(6) disinfection of medical devices, and
(7) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

ISO 13485, F2052, F2213, F2503

medical implant, *n*—structure or device that is placed within the body of the patient for medical diagnostic or therapeutic purposes. **F2182**

medio-lateral (ML), *n*—orientation that is aligned with the y-axis in the defined coordinate system. **F1223**

melamine plastic, *n*—plastic based on resins made by the condensation or melamine and aldehydes. **F1251**

mesh, *n*—alignment of opposing teeth. The teeth may be in-line or angled. **F1638**

micron (µ), *n*—0.001 mm, also known as a micrometre; measurement of cell diameter. **F2149, F2312**

microorganism, *n*—bacteria, fungi, yeast, mold, viruses, and other infectious agents. However, it should be noted that not all microorganisms are infectious or pathogenic. **F2312**

microorganisms, *n*—bacteria, fungi, yeast, mold, viruses, and other infectious agents. **F2212**

DISCUSSION—Not all microorganisms are infectious or pathogenic.

middle-ear transfer function, H_{TV}, *n*—stapes velocity (unimplanted) produced by an ear-canal sound pressure, divided by the ear-canal sound pressure, in units of mm/s/Pa: $H_{TV} = v_U/p_T$. **F2504**

ML condylar radius, *n*—geometrical curvature of the component's condyle in the frontal plane. **F1223**

ML dimension, *n*—any geometrical length aligned with the ML orientation. **F1223**

ML displacement, *n*—relative linear translation between components in the ML direction. **F1223**

ML shear load, *n*—force applied to the moveable component with its vector aligned in the ML direction causing or intending to cause an ML displacement. **F1223**

modified working end, *n*—working surfaces possessing superior hardness characteristics which are either the result of depositing various materials on the base metal or the result of permanently securing an insert (such as by brazing) to the base metal. **F1325**

DISCUSSION—The typical method of modifying the working end of the suture needle holder is to use jaw inserts or to plasma deposit (flame plate) materials with improved wear characteristics such as tungsten carbide or stellite. For the jaw insert method, the insert is brazed to the jaw face with a uniform deposit of silver solder which is free of crevices at all interfaces. For the flame plating method, a uniform layer of material is deposited which is 0.004 ± 0.001 in. thick.

modified working ends, *n*—working surfaces possessing superior hardness characteristics that are the result of either depositing various materials on the base metal or securing an insert permanently (such as by brazing) to the base metal (see Note 3 of Specification F1613). **F1613**

molecular mass average (molecular weight average), *n*—the given molecular weight (Mw) of a chitosan will always represent an average of all of the molecules in the population. The most common ways to express the Mw are as the number average ($\bar{M}_n$) and the weight average ($\bar{M}_w$). The two averages are defined by the following equations:

$$\bar{M}_n = \frac{\sum_i N_i M_i}{\sum_i N_i}$$

and

$$\bar{M}_w = \frac{\sum_i W_i M_i}{\sum_i W_i} = \frac{\sum_i N_i M_i^2}{\sum_i N_i M_i}$$

where:

N_i = number of molecules having a specific molecular weight M_i and

w_i = weight of molecules having a specific molecular weight M_i. In a polydisperse molecular population the relation $\bar{M}_w > \bar{M}_n$ is always valid. The coefficient $\bar{M}_w/\bar{M}_n$ is referred to as the polydispersity index, and will typically be in the range 1.5 to 3.0 for commercial chitosans.

monomer, *n*—relatively simple compound which can react to form a polymer. (See also **polymer**.) **F1251**

motion segment, *n*—two adjacent vertebrae, the intervening disc, and the associated ligamentous structures. **F1582**

mouse teeth, *n*—distal tip teeth that interdigitate. **F1638**

MR compatible, *adj*—device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions. **F2182**

MR conditional, *adj*—item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required. **F2119, F2503**

MR safe, *adj*—device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions. **F2182**

MR-safe, *adj*—item that poses no known hazards in all MR environments. **F2119, F2503**

DISCUSSION—MR-Safe items include nonconducting, nonmagnetic items such as a plastic petri dish. An item may be determined to be MR-Safe by providing a scientifically based rationale rather than test data.

MR-unsafe, *adj*—item that is known to pose hazards in all MR environments. **F2119, F2503**

DISCUSSION—MR-Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

mutagen, *n*—any physical or chemical agent capable of inducing a mutation. **F1280**

mutation, *n*—any heritable change in the genetic material, not caused by genetic segregation or genetic recombination, and that is transmitted to daughter cells. **F1280**

***N*,** *n*—variable representing a specified number of cycles. **F1264**

natural materials, *n*—synthesized or produced by living cells. **F2027, F2312**

needle ducility, *n*—measure of the amount of plastic bending a needle can withstand. **F1840**

needle length, *n*—distance measured along the needle curvature from end to end. **F1840**

needle radius, *n*—radius of the uniformly curved portion or portions of the needle measured from the centerline of the needle body. **F1840**

needle stop, *n*—injection port component used to limit hypodermic needle penetration through the port. **F1441**

needle wire diameter, *n*—gage or thickness of the needle wire, measured at a location between the needle body and the attachment area, where either no or minimal work has taken place. **F1840**

negative control, *n*—material, such as a polyethylene, that produces little or no hemolysis (<2 % after subtraction of the blank) in the test procedure. It is desirable that the control specimens have the same configuration as the test samples. **F756**

net volumetric wear NV_i of wear specimen (mm^3), *n*—$NV_i = NW_i/\rho$ at end of cycle interval *i* where ρ = mass density (for example, units of g/mm^3) of the wear material. **F2423**

net wear NW_i of wear specimen (g), *n*—$NW_i = (W_0 - W_i) + (S_i - S_0)$; loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval *i*. **F2423**

neurosurgical instrument, *n*—any cooperative device used during surgical procedures involving the implantation of neurosurgical implants. **F701**

nitinol, *n*—generic name for a Ni-Ti alloy. **F2005**

no load motion, *n*—some devices have a degree of free motion at fixation points which allows relative motion to occur between the device and the bone with no elastic strain in the device and no (or minimal) change in load. This is termed "no load motion." **F1264**

nominal saturated moisture content, Ms (%), *n*—approximation of the amount of moisture absorbed by a specimen at saturation, expressed as a percentage of the weight of absorbed moisture at approximate saturation divided by the initial specimen weight, as follows: **F1634**

$$M_s, \% = \frac{W_s - W_b}{W_b} \times 100$$

where:

W_s = specimen weight at approximate saturation, g, and
W_b = initial (baseline) specimen weight at $t = 0$ and standard laboratory atmosphere, g.

non-animal derived, *n*—term describing the absence of any animal-derived tissue, proteins, or products in the manufacturing process. **F2347**

nonaqueous solvent, *n*—in this assay refers to the organic or nonpolar solvent, which shall be dimethylsulfoxide (DMSO) or acetone olive oil (AOO). **F2148**

nonrecoverable movement, *n*—displacement of the stent relative to the balloon such that if the shearing force was reduced to zero, the stent would remain displaced in the direction of the shearing force relative to the initial placement on the balloon. The force at which non-recoverable movement begins is defined as the initial displacement force. **F2394**

non-soluble debris, *n*—residue including metals, organic solids, inorganic solids, and ceramics. **F2459**

nontapping screw, *n*—screw that has a tip that does not contain a flute. Nontapping screws usually require a tap to be inserted into the pilot hole before the insertion of the screw, when used in moderate or hard bone. **F543**

non-water soluble residue, *n*—residue soluble in solvents other than water. Inclusive in this are oils, greases, hydrocarbons, and low molecular weight polymers. Typical solvents used to dissolve these residues include chlorinated or fluorinated solvents, or low molecular weight hydrocarbons. **F2459**

nucleation, *n*—formation of ice from a supercooled aqueous solution by random aggregation of water molecules into clusters with ice-like properties. Nucleation may be homogenous (spontaneous) or heterogenous (catalyzed by a substrate that reduces the thermodynamic barrier to cluster formation). **F2386**

null position, *n*—core position within the sensor housing where the sensor voltage output is zero (some sensors do not have a null position). **F2537**

nylon plastic, *n*—plastic based on resins composed principally of a long-chain synthetic polymeric amide which has recurring amide groups as an integral part of the main polymer chain. **F1251**

offset angular displacement, *n*—(distance OB—Fig. 6) offset on the angular displacement axis equal to 2 % of the intervertebral height, *H*, divided by the maximum radius of the implant in the *XY*-plane; for example, for an artificial intervertebral disc with a height of 10 mm and a maximum radius in the *XY*-plane of 9 mm, distance OB = (0.02) (10 mm) / (9 mm) = 0.022 radians = 1.3°. **F2346**

offset correction, *n*—removal of any offset in a sensor's output so that at zero displacement, zero voltage is recorded. **F2537**

offset displacement, *n*—(distance OB—Fig. 6) offset on the linear displacement axis equal to 2 % of the intervertebral height (for example, 0.2 mm for a 10 mm intervertebral height). **F2346**

olefin plastic, *n*—plastic based on polymers made by the polymerization of olefins or copolymerization of olefins with other monomers, the olefins being at least 50 mass %. **F1251**

oligomer, *n*—polymer consisting of only a few monomer units such as a dimer, trimer, tetramer, and so forth, or their mixtures. **F1251**

one-part elastomer, *n*—elastomer supplied in the uncured form in one package containing all of the formulation components. It does not require mixing before fabrication. **F2042**

0.2 % offset displacement (mm), *n*—permanent displacement equal to 0.002 times the test gage section length for the specific test, in mm. The test gage section length is equal to the bending moment arm for spinal screw tests. The test gage section length is equal to the center span distance for spinal plate and rod tests where the loading rollers are directly contacting the test specimen (Fig. A2.1 and Fig. A3.1 of Specifications and Test Methods F2193). The test gage section length is equal to the unsupported distance between the ends of the extension segments for spinal plate and rod tests where extension segments are used to load the test sample (Fig. A2.2 of Specifications and Test Methods F2193) (distance *0B* in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

open cell, *n*—cell not totally enclosed by its walls, and hence interconnecting with other cells. (See **closed cell**.) **F1251**

open cryotip, *n*—device specifically designed to apply the cryogen directly to the target tissue. **F882**

open section, *n*—any cross section perpendicular to the longitudinal axis of a hollow IMFD in which there is a discontinuity of the outer wall. To orient the IMFD for testing and insertion, the desired relationship of the discontinuity to the sagittal and coronal planes should be described for the intended applications. **F1264**

open wound, *n*—wound that communicates with the atmosphere by direct exposure. **Dorland's, F2311, F2312**

organosol, *n*—suspension of a finely divided plastic in a plasticizer, together with a volatile organic liquid.

DISCUSSION—The volatile liquid evaporates at elevated temperatures, and the resulting residue is a homogeneous plastic mass, provided the temperature is high enough to accomplish mutual solution of the plastic and plasticizer. **F1251**

orientation means, *n*—any locus on the surface of the implant that is modified to assist the surgeon to position the implant. **F881**

orientation means, *n*—any mark or palpable portion of an implantable breast prosthesis to assist the surgeon in positioning the implant. **F703, F2051**

orientation means, *n*—any mark or palpable portion of a soft tissue expander to assist the surgeon in positioning. **F1441**

oxidation index (OI), *n*—oxidation index (OI) is defined as the ratio of the area of the carbonyl absorption peak(s) centered near 1720 cm^{-1} to the area of the absorption peak(s) centered near 1370 cm^{-1} , as shown in Fig. 1 of F2102. Note that the peak areas are computed after subtracting out the appropriate baseline, as further discussed in Section 6 of F2102. **F2102**

oxidation index profile, *n*—oxidation index profile is the graphical representation of variation of the sample's oxidation index with distance from its articular surface or the surface of interest. This is a plot of an OI versus DL. Typically, the graph will show the profile through the entire thickness of the sample. **F2102**

paramagnetic material, *n*—material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force. **F2052, F2213**

partial replacement disc, *n*—structure intended to restore a portion of the support and motion or a portion thereof, between adjacent vertebral bodies. **F1582**

partial thickness skin wound, *n*—skin wound with the loss of the epidermis and part of the dermis, but retaining a layer of viable dermal tissue that includes the sources of epidermal cells from which the wound can heal spontaneously by epidermal tissue regeneration. **F2311, F2312**

partial thromboplastin time (PTT) assay, *n*—modification of the Activated Partial Thromboplastin Time (APTT) assay; unlike the APTT test, the PTT assay uses reagent (rabbit brain cephalin) without activating substances (silica, kaolin, elagic acid.) The material being tested acts as the activator. **F2382**

partially threaded screw, *n*—screw whose threaded portion does not extend fully from the screw point to the screw head but instead has a smooth shaft running between the head and threads. **F543**

passage, *n*—transfer or transplantation of cells, with or without dilution, from one culture vessel to another. It is understood that any time cells are transferred from one vessel to another, a certain portion of the cells may be lost and, therefore, dilution of cells, whether deliberate or not, may occur. This term is synonymous with the term *subculture*. **F2664**

passage number, *n*—number of times the cells in the culture have been subcultured or passaged. In descriptions of this process, the ratio or dilution of the cells should be stated so that the relative cultural age can be ascertained. **F2664**

passivation, *n*—changing of the chemically active surface of stainless steel to a much less reactive state. **F921**

passivation, *n*—process to render the surface condition of stainless steel chemically inactive. **F1078**

passive implant, *n*—implant that serves its function without supply of electrical power. **F2182, F2213**

patch, *n*—piece of silicone elastomer that covers and seals the hole that results from the manufacturing process of shell fabrication. **F2051**

patch or base, *n*—piece of silicone elastomer or reinforced silicone elastomer, which covers and seals the hole which results from the manufacturing process of shell fabrication. **F1441**

patella, *n*—bone of the knee joint which articulates within the trochlear groove of the femur. **F2451**

PBS, *n*—phosphate buffered saline, pH 7.2. **F2148**

peak load, *n*—initial local maximum in the load versus displacement curve (Fig. 1). In certain radiation crosslinked UHMWPE materials, the load versus displacement curve increases monotonically and a shoulder, rather than an initial peak load, may be observed. **F2183**

percent error, *n*—the difference between a measurement of a reference standard and the actual length of the reference standard divided by the actual length of the reference standard and the result converted to a percent. **F2537**

% hemolysis, *n*—quotient of the free plasma hemoglobin (mg/mL) released as a result of contact with test material or extract divided by the total hemoglobin (mg/mL) present in the blood solution multiplied by 100. **F756**

DISCUSSION—This is synonymous with hemolytic index.

permanent deformation, *n*—remaining linear or angular displacement (axial—mm, angular—degrees or radians) relative to the initial unloaded condition of the artificial intervertebral disc after the applied load or moment has been removed. **F2346**

permanent displacement (mm), *n*—total displacement in mm remaining after the applied load has been removed from the test specimen. **F2193**

permeability, *n*—measure of fluid, particle, or gas flow through an open pore structure. **F2450**

phenolic plastic, *n*—plastic based on resins made by the condensation of phenols, such as phenol and cresol, with aldehydes. **F1251**

phosphate buffered saline (PBS) (Ca and Mg free), *n*—use of phosphate buffered saline is preferable to the use of saline to maintain the pH. The use of magnesium- and calcium-free PBS is necessary to maintain the anticoagulant properties of the chelating agents used in collecting the blood. It is used as the background or "blank" for a hemolysis test. **F756**

pilot hole, *n*—hole drilled into the bone into which the screw tip is inserted. The pilot hole is normally slightly larger than the screw's core diameter. However, if the screw is to be used to provide compression across a fracture, a portion of the pilot hole may be larger to allow for a clearance fit. **F543**

pilot holes in test block, *n*—pilot holes shall be drilled in the test block for insertion and removal of the test specimen. See Specification F543, Annex 2. **F2502**

pit, *n*—*in plastics*, an imperfection, a small crater in the surface, the depth and width of which are approximately the same order of magnitude. **F1251**

pitch, *n*—the length between the thread crests. **F543**

plasma hemoglobin, *n*—amount of hemoglobin in the plasma. **F756**

plasma-sprayed hydroxyapatite coating, *n*—coating, consisting of at least 50 % hydroxyapatite by weight, prepared by plasma-spraying hydroxyapatite on a substrate. **F2024**

plastic, *n*—any of numerous polymeric materials that are usually thermoplastic or thermosetting, of high molecular weight and that can be molded, cast extruded, drawn, laminated, or otherwise fabricated into objects, powders, beads, films, filaments, fibers, or other shapes (Webster Modified). **F1251**

plasticizer, *n*—substance incorporated into a material to increase its workability, flexibility, or distensibility of the material. **F1251, F665**

plastisol, *n*—liquid suspension of a finely divided PVC polymer or copolymer in a plasticizer.

DISCUSSION—The polymer does not dissolve appreciably in the plasticizer at room temperature but does dissolve at elevated temperatures to form a homogeneous plastic mass (plasticized polymer). **F1251**

plate, *n*—longitudinal element asymmetrical in the transverse plane and designed to resist tension, compression, bending, and torsion. **F1582**

point, *n*—portion of the needle intended to initiate tissue penetration. **F1840**

point configuration, *n*—shape of the point. Some common point configurations include, but are not limited to: taper, trocar, blunt, spatulated, conventional cutting edge, reverse cutting edge, cutting taper, and side cutting needle. **F1840**

pole of the articulating surface, *n*—pole of an articulating surface is defined by a point at the intercept of the revolution axis of the component and the spherical articulation surface. **F2033**

polybutylene, *n*—polymer prepared by the polymerization of butene as the sole monomer. (See also **polybutylene plastic** and **butylene plastic**.) **F1251**

polybutylene plastic, *n*—plastic based on polymers made with butene as essentially the sole monomer. **F1251**

polycarbonate, *n*—polymer in which the repeating structural unit in the chain is a carbonic acid ester of Bisphenol A. **F1251**

polyester, *n*—polymer in which the repeated structural unit in the chain is of the ester type.

DISCUSSION—The polyester is linear and thermoplastic if derived, either actually or formally, from *(a)* mono-hydroxy-mono-carboxylic acids by selfesterification, or *(b)* the interaction of diols and dicarboxylic acids. **F1251**

polyether, *n*—polymer in which the repeated structural unit in the chain is of the ether type. **F1251**

polyethylene, *n*—polymer prepared by the polymerization of ethylene as the sole monomer. (See also **polyethylene plastic** and **ethylene plastic**.) **F1251**

polyethylene plastic, *n*—plastic based on polymers made with ethylene as essentially the sole monomer.

DISCUSSION—In common usage for this plastic, essentially means no less than 85 % ethylene and no less than 95 % total olefins. **F1251**

polyethylene terephthalate, *n*—polymer derived from terephthalic acid and ethylene glycol by condensation polymerization. **F1251**

polymer, *n*—long chain molecule composed of monomers including both natural and synthetic materials, for example, collagen, polycaprolactone. **F2450**

polymer, *n*—substance consisting of molecules characterized by the repetition (neglecting ends, branch junctions, and other minor irregularities) of one or more types of monomeric units. (See **copolymer**.) **F1251**

polymerization, *n*—chemical reaction in which monomers are linked together to form polymers. (See also **polycondensation** and **polyaddition**.) **F1251**

polyolefin, *n*—polymer prepared by the polymerization of an olefin(s) as the sole monomer(s). (See also **polyolefin plastic**, **olefin plastic**.) **F1251**

polyolefin plastic, *n*—plastic based on polymers made with an olefin(s) as essentially the sole monomer(s). **F1251**

polyoxymethylene, *n*—polymer in which the repeated structural unit in the chain is oxymethylene.

DISCUSSION—Polyoxymethylene is theoretically the simplest member of the generic class of polyacetals. **F1251**

polypropylene, *n*—polymer prepared by the polymerization of propylene as the sole monomer. (See also **polypropylene plastic**, **propylene plastic**.) **F1251**

polystyrene, *n*—polymer prepared by the polymerization of styrene as the sole monomer. (See also **styrene plastic**.) **F1251**

polyterephthalate, *n*—thermoplastic polyester in which the terephthalate group is a repeated structural unit in the polymer chain. **F1251**

poly(vinyl acetate), *n*—polymer prepared by the polymerization of vinyl acetate as the sole monomer. **F1251**

poly(vinyl alcohol), *n*—polymer prepared by the essentially complete hydrolysis of polyvinyl ester. **F1251**

poly(vinyl chloride), *n*—polymer prepared by the polymerization of vinyl chloride as the sole monomer. **F1251**

pore, *n*—liquid (fluid or gas) filled externally connecting channel, void, or open space within an otherwise solid or gelatinous material (for example, textile meshes composed of many or single fibers (textile based scaffolds), open cell foams, (hydrogels). Synonyms: *open-pore*, *through-pore*. **F2450**

pores, *n*—inherent or induced network of channels and open spaces within an otherwise solid structure. **F2150, F2312**

porogen, *n*—material used to create pores within an inherently solid material. **F2450**

DISCUSSION—For example, a polymer dissolved in an organic solvent is poured over a water-soluble powder. After evaporation of the solvent, the porogen is leached out, usually by water, to leave a porous structure. The percentage of porogen needs to be high enough to ensure that all the pores are interconnected.

porometry, *n*—determination of the distribution of open pore diameters relative to the direction of fluid flow by the displacement of a nonvolatile wetting fluid as a function of pressure. **F2450**

porometry, *n*—determination of the distribution of pore diameters relative to direction of fluid flow by the displacement of a wetting liquid as a function of pressure. **F2150, F2312**

porosimetry, *n*—determination of pore volume and pore size distribution through the use of a nonwetting liquid (typically mercury) intrusion into a porous material as a function of pressure. **F2150, F2312, F2450**

porosity, *n*—property of a solid which contains an inherent or induced network of channels and open spaces.

DISCUSSION—Porosity can be measured by the ratio of pore (void) volume to the apparent (total) volume of a porous material and is commonly expressed as a percentage. **F2150, F2312, F2450**

porous coating, *n*—coating on an implant deliberately applied to contain void regions with the intent of enhancing the fixation of the implant. **F1854**

porous coating, *n*—region on the exterior surface of the shell characterized by interconnecting subsurface pores, generally with volume porosity between 30 to 70 %, average pore size between 100 to 1000 µm, and a thickness between 500 to 1500 µm. This porous layer may be manufactured directly into the device by casting or by various electro/chemical/thermal/mechanical means, or applied as a coating of particles, beads, or mesh by processes such as sintering or plasma spray. **F2091**

positive control, *n*—material capable of consistently producing a hemolysis of at least 8 % after subtraction of the results of the blank. **F756**

DISCUSSION—Suggested materials include, but are not limited to, BUNA N (Aero Rubber and other suppliers) and plastisol (Plasti-Coat, Watertown CT).

positive control, *n*—substance capable of consistently stimulating lymphocyte proliferation. **F2148**

post, *n*—non-threaded anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of a non-threaded hole in the bony element. **F1582**

post-in-well feature, *n*—TKR design which tends to influence kinematics through the coupling of a prominent eminence with a recess or housing in a mating component. **F1223**

post-preservation processing, *v*—manipulation of cells or tissue after completion of the preservation process. These steps include, but are not limited to, washing of the cells or tissue to remove the preservation medium/solution and/or specific chemical or biological agents; dilution or concentration of the cells or tissue; and warming to temperatures appropriate for the normal or desired physiological or biochemical functions, or both, of the cells or tissue. **F2386**

potential critical stress concentrator (CSC), *n*—any change in section modulus, material property, discontinuity, or other feature of a design expected to cause a concentration of stress that is located in a region of the IMFD expected to be highly stressed under the normal anticipated loading conditions. **F1264**

potentiodynamic cyclic polarization (forward and reverse polarization), *n*—technique in which the potential of the test specimen is controlled and the corrosion current measured by a potentiostat. The potential is scanned in the positive or noble (forward) direction as defined in Practice G3. The potential scan is continued until a predetermined potential or current density is reached. Typically, the scan is run until the transpassive region is reached, and the specimen no longer demonstrates passivity, as defined in Practice G3. The potential scan direction then is reversed until the specimen repassivates or the potential reaches a preset value. **F2129**

potentiostat, *n*—instrument for automatically maintaining an electrode in an electrolyte at a constant potential or controlled potentials with respect to a suitable reference electrode (see Terminology G15). **F2129**

power supply, *n*—regulated voltage source with output equal to that required by the sensor for proper operation. **F2537**

preload, *n*—resultant force $F_{preload}$ applied to the superior or inferior fixture-end plate that simulates the *in vivo* load that an IVD prosthesis (original healthy disc) must resist. **F2423**

DISCUSSION—Based on a healthy disc, the primary component would be an axial compressive force F_Z in the direction of the negative global *Z* axis, and it would pass through the *in vivo* physiologic instantaneous center of rotation (COR) of the IVD prosthesis. Shear components in the *XY* plane would be F_X and F_Y. Lateral bending moment M_X and flexion/extension moment M_Y components would be created about the initial COR when the preload force does not pass through it

prepolymer, *n*—polymer of degree of polymerization between that of the monomer or monomers and the final polymer. **F1251**

pre-preservation processing, *n*—manipulation of cells or tissue prior to the initiation of preservation. These steps include, but are not limited to, selection of specific cell populations for freezing, centrifugation to modify cell density, introduction of specific chemical or biological agents, and cooling. **F2386**

preservation medium, *n*—specific formulation of an aqueous or nonaqueous solution in which a population of cells or a tissue will be preserved. **F2386**

preservation technologies:— F2386

anhydrobiotic preservation, n—preservation by vaporization and removal of water.

(1) desiccation, n—process for anhydrobiotic preservation in which water is removed by evaporation.

(2) freeze-drying, n—process for anhydrobiotic preservation in which ice crystals are formed by freezing, and water is removed by sublimation and evaporation.

(3) lyophilization, n—in common usage, a synonym for freeze-drying. Whereas etymologically, this term also comprises other methods for anhydrobiotic preservation, care should be taken to avoid ambiguity.

cryopreservation, n—preservation by cooling to a temperature below the equilibrium freezing temperature of the preservation solution, such that there is solidification. The resulting solid may be either crystalline or amorphous, or a combination of crystalline and amorphous phases.

(1) freezing, v—cryopreservation by formation of crystals. Frozen cell suspensions or TEMPs typically contain both crystalline and amorphous water.

(2) vitrification, n—cryopreservation by formation of glass. Vitrified cell suspensions or TEMPs may contain small amounts of crystalline water.

hypothermic preservation, n—preservation by cooling to any temperature below normothermic culture temperatures, such that biological components are suspended in a liquid phase. Hypothermic storage temperatures may be either above or below the equilibrium freezing temperature.

preserve, *v*—to stabilize for the purposes of maintaining the specific mechanical, structural, metabolic, or biological characteristics. **F2386**

pre-test treatment, *n*—treatment of the stent delivery system prior to the evaluation of securement that simulates preparatory, environmental, mechanical or other conditions that may be encountered prior to or during clinical use of the device. Examples include subjecting the devices to elevated shipping temperature/humidity, catheter preparation per use instructions, pre-soaking, bending treatments, tracking treatments (tracking fixture, see definition below) and tracking through lesion treatments (lesion fixture, see definition below). **F2394**

pre-test treatment lesion fixture, *n*—pre-test treatment fixture used to simulate an anatomical vasculature and lesion. Use of the fixture with a guide catheter, a guide-wire, and the stent-balloon catheter delivery system is intended to simulate the bending, frictional and mechanical resistance forces of tracking the device across the lesion site that may be encountered in the clinical setting. **F2394**

pre-test treatment tracking fixture, *n*—pre-test treatment fixture used to simulate an anatomical vasculature. Use of the fixture with a guide catheter, a guide-wire and the stent-balloon catheter delivery system is intended to simulate the bending and frictional forces of tracking the device to the lesion site that may be encountered in the clinical setting. See the engineering diagrams in the Appendix of Guide F2394. Note that these engineering diagrams simulate vessels with a moderately difficult degree of coronary tortuousity but do not include simulated lesions. **F2394**

primary healing, *n*—healing by first intention. **F2312**

primary wound closure, *n*—wound closure for healing by first intention. **F2312**

processed biologics, *n*—cells, tissues, or organs that have undergone manipulation for use in the manufacture of TEMPs; processing here extends beyond the minimal manipulation or processing as it is applied in the field of structural, reproductive and metabolic tissue transplantation.[20] A processed biologic may be used as a component of a TEMP. **F2312**

processing, *vt*—any activity performed on cells, tissues, and organs other than recovery, such as preparation and preservation for storage and packaging. **F2312**

processing aids, *n*—any constituent intentionally used in the processing of the raw material to fulfill a certain technological purpose during treatment or processing, which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product (<5 % by weight), provided that these residues do not present any health risk. Some examples would be: binders, lubricants, compaction aids, disintegrants, plasticizers, deflocculants, wetting agents, water retention agents, antistatic agents, antifoam agents, foam stabilizers, chelating or sequestering agents, phase stabilizers, and so forth. **F2224**

processing materials, *n*—any item or material that is not a component of the TEMP and is in contact with the cells, tissues, and organs during processing. **F2312**

[20] FDA Final Rule Governing Human Tissue Intended for Transplantation, 21 CFR, Part 1270, Section 1271.3(f), 1998.

propylene plastic, *n*—plastic based on polymers of propylene or copolymers of propylene with other monomers, the propylene being in the greatest amount by mass. **F1251**

proximal, *adj*—refers to the balloon end of the catheter, since when in position for clinical use, the balloon end is proximal or closest to the patient. **F623**

proximal end, *n*—that portion of the instrument that is closest to the surgeon when in use. **F921, F1078**

pseudoelasticity, *n*—*see* **superelasticity**. **F2005**

puncture force, *n*—minimum force applied to the representative sharp object that causes its tip to penetrate (exit) the opposite side of the test specimen from the side that it entered when tested in accordance with the test procedure portion, Section 6, of Specification F2132. **F2132**

puncture resistant, *adv*—region of uniform material and thickness is defined as puncture resistant if it meets Section 4 of this specification when tested in accordance with Section 6 of Specification F2132. **F2132**

puncture test specimen, *n*—test specimen that has been punctured using the puncture test described in 6.3, and subsequently evaluated using the direct or indirect methods described in 7.1 and 7.2 of Specification F2132. **F2132**

pyrogen, *n*—any substance that produces fever. **F2312, F2315**

pyrogen, *n*—any substance that produces fever when administered parenterally. **F2103, F2347**

***Rc*—**radius of curvature for single radius axisymmetric domes only. **F1672**

R-phase, *n*—(in nitinol), intermediate phase which may form between austenite and martensite.

DISCUSSION—This occurs in Ni-Ti shape memory alloys under certain conditions. The crystal lattice of the R-Phase is a rhombohedral distortion of the cubic austenite crystal lattice structure, hence the name "R-phase." **F2005**

R-phase finish temperature (R_f), *n*—(in nitinol), temperature at which the transformation from austenite to R-phase is completed on cooling in a two-stage transformation (Fig. 2). **F2005**

R-phase peak temperature (R_p), *n*—(in nitinol), temperature of the exothermic peak position on the DSC curve upon cooling for the austenite to R-phase transformation (Fig. 2). **F2005**

R-phase start temperature (R_s), *n*—(in nitinol), temperature at which the transformation from austenite to R-phase begins on cooling in a two-stage transformation (Fig. 2). **F2005**

R'-phase finish temperature (R'_f), *n*—(in nitinol), temperature at which the martensite to R-phase transformation is completed on heating in a two-stage transformation (Fig. 2). **F2005**

R'-phase peak temperature (R'_p), *n*—(in nitinol), temperature of the endothermic peak position on the DSC curve upon heating, for the martensite to R-phase transformation in a two-stage transformation (Fig. 2). **F2005**

R'-phase start temperature (R'_s), *n*—(in nitinol), temperature at which the martensite to R-phase transformation begins on heating in a two-stage transformation (Fig. 2). **F2005**

***R* value,** *n*—*R* value is the ratio of the minimum force to the maximum force. **F1440**

$$R = \frac{\text{minimum force}}{\text{maximum force}}$$

***R* value,** *n*—*R* value is the ratio of the minimum load to the maximum load. **F1800, F2580**

$$R = \frac{minimum\ load}{maximum\ load}$$

radial component, *n*—articulating member inserted into the radius for articulation with the carpal component. **F1357**

radio frequency (RF) magnetic field, *n*—magnetic field in MRI that is used to flip the magnetic moments. The frequency of the RF field is γB_0 where γ is the gyromagnetic constant, 42.56 MHz/T for protons, and B_0 is the static magnetic field in Tesla. **F2182, F2503**

radio pair, *n*—one set of RSA radiographs which were taken simultaneously. **F2385**

radiographic marker, *n*—nonstructural, generally thin wire, designed to be apparent on X-rays taken after placement of implants that otherwise would be unapparent on such X-rays. **F2091**

radiostereometric analysis (RSA), *n*—method developed by Goren Selvik for measuring relative motion between two parts from clinical radiographs.[21] This method uses *in vivo* tantalum beads, an external reference cage, and two X-ray generators that take two exposures simultaneously. There are several commercially available software/hardware packages for RSA analysis. **F2385**

ratchets, *n*—portion of both the female and the male members possessing inclined teeth that forms the locking mechanism. **F921**

rated volume, *n*—stated volume of inflation of the retention balloon of the enteral feeding device in the manufacturers labeling and instructions for use. **F2528**

raw count, *n*—enumeration of the cell population not corrected for coincidence. **F2149, F2312**

read time, *n*—time during which data is collected to detect a clot. **F2382**

recipient, *n*—individual or organism into whom materials are grafted or implanted. **F2312**

reconstitute, *v*—to add a solvent or diluent to an anhydrobiotically preserved sample in order to dissolve or suspend its components. **F2386**

[21] Selvik, G., et al., "Roentgen Stereophotogrammetric Analysis (RSA) in Total Hip and Knee Joint Replacement," Biomechanical Measurement in Orthopaedic Practice, D. Harris, Editor, Clarendon Press, Oxford, 1985, pp. 274-282.

recovery, *n*—obtaining of cells or tissues which may be used for the production of TEMPs. **F2312**

referee test method, *n*—method cited in the published specification for the device. This method and the corresponding requirements will be invoked when the performance of the medical device will be questioned. The manufacturer need not use this referee test method in his usual inspection and quality control. **F623**

Reference Line L1, distal stem axis, *n*—medial-lateral (M-L) centerline of the most distal 50 mm of stem in the A-P projection. **F1440**

Reference Line L2:—

collared device, n—plane of the distal side of the collar in the A-P projection. **F1440**

collarless device, n—resection plane recommended for the device in the A-P projection. **F1440**

Reference Point P1, *n*—spherical center of the prosthesis head. **F1440**

Reference Point P3:—

collared device, n—intersection of the principal axis of the collar (L2) with the medial surface of the stem in the A-P projection. **F1440**

collarless device, n—intersection of the resection plane (L2) with the medial surface of the stem in the A-P projection. **F1440**

Reference Point P4, *n*—distal tip of the stem. **F1440**

Reference Point P6[22], *n*—intersection of the cantilever plane with the medial surface of the stem in the A-P projection. **F1440**

reflux system, *n*—apparatus containing an extraction vessel and a solvent return system. It is designed to allow boiling of the solvent in the extraction vessel and to return any vaporized solvent to the extraction vessel. **F2459**

regenerative biology, *n*—scientific discipline that endeavors to understand how tissues and organs are replaced naturally. The principles of regenerative biology can be applied in tissue engineering to generate TEMPs. **F2312**

regenerative medicine, *n*—branch of medical science that applies the principles of regenerative biology to specifically restore or recreate the structure and function of human cells, tissues, and organs that do not adequately regenerate. **F2312**

region of uniform material and thickness, *n*—sharps-contact areas of the container, in aggregate, that are made of the same homogeneous, composite, or laminated material, and, as a consequence of fabrication or design or both, are expected to have the same material and thickness as compared to other areas of the container. For example, in molded containers, the corners could be expected to be of different thickness than the sides and bottom, resulting in different regions of uniform material and thickness. Labels, tabs, membranes, or thin films covering openings in the container are considered separate regions of uniform material and thickness. **F2132**

reinforced plastic, *n*—plastic with high strength fillers imbedded in the composition, resulting in some mechanical properties superior to those of the base resin. (See also **filler**.)

DISCUSSION—The reinforcing fillers are usually fibers, fabrics, or mats made of fibers. **F1251**

reinforced silicone elastomer, *n*—composite of silicone elastomer and an embedded textile made from polyethylene terephthalate (such as Dacron®) fibers. **F1441**

reins, *n*—solid or pseudosolid organic material often of high molecular weight, which exhibits a tendency to flow when subjected to stress, usually has a softening or melting range, and usually fractures conchoidally.

DISCUSSION—In a broad sense, the term is used to designate any polymer that is basic material for plastics. **F1251**

removal torque, *n*—amount of torque required to overcome the frictional force between the screw and the material used for testing while removing the screw from the material (for example, counterclockwise rotation for right-hand thread). **F543**

reparative medicine, *n*—branch of medical science whereby clinicians use surgical methods to repair or modify the structure and function of patient's cells, tissues, or organs. The principles of reparative medicine can be applied in tissue engineering to generate TEMPs. **F2312**

replacement disc, *n*—structure intended to restore support and motion between adjacent vertebral bodies. **F1582**

reprocessing, *vt*—reworking of cells, tissues, and organs of unacceptable quality from a defined stage of processing, so that the quality may be rendered acceptable by one or more additional operations. **F2312**

residence time, *n*—time at which an implanted material (synthetic or natural) can no longer be detected in the host tissue. **F2451**

residual elongation, El_r[%], *n*—difference between the strain at a stress of 7.0 MPa during unloading and the strain at a stress of 7.0 MPa during loading. **F2516**

residual elongation (El_r[%]), *n*—(in nitinol), strain after tensile loading to 6 % strain and unloading to 7 MPa. **F2005**

resin, *n*—any polymer that is a basic material for plastics.[23] **F1635**

retention element, *n*—any ring, taper, wire, or other protrusion or cavity from the interior surface of the shell or the exterior surface of the bearing element that is intended to affix the bearing element to the shell. **F2091**

[22] The reference points and lines are consistent with the Proposed Standard Specification for Cementable Total Hip Prostheses with Femoral Stems. The reference points "P2" and "P5" in that proposed specification are not relevant to this practice. Consequently, they are not used in this practice.

[23] *Polymer Technology Dictionary*, Tony Whelan, Ed., Chapman & Hall, 1994.

reuse, *n*—repeated or multiple use of any medical component (whether labeled SUD or reusable) with reprocessing (cleaning, disinfection, or sterilization, or combination thereof) between patient uses. **F2459**

rewarm, *v*—to warm from preservation temperature to a temperature required for use (for example, additional culture or clinical use). **F2386**

Reynolds number, *n*—dimensionless number expressing the ratio of inertia forces to viscous forces in a moving fluid. The number is given by *VLr/m* where *V*, is the fluid's velocity, *L* is a characteristic length or distance such as pipe diameter, *r* is the fluid's mass density, and *m* is the fluid's dynamic viscosity. **F4410, F2664**

rhBMP, *n*—recombinant human bone morphogenetic protein. **F2312**

ride, *n*—edge that acts as a cam **F1078**

ride relief, *n*—contoured area between the shank and ride. **F1078**

rigid plastic, *n*—for purposes of general classification, a plastic that has a modulus of elasticity either in flexure or in tension greater than 700 MPa (100 000 psi) at 23°C and 50 % relative humidity when tested in accordance with Test Methods D747, D790, D638, or D882. **F1251**

rod, *n*—longitudinal element symmetrical in the transverse plane designed to resist tension, compression, bending, and torsion. **F1582**

rod diameter (mm), *n*—length in mm of a chord passing through the center of the rod's cross section. **F2193**

rod length (mm), *n*—overall dimension measured in mm between the ends of a given rod. **F2193**

room temperature vulcanization (RTV), *n*—one-part elastomer which cures in the presence of atmospheric moisture. Little, if any, acceleration of cure rate is realized by increasing temperature. Because cure is dependent upon diffusion of water into the elastomer, cure in depths of greater than 0.64 cm is not recommended. **F2042**

rotary laxity (RL), *n*—degree of relative angular motion permitted of moveable component about the z-axis as governed by inherent geometry and load conditions. **F1223**

rotary torque, *n*—moment applied to the moveable component with its vector aligned to an axis parallel to the z-axis and causing or intending to cause an internal or external rotation. **F1223**

rounded blade, *n*—blade having a radius on its outer surface which forms a transition between the outer edge and the cutting edges. **F1078**

rubber, *n*—elastic substance derived from various tropical plants, such as the general Hevea and Ficus, essentially a polymer of isoprene; the term is frequently applied to both natural and synthetic elastic substances (Webster Modified). **F1251**

ruggedness, *n*—degree of reproducibility of the same sample under a variety of normal conditions; for example, different operators. **F2149, F2312**

run out (cycles), *n*—maximum number of cycles that a test needs to be carried to if functional failure has not yet occurred. **F2423**

runout, *n*—predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed. For the purposes of this test method, the runout will be 5 million load cycles. **F2118**

safety, *n*—freedom from unacceptable risk in the MR environment. **F2503**

saline, *n*—0.9 % sodium chloride (aqueous, polar solvent). **F2148**

saline, *n*—only sodium chloride for injection (USP) is recommended for filling lumens of inflatable breast prosthesis. **F2051**

saline, *n*—only sodium chloride for injection (USP) is recommended for filling lumens of soft tissue expanders. **F1441**

saline, *n*—sodium chloride injection USP. **F703**

saran plastic, *n*—*see* **vinylidene chloride plastic**. **F1251**

scaffold, *n*—support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues. **F2312, F2450, F2664**

scan rate, *n*—rate at which the controlling voltage is changed. **F2129**

scar, *n*—fibrous tissue replacing normal tissues destroyed by injury or disease. **Stedman's,[24] F2311, F2312**

scissoring, *v*—lateral misalignment. **F1638**

screw, *n*—fastener which joins the scissor halves. **F1078**

screw, *n*—anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads. **F1582**

screw head, *n*—end of the screw which is opposite of the tip and from which the means of inserting the screw is coupled. **F543**

screw interconnection, *n*—interconnection having an implant component sandwiched between the screw head (or screw thread) and bony element or other implant components. **F1582**

screw length, *n*—overall length of the screw measured from the screw head to the screw tip. **F543**

screw thread, *n*—helical groove on a cylindrical or conical surface. The projecting helical ridge thus formed is called a

[24] Stedman, T. L., *Stedman's Medical Dictionary*, 27th Ed., Lippincott Williams & Wilkins, Philadelphia, 2000.

screw thread, consisting of peaks (crests) and valleys (roots). **F543**

secondary healing, *n*—healing by second intention. **F2312**

secondary wound closure, *n*—wound closure for healing by second intention. **F2312**

securement test, guide-type, *n*—stent securement test that is similar to the clinical scenario of pulling an undeployed stent delivery system back into a guide catheter, arterial sheath or hemostasis valve. Examples include guides, rings, or shims ideally designed to engage the stent end or body but not the catheter balloon. The shim securement test, described in Section 7 of Guide F2394, uses complementary thin, rigid plates with rounded "V" notches that are sized to circumferentially engage the stent end but not the catheter balloon. See the engineering diagrams in the Appendix of Guide F2394. **F2394**

securement test, lesion-type, *n*—stent securement test that is similar to the clinical scenario of pushing or pulling an undeployed stent delivery system through or around a fibrous or calcified lesion. Examples include tape, nubs, protrusions or sandpaper ideally designed to engage the stent end or body but not the catheter balloon. **F2394**

seeding, *v*—deliberate initiation of ice crystal formation in a supercooled aqueous solution under controlled conditions. When ice forms either spontaneously or as a result of the inclusion of nucleating agents in the cryopreservation solution, this is referred to as nucleation. **F2386**

segmented polyurethane, *n*—family of polymers in which ester or ether groups, connected by hydrocarbon chains, occur as blocks that are coupled by urethane and urea groups. **F624**

self-locking screw, *n*—threaded anchor design that undergoes a deformation process at the end of the insertion process which results in the screw's locking to the mating spinal construct element. **F2193**

self-tapping force (N), *n*—amount of axial force required to engage the self-tapping features of self-tapping style screws when tested in accordance with Annex A4 of Specification F543. **F543**

self-tapping screw, *n*—a screw that has any number of flutes at its tip which are intended to cut the screw's thread form into the bone upon insertion. **F543**

semirigid plastic, *n*—for purposes of general classification, a plastic that has a modulus of elasticity either in tension of between 70 and 700 MPa (10 000 and 100 000 psi) at 23°C and 50 % relative humidity when tested in accordance with Test Methods D747, D790, or D882. **F1251**

senescence, *n—in vertebrate cell cultures*, the property attributable to finite cell cultures; namely, their inability to grow beyond a finite number of population doublings. Neither invertebrate nor plant cell cultures exhibit this property. This term is synonymous with *in vitro senescence*. **F2664**

sensor housing, *n*—central hole in a linear displacement sensor that senses movement of the core within it. **F2537**

serrations, *n*—corrugations in the cutting edge of the blades. **F1078**

serrations or teeth, *n*—gripping or clamping surfaces of the jaws. **F921**

set, *n*—positioning of the blade for proper cutting action. **F1078**

set, *n*—at rest position of the instrument halves that will provide the intended closing relationship of fit and force. **F1638**

shaft screw, *n*—threaded anchor having an unthreaded shank equal to its thread diameter. **F2193**

shank, *n*—part of either the female or the male member that yields configuration, length, and leverage. **F921**

shank, *n—(1)* part of either scissor half that yields configuration, length, and leverage; *(2)* part of the scissor between the finger ring and joint. **F1078**

shape memory alloy, *n*—metal that, after an apparent plastic deformation in the martensitic phase, undergoes a thermoelastic change in crystal structure when heated through its transformation temperature range resulting in a recovery of the deformation. **F2005**

sharps, *n*—items used in medical treatment, diagnoses, or research that may cause puncture wounds, cuts, or tears in skin or mucous membranes, including, but not limited to: hypodermic, surgical, suture, and IV needles; Pasteur pipets, lancets, razors, scalpels, and other blades and sharp objects. **F2132**

sharps-contact areas, *n*—material of a container that represents those surfaces that enclose sharps within the container, when in its final closure configuration (that is, disposal configuration). **F2132**

shear load; shear translation, *n*—force and displacement, respectively, parallel to the glenoid plane, applied, for example, in the superior/inferior or anterior/posterior direction (see Figs. 1 and 2 of Test Methods F2028); the shear load simulates the net shear external and active and passive soft tissue forces. **F2028**

shear stress, *n*—components of stress that act parallel to the plane of the surface.[25] **F2664**

sheeting, *n*—form of plastic in which the thickness is very small in proportion to length and width and in which the plastic is present as a continuous phase throughout, with or without filler. (See also **film**.) **F1251**

shell, *n*—metal structure supporting the articulating surface material, and which may be fixed rigidly to the articulating

[25] Curtis, A., "Substratum Nanotopography and the Adhesion of Biological Cells: Are Symmetry and Regularity of Nanotopography Important?" *Biophysical Chemistry*, 94, 2001, pp. 275–283.

surface or fixed such that it allows the articulating surface to rotate or translate. **F2091**

shell, *n*—silicone elastomer continuous layer or membrane container (sac) which encloses a lumen of an implantable breast prosthesis. **F2051**

shell, *n*—silicone elastomer continuous layer or membrane container (sac) which encloses a lumen of a soft tissue expander. **F1441**

shell, *n*—silicone elastomer continuous layer or membrane container (sac) that encloses a lumen or multiple lumens of an implantable breast prosthesis. **F703**

sideplate, *n*—that portion of the angle device generally aligned with the bone's long axis which attaches to the bone via bone screws (see Fig. 1 and Fig. 2 of Specification F384). **F384**

sideplate length, *L*, *n*—distance from the free end of the sideplate to the interior vertex of the barrel/sideplate junction, shown in Fig. 1 and Fig. 2 of Specification F384. **F384**

sideplate thickness, *b*, *n*—thickness of the sideplate as shown in Fig. 1 and Fig. 2 of Specification F384. **F384**

sideplate width, *w*, *n*—width of the sideplate as shown in Fig. 1 and Fig. 2 of Specification F384. **F384**

signal conditioner, *n*—electronic equipment that acts to convert the raw electrical output from the linear displacement sensor into a more useful signal by amplification and filtering. **F2537**

silicone base, *n*—uniformly blended mixture of silicone polymers, fillers, and additives which does not contain crosslinkers or catalyst. **F2038**

silicone elastomer, *n*—elastomer containing cross-linked silicone polymer and fillers, usually silica. **F1251**

silicone elastomer, *n*—elastomer containing cross-linked silicone polymer and fumed amorphous (noncrystalline) silica as a reinforcing filler. **F703, F1441, F2051**

silicone elastomer, *n*—uncured elastomer that has been subjected to conditions which cause it to become crosslinked. Elastomers may be either high consistency rubbers, low consistency rubbers, or RTVs (see following). **F2038**

foams, n—are crosslinked materials which have a component added to them that generates a volatile gas as the material is being vulcanized. This results in a material with a very low density. These are usually two-part formulations utilizing a platinum catalyzed addition cure system. They conform to an irregular surface as they expand to provide intimate contact and protection from the environment but are more rigid and provide more strength than gels. Since foams are expanded elastomers, on a weight basis they are highly crosslinked relative to gels. Most cure conditions will result in a closed cell foam. **F2038**

gels, n—are lightly crosslinked materials having no or relatively low levels of reinforcement beyond that provided by the crosslinked polymer. They are usually two-part formulations utilizing a platinum catalyzed addition cure system. The hardness of the gel can be adjusted within wide limits. The material is not usually designed to bear heavy loads but rather to conform to an irregular surface providing intimate contact. As a result, loads are distributed over a wider area. These materials may also be used to provide protection from environmental contaminants. **F2038**

high consistency rubbers (HCRS, n—are materials which cannot be pumped by conventional pumping equipment. They normally must be processed using high shear equipment such as a two-roll mill and parts are typically fabricated using compression or transfer molding techniques. **F2038**

low consistency rubbers or liquid silicone rubbers (LSRS), n—are normally flowable materials which can be readily pumped. They can be mixed by pumping through static mixers and parts can be fabricated using injection molding techniques. **F2038**

RTVs (room temperature vulcanization), n—are one-part elastomers which cure in the presence of atmospheric moisture. Little, if any, acceleration of cure rate is realized by increasing temperature. Because cure is dependent upon diffusion of water into the elastomer, cure in depths greater than 0.25 in. (0.635 cm) is not recommended. **F2038**

silicone gel, *n*—semisolid material consisting of a crosslinked silicone polymer network in which liquid silicone polymer is held (see definition of gel in Terminology F1251). **F703**

silicone polymer, *n*—polymer of alternating silicon-oxygen atoms consisting of repeating of diorganosiloxy groups. **F1251**

silicone polymer, *n*—polymer chains having a backbone consisting of repeating silicon-oxygen atoms where each silicon atom bears two organic groups. The organic groups are typically methyl, but can be vinyl, phenyl, fluorine, or other organic groups. **F2038**

simulated gastric fluid, *n*—solution consisting of hydrochloric acid, salt and pepsin with a pH of approximately 1.2, per USP standard recipe. **F2528**

single-use component (SUD), *n*—disposable component; intended to be used on one patient during a single procedure. **F2459**

size, *n*—identification of a screw based on its nominal thread diameter, as defined in Section 6 of Specification F543. **F543**

size thresholds, *n*—instrument's lower and upper size settings for the particular cell population; adjustable "size gate." Cells or fragments outside the size settings are excluded from the analyses. **F2149, F2312**

skeletal maturity, *n*—age at which the epiphyseal plates are fused. **F2451**

skin, *n*—outer integument or covering of the body, consisting of the dermis and the epidermis, and resting upon the subcutaneous tissues. **Dorland's, F2311, F2312**

skin allograft therapy, *n*—treatment of skin wound or skin ulcer by the temporary topical application of skin allograft(s). **F2311, F2312**

skin replacement surgery, *n*—surgery that permanently replaces lost skin with healthy skin. **F2311, F2312**

skin substitute, *n*—biomaterial, engineered tissue, or combination of biomaterials and cells or tissues that can be substituted for a skin allograft, a skin autograft, an epidermal autograft, or a dermal autograft in a clinical procedure. **F2311, F2312**

sleeve interconnection, *n*—interconnection in which an implant component passes through any opening that limits motion in one or more planes. **F1582**

small punch test, *n*—test wherein the specimen is of miniature size relative to conventional mechanical test specimens, is disk-shaped, and is loaded axisymmetrically in bending by a hemispherical-head punch. **F2183**

S-N diagram, *n*—plot of stress against the number of cycles to failure. The stress can be maximum stress S_{max}, minimum stress S_{min}, stress range S or S_r, or alternating stress S_a. The diagram indicates the *S-N* relationship for a specified value of S_m (*mean stress*) *A*, or *R* (*load* or *stress ratio*), and a specified probability of survival. For *N*, a log scale is almost always used. For *S*, a linear scale is used most often, but a log scale is sometimes used.

DISCUSSION—See Definitions E1150. **F1582**

solid core, *n*—screw that does not contain a cannulation along its longitudinal axis. **F543**

solubility, *n*—measure of the extent to which the material can be dissolved.

DISCUSSION—In the context of collagen, refers to the dissociation of the fibrillar aggregates of collagen molecules into a solution. Native Type I collagen which is soluble in dilute acids, but not soluble in neutral pH conditions is termed "insoluble" or "acid soluble" while simple aggregates of non-fibrillar collagen soluble in neutral salt solutions are termed "neutral salt soluble." Post translational surface charge modifications may alter the solubility of collagen in neutral pH condition. **F2212, F2312**

solution anneal, solution heat treatment, *v*—to heat treat in order to remove precipitates. **F2005**

somatic cell, *n*—is any cell other than a germ or stem cell. Somatic cells may be used as a component of a TEMP. **F2312**

somatic cell therapy, *n*—"is the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries in humans by the administration of autologous, allogeneic, or xenogeneic cells that have been manipulated or altered *ex vivo*. Manufacture of products for somatic cell therapy involves the *ex vivo* propagation, expansion, selection, or pharmacologic treatment of cells, or other alteration of their biological characteristics." For the purposes of TEMPs somatic cell therapy technologies can be applied in tissue engineering to generate TEMPs, for human and non-human use. **F2312**

somatic cell therapy products, *n*—"are defined as autologous (that is, self), allogeneic (that is, intra-species), or xenogeneic (that is, inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics *ex vivo* to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries." Somatic cell therapy products may be used as a component of a TEMP. **F2312**

sound pressure at threshold, $p_{threshold}$, *n*—stimulus sound field pressure at the threshold of audibility. **F2504**

specific absorption rate (SAR), *n*—mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg. **F2182, F2503**

specimen failure, *n*—condition at which the specimen completely breaks or is damaged to such an extent that the load frame is no longer able to apply the intended stress within the required limits. **F2118**

specimen portion, *n*—unit or units of plastic placed into the extraction vehicle. **F619**

split thickness skin autograft, *n*—skin [auto]graft consisting of the epidermis and a portion of dermis. **Dorland's, F2311, F2312**

stabilizer, *n*—substance added to a plastic that will retard the deterioration of the plastic due to the effects of heat, light, or oxidation. **F665**

stainless steel, *n*—raw material on the instrument that is in accordance with Specification F899. **F921, F1078**

standard laboratory atmosphere, *n*—laboratory atmosphere having a temperature of 23 ± 2°C and a relative humidity of 50 ± 10 %. **F1634**

stapes velocity (IMEHD-aided), v_A, *n*—translational velocity of the stapes when driven by the IMEHD output transducer, specified in units of mm/s. **F2504**

stapes velocity (unimplanted), v_U, *n*—translational velocity of the stapes when driven by sound input to the middle ear specified in units of mm/s. **F2504**

staple, *n*—anchor component that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components by using at least two interconnected posts. **F1582**

static test, *n*—single cycle loading tests designed to evaluate the mechanical properties of materials, components, interconnections, subconstructs, constructs, subassemblies, or assemblies.

DISCUSSION—The mechanical properties can include stiffness, flexibility, failure loads and stresses, and yield and ultimate strengths defined in the associated test standard, that is, the properties associated with elastic and inelastic reactions when force is applied or those that involve a relationship between stress and strain. **F1582**

stem cells, *n*—progenitor cells capable of self-replication, proliferation, and differentiation. **F2312**

stem reference angle *X*, *n*—angle between the stem reference line and the line of load application. **F1440**

stem reference line, *n*—line passing through Reference Point P6 and the center of the prosthesis head (P1). **F1440**

stent recoil, *n*—amount, expressed as a percentage, by which the diameter of a stent changes from the expanded diameter measured with the stent on the inflated delivery balloon to the final value measured after deflating the balloon. **F2079**

sterility, *n*—generally, the state of being free of microorganisms. For purposes of this specification, sterility is defined as freedom from microorganisms when tested according to the methodology defined by the USP for nonparenteral devices. **F623**

sterility, *n*—state of being free from viable micro-organisms. **F2528**

sterilization, *n*—destruction or removal of all microorganisms in or about an object, as by, chemical agents, electron beam, gamma irradiation, ultraviolet (UV) exposure, or filtration. **F2312**

sterilization, *n*—destruction or removal of all microorganisms in or about an object. **F2212**

DISCUSSION—Examples are by chemical agents, electron beam, gamma irradiation, ultraviolet (UV) exposure, or filtration.

stiffness (axial—n/mm, angular—n·mm/degree or n·mm/radian), *n*—slope of the initial linear portion of the load-displacement curve or the slope of the initial linear portion of the moment-angular displacement curve. This is illustrated as the slope of the line OG in Fig. 6. If the device does not exhibit a linear initial load/displacement curve, the displacement should be reported at 30, 60, and 90 % of the yield load or moment. **F2346**

stop pin, *n*—pin of preset length affixed to the inside of one of the tweezer halves designed to limit teeth contact upon closure and prevent their damage. **F1638**

storage temperature, *n*—temperature at which the cells, tissue, or TEMP is held after completion of the cooling process. **F2386**

strand, *n*—group of wires helically twisted together. **F2180**

stress, S, *n*—intensity at a point in a body of the forces or components of force that act on a given plane through the point.

DISCUSSION—Stress is expressed in units of force per unit area (pounds-force per square inch, megapascals, and so forth). (See Terminology E6.) **F1582**

stress-crack, *n*—external or internal crack in a plastic caused by tensile stresses less than its short-time mechanical strength.

DISCUSSION—The development of such cracks is frequently accelerated by the environment to which the plastic is exposed. The stresses which cause cracking may be present internally or externally or may be combinations of these stresses. **F1251**

stress level, *n*—value of stress at which a series of duplicate tests are performed. For the purposes of this test method, the stress level is reported as the maximum stress applied to the specimen. **F2118**

stroke rate, *n*—rate of the stroke displacement of the force applicator. **F2345**

structural stiffness, *n*—maximum slope of the elastic portion of the load-displacement curve as defined and measured according to the test conducted. For bending in a specified plane, this term is defined and determined in the static four-point bend test described in Annex A1 of Specification and Test Methods F1264. **F1264**

stylus tip, *n*—stylus tip is the tip of the measuring device (diamond or Focodyn) that measures the surface roughness. A stylus has a pseudoconical shape with a hemispherical tip. Typical sizes for the tip are 2, 5, or 10 µm. The selection of the stylus tip is dependent on the range of the roughness measured. **F2033**

styrene plastic, *n*—plastic based on polymers of styrene or copolymers of styrene with other monomers, the styrene being greatest amount by mass. **F1251**

subassembly, *n*—any portion of an implant assembly that is composed of two or more components. **F1582**

subchondral plate, *n*—margin of compact bone in direct apposition to the articular cartilage. **F2451**

subconstruct, *n*—any portion of an implant construct that is composed of two or more components including the spine, pelvis, ribs, or substitute structure. **F1582**

subluxation load, *n*—peak shear load required for subluxation, for example, the peak resistive force at the glenoid articular rim opposing movement of the humeral head. **F2028**

subluxation translation, *n*—distance from the glenoid origin (see Fig. 2 of Test Methods F2028), parallel to the glenoid plane, to the point at which the subluxation load occurs. **F2028**

substrate, *n*—solid material to which the porous coating is attached. **F1854**

substrate failure, *n*—failure of the tissue substrate. **F2458**

substrate interface, *n*—region where the porous coating is attached to the substrate. **F1854**

substrates, *n*—raw or virgin materials that will ultimately be used in tissue-engineered medical products for growth, support, or delivery of cells or biomolecules. **F2027, F2312**

supercool, *v*—to cool to a temperature below the equilibrium melting point of the solution without initiating ice formation. **F2386**

superelasticity, *n*—nonlinear recoverable deformation behavior of Ni-Ti shape memory alloys at temperatures above the austenite finish temperature (A_f).

DISCUSSION—The nonlinear deformation arises from the stress-induced formation of martensite on loading and the spontaneous reversion of this crystal structure to austenite upon unloading. **F2005**

superior/inferior (SI), anterior/posterior (AP), *n*—SI axis is the longest dimension and the AP axis the widest dimension of the glenoid (see Fig. 2 of Test Methods F2028). **F2028**

supplied form, *n*—condition of the foam product when received from the supplier by the end user. **F1839**

liquid, n—two liquid components (base and activator) that can be mixed by the end user to produce a rigid, unicellular foam slab. **F1839**

solid, n—foam is in a uniform solid form, such as a slab, plate, or block. **F1839**

supported stem length, *n*—vertical distance between the distal tip of the stem (P4) and the cantilever plane. **F1440**

surface area, *n*—projected surface area of a part. This area does not include the internal porosity of parts with cancellous, porous, or wire structure. **F2459**

surface finish, *n*—measured roughness of surface of taper cone or head bore as determined by DIN 4768. **F2345**

surface oxidation index (SOI), *n*—sample's surface oxidation index (SOI) is the average of the oxidation indices from the sample's articular surface, or the surface of interest, to a depth of 3-mm subsurface. **F2102**

surface profile, *n*—surface profile formed by the intersection of a real surface by a specified plane. It is customary to select a plane that lies perpendicular to the direction of lay unless otherwise indicated. **ISO 13565-1 and ISO 4287, F2664**

surface texturing, *n*—repetitive or random deviations from the nominal surface that forms the three dimensional topography of the surface. **F2091**

surgical scissors with inserts, *n*—stainless steel instrument, available in various sizes and configurations, used in surgical procedures for cutting body tissue, gauze, and suture. An instrument of this type has tungsten carbide, stellite, or other inserts. **F1078**

suspension, *n*—dispersion of a solid through a liquid with a particle size large enough to be detected by purely optical means. **F2212, F2312**

swage, *n*—term used to describe any attachment method that uses mechanical force to crimp the end of the needle and firmly hold the suture in place. **F1840**

syngeneic, *n*—cells, tissues, and organs in which the donor has an unreactive genotype with the recipient. Synonyms: *syngraft*, *isograft*, *isogeneic*, or *isogenic*. **F2312**

synovial fluid, *n*—fluid secreted by synovium providing lubrication and nutrition to the joint surfaces. **F2451**

synovium, *n*—epithelial lining of synovial joint cavities that produce synovial fluid. **F2451**

T_1**—**total overall prosthetic thickness, for example, from the apex of the dome to the free end of pegs or other fixation geometry. **F1672**

T_2**—**thickness of the patellar prosthesis from the plane of the bone-prosthesis interface (excluding pegs, keels, and so forth) to the apex of the articulating surface. **F1672**

T_3**—**minimum polymer thickness of the patellar prosthesis in direct contact with the femoral component that is "at risk" for wear; this is measured perpendicular to the tangent of the wear surface at the point of contact with the femoral component. **F1672**

DISCUSSION—The dimension T_3 is described in Fig. 1 and Fig. 2 of Specification F1672 to be a distance from a surface contact point to an internal peg or an edge of the metal back. The exact location of the minimum thickness at risk may be at a different site and will depend on the design of the patella prosthesis and the mating femoral component. For devices manufactured from a single material, T_3 should be measured from the wear surface to the back of the fixation surface.

tack, *n*—ability of an adhesive to form a bond to a surface after brief contact under light pressure. **F2664**

target tissue, *n*—specific anatomical area intended to be treated. **F882**

TCA, *n*—5 % trichloroacetic acid. **F2148**

teeth, *n*—serrations formed on the inside faces of the distal end of the tweezer halves. **F1638**

telomer, *n*—polymer composed of molecules having terminal groups incapable of reacting with additional monomers, under the conditions of the synthesis, to form larger polymer molecules of the same chemical type. **F1251**

temperature profile, *n*—the time-temperature history of a sample during cooling or warming. **F2386**

tesla, (T), *n*—SI unit of magnetic induction equal to 10^4 gauss (G). **F2052, F2213, F2503**

test block, *n*—component of the test apparatus for mounting the artificial intervertebral disc in the intended test configuration. **F2346**

test block, *n*—test block shall be fabricated from a uniform material that conforms to Specification F1839. See Specification F543, Annex 2. **F2502**

test frequency, *n*—rate of cyclic repetition of fatigue loading in cycles per second. **F2345**

test specimen, *n*—sample of material being evaluated for puncture resistance that is taken from the actual container (direct method) or a representative example of the material and thickness having the same characteristics as the actual container (indirect method). Refer to Section 5 of Specification F2132. **F2132**

test specimen, *n*—test specimen shall be a completely fabricated and finished bioabsorbable bone screw. **F2502**

testing fixture, *n*—torsion testing apparatus that is to be used for applying the required torque to the specimen shall be calibrated for the range of torques and rotational displacements used in the determination. A suitable testing fixture for the torsional yield strength-maximum torque-breaking angle test is illustrated in Fig. A1.1 of Specification and Test Methods F2502. **F2502**

thaw, *v*—to warm from a cryopreserved state to a temperature above the melting point of the preservation medium. **F2386**

thermal insulation, *n*—material or technique, or both, used to prevent unintended cryonecrosis, inflammatory responses, or cryoadhesion to nontarget tissue. **F882**

thermocouple, *n*—junction of two dissimilar metals that produce an output voltage proportional to the temperature of the junction. When used in conjunction with a cryometer(s), the output is directly correlated to the temperature to which the sensing junction is exposed. **F882**

thermoelastic martensitic transformation, *n*—(in nitinol), diffusion-less thermally reversible phase change characterized by a change in crystal structure.

DISCUSSION—This is a process in which an incremental change in temperature produces a proportionate increase or decrease in the amount of phase change. **F2005**

thermoplastic, *n*—plastic that repeatedly can be softened by heating and hardened by cooling through a temperature range characteristic of the plastic, and that in the softened state can be shaped by flow into articles by molding or extrusion. **F1251**

thermoplastic polyurethane, *n*—linear or segmented polyurethanes that can be melted for processing without significant crosslinking or degradation. They are most frequently synthesized by reacting diols with diisocyanates. **F624**

thermoset plastic, *n*—plastic that, after having been cured by heat or other means, is substantially infusible and insoluble. **F1251**

THR, *n*—total hip replacement. **F2345**

thread diameter, *n*—largest diameter of the threaded portion of the screw measured over the thread crests. This is also known as the major diameter. **F543**

thread diameter, *n*—maximum outside diameter of the lag screw (see Fig. 1 of Specification F384). **F384**

thread length, *n*—length of the threaded portion of the screw, measured from the thread runout to the screw tip. **F543**

thread length, *n*—straight line distance measured between the tip and thread runout positions of the screw (see Fig. 1 of Specification F384). **F384**

thread runout, *n*—intersection of the screw thread with either the screw shaft or screw head. **F543**

through-pores, *n*—inherent or induced network of voids or channels that permit flow of fluid (liquid or gas) from one side of the structure to the other. **F2450**

tibial eminence, *n*—raised geometrical feature separating the tibial condyles. **F1223**

tidemark, *n*—anatomic site in articular cartilage corresponding to the margin between cartilage and the underlying calcified cartilage. **F2451**

tissue, *n*—aggregation of similarly specialized cells united in the performance of a particular function. **Dorland's, F2311, F2312**

tissue adhesive, *n*—any material used as a medical device to help secure the apposition of two wound edges or opposed soft tissues. **F2458**

tissue engineered medical product (TEMP), *n*—medical product that repairs, modifies or regenerates the recipient's cells, tissues, and organs or their structure and function, or both.

DISCUSSION—TEMPs derive their therapeutic potential from various components used alone or used in various combinations. Components may be biological products (that is, cells, organs, tissues, derivatives, and processed biologics), biomaterials (that is, substrates and scaffolds), biomolecules, devices, and drugs. TEMPs may be used *in vivo*, *ex vivo*, or *in vitro* for treatment of disease and injuries and for elective surgery or for diagnostic means. TEMPs are unique from conventional organ transplants in that they exclude biologics used for immediate transplantation or immediate preservation for later transplantation. **F2312**

tissue engineered medical products (TEMPs), *n*—medical products that repair, modify, or regenerate the recipients' cells, tissues, and organs, or their structure and function, or combination thereof. TEMPs may achieve a therapeutic potential from cells, biomolecules, scaffolds, and other materials, and processed tissues and derivatives used in various combinations or alone. TEMPs are unique from conventional organ transplants. TEMPs may be used *in vivo* or *in vitro* for disease, injury, elective surgery, and as a diagnostic. **F2211**

tissue engineering, *n*—application, *in vivo* and *in vitro*, of scientific principles and technologies to form tissue engineered medical products (TEMPs) used for medical treatments and as diagnostics. The various technologies and principles are common practices and methods in engineering and biomedical sciences such as cell, gene, or drug therapy, embryology or other forms of developmental biology, surgical methods and technologies used to create traditional devices and biologics. Tissue engineering could be applied to create products for non-human use as well. **F2211**

tissue engineering, *vivon*, *n*—application, *in vivo* and *in vitro* of scientific principles and technologies to form tissue engineered medical products (TEMPs) used for medical treatments and diagnoses as diagnostics.

DISCUSSION—The various principles technologies and principles are common practices and methods in engineering and biomedical sciences such as cell, gene, or drug therapy, embryology or other forms of developmental and biology, surgical reparative methods and technologies can used to create traditional devices and biologics. Tissue engineering could be applied to create products for non-human use as well. **F2312**

tissue forceps, *n*—device formed in two generally symmetrical halves with their proximal ends secured together and set so

their distal ends will stay separated unless pressed together. **F1638**

tissue regeneration, *n*—healing in which lost tissue is replaced by proliferation of cells, which reconstruct the normal architecture. **medweb,[26] F2311, F2312**

tissue repair, *n*—healing in which lost tissue is replaced by a fibrous scar, which is produced from granulation tissue. **medweb, F2311, F2312**

tissue sealant, *n*—surface coating with adequate adhesive strength to prevent leakage of body fluids. **F2458**

tolerance, *n*—acceptable deviations from the nominal size of any dimension describing the IMFD. **F1264**

tolerances, *n*—allowable deviation from a standard size. In usual engineering practice, the maximum permitted size is denoted by a plus sign followed by the tolerance and the minimum permitted size denoted by a minus sign followed by the tolerance. In this standard, the label French size has tolerances given for several dimensions. For example, +3, -1 means that a nominal 14 label French size can be permitted to go as high as 17, but not below 13. Another way of writing tolerance, when both tolerances are equal, is: ±2, meaning the 14 label French size must be between 12 French and 16 French. **F623**

top scissor half, *n*—component which contains the screw head at assembly. **F1078**

torque transducer, *n*—transducer to translate the applied torque into an electrical signal amenable to continuous recording, calibrated over the range of torques, both in the clockwise and counterclockwise rotation, to be encountered in the test method, shall be provided. **F2502**

torsion yield moment (N·m), *n*—applied torque in N-m at which the screw reaches its proportional limit when tested in accordance with Specification and Test Methods F543, Annex A1. The value is determined by using an offset method with a 2° angular offset. **F2193**

torsional displacement transducer, *n*—transducer to translate the angle of twist into an electrical signal amenable to continuous recording, calibrated over the range of angles to be encountered in the test and an accuracy of ±1 % of reading, both in the clockwise and counterclockwise rotation, shall be used. **F2502**

torsional yield strength (N-m), *n*—point at which the screw reaches its proportional limit when tested in accordance with Annex A1 of Specification F543. This will be determined by the offset method. A 2° offset value will be used. **F543**

tortuosity, *n*—measure of the mean free path length of through-pores relative to the sample thickness. Alternative definition: The squared ratio of the mean free path to the minimum possible path length. **F2450**

total displacement (mm), *n*—distance in mm, in the direction of the applied load, which the load application point has moved relative to the zero load intercept of the initial linear segment of the load versus displacement curve (point *0* in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

total elemental level, *n*—total weight of particulate matter and corrosion ions generated by fretting wear and fretting corrosion. Most analytical techniques are unable to accurately differentiate between ions and particulates, and therefore, total elemental level refers to all matter and corrosion products released by fretting wear and corrosion. **F1875**

total wrist replacement, *n*—prosthetic parts substituted for the native opposing radial and carpal articulating surfaces. **F1357**

trabecular bone, *n*—classification of ossified boney connective tissue characterized by spicules surrounded by marrow space. **F2451**

tractive forge, *n*—cryoadhesive attraction between the cryotip and the target tissue. **F882**

transformation temperature range, *n—in a shape memory alloy*, the temperature range in which a change of phase occurs. **F2005**

transplantation, *n*—for therapeutic purposes, the process of implanting in one part, cells, tissue(s), or organ(s) taken from another part or from another individual.

DISCUSSION—Transplantation in this sense is regulated by the U.S. Food and Drug Administration (FDA) under 21 CFR Parts 16 and 1270 and 21 CFR Parts 207, 807, and 1271. **F2312**

transverse element, *n*—component or subassembly that links longitudinal members together. **F1582**

trans-vinylene index (TVI), *n*—trans-vinylene index is defined as the ratio of the absorption peak area between 950 and 980 cm-1 to the absorption peak area between 1330 and 1396 cm^{-1}. **F2381**

trans-vinylene index profile, *n*—trans-vinylene index profile is defined as the graphical representation of variation of the sample's trans-vinylene index with distance from its articular surface or the surface of interest. This is a plot of TVI versus DL. Typically, the graph will show the profile through the entire thickness of the sample. **F2381**

tritiated thymidine, *n*—^{H3}methyl thymidine, specific activity 2 Ci/mM (in PBS) I^{125} IUDR-radioactive uridine. **F2148**

trochlear groove, *n*—anatomic site on the distal end of the femur corresponding to the region of articulation with the patella. **F2451**

tubing length adapter, *n*—tissue expander component used to connect more than one piece of remote port tubing. **F1441**

[26] Hiley, P., and Barber, P. C., *General Pathology (Pathology Foundation Course)*, Chapter 3, Healing and Repair, Department of Pathology, University of Birmingham, U.K., http://medweb.bham.ac.uk/http/depts/path/Teaching/foundat/repair/healing.html.

tubing/shell junction, *n*—junction of the remote port tubing to the shell of the tissue expander. **F1441**

2,4 dinitrochlorobenzene (DNCB), *n*—strong sensitizer, used as a positive control. **F2147**

two-part elastomer, *n*—elastomer supplied in two packages which must be mixed in specified proportions before fabrication. **F2042**

types of cure, *n*—based upon the cure chemistry used, silicone elastomers used in medical applications fall into one of three categories: condensation cure, peroxide cure, and addition cure. **F2038**

addition cure, n—two-part elastomers which must first be mixed together and then cure by addition of a silylhydride to a vinyl silane in the presence of a platinum catalyst. **F2038**

condensation cure, n—these materials liberate an organic leaving group during curing and are normally catalyzed by an organometallic compound. **F2038**

one-part, n—material supplied ready to use in an air tight container which cures upon exposure to atmospheric moisture. The material cures from the surface down and cure depths of greater than about 0.25 inches (0.635 cm) are not practical. **F2038**

peroxide cure, n—one-part formulations vulcanized by free radicals generated by the decomposition of an organic peroxide. **F2038**

two-part, n—material supplied in two separate containers which must be intimately mixed in the prescribed proportions shortly before use. Because they do not rely upon dispersion of atmospheric moisture into the silicone, the cure depth is not limited. **F2038**

ulcer, *n*—local defect, or excavation of the surface of an organ or tissue, which is produced by the sloughing of inflammatory necrotic tissue. **Dorland's, F2311, F2312**

ultimate displacement, *n*—displacement at rupture (failure) of the specimen (Fig. 1 of F2183). **F2183**

ultimate displacement (axial—mm, angular—degrees or radians), *n*—linear or angular displacement associated with the ultimate load or ultimate moment. This is illustrated as the displacement, OF, in Fig. 6 of Test Methods F2346. **F2346**

ultimate load, *n*—load at rupture (failure) of the specimen (Fig. 1 of F2183). **F2183**

ultimate load or moment (axial—n, angular—n·mm), *n*—maximum applied load, *F*, or moment, *M*, transmitted by the pushrod (assumed equal to force and moment component parallel to and indicated by load or torque cell) to the artificial intervertebral disc assembly. This is illustrated as point E in Fig. 6 of Test Methods F2346. **F2346**

ultimate strength, *n*—maximum force parameter (for example, load, moment, torque, stress, and so forth) that the structure can support defined and measured according to the test conducted. **F1264**

uncured elastomer, *n*—silicone base which contains cross-linker and/or catalyst but has not been vulcanized. **F2038**

ungraded, *adj*—foam that does not fit into one of the five grades specified in 3.1 because of the foam not meeting one or more of the physical or mechanical requirements of Section 4 of Specification F1839. **F1839**

uniform elongation, El_u[%], *n*—elongation determined at the maximum force sustained by the test piece just prior to necking, or fracture, or both. **F2516**

uniform width, *n*—referring to a bone plate where the width is constant along the bone plate's length. **F382**

unloaded moment arm, *n*—perpendicular distance between the line of load application and the geometric centroid of the stem cross section at the cantilever plane. **F1440**

unsupported stem length, *n*—vertical distance between Point P3 and the cantilever plane. **F1440**

upper plateau strength (UPS), *n*—stress at 3 % strain during loading of the sample. **F2516**

upper plateau strength (UPS), *n*—(in nitinol), stress at 3 % strain during tensile loading of the sample. **F2005**

urethane plastic, *n*—plastic based on polymers in which the repeated structural units in the chains are of the urethane type, or on copolymers in which urethane and other types of repeated structural units are present in the chains. **F1251**

valgus-varus constraint, *n*—degree of relative angular motion allowed between the femoral and tibial components of post-in-well designs (or similar designs) in the coronal plane. **F1223**

valve, *n*—sealable or self sealing opening in an inflatable prosthesis, extending from the exterior surface of the shell into a lumen, designed to facilitate addition of saline at the time of use or postoperatively to adjust prosthesis volume. **F2051**

valve, *n*—user-sealable or self-sealing opening in an inflatable or gel saline prosthesis, extending from the exterior surface of the shell into a lumen, designed to facilitate adding or removing saline to or from the prosthesis to increase or decrease prosthesis volume. **F703**

vehicle controls, *n*—aqueous, polar solvent and a non-aqueous, nonpolar solvent. **F2148**

vertebral body replacement device, *n*—structure which is designed to restore anatomic position and support to a section of spine lacking one or more vertebral bodies and intervening disc(s). **F1582**

vertebral span, *n*—number of vertebra that are spanned by the longitudinal element, including the vertebrae containing anchor components. **F1582**

vinyl chloride plastics, *n*—plastics based on polymers of vinyl chloride or copolymers of vinyl chloride with other monomers, the vinyl chloride being the comonomer of the highest concentration by mass. **F665**

virgin polymer, *n*—the form of poly(glycolide) or poly(glycolide-co-lactide) as synthesized from its monomers and prior to fabrication into a medical device. **F2313**

virgin polymer, *n*—initially delivered form of a polymer as synthesized from its monomers and prior to any processing or fabrication into a medical device. **F2579**

viscosity, *n*—property of resistance of flow exhibited with the body of a material.

DISCUSSION—In testing, the ratio of the shearing stress to the rate of shear of a fluid. Viscosity is usually taken to mean "Newtonian viscosity," in which case the ratio of shearing stress to rate of shearing strain is constant. In non-Newtonian behavior, which is the usual case with plastics materials, the ratio varies with the shearing rate. Such ratios are often called the "apparent viscosities" at the corresponding shear rates. (See **viscosity coefficient**.) **F1251**

void, *n*—*(1)* in a solid plastic, an unfilled space of such size that it scatters radiant energy such as light, *(2)* a cavity unintentionally formed in a cellular material and substantially larger than the characteristic individual cells. **F1251**

vulcanization, *n*—irreversible process in which covalent chemical bonds are formed between silicone polymer chains. During vulcanization, the material changes from a flowable or moldable compound to an elastomeric material which cannot be reshaped except by its physical destruction. **F2038**

W_1—maximum medial-lateral width of the articulating surface in the frontal plane. **F1672**

W_2—maximum medial-lateral width of the metal back in the frontal plane. **F1672**

warming rate, *n*—instantaneous rate of change of temperature during warming. **F2386**

wear, *n*—damage to a solid surface, generally involving progressive loss of material, due to relative motion between that surface and a contacting substance or substances. **F1875**

wear, *n*—progressive loss of material from the device(s) or device components as a result of relative motion at the surface with another body as measured by the change in mass of the IVD prosthesis or components of the IVD prosthesis. Or in the case of a nonarticulating, compliant IVD prosthesis, wear is defined simply as the loss of material from the prosthesis. **F2423**

DISCUSSION—Note that inferior and superior bone interface components are excluded from this definition.

weight S_i of soak control specimen (g), *n*—S_0 initial and S_i at end of cycle interval *i*. **F2423**

weight W_i of wear specimen (g), *n*—W_0 initial and W_i at end of cycle interval *i*. **F2423**

wire, *n*—individual element (typically a cylindrical rod) making up a strand. **F2180**

wire, *n*—single strand flexible anchor component with a circular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components. A series of wire components can be bound together to form a cable (see **cable**). **F1582**

work to failure, *n*—area under the load versus displacement curve (Fig. 1 of F2183). **F2183**

working length, *n*—length of uniform cross section of the IMFD intended to obtain some type of fit to the medullary canal in the area of the diaphysis. **F1264**

working surface, *n*—ground and polished face of the metallographic mount where the measurements are made. **F1854**

worst case conditions, *n*—maximum pressures or temperatures, or both, a cryosystem may encounter when used according to the manufacturer's instructions. **F882**

wound, *n*—injury or damage, usually restricted to those caused by physical means with disruption of the normal continuity of structures. Called also injury and trauma. **Dorland's, F2311, F2312**

wound closure, *n*—provision of an epithelial cover over a wound; it can be accomplished by approximating wound edges, performing a skin [auto]graft, or allowing spontaneous healing from the edges. **Churchill's,[27] F2311, F2312**

wound contraction, *n*—shrinkage and spontaneous closure of open skin wounds. **Dorland's, F2311, F2312**

wound contracture, *n*—condition of fixed high resistance to passive stretch of muscle, skin or joints resulting from fibrosis and scarring of the skin or the tissues supporting the muscles or the joints, or both. (This definition is a modification of Dorland's definition of contracture, "a condition of fixed high resistance to passive stretch of muscle, resulting from fibrosis of the tissues supporting the muscles or the joints, or disorders of the muscle fibers," because that definition does not address fibrosis and scarring in skin. **F2311, F2312**

wound inflammation, *n*—localized protective response elicited by injury or destruction of tissues, which serves to destroy, dilute, or wall off (sequester) both the injurious agent and the injured tissue.

DISCUSSION—It is characterized in the acute form by the classical signs of pain (dolor), heat (calor) redness (rubor), swelling (tumor), and loss of function (functio laesa). Histologically, it involves a complex series of events, including dilation of arterioles, capillaries, and venules, with increased permeability and blood flow; exudation of fluids, including plasma proteins; and leukocytic migration into the inflammatory focus. **Dorland's, F2311, F2312**

xenogeneic or xenogenic, *n*—cells, tissues, and organs in which the donor and recipient belong to different species. Synonyms: *xenogenous*, *heterogeneic*, or *heterologous*. **F2312**

xenogeneic, *adj*—derived from individuals of a different, specified species. For example, bovine bone, when used as an implant material in humans, is xenogeneic. **F1581**

[27] *Churchill's Illustrated Medical Dictionary*, Churchill Livingstone, New York, 1989.

xenograft, *n*—graft of tissue transplanted between animals of different species. Called also heterograft, heterologous graft and heteroplastic graft.[28] **Dorland's, F2311, F2312**

xenotransplantation, *n*—any procedure that involves the transplantation or infusion into a human recipient of either *(1)* live cells, tissues, or organs from a nonhuman animal source or *(2)* human body fluids, cells, tissues, or organs that have had *ex vivo* contact with live nonhuman cells, tissues, or organs. **F2312**

xenotransplantation, *n*—any procedure that involves the transplantation or infusion into a human recipient of either *(1)* live cells, tissues, or organs from a nonhuman animal source or *(2)* human body fluids, cells, tissues, or organs that have had *ex vivo* contact with live nonhuman cells, tissues, or organs.[29] **F2311**

xenotransplantation products, *n*—xeno-transplantation products include live cells, tissues or organs used in xenotransplantation. **F2311**

DISCUSSION—Xenografts and xenotransplantation products comprise overlapping but not congruent groups of skin substitutes. Autograft, allograft, and xenograft are traditional terms to describe tissue used in surgical procedures. Because autograft involves the harvesting of the patient's own tissue, care is taken to preserve its viability. However, allograft and xenograft are not necessarily alive and may have been frozen for storage. Skin substitutes may combine attributes of autograft, allograft, xenograft, and xenotransplantation products, depending on the origin of cells or tissues used in their manufacture, and whether these components are alive or not. For example, a substitute for epidermal autograft composed of cultured autologous epidermal cells grown on a feeder layer of live non-human cells is a xenotransplantation product as well as an autograft substitute.

yield bend angle, *n*—angle at which the yield bend moment occurs. **F1840**

yield bend moment, *n*—amount of moment required to initiate plastic deformation during a bend test. **F1840**

yield displacement, *n*—linear displacement (mm) or angular displacement (degrees or radians) when an artificial intervertebral disc has a permanent deformation equal to the offset displacement or offset angular displacement. This is illustrated as the distance *OA* in Fig. 6 of Test Methods F2346. **F2346**

yield displacement (mm), *n*—total displacement in mm associated with the bending yield strength (distance 0A in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

yield load or moment, *n*—applied load, *F*, or moment, *M*, transmitted by the pushrod (assumed equal to force component parallel to and indicated by load or torque cell) required to produce a permanent deformation equal to the offset displacement or the offset angular displacement. This is illustrated as point D in Fig. 6 of Test Methods F2346. **F2346**

yield strength, *n*—force parameter (for example, load, moment, torque, stress, and so forth) which initiates permanent deformation as defined and measured according to the test conducted. **F1264**

[28] Note that the United States Public Health Service (USPHS) and the United States Food and Drug Administration define "Xenotransplantation" more broadly as "any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, tissues, or organs that have had *ex vivo* contact with live nonhuman animal cells, tissues or organs." Because this terminology is intended to classify skin substitutes by clinical equivalency, and not by composition, the dictionary definition is used, for this terminology only. It should be understood that an allograft or autograft substitute may include animal components which cause it to be also a xenotransplant by the Food and Drug Administration definition.

[29] Guidance for Industry, Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), April 2003.

APPENDIXES

(Nonmandatory Information)

X1. TERMS BY SUBCOMMITTEE

POLYMERIC MATERIALS

X1.1 F04.11 Polymeric Materials

accelerator, *n*—additive used to increase the rate of cure. An accelerator may also be a catalyst, or it may actually change composition and, therefore, not qualify as a catalyst. **F602**

acetal plastic, *n*—plastic based on polymers having a predominance of acetal linkages in the main chain. (See also **polyoxymethylene**.) **F1251**

acrylic plastic, *n*—plastic based on polymers made with acrylic acid or a structural derivative of acrylic acid. **F1251**

addition polymerization, *n*—polymerization in which monomers are linked together without the splitting off of water or other simple molecules and involves the opening of a double bond. **F1251**

additive, *n*—chemical added to epoxy resins or hardeners to modify the handling characteristics or cured properties, or both, of the epoxy-hardener combination. **F602**

diluent, n—chemical used in admixture to modify or enhance the properties of either or both the uncured or cured formulations. A primary use is to reduce the viscosity of the mixed system although other properties such as exotherm rate, stiffness, moisture absorption, and so forth, may be modified or enhanced also. **F602**

filler, n—a relatively inert solid particulate material added to an epoxy formulation to modify its strength, permanence, working properties, or other qualities, or to lower costs. **F602**

nonreactive diluent, n—a diluent not containing chemically reactive functional groups. **F602**

reactive diluent, n—a diluent that reacts chemically with the epoxy resin or hardener, or both, during cure. **F602**

additives, *n*—component of a silicone elastomer used in relatively small amounts to perform functions such as marking, coloring, or providing opacity to the elastomer. **F2038**

aging, *n*—the process of exposing materials to an environment for an interval of time. **F1251**

aging effect, *n*—change in a material brought about by exposure of the material to an environment for an interval of time. **F1251**

alkyd resin, *n*—polyester convertible into a crosslinked form; requiring a reactant of functionality higher than two, or having double bonds. **F1251**

apparent density, *n*—*see* **density, apparent**. **F1251**

artificial weathering, *n*—exposure of a material to laboratory conditions that simulate outdoor weathering.

DISCUSSION—Exposure conditions may be cyclic, involving changes in temperature, relative humidity, radiant energy, and many other elements found in the atmosphere in various geographical areas. The laboratory exposure conditions are usually intensified beyond those encountered in actual out-door exposure to accelerate the effect. **F1251**

blister, *n*—in sheet plastics, an imperfection, a rounded elevation of the surface, with boundaries that may be more or less sharply defined, somewhat resembling in shape a blister on the human skin. **F1251**

block copolymer, *n*—essentially linear copolymer in which there are repeated sequences of polymeric segments of different chemical structure. **F1251**

bloom, *n*—visible exudation or efflorescence of a performance additive on the surface of a material. **F1251**

bulk density, *n*—weight per unit volume of a material including voids inherent in the material as tested.

DISCUSSION—This term is sometimes used synonymously with apparent density. **F1251**

bulk factor, *n*—ratio of the volume of a given mass of molding material to its volume in the molded form.

DISCUSSION—The bulk factor is also equal to the ratio of the density of the material to its apparent density in the unmolded form. **F1251**

butylene plastic, *n*—plastic based on resins made by the polymerization of butene or copolymerization of butene with one or more unsaturated compounds, the butene being in greatest amount by weight. **F1251**

cast film, *n*—film made by depositing a layer of plastic, either molten, in solution, or in a dispersion, onto a surface, solidifying the deposit and removing the film from the surface. **F1251**

catalyst, *n*—component of a silicone elastomer formulation that initiates the crosslinking reaction when the material is vulcanized. **F2038**

cell, *n*—a small partially or completely enclosed cavity. **F1251**

cell, closed, *n*—*see* **closed cell**.

cell, open, *n*—*see* **open cell**.

chain extender, *n*—*(1)* active hydrogen containing compound such as a diol or diamine used to increase the molecular weight of an isocyanate-terminated prepolymer by chemical reaction; *(2)* diisocyanate used to extend a polyol-terminated polyurethane by chemical reaction. **F624**

chain terminating agent, *n*—active hydrogen containing a compound such as a monofunctional alcohol, amine, or acid that reacts with the isocyanate group of a prepolymer to prevent further chain growth. **F624**

chemically foamed polymeric material, *n*—cellular material in which the cells are formed by gases generated by thermal decomposition or other chemical reaction. **F1251**

chlorofluorocarbon plastic, *n*—plastic based on polymers made with monomers composed of chlorine, fluorine, and carbon only. **F1251**

chlorofluorohydrocarbon plastic, *n*—plastic based on polymers made with monomers composed of chlorine, fluorine, hydrogen, and carbon only. **F1251**

closed cell, *n*—cell totally enclosed by its walls and hence not interconnecting with other cells. (See also **cell** and **open cell**.) **F1251**

closed-cell foamed plastic, *n*—plastic in which almost all the cells are noninterconnecting. **F1251**

cold flow, *n*—*see* preferred term **creep**. **F1251**

compression molding, *n*—process for molding a material in a confined cavity by applying pressure and usually heat. **F1251**

condensation polymer, *n*—polymerization in which during an acid/base reaction a small molecule is often split out. **F1251**

copolymer, *n*—polymer consisting of molecules characterized by the repetition (neglecting ends, branch junctions and other irregularities) of two or more different types of monomeric units. See **polymer**. **F1251**

copolymerization, *n*—*see* **polymerization** and **copolymer**. **F1251**

crazing, *n*—apparent fine cracks at or under the surface of a plastic.

DISCUSSION—The crazed areas are composed of polymeric material of lower density than the surrounding matrix. **F1251**

creep, *n*—time-dependent part of strain resulting from stress. **F1251**

crosslinker or cross-linking agent, *n*—component of a silicone elastomer that is a reactant in the crosslinking reaction that occurs when an elastomer is vulcanized. **F2038**

cure, *v*—to change the properties of a polymeric system into a more stable, usable condition by the use of heat, radiation, or reaction with chemical additives.

DISCUSSION—Cure may be accomplished, for example, by removal of solvent or crosslinking. **F1251**

cure, *v*—to change the properties of a polymeric system into a final, more stable, usable condition by the use of heat, radiation, or reaction with chemical additives. **F602**

cure cycle, n—schedule of time periods at specified conditions to which a reacting thermosetting material is subjected to reach a specified property level. **F602**

cure time, n—interval of time from the start of reaction to the time at which specified properties of the reacting thermosetting composition are reached. For materials that react under the conditions of mixing, the start of reaction is the time of initial exposure to the conditions necessary for reaction to occur. **F602**

functionally cured, v—term used to denote an epoxy plastic that has attained sufficient cure to achieve stable properties. **F602**

fully cured, v—term used to denote total disappearance of epoxy groups as detected by infrared spectroscopy, or other equally sensitive physicochemical methods. **F602**

one-component system, n—a formulation based on an epoxy resin preblended with a heat, moisture, or otherwise activated curing agent or catalyst. The mixture is storable but cures under the appropriate activation conditions. **F602**

postcure, n—additional and separate curing operations to which a "hardened" thermosetting plastic composition is subjected in order to enhance one or more properties. Also used to ensure stabilization of physical properties under use conditions. **F602**

two-component system, n—formulation based on an epoxy resin to which a curing agent or catalyst is added just prior to use. **F602**

curing agent or hardener, *n*—compound normally used in a predetermined concentration to react chemically (copolymerize) by means of several different mechanisms (for example, condensation or addition polymerization) with or without heat or pressure in order to change its form from a liquid or fusible, friable, soluble solid to an infusible, insoluble solid having useful and desirable application or end-use properties. **F602**

initiator, n—additive used to cause a thermosetting resin to react with itself (polymerize). Usually, these additives—used in relatively very small amounts—initiate homopolymerization of the epoxy resin resulting in ether linkages. **F602**

DISCUSSION—The term "catalyst" is frequently misused to denote any material added to a resin to cause a reaction to occur. This usage should be discouraged. The Society of Plastics Industries defines a catalyst as "a compound which alters the speed of a reaction without changing its original composition."

cyclics and linears, *n*—low molecular weight volatile cyclic siloxane species are referred to using the "D" nomenclature which designates the number of Si-O linkages in the material (usually D_4-D_{20}); species from D_7 to D_{40} (or more) may be called "macrocyclics". Linears are straight chain oligomers that may be volatile or of higher molecular weight, depending on chain length; they are designated by "M" and "D" combinations, where "M" is R_3Si-O, and D is as explained above; "R" is usually methyl. (For example, MDM is $(CH_3)_3SiOSiOSi(CH_3)_3$). Low molecular weight species are present in silicone components to varying degrees depending on process and storage. The levels of macrocyclics that can be removed from silicone polymers by vacuum, high temperature stripping, or oven post-cure is dependent on the conditions used. **F2038**

density, apparent, *n*—weight in air of a unit of volume of a material.

DISCUSSION—This term is sometimes used synonymously with bulk density. **F1251**

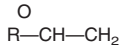
density, bulk, *n*—weight in air of a unit of volume of a material.

DISCUSSION—This term is commonly used synonymously with apparent density. **F1251**

dispersion, *n*—uncured silicone elastomer dispersed in a suitable solvent to allow application of a thin layer of elastomer to a substrate by either dipping or spraying. **F2038**

elastomer, *n*—macromolecular material that at room temperature returns rapidly to approximately its initial dimensions and shape after substantial deformation by a weak stress and release of the stress. **F1251**

epoxy, *n*—oxirane ring structures. **F602**



epoxy plastic, n—thermoplastic or thermosetting plastics containing ether or hydroxyalkyl repeating units or both, resulting from the ring-opening reactions of lower molecular weight polyfunctional oxirane resins or compounds, with catalysts or with various polyfunctional acidic or basic coreactants. **F602**

epoxy resin, n—generally, any resin (liquid or solid) with a chemical structure at least difunctional in oxirane. Specifically for this standard, the diglycidyl ethers of bisphenol A or the equivalent. These compounds are defined as Grade 1 in Specification D1763. **F602**

epoxy plastic, *n*—thermoplastic or thermosetting plastic containing ether or hydroxyalkyl repeating units, or both, resulting from the ring-opening reactions of lower-molecular weight polyfunctional oxirane resins, or compounds, with catalysts or with various polyfunctional acidic or basic coreactants.

DISCUSSION—Epoxy plastics often are modified by the incorporation of diluents, plasticizers, fillers, thixotropic agents, or other materials. **F1251**

ethylene plastic, *n*—plastic based on polymers of ethylene or copolymers of ethylene with other monomers, the ethylene being in greatest amount by mass. **F1251**

filler, *n*—relatively inert material added to a plastic to modify its strength, performance, working properties, or other qualities, or to lower costs. (See also **reinforced plastic**.) **F1251, F665**

filler, *n*—finely divided solid that is intimately mixed with silicone polymers during manufacture to achieve specific properties. The fillers used in silicone elastomers are one of two types:

extending fillers, n—typically have lower surface area and lower cost than reinforcing fillers. They include crystalline forms of silica and diatomaceous earths. While they provide some reinforcement, because they are relatively inexpensive, they are used primarily to extend the bulk of the silicone. **F2038**

reinforcing fillers, n—usually have high surface areas and are amorphous in nature such as fumed or precipitated silica. Such fillers impart high strength and elastomeric physical properties to the elastomer. **F2038**

fabrication, *n*—process by which the uncured elastomer is converted into a fully vulcanized elastomer of the desired size and shape. This process may occur in the same facility as the manufacture of the uncured elastomer but is more typically performed at the facility of a customer of the silicone manufacturer. **F2042**

calendaring, v—the process of forming an uncured, mixed elastomer into a thin sheet or film by passing it between two rolls. **F2042**

compression molding, v—process in which the uncured elastomer is placed in an open mold. The mold is closed and pressure applied to the mold to fill the cavity. Heat is applied to vulcanize the elstomer, the mold is than opened and the fabricated part is removed. **F2042**

dispersion, n—the process of placing an uncured elastomer in a solvent. This lowers the viscosity of the material and is usually done to allow the fabrication of thinner films that can be obtained by calendaring or to form coatings. Following dispersion use, the solvent must be removed either before or during the vulcanization process. Care must be taken to assure that the solvent is compatible with the elastomer, to prevent preferential settling of the components of the formulation by excessive dilution of the elastomer. **F2042**

extrusion, n—a continuous process in which the mixed, uncured elastomer is forced through an orifice having the desired cross-sectional profile. The elastomer is then vulcanized by passing it through either a hot air or radiant heat oven. The most common application of extrusion processing is the fabrication of tubing but it can be used to produce other items as well. **F2042**

freshening, v—because of the interaction that can occur between the fumed silica and silicone polymers, thick uncured high consistency elastomers can become so stiff over time that they are very difficult to process. To overcome this problem, a two–roll mill is used to disrupt this interaction, resulting in a material which is easier to fabricate. This process is called freshening and is typically done immediately before catalyzation. **F2042**

injection molding, v—fabrication of elastomers into forms defined by molds constructed so that the uncured elastomer can be transferred by pumping into the closed mold. This method requires venting of the mold in some manner. The elastomer may be vulcanized by heating the mold after it is filled but more typically the molding conditions (temperature and filling rate) are adjusted so that uncured elastomer can be added to a pre-heated mold in which it will then cure. The mold is than opened and the part removed and post-cured, if necessary. **F2042**

post-cure, n—the process of subjecting a vulcanized elastomer to elevated temperature, usually in a hot-air oven, after its initial fabrication. This process step is done to complete cross-linking of the object, remove peroxide by-products, and eliminate changes in its physical properties. Post-cure is often necessary when the component is only partially cross-liked by molding; it is performed in an attempt to accelerate molding process, and increase its output. **F2042**

transfer molding, v—process in which the mixed, uncured elastomer is placed in a compartment connected to the mold. The compartment is then closed, pressure is applied to transfer the uncured elastomer to the mold, filling the cavity. Heat and pressure are applied to the mold to vulcanize the elastomer, the mold is then opened, and the fabricated part is removed. **F2042**

film, *n*—in plastics, term for sheeting having a nominal thickness not greater than 0.25 mm (0.01 in.). (See also **sheeting**.) **F1251**

fluorocarbon plastic, *n*—plastic based on polymers made with monomers composed of fluorine and carbon only.

DISCUSSION—When the monomer is essentially tetrafluoro-ethylene, the prefix TFE may be used to designate these materials. When the resins are copolymers of tetrafluoro-ethylene and hexafluoropropylene, the resins may be designated with the prefix FEP. Other prefixes may be adopted to designate other fluorocarbon plastics. **F1251**

fluorohydrocarbon plastic, *n*—plastic based on polymers made with monomers composed of fluorine, hydrogen, and carbon only. **F1251**

fluoroplastic, *n*—plastic based on polymers with monomers containing one or more atoms of fluorine or copolymers of such monomers with other monomers, the fluorine-containing monomer(s) being in greatest amount by mass. (See also **fluorocarbon plastic**, **chlorofluorocarbon plastic**, **fluorohydrocarbon plastic**, and **chlorofluorohydrocarbon plastic**.) **F1251**

foam, *n*—cross-linked material that has a component added to it which generates a volatile gas as the material is being vulcanized. This vulcanization process results in a material with a relatively low density. Foams are usually two-part formulations utilizing a platinum catalyzed addition cure system. They conform as they expand to irregular surfaces just as gels do to provide intimate contact and protection

from the environment but are more rigid and provide more strength than gels. Since foams are expanded elastomers, on a weight basis, they are highly crosslinked relative to gels. Most cure conditions will result in a closed cell foam. **F2042**

gel, *n—in polymer*, a semisolid system consisting of a network of solid aggregates in which liquid is held.

DISCUSSION—Gels have very low strengths and do not flow like a liquid. They are soft, flexible, and may rupture under their own weight unless supported externally. **F1251**

gel, *n—in polymerization*, the initial jelly-like solid phase that develops during the formation of a resin from a liquid. **F1251**

gel, *n—with vinyl plastisols*, a state between liquid and solid that occurs in the initial stages of heating, or upon prolonged storage. **F1251**

gel, *n*—lightly crosslinked material having no or relatively low levels of reinforcement beyond that provided by the crosslinked polymer. Gels are usually two-part formulations utilizing a platinum catalyzed addition cure system. The hardness of the gel can be adjusted within wide limits. The material is not usually designed to bear a heavy load but rather to conform to an irregular surface providing intimate contact. As a result, loads are distributed over a wider area. These materials may also be used to provide protection from environmental contaminants. **F2042**

haze, *n—in plastics*, the cloudy or turbid aspect or appearance of an otherwise transparent material caused by light scattered from within the specimen or from its surfaces.

DISCUSSION—For the purpose of Test Method D1003, haze is the percentage of transmitted light which, in passing through the specimen, deviates from the incident beam through forward scatter more than 2.5° on the average. **F1251**

high consistency rubber (HCR), *n*—elastomer having a viscosity such that it cannot be moved or transferred by readily available pumping equipment. These elastomers are fabricated using high shear equipment such as a two-roll mill and cannot be injection molded. They are typically used in compression or transfer molding and extrusion processes. **F2042**

inhibitor, *n*—component of a silicone elastomer added to moderate the rate of the crosslinking reaction. **F2038**

isotactic, *adj*—pertaining to a type of polymeric molecular structure containing a sequence of regularly spaced asymmetric atoms arranged in like configuration in a polymer chain. **F1251**

laminate, *n*—product made by bonding together two or more layers of material or materials.

DISCUSSION—A single resin-impregnated sheet of paper, fabric, or glass mat, for example, is not considered a laminate. Such a single-sheet construction may be called a "lamina." **F1251**

laminate, cross-plied, *n*—nonparallel laminate. **F1251**

laminate, parallel, *n*—laminate in which all layers or plies are oriented with their principal direction (grain or strongest direction in tension) parallel with the principal direction of the laminate. **F1251**

linear polyurethane, *n*—polymer whose backbone consists of urethane groups joined by hydrocarbon chains with little or no cross linking. **F624**

liquid silicone rubber or low consistency silicone rubber (LSR), *n*—elastomer having a viscosity such that it can be moved or transferred by readily available pumping equipment. LSRs are typically used in injection molding operations. **F2042**

lot or batch, *n*—quantity of material made with a fixed, specified formulation in a single, manufacturing run carried out under specific processing techniques and conditions. **F2038**

manufacture, *v*—process which occurs in the supplier's facility in which the various components of the elastomer are brought together, allowed to interact, and are packaged to provide the uncured elastomer for sale. **F2042**

melamine plastic, *n*—plastic based on resins made by the condensation or melamine and aldehydes. **F1251**

monomer, *n*—relatively simple compound which can react to form a polymer. (See also **polymer**.) **F1251**

nylon plastic, *n*—plastic based on resins composed principally of a long-chain synthetic polymeric amide which has recurring amide groups as an integral part of the main polymer chain. **F1251**

olefin plastic, *n*—plastic based on polymers made by the polymerization of olefins or copolymerization of olefins with other monomers, the olefins being at least 50 mass %. **F1251**

oligomer, *n*—polymer consisting of only a few monomer units such as a dimer, trimer, tetramer, and so forth, or their mixtures. **F1251**

one-part elastomer, *n*—elastomer supplied in the uncured form in one package containing all of the formulation components. It does not require mixing before fabrication. **F2042**

open cell, *n*—cell not totally enclosed by its walls, and hence interconnecting with other cells. (See **closed cell**.) **F1251**

organosol, *n*—suspension of a finely divided plastic in a plasticizer, together with a volatile organic liquid.

DISCUSSION—The volatile liquid evaporates at elevated temperatures, and the resulting residue is a homogeneous plastic mass, provided the temperature is high enough to accomplish mutual solution of the plastic and plasticizer. **F1251**

phenolic plastic, *n*—plastic based on resins made by the condensation of phenols, such as phenol and cresol, with aldehydes. **F1251**

pit, *n—in plastics*, an imperfection, a small crater in the surface, the depth and width of which are approximately the same order of magnitude. **F1251**

plastic, *n*—any of numerous polymeric materials that are usually thermoplastic or thermosetting, of high molecular weight and that can be molded, cast extruded, drawn, laminated, or otherwise fabricated into objects, powders, beads, films, filaments, fibers, or other shapes (Webster Modified). **F1251**

plasticizer, *n*—substance incorporated into a material to increase its workability, flexibility, or distensibility of the material. **F1251, F665**

plastisol, *n*—liquid suspension of a finely divided PVC polymer or copolymer in a plasticizer.

DISCUSSION—The polymer does not dissolve appreciably in the plasticizer at room temperature but does dissolve at elevated temperatures to form a homogeneous plastic mass (plasticized polymer). **F1251**

polybutylene, *n*—polymer prepared by the polymerization of butene as the sole monomer. (See also **polybutylene plastic** and **butylene plastic**.) **F1251**

polybutylene plastic, *n*—plastic based on polymers made with butene as essentially the sole monomer. **F1251**

polycarbonate, *n*—polymer in which the repeating structural unit in the chain is a carbonic acid ester of Bisphenol A. **F1251**

polyester, *n*—polymer in which the repeated structural unit in the chain is of the ester type.

DISCUSSION—The polyester is linear and thermoplastic if derived, either actually or formally, from *(a)* mono-hydroxy-mono-carboxylic acids by selfesterification, or *(b)* the interaction of diols and dicarboxylic acids. **F1251**

polyether, *n*—polymer in which the repeated structural unit in the chain is of the ether type. **F1251**

polyethylene, *n*—polymer prepared by the polymerization of ethylene as the sole monomer. (See also **polyethylene plastic** and **ethylene plastic**.) **F1251**

polyethylene plastic, *n*—plastic based on polymers made with ethylene as essentially the sole monomer.

DISCUSSION—In common usage for this plastic, essentially means no less than 85 % ethylene and no less than 95 % total olefins. **F1251**

polyethylene terephthalate, *n*—polymer derived from terephthalic acid and ethylene glycol by condensation polymerization. **F1251**

polymer, *n*—substance consisting of molecules characterized by the repetition (neglecting ends, branch junctions, and other minor irregularities) of one or more types of monomeric units. (See **copolymer**.) **F1251**

polymerization, *n*—chemical reaction in which monomers are linked together to form polymers. (See also **polycondensation** and **polyaddition**.) **F1251**

polyolefin, *n*—polymer prepared by the polymerization of an olefin(s) as the sole monomer(s). (See also **polyolefin plastic**, **olefin plastic**.) **F1251**

polyolefin plastic, *n*—plastic based on polymers made with an olefin(s) as essentially the sole monomer(s). **F1251**

polyoxymethylene, *n*—polymer in which the repeated structural unit in the chain is oxymethylene.

DISCUSSION—Polyoxymethylene is theoretically the simplest member of the generic class of polyacetals. **F1251**

polypropylene, *n*—polymer prepared by the polymerization of propylene as the sole monomer. (See also **polypropylene plastic**, **propylene plastic**.) **F1251**

polystyrene, *n*—polymer prepared by the polymerization of styrene as the sole monomer. (See also **styrene plastic**.) **F1251**

polyterephthalate, *n*—thermoplastic polyester in which the terephthalate group is a repeated structural unit in the polymer chain. **F1251**

poly(vinyl acetate), *n*—polymer prepared by the polymerization of vinyl acetate as the sole monomer. **F1251**

poly(vinyl alcohol), *n*—polymer prepared by the essentially complete hydrolysis of polyvinyl ester. **F1251**

poly(vinyl chloride), *n*—polymer prepared by the polymerization of vinyl chloride as the sole monomer. **F1251**

prepolymer, *n*—polymer of degree of polymerization between that of the monomer or monomers and the final polymer. **F1251**

propylene plastic, *n*—plastic based on polymers of propylene or copolymers of propylene with other monomers, the propylene being in the greatest amount by mass. **F1251**

reinforced plastic, *n*—plastic with high strength fillers imbedded in the composition, resulting in some mechanical properties superior to those of the base resin. (See also **filler**.)

DISCUSSION—The reinforcing fillers are usually fibers, fabrics, or mats made of fibers. **F1251**

reins, *n*—solid or pseudosolid organic material often of high molecular weight, which exhibits a tendency to flow when subjected to stress, usually has a softening or melting range, and usually fractures conchoidally.

DISCUSSION—In a broad sense, the term is used to designate any polymer that is basic material for plastics. **F1251**

rigid plastic, *n*—for purposes of general classification, a plastic that has a modulus of elasticity either in flexure or in tension greater than 700 MPa (100 000 psi) at 23°C and 50 % relative humidity when tested in accordance with Test Methods D747, D790, D638, or D882. **F1251**

room temperature vulcanization (RTV), *n*—one-part elastomer which cures in the presence of atmospheric moisture. Little, if any, acceleration of cure rate is realized by increasing temperature. Because cure is dependent upon diffusion of water into the elastomer, cure in depths of greater than 0.64 cm is not recommended. **F2042**

rubber, *n*—elastic substance derived from various tropical plants, such as the general Hevea and Ficus, essentially a

polymer of isoprene; the term is frequently applied to both natural and synthetic elastic substances (Webster Modified). **F1251**

saran plastic, *n—see* **vinylidene chloride plastic**. **F1251**

segmented polyurethane, *n*—family of polymers in which ester or ether groups, connected by hydrocarbon chains, occur as blocks that are coupled by urethane and urea groups. **F624**

semirigid plastic, *n*—for purposes of general classification, a plastic that has a modulus of elasticity either in tension of between 70 and 700 MPa (10 000 and 100 000 psi) at 23°C and 50 % relative humidity when tested in accordance with Test Methods D747, D790, or D882. **F1251**

sheeting, *n*—form of plastic in which the thickness is very small in proportion to length and width and in which the plastic is present as a continuous phase throughout, with or without filler. (See also **film**.) **F1251**

silicone base, *n*—uniformly blended mixture of silicone polymers, fillers, and additives which does not contain crosslinkers or catalyst. **F2038**

silicone elastomer, *n*—elastomer containing cross-linked silicone polymer and fillers, usually silica. **F1251**

silicone elastomer, *n*—uncured elastomer that has been subjected to conditions which cause it to become crosslinked. Elastomers may be either high consistency rubbers, low consistency rubbers, or RTVs (see following). **F2038**

foams, n—are crosslinked materials which have a component added to them that generates a volatile gas as the material is being vulcanized. This results in a material with a very low density. These are usually two-part formulations utilizing a platinum catalyzed addition cure system. They conform to an irregular surface as they expand to provide intimate contact and protection from the environment but are more rigid and provide more strength than gels. Since foams are expanded elastomers, on a weight basis they are highly crosslinked relative to gels. Most cure conditions will result in a closed cell foam. **F2038**

gels, n—are lightly crosslinked materials having no or relatively low levels of reinforcement beyond that provided by the crosslinked polymer. They are usually two-part formulations utilizing a platinum catalyzed addition cure system. The hardness of the gel can be adjusted within wide limits. The material is not usually designed to bear heavy loads but rather to conform to an irregular surface providing intimate contact. As a result, loads are distributed over a wider area. These materials may also be used to provide protection from environmental contaminants. **F2038**

high consistency rubbers (HCRS, n—are materials which cannot be pumped by conventional pumping equipment. They normally must be processed using high shear equipment such as a two-roll mill and parts are typically fabricated using compression or transfer molding techniques. **F2038**

low consistency rubbers or liquid silicone rubbers (LSRS), n—are normally flowable materials which can be readily pumped. They can be mixed by pumping through static mixers and parts can be fabricated using injection molding techniques. **F2038**

RTVs (room temperature vulcanization), n—are one-part elastomers which cure in the presence of atmospheric moisture. Little, if any, acceleration of cure rate is realized by increasing temperature. Because cure is dependent upon diffusion of water into the elastomer, cure in depths greater than 0.25 in. (0.635 cm) is not recommended. **F2038**

silicone polymer, *n*—polymer of alternating silicon-oxygen atoms consisting of repeating of diorganosiloxy groups. **F1251**

silicone polymer, *n*—polymer chains having a backbone consisting of repeating silicon-oxygen atoms where each silicon atom bears two organic groups. The organic groups are typically methyl, but can be vinyl, phenyl, fluorine, or other organic groups. **F2038**

stabilizer, *n*—substance added to a plastic that will retard the deterioration of the plastic due to the effects of heat, light, or oxidation. **F665**

stress-crack, *n*—external or internal crack in a plastic caused by tensile stresses less than its short-time mechanical strength.

DISCUSSION—The development of such cracks is frequently accelerated by the environment to which the plastic is exposed. The stresses which cause cracking may be present internally or externally or may be combinations of these stresses. **F1251**

styrene plastic, *n*—plastic based on polymers of styrene or copolymers of styrene with other monomers, the styrene being greatest amount by mass. **F1251**

telomer, *n*—polymer composed of molecules having terminal groups incapable of reacting with additional monomers, under the conditions of the synthesis, to form larger polymer molecules of the same chemical type. **F1251**

thermoplastic, *n*—plastic that repeatedly can be softened by heating and hardened by cooling through a temperature range characteristic of the plastic, and that in the softened state can be shaped by flow into articles by molding or extrusion. **F1251**

thermoplastic polyurethane, *n*—linear or segmented polyurethanes that can be melted for processing without significant crosslinking or degradation. They are most frequently synthesized by reacting diols with diisocyanates. **F624**

thermoset plastic, *n*—plastic that, after having been cured by heat or other means, is substantially infusible and insoluble. **F1251**

two-part elastomer, *n*—elastomer supplied in two packages which must be mixed in specified proportions before fabrication. **F2042**

types of cure, *n*—based upon the cure chemistry used, silicone elastomers used in medical applications fall into one of three categories: condensation cure, peroxide cure, and addition cure. **F2038**

addition cure, n—two-part elastomers which must first be mixed together and then cure by addition of a silylhydride to a vinyl silane in the presence of a platinum catalyst. **F2038**

condensation cure, n—these materials liberate an organic leaving group during curing and are normally catalyzed by an organometallic compound. **F2038**

one-part, n—material supplied ready to use in an air tight container which cures upon exposure to atmospheric moisture. The material cures from the surface down and cure depths of greater than about 0.25 inches (0.635 cm) are not practical. **F2038**

peroxide cure, n—one-part formulations vulcanized by free radicals generated by the decomposition of an organic peroxide. **F2038**

two-part, n—material supplied in two separate containers which must be intimately mixed in the prescribed proportions shortly before use. Because they do not rely upon dispersion of atmospheric moisture into the silicone, the cure depth is not limited. **F2038**

uncured elastomer, *n*—silicone base which contains cross-linker and/or catalyst but has not been vulcanized. **F2038**

urethane plastic, *n*—plastic based on polymers in which the repeated structural units in the chains are of the urethane type, or on copolymers in which urethane and other types of repeated structural units are present in the chains. **F1251**

vinyl chloride plastics, *n*—plastics based on polymers of vinyl chloride or copolymers of vinyl chloride with other monomers, the vinyl chloride being the comonomer of the highest concentration by mass. **F665**

virgin polymer, *n*—the form of poly(glycolide) or poly(glycolide-co-lactide) as synthesized from its monomers and prior to fabrication into a medical device. **F2313**

virgin polymer, *n*—initially delivered form of a polymer as synthesized from its monomers and prior to any processing or fabrication into a medical device. **F2579**

viscosity, *n*—property of resistance of flow exhibited with the body of a material.

DISCUSSION—In testing, the ratio of the shearing stress to the rate of shear of a fluid. Viscosity is usually taken to mean "Newtonian viscosity," in which case the ratio of shearing stress to rate of shearing strain is constant. In non-Newtonian behavior, which is the usual case with plastics materials, the ratio varies with the shearing rate. Such ratios are often called the "apparent viscosities" at the corresponding shear rates. (See **viscosity coefficient**.) **F1251**

void, *n—(1)* in a solid plastic, an unfilled space of such size that it scatters radiant energy such as light, *(2)* a cavity unintentionally formed in a cellular material and substantially larger than the characteristic individual cells. **F1251**

vulcanization, *n*—irreversible process in which covalent chemical bonds are formed between silicone polymer chains. During vulcanization, the material changes from a flowable or moldable compound to an elastomeric material which cannot be reshaped except by its physical destruction. **F2038**

METALLURGICAL MATERIALS

X1.2 F04.12 Metallurgical Materials

active austenite finish temperature, *n*—(in nitinol), term used to denote austenite finish temperature of a finished wire, tube, or component as determined by a bend and free recovery method rather than by DSC. **F2005**

alloy phase, *n—in a shape memory alloy*, the crystal structure stable at a particular temperature and stress. **F2005**

anneal, *v*—to heat treat in order to remove the effect of cold-working. **F2005**

austenite, *n*—high temperature parent phase in Ni-Ti shape memory alloys with a B2 crystal structure. This phase transforms to R-phase or martensite, or both, on cooling. **F2005**

austenite finish temperature (A_f), *n*—(in nitinol), temperature at which the martensite to austenite transformation is completed on heating in a single-stage transformation (Fig. 1) or the temperature at which the R-phase to austenite transformation is completed on heating in a two-stage transformation (Fig. 2). **F2005**

austenite peak temperature (A_p), *n*—(in nitinol), temperature of the endothermic peak position on the differential scanning calorimeter (DSC) curve upon heating for the martensite to austenite transformation in a single-stage transformation (Fig. 1) or the temperature of the endothermic peak position on the DSC curve upon heating for the R-phase to austenite transformation in a two-stage transformation (Fig. 2). **F2005**

austenite start temperature (A_s), *n*—(in nitinol), temperature at which the martensite to austenite transformation begins on heating in a single-stage transformation (Fig. 1) or the temperature at which the R-phase to austenite transformation begins on heating in a two-stage transformation (Fig. 2). **F2005**

bend and free recovery (BFR), *n*—(in nitinol), test method for determining austenite transformation temperatures on heating.

DISCUSSION—The test involves cooling a wire or tube specimen below the M_f temperature, deforming the specimen in a controlled fashion, then heating through the austenite transformation. By measuring the shape memory response of the specimen A_s and A_f, temperatures can be determined. This test method is covered in Test Method F2082. **F2005**

degradation, *n*—deleterious change in the chemical structure, physical properties, or appearance of a plastic. **F1251**

differential scanning calorimeter (DSC), *n*—device that is capable of heating a test specimen and a reference at a controlled rate and of automatically measuring the difference in heat flow between the specimen and the reference both to the required sensitivity and precision. **F2005**

differential scanning calorimetry (DSC), *n*—technique in which the difference in heat flow into or out of a substance and an inert reference is measured as a function of temperature while the substance and the reference material are

subjected to a controlled temperature program. This test method, as it applies to Ni-Ti shape memory alloys, is covered in Test Method F2004. **F2005**

free recovery, *n*—unconstrained motion of a shape memory alloy upon heating and transformation to austenite after deformation below the austenite phase. **F2005**

linear elasticity, *n*—linear recoverable deformation behavior.

DISCUSSION—No significant phase transformation event occurs while straining the material and the tensile load-extension or stress-strain plot is linear upon loading and unloading. **F2005**

lower plateau strength (LPS), *n*—(in nitinol), stress at 2.5 % strain during tensile unloading of the sample, after loading to 6 % strain. **F2005**

martensite, *n*—lowest temperature phase in Ni-Ti shape memory alloys with a B19' (B19 prime) monoclinic crystal structure. **F2005**

martensite deformation temperature (M_d), *n*—(in nitinol), highest temperature at which martensite will form from the austenite phase in response to an applied stress. **F2005**

martensite finish temperature (M_f), *n*—(in nitinol), temperature at which the transformation from austenite to martensite is completed on cooling in a single-stage transformation (Fig. 1) or the temperature at which the transformation from R-phase to martensite is completed on cooling in a two-stage transformation (Fig. 2). **F2005**

martensite peak temperature (M_p), *n*—(in nitinol), temperature of the exothermic peak position on the DSC curve upon cooling for the austenite to martensite transformation (Fig. 1) or the R-phase to martensite transformation (Fig. 2). **F2005**

martensite start temperature (M_s), *n*—(in nitinol), temperature at which the transformation from austenite to martensite begins on cooling in a single-stage transformation (Fig. 1) or the temperature at which the transformation from R-phase to martensite begins on cooling in a two-stage transformation (Fig. 2). **F2005**

nitinol, *n*—generic name for a Ni-Ti alloy. **F2005**

pseudoelasticity, *n*—*see* **superelasticity**. **F2005**

residual elongation (El_r[%]), *n*—(in nitinol), strain after tensile loading to 6 % strain and unloading to 7 MPa. **F2005**

R-phase, *n*—(in nitinol), intermediate phase which may form between austenite and martensite.

DISCUSSION—This occurs in Ni-Ti shape memory alloys under certain conditions. The crystal lattice of the R-Phase is a rhombohedral distortion of the cubic austenite crystal lattice structure, hence the name "R-phase." **F2005**

R-phase finish temperature (R_f), *n*—(in nitinol), temperature at which the transformation from austenite to R-phase is completed on cooling in a two-stage transformation (Fig. 2). **F2005**

R-phase peak temperature (R_p), *n*—(in nitinol), temperature of the exothermic peak position on the DSC curve upon cooling for the austenite to R-phase transformation (Fig. 2). **F2005**

R-phase start temperature (R_s), *n*—(in nitinol), temperature at which the transformation from austenite to R-phase begins on cooling in a two-stage transformation (Fig. 2). **F2005**

R'-phase finish temperature (R'_f), *n*—(in nitinol), temperature at which the martensite to R-phase transformation is completed on heating in a two-stage transformation (Fig. 2). **F2005**

R'-phase peak temperature (R'_p), *n*—(in nitinol), temperature of the endothermic peak position on the DSC curve upon heating, for the martensite to R-phase transformation in a two-stage transformation (Fig. 2). **F2005**

R'-phase start temperature (R'_s), *n*—(in nitinol), temperature at which the martensite to R-phase transformation begins on heating in a two-stage transformation (Fig. 2). **F2005**

shape memory alloy, *n*—metal that, after an apparent plastic deformation in the martensitic phase, undergoes a thermoelastic change in crystal structure when heated through its transformation temperature range resulting in a recovery of the deformation. **F2005**

solution anneal, solution heat treatment, *v*—to heat treat in order to remove precipitates. **F2005**

superelasticity, *n*—nonlinear recoverable deformation behavior of Ni-Ti shape memory alloys at temperatures above the austenite finish temperature (A_f).

DISCUSSION—The nonlinear deformation arises from the stress-induced formation of martensite on loading and the spontaneous reversion of this crystal structure to austenite upon unloading. **F2005**

thermoelastic martensitic transformation, *n*—(in nitinol), diffusion-less thermally reversible phase change characterized by a change in crystal structure.

DISCUSSION—This is a process in which an incremental change in temperature produces a proportionate increase or decrease in the amount of phase change. **F2005**

transformation temperature range, *n—in a shape memory alloy*, the temperature range in which a change of phase occurs. **F2005**

upper plateau strength (UPS), *n*—(in nitinol), stress at 3 % strain during tensile loading of the sample. **F2005**

CERAMIC MATERIALS

X1.3 F04.13 Ceramic Materials

allogeneic, *adj*—derived from different individuals of the same species. **F1581**

amorphous calcium phosphate, *n*—noncrystalline calcium phosphate. **F1609**

anorganic, *adj*—denoting tissue (for example, bone) from which the organic material has been totally removed. Also referred to as *deorganified*, *deproteinized* or *deproteinated*. **F1581**

apatite, *n*—mineral substance having the molecular formula $Ca_{10}(X)_2(PO_4)_6$ where X=OH (hydroxyapatite or hydroxylapatite), CO_3 (carbonated apatite), F or C1 (**8**). **F1581**

beta tricalcium phosphate, *n*—calcium phosphate substance of empirical chemical formula, $Ca_3(PO_4)_2$ (see Specification F1088). **F1609**

calcium phosphate, *n*—any one of a number of inorganic chemical compounds containing calcium and phosphate ions as its principal constituents. **F1609**

calcium sulfate anhydrite, *n*—chemical substance having approximate molecular formula of $CaSO_4$. **F2224**

calcium sulfate dihydrate, *n*—chemical having the approximate molecular formula of $CaSO_4 \cdot 2H_2O$. This substance is also known as gypsum. **F2224**

calcium sulfate hemihydrate, *n*—chemical substance having approximate molecular formula of $CaSO_4 \cdot 1/2H_2O$ or $CaSO_4 \cdot H_2O \cdot CaSO_4$. The mineral name of this substance is bassanite and the substance is also known as Plaster of Paris in the clinical literature **F2224**

coating, *n*—layer of mechanically or chemically attached material covering a substrate material. **F1609**

crystalline phases:— F2024

Chemical and Mineral Names	Formula	PDF Card No. 3
whitlockite beta-tricalcium phosphate	β-$Ca_3(PO_4)_2$	9-169
calcium phosphate alpha-tricalcium phosphate	α-$Ca_3(PO_4)_2$	9-348
lime calcium oxide	CaO	37-1497
hydroxyapatite (hydroxylapatite)	$Ca_5(PO_4)_3OH$	9-432

hydroxylapatite, *n*—calcium phosphate crystalline compound of empirical chemical formula, $Ca_5(PO_4)_3OH$ (see Specification F1185). **F1609**

plasma-sprayed hydroxyapatite coating, *n*—coating, consisting of at least 50 % hydroxyapatite by weight, prepared by plasma-spraying hydroxyapatite on a substrate. **F2024**

processing aids, *n*—any constituent intentionally used in the processing of the raw material to fulfill a certain technological purpose during treatment or processing, which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product (<5 % by weight), provided that these residues do not present any health risk. Some examples would be: binders, lubricants, compaction aids, disintegrants, plasticizers, deflocculants, wetting agents, water retention agents, antistatic agents, antifoam agents, foam stabilizers, chelating or sequestering agents, phase stabilizers, and so forth. **F2224**

xenogeneic, *adj*—derived from individuals of a different, specified species. For example, bovine bone, when used as an implant material in humans, is xenogeneic. **F1581**

MATERIAL TEST METHODS

X1.4 F04.15 Material Test Methods

adhesive failure, *n*—failure of the adhesive/substrate bond. **F2548**

adhesive strength, *n*—strength of the tissue adhesive/substrate interface. **F2548**

artifact width, *n*—maximum distance (mm) from the edge of the implant to the fringe of the resulting image artifact found in the entire set of images acquired using this test method. **F2119**

bulk oxidation index (BOI), *n*—sample's bulk oxidation index (BOI) is the average of the oxidation indices collected over a 500-mm section at the center of the sample. **F2102**

DISCUSSION—Typically, this is a plateau region with the smallest oxidation indices.

DISCUSSION—For samples less than about 8 to 10 mm thick, this central region may display the sample's highest oxidation indices, depending on its state of oxidation.

calibrated range, *n*—distance over which the linear displacement sensor system is calibrated. **F2537**

calibration certificate, *n*—certification that the sensor meets indicated specifications for its particular grade or model and whose accuracy is traceable to the National Institute of Standards and Technology or another international standard. **F2537**

cohesive failure, *n*—failure of the internal adhesive bond. **F2458**

cohesive strength, *n*—internal strength of the adhesive. **F2458**

core, *n*—central rod that moves in and out of the sensor. **F2537**

DISCUSSION—It is preferable that the sensors prevent the core from exiting the sensor housing.

corrosive wear, *n*—wear in which chemical or electrochemical reaction with the environment is significant. **F1875**

coverage, *n*—length, parallel to the taper surface, that the bore and cone interfaces are in contact. **F1875**

crevice corrosion, *n*—localized corrosion of a metal surface at, or immediately adjacent to, an area that is shielded from full exposure to the environment because of close proximity between the metal and the surface of another material. **F1875**

data acquisition system, *n*—system generally consisting of a terminal block, data acquisition card, and computer that acquire electrical signals and allows them to be captured by a computer. **F2537**

depth locator (DL), *n*—measurement of the distance from the articular surface, or surface of interest, that a spectrum was collected and a corresponding OI calculated. **F2102**

depth locator (DL), *n*—measurement of the distance from the articular surface, or surface of interest, that a spectrum was collected and a corresponding TVI calculated. **F2381**

diamagnetic material, *n*—material whose relative permeability is less than unity. **F2052, F2213**

differential variable reluctance transducer (DVRT), *n*—linear displacement sensor made of a sensor housing and a core. The sensor housing contains a primary coil and a secondary coil. Core position is detected by measuring the coils' differential reluctance. **F2537**

external circuit, *n*—wires, connectors, measuring devices, current sources, and so forth that are used to bring about or measure the desired electrical conditions within the test cell. **F1875**

femoral head neck extension, *n*—distance parallel to the taper axis, from the nominal neck offset length (*k*), as defined in Specification F1636, and the center of the head. Such variants from the nominal length are used to adjust for resection level, leg length, and so forth. A positive neck extension equates to the center of the head being located further away from the stem. **F1875**

ferromagnetic material, *n*—material whose magnetic moments are ordered and parallel producing magnetization in one direction. **F2052, F2213**

field, *n*—image of a portion of the working surface upon which measurements are performed. **F1854**

free recovery, *n*—unconstrained motion of a shape memory alloy upon heating and transformation to austenite after deformation in a lower temperature phase. **F2082**

fretting, *n*—small amplitude oscillatory motion, usually tangential, between two solid surfaces in contact. **F1875**

fretting corrosion, *n*—deterioration at the interface between contacting surfaces as the result of corrosion and slight oscillatory slip between the two surfaces. **F1875**

fretting wear, *n*—wear arising as a result of fretting. **F1875**

hazard, *n*—potential source of harm. **ISO/IEC Guide 51, F2503**

hydrolytically degradable polymer (HDP), *n*—any polymeric material in which the primary mechanism of chemical degradation in the body is by hydrolysis (water reacting with the polymer resulting in cleavage of the chain). **F1635**

image artifact, *n*—pixel in an image is considered to be part of an image artifact if the intensity is changed by at least 30 % when the device is present compared to a reference image in which the device is absent. **F2119**

intercept, *n*—point on a measurement grid line projected on a field where the line crosses from solid to void or vice versa. **F1854**

ionic compounds/water soluble residue, *n*—residue that is soluble in water, including surfactants and salts. **F2459**

isocenter, *n*—geometric center of the gradient coil system, which generally is the geometric center of a scanner with a cylindrical bore. **F2182**

item, *n*—medical device or other object that may be brought into the MR environment. **F2503**

linear displacement sensor, *n*—electrical sensor that converts linear displacement to electrical output. **F2537**

linear displacement sensor system, *n*—system consisting of a linear displacement sensor, power supply, signal conditioner, and data acquisition system. **F2537**

linear variable differential transformer (LVDT), *n*—linear displacement sensor made of a sensor housing and a core. The sensor housing contains a primary coil and two secondary coils. When an ac excitation signal is applied to the primary coil, voltages are induced in the secondary coils. The magnetic core provides the magnetic flux path linking the primary and secondary coils. Since the two voltages are of opposite polarity, the secondary coils are connected in series opposing in the center, or null position. When the core is displaced from the null position, an electromagnetic imbalance occurs. This imbalance generates a differential ac output voltage across the secondary coils, which is linearly proportional to the direction and magnitude of the displacement. When the core is moved from the null position, the induced voltage in the secondary coil, toward which the core is moved, increases while the induced voltage in the opposite secondary coil decreases. **F2537**

lower plateau strength (LPS), *n*—stress at 2.5 % strain during unloading of the sample, after loading to 6 % strain. **F2516**

magnetic field strength (*H* in A/m), *n*—strength of the applied magnetic field. **F2052, F2213**

magnetic induction or magnetic flux density (*B* in *T*), *n*—that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_o is the static field in an MR system. Plain type indicates a scalar (for example, *B*) and bold type indicates a vector (for example, *B*). **F2052, F2213, F2503**

magnetic resonance (MR), *n*—resonant absorption of electromagnetic energy by an ensemble of atomic particles situated in a magnetic field. **F2052, F2213, F2503**

magnetic resonance diagnostic device, *n*—device intended for general diagnostic use to present images which reflect the spatial distribution or magnetic resonance spectra, or both, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images or spectra, or both, may also be produced. **F2052, F2213**

magnetic resonance (MR) environment, *n*—area within the 5 G line of an MR system. **F2182**

magnetic resonance (MR) environment, *n*—volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire three dimensional volume of space surrounding the MR scanner. For cases in which the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment. **F2052, F2119, F2213, F2503**

magnetic resonance equipment (MR equipment), *n*—medical electrical equipment which is intended for *in-vivo* magnetic resonance examination of a patient. The MR equipment comprises all parts in hardware and software from the supply mains to the display monitor. The MR equipment is a Programmable Electrical Medical System (PEMS). **F2052, F2213**

magnetic resonance examination (MR examination), *n*—process of acquiring data by magnetic resonance from a patient. **F2052, F2213**

magnetic resonance imaging (MRI), *n*—diagnostic imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei. **F2182**

magnetic resonance imaging (MRI), *n*—imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei. **F2119, F2213**

magnetic resonance system (MR system), *n*—ensemble of MR equipment, accessories, including means for display, control, energy supplies, and the MR environment. **IEC 60601-2-33, F2052, F2182, F2213**

magnetically induced displacement force, *n*—force produced when a magnetic object is exposed to the spatial gradient of a magnetic field. This force will tend to cause the object to translate in the gradient field. **F2052, F2213, F2503**

magnetically induced torque, *n*—torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque. **F2213, F2503**

magnetization (M in T), *n*—magnetic moment per unit volume. **F2213**

measurement grid lines, *n*—evenly spaced grid of parallel lines all of the same length. **F1854**

median fatigue strength at N cycles, *n*—maximum stress at which 50 % of the specimens of a given sample would be expected to survive *N* loading cycles. For the purposes of this test method, the fatigue strength will be determined at 5 million load cycles. A rationale for this is provided in the Appendix X1.4 of F2118. **F2118**

medical device, *n*—any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

(1) diagnosis, prevention, monitoring, treatment, or alleviation of disease,
(2) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury,
(3) investigation, replacement, modification, or support of the anatomy or of a physiological process,
(4) supporting or sustaining life,
(5) control of conception,
(6) disinfection of medical devices, and
(7) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

ISO 13485, F2052, F2213, F2503

medical implant, *n*—structure or device that is placed within the body of the patient for medical diagnostic or therapeutic purposes. **F2182**

MR compatible, *adj*—device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions. **F2182**

MR conditional, *adj*—item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required. **F2119, F2503**

MR safe, *adj*—device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions. **F2182**

MR-safe, *adj*—item that poses no known hazards in all MR environments. **F2119, F2503**

DISCUSSION—MR-Safe items include nonconducting, nonmagnetic items such as a plastic petri dish. An item may be determined to be MR-Safe by providing a scientifically based rationale rather than test data.

MR-unsafe, *adj*—item that is known to pose hazards in all MR environments. **F2119, F2503**

DISCUSSION—MR-Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

non-soluble debris, *n*—residue including metals, organic solids, inorganic solids, and ceramics. **F2459**

non-water soluble residue, *n*—residue soluble in solvents other than water. Inclusive in this are oils, greases, hydrocarbons, and low molecular weight polymers. Typical solvents used to dissolve these residues include chlorinated or fluorinated solvents, or low molecular weight hydrocarbons. **F2459**

null position, *n*—core position within the sensor housing where the sensor voltage output is zero (some sensors do not have a null position). **F2537**

offset correction, *n*—removal of any offset in a sensor's output so that at zero displacement, zero voltage is recorded. **F2537**

oxidation index (OI), *n*—oxidation index (OI) is defined as the ratio of the area of the carbonyl absorption peak(s) centered near 1720 cm^{-1} to the area of the absorption peak(s) centered near 1370 cm^{-1}, as shown in Fig. 1 of F2102. Note that the peak areas are computed after subtracting out the appropriate baseline, as further discussed in Section 6 of F2102. **F2102**

oxidation index profile, *n*—oxidation index profile is the graphical representation of variation of the sample's oxidation index with distance from its articular surface or the surface of interest. This is a plot of an OI versus DL. Typically, the graph will show the profile through the entire thickness of the sample. **F2102**

paramagnetic material, *n*—material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force. **F2052, F2213**

passive implant, *n*—implant that serves its function without supply of electrical power. **F2182, F2213**

peak load, *n*—initial local maximum in the load versus displacement curve (Fig. 1). In certain radiation crosslinked UHMWPE materials, the load versus displacement curve increases monotonically and a shoulder, rather than an initial peak load, may be observed. **F2183**

percent error, *n*—the difference between a measurement of a reference standard and the actual length of the reference standard divided by the actual length of the reference standard and the result converted to a percent. **F2537**

porous coating, *n*—coating on an implant deliberately applied to contain void regions with the intent of enhancing the fixation of the implant. **F1854**

potentiodynamic cyclic polarization (forward and reverse polarization), *n*—technique in which the potential of the test specimen is controlled and the corrosion current measured by a potentiostat. The potential is scanned in the positive or noble (forward) direction as defined in Practice G3. The potential scan is continued until a predetermined potential or current density is reached. Typically, the scan is run until the transpassive region is reached, and the specimen no longer demonstrates passivity, as defined in Practice G3. The potential scan direction then is reversed until the specimen repassivates or the potential reaches a preset value. **F2129**

potentiostat, *n*—instrument for automatically maintaining an electrode in an electrolyte at a constant potential or controlled potentials with respect to a suitable reference electrode (see Terminology G15). **F2129**

power supply, *n*—regulated voltage source with output equal to that required by the sensor for proper operation. **F2537**

radio frequency (RF) magnetic field, *n*—magnetic field in MRI that is used to flip the magnetic moments. The frequency of the RF field is γB_0 where γ is the gyromagnetic constant, 42.56 MHz/T for protons, and B_0 is the static magnetic field in Tesla. **F2182, F2503**

reflux system, *n*—apparatus containing an extraction vessel and a solvent return system. It is designed to allow boiling of the solvent in the extraction vessel and to return any vaporized solvent to the extraction vessel. **F2459**

residual elongation, El_r[%], *n*—difference between the strain at a stress of 7.0 MPa during unloading and the strain at a stress of 7.0 MPa during loading. **F2516**

resin, *n*—any polymer that is a basic material for plastics. **F1635**

reuse, *n*—repeated or multiple use of any medical component (whether labeled SUD or reusable) with reprocessing (cleaning, disinfection, or sterilization, or combination thereof) between patient uses. **F2459**

runout, *n*—predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed. For the purposes of this test method, the runout will be 5 million load cycles. **F2118**

safety, *n*—freedom from unacceptable risk in the MR environment. **F2503**

scan rate, *n*—rate at which the controlling voltage is changed. **F2129**

sensor housing, *n*—central hole in a linear displacement sensor that senses movement of the core within it. **F2537**

signal conditioner, *n*—electronic equipment that acts to convert the raw electrical output from the linear displacement sensor into a more useful signal by amplification and filtering. **F2537**

single-use component (SUD), *n*—disposable component; intended to be used on one patient during a single procedure. **F2459**

small punch test, *n*—test wherein the specimen is of miniature size relative to conventional mechanical test specimens, is disk-shaped, and is loaded axisymmetrically in bending by a hemispherical-head punch. **F2183**

specific absorption rate (SAR), *n*—mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg. **F2182, F2503**

specimen failure, *n*—condition at which the specimen completely breaks or is damaged to such an extent that the load

frame is no longer able to apply the intended stress within the required limits. **F2118**

stress level, *n*—value of stress at which a series of duplicate tests are performed. For the purposes of this test method, the stress level is reported as the maximum stress applied to the specimen. **F2118**

substrate, *n*—solid material to which the porous coating is attached. **F1854**

substrate failure, *n*—failure of the tissue substrate. **F2458**

substrate interface, *n*—region where the porous coating is attached to the substrate. **F1854**

surface area, *n*—projected surface area of a part. This area does not include the internal porosity of parts with cancellous, porous, or wire structure. **F2459**

surface oxidation index (SOI), *n*—sample's surface oxidation index (SOI) is the average of the oxidation indices from the sample's articular surface, or the surface of interest, to a depth of 3-mm subsurface. **F2102**

tesla, (T), *n*—SI unit of magnetic induction equal to 10^4 gauss (G). **F2052, F2213, F2503**

tissue adhesive, *n*—any material used as a medical device to help secure the apposition of two wound edges or opposed soft tissues. **F2458**

tissue sealant, *n*—surface coating with adequate adhesive strength to prevent leakage of body fluids. **F2458**

total elemental level, *n*—total weight of particulate matter and corrosion ions generated by fretting wear and fretting corrosion. Most analytical techniques are unable to accurately differentiate between ions and particulates, and therefore, total elemental level refers to all matter and corrosion products released by fretting wear and corrosion. **F1875**

trans-vinylene index (TVI), *n*—trans-vinylene index is defined as the ratio of the absorption peak area between 950 and 980 cm-1 to the absorption peak area between 1330 and 1396 cm^{-1}. **F2381**

trans-vinylene index profile, *n*—trans-vinylene index profile is defined as the graphical representation of variation of the sample's trans-vinylene index with distance from its articular surface or the surface of interest. This is a plot of TVI versus DL. Typically, the graph will show the profile through the entire thickness of the sample. **F2381**

ultimate displacement, *n*—displacement at rupture (failure) of the specimen (Fig. 1 of F2183). **F2183**

ultimate load, *n*—load at rupture (failure) of the specimen (Fig. 1 of F2183). **F2183**

uniform elongation, El_u[%], *n*—elongation determined at the maximum force sustained by the test piece just prior to necking, or fracture, or both. **F2516**

upper plateau strength (UPS), *n*—stress at 3 % strain during loading of the sample. **F2516**

wear, *n*—damage to a solid surface, generally involving progressive loss of material, due to relative motion between that surface and a contacting substance or substances. **F1875**

work to failure, *n*—area under the load versus displacement curve (Fig. 1 of F2183). **F2183**

working surface, *n*—ground and polished face of the metallographic mount where the measurements are made. **F1854**

BIOCOMPATIBILITY TEST METHODS

X1.5 F04.16 Biocompatibility Test Methods

activator, *n*—medical material that demonstrates a shortened clotting time; an initiator of the intrinsic coagulation pathway. **F2382**

antigens, *n*—these are substances that stimulate the host to produce an immune response. **F1905**

AOO, *n*—acetone olive oil solution (4:1 v/v) is a suitable nonpolar solvent. **F2148**

aqueous solvent, *n*—in this assay refers to the polar solvent, saline. **F2148**

blank, *n*—extraction vehicle not containing the specimen under test which is used for comparison with the extract liquid. **F619**

blank time, *n*—period at the beginning of an assay when no data is taken. This is done to eliminate interference from premixing reagents, bubbles, and so forth. **F2382**

cell mediated immunity (CMI), *n*—some antigens stimulate the production of lymphocytes that react specifically with the antigen. These cells do not circulate widely in the host and are generally located at the site of antigen deposition. The use of living lymphocytes is required to test for CMI to an antigen. **F1905**

clastogen, *n*—any agent that is capable of inducing chromosome breaks. **E1280**

comparative hemolysis, *n*—comparison of the hemolytic index produced by a test material compared with that produced by a standard reference material such as polyethylene at the same test conditions. **F756**

complement, *n*—this is a complex system of circulating proteins (enzymes, pro-enzymes, and co-factors) found in the blood. This system is usually activated by antigen-antibody reactions and is a reflection of humoral immunity. However, it is apparent that other factors can activate the complement system. These include large polysaccharides and various materials and tissues. Activation of complement can affect the immune system, inflammation, and vascular activity with fever and shock as a consequence of complement activation in the host. **F1905**

cyanmethemoglobin reagent, *n*—reagent to which whole blood, plasma, or test supernatant is added that quickly

converts most of the forms of hemoglobin to the single cyanmethemoglobin form for quantification at its 540-nm spectrophotometric peak. The reagent (based on that by van Kampen and Zijlstra **(1)**, pH 7.0-7.4), is made with 0.14-g potassium phosphate, 0.05-g potassium cyanide, 0.2-g potassium ferricyanide, and 0.5 to 1 mL of nonionic detergent diluted to 1 L with distilled water. The conversion time of this reagent is 3 to 5 min. This reagent is recommended by the National Commission for Clinical Laboratory Studies (NCCLS) and may be made from the chemicals or purchased from supply houses. The first cyanmethemoglobin reagent used to measure total blood hemoglobin concentration was Drabkin's Reagent (1 g of sodium bicarbonate, 0.05 g of potassium cyanide, 0.2 g of potassium ferricyanide, and diluted with distilled water to 1 L). The disadvantages of using the Drabkin's reagent versus the NCCLS cyanmethemoglobin reagent are that it has a conversion time of 15 min and pH of 8.6 which may cause turbidity. However, it is still available as individual chemicals or kits such as Sigma 525-A. The Drabkin's and cyanmethemoglobin reagents were developed to quantify the high hemoglobin concentration normally found in whole blood (for example, 15 000 mg/dL). By modifying the sample dilution volumes and accounting for background interference, these reagents can also be used to measure much lower plasma or supenatant hemoglobin concentrations as well (Moore et al, Malinauskas **(2)**, **(3)**). **F756**

direct contact test, *n*—test for the hemolytic property performed with the test material in direct contact with the blood. **F756**

DMSO, *n*—dimethylsulfoxide (nonaqueous, suitable organic solvent). **F2148**

DNCB, *n*—2,4-dinitrochlorobenzene. **F2148**

duplicate flag, *n*—agreement between the results of duplicate samples in percent. For example, if set to "15," the difference between the two channels must be less than or equal to 15 %. If the variance in clot times exceeds this percentage, an asterisk "*" will be printed by the average results on the report. **F2382**

equilibration time, *n*—time allowed for the plasma samples to warm to 37°C. The fibrometer can be set to zero if samples are pre-warmed to this temperature. **F2382**

extract liquid, *n*—that liquid which, after extraction of the specimen, is used in tests. **F619**

extract test, *n*—test for the hemolytic property performed with an isotonic extract of the test material, as described in F619, in contact with the blood. **F756**

extraction vehicle, *n*—liquid specified for use in testing the plastic. **F619**

formalin, *n*—1⁄10 dilution of 37 to 39 % formaldehyde solution (formaldehyde) in PBS. **F2148**

Freund's Complete Adjuvant (FCA), *n*—commercially-available mixture of oil and Mycobacterium that is known to elicit an immune response. **F2147**

gene mutation, *n*—any heritable change whose physical extent is restricted to the limits of a single gene. **E1280**

Guinea Pig Maximization Test (GPMT), *n*—procedure described in Practice F720 accepted as a "worst case" assay for allergenic potential. **F2147**

hemolysis, *n*—destruction of erythrocytes resulting in the liberation of hemoglobin into the plasma or suspension medium. **F756**

humoral immunity, *n*—some antigens stimulate the host to produce antibodies (immunoglobulins) that are specific for the antigen and react with the antigen. Antibodies circulate in the blood and tissue fluids. The antibodies produced can be detected using blood from the host. **F1905**

ICCVAM, *n*—Interagency Coordinating Committee on the Validation of Alternative Methods. **F2148**

inflammatory factors, *n*—various soluble substances may be produced by lymphocytes in response to an antigen. This may occur in humoral immune responses or in CMI. These substances may influence the function of other cells and are called cytokines. Many of these act on various white cells and are called interleukins. They are reflection of antigenic stimulation of the host. **F1905**

mutagen, *n*—any physical or chemical agent capable of inducing a mutation. **F1280**

mutation, *n*—any heritable change in the genetic material, not caused by genetic segregation or genetic recombination, and that is transmitted to daughter cells. **F1280**

negative control, *n*—material, such as a polyethylene, that produces little or no hemolysis (<2 % after subtraction of the blank) in the test procedure. It is desirable that the control specimens have the same configuration as the test samples. **F756**

nonaqueous solvent, *n*—in this assay refers to the organic or nonpolar solvent, which shall be dimethylsulfoxide (DMSO) or acetone olive oil (AOO). **F2148**

partial thromboplastin time (PTT) assay, *n*—modification of the Activated Partial Thromboplastin Time (APTT) assay; unlike the APTT test, the PTT assay uses reagent (rabbit brain cephalin) without activating substances (silica, kaolin, elagic acid.) The material being tested acts as the activator. **F2382**

% hemolysis, *n*—quotient of the free plasma hemoglobin (mg/mL) released as a result of contact with test material or extract divided by the total hemoglobin (mg/mL) present in the blood solution multiplied by 100. **F756**

DISCUSSION—This is synonymous with hemolytic index.

PBS, *n*—phosphate buffered saline, pH 7.2. **F2148**

phosphate buffered saline (PBS) (Ca and Mg free), *n*—use of phosphate buffered saline is preferable to the use of saline to maintain the pH. The use of magnesium- and calcium-free PBS is necessary to maintain the anticoagulant properties of

the chelating agents used in collecting the blood. It is used as the background or "blank" for a hemolysis test. **F756**

plasma hemoglobin, *n*—amount of hemoglobin in the plasma. **F756**

positive control, *n*—material capable of consistently producing a hemolysis of at least 8 % after subtraction of the results of the blank. **F756**

DISCUSSION—Suggested materials include, but are not limited to, BUNA N (Aero Rubber and other suppliers) and plastisol (Plasti-Coat, Watertown CT).

positive control, *n*—substance capable of consistently stimulating lymphocyte proliferation. **F2148**

read time, *n*—time during which data is collected to detect a clot. **F2382**

saline, *n*—0.9 % sodium chloride (aqueous, polar solvent). **F2148**

specimen portion, *n*—unit or units of plastic placed into the extraction vehicle. **F619**

TCA, *n*—5 % trichloroacetic acid. **F2148**

tritiated thymidine, *n*—^{H3}methyl thymidine, specific activity 2 Ci/mM (in PBS) I^{125} IUDR-radioactive uridine. **F2148**

2,4 dinitrochlorobenzene (DNCB), *n*—strong sensitizer, used as a positive control. **F2147**

vehicle controls, *n*—aqueous, polar solvent and a non-aqueous, nonpolar solvent. **F2148**

OSTEOSYNTHESIS

X1.6 F04.21 Osteosynthesis

anchor, *n*—bioabsorbable device or a component of a bioabsorbable device that provides the attachment to the bone. **F2502**

angle, *n*—defined at either the barrel/sideplate or blade/sideplate junction (see Fig. 1 and Fig. 2 of Specification F384). **F384**

angled device, *n*—class of orthopedic devices for the fixation of fractures in the methaphyseal areas of long bones that has a component aligned at an angle to the bone's long axis. **F384**

auto compression, *n*—type of bone plate that by its design can generate a compressive force between adjacent unconnected bone fragments through the use of one or more ramped holes or another type of slot geometry. This ramp or slot geometry contacts the underside of the screw head, and induces compressive force as the screw is inserted and tightened to the bone plate. **F382**

axial pullout strength, *n*—tensile force required to fail or remove a bone screw from a material into which the screw has been inserted. **F543**

barrel, *n*—portion of an angled device which captures the lag screw (see Fig. 1 of Specification F384). **F384**

barrel length, L_{BR}, *n*—distance from the free end of the barrel to the interior vertex of the barrel/sideplate junction (see Fig. 1 of Specification F384). **F384**

bending compliance, *n*—reciprocal of the stiffness of the IMFD under a bending load in a specified plane as defined and determined in the static four-point bend test described in Annex A1 in Specification Test Methods F1264. **F1264**

bending stiffness, K (N/mm), *n—of a bone plate*, the maximum slope of the linear elastic portion of the load versus load-point displacement curve for a bone plate when tested according to the test method of Annex A1 of Specification F382. **F382**

bending strength (N-m), *n—of a bone plate*, the bending moment necessary to produce a 0.2 % offset displacement in the bone plate when tested as described in Annex A1 of Specification F382. **F382**

bending strength, *n—of the sideplate*, the bending moment necessary to produce a 0.2 % offset displacement in the sideplate when tested as described in Annex A1 of Specification and Test Methods F382. **F384**

bending structural stiffness, El (N-m^2), *n—of a bone plate*, the bone plate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration when tested according to the method described in Annex A1 of Specification F382. **F382**

bending structural stiffness, El_e, *n—of the sideplate*, the sideplate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration when tested according to the method described in Annex A1 of Specification and Test Methods F382. **F384**

bioabsorbable device, *n*—class of implants that are designed to deteriorate by means of biological resorption once they are implanted into the body. **F2502**

biological resorption, *n*—process by which degraded biomaterials (that is, products of degradation) are eliminated or incorporated, or both, by means of physiological metabolic routes. **F2502**

blade, *n*—portion of an angled device which transmits the off axis loading of the anatomical loading condition to the sideplate portion of the angled device (see Fig. 2 of Specification F384). **F384**

blade length, L_{BD}, *n*—distance from the free end of the blade to the interior vertex of the blade/sideplate junction (see Fig. 2 of Specification F384). **F384**

bone anchor, *n*—bioabsorbable device that provides a means to attach soft tissue to bone with a suture. **F2502**

bone plate, *n*—device with two or more holes or slots, or both, and a cross section that consists of at least two dimensions (width and thickness), which generally are not the same in magnitude. The device is intended to provide alignment and fixation of two or more bone sections, primarily by spanning the fracture or defect. **F2502**

bone plate, *n*—metallic device with two or more holes or slot(s), or both, and a cross section that consists of at least two dimensions (width and thickness) which generally are not the same in magnitude. The device is intended to provide alignment and fixation of two or more bone sections, primarily by spanning the fracture or defect. The device is typically fixed to the bone through the use of bone screws or cerclage wire. A partial list of general types of bone plates is given in 4.1 of Specification F382. **F382**

bone plate length, *L* (mm), *n*—linear dimension of the bone plate measured along the longitudinal axis as illustrated in Fig. A4.2 of Specification and Test Methods F2502. **F2502**

bone plate length, *L* (mm), *n*—linear dimension of the bone plate measured along the longitudinal axis as illustrated in Fig. 2 of Specification F382. **F382**

bone plate thickness, *b* (mm), *n*—linear dimension of the bone plate measured parallel to the screw hole axis as shown in Fig. A4.2 of Specification and Test Methods F2502. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section. **F2502**

bone plate thickness, *b* (mm), *n*—linear dimension of the bone plate measured parallel to the screw hole axis as shown in Fig. 1a, 1b, and Fig. 2 of Specification F382. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section. **F382**

bone plate width, *w* (mm), *n*—linear dimension of the bone plate measured perpendicular to both the length and thickness axes as shown in Fig. A4.2 of Specification and Test Methods F2502. **F2502**

bone plate width, *w* (mm), *n*—linear dimension of the bone plate measured perpendicular to both the length and thickness axes as shown in Fig. 2 of Specification F382. **F382**

breaking angle, *n*—angle of rotation when the screw fails in torsion as demonstrated by a rapid decrease in the indicated torque. **F543**

buttress thread, *n*—asymmetrical thread profile characterized by a pressure flank which is nearly perpendicular to the screw axis. **F543**

cable, *n*—group of strands helically twisted together. **F2180**

cancellous screw, *n*—screw designed primarily to gain purchase into cancellous bone. Cancellous screws typically have a HB thread and may or may not be fully threaded. **F543**

closed section, *n*—any cross section perpendicular to the longitudinal axis of a solid IMFD or hollow IMFD in which there is no discontinuity of the outer wall. To orient the IMFD for testing and for insertion, the desired relationship of any irregularities, asymetries, and so forth, to the sagittal and coronal planes should be described for the intended applications. **F1264**

compression bending stiffness, (K), *n—of a device*, the maximum slope of the linear elastic portion of the load versus displacement curve, when tested as described in Annex A1 of Specification F384. **F384**

compression bending strength, *n—of a device*, the bending moment necessary to produce a 0.2 % offset displacement in the device when tested as described in Annex A1 of Specification F384. **F384**

contouring, *v*—manipulation and bending of a bone plate, either pre-operatively or intra-operatively, to match the anatomic geometry of the intended fixation location. **F382**

core diameter, *n*—smallest diameter of the threaded portion of the screw measured at the thread root. This is also known as the minor diameter or root diameter. **F543**

cortical screw, *n*—screw designed primarily to gain biocortical purchase into cortical bone. Cortical screws typically have a HA thread and are fully threaded. **F543**

crescent section, *n*—bone plate cross-section shape (perpendicular to the long axis of the bone plate) where the thickness is not constant along the section. Typically the section is thickest along the bone plate's centerline and tapers to a smaller thickness at the bone plate's edges (see Fig. 1b of Specification F382.) **F382**

data acquisition device, *n*—data recorder shall be suitable to continuously record torque versus angle of rotation, as well as linear displacement, calibrated in units of Newton-metres for torque and degrees for angle of rotation. The value of torque shall have a resolution of 5 % of torsional yield strength. The angular displacement scale shall have a minimum sensitivity so as to enable an accurate offset measurement capability for a 2° angular displacement (see A1.5.3 of Specification and Test Methods F2502). **F2502**

deterioration (of a bioabsorbable device), *n*—action or process that results in a reduction of mass or mechanical performance properties, or both. **F2502**

diameter, *n*—distance between opposing points across the circle circumscribing either the strand or cable as illustrated in Figs. 1 and 2 of Specification F2180 (see MIL-DTL-83420J, MIL-DTL-83420/1B and MIL-DTL-83420/2B). **F2180**

failure strength, *n*—force parameter (for example, load, moment, torque, stress, and so forth) required to meet the failure criteria defined and measured according to the test conducted. **F1264**

fatigue life, *n*—number of loading cycles of a specified character that a given specimen sustains before failure of a specified nature occurs. **F382, F384**

fatigue strength at *N* cycles, *n*—estimate of the cyclic forcing parameter (for example, load, moment, torque, stress, and so on) at a given load ratio, for which 50 % of the specimens within a given sample population would be expected to survive *N* loading cycles. **F382, F384**

fatigue strength at N cycles, *n*—maximum cyclic force parameter (for example, load, moment, torque, stress, and so

forth) for a given load ratio, which produces device structural damage or meets some other failure criterion in no less than *N* cycles as defined and measured according to the test conducted. **F1264**

final form, *n*—condition of the foam product when used by the end user to perform tests of orthopaedic devices or instruments. The condition of the foam product of which all physical and mechanical tests required by this specification are performed. **F1839**

solid—foam is in a uniform solid form, such as a slab, plate, or block. **F1839**

foam rise direction, *n*—nominal direction that the foam rises during the polymerization ("foaming") process, either at the suppliers production facilities for the solid supplied foam, or at the end-users facilities for foam produced from the liquid supplied form. The foam rise direction shall be marked on the foam block or indicated in the shipping documentation for foam that is supplied in the solid form. **F1839**

gage length, *n*—distance between the holding device, for example, a split collet, and the underside of the screw head. **F543**

grades, *n*—grade designation refers to the nominal density of the foam, in its solid final form, expressed in units of kg/m^3 (lbm/ft^3). Five grades of foam have been defined in Specification F1839. Their nominal densities are: **F1839**

Grade 10:	160.2 kg/m^3 (10.0 lbm/ft^3)
Grade 12:	192.2 kg/m^3 (12.0 lbm/ft^3)
Grade 15:	240.3 kg/m^3 (15.0 lbm/ft^3)
Grade 20:	320.4 kg/m^3 (20.0 lbm/ft^3)
Grade 40:	640.7 kg/m^3 (40.0 lbm/ft^3)

grip length, *n*—length of threads held fast in the split collet or other holding mechanism. **F543**

hydrolytically degradable polymer (HDP), *n*—any polymeric material in which the primary mechanism of chemical degradation in the body is by hydrolysis (water reacting with the polymer resulting in cleavage of the chain). **F2502**

IMFD curvature, *n*—dimensions of size and locations of arcs of the curvature, or mathematical description of the curvature, or other quantitative descriptions to which the curvature is manufactured along with tolerances. To orient the IMFD for testing and for insertion, the desired relationship of the curvature to the sagittal and coronal planes should be described for the intended applications. **F1264**

IMFD diameter, *n*—diameter of the circumscribed circle, which envelops the IMFDs' cross section when measured along the IMFDs' working length. If the diameter is not constant along the working length, then the site of measurement should be indicated. **F1264**

IMFD length, *n*—length of a straight line between the most proximal and distal ends of the IMFD. **F1264**

insertion depth (mm), *n*—linear advancement of the bioabsorbable device into the test block measured relative to its seated position at the test block's surface prior to testing. **F2502**

insertion depth, *n*—threaded length as inserted into the test block. **F543**

insertion torque, *n*—amount of torque required to overcome the frictional force between the screw and the material used for testing while driving the screw into the material. **F543**

lag screw, *n*—that component of a compression hip screw angled device which is threaded into the metaphyses and transmits the off axis load to the sideplate through the barrel (see Fig. 1 of Specification F384). **F384**

lag screw length, *n*—straight line distance measured between the proximal and distal ends of the lag screw (see Fig. 1 of Specification F384). **F384**

lay (or twist), *n*—helical form taken by the wires in a strand and by the strands in a cable (see MIL-DTL-83420J). **F2180**

DISCUSSION—In a "Right Lay" situation, the wires of the strand (or the strands in a cable) are oriented in the same direction as the thread on a right-hand screw.

length of lay (or pitch), *n*—distance parallel to the axis of the strand (or cable) in which a wire (or strand) makes one complete turn about the axis. **F2180**

***M*×*N*,** *n*—construction designation for strands and cables. In this construction designation M represents the number of strands in the cable and N represents the number of wires in each strand. **F2180**

DISCUSSION—Some examples of strand constructions are 1×7 and 1×3. Similar examples of cable constructions are 7×7 and 7×19.

maximum torque (N-m), *n*—largest value of torque recorded during the period of rotation before screw failure in torsional shear when tested in accordance with Annex A1 of Specification F543. **F543**

***N*,** *n*—variable representing a specified number of cycles. **F1264**

no load motion, *n*—some devices have a degree of free motion at fixation points which allows relative motion to occur between the device and the bone with no elastic strain in the device and no (or minimal) change in load. This is termed "no load motion." **F1264**

nontapping screw, *n*—screw that has a tip that does not contain a flute. Nontapping screws usually require a tap to be inserted into the pilot hole before the insertion of the screw, when used in moderate or hard bone. **F543**

open section, *n*—any cross section perpendicular to the longitudinal axis of a hollow IMFD in which there is a discontinuity of the outer wall. To orient the IMFD for testing and insertion, the desired relationship of the discontinuity to the sagittal and coronal planes should be described for the intended applications. **F1264**

partially threaded screw, *n*—screw whose threaded portion does not extend fully from the screw point to the screw head but instead has a smooth shaft running between the head and threads. **F543**

pilot hole, *n*—hole drilled into the bone into which the screw tip is inserted. The pilot hole is normally slightly larger than the screw's core diameter. However, if the screw is to be used to provide compression across a fracture, a portion of the pilot hole may be larger to allow for a clearance fit. **F543**

pilot holes in test block, *n*—pilot holes shall be drilled in the test block for insertion and removal of the test specimen. See Specification F543, Annex 2. **F2502**

pitch, *n*—the length between the thread crests. **F543**

potential critical stress concentrator (CSC), *n*—any change in section modulus, material property, discontinuity, or other feature of a design expected to cause a concentration of stress that is located in a region of the IMFD expected to be highly stressed under the normal anticipated loading conditions. **F1264**

removal torque, *n*—amount of torque required to overcome the frictional force between the screw and the material used for testing while removing the screw from the material (for example, counterclockwise rotation for right-hand thread). **F543**

screw head, *n*—end of the screw which is opposite of the tip and from which the means of inserting the screw is coupled. **F543**

screw length, *n*—overall length of the screw measured from the screw head to the screw tip. **F543**

screw thread, *n*—helical groove on a cylindrical or conical surface. The projecting helical ridge thus formed is called a screw thread, consisting of peaks (crests) and valleys (roots). **F543**

self-tapping force (N), *n*—amount of axial force required to engage the self-tapping features of self-tapping style screws when tested in accordance with Annex A4 of Specification F543. **F543**

self-tapping screw, *n*—a screw that has any number of flutes at its tip which are intended to cut the screw's thread form into the bone upon insertion. **F543**

sideplate, *n*—that portion of the angle device generally aligned with the bone's long axis which attaches to the bone via bone screws (see Fig. 1 and Fig. 2 of Specification F384). **F384**

sideplate length, *L*, *n*—distance from the free end of the sideplate to the interior vertex of the barrel/sideplate junction, shown in Fig. 1 and Fig. 2 of Specification F384. **F384**

sideplate thickness, *b*, *n*—thickness of the sideplate as shown in Fig. 1 and Fig. 2 of Specification F384. **F384**

sideplate width, *w*, *n*—width of the sideplate as shown in Fig. 1 and Fig. 2 of Specification F384. **F384**

size, *n*—identification of a screw based on its nominal thread diameter, as defined in Section 6 of Specification F543. **F543**

solid core, *n*—screw that does not contain a cannulation along its longitudinal axis. **F543**

strand, *n*—group of wires helically twisted together. **F2180**

structural stiffness, *n*—maximum slope of the elastic portion of the load-displacement curve as defined and measured according to the test conducted. For bending in a specified plane, this term is defined and determined in the static four-point bend test described in Annex A1 of Specification and Test Methods F1264. **F1264**

supplied form, *n*—condition of the foam product when received from the supplier by the end user. **F1839**

liquid, n—two liquid components (base and activator) that can be mixed by the end user to produce a rigid, unicellular foam slab. **F1839**

solid, n—foam is in a uniform solid form, such as a slab, plate, or block. **F1839**

test block, *n*—test block shall be fabricated from a uniform material that conforms to Specification F1839. See Specification F543, Annex 2. **F2502**

test specimen, *n*—test specimen shall be a completely fabricated and finished bioabsorbable bone screw. **F2502**

testing fixture, *n*—torsion testing apparatus that is to be used for applying the required torque to the specimen shall be calibrated for the range of torques and rotational displacements used in the determination. A suitable testing fixture for the torsional yield strength-maximum torque-breaking angle test is illustrated in Fig. A1.1 of Specification and Test Methods F2502. **F2502**

thread diameter, *n*—largest diameter of the threaded portion of the screw measured over the thread crests. This is also known as the major diameter. **F543**

thread diameter, *n*—maximum outside diameter of the lag screw (see Fig. 1 of Specification F384). **F384**

thread length, *n*—length of the threaded portion of the screw, measured from the thread runout to the screw tip. **F543**

thread length, *n*—straight line distance measured between the tip and thread runout positions of the screw (see Fig. 1 of Specification F384). **F384**

thread runout, *n*—intersection of the screw thread with either the screw shaft or screw head. **F543**

tolerance, *n*—acceptable deviations from the nominal size of any dimension describing the IMFD. **F1264**

torque transducer, *n*—transducer to translate the applied torque into an electrical signal amenable to continuous recording, calibrated over the range of torques, both in the clockwise and counterclockwise rotation, to be encountered in the test method, shall be provided. **F2502**

torsional displacement transducer, *n*—transducer to translate the angle of twist into an electrical signal amenable to continuous recording, calibrated over the range of angles to be encountered in the test and an accuracy of ±1 % of reading, both in the clockwise and counterclockwise rotation, shall be used. **F2502**

torsional yield strength (N-m), *n*—point at which the screw reaches its proportional limit when tested in accordance with Annex A1 of Specification F543. This will be determined by the offset method. A 2° offset value will be used. **F543**

ultimate strength, *n*—maximum force parameter (for example, load, moment, torque, stress, and so forth) that the structure can support defined and measured according to the test conducted. **F1264**

ungraded, *adj*—foam that does not fit into one of the five grades specified in 3.1 because of the foam not meeting one or more of the physical or mechanical requirements of Section 4 of Specification F1839. **F1839**

uniform width, *n*—referring to a bone plate where the width is constant along the bone plate's length. **F382**

wire, *n*—individual element (typically a cylindrical rod) making up a strand. **F2180**

working length, *n*—length of uniform cross section of the IMFD intended to obtain some type of fit to the medullary canal in the area of the diaphysis. **F1264**

yield strength, *n*—force parameter (for example, load, moment, torque, stress, and so forth) which initiates permanent deformation as defined and measured according to the test conducted. **F1264**

ARTHROPLASTY

X1.7 F04.22 Arthroplasty

anterior curvature, *n*—condylar design which is generally planar except for a concave—upward region anteriorly on the tibial component. **F1223**

anterior posterior (AP), *n*—any geometrical length aligned with the AP orientation. **F1223**

AP displacement, *n*—relative linear translation between components in the AP direction. **F1223**

AP draw load, *n*—force applied to the movable component with its vector aligned in the AP direction causing or intending to cause an AP displacement. **F1223**

articular insert, *n*—polymeric prosthetic portion of a multiple piece glenoid component that articulates with the humeral head. **F1829**

axial load; axial translation, *n*—force and displacement, respectively, perpendicular to the glenoid plane; the axial load simulates the net compressive external and muscle forces (see Fig. 1 of Test Methods F2028). **F2028**

bearing element, *n*—articulating surface element between the femoral head and shell or bonding agent (bone cement). **F2091**

bearing surface, *n*—those regions of the component which are intended to contact its counterpart for load transmission. **F1223**

biconcave, *n*—condylar design with pronounced AP and ML condylar radii seen as a "dish" in the tibial component or a "toroid" in the femoral component. **F1223**

cantilever plane, *n*—plane perpendicular to the line of load application at the level on the stem where the stem becomes unsupported. **F1440**

carpal component, *n*—articulating member inserted into or through the carpal bones. **F1357**

cavity, *n*—any slot, cut, hole, or other feature within the shell intended to accommodate modular adjunct fixation elements; instruments for insertion, extraction, and so forth; or for manufacturing purposes. **F2091**

circularity, *n*—deviations of taper cross section from a perfect circle. **F2345**

condyles, *n*—entity designed to emulate the joint anatomy and used as a bearing surface primarily for transmission of the joint reaction force with geometrical properties which tend to govern the general kinematics of the TKR. **F1223**

cone, *n*—proximal end of the femoral component fabricated as a truncated right cone and used to engage with a mating conical bore of the modular femoral head. **F2345**

cone angle, *n*—included angle of cone (Fig. 1 of Test Methods F2345). **F2345**

coordinate system/axes, *n*—three orthogonal axes are defined as follows: **F2385**

origin, n—center of the coordinate system is located at either the geometric center of the acetabular component segment or the center of a circle defined using the edge of the acetabular component.

X-axis, n—positive X-axis is to be directed in the medial direction independent of which hip is to be studied. Some software programs correct the sign of this value but the user must insure that the protocol maintains the convention, (that is, which way is the patient facing).

Y-axis, n—positive Y-axis is to be fixed in the superior direction.

Z-axis, n—positive Z-axis is to be fixed in the posterior direction.

cumulative moisture content, M_t (%), *n*—amount of absorbed moisture in a material at a given time t, expressed as a percentage of the weight of absorbed moisture divided by the initial specimen weight, as follows: **F1634**

$$M_t\% = \frac{W_i - W_b}{W_b} \times 100$$

where:

W_i = current specimen weight, g, and
W_b = initial (baseline) specimen weight at $t = 0$ and standard laboratory atmosphere, g.

cutoff length, *n*—cutoff length defines the maximal value of the mean twist of profile irregularities that shall be considered in the roughness measurement, that is, with a cutoff

length of 0.8 mm, the profile irregularities with a mean twist higher than 0.8 mm shall not be considered.

DISCUSSION—Precise definitions of roughness parameters, cutoff length, and roundness are given in ISO 4287/1, ISO 5436, ISO 4291, and ISO 6318:1985.

distal stem axis, *n*—centerline in the anterior/posterior projection of the most distal 50 mm of the stem. **F1440**

distraction, *n*—separation of the femoral component(s) from the tibial component(s) in the *z*-direction. **F1223**

edge detection, *n*—method of image analysis used to determine the two dimensional or three dimensional center point of a curved surface. Many computational methods of edge detection exist. **F2385**

edge displacements, *n*—translation, perpendicular to the glenoid plane, of a specific point on the outside edge of the glenoid, when subjected to loading (see Fig. 3 of Test Methods F2028). **F2028**

equator of the articulating surface, *n*—equator of the articulating surface is the circle normal to the revolution axis of the component, the center of which is the center of the spherical articulating surface. **F2033**

estimated maximum bending moment, *n*—maximum load times the unloaded moment arm. **F1440**

femoral neck-axis, *n*—centerline or axis of symmetry of the femoral cone. **F2345**

fixation element, *n*—any peg, spike, threadform, or other protrusion from the exterior surface of the shell intended to increase the surface contact or mechanical interlock between the component, the bonding agent, or the natural acetabulum or a combination thereof. **F2091**

flange, *n*—rim extending from the entry diameter of bearing element. **F2091**

flexion angle, *n*—angulation of the femoral component (about an axis parallel to the y-axis) from the fully extended knee position to a position in which a "local" vertical axis on the component now points posteriorly. **F1223**

DISCUSSION—For many implants, 0° of flexion can be defined as when the undersurface of the tibial component is parallel to the femoral component surface that *in vivo* contacts the most distal surface of the femur. This technique may not be possible for some implants that are designed to have a posterior tilt of the tibial component. In these cases, the user shall specify how the 0° of flexion position was defined.

geometric centroid (cantilever plane), *n*—point in a cross-sectional area of the cantilever plane whose coordinates are the mean values of the coordinates of all the points in the area. **F1440**

glenoid, *n*—prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a prosthetic replacement of the humeral head. It may consist of one or more components from one or more materials, for example, either all-polyethylene or a metal baseplate with a polymeric insert. **F2028**

glenoid backing, *n*—metallic or composite material prosthetic portion of a multiple piece glenoid component that attaches to the scapula. **F1829**

glenoid component, *n*—prosthetic portion that replaces the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement. **F1829**

glenoid plane, *n*—in symmetric glenoids, the plane is defined by joining the two articular edges; in planar and asymmetric glenoids, it is defined by the back surface. **F2028**

H_1—articulating surface superior-inferior height in the frontal plane. **F1672**

H_2—metal back superior-inferior height in the frontal plane. **F1672**

head size, *n*—nominal spherical diameter of the head (generally standardized, but not limited to 22, 26, 28, 32, and 36 mm for total hips.) **F2345**

hinge, *n*—mechanical physical coupling between femoral and tibial components which provides a singular axis about which flexion occurs. **F1223**

humeral head, *n*—prosthetic portion that replaces the proximal humerus or humeral head and articulates with the natural glenoid fossa or a prosthetic replacement. **F2028**

hyperextension stop, *n*—geometrical feature which arrests further progress of flexion angles of negative value. **F1223**

installation load, *n*—force, applied at 0° from femoral neck axis, used to settle the head on the cone before testing. **F2345**

internal-external rotation, *n*—relative angulation of the moveable component about an axis parallel to the *z*-axis. **F1223**

joint reaction force, *n*—applied load whose vector is directed parallel to the z-axis, generally considered parallel to tibial longitudinal axis. **F1223**

line of load application, *n*—loading axis of the test machine. **F1440**

liquid, *n*—water, saline solution, calf serum, or any other liquid solution that is used to condition PMC specimens. **F1634**

load axis, *n*—line of action of the compressive force applied to the head. **F2345**

load axis angle, *n*—measured angle "L" between the line of action of the applied force and femoral neck axis (see Fig. 5 of Test Methods F2345). **F2345**

load magnitude, *n*—peak (absolute value) compressive force of the applied constant amplitude cyclic force. **F2345**

load rate, *n*—rate of applied compressive force. **F2345**

markers, *n*—tantalum beads 1.0 mm, 0.8 mm, or 0.5 mm in diameter. **F2385**

cage markers, n—tantalum beads held in an external reference frame used to create a three dimensional coordinate system for measuring relative displacements.

implant markers, n—in vivo markers placed on the implant to define the implant as a rigid body.

segment, n—three-dimensional rigid body defined by a minimum of three markers.

medio-lateral (ML), *n*—orientation that is aligned with the y-axis in the defined coordinate system. **F1223**

ML condylar radius, *n*—geometrical curvature of the component's condyle in the frontal plane. **F1223**

ML dimension, *n*—any geometrical length aligned with the ML orientation. **F1223**

ML displacement, *n*—relative linear translation between components in the ML direction. **F1223**

ML shear load, *n*—force applied to the moveable component with its vector aligned in the ML direction causing or intending to cause an ML displacement. **F1223**

nominal saturated moisture content, Ms (%), *n*—approximation of the amount of moisture absorbed by a specimen at saturation, expressed as a percentage of the weight of absorbed moisture at approximate saturation divided by the initial specimen weight, as follows: **F1634**

$$M_s, \% = \frac{W_s - W_b}{W_b} \times 100$$

where:

W_s = specimen weight at approximate saturation, g, and
W_b = initial (baseline) specimen weight at $t = 0$ and standard laboratory atmosphere, g.

pole of the articulating surface, *n*—pole of an articulating surface is defined by a point at the intercept of the revolution axis of the component and the spherical articulation surface. **F2033**

porous coating, *n*—region on the exterior surface of the shell characterized by interconnecting subsurface pores, generally with volume porosity between 30 to 70 %, average pore size between 100 to 1000 μm, and a thickness between 500 to 1500 μm. This porous layer may be manufactured directly into the device by casting or by various electro/chemical/thermal/mechanical means, or applied as a coating of particles, beads, or mesh by processes such as sintering or plasma spray. **F2091**

post-in-well feature, *n*—TKR design which tends to influence kinematics through the coupling of a prominent eminence with a recess or housing in a mating component. **F1223**

***Rc*—**radius of curvature for single radius axisymmetric domes only. **F1672**

***R* value,** *n—R* value is the ratio of the minimum force to the maximum force. **F1440**

$$R = \frac{\text{minimum force}}{\text{maximum force}}$$

***R* value,** *n—R* value is the ratio of the minimum load to the maximum load. **F1800, F2580**

$$R = \frac{\textit{minimum load}}{\textit{maximum load}}$$

radial component, *n*—articulating member inserted into the radius for articulation with the carpal component. **F1357**

radio pair, *n*—one set of RSA radiographs which were taken simultaneously. **F2385**

radiographic marker, *n*—nonstructural, generally thin wire, designed to be apparent on X-rays taken after placement of implants that otherwise would be unapparent on such X-rays. **F2091**

radiostereometric analysis (RSA), *n*—method developed by Goren Selvik for measuring relative motion between two parts from clinical radiographs. This method uses *in vivo* tantalum beads, an external reference cage, and two X-ray generators that take two exposures simultaneously. There are several commercially available software/hardware packages for RSA analysis. **F2385**

Reference Line L1, distal stem axis, *n*—medial-lateral (M-L) centerline of the most distal 50 mm of stem in the A-P projection. **F1440**

Reference Line L2:—

collared device, n—plane of the distal side of the collar in the A-P projection. **F1440**

collarless device, n—resection plane recommended for the device in the A-P projection. **F1440**

Reference Point P1, *n*—spherical center of the prosthesis head. **F1440**

Reference Point P3:—

collared device, n—intersection of the principal axis of the collar (L2) with the medial surface of the stem in the A-P projection. **F1440**

collarless device, n—intersection of the resection plane (L2) with the medial surface of the stem in the A-P projection. **F1440**

Reference Point P4, *n*—distal tip of the stem. **F1440**

Reference Point P6, *n*—intersection of the cantilever plane with the medial surface of the stem in the A-P projection. **F1440**

retention element, *n*—any ring, taper, wire, or other protrusion or cavity from the interior surface of the shell or the exterior surface of the bearing element that is intended to affix the bearing element to the shell. **F2091**

rotary laxity (RL), *n*—degree of relative angular motion permitted of moveable component about the z-axis as governed by inherent geometry and load conditions. **F1223**

rotary torque, *n*—moment applied to the moveable component with its vector aligned to an axis parallel to the z-axis and causing or intending to cause an internal or external rotation. **F1223**

shear load; shear translation, *n*—force and displacement, respectively, parallel to the glenoid plane, applied, for example, in the superior/inferior or anterior/posterior direction (see Figs. 1 and 2 of Test Methods F2028); the shear load simulates the net shear external and active and passive soft tissue forces. **F2028**

shell, *n*—metal structure supporting the articulating surface material, and which may be fixed rigidly to the articulating surface or fixed such that it allows the articulating surface to rotate or translate. **F2091**

standard laboratory atmosphere, *n*—laboratory atmosphere having a temperature of 23 ± 2°C and a relative humidity of 50 ± 10 %. **F1634**

stem reference angle *X*, *n*—angle between the stem reference line and the line of load application. **F1440**

stem reference line, *n*—line passing through Reference Point P6 and the center of the prosthesis head (P1). **F1440**

stroke rate, *n*—rate of the stroke displacement of the force applicator. **F2345**

stylus tip, *n*—stylus tip is the tip of the measuring device (diamond or Focodyn) that measures the surface roughness. A stylus has a pseudoconical shape with a hemispherical tip. Typical sizes for the tip are 2, 5, or 10 µm. The selection of the stylus tip is dependent on the range of the roughness measured. **F2033**

subluxation load, *n*—peak shear load required for subluxation, for example, the peak resistive force at the glenoid articular rim opposing movement of the humeral head. **F2028**

subluxation translation, *n*—distance from the glenoid origin (see Fig. 2 of Test Methods F2028), parallel to the glenoid plane, to the point at which the subluxation load occurs. **F2028**

superior/inferior (SI), anterior/posterior (AP), *n*—SI axis is the longest dimension and the AP axis the widest dimension of the glenoid (see Fig. 2 of Test Methods F2028). **F2028**

supported stem length, *n*—vertical distance between the distal tip of the stem (P4) and the cantilever plane. **F1440**

surface finish, *n*—measured roughness of surface of taper cone or head bore as determined by DIN 4768. **F2345**

surface texturing, *n*—repetitive or random deviations from the nominal surface that forms the three dimensional topography of the surface. **F2091**

***T_1*—**total overall prosthetic thickness, for example, from the apex of the dome to the free end of pegs or other fixation geometry. **F1672**

***T_2*—**thickness of the patellar prosthesis from the plane of the bone-prosthesis interface (excluding pegs, keels, and so forth) to the apex of the articulating surface. **F1672**

***T_3*—**minimum polymer thickness of the patellar prosthesis in direct contact with the femoral component that is "at risk" for wear; this is measured perpendicular to the tangent of the wear surface at the point of contact with the femoral component. **F1672**

DISCUSSION—The dimension T_3 is described in Fig. 1 and Fig. 2 of Specification F1672 to be a distance from a surface contact point to an internal peg or an edge of the metal back. The exact location of the minimum thickness at risk may be at a different site and will depend on the design of the patella prosthesis and the mating femoral component. For devices manufactured from a single material, T_3 should be measured from the wear surface to the back of the fixation surface.

test frequency, *n*—rate of cyclic repetition of fatigue loading in cycles per second. **F2345**

THR, *n*—total hip replacement. **F2345**

tibial eminence, *n*—raised geometrical feature separating the tibial condyles. **F1223**

total wrist replacement, *n*—prosthetic parts substituted for the native opposing radial and carpal articulating surfaces. **F1357**

unloaded moment arm, *n*—perpendicular distance between the line of load application and the geometric centroid of the stem cross section at the cantilever plane. **F1440**

unsupported stem length, *n*—vertical distance between Point P3 and the cantilever plane. **F1440**

valgus-varus constraint, *n*—degree of relative angular motion allowed between the femoral and tibial components of post-in-well designs (or similar designs) in the coronal plane. **F1223**

***W_1*—**maximum medial-lateral width of the articulating surface in the frontal plane. **F1672**

***W_2*—**maximum medial-lateral width of the metal back in the frontal plane. **F1672**

SPINAL DEVICES

X1.8 F04.25 Spinal Devices

anchor, *n*—components that are directly attached to the bony elements of the spine (sacrum, lamina, pedicle, vertebral body, spinous process, transverse process, the pelvis, or ribs). **F1582**

artificial intervertebral disc, *n*—synthetic structure that is permanently implanted in the disc space between two adjacent vertebral bodies to provide spinal column support and allow intervertebral motion. **F2346**

assembly, *n*—complete implant configuration (not including spine, pelvis, ribs, or substitute material) as intended for surgical use. **F1582**

axial pull-out load (N), *n*—tensile force in N required to fail or remove a screw from a material into which the screw has been inserted when tested in accordance with Specification and Test Methods F543, Annex A3. **F2193**

band, *n*—flexible anchor component with a noncircular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components using a

knot or similar tying mechanism, forming a locked, closed loop. F1582

bending fatigue runout moment (N·m), *n*—value in N-m of the maximum moment that can be applied to a spinal component where all of the tested samples have experienced 2 500 000 loading cycles without a failure at a specific *R*-ratio. F2193

bending moment arm, *L* (mm), *n*—distance in mm between the point where the test sample is gripped (typically the axis of the longitudinal element) and the line-of-action for the applied force prior to any deformation of of the assembly. (See dimension L of Fig. A4.2 of Specifications and Test Methods F2193). F2193

bending stiffness, *S* (N/mm), *n*—slope in N/mm of the initial linear elastic portion of the load versus total displacement curve (slope of line *0m* in Fig. A4.1 of Specifications and Test Methods F2193). F2193

bending ultimate moment (N·m), *n*—maximum bending moment in N-m that can be applied to a test sample. This would correspond to the bending moment at Point *E* in Fig. A4.1 of Specifications and Test Methods F2193. F2193

bending yield moment (N·m), *n*—bending moment in N-m necessary to produce a 0.2 % offset displacement in the spinal component. If the specimen fractures before the test reaches the 0.2 % offset displacement point, the bending yield moment shall be defined as the bending moment at fracture (point *D* in Fig. A4.1 of Specifications and Test Methods F2193). F2193

bolt, *n*—anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads with the lead threads accomodating a nut thus sandwiching the bony element or implant component between the nut or washer and bolt head or other fixed stop. F1582

bolt interconnection, *n*—interconnection having an implant component sandwiched between two nuts or between a nut and fixed stop. F1582

cable, *n*—multi-strand, flexible longitudinal element designed primarily to resist axial tension loading. F1582

clamp, *n*—interconnection component whose mechanism to secure the longitudinal element is through a squeezing action.

DISCUSSION—For example, crimps, wedges, set screws. F1582

component, *n*—any single element used in an assembly. F1582

construct, *n*—a complete implant configuration attached to and including the spine, pelvis, ribs or substitute material as intended for surgical use. F1582

coordinate system/axes, *n*—global *XYZ* orthogonal axes are defined following a right-handed Cartesian coordinate system in which the *XY* plane is to bisect the sagittal plane angle between superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The global axes are stationary relative to the IVD prostheses' inferior end plate fixture, which, in this guide, is also considered to be stationary with respect to the test machine's frame. Lower case letters, *xyz*, denote a local, moving orthogonal coordinate system attached to the superior end plate fixturing with directions initially coincident with those of the global *XYZ* axes, respectively. The 3-D motion of the superior relative to inferior end plate fixture is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z*, axial rotation; *x*, lateral bending; and *y*, flexion-extension). F2483

origin, n—center of the global coordinate system is located at the initial position of the total disc replacement's instantaneous center of rotation (COR). F1582

X-axis, n—positive *X*-axis is a global fixed axis relative to the testing machine's stationary base and is to be directed anteriorly relative to the specimen's initial unloaded position.

Y-axis, n—positive *Y*-axis is a global fixed axis relative to the testing machine's stationary base and is directed laterally relative to the specimen's initial unloaded position.

Z-axis, n—positive *Z*-axis is a global fixed axis relative to the testing machine's stationary base and is to be directed superiorly relative to the specimen's initial unloaded position.

x-axis, n—positive *x*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed anteriorly relative to the prosthesis.

y-axis, n—positive *y*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed laterally relative to the prosthesis.

z-axis, n—positive *z*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed superiorly relative to the prosthesis.

coordinate system/axes, *n*—three orthogonal axes are defined by Terminology F1582. The center of the coordinate system is located at the geometric center of the artificial intervertebral disc. Alternative coordinate systems may be used with justification. The *XY*-plane is to bisect the superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The positive *Z*-axis is to be directed perpendicular to the bisector of the disc space, oriented in the superior direction. The positive *X*-axis is parallel to the intervertebral space, oriented in the anterior direction and the positive *Y*-axis is parallel to the disc space, oriented in the left direction. Force components parallel to the *XY*-plane are shear components of loading. The compressive axial force is defined to be the component in the negative *Z* direction. Torsional load is defined to be the component of moment parallel to the *Z*-axis. F2346

degradation, *n*—loss of material or function or material properties as a result of causes other than that associated with wear. F2423

expansion anchor, *n*—component that forms a connection to bony element by means of a mechanism which enlarges once the component is inserted into the bony elements. F1582

expansion head screw, *n*—threaded anchor that is designed so that the head can be elastically deformed, through mechanical means, to establish an interconnection with another spinal construct element. **F2193**

exposed length (mm), *n*—linear distance measured in mm between the surface of the test block that the screw is embedded in during the test and the location where the screw is anchored (typically the axis of the longitudinal element) in the test fixture (see Fig. A4.2 of Specifications and Test Methods F2193). **F2193**

fatigue, *n*—process of progressive localized permanent structural change occurring in a material subjected to conditions that produce fluctuating stresses and strains at some point or points and that may culminate in cracks or complete fracture after a sufficient number of fluctuations.

DISCUSSION—See Definitions E1150. **F1582**

fatigue life, *n*—number of cycles, *N*, that the artificial intervertebral disc can sustain at a particular load or moment before functional failure occurs. **F2346**

fatigue life, *n*—number of loading cycles, *N*, of a specified character that a given specimen sustains before failure of a specified nature occurs. **F1582**

DISCUSSION—See Definitions E1150.

fatigue strength at N Cycles, S_n [FL^{-2}], *n*—value of stress for failure at exactly *N* cycles as determined from an *S-N* diagram. The value S_n thus determined is subject to the same conditions as those that apply to the *S-N* diagram.

DISCUSSION—The value of S_n which is commonly found in the literature is the value of *S* max (maximum stress) or S_a (stress amplitude) at which 50 % of the specimens of a given sample could survive *N* stress cycles in which S_{nm} (mean stress) = 0. This is also known as the median fatigue strength for *N* cycles (see Definitions E1150). **F1582**

fatigue test, *n*—test designed to evaluate the cyclic load properties of a material, component, interconnection, subconstruct, construct, subassembly, or assembly. **F1582**

fluid absorption, *n*—fluid absorbed by the device material during testing or while implanted *in vivo*. **F2423**

functional failure, *n*—permanent deformation or wear that renders the IVD prosthesis assembly ineffective or unable to resist load/motion or any secondary effects that result in a reduction of clinically relevant motions or the motions intended by the design of the device. **F2423**

functional failure, *n*—permanent deformation that renders the artificial intervertebral disc ineffective or unable to adequately resist load. **F2346**

gross failure, *n*—permanent displacement resulting from fracture or plastic deformation in excess of the yield displacement that renders the spinal component ineffective in fulfilling its intended function. **F2193**

hook, *n*—anchoring component that fastens to the spine by means of a curved blade passed under or over lamina, transverse or spinous processes or into an anatomic or surgically created notch or opening. **F1582**

hook blade, *n*—that portion of a spinal hook that is placed under, over, or into a bony structure to provide attachment. **F1582**

hook body, *n*—that portion of a spinal hook that connects the hook blade to the longitudinal element. **F1582**

hybrid longitudinal element, *n*—longitudinal element consisting of two or more types of longitudinal elements of different size or cross-section manufactured into a single element. **F1582**

ideal insertion location, *n*—location of the artificial disc in the intervertebral space that is suggested in the manufacturer's surgical installation instructions. The ideal insertion location is to be described with respect to the simulated inferior and superior vertebral bodies (polyacetal or metal blocks) and will be dictated by the device design. **F2346**

insertion depth (mm), *n*—linear advancement in mm of the screw into the test block measured relative to its seated position at the test block's surface prior to testing. **F2193**

intended method of application, *n*—artificial intervertebral discs may contain different types of features to stabilize the implant-tissue interface such as threads, spikes, and textured surfaces. Each type of feature has an intended method of application or attachment to the spine. **F2346**

intended spinal location, *n*—anatomic region of the spine intended for the artificial intervertebral disc. Artificial intervertebral discs may be designed and developed for specific regions of the spine such as the cervical, thoracic, and lumbar spine. Also, since different surgical approaches may exist, the description of the intended spinal location should include both the indicated spinal levels and the ideal insertion locations within the intervertebral space allowed at each level. **F2346**

interbody spacer, *n*—structure (biologic or synthetic) to replace (partially or totally) the vertebral body or intervertebral disk(s), or both. **F1582**

interconnection, *n*—mechanical interface or connection mechanism between at least two components or between components and bony elements of the spine, pelvis, or ribs. **F1582**

interface, *n*—one of the two mating surfaces, lines or points of contact within an interconnection between two components, between any component and bone, or between two bony elements. **F1582**

interval net volumetric wear rate VR_i during cycle interval *i* (mm^3/million cycles), *n*—$VR_i = WR_i/\rho$, where ρ = mass density (for example, units of g/mm^3) of the wear material. **F2423**

interval net wear rate WR_i during cycle interval *i* (g/million cycles), *n*—$WR_i = ((NW_i - NW_{i-1})/(\text{number of cycles in interval } i)) * 10^6$. **F2423**

DISCUSSION—For $i = 1$, $NW_{i-1} = 0$.

intervertebral body fusion devices, *n*—structure that is placed in the disc space between two adjacent vertebral bodies to provide support for eventual arthrodeses of the two adjacent vertebral bodies. **F1582**

intervertebral body fusion cage, *n*—hollow device that contains graft material. **F1582**

intervertebral disc (IVD) prosthesis, *n*—nonbiologic structure intended to restore the support and motion or a portion thereof between adjacent vertebral bodies. **F2423**

intervertebral height, *n*—minimum distance parallel to the Z-axis in the YZ-plane between the unaltered simulated vertebral bodies: minimum height of 2 mm and maximum height of 16.5 mm. See Fig. 1 of Test Methods F2346. **F2346**

kinematic profile, *n*—relative motion between adjacent vertebral bodies that the IVD prosthesis is subjected to while being tested. **F2423**

load point, *n*—point through which the resultant force on the intervertebral device passes; that is, the geometric center of the superior fixture's sphere (see Figs. 2–4 of Test Methods F2346). **F2346**

load profile, *n*—loading that the device experiences while being tested under a defined kinematic profile or the loading that the IVD prosthesis is subject to if tested in load control. **F2423**

load ratio, R, A, *n*—in fatigue loading, the algebraic ratio of the two loading parameters of a cycle.

DISCUSSION—The most widely used ratios are:

$$R = \frac{\text{Minimum Load}}{\text{Maximum Load}} = \frac{P_{\min}}{P_{\max}}$$

or

$$\frac{S_{\min}}{S_{\max}}$$

or

$$R = \frac{\text{Valley Load}}{\text{Peak Load}}$$

and

$$A = \frac{\text{Loading Amplitude}}{\text{Mean Load}} = \frac{Pa}{Pm}$$

or

$$\frac{Sa}{Sm}$$

or

$$A = \frac{(\text{Maximum Load} - \text{Minimum Load})}{(\text{Maxium Load} + \text{Minimum Load})} = \frac{(P_{\max} - P_{\min})}{(P_{\max} + P_{\min})}$$

F1528

locking screw, *n*—threaded anchor that is rigidly connected to the longitudinal element of the spinal construct. **F2193**

longitudinal element, *n*—component whose long axis is parallel, or nearly so, to the long axis of the spine. **F1582**

maximum run-out load or moment, *n*—maximum load or moment for a given test that can be applied to an artificial intervertebral disc where all of the tested constructs have withstood 10 000 000 cycles without functional failure. **F2346**

mechanical deterioration, *n*—deterioration that is visible to the naked eye and is associated with mechanical damage to the device under test (for example, initiation of fatigue crack or surface wear). **F2346**

mechanical failure, *n*—failure associated with a defect in the material (for example, fatigue crack) or of the bonding between materials that may or may not produce functional failure. **F2423**

median bending fatigue moment at *N* cycles (N·m), *n*—value in N-m of the maximum moment that can be applied to a spinal component for which 50 % of the test specimens of a given sample can be expected to survive *N* loading cycles at a specific *R*-ratio. **F**

motion segment, *n*—two adjacent vertebrae, the intervening disc, and the associated ligamentous structures. **F1582**

net volumetric wear NV_i of wear specimen (mm^3), *n*—$NV_i = NW_i/\rho$ at end of cycle interval *i* where ρ = mass density (for example, units of g/mm^3) of the wear material. **F2423**

net wear NW_i of wear specimen (g), *n*—$NW_i = (W_0 - W_i) + (S_i - S_0)$; loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval *i*. **F2423**

0.2 % offset displacement (mm), *n*—permanent displacement equal to 0.002 times the test gage section length for the specific test, in mm. The test gage section length is equal to the bending moment arm for spinal screw tests. The test gage section length is equal to the center span distance for spinal plate and rod tests where the loading rollers are directly contacting the test specimen (Fig. A2.1 and Fig. A3.1 of Specifications and Test Methods F2193). The test gage section length is equal to the unsupported distance between the ends of the extension segments for spinal plate and rod tests where extension segments are used to load the test sample (Fig. A2.2 of Specifications and Test Methods F2193) (distance *0B* in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

offset angular displacement, *n*—(distance OB—Fig. 6) offset on the angular displacement axis equal to 2 % of the intervertebral height, *H*, divided by the maximum radius of the implant in the *XY* -plane; for example, for an artificial intervertebral disc with a height of 10 mm and a maximum radius in the *XY*-plane of 9 mm, distance OB = (0.02) (10 mm) / (9 mm) = 0.022 radians = 1.3°. **F2346**

offset displacement, *n*—(distance OB—Fig. 6) offset on the linear displacement axis equal to 2 % of the intervertebral height (for example, 0.2 mm for a 10 mm intervertebral height). **F2346**

partial replacement disc, *n*—structure intended to restore a portion of the support and motion or a portion thereof, between adjacent vertebral bodies. **F1582**

permanent deformation, *n*—remaining linear or angular displacement (axial—mm, angular—degrees or radians) relative to the initial unloaded condition of the artificial intervertebral disc after the applied load or moment has been removed. **F2346**

permanent displacement (mm), *n*—total displacement in mm remaining after the applied load has been removed from the test specimen. **F2193**

plate, *n*—longitudinal element asymmetrical in the transverse plane and designed to resist tension, compression, bending, and torsion. **F1582**

post, *n*—non-threaded anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of a non-threaded hole in the bony element. **F1582**

preload, *n*—resultant force $F_{preload}$ applied to the superior or inferior fixture-end plate that simulates the *in vivo* load that an IVD prosthesis (original healthy disc) must resist. **F2423**

DISCUSSION—Based on a healthy disc, the primary component would be an axial compressive force F_Z in the direction of the negative global *Z* axis, and it would pass through the *in vivo* physiologic instantaneous center of rotation (COR) of the IVD prosthesis. Shear components in the *XY* plane would be F_X and F_Y. Lateral bending moment M_X and flexion/extension moment M_Y components would be created about the initial COR when the preload force does not pass through it

replacement disc, *n*—structure intended to restore support and motion between adjacent vertebral bodies. **F1582**

rod, *n*—longitudinal element symmetrical in the transverse plane designed to resist tension, compression, bending, and torsion. **F1582**

rod diameter (mm), *n*—length in mm of a chord passing through the center of the rod's cross section. **F2193**

rod length (mm), *n*—overall dimension measured in mm between the ends of a given rod. **F2193**

run out (cycles), *n*—maximum number of cycles that a test needs to be carried to if functional failure has not yet occurred. **F2423**

screw, *n*—anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads. **F1582**

screw interconnection, *n*—interconnection having an implant component sandwiched between the screw head (or screw thread) and bony element or other implant components. **F1582**

self-locking screw, *n*—threaded anchor design that undergoes a deformation process at the end of the insertion process which results in the screw's locking to the mating spinal construct element. **F2193**

shaft screw, *n*—threaded anchor having an unthreaded shank equal to its thread diameter. **F2193**

sleeve interconnection, *n*—interconnection in which an implant component passes through any opening that limits motion in one or more planes. **F1582**

S-N diagram, *n*—plot of stress against the number of cycles to failure. The stress can be maximum stress S_{max}, minimum stress S_{min}, stress range *S* or S_r, or alternating stress S_a. The diagram indicates the *S-N* relationship for a specified value of S_m (*mean stress*) *A*, or *R* (*load* or *stress ratio*), and a specified probability of survival. For *N*, a log scale is almost always used. For *S*, a linear scale is used most often, but a log scale is sometimes used.

DISCUSSION—See Definitions E1150. **F1582**

staple, *n*—anchor component that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components by using at least two interconnected posts. **F1582**

static test, *n*—single cycle loading tests designed to evaluate the mechanical properties of materials, components, interconnections, subconstructs, constructs, subassemblies, or assemblies.

DISCUSSION—The mechanical properties can include stiffness, flexibility, failure loads and stresses, and yield and ultimate strengths defined in the associated test standard, that is, the properties associated with elastic and inelastic reactions when force is applied or those that involve a relationship between stress and strain. **F1582**

stiffness (axial—n/mm, angular—n·mm/degree or n·mm/radian), *n*—slope of the initial linear portion of the load-displacement curve or the slope of the initial linear portion of the moment-angular displacement curve. This is illustrated as the slope of the line OG in Fig. 6. If the device does not exhibit a linear initial load/displacement curve, the displacement should be reported at 30, 60, and 90 % of the yield load or moment. **F2346**

stress, S, *n*—intensity at a point in a body of the forces or components of force that act on a given plane through the point.

DISCUSSION—Stress is expressed in units of force per unit area (pounds-force per square inch, megapascals, and so forth). (See Terminology E6.) **F1582**

subassembly, *n*—any portion of an implant assembly that is composed of two or more components. **F1582**

subconstruct, *n*—any portion of an implant construct that is composed of two or more components including the spine, pelvis, ribs, or substitute structure. **F1582**

test block, *n*—component of the test apparatus for mounting the artificial intervertebral disc in the intended test configuration. **F2346**

torsion yield moment (N·m), *n*—applied torque in N-m at which the screw reaches its proportional limit when tested in accordance with Specification and Test Methods F543, Annex A1. The value is determined by using an offset method with a 2° angular offset. **F2193**

total displacement (mm), *n*—distance in mm, in the direction of the applied load, which the load application point has moved relative to the zero load intercept of the initial linear segment of the load versus displacement curve (point *0* in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

transverse element, *n*—component or subassembly that links longitudinal members together. **F1582**

ultimate displacement (axial—mm, angular—degrees or radians), *n*—linear or angular displacement associated with the ultimate load or ultimate moment. This is illustrated as the displacement, OF, in Fig. 6 of Test Methods F2346. **F2346**

ultimate load or moment (axial—n, angular—n·mm), *n*—maximum applied load, *F*, or moment, *M*, transmitted by the pushrod (assumed equal to force and moment component parallel to and indicated by load or torque cell) to the artificial intervertebral disc assembly. This is illustrated as point E in Fig. 6 of Test Methods F2346. **F2346**

vertebral body replacement device, *n*—structure which is designed to restore anatomic position and support to a section of spine lacking one or more vertebral bodies and intervening disc(s). **F1582**

vertebral span, *n*—number of vertebra that are spanned by the longitudinal element, including the vertebrae containing anchor components. **F1582**

wear, *n*—progressive loss of material from the device(s) or device components as a result of relative motion at the surface with another body as measured by the change in mass of the IVD prosthesis or components of the IVD prosthesis. Or in the case of a nonarticulating, compliant IVD prosthesis, wear is defined simply as the loss of material from the prosthesis. **F2423**

DISCUSSION—Note that inferior and superior bone interface components are excluded from this definition.

weight S_i of soak control specimen (g), *n*—S_0 initial and S_i at end of cycle interval *i*. **F2423**

weight W_i of wear specimen (g), *n*—W_0 initial and W_i at end of cycle interval *i*. **F2423**

wire, *n*—single strand flexible anchor component with a circular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components. A series of wire components can be bound together to form a cable (see **cable**). **F1582**

yield displacement, *n*—linear displacement (mm) or angular displacement (degrees or radians) when an artificial intervertebral disc has a permanent deformation equal to the offset displacement or offset angular displacement. This is illustrated as the distance *OA* in Fig. 6 of Test Methods F2346. **F2346**

yield displacement (mm), *n*—total displacement in mm associated with the bending yield strength (distance 0A in Fig. A4.1 of Specifications and Test Methods F2193). **F2193**

yield load or moment, *n*—applied load, *F*, or moment, *M*, transmitted by the pushrod (assumed equal to force component parallel to and indicated by load or torque cell) required to produce a permanent deformation equal to the offset displacement or the offset angular displacement. This is illustrated as point D in Fig. 6 of Test Methods F2346. **F2346**

CARDIOVASCULAR STANDARDS

X1.9 F04.30 Cardiovascular Standards

balloon expandable stent, *n*—stent that is expanded at the treatment site by a balloon catheter. The stent material is plastically deformed by the balloon expansion such that the stent remains expanded after deflation of the balloon. **F2394**

continuous flow blood pump, *n*—blood pump that produces continuous blood flow due to its rotary motion. **F1841**

crimp, *v*—to secure the stent on the delivery system by radially compressing and plastically deforming the stent onto the balloon. **F2394**

delivery system, *n*—system similar to a balloon dilatation catheter that is used to deliver and deploy a stent at the target site and then removed. **F2394**

dislodgment force, peak, *n*—stent securement test endpoint characterizing the peak or maximum force required to completely dislodge the stent from the delivery system balloon. During a test, this force will occur after or coincide with the initial displacement force. (See Fig. X2.1 of Guide F2394.) **F2394**

displacement force, critical distance peak, *n*—stent securement test endpoint characterizing the maximum force required to displace the stent with respect to the balloon a critical distance. This critical distance is the minimum of the following two distances. The first is the distance at which the undamaged stent could overhang the balloon body resulting in a clinically significant, incomplete end deployment. The second is the length (distance) of stent compression or buckling that could result in a clinically significant incomplete deployment of the stent against the vessel walls. (See Fig. X2.1 of Guide F2394.) **F2394**

displacement force, initial, *n*—stent securement test endpoint characterizing the initial force required to displace the stent with respect to the balloon such that the displacement is a non-recoverable movement (see 3.1.15). (See Fig. X2.1 of Guide F2394.) **F2394**

displacement force, initial peak, *n*—stent securement test endpoint characterizing the first peak in force that occurs during or after stent displacement with respect to the balloon. (See Fig. X2.1 of Guide F2394.) **F2394**

end flaring, *n*—distal or proximal outward conical opening of the diameter of the stent on the balloon. End flaring is a contributing factor to the probability that the stent may become caught during withdrawal into a guide catheter while tracking through a lesion. **F2394**

failure mode effect analysis (FMEA), *n*—analytical approach to methodically determine and address all possible product failure modes, their associated causes, and their criticality. Used to evaluate designs, prioritize testing, and track risk reducing improvements to the product. **F2394**

free plasma hemoglobin, *n*—amount of hemoglobin (iron or heme-containing protein) in plasma. **F1841**

gauge length, *n*—initial unstressed length of catheter tubing between the proximal end of the stent to the grips which engage the catheter tubing. **F2394**

grips, *n*—means of applying force to the stent and balloon catheter to displace or dislodge the stent relative to the balloon. In particular, grips refer to the end of a device which makes the contact with the stent. Typical grips used to apply force to the stent include shims (as used in Figs. X2.5–X2.8 of Guide F2394); tape which sticks to the stent but not the balloon; an iris which can be narrowed down to allow the balloon to slip by but not the stent; or nubs which contact the stent but not the balloon. **F2394**

guide catheter, *n*—tube designed to transport the guide-wire and the stent delivery system into the target vessel. **F2394**

guide-wire, *n*—wire designed to aid in balloon, ultrasound, atherectomy, or stent placement during endovascular procedures. **F2394**

hemolysis, *n*—damage to erythrocytes resulting in the liberation of hemoglobin into the plasma. **F1841**

Index of Hemolysis:— **F1841**

modified index of hemolysis, n—mass of hemoglobin released into plasma normalized by the total amount of hemoglobin pumped through the loop.

normalized index of hemolysis, n—added grams of plasma free hemoglobin per 100 l of blood pumped, corrected for plasma volume using hematocrit and normalized by flow rate and circulation time.

normalized milligram index of hemolysis, n—normalized index of hemolysis expressed by milligram value of free plasma hemoglobin.

labeled diameter, *n*—nominal deployed size of a stent as indicated on its manufacturer's label. **F2079**

mandrel, *n*—wire that may be used as an alternative to the intended guide-wire to provide support for the catheter guide-wire lumen for some test procedures. **F2394**

nonrecoverable movement, *n*—displacement of the stent relative to the balloon such that if the shearing force was reduced to zero, the stent would remain displaced in the direction of the shearing force relative to the initial placement on the balloon. The force at which non-recoverable movement begins is defined as the initial displacement force. **F2394**

pre-test treatment, *n*—treatment of the stent delivery system prior to the evaluation of securement that simulates preparatory, environmental, mechanical or other conditions that may be encountered prior to or during clinical use of the device. Examples include subjecting the devices to elevated shipping temperature/humidity, catheter preparation per use instructions, pre-soaking, bending treatments, tracking treatments (tracking fixture, see definition below) and tracking through lesion treatments (lesion fixture, see definition below). **F2394**

pre-test treatment lesion fixture, *n*—pre-test treatment fixture used to simulate an anatomical vasculature and lesion. Use of the fixture with a guide catheter, a guide-wire, and the stent-balloon catheter delivery system is intended to simulate the bending, frictional and mechanical resistance forces of tracking the device across the lesion site that may be encountered in the clinical setting. **F2394**

pre-test treatment tracking fixture, *n*—pre-test treatment fixture used to simulate an anatomical vasculature. Use of the fixture with a guide catheter, a guide-wire and the stent-balloon catheter delivery system is intended to simulate the bending and frictional forces of tracking the device to the lesion site that may be encountered in the clinical setting. See the engineering diagrams in the Appendix of Guide F2394. Note that these engineering diagrams simulate vessels with a moderately difficult degree of coronary tortuousity but do not include simulated lesions. **F2394**

securement test, guide-type, *n*—stent securement test that is similar to the clinical scenario of pulling an undeployed stent delivery system back into a guide catheter, arterial sheath or hemostasis valve. Examples include guides, rings, or shims ideally designed to engage the stent end or body but not the catheter balloon. The shim securement test, described in Section 7 of Guide F2394, uses complementary thin, rigid plates with rounded "V" notches that are sized to circumferentially engage the stent end but not the catheter balloon. See the engineering diagrams in the Appendix of Guide F2394. **F2394**

securement test, lesion-type, *n*—stent securement test that is similar to the clinical scenario of pushing or pulling an undeployed stent delivery system through or around a fibrous or calcified lesion. Examples include tape, nubs, protrusions or sandpaper ideally designed to engage the stent end or body but not the catheter balloon. **F2394**

stent recoil, *n*—amount, expressed as a percentage, by which the diameter of a stent changes from the expanded diameter measured with the stent on the inflated delivery balloon to the final value measured after deflating the balloon. **F2079**

NEUROSURGICAL STANDARDS

X1.10 F04.31 Neurosurgical Standards

clip applier, *n*—any clip holder designed specifically for a particular type clip used during surgical procedures involving the implantation of intracranial aneurysm clips. This device is referred to in this practice as a clip applier **F700**

cranioplasty plate, *n*—implanted prosthetic device used to repair or cover a skull defect or hole. **F622**

intracranial aneurysm clip, *n*—device introduced surgically to occlude the blood inlet into an intracranial aneurysm with the intention that it remain within the body following the surgery. This device is referred to in this practice as an

"implant," specifically as an intracranial aneurysm clip. **F700**

neurosurgical instrument, *n*—any cooperative device used during surgical procedures involving the implantation of neurosurgical implants. **F701**

PLASTIC AND RECONSTRUCTIVE SURGERY

X1.11 F04.32 Plastic and Reconstructive Surgery

barrier coat, *n*—silicone elastomer layer that is part of the shell of a silicone gel implantable breast prosthesis that retards silicone bleed. **F703**

fixation site, *n*—area of the shell of an implantable breast prosthesis containing material that allows tissue ingrowth. **F703**

fixation site, *n*—area on the surface of the implant which has material on it that allows tissue ingrowth. **F881**

fused or adhered joints, *n*—all junctures of dissimilar materials; and all junctures of fully or partly formed or preformed materials bonded or fused together to form a single implant unit. **F881**

DISCUSSION—Implants made from one material by a single charge of unvulcanized elastomer by one-step compression, transfer, or reactive injection molding are not considered to have fused or adhered joints.

fused or adhered joints (seams), *n*—sites in the shell or other parts of an implantable breast prosthesis where materials have been joined (fused or bonded) together, with or without an adhesive, as part of the manufacturing process. **F703, F2051**

fused or adhered joints (seams), *n*—sites in the shell or other parts of the tissue expander device where materials have been joined (fused or bonded) together, with or without adhesive, as part of the manufacturing process. **F1441**

gel bleed, *n*—diffusion of liquid silicone components of silicone gel through the shell of an implantable breast prosthesis. **F703**

gel-filled breast prosthesis, *n*—implantable breast prosthesis designed and provided with a prefilled, fixed volume of silicone gel. **F703**

Type I breast prosthesis, n—implantable breast prosthesis containing a single lumen containing a fixed amount of silicone gel.

DISCUSSION—The lumen of a Type I breast prostheses is not accessible for volume adjustments of any kind.

Type II breast prosthesis, n—implantable breast prosthesis comprised of two complete lumens, one inside the other.

DISCUSSION—The inner lumen of a Type II implantable breast prosthesis contains a fixed amount of silicone gel and is not accessible for volume adjustments of any kind. The outer lumen is provided with a valve to facilitate filling the void between the inner and outer lumens with saline to adjust the total volume of the prosthesis, at the time of use. The valve system may also be designed to facilitate post-operative saline volume adjustment by following the instructions provided in the product literature.

Type III breast prosthesis, n—implantable breast prosthesis comprised of two complete lumens, one inside the other.

DISCUSSION—The area between the inner and outer lumens contains a fixed amount of silicone gel and is not accessible for volume adjustments of any kind. The inner lumen is contained within the silicone gel contained in the outer lumen and has a valve system to facilitate filling the inner lumen with saline to increase the volume of the prosthesis at the time of use. The valve system may also be designed to facilitate post-operative saline volume adjustment by following the instructions provided in product literature.

inflatable breast prosthesis, *n*—implantable breast prostheses not containing silicone gel—implantable breast prostheses designed and provided prefilled with saline or empty and to be filled with saline at the time of use to adjust the volume of the prosthesis. **F2051**

Type 1, n—fixed volume inflatable breast prosthesis—an implantable breast prosthesis composed of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with saline at the time of use.

Type 2, n—variable volume inflatable breast prosthesis—an implantable breast prosthesis composed of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with a portion of the volume of saline at the time of use. The valve system is designed to facilitate further post-operative adjustment with saline as instructed in product literature.

Type 3, n—fixed volume inflatable breast prosthesis—an implantable breast prosthesis composed of a single lumen, prefilled with saline by the manufacturer prior to time of use.

injection port, *n*—port through which an injection to inflate or deflate the variable volume device is made. **F1441**

remote port, n—port that is remote from the shell and attached to the shell by means of tubing.

self-contained (integrated) port, n—port that is integral to the device shell.

injection surface, *n*—area of the injection port recommended by the manufacturer for needle insertion to inflate or deflate the device. **F1441**

low bleed, *n*—silicone gel implantable breast prostheses designed to have minimal silicone bleed when tested using the test method in 9.2.1 in Specification F703. **F703**

lumen, *n*—cavity within a shell and patch or base, accessible by an injection port, to facilitate the addition of saline to adjust the volume of the soft tissue expander. **F1441**

lumen, *n*—cavity within a shell of an implantable breast prosthesis. **F703**

DISCUSSION—A lumen may contain either a fixed, nonadjustable volume of silicone gel, or it may be entirely or partly empty and intended to be inflated (filled) with saline. Inflatable lumens are accessible by valve to facilitate the addition of saline to adjust the volume of the prosthesis at the time of use. More than one lumen may be formed within a shell by silicone elastomer membrane partitions.

lumen, *n*—cavity within a shell of an implantable breast prosthesis. Inflatable lumens are accessible by valve to facilitate the addition of saline to adjust the volume of the prosthesis at the time of use. **F2051**

needle stop, *n*—injection port component used to limit hypodermic needle penetration through the port. **F1441**

orientation means, *n*—any locus on the surface of the implant that is modified to assist the surgeon to position the implant. **F881**

orientation means, *n*—any mark or palpable portion of an implantable breast prosthesis to assist the surgeon in positioning the implant. **F703, F2051**

orientation means, *n*—any mark or palpable portion of a soft tissue expander to assist the surgeon in positioning. **F1441**

patch, *n*—piece of silicone elastomer that covers and seals the hole that results from the manufacturing process of shell fabrication. **F2051**

patch or base, *n*—piece of silicone elastomer or reinforced silicone elastomer, which covers and seals the hole which results from the manufacturing process of shell fabrication. **F1441**

reinforced silicone elastomer, *n*—composite of silicone elastomer and an embedded textile made from polyethylene terephthalate (such as Dacron®) fibers. **F1441**

saline, *n*—only sodium chloride for injection (USP) is recommended for filling lumens of inflatable breast prosthesis. **F2051**

saline, *n*—only sodium chloride for injection (USP) is recommended for filling lumens of soft tissue expanders. **F1441**

saline, *n*—sodium chloride injection USP. **F703**

shell, *n*—silicone elastomer continuous layer or membrane container (sac) which encloses a lumen of an implantable breast prosthesis. **F2051**

shell, *n*—silicone elastomer continuous layer or membrane container (sac) which encloses a lumen of a soft tissue expander. **F1441**

shell, *n*—silicone elastomer continuous layer or membrane container (sac) that encloses a lumen or multiple lumens of an implantable breast prosthesis. **F703**

silicone elastomer, *n*—elastomer containing cross-linked silicone polymer and fumed amorphous (noncrystalline) silica as a reinforcing filler. **F703, F1441, F2051**

silicone gel, *n*—semisolid material consisting of a crosslinked silicone polymer network in which liquid silicone polymer is held (see definition of gel in Terminology F1251). **F703**

tubing length adapter, *n*—tissue expander component used to connect more than one piece of remote port tubing. **F1441**

tubing/shell junction, *n*—junction of the remote port tubing to the shell of the tissue expander. **F1441**

valve, *n*—sealable or self sealing opening in an inflatable prosthesis, extending from the exterior surface of the shell into a lumen, designed to facilitate addition of saline at the time of use or postoperatively to adjust prosthesis volume. **F2051**

valve, *n*—user-sealable or self-sealing opening in an inflatable or gel saline prosthesis, extending from the exterior surface of the shell into a lumen, designed to facilitate adding or removing saline to or from the prosthesis to increase or decrease prosthesis volume. **F703**

MEDICAL/SURGICAL INSTRUMENTS

X1.12 F04.33 Medical/Surgical Instruments

atraumatic, *adv*—teeth that would interdigitate except for being spaced apart a predesigned distance so they will not stress, crush, or otherwise traumatize the tissue being grasped. **F1638**

attachment area, *n*—portion of the needle where the attachment of the suture takes place. For example, eyed, drilled, and channel. **F1840**

blade, *n*—segment that contains the cutting edge which may be with or without serrations. **F1078**

blade alignment, *n*—positioning of the blades with respect to tip match-up and blade setting. **F1078**

body, *n*—central portion of the needle intended to be grasped by the needle holder. **F1840**

bottom scissor half, *n*—component which contains the threaded end of the screw. **F1078**

box lock, *n*—junction where the female member and the male member are secured forming the pivoting feature. **F921**

chamfer, *n*—broken edge of the jaw serrations and the external edges of the box lock surfaces. **F921**

chamfer, *n*—broken external edges of the instrument. **F1078**

chord length, *n*—straight line distance between the two ends of a curved needle. **F1840**

closed cryotip, *n*—hollow, closed end usually shaped to fit a particular anatomical site where the cryogen cools the external surface which is applied to the target tissue. **F882**

closed cryotip reference temperature, *n*—average of the minimum/maximum cycle temperature variation at the end of the freeze cycle. **F882**

compressed gas cylinder, *n*—container that is specifically designed to store a gas or liquid under elevated pressure conditions. **F882**

compressed gas cylinder connector, *n*—device specifically designed to attach to a cylinder for proper and safe removal of its contents. **F882**

container, *n*—product used for the containment of discarded medical needles and other sharps. **F2132**

corrosion, *n*—formation of rust. **F921, F1078**

cryoadhesion, *n*—cryotip attachment to target tissue. **F882**

cryogen, *n*—substance used to obtain reduced temperatures. Cryogens are usually classed by their boiling points. The most common cryogens and their respective boiling points are as follows: **F882**

Cryogen	Boiling Point at S.T.P., °C
Freon 12	-29.8
Freon 22	-49.8
Carbon Dioxide (CO_2)	-78.6
Nitrous Oxide (N_2O)	-88.5
Liquid Nitrogen (LN_2)	-195.8

cryometer, *n*—device for measuring low temperature(s) when used with a temperature sensor such as a thermocouple. **F882**

cryonecrosis, *n*—destruction of tissue cells using a cryosystem. **F882**

cryoprobe, *n*—instrument used to deliver the cryogen to the cryotip or open tip. For a cryotip, a cryoprobe also directs the cryogen away from the target tissue. **F882**

cryosystem, *n*—all parts of a system excluding the cryogen and its container, unless supplied by the manufacturer, that is designed to apply or use a cryogen. **F882**

curvature, *n*—shape of the needle viewed in profile. Some common shapes include, but are not limited to: straight, ½ curve or "ski", ⅛ circle, ¼ circle, ⅜ circle, ½ circle, ⅝ circle, and compound curvature. **F1840**

cutting edge, *n*—cutting edges are made of various goemetric shapes, that is, triangular, diamond, and hexagonal. The various edges may be sharpened by the manufacturer depending on the user performance. **F1840**

defrost, *v*—ability to return the cryotip to ambient temperature. **F882**

Dewar, *n*—vacuum-insulated container that is specifically designed to store a liquid cryogen. **F882**

Dewar withdrawal device, *n*—device specifically designed to attach to a dewar for proper and safe removal of its contents. **F882**

disposable, *adj*—any device that is designated to be discarded after use. **F882**

distal end, *n*—working end, comprised of two jaws, that is furthest from the surgeon when in use. **F921**

distal end, *n*—working end, comprised of two blades, that is furthest from the surgeon when in use. **F1078**

elasticity, *n*—capacity of the instrument to undergo induced stress without permanent distortion or breakage of any component. **F921**

female member, *n*—component that accommodates and encloses the male member at the box lock junction. **F921**

finger rings, *n*—feature of both the female and the male members that forms the gripping surface for the surgeon (commonly classified as the ring-handled feature in ISO 7151). **F921**

finger rings, *n*—feature of the scissors that forms the gripping surface for the surgeon (commonly classified as the ring-handled feature). **F1078**

finish, *n*—final surface visual appearance classified as follows:

bright or mirror finish, n—highly reflective surface.

satin, matte, or black finish, n—reduced reflective surface (as compared to bright or mirror finish) varying from a dull appearance to a blackened surface. **F921, F1078, F1840**

guide pin, *n*—pin affixed to the inside of one of the forceps halves that aligns with a hole on the other tweezer half without protruding through when closed. **F1638**

guide pin hole, *n*—hole in one forceps half into which the guide pin fits without passing through when closed. **F1638**

hardness, *n*—measurement of the resistance to indentation **F921, F1078**

hemostatic forceps, *n*—instrument, available in various sizes and configurations, used in surgical procedures for the compression of blood vessels and the grasping of tissue. **F921**

interdigitation, *n*—interlocking or meshing of the female and male jaw serrations. **F921**

inflammatory response, *n*—irritation of tissue cells as a result of using a cryosystem. **F882**

jaw alignment, *n*—positioning of the female and male jaws with respect to interdigitation (related to box lock function and ratchet performance). **F921**

jaws, *n*—parts that contain serrations to interrupt the flow of blood through any vessel. **F921**

joint, *n*—junction where the scissor blades are secured by a screw allowing the instrument to pivot. **F1078**

male member, *n*—component that is inserted through the female member and secured to the female member at the box lock junction. **F921**

material, *n*—substance(s) used in the construction of a sharps container. **F2132**

maximum bend moment, *n*—greatest moment applied to a needle during a bend test. **F1840**

mechanical integrity, *n*—ability of all components of a cryosystem to withstand the pressures and temperatures that may be encountered during use as recommended by the manufacturer. **F882**

mesh, *n*—alignment of opposing teeth. The teeth may be in-line or angled. **F1638**

modified working end, *n*—working surfaces possessing superior hardness characteristics which are either the result of depositing various materials on the base metal or the result of permanently securing an insert (such as by brazing) to the base metal. **F1325**

DISCUSSION—The typical method of modifying the working end of the suture needle holder is to use jaw inserts or to plasma deposit (flame

plate) materials with improved wear characteristics such as tungsten carbide or stellite. For the jaw insert method, the insert is brazed to the jaw face with a uniform deposit of silver solder which is free of crevices at all interfaces. For the flame plating method, a uniform layer of material is deposited which is 0.004 ± 0.001 in. thick.

modified working ends, *n*—working surfaces possessing superior hardness characteristics that are the result of either depositing various materials on the base metal or securing an insert permanently (such as by brazing) to the base metal (see Note 3 of Specification F1613). **F1613**

mouse teeth, *n*—distal tip teeth that interdigitate. **F1638**

needle ducility, *n*—measure of the amount of plastic bending a needle can withstand. **F1840**

needle length, *n*—distance measured along the needle curvature from end to end. **F1840**

needle radius, *n*—radius of the uniformly curved portion or portions of the needle measured from the centerline of the needle body. **F1840**

needle wire diameter, *n*—gage or thickness of the needle wire, measured at a location between the needle body and the attachment area, where either no or minimal work has taken place. **F1840**

open cryotip, *n*—device specifically designed to apply the cryogen directly to the target tissue. **F882**

passivation, *n*—changing of the chemically active surface of stainless steel to a much less reactive state. **F921**

passivation, *n*—process to render the surface condition of stainless steel chemically inactive. **F1078**

point, *n*—portion of the needle intended to initiate tissue penetration. **F1840**

point configuration, *n*—shape of the point. Some common point configurations include, but are not limited to: taper, trocar, blunt, spatulated, conventional cutting edge, reverse cutting edge, cutting taper, and side cutting needle. **F1840**

proximal end, *n*—that portion of the instrument that is closest to the surgeon when in use. **F921, F1078**

puncture force, *n*—minimum force applied to the representative sharp object that causes its tip to penetrate (exit) the opposite side of the test specimen from the side that it entered when tested in accordance with the test procedure portion, Section 6, of Specification F2132. **F2132**

puncture resistant, *adv*—region of uniform material and thickness is defined as puncture resistant if it meets Section 4 of this specification when tested in accordance with Section 6 of Specification F2132. **F2132**

puncture test specimen, *n*—test specimen that has been punctured using the puncture test described in 6.3, and subsequently evaluated using the direct or indirect methods described in 7.1 and 7.2 of Specification F2132. **F2132**

ratchets, *n*—portion of both the female and the male members possessing inclined teeth that forms the locking mechanism. **F921**

region of uniform material and thickness, *n*—sharps-contact areas of the container, in aggregate, that are made of the same homogeneous, composite, or laminated material, and, as a consequence of fabrication or design or both, are expected to have the same material and thickness as compared to other areas of the container. For example, in molded containers, the corners could be expected to be of different thickness than the sides and bottom, resulting in different regions of uniform material and thickness. Labels, tabs, membranes, or thin films covering openings in the container are considered separate regions of uniform material and thickness. **F2132**

ride, *n*—edge that acts as a cam **F1078**

ride relief, *n*—contoured area between the shank and ride. **F1078**

rounded blade, *n*—blade having a radius on its outer surface which forms a transition between the outer edge and the cutting edges. **F1078**

scissoring, *v*—lateral misalignment. **F1638**

screw, *n*—fastener which joins the scissor halves. **F1078**

serrations, *n*—corrugations in the cutting edge of the blades. **F1078**

serrations or teeth, *n*—gripping or clamping surfaces of the jaws. **F921**

set, *n*—positioning of the blade for proper cutting action. **F1078**

set, *n*—at rest position of the instrument halves that will provide the intended closing relationship of fit and force. **F1638**

shank, *n*—part of either the female or the male member that yields configuration, length, and leverage. **F921**

shank, *n—(1)* part of either scissor half that yields configuration, length, and leverage; *(2)* part of the scissor between the finger ring and joint. **F1078**

sharps, *n*—items used in medical treatment, diagnoses, or research that may cause puncture wounds, cuts, or tears in skin or mucous membranes, including, but not limited to: hypodermic, surgical, suture, and IV needles; Pasteur pipets, lancets, razors, scalpels, and other blades and sharp objects. **F2132**

sharps-contact areas, *n*—material of a container that represents those surfaces that enclose sharps within the container, when in its final closure configuration (that is, disposal configuration). **F2132**

stainless steel, *n*—raw material on the instrument that is in accordance with Specification F899. **F921, F1078**

stop pin, *n*—pin of preset length affixed to the inside of one of the tweezer halves designed to limit teeth contact upon closure and prevent their damage. **F1638**

surgical scissors with inserts, *n*—stainless steel instrument, available in various sizes and configurations, used in surgical

procedures for cutting body tissue, gauze, and suture. An instrument of this type has tungsten carbide, stellite, or other inserts. **F1078**

swage, *n*—term used to describe any attachment method that uses mechanical force to crimp the end of the needle and firmly hold the suture in place. **F1840**

target tissue, *n*—specific anatomical area intended to be treated. **F882**

teeth, *n*—serrations formed on the inside faces of the distal end of the tweezer halves. **F1638**

test specimen, *n*—sample of material being evaluated for puncture resistance that is taken from the actual container (direct method) or a representative example of the material and thickness having the same characteristics as the actual container (indirect method). Refer to Section 5 of Specification F2132. **F2132**

thermal insulation, *n*—material or technique, or both, used to prevent unintended cryonecrosis, inflammatory responses, or cryoadhesion to nontarget tissue. **F882**

thermocouple, *n*—junction of two dissimilar metals that produce an output voltage proportional to the temperature of the junction. When used in conjunction with a cryometer(s), the output is directly correlated to the temperature to which the sensing junction is exposed. **F882**

tissue forceps, *n*—device formed in two generally symmetrical halves with their proximal ends secured together and set so their distal ends will stay separated unless pressed together. **F1638**

top scissor half, *n*—component which contains the screw head at assembly. **F1078**

tractive forge, *n*—cryoadhesive attraction between the cryotip and the target tissue. **F882**

worst case conditions, *n*—maximum pressures or temperatures, or both, a cryosystem may encounter when used according to the manufacturer's instructions. **F882**

yield bend angle, *n*—angle at which the yield bend moment occurs. **F1840**

yield bend moment, *n*—amount of moment required to initiate plastic deformation during a bend test. **F1840**

UROLOGICAL MATERIALS AND DEVICES

X1.13 F04.34 Urological Materials and Devices

balloon (Foley) catheter, *n*—indwelling catheter retained in the bladder by a balloon that is inflated with liquid. **F623**

DISCUSSION—A two-way balloon catheter has a drainage lumen and inflation lumen (see Fig. 1). Common balloon inflation sizes are 5 cm^3 with the 5-cm^3 balloon being used to hold the catheter in place for normal usage, and 30 cm^3 where so designated when a larger balloon is used. A three-way balloon catheter is used for continuous bladder irrigation and features both a drainage lumen and an irrigation lumen (but as noted above is excluded from consideration in this specification).

French size, *n*—scale used for denoting the size of other tubular instruments and devices, each unit being roughly equivalent to 0.33 mm in diameter. Label French sizes are as follows: **F623**

French Size	Outside Diameter, in. (mm)
12	0.157 (4.0)
13	0.171 (4.3)
14	0.184 (4.7)
15	0.197 (5.0)
16	0.210 (5.3)
17	0.223 (5.7)
18	0.236 (6.0)
19	0.249 (6.3)
20	0.262 (6.7)
21	0.276 (7.0)
22	0.289 (7.3)
23	0.302 (7.7)
24	0.315 (8.0)
25	0.328 (8.3)
26	0.341 (8.7)

lumen, *n*—channel within a tube. **F623**

proximal, *adj*—refers to the balloon end of the catheter, since when in position for clinical use, the balloon end is proximal or closest to the patient. **F623**

referee test method, *n*—method cited in the published specification for the device. This method and the corresponding requirements will be invoked when the performance of the medical device will be questioned. The manufacturer need not use this referee test method in his usual inspection and quality control. **F623**

sterility, *n*—generally, the state of being free of microorganisms. For purposes of this specification, sterility is defined as freedom from microorganisms when tested according to the methodology defined by the USP for nonparenteral devices. **F623**

tolerances, *n*—allowable deviation from a standard size. In usual engineering practice, the maximum permitted size is denoted by a plus sign followed by the tolerance and the minimum permitted size denoted by a minus sign followed by the tolerance. In this standard, the label French size has tolerances given for several dimensions. For example, +3, -1 means that a nominal 14 label French size can be permitted to go as high as 17, but not below 13. Another way of writing tolerance, when both tolerances are equal, is: ±2, meaning the 14 label French size must be between 12 French and 16 French. **F623**

GI APPLICATIONS

X1.14 F04.35 GI Applications

balloon integrity (resistance to rupture), *n*—volume of liquid that corresponds with balloon failure, or bursting. **F2528**

distal, *adj*—refers to the balloon end of the enteral feeding device. **F2528**

enteral feeding device with retention balloon, *n*—two-way medical device intended to provide a means of nutrition or administration of medication, or both, to patients by means of natural orifice (nasal, oral, transluminal) or a surgically

created stoma, or both, consisting of a drainage lumen and inflation lumen (see Fig. 1 of Test Methods F2528). Common balloon inflation sizes are 5, 15, and 20 cm^3. **F2528**

French size (Fr), *n*—scale used for denoting the size of catheters and other tubular instruments. The French size value is three times the outer diameter of the tube as measured in millimetres. For example, a diameter of 18 Fr indicates a diameter of 6 mm. **F2528**

inflation volume, *n*—volume of liquid used to inflate the retention balloon of the enteral feeding device for proposed testing in this standard. **F2528**

rated volume, *n*—stated volume of inflation of the retention balloon of the enteral feeding device in the manufacturers labeling and instructions for use. **F2528**

simulated gastric fluid, *n*—solution consisting of hydrochloric acid, salt and pepsin with a pH of approximately 1.2, per USP standard recipe. **F2528**

sterility, *n*—state of being free from viable micro-organisms. **F2528**

IMPLANTABLE HEARING DEVICES (IHDs)

X1.15 F04.37 Implantable Hearing Devices (IHDs)

acousto-electric transfer function, H_{SE}, *n*—electrical input to the IMEHD output transducer *E* produced by a sound field, divided by the input sound field pressure p_S: $H_{SE} = E/p_S$. **F2504**

DISCUSSION—H_{SE} will depend on the particular gain settings used, for example, full-on gain or minimal gain. The gain should be reported whenever that transfer function is used.

acousto-vibrational transfer function (IMEHD aided), H_{SVA}, *n*—stapes velocity (IMEHD aided) divided by the input sound field pressure: $H_{SVA} = v_A/p_S$. **F2504**

DISCUSSION—This quantity can be measured directly or computed from the product of the electro-vibrational transfer function, H_{EV}, and the acousto-electric transfer function, H_{SE}, measured in the IMEHD-aided condition: $H_{SVA} = v_A/p_S$.

acousto-vibrational transfer function (unimplanted), H_{SVU}, *n*—stapes velocity (unimplanted) when driven by the input sound field, divided by the input sound field pressure: $H_{SVU} = v_U/p_S$. **F2504**

DISCUSSION—This quantity can be measured directly or computed from the product of the middle-ear transfer function, H_{TV}, and the ear-canal transfer function, H_{ST}, measured in the unimplanted condition: $H_{SVU} = v_U/p_S = H_{ST} \cdot H_{TV}$.

coupling, *n*—points and methods of attachment. **F2504**

displacement, *n*—integral of velocity measured in nanometres. **F2504**

ear-canal pressure transfer function, H_{ST}, *n*—ear canal sound pressure, p_T, produced by the input sound field pressure, p_S, in the unimplanted case, divided by that input sound field pressure: $H_{ST} = p_T/p_S$; this quantity is unitless. **F2504**

ear-canal sound pressure, p_T, *n*—sound pressure produced in the ear canal, at the tympanic membrane, by a sound field stimulus, specified in units of pascals. **F2504**

electro-vibrational transfer function, H_{EV}, *n*—stapes velocity (IMEHD-aided) when driven by the IMEHD output transducer, divided by the transducer input: $H_{EV} = v_A/E$. **F2504**

equivalent hearing level, L_H, *n*—ratio of an equivalent sound pressure, p_Q, relative to the sound field pressure, p_{RETSPL}, at 0° incidence that is just detectable monaurally by a normally hearing individual, as defined in ANSI S3.6, Table 9, expressed in decibels: $L_H = 20 \cdot \log_{10}(p_Q/p_{RETSPL})$. **F2504**

equivalent sound pressure, p_Q, *n*—unimplanted input sound field pressure needed to produce a stapes velocity equal to that produced by a specified IMEHD input in the IMEHD-aided condition: $p_Q = E \cdot H_{ES}$. **F2504**

DISCUSSION—The equivalent sound pressure is the product of the equivalent sound pressure transfer function, H_{ES}, and the IMEHD output transducer electrical input *E*: $p_Q = E \cdot H_{ES}$. The equivalent sound pressure can be expressed as equivalent sound pressure level in units of decibels, SPL_{eq}, calculated as $20 \cdot \log_{10}(p_Q/2 \cdot 10^{-5}$ Pa).

equivalent sound pressure level, L_Q, *n*—logarithmic representation of equivalent sound pressure, $L_Q = 20 \cdot \log_{10}(p_Q)$. **F2504**

equivalent sound pressure transfer function, H_{ES}, *n*—unimplanted sound field pressure needed to produce a stapes velocity equivalent to that produced by an electrical IMEHD input in the IMEHD-aided condition, divided by the IMEHD input. **F2504**

DISCUSSION—If the electrical IMEHD input produces a linear change in stapes velocity with a change in input electrical stimulus, the equivalent sound pressure transfer function, H_{ES}, can be computed as the quotient between the vibro-electric transfer function (IMEHD-aided), H_{EV}, and the vibro-acoustic transfer function (unimplanted), H_{SVU}: $H_{ES} = (v/E)/(v/p_S) = H_{EV}/H_{SVU}$.

hearing level (HL), *L*, *n*—ratio of the input sound field pressure, p_S, relative to the sound field pressure p_{RETSPL} at 0° incidence that is just detectable monaurally by a normally hearing individual, as defined in ANSI S3.6, Table 9, expressed in decibels as: $L = 20 \cdot \log_{10}(p_S/p_{RETSPL})$. **F2504**

IMEHD electrical input at threshold $E_{threshold}$, *n*—electrical input to the IMEHD output transducer at threshold of audibility. **F2504**

IMEHD harmonic distortion, *n*—harmonic distortion of the stapes velocity IMEHD-aided analogous to ANSI S3.22, Section 6.11S, from sinusoidal inputs of the frequencies 500, 800, and 1600 Hz; input levels shall be $E_{max} - 20$ dB. **F2504**

IMEHD output transducer, *n*—electromechanical output transducer of the IMEHD. **F2504**

IMEHD output transducer frequency range, *n*—using the equivalent sound pressure transfer function, HES, draw a horizontal line at the average for 1000, 1600, and 2500 Hz, then subtract 20 dB, or divide by 10; the lower and the upper bounds of the frequency response range are where the average line crosses the transfer function curve. **F2504**

IMEHD output transducer input, *E*, *n*—electrical input to the IMEHD output transducer, specified in volts or amperes, as appropriate for the particular device. **F2504**

IMEHD system frequency range, *n*—using the insertion gain transfer function (velocity), H_{VV}, draw a horizontal line at the average for 1000, 1600, and 2500 Hz, then subtract 20 dB, or divide by 10; the lower and the upper bounds of the frequency response range are where the average line crosses the transfer function curve. **F2504**

input sound field pressure, p_S, *n*—sound stimulus measured in the free field and presented to the listener in either the IMEHD-aided or unimplanted condition, specified in units of pascals. **F2504**

insertion gain transfer function (sound field), H_{SS}, *n*—ratio of the equivalent sound pressure produced in the IMEHD-aided case with a given electrical input to the IMEHD output transducer and the input sound field pressure used as input in the IMEHD-aided case required to produce the same IMEHD output transducer electrical input: $H_{SS} = p_E/p_S$; this ratio is unitless. **F2504**

DISCUSSION—With a linear sound signal processor, the insertion gain (sound field) can be computed from the product of the equivalent sound pressure transfer function, H_{ES}, and the electro-acoustic transfer function, H_{SE}: $H_{SS} = p_E/p_S = H_{SE} \cdot H_{ES}$. H_{SS} will depend on the particular gain settings used, for example, full-on gain or minimal gain. The gain should be reported whenever that transfer function is used

insertion gain transfer function (velocity), H_{V_v}, *n*—ratio of the stapes velocity (IMEHD-aided) and the stapes velocity (unimplanted) produced by a given input sound field: $H_{V_v} = v_A/v_U$; the ratio is unitless and can be expressed in decibels as $20 \cdot \log_{10}(H_{V_v})$. **F2504**

DISCUSSION—With a linear sound signal processor and IMEHD, that is, a processor whose electrical output E is proportional to the input sound field pressure, p_S, and an IMEHD whose vibrational output is proportional to its electrical output, the insertion gain (sound field), H_{SS}, will equal the insertion gain transfer function (velocity), H_{VV}.

maximum electrical transducer input, E_{max}, *n*—maximum electrical output of the sound signal processor, specified as peak-to-peak or root mean square value, specified in volts or amperes, as appropriate for the particular device. **F2504**

maximum equivalent sound pressure, $p_{E,max}$, *n*—equivalent sound pressure that corresponds to the maximum electrical output E_{max} of the implant electronics, $p_{E,max} = E_{max} \cdot H_{ES}$. **F2504**

maximum equivalent sound pressure level, $L_{E,max}$, *n*—logarithmic representation of the maximum equivalent sound pressure $L_{E,max} = 20 \cdot \log_{10}(p_{E,max}/2 \cdot 10^{-5}$ Pa). **F2504**

maximum insertion gain transfer function (sound field), $H_{SS,max}$, *n*—maximum insertion gain transfer function (sound field) that can be achieved with the implant electronics. **F2504**

middle-ear transfer function, H_{TV}, *n*—stapes velocity (unimplanted) produced by an ear-canal sound pressure, divided by the ear-canal sound pressure, in units of mm/s/Pa: $H_{TV} = v_U/p_T$. **F2504**

sound pressure at threshold, $p_{threshold}$, *n*—stimulus sound field pressure at the threshold of audibility. **F2504**

stapes velocity (IMEHD-aided), v_A, *n*—translational velocity of the stapes when driven by the IMEHD output transducer, specified in units of mm/s. **F2504**

stapes velocity (unimplanted), v_U, *n*—translational velocity of the stapes when driven by sound input to the middle ear specified in units of mm/s. **F2504**

CLASSIFICATION AND TERMINOLOGY FOR TEMPS

X1.16 F04.41 Classification and Terminology for TEMPs

adventitious agents, *n*—unintentionally introduced microbiological or other infectious contaminant. In the production of TEMPs, these agents may be unintentionally introduced into the process stream or the final product, or both. **F2312**

alginate, *n*—polysaccharide obtained from some of the more common species of marine algae, consisting of an insoluble mix of calcium, magnesium, sodium, and potassium salts.

DISCUSSION—Alginate exists in brown algae as its most abundant polysaccharide, mainly occurring in the cell walls and intercellular spaces of brown seaweed and kelp. Alginate's main function is to contribute to the strength and flexibility of the seaweed plant. Alginate is classified as a hydrocolloid. The most commonly used alginate is sodium alginate. Sodium alginate and, in particular, calcium cross-linked alginate gels are used in Tissue Engineered Medical Products (TEMPs) as biomedical matrices, controlled drug delivery systems, and for immobilizing living cells. **F2312**

allogeneic or allogenic, *adj*—cells, tissues, and organs in which the donor and recipient are genetically different individuals of the same species. Synonyms: *allograft* and *homograft*. **F2312**

allograft, *n*—graft of tissue between individuals of the same species but of disparate genotype. Called also *allogeneic graft* and *homograft*. **Dorland's, F2311, F2312**

APA bead, *n*—alginate-poly-L-lysine-alginate bead. **F2312**

autograft, *n*—graft of tissue derived from another site in or on the body of the organism receiving it. **Dorland's, F2311, F2312**

autologous, *adj*—cells, tissues, and organs in which the donor and recipient is the same individual. Synonyms: *autogenous*, *autograft*, or *autotransfusion*, a *self-to-self graft*. **F2312**

bioactive agents, *n*—any molecular component in, on, or with the interstices of a device that is intended to elicit a desired tissue or cell response.

DISCUSSION—Growth factors, antibiotics, and antimicrobials are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included. **F2312**

biological product, *n*—"any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or

its derivatives (or any trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man."

DISCUSSION—The term analogous product is interpreted to encompass somatic cell and gene therapy. A biological product may be used as a component of a TEMP. For the purposes of TEMPs, these biological products may be of any origin (that is, organism), tissue type, developmental stage, and may be living, non-living, and genetically or otherwise modified. **F2312**

biomaterial, *n*—any substance (other than a drug), synthetic or natural, that can be used as a system or part of a system that treats, augments, or replaces any tissue, organ, or function of the body. **Dorland's, F2311, F2312**

biomolecule, *n*—biologically active peptide, protein, carbohydrate, vitamin, lipid, or nucleic acid produced by and purified from naturally occurring or recombinant organisms, tissues or cell lines or synthetic analogs of such molecules. A biomolecule may be used as a component of a TEMP. **F2312**

biomolecule therapy, *n*—use of biomolecules to repair, modify, or regenerate the recipient's cells, tissues, or organs or their structure and function, or both. Biomolecule therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

cell, *n*—"the smallest structural unit of an organism that is capable of independent functioning, consisting of one or more nuclei, cytoplasm, and various organelles, all surrounded by a semipermeable cell membrane."

DISCUSSION—Cells are highly variable and specialized in both structure and function, though all must at some stage synthesize proteins and nucleic acids, use energy, and reproduce. A cell or cells may be of any origin (that is, organism), tissue type, developmental stage, and may be living, non-living, and genetically or otherwise modified. Cells may be used as a component of a TEMP. **F2312**

cell culture, *n*—*in vitro* growth or maintenance of cells. **F2312**

cell therapy, *n*—administration of cells (any kind and form) to repair, modify or regenerate the recipient's cells, tissues, and organs or their structure and function, or both. Cell therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

channelyzer, *n*—pulse height analyzer; places voltage pulses into appropriate size bins for the size distribution data. **F2312**

chitosan, *n*—linear polysaccharide consisting of β(1→4) linked 2-acetamido-2-deoxy-D-glucopyranose (GlcNAc) and 2-amino-2-deoxy-D-glucopyranose (GlcN). Chitosan is a polysaccharide derived by *N*-deacetylation of chitin. **F2312**

coincidence, *n*—more than one cell transversing the aperture at the same time. **F2312**

collagen, *n*—Type I collagen is a member of a family of structural proteins found in animals.

DISCUSSION—Type I collagen is part of the fibrillar group of collagens. It derives from the COL1A1 and COL1A2 genes, which express the alpha chains of the collagen. All collagens have a unique triple helical structure configuration of three polypeptide units known as alpha-chains. Proper alignment of the alpha chains of the collagen molecule requires a highly complex enzymatic and chemical interaction *in vivo*. As such, preparation of the collagen by alternate methods may result in improperly aligned alpha chains and, putatively, increase the immunogenicity of the collagen. Collagen is high in glycine, L-alanine, L-proline, and 4-hydroxyproline, low in sulfur, and contains no L-tryptophan. Natural, fibrillar Type I collagen is normally soluble in dilute acids and alkalis. When heated (for example, above approximately 40°C), collagen is denatured to single alpha chains (gelatin). At each end of the chains are short non-helical domains called telopeptides, which are removed in some collagen preparations. Through non-covalent interactions with sites on adjacent helixes, fibrillogenesis is achieved. Subsequently, non-reducible cross-links are formed. Type I collagen can be associated with Type III and Type V collagen and also with the other non-collagenous proteins like elastin and other structural molecules like glycosaminoglycans and complex lipoproteins and glycoproteins. **F2312**

combination product, *n*—as defined in 21 CFR § 3.2(e), the term combination product includes: *(1)* A product comprised of two or more regulated components, that is, drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; *(2)* Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; *(3)* A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, for example, to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or *(4)* Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect." Furthermore, "many somatic cell products administered to patients will be combinations of a biological product and a device or of a drug, a biological product, and a device." The term "combination product" may apply to TEMPs. **F2312**

corrected count, *n*—cell count corrected for coincidence. **F2312**

cross-contamination, *n*—unintended presence of a cell or a material with another cell or material. **F2312**

degree of deacetylation, *n*—fraction or percentage of glucosamine units (GlcN: deacetylated monomers) in a chitosan polymer molecule. **F2312**

depolymerization, *n*—reduction in length of a polymer chain to form shorter polymeric units. Depolymerization may reduce the polymer chain to oligomeric or monomeric units, or both. **F2312**

dermal autograft, *n*—skin [autograft] from which epidermis and subcutaneous fat have been removed; used instead of fascia7 in various plastic [surgery] procedures. **Dorland's F2311, F2312**

device, *n*—"an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,...which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Devices are "intended to affect the structure or any function of the body." (Section 201(h)(1)).

DISCUSSION—Device criteria: "A liquid, powder, or other similar formulation intended only to serve as a component, part or accessory to a device with a primary mode of action that is physical in nature."9 A device may be used as a component of a TEMP. **F2312**

disinfection, *n*—destruction or reduction of pathogenic and other kinds of microorganisms by thermal or chemical means (for example, alcohol, antibiotics, germicides). **F2312**

donor, *n*—living or deceased organism who is the source of cells or tissues, or both, for research or further processing for transplantation in accordance with established medical criteria and procedures. **F2312**

dressing, *n*—any of various materials utilized for covering and protecting a wound. **Dorland's, F2311, F2312**

drug, *n*—"articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Drugs are "intended to affect the structure or any function of the body of man or other animals." (Section 201(g)(1)).

DISCUSSION—Drug criteria: "A liquid, powder, tablet or other similar formulation that achieves its primary intended purpose through chemical action within or on the body, or by being metabolized." A drug may be used as a component of a TEMP. **F2312**

drug therapy, *n*—is the delivery of drug(s) that stimulate a specific physiologic (metabolic) response. Drug therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

electrolyte, *n*—diluent, offering slight conductivity, in which cells are suspended. **F2312**

encapsulation, *n*—procedure by which biological materials, such as cells, tissues, or proteins, are enclosed within a microscopic or macroscopic semipermeable barrier. **F2312**

engraftment, *n*—incorporation of grafted tissue into the body of the host. **Dorland's, F2311, F2312**

endotoxin, *n*—high molecular weight lipopolysaccharide (LPS) complex associated with the cell wall of gram-negative bacteria that is pyrogenic in humans. Though endotoxins are pyrogens, not all pyrogens are endotoxins. **F2312**

epidermal autograft, *n*—autograft consisting primarily of epidermal tissue, including keratinocyte stem cells, but with little dermal tissue. **F2312**

extracellular matrix, *n*—"(ECM), any material produced by cells and excreted to the extracellular space within the tissues. It takes the form of both ground substance and fibers and is composed chiefly of fibrous elements, proteins involved in cell adhesion, and glycosaminoglycans and other space-filling molecules. It serves as a scaffolding holding tissues together and its form and composition help determine tissue characteristics." Extracellular matrix, a biological material or tissue derivative, may be used as a component of a TEMP. **F2312**

femtolitre, *n*—cubic micron; a measurement of cell volume. **F2312**

full thickness skin autograft, *n*—skin [auto]graft consisting of the epidermis and the full thickness of the dermis. **Dorland's, F2311, F2312**

full-thickness skin wound, *n*—skin wound with the loss of epidermis, and all of the dermis or at least the depth of dermis that includes most or all sources of epidermal cells from epidermal adnexae (glands and follicles). **F2311, F2312**

GDF, *n*—growth and differentiation factor. **F2312**

gel, *n*—three-dimensional network structure arising from intermolecular polymer chain interactions.

DISCUSSION—Such chain interactions may be covalent, ionic, hydrogen bond, or hydrophobic in nature. See also Terminology F1251. **F2312**

gene therapy, *n*—"is a medical intervention based on modification of the genetic material of living cells. Cells may be modified *ex vivo* for subsequent administration or may be altered *in vivo* by gene therapy products given directly to the subject. When the genetic manipulation is performed *ex vivo* on cells that are then administered to the patient, this is also a type of somatic cell therapy. The genetic manipulation may be intended to prevent, treat, cure, diagnose, or mitigate disease or injuries in humans." Gene therapy technologies can be applied in tissue engineering to generate TEMPs. **F2312**

gene therapy products, *n*—"are defined for the purpose of this statement as products containing genetic material administered to modify or manipulate the expression of genetic material or to alter the biological properties of living cells." **F2312**

genetically modified, *vt*—referring to cells, tissues, and organs of any origin that have an altered or modified genetic content. **F2312**

genetic material, *n*—is nucleic acid (either deoxyribonucleic acid or ribonucleic acid).

DISCUSSION—Genetic material is also known as DNA, RNA, genetic element, gene, factor, allele, operon, structural gene, regulator gene, operator gene, gene complement, genome, genetic code, codon, anticodon, messenger RNA (mRNA), transfer RNA (tRNA), ribosomal

extrachromosomal genetic element, plasmagene, plasmid, transposon, gene mutation, gene sequence, exon, intron (modified version).12 Genetic material may be used as a component of a TEMP. **F2312**

graft, *n*—any tissue or organ for implantation or transplantation. **Dorland's, F2311, F2312**

graft take, *n*—engraftment. **F2311, F2312**

granulations, *n*—granulation tissue. **F2311, F2312**

granulation tissue, *n*—newly formed vascular tissue normally produced in the healing of wounds of soft tissue and ultimately forming the cicatrix [scar]; it consists of small, translucent, red, nodular masses or granulations that have a velvety appearance. **Dorland's, F2311, F2312**

heal, *v*—to restore wounded parts or to make healthy. **Dorland's, F2311, F2312**

healing, *n*—restoration of integrity to injured tissue. **Dorland's, F2311, F2312**

DISCUSSION—In the surgical wound closure, an important distinction is made according to whether the surgeon expects the healing to be accomplished by granulation tissue. This distinction is made because in the normal physiology of wound healing, granulation tissue matures into scar with wound contracture, which is an undesirable outcome. Wound closure "by approximating the wound edges or performing a skin autograft" is called "healing by first intention," and wound closure by "allowing spontaneous healing from the edges" is called "healing by second intention."

healing by first intention, *n*—healing in which union or restoration of continuity occurs directly without intervention of granulations. **Dorland's, F2311, F2312**

healing by second intention, *n*—union by closure of a wound with granulations which form from the base and both sides toward the surface of the wound. **Dorland's, F2311, F2312**

hydrocolloid, *n*—water-soluble polymer of colloidal nature when hydrated. **F2312**

immobilization, *n*—entrapment of materials, such as cells, tissues, or proteins within, or bound to, a matrix. **F2312**

implantation, *n*—procedure of inserting materials such as a cell(s), tissue(s), or organ(s) for therapeutic purposes. Synonym: *graft* or *grafting*. TEMPs may be applied to a recipient by implantation or grafting. **F2312**

in-process control, *n*—monitoring and, if necessary, adjustments performed to ensure that the process conforms to its specification. The control of the environment or equipment may be part of in-process control. **F2312**

lesion, *n*—any pathological or traumatic discontinuity of tissue or loss of function of a part. In this guide, "skin lesion" is intended to encompass skin wounds and skin ulcers. **F2311, F2312**

maintenance therapy, *n*—therapy of chronically ill patients that is aimed at keeping the pathology at its present level and preventing exacerbation. **F2311, F2312**

manufacture, *v*—"any or all steps in the recovery, screening, testing, processing, storage, labeling, packaging or distribution of any human cellular or tissue-based product."

DISCUSSION—For TEMPs, manufacture is expanded to include production of products *in vitro* or *in vivo*. TEMPs may also include the use of non-human cellular or tissue-based materials in any manufacturing steps. **F2312**

micron (μ), *n*—0.001 mm, also known as a micrometre; measurement of cell diameter. **F2312**

microorganism, *n*—bacteria, fungi, yeast, mold, viruses, and other infectious agents. However, it should be noted that not all microorganisms are infectious or pathogenic. **F2312**

natural materials, *n*—synthesized or produced by living cells. **F2312**

open wound, *n*—wound that communicates with the atmosphere by direct exposure. **Dorland's, F2311, F2312**

partial thickness skin wound, *n*—skin wound with the loss of the epidermis and part of the dermis, but retaining a layer of viable dermal tissue that includes the sources of epidermal cells from which the wound can heal spontaneously by epidermal tissue regeneration. **F2311, F2312**

pores, *n*—inherent or induced network of channels and open spaces within an otherwise solid structure. **F2312**

porometry, *n*—determination of the distribution of pore diameters relative to direction of fluid flow by the displacement of a wetting liquid as a function of pressure. **F2312**

porosimetry, *n*—determination of pore volume and pore size distribution through the use of a nonwetting liquid (typically mercury) intrusion into a porous material as a function of pressure. **F2312**

porosity, *n*—property of a solid which contains an inherent or induced network of channels and open spaces.

DISCUSSION—Porosity can be measured by the ratio of pore (void) volume to the apparent (total) volume of a porous material and is commonly expressed as a percentage. **F2312**

primary healing, *n*—healing by first intention. **F2312**

primary wound closure, *n*—wound closure for healing by first intention. **F2312**

processed biologics, *n*—cells, tissues, or organs that have undergone manipulation for use in the manufacture of TEMPs; processing here extends beyond the minimal manipulation or processing as it is applied in the field of structural, reproductive and metabolic tissue transplantation.14 A processed biologic may be used as a component of a TEMP. **F2312**

processing, *vt*—any activity performed on cells, tissues, and organs other than recovery, such as preparation and preservation for storage and packaging. **F2312**

processing materials, *n*—any item or material that is not a component of the TEMP and is in contact with the cells, tissues, and organs during processing. **F2312**

pyrogen, *n*—any substance that produces fever. F2312

raw count, *n*—enumeration of the cell population not corrected for coincidence. F2312

recipient, *n*—individual or organism into whom materials are grafted or implanted. F2312

recovery, *n*—obtaining of cells or tissues which may be used for the production of TEMPs. F2312

regenerative biology, *n*—scientific discipline that endeavors to understand how tissues and organs are replaced naturally. The principles of regenerative biology can be applied in tissue engineering to generate TEMPs. F2312

regenerative medicine, *n*—branch of medical science that applies the principles of regenerative biology to specifically restore or recreate the structure and function of human cells, tissues, and organs that do not adequately regenerate. F2312

reparative medicine, *n*—branch of medical science whereby clinicians use surgical methods to repair or modify the structure and function of patient's cells, tissues, or organs. The principles of reparative medicine can be applied in tissue engineering to generate TEMPs. F2312

reprocessing, *vt*—reworking of cells, tissues, and organs of unacceptable quality from a defined stage of processing, so that the quality may be rendered acceptable by one or more additional operations. F2312

rhBMP, *n*—recombinant human bone morphogenetic protein. F2312

ruggedness, *n*—degree of reproducibility of the same sample under a variety of normal conditions; for example, different operators. F2312

scaffold, *n*—support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues. F2312

scar, *n*—fibrous tissue replacing normal tissues destroyed by injury or disease. **Stedman's, F2311,** F2312

secondary healing, *n*—healing by second intention. F2312

secondary wound closure, *n*—wound closure for healing by second intention. F2312

size thresholds, *n*—instrument's lower and upper size settings for the particular cell population; adjustable "size gate." Cells or fragments outside the size settings are excluded from the analyses. F2312

skin, *n*—outer integument or covering of the body, consisting of the dermis and the epidermis, and resting upon the subcutaneous tissues. **Dorland's, F2311,** F2312

skin allograft therapy, *n*—treatment of skin wound or skin ulcer by the temporary topical application of skin allograft(s). **F2311,** F2312

skin replacement surgery, *n*—surgery that permanently replaces lost skin with healthy skin. **F2311,** F2312

skin substitute, *n*—biomaterial, engineered tissue, or combination of biomaterials and cells or tissues that can be substituted for a skin allograft, a skin autograft, an epidermal autograft, or a dermal autograft in a clinical procedure. **F2311,** F2312

solubility, *n*—measure of the extent to which the material can be dissolved.

DISCUSSION—In the context of collagen, refers to the dissociation of the fibrillar aggregates of collagen molecules into a solution. Native Type I collagen which is soluble in dilute acids, but not soluble in neutral pH conditions is termed "insoluble" or "acid soluble" while simple aggregates of non-fibrillar collagen soluble in neutral salt solutions are termed "neutral salt soluble." Post translational surface charge modifications may alter the solubility of collagen in neutral pH condition. F2312

somatic cell, *n*—is any cell other than a germ or stem cell. Somatic cells may be used as a component of a TEMP. F2312

somatic cell therapy, *n*—"is the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries in humans by the administration of autologous, allogeneic, or xenogeneic cells that have been manipulated or altered *ex vivo*. Manufacture of products for somatic cell therapy involves the *ex vivo* propagation, expansion, selection, or pharmacologic treatment of cells, or other alteration of their biological characteristics." For the purposes of TEMPs somatic cell therapy technologies can be applied in tissue engineering to generate TEMPs, for human and non-human use. F2312

somatic cell therapy products, *n*—"are defined as autologous (that is, self), allogeneic (that is, intra-species), or xenogeneic (that is, inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics *ex vivo* to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries." Somatic cell therapy products may be used as a component of a TEMP. F2312

split thickness skin autograft, *n*—skin [auto]graft consisting of the epidermis and a portion of dermis. **Dorland's, F2311,** F2312

stem cells, *n*—progenitor cells capable of self-replication, proliferation, and differentiation. F2312

sterilization, *n*—destruction or removal of all microorganisms in or about an object, as by, chemical agents, electron beam, gamma irradiation, ultraviolet (UV) exposure, or filtration. F2312

substrates, *n*—raw or virgin materials that will ultimately be used in tissue-engineered medical products for growth, support, or delivery of cells or biomolecules. F2312

suspension, *n*—dispersion of a solid through a liquid with a particle size large enough to be detected by purely optical means. F2312

syngeneic, *n*—cells, tissues, and organs in which the donor has an unreactive genotype with the recipient. Synonyms: *syngraft*, *isograft*, *isogeneic*, or *isogenic*. F2312

tissue, *n*—aggregation of similarly specialized cells united in the performance of a particular function. **Dorland's, F2311, F2312**

tissue engineered medical product (TEMP), *n*—medical product that repairs, modifies or regenerates the recipient's cells, tissues, and organs or their structure and function, or both.

DISCUSSION—TEMPs derive their therapeutic potential from various components used alone or used in various combinations. Components may be biological products (that is, cells, organs, tissues, derivatives, and processed biologics), biomaterials (that is, substrates and scaffolds), biomolecules, devices, and drugs. TEMPs may be used *in vivo*, *ex vivo*, or *in vitro* for treatment of disease and injuries and for elective surgery or for diagnostic means. TEMPs are unique from conventional organ transplants in that they exclude biologics used for immediate transplantation or immediate preservation for later transplantation. **F2312**

tissue engineered medical products (TEMPs), *n*—medical products that repair, modify, or regenerate the recipients' cells, tissues, and organs, or their structure and function, or combination thereof. TEMPs may achieve a therapeutic potential from cells, biomolecules, scaffolds, and other materials, and processed tissues and derivatives used in various combinations or alone. TEMPs are unique from conventional organ transplants. TEMPs may be used *in vivo* or *in vitro* for disease, injury, elective surgery, and as a diagnostic. **F2211**

tissue engineering, *n*—application, *in vivo* and *in vitro*, of scientific principles and technologies to form tissue engineered medical products (TEMPs) used for medical treatments and as diagnostics. The various technologies and principles are common practices and methods in engineering and biomedical sciences such as cell, gene, or drug therapy, embryology or other forms of developmental biology, surgical methods and technologies used to create traditional devices and biologics. Tissue engineering could be applied to create products for non-human use as well. **F2211**

tissue engineering, *vivon*, *n*—application, *in vivo* and *in vitro* of scientific principles and technologies to form tissue engineered medical products (TEMPs) used for medical treatments and diagnoses as diagnostics.

DISCUSSION—The various principles technologies and principles are common practices and methods in engineering and biomedical sciences such as cell, gene, or drug therapy, embryology or other forms of developmental and biology, surgical reparative methods and technologies can used to create traditional devices and biologics. Tissue engineering could be applied to create products for non-human use as well. **F2312**

tissue regeneration, *n*—healing in which lost tissue is replaced by proliferation of cells, which reconstruct the normal architecture. **medweb, F2311, F2312**

tissue repair, *n*—healing in which lost tissue is replaced by a fibrous scar, which is produced from granulation tissue. **medweb, F2311, F2312**

transplantation, *n*—for therapeutic purposes, the process of implanting in one part, cells, tissue(s), or organ(s) taken from another part or from another individual.

DISCUSSION—Transplantation in this sense is regulated by the U.S. Food and Drug Administration (FDA) under 21 CFR Parts 16 and 1270 and 21 CFR Parts 207, 807, and 1271. **F2312**

ulcer, *n*—local defect, or excavation of the surface of an organ or tissue, which is produced by the sloughing of inflammatory necrotic tissue. **Dorland's, F2311, F2312**

wound, *n*—injury or damage, usually restricted to those caused by physical means with disruption of the normal continuity of structures. Called also injury and trauma. **Dorland's, F2311, F2312**

wound closure, *n*—provision of an epithelial cover over a wound; it can be accomplished by approximating wound edges, performing a skin [auto]graft, or allowing spontaneous healing from the edges. **Churchill's, F2311, F2312**

wound contraction, *n*—shrinkage and spontaneous closure of open skin wounds. **Dorland's, F2311, F2312**

wound contracture, *n*—condition of fixed high resistance to passive stretch of muscle, skin or joints resulting from fibrosis and scarring of the skin or the tissues supporting the muscles or the joints, or both. (This definition is a modification of Dorland's definition of contracture, "a condition of fixed high resistance to passive stretch of muscle, resulting from fibrosis of the tissues supporting the muscles or the joints, or disorders of the muscle fibers," because that definition does not address fibrosis and scarring in skin. **F2311, F2312**

wound inflammation, *n*—localized protective response elicited by injury or destruction of tissues, which serves to destroy, dilute, or wall off (sequester) both the injurious agent and the injured tissue.

DISCUSSION—It is characterized in the acute form by the classical signs of pain (dolor), heat (calor) redness (rubor), swelling (tumor), and loss of function (functio laesa). Histologically, it involves a complex series of events, including dilation of arterioles, capillaries, and venules, with increased permeability and blood flow; exudation of fluids, including plasma proteins; and leukocytic migration into the inflammatory focus. **Dorland's, F2311, F2312**

xenogeneic or xenogenic, *n*—cells, tissues, and organs in which the donor and recipient belong to different species. Synonyms: *xenogenous*, *heterogeneic*, or *heterologous*. **F2312**

xenograft, *n*—graft of tissue transplanted between animals of different species. Called also heterograft, heterologous graft and heteroplastic graft. **Dorland's, F2311, F2312**

xenotransplantation, *n*—any procedure that involves the transplantation or infusion into a human recipient of either *(1)* live cells, tissues, or organs from a nonhuman animal source or *(2)* human body fluids, cells, tissues, or organs that have had *ex vivo* contact with live nonhuman cells, tissues, or organs. **F2312**

xenotransplantation, *n*—any procedure that involves the transplantation or infusion into a human recipient of either *(1)* live cells, tissues, or organs from a nonhuman animal source or *(2)* human body fluids, cells, tissues, or organs that

have had *ex vivo* contact with live nonhuman cells, tissues, or organs. **F2311**

xenotransplantation products, *n*—xeno-transplantation products include live cells, tissues or organs used in xenotransplantation. **F2311**

DISCUSSION—Xenografts and xenotransplantation products comprise overlapping but not congruent groups of skin substitutes. Autograft, allograft, and xenograft are traditional terms to describe tissue used in surgical procedures. Because autograft involves the harvesting of the patient's own tissue, care is taken to preserve its viability. However, allograft and xenograft are not necessarily alive and may have been frozen for storage. Skin substitutes may combine attributes of autograft, allograft, xenograft, and xenotransplantation products, depending on the origin of cells or tissues used in their manufacture, and whether these components are alive or not. For example, a substitute for epidermal autograft composed of cultured autologous epidermal cells grown on a feeder layer of live non-human cells is a xenotransplantation product as well as an autograft substitute.

BIOMATERIALS AND BIOMOLECULES FOR TEMPs

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adventitious agents, *n*—unintentionally introduced microbiological or other infectious contaminant. In the production of TEMPs, these agents may be unintentionally introduced into the process stream or the final product, or both. **F2212**

alginate, *n*—polysaccharide obtained from some of the more common species of marine algae, consisting of an insoluble mix of calcium, magnesium, sodium, and potassium salts.

DISCUSSION—Alginate exists in brown algae as its most abundant polysaccharide, mainly occurring in the cell walls and intercellular spaces of brown seaweed and kelp. Alginate's main function is to contribute to the strength and flexibility of the seaweed plant. Alginate is classified as a hydrocolloid. The most commonly used alginate is sodium alginate. Sodium alginate and, in particular, calcium cross-linked alginate gels are used in Tissue Engineered Medical Products (TEMPs) as biomedical matrices, controlled drug delivery systems, and for immobilizing living cells. **F2259**

bioactive agents, *n*—any molecular component in, on, or within the interstices of a device that elicits a desired tissue or cell response. Growth factors, antibiotics, and antimicrobials are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included. **F2150**

bioactive agent, *n*—any molecular component in, on, or within the interstices of a device that is intended to elicit a desired tissue or cell response.

DISCUSSION—Growth factors and antibiotics are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included. **F2450**

blind (end)-pore, *n*—pore that is in contact with an exposed internal or external surface through a single orifice smaller than the pore's depth. **F2450**

chitosan, *n*—linear polysaccharide consisting of β(1→4) linked 2-acetamido-2-deoxy-D-glucopyranose (GlcNAc) and 2-amino-2-deoxy-D-glucopyranose (GlcN). **F2103**

DISCUSSION—Chitosan is a polysaccharide derived by N-deacetylation of chitin.

chitosan, *n*—linear polysaccharide consisting of β(1→4) linked 2-acetamido-2-deoxy-D-glucopyranose (GlcNAc) and 2-amino-2-deoxy-D-glucopyranose (GlcN). Chitosan is a polysaccharide derived by N-deacetylation of chitin. **F2260**

closed cell, *n*—void isolated within a solid, lacking any connectivity with an external surface. Synonym: *closed pore*. **F2450**

collagen, *n*—Type I collagen is a member of a family of structural proteins found in animals.

DISCUSSION—Type I collagen is part of the fibrillar group of collagens. It derives from the COL1A1 and COL1A2 genes, which express the alpha chains of the collagen. All collagens have a unique triple helical structure configuration of three polypeptide units known as alpha-chains. Proper alignment of the alpha chains of the collagen molecule requires a highly complex enzymatic and chemical interaction *in vivo*. As such, preparation of the collagen by alternate methods may result in improperly aligned alpha chains and, putatively, increase the immunogenicity of the collagen. Collagen is high in glycine, L-alanine, L-proline, and 4-hydroxyproline, low in sulfur, and contains no L-tryptophan. Natural, fibrillar Type I collagen is normally soluble in dilute acids and alkalis. When heated (for example, above approximately 40°C), collagen is denatured to single alpha chains (gelatin). At each end of the chains are short non-helical domains called telopeptides, which are removed in some collagen preparations. Through non-covalent interactions with sites on adjacent helixes, fibrillogenesis is achieved. Subsequently, non-reducible cross-links are formed. Type I collagen can be associated with Type III and Type V collagen and also with the other non-collagenous proteins like elastin and other structural molecules like glycosaminoglycans and complex lipoproteins and glycoproteins. **F2212, F2312**

decomposition, *n*—structural changes of chitosans as a result of exposure to environmental, chemical, or thermal factors, such as temperatures greater than 200°C. **F2103**

DISCUSSION—Decomposition can result in deleterious changes to the chitosan.

decomposition, *n*—structural changes of hyaluronan due to exposure to environmental, chemical, or thermal factors. Decomposition may occur at temperatures as low as 121°C during autoclaving. Decomposition can result in deleterious changes to the hyaluronan. **F2347**

degradation, *n*—change in chemical, physical, or molecular structure or appearance (that is, gross morphology) of material. **F2212**

degradation, *n*—change in the chemical structure, physical properties, or appearance of a material. **F2103**

DISCUSSION—Degradation of polysaccharides occurs by means of cleavage of the glycosidic bonds, usually by acid —catalyzed hydrolysis. Degradation can also occur thermally. Note that degradation is not synonymous with decomposition. Degradation is often used as a synonym for depolymerization when referring to polymers.

degradation, *n*—change in the chemical structure, physical properties, or appearance of a material. Degradation of polysaccharides occurs via cleavage of the glycosidic bonds. It is important to note that degradation is not synonymous with decomposition. Degradation is often used as a synonym for depolymerization when referring to polymers. **F2259, F2260**

degradation, *n*—change in the chemical structure, physical properties or appearance of a material. Degradation of polysaccharides occurs via cleavage of the glycosidic bonds, usually by acid catalyzed hydrolysis. Degradation can also occur thermally and by alkali. It is important to note that degradation is not synonymous with decomposition. Degradation is often used as a synonym for depolymerization when referring to polymers. Degradation (depolymerization) of hyaluronan may also occur enzymatically by the action of hyaluronidases. **F2347**

degree of deacetylation, *n*—fraction or percentage of glucosamine units (deacetylated monomers) in a chitosan polymer molecule. **F2103**

degree of deacetylation, *n*—fraction or percentage of glucosamine units (GlcN: deacetylated monomers) in a chitosan polymer molecule. **F2260, F2312**

depolymerization, *n*—reduction in the length of a polymer chain to form shorter polymeric units. **F2259, F2260**

depolymerization, *n*—reduction in length of a polymer chain to form shorter polymeric units. **F2103**

DISCUSSION—Depolymerization may reduce the polymer chain to oligomeric or monomeric units, or both. In chitosan, hydrolysis of the glycosidic bonds is the primary mechanism.

depolymerization, *n*—reduction in length of a polymer chain to form shorter polymeric units. Depolymerization may reduce the polymer chain to smaller molecular weight polymers, oligomeric, or monomeric units, or combination thereof. In hyaluronan, acid hydrolysis of the glycosidic bonds is the primary mechanism. **F2347**

endotoxin, *n*—high-molecular-weight lipopolysaccharide (LPS) complex associated with the cell wall of gram-negative bacteria that is pyrogenic in humans. **F2103, F2212**

DISCUSSION—Though endotoxins are pyrogens, not all pyrogens are endotoxins.

endotoxin, *n*—high molecular weight lipopolysaccharide (LPS) complex associated with the cell wall of gram-negative bacteria that is pyrogenic in humans. Though endotoxins are pyrogens, not all pyrogens are endotoxins. **F2347**

hyaluronan, *n*—polysaccharide with a disaccharide repeating unit composed of D-glucuronic acid and *N*-acetyl-D-glucosamine in β-(1→3) linkage. Each disaccharide unit is attached to the next by β-(1→4) bonds. Hyaluronan is a linear polymer. Other common names are hyaluronic acid and sodium hyaluronate. **F2347**

hydrocolloid, *n*—water-soluble polymer of colloidal nature when hydrated. **F2312, F2347**

hydrogel, *n*—water-based open network of polymer chains that are cross-linked either chemically or through crystalline junctions or by specific ionic interactions. **F2450**

microorganisms, *n*—bacteria, fungi, yeast, mold, viruses, and other infectious agents. **F2212**

DISCUSSION—Not all microorganisms are infectious or pathogenic.

molecular mass average (molecular weight average), *n*—the given molecular weight (Mw) of a chitosan will always represent an average of all of the molecules in the population. The most common ways to express the Mw are as the number average ($\bar{M}_n$) and the weight average ($\bar{M}_w$). The two averages are defined by the following equations:

$$\bar{M}_n = \frac{\sum_i N_i M_i}{\sum_i N_i}$$

and

$$\bar{M}_w = \frac{\sum_i W_i M_i}{\sum_i W_i} = \frac{\sum_i N_i M_i^2}{\sum_i N_i M_i}$$

where:

N_i = number of molecules having a specific molecular weight M_i and

w_i = weight of molecules having a specific molecular weight M_i. In a polydisperse molecular population the relation $\bar{M}_w > \bar{M}_n$ is always valid. The coefficient $\bar{M}_w/\bar{M}_n$ is referred to as the polydispersity index, and will typically be in the range 1.5 to 3.0 for commercial chitosans.

natural materials, *n*—synthesized or produced by living cells. **F2027**

non-animal derived, *n*—term describing the absence of any animal-derived tissue, proteins, or products in the manufacturing process. **F2347**

permeability, *n*—measure of fluid, particle, or gas flow through an open pore structure. **F2450**

polymer, *n*—long chain molecule composed of monomers including both natural and synthetic materials, for example, collagen, polycaprolactone. **F2450**

pore, *n*—liquid (fluid or gas) filled externally connecting channel, void, or open space within an otherwise solid or gelatinous material (for example, textile meshes composed of many or single fibers (textile based scaffolds), open cell foams, (hydrogels). Synonyms: *open-pore*, *through-pore*. **F2450**

pores, *n*—inherent or induced network of channels and open spaces within an otherwise solid structure. **F2150**

porogen, *n*—material used to create pores within an inherently solid material. **F2450**

DISCUSSION—For example, a polymer dissolved in an organic solvent is poured over a water-soluble powder. After evaporation of the solvent, the porogen is leached out, usually by water, to leave a porous structure. The percentage of porogen needs to be high enough to ensure that all the pores are interconnected.

porometry, *n*—determination of the distribution of open pore diameters relative to the direction of fluid flow by the displacement of a nonvolatile wetting fluid as a function of pressure. **F2450**

porometry, *n*—determination of the distribution of pore diameters relative to direction of fluid flow by the displacement of a wetting liquid as a function of pressure. **F2150**

porosimetry, *n*—determination of pore volume and pore size distribution through the use of a nonwetting liquid (typically mercury) intrusion into a porous material as a function of pressure. **F2150, F2450**

porosity, *n*—property of a solid which contains an inherent or induced network of channels and open spaces. Porosity can be measured by the ratio of pore (void) volume to the apparent (total) volume of a porous material and is commonly expressed as a percentage. **F2150, F2450**

pyrogen, *n*—any substance that produces fever when administered parenterally. **F2103, F2347**

scaffold, *n*—support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues. **F2450**

solubility, *n*—measure of the extent to which the material can be dissolved. **F2212**

DISCUSSION—In the context of collagen, refers to the dissociation of the fibrillar aggregates of collagen molecules into a solution. Native Type I collagen which is soluble in dilute acids, but not soluble in neutral pH conditions is termed "insoluble" or "acid-soluble," while simple aggregates of non-fibrillar collagen soluble in neutral salt solutions are termed "neutral salt-soluble." Post translational surface charge modifications may alter the solubility of collagen in neutral pH condition.

sterilization, *n*—destruction or removal of all microorganisms in or about an object. **F2212**

DISCUSSION—Examples are by chemical agents, electron beam, gamma irradiation, ultraviolet (UV) exposure, or filtration.

substrates, *n*—raw or virgin materials that will ultimately be used in tissue-engineered medical products for growth, support, or delivery of cells or biomolecules. **F2027**

suspension, *n*—dispersion of a solid through a liquid with a particle size large enough to be detected by purely optical means. **F2212**

through-pores, *n*—inherent or induced network of voids or channels that permit flow of fluid (liquid or gas) from one side of the structure to the other. **F2450**

tortuosity, *n*—measure of the mean free path length of through-pores relative to the sample thickness. Alternative definition: The squared ratio of the mean free path to the minimum possible path length. **F2450**

CELLS AND TISSUE ENGINEERED CONSTRUCTS FOR TEMPs

X1.18 F04.43 Cells and Tissue Engineered Constructs for TEMPs

adhesion, *n*—physiochemical state by which a cell is coupled to a non-cell surface by interfacial forces, which may consist of covalent or ionic forces. **F2664**

alginate, *n*—polysaccharide obtained from some of the more common species of marine algae, consisting of an insoluble mix of calcium, magnesium, sodium, and potassium salts.

DISCUSSION—Alginate exists in brown algae as its most abundant polysaccharide, mainly occurring in the cell walls and intercellular spaces of brown seaweed and kelp. Alginate's main function is to contribute to the strength and flexibility of the seaweed plant. Alginate is classified as a hydrocolloid. The most commonly used alginate is sodium alginate. Sodium alginate and, in particular, calcium cross-linked alginate gels are used in Tissue Engineered Medical Products (TEMPs) as biomedical matrices, controlled drug delivery systems, and for immobilizing living cells. **F2315**

APA bead, *n*—alginate-poly-L-lysine-alginate bead. **F2315**

biomarker, *n*—biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment. **F2664**

biomaterial, *n*—any substance (other than a drug), synthetic or natural, that can be used as a system or part of a system that treats, augments, or replaces any tissue, organ, or function of the body. **F2312, F2664**

channelyzer, *n*—pulse height analyzer; places voltage pulses into appropriate size bins for the size distribution data. **F2149**

coincidence, *n*—more than one cell transversing the aperture at the same time. **F2149**

cooling rate, *n*—absolute value of the instantaneous rate of change of temperature during cooling. **F2386**

corrected count, *n*—cell count corrected for coincidence. **F2149**

cryopreservation solution, *n*—preservation medium to which has been added one or more cryoprotectants. **F2386**

cryoprotectant, *n*—chemical or biological substance or mixture of substances used to protect cells or matrix, or both, during cryopreservation and rewarming. In general usage, a cryoprotectant is added to a preservation medium to form a cryopreservation solution. **F2386**

cytocrit, *n*—ratio of cell volume to the total volume of solution and cells for a cell suspension. **F2386**

detachment, *n*—process whereby an adhered cell or group of cells is actively detached from a surface. **F2664**

dry shipper, *n*—storage and transportation device for frozen products that contains a liquid nitrogen (LN) absorbent material in the walls of the container. This device is designed to maintain cryogenic temperature for several days. **F2386**

electrolyte, *n*—diluent, offering slight conductivity, in which cells are suspended. **F2149**

encapsulation, *n*—procedure by which biological materials, such as cells, tissues, or proteins, are enclosed within a microscopic or macroscopic semipermeable barrier. **F2315**

endotoxin, *n*—pyrogenic lipopolysaccharides derived from bacterial cell walls, usually associated with membrane protein unless purified. Though endotoxins are pyrogens, not all pyrogens are endotoxins. **F2315**

equilibrium freezing temperature, *n*—temperature at which an aqueous solution of a given composition is in equilibrium with ice. **F2386**

eutectic point, *n*—temperature(s) at which the solute(s) in a solution become saturated due to freeze-concentration and precipitate from the solution, causing the unfrozen liquid water to simultaneously freeze. **F2386**

femtolitre, *n*—cubic micron; a measurement of cell volume. **F2149**

gel, *n*—three-dimensional network structure arising from intermolecular polymer chain interactions. Such chain interactions may be covalent, ionic, hydrogen bond, or hydrophobic in nature. See also Terminology F1251. **F2315**

glass transition temperature, *n*—temperature at which the heat capacity associated with translational molecular motions vanishes during cooling or appears during warming. The glass transition temperature is the formal transition point between the glassy state and the liquid state. **F2386**

hydrophilic, *adj*—having a strong affinity for water, wettable. **F22, F2664**

immobilization, *n*—entrapment of materials, such as cells, tissues, or proteins within, or bound to, a matrix. **F2315**

implant, *n*—substance or object that is put in the body as a prosthesis, or for treatment or diagnosis. **F2664**

laminar flow, *n*—well-ordered, patterned flow of fluid layers assumed to slide over one another. **F2664**

lay, *n*—direction of the predominant surface pattern. **ISO 13565-1, F2664**

micron (μ), *n*—0.001 mm, also known as a micrometre; measurement of cell diameter. **F2149**

nucleation, *n*—formation of ice from a supercooled aqueous solution by random aggregation of water molecules into clusters with ice-like properties. Nucleation may be homogenous (spontaneous) or heterogenous (catalyzed by a substrate that reduces the thermodynamic barrier to cluster formation). **F2386**

passage, *n*—transfer or transplantation of cells, with or without dilution, from one culture vessel to another. It is understood that any time cells are transferred from one vessel to another, a certain portion of the cells may be lost and, therefore, dilution of cells, whether deliberate or not, may occur. This term is synonymous with the term *subculture*. **F2664**

passage number, *n*—number of times the cells in the culture have been subcultured or passaged. In descriptions of this process, the ratio or dilution of the cells should be stated so that the relative cultural age can be ascertained. **F2664**

post-preservation processing, *v*—manipulation of cells or tissue after completion of the preservation process. These steps include, but are not limited to, washing of the cells or tissue to remove the preservation medium/solution and/or specific chemical or biological agents; dilution or concentration of the cells or tissue; and warming to temperatures appropriate for the normal or desired physiological or biochemical functions, or both, of the cells or tissue. **F2386**

pre-preservation processing, *n*—manipulation of cells or tissue prior to the initiation of preservation. These steps include, but are not limited to, selection of specific cell populations for freezing, centrifugation to modify cell density, introduction of specific chemical or biological agents, and cooling. **F2386**

preservation medium, *n*—specific formulation of an aqueous or nonaqueous solution in which a population of cells or a tissue will be preserved. **F2386**

preservation technologies:— F2386

anhydrobiotic preservation, n—preservation by vaporization and removal of water.

(1) desiccation, n—process for anhydrobiotic preservation in which water is removed by evaporation.

(2) freeze-drying, n—process for anhydrobiotic preservation in which ice crystals are formed by freezing, and water is removed by sublimation and evaporation.

(3) lyophilization, n—in common usage, a synonym for freeze-drying. Whereas etymologically, this term also comprises other methods for anhydrobiotic preservation, care should be taken to avoid ambiguity.

cryopreservation, n—preservation by cooling to a temperature below the equilibrium freezing temperature of the preservation solution, such that there is solidification. The resulting solid may be either crystalline or amorphous, or a combination of crystalline and amorphous phases.

(1) freezing, v—cryopreservation by formation of crystals. Frozen cell suspensions or TEMPs typically contain both crystalline and amorphous water.

(2) vitrification, n—cryopreservation by formation of glass. Vitrified cell suspensions or TEMPs may contain small amounts of crystalline water.

hypothermic preservation, n—preservation by cooling to any temperature below normothermic culture temperatures, such that biological components are suspended in a liquid phase. Hypothermic storage temperatures may be either above or below the equilibrium freezing temperature.

preserve, *v*—to stabilize for the purposes of maintaining the specific mechanical, structural, metabolic, or biological characteristics. **F2386**

pyrogen, *n*—any substance that produces fever. **F2315**

raw count, *n*—enumeration of the cell population not corrected for coincidence. **F2149**

reconstitute, *v*—to add a solvent or diluent to an anhydrobiotically preserved sample in order to dissolve or suspend its components. **F2386**

rewarm, *v*—to warm from preservation temperature to a temperature required for use (for example, additional culture or clinical use). **F2386**

Reynolds number, *n*—dimensionless number expressing the ratio of inertia forces to viscous forces in a moving fluid. The

number is given by VLr/m where V, is the fluid's velocity, L is a characteristic length or distance such as pipe diameter, r is the fluid's mass density, and m is the fluid's dynamic viscosity. **F4410, F2664**

ruggedness, *n*—degree of reproducibility of the same sample under a variety of normal conditions; for example, different operators. **F2149**

scaffold, *n*—support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues. **F2312, F2664**

seeding, *v*—deliberate initiation of ice crystal formation in a supercooled aqueous solution under controlled conditions. When ice forms either spontaneously or as a result of the inclusion of nucleating agents in the cryopreservation solution, this is referred to as nucleation. **F2386**

senescence, *n*—*in vertebrate cell cultures*, the property attributable to finite cell cultures; namely, their inability to grow beyond a finite number of population doublings. Neither invertebrate nor plant cell cultures exhibit this property. This term is synonymous with *in vitro senescence*. **F2664**

shear stress, *n*—components of stress that act parallel to the plane of the surface. **F2664**

size thresholds, *n*—instrument's lower and upper size settings for the particular cell population; adjustable "size gate." Cells or fragments outside the size settings are excluded from the analyses. **F2149**

storage temperature, *n*—temperature at which the cells, tissue, or TEMP is held after completion of the cooling process. **F2386**

supercool, *v*—to cool to a temperature below the equilibrium melting point of the solution without initiating ice formation. **F2386**

surface profile, *n*—surface profile formed by the intersection of a real surface by a specified plane. It is customary to select a plane that lies perpendicular to the direction of lay unless otherwise indicated. **ISO 13565-1 and ISO 4287, F2664**

tack, *n*—ability of an adhesive to form a bond to a surface after brief contact under light pressure. **F2664**

temperature profile, *n*—the time-temperature history of a sample during cooling or warming. **F2386**

thaw, *v*—to warm from a cryopreserved state to a temperature above the melting point of the preservation medium. **F2386**

warming rate, *n*—instantaneous rate of change of temperature during warming. **F2386**

ASSESSMENT FOR TEMPs

X1.19 F04.44 Assessment for TEMPs

cartilage regeneration, *n*—formation of articular-like cartilage that has histologic, biochemical, and mechanical properties similar to that of native articular cartilage. **F2451**

cartilage repair, *n*—process of healing injured cartilage or its replacement through cell proliferation and synthesis of new extracellular matrix. **F2451**

compact bone, *n*—classification of ossified boney connective tissue characterized by the presence of osteons containing lamellar bone. **F2451**

femoral condyles, *n*—anatomic site corresponding to the distal end of the femur characterized by medial and lateral convex surfaces that are lined by cartilage and articulate with the proximal tibia and medial and lateral menisci. **F2451**

fibrocartilage, *n*—disorganized cartilagenous tissue having an abnormally high content of type I collagen. **F2451**

growth plate, *n*—anatomic location within the epiphyseal region of long bones corresponding to the site of growth of bone through endochondral bone formation. The growth plate in skeletally mature animals is fused. **F2451**

hyaline articular cartilage, *n*—cartilagenous connective tissue located in diarthrodial joints and characterized by its localization to articulating surfaces. **F2451**

marrow, *n*—also called *myeloid tissue*; soft, gelatinous tissue that fills the cavities of the bones. It is either red or yellow, depending upon the preponderance of vascular (red) or fatty (yellow) tissue. **F2451**

matrix, *n*—term applied to either the exogenous implanted scaffold or the endogenous extracelluar substance (otherwise known as extracellular matrix) derived from the host. **F2451**

patella, *n*—bone of the knee joint which articulates within the trochlear groove of the femur. **F2451**

residence time, *n*—time at which an implanted material (synthetic or natural) can no longer be detected in the host tissue. **F2451**

skeletal maturity, *n*—age at which the epiphyseal plates are fused. **F2451**

subchondral plate, *n*—margin of compact bone in direct apposition to the articular cartilage. **F2451**

synovial fluid, *n*—fluid secreted by synovium providing lubrication and nutrition to the joint surfaces. **F2451**

synovium, *n*—epithelial lining of synovial joint cavities that produce synovial fluid. **F2451**

tidemark, *n*—anatomic site in articular cartilage corresponding to the margin between cartilage and the underlying calcified cartilage. **F2451**

trabecular bone, *n*—classification of ossified boney connective tissue characterized by spicules surrounded by marrow space. **F2451**

trochlear groove, *n*—anatomic site on the distal end of the femur corresponding to the region of articulation with the patella. **F2451**

ADVENTITIOUS AGENTS SAFETY

X1.20 F04.45 Adventitious Agents Safety

adventitious agents, *n*—unintentionally introduced microbiological or other infectious contaminant. In the production of TEMPs, these agents may be unintentionally introduced into the manufacturing process or into the final product or both. (See Terminology F2312.) **F2383**

DISCUSSION—In this guide, adventitious agents also include microbiological or other infectious contaminants that may be endogenous to the starting cells or tissue.

endotoxin, *n*—high molecular weight lipopolysaccharide (LPS) complex associated with the cell wall of gram-negative bacteria that is pyrogenic in humans. Though endotoxins are pyrogens, not all pyrogens are endotoxins. (See Terminology F2312.) **F2383**

X2. HISTORY OF THE F04 TERMINOLOGY STANDARD

X2.1 Prior to May 2009, F04 maintained multiple terminology standards. Each standard was developed with the intent to separate terms by specialty area within the medical and surgical materials and devices community. As displayed in Section 3.1 on Historical ASTM Standards, this included documents for Hemostatic Forceps (F921), Surgical Scissors—Inserted and Non-Inserted Blades (F1078), Polymeric Biomaterials in Medical and Surgical Devices (F1251), Spinal Implants (F1582), Surgical Tissue/Dressing/Pick-Up Forceps (Thumb-Type) (F1638), Surgical Suture Needles (F1840), Nickel-Titanium Shape Memory Alloys (F2005), and Tissue Engineered Medical Products (F2312).

X2.2 It became evident that a singular, coordinated effort of the Committee regarding terminology was needed, as terms began to develop multiple definitions. In some cases, multiple definitions were warranted based on the variety of possible uses and applications of a term within different sectors and products of the community. In other cases, multiple definitions were developed where a single, standardized definition would have been appropriate. Both circumstances introduced confusion without a coordinated reference document of the Committee that mapped terminology use. Unwarranted duplication started to provide standardization problems.

X2.3 During 2009 and 2010, Terminology standards F921, F1078, F1251, F1582, F1638, F1840, F2005, and F2312 had their terms consolidated into this standard. In addition, each F04 technical standard was reviewed to ensure all terms defined within it was captured in this standard. Each term, and its definition, was traced to a source document (the originating terminology standard and any technical standard in which it is defined). Each of the multiple standard terminologies were then allowed to be either maintained or withdrawn at the discretion of the respective subcommittee.

X2.4 In 2009, to accompany the creation of this consolidated terminology standard, Committee F04 adopted a terminology policy. This policy is contained within the Committee Bylaws and is available to any interested party upon request. It states:

X2.4.1 That a subcommittee of the Committee shall be dedicated to the maintenance of this document and the Committee's terminology policy.

X2.4.1.1 Officers of the committee are members of this subcommittee, in addition to any interested parties.

X2.4.2 That at a minimum, this standard will be updated annually (at a time corresponding to the publication of the Annual Book of ASTM Standards containing this terminology standard) by the ASTM Editor for F04. This update will ensure that all terms defined in approved F04 technical standards are reflected in this standard. Any terms that need to be reflected herein may be editorially copied into it.

X2.4.3 That an objective of this document is to demonstrate where duplication in Committee terminology exists, and charges the subcommittee of jurisdiction over this standard to coordinate definitions.