Designation: F2027 – 16

Standard Guide for Characterization and Testing of Raw or Starting Materials for Tissue-Engineered Medical Products[1]

This standard is issued under the fixed designation F2027; 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 document provides guidance on writing a materials specification for raw or starting materials intended for use in tissue engineering scaffolds for growth, support, or delivery of cells and/or biomolecules. This guide does not apply to materials that are already in a scaffold form or are finished tissue-engineered medical products.

1.2 The purpose of this guide is to provide a compendium of relevant existing standards and test methods for materials already commonly used within medical products and to provide characterization guidance for interim use of raw materials for which a standard does not exist.

1.3 This guide covers specifications and characterizations of all the major classes of materials including polymers, ceramics, metals, composites, and natural tissues of human, animal, or plant origin. This guide does not apply to pharmaceuticals.

1.4 This guide is focused on specification of chemical, physical, and mechanical properties of the raw or starting material. It does not include safety and biocompatibility requirements since safety and biocompatibility testing is typically done on materials fabricated into a final form to include all possible effects of fabrication and sterilization techniques.

1.5 Compliance with materials specifications developed in accordance with this standard may not necessarily result in a material suitable for its intended purpose. Additional testing specific to the intended use may be required.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1763 Specification for Epoxy Resins

D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]

E1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products (Withdrawn 2014)[3]

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)

F451 Specification for Acrylic Bone Cement

F560 Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)

F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F602 Criteria for Implantable Thermoset Epoxy Plastics

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application

F619 Practice for Extraction of Medical Plastics

F624 Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Biomedical Applications

F639 Specification for Polyethylene Plastics for Medical Applications

F641 Specification for Implantable Epoxy Electronic Encapsulants

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs.

Current edition approved Oct. 1, 2016. Published December 2016. Originally approved in 2000. Last previous edition approved in 2008 as F2027 – 08. DOI: 10.1520/F2027-16.

[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.

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
F665 Classification for Vinyl Chloride Plastics Used in Biomedical Application
F702 Specification for Polysulfone Resin for Medical Applications
F755 Specification for Selection of Porous Polyethylene for Use in Surgical Implants
F997 Specification for Polycarbonate Resin for Medical Applications
F1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation
F1185 Specification for Composition of Hydroxylapatite for Surgical Implants
F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]
F1377 Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)
F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
F1538 Specification for Glass and Glass Ceramic Biomaterials for Implantation
F1579 Specification for Polyaryletherketone (PAEK) Polymers for Surgical Implant Applications (Withdrawn 2011)[3]
F1581 Specification for Composition of Anorganic Bone for Surgical Implants
F1634 Practice for ***In-Vitro*** Environmental Conditioning of Polymer Matrix Composite Materials and Implant Devices
F1635 Test Method for ***in vitro*** Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants
F1713 Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130)
F1855 Specification for Polyoxymethylene (Acetal) for Medical Applications
F1873 Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications (Withdrawn 2007)[3]
F1876 Specification for Polyetherketoneetherketoneketone (PEKEKK) Resins for Surgical Implant Applications (Withdrawn 2012)[3]
F1877 Practice for Characterization of Particles
F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants
F2026 Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
F2064 Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications
F2103 Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications
F2150 Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products
F2212 Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)
F2259 Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (^{1}H NMR) Spectroscopy
F2260 Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance (^{1}H NMR) Spectroscopy
F2313 Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide
F2347 Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications
F2579 Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants
F2848 Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
F3160 Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants

2.2 *Other Document:*
U.S. Pharmacopeia, Edition XXX or current edition[4]
ISBT 128 The Global Information Standard for Medical Products of Human Origin[5]

2.3 *ISO and CEN Standards:*[6]
ISO 6474 Implants for Surgery—Ceramic Materials Based on Alumina
ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing
ISO 10993-9—Part 9: Framework for Identification and Quantification of Potential Degradation Products
ISO 10993-12—Part 12: Sample Preparation and Reference Materials
ISO 111607 Product Packaging
ISO/DIS 10993-13—Part 13: Identification and Quantification of Potential Degradation Products from Polymeric Medical Devices
ISO/DIS 10993-14—Part 14: Identification and Quantification of Potential Degradation Products from Ceramics
ISO/DIS 10993-15—Part 15: Identification and Quantification of Potential Degradation Products from Metals and Alloys

[4] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.
[5] Available from ICCBBA, P.O. Box 1309, San Bernadino, CA 92423-1309, http://iccba.org.
[6] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

ISO/DIS 10993-17—Part 17: Methods for the Establishment of Allowable Limits for Leachable Substances using Health-Based Risk Assessment
ISO/CD 10993-18—Part 18: Chemical Characterization of Materials
BSI BS EN 22442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices—Part 1: Analysis and Management of Risk
BSI BS EN 22442-2 Animal Tