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Standard Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices[1]

This standard is issued under the fixed designation F 1251; 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 covers polymeric biomaterials in medical and surgical devices. Terms are defined as they are used relative to medical and surgical materials and devices. Terms that are generally understood and in common usage or adequately defined in other readily available references are not included except where particular delineation to biomaterials may be more clearly stated.

1.2 This terminology is therefore intended to be selective of terms used generally in materials science and technology and published in a number of documents, such as those listed in the succeeding sections. The listing is also intended to define terms that appear prominently within other ASTM standards and do not appear elsewhere.

1.3 The definitions are substantially identical to those published in other ASTM standards on metals, ceramics and glass, rubbers and polymers, and so forth, or published by other standards writing organizations, such as International Standards Organization (ISO), American Institute of Mechanical Engineers (AIME), American Society of Plastic and Reconstructive Surgeons (ASPR), and Tissue Culture Association (TCA).

1.4 A need exists for this terminology to supplement current documents on terminology which concentrate on materials. This terminology covers each of the following disciplines: plastics (polymers), rubber (elastomers), and textiles (polymer derived).

1.5 An increasing number of product (polymeric, metallurgical, and ceramic types) designations and designations for chemical, physical, mechanical, and analytical tests and standards are coming into common usage in the literature and commerce of biomaterials in medical and surgical devices and clinical services. Section 2 lists those documents referenced in this terminology.

1.6 Table 1 lists abbreviated, anagramic designations. Annex A1 is a thesaurus of general usage terms relating to biomaterials.

2. Referenced Documents

2.1 *ASTM Standards:*

D 638 Test Method for Tensile Properties of Plastics[2]

D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam[2]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[2]

D 882 Test Methods for Tensile Properties of Thin Plastic Sheeting[2]

D 1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics[2]

SI 10 –02 American National Standard for Use of the International System of Units (SI): The Modern Metric System[3]

3. Terminology

3.1 *Definitions:*

acetal plastic, *n*—a plastic based on polymers having a predominance of acetal linkages in the main chain. (See also polyoxymethylene.) **D20**

acrylic plastic, *n*—a plastic based on polymers made with acrylic acid or a structural derivative of acrylic acid. **D20**

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. **D20**

aging, *n*—the process of exposing materials to an environment for an interval of time. **D20**

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

alkyd resin, *n*—a polyester convertible into a crosslinked form; requiring a reactant of functionality higher than two, or having double bonds. **D20**

apparent density—see **density, apparent.**

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

DISCUSSION—Exposure conditions may be cyclic, involving changes

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[2] *Annual Book of ASTM Standards,* Vol 08.01.

[3] Excerpts in Related Material sections of all other volumes.

TABLE 1 Abbreviated, Anagramic Designations—Acronyms[A,B]

Term	Classification	Descriptive Term in Full
AAS	analytic, chemical	atomic absorption spectroscopy
ABC	plastic, polymer	acryline bone cement
ABS	plastic, polymer	acrylonitrile-butadiene-styrene polymer
AN	polymer, monomer	acrylonitrile
ATR-IR	analytic, chemical	attenuated total reflectance—infrared
CA	plastic, polymer	cellulose acetate (sheet X ray)
CAB	plastic, polymer	cellulose acetate-butyrate
CP	plastic, polymer	cellulose propionate or cellulose acetate-propionate
DSC	analytic, physical	differential scanning calorimetry
DTA	analytic, physical	differential thermal analysis
EDTA	analyses	ethylene dinitrilo tetraacetic acid
EPM/EPDM	elastomer	ethylene-propylene terpolymer
EPR	elastomer	see EPM/EDPM above
ESCA	analytic, chemical	used for X-ray photoelectron spectroscopy
ETFE	analytic, chemical	(ethylene-tetrafluoroethylene-fluoroplastics)
FEP	plastics, polymers	perfluoro(ethylene-propylene) copolymer
GC	analytic, chemical	gas chromatography
HEMA	plastic, polymer	hydroxyethyl methacrylate (polymer)
HPLC	analytic, chemical	high performance liquid chromatography
IR	analytic, physical	infrared spectroscopy (for example, IR scan)
kPA	mechanical, physical	kiloPascal (unit of pressure—see Practice E 380, Appendix)
MPa	mechanical, physical	megaPascal (unit of pressure—see Practice E 380, Appendix)
MW (mw)	physical, molecular	molecular weight
MWD (mwd)	physical, molecular	molecular weight distribution (see mw, above)
MRI	clinical	magnetic resonance imaging (diagnostic application of nmr)
MRS	analytic, chemical	magnetic resonance spectroscopy (diagnostic application of nmr)
NBR	elastomer, polymer	nitrile-butadiene rubber
NMR (nmr)	analytic, physical	nuclear magnetic resonance
PB	elastomer, polymer	polybutylene
PC	plastic, polymer	polycarbonate
PCTFE	plastic, polymer	polychlorotrifluoroethylene
PDMS	elastomer, polymer fluid	silicone, polydimethyl siloxane
PE	plastic, polymer	polyethylene
PET	plastic, polymer	poly(ethylene terephthalate)
PFA	plastic, polymer	perfluoroalkoxy fluorocarbon polymer
PMMA	plastic, polymer	poly(methyl methacrylate)
PTFE	plastic, polymer	polytetrafluoroethylene
PU	plastic or elastomer polymer	polyurethane
PVA	plastic, polymer	poly(vinyl alcohol) (often poly(vinyl acetate))
PVAc	plastic, polymer	poly(vinyl acetate)
PVC	plastic, polymer	poly(vinyl chloride)
PVDC	plastic, polymer	poly(vinylidene chloride)
PVP	polymer	poly(vinyl pyttolidone)
RTV	elastomer, plastic	room temperature vulcanization
SAN	elastomer, polymer	styrene-acrylonitrile polymer
SB	elastomer, polymer	styrene-butadiene polymer
SEM	analytic, microscopy	scanning electron microscopy (cf TEM)
SR	elastomer, polymer	styrene rubber (elastomer)
TEM	analytic, microscopy	transmission electron microscopy (cf SEM)
TAR	device or prosthesis	total ankle replacement
TER	device or prosthesis	total elbow replacement
THR	device or prosthesis	total hip replacement
TJR	device or prosthesis	total joint replacement
TKR	device or prosthesis	total knee replacement
TSR	device or prosthesis	total shoulder replacement
TWR	device or prosthesis	total wrist replacement
UHMW	plastic, polymer	ultrahigh molecular weight polyethylene (stated polymer)
UMHWPE	plastic, polymer	ultrahigh molecular weight polyethylene (see UHMW)
UV	analytic, physical	ultraviolet light spectroscopy
VCM	polymer, monomer	vinyl chloride monomer content
XPS	analytic, chemical	X-ray photoelectric spectroscopy (also called ESCA)
XRD	analytic, physical	X-ray diffraction

[A] If a method or name is used for the first time in a text (paper, etc.), it must be presented in full with the abbreviation in brackets.
[B] If the text is long or consists of several chapters, the full name must be repeated in reasonable sequences, at least when first mentioned in a new chapter.

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. **D20**

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. **D20**

block copolymer, *n*—an essentially linear copolymer in which there are repeated sequences of polymeric segments of different chemical structure. **D20**

bloom, *n*—a visible exudation or efflorescence of a performance additive on the surface of a material. **D20**

bulk density—the 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.

bulk factor, *n*—the 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. **D20**
ISO

butylene plastic—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. **D20**

cast film, *n*—a 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. **D20**

cell, *n*—a small partially or completely enclosed cavity. **D20**

cell, closed—see **closed cell.**

cell, open—see **open cell.**

chemically foamed polymeric material, *n*—a cellular material in which the cells are formed by gases generated by thermal decomposition or other chemical reaction. **D20**

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

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

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

closed-cell foamed plastic, *n*—a plastic in which almost all the cells are noninterconnecting. **D20**

cold flow—see preferred term **creep.**

compression molding, *n*—a process for molding a material in a confined cavity by applying pressure and usually heat. **D20**

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

copolymer, *n*—a 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.** **D20**

copolymerization—see **polymerization** and **copolymer.**

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.

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

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. **ISO**

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

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

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

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

DISCUSSION—This term is commonly used synonymously with apparent density (1973). **D20**

elastomer, *n*—a 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. **D20**

epoxy plastic, *n*—a 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. **D20**

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

filler, *n*—a 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.**)

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

fluorocarbon plastic, *n*—a 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. **ISO**

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

fluoroplastic, *n*—a 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.**)

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.

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

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

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 D 1003, 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.

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.

laminate, *n*—a 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." **ISO**

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

laminate, parallel, *n*—a 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.

melamine plastic, *n*—plastic based on resins made by the condensation or melamine and aldehydes. **D20**

monomer, *n*—a relatively simple compound which can react to form a polymer. (See also **polymer.**) **D14, D20**

nylon plastic, *n*—a 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. **D20**

olefin plastic, *n*—a plastic based on polymers made by the polymerization of olefins or copolymerization of olefins with other monomers, the olefins being at least 50 mass %. **D11, D20, F17**

oligomer, *n*—a polymer consisting of only a few monomer units such as a dimer, trimer, tetramer, and so forth, or their mixtures.

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

organosol, *n*—a 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. **D20**

phenolic plastic, *n*—a plastic based on resins made by the condensation of phenols, such as phenol and cresol, with aldehydes. **D20**

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.

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*).

plasticizer, *n*—a substance incorporated into a material to increase its workability, flexibility, or distensibility of the material.

plastisol, *n*—a 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).

polybutylene, *n*—a polymer prepared by the polymerization of butene as the sole monomer. (See also **polybutylene plastic** and **butylene plastic.**)

polybutylene plastic, plastic based on polymers made with butene as essentially the sole monomer. **D20**

polycarbonate, *n*—a polymer in which the repeating structural unit in the chain is a carbonic acid ester of Bisphenol A. **D20**

polyester, *n*—a 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. **ISO**

polyether, *n*—a polymer in which the repeated structural unit in the chain is of the ether type. **D20**

polyethylene, *n*—a polymer prepared by the polymerization of ethylene as the sole monomer. (See also **polyethylene plastic** and **ethylene plastic.**)

polyethylene plastic—a 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.

polyethylene terephthalate, *n*—a polymer derived from terephthalic acid and ethylene glycol by condensation polymerization.

polymer, *n*—a 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.**) **IUPAC**

polymerization—a chemical reaction in which monomers are linked together to form polymers. (See also **polycondensation** and **polyaddition.**) **D20**

polyolefin, *n*—a polymer prepared by the polymerization of an olefin(s) as the sole monomer(s). (See also **polyolefin plastic, olefin plastic.**) **D20**

polyolefin plastic—a plastic based on polymers made with an olefin(s) as essentially the sole monomer(s).

polyoxymethylene, *n*—a 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. **ISO**

polypropylene, *n*—a polymer prepared by the polymerization of propylene as the sole monomer. (See also **polypropylene plastic, propylene plastic.**) **D20**

polystyrene, *n*—a polymer prepared by the polymerization of styrene as the sole monomer. (See also **styrene plastic.**) **D20**

polyterephthalate, *n*—a thermoplastic polyester in which the terephthalate group is a repeated structural unit in the polymer chain. **D20**

poly(vinyl acetate), *n*—a polymer prepared by the polymerization of vinyl acetate as the sole monomer. **D20, E12**

poly(vinyl alcohol), *n*—a polymer prepared by the essentially complete hydrolysis of polyvinyl ester. **D20**

poly(vinyl chloride), *n*—a polymer prepared by the polymerization of vinyl chloride as the sole monomer. **D20**

prepolymer, *n*—a polymer of degree of polymerization between that of the monomer or monomers and the final polymer. **ISO**

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

reinforced plastic, *n*—a 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.

reins, *n*—a 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. **D20**

rigid plastic—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 D 747, D 790, D 638, or D 882. **D20**

rubber, *n*—an 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*)

saran plastic—see **vinylidene chloride plastic.**

semirigid plastic—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 D 747, D 790, or D 882. **D20**

sheeting, *n*—a 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.**) **D20**

silicone elastomer, *n*—an elastomer containing cross-linked silicone polymer and fillers, usually silica. **D20**

silicone polymer, *n*—a polymer of alternating silicon-oxygen atoms consisting of repeating of diorganosiloxy groups. **D20**

stress-crack, *n*—an 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. **D20**

styrene plastic, *n*—a plastic based on polymers of styrene or copolymers of styrene with other monomers, the styrene being greatest amount by mass. **ISO, D20**

telomer, *n*—a 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. **D20, F17**

thermoplastic, *n*—a 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. **D20**

thermoset plastic, *n*—a plastic that, after having been cured by heat or other means, is substantially infusible and insoluble. **D20**

urethane plastic—a 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. **ISO, D20**

viscosity, *n*—the 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.**) **D20 ISO**

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. **ISO, D20**

ANNEX

(Mandatory Information)

A1. THESAURUS OF GENERAL USAGE TERMS PERTINENT TO BIOMATERIALS

A1.1 *Designated Term:*

additive (in formulation)
additive, adventitious
amorphous
biocompatible
biomaterial
biomechanical
biomedical
catalyst (in polymerization)
carcinogen
chromatography
collagen
compliance
conversion (non-metric to metric units)
cosmetic
crystalline
dalton
delivery system
drug release
elastic (in elasticity)
encapsulated
explant
extractive
etched (surfaces)
filled (in composition)
formulation
primary culture
rounding
serum
subculture
tissue culture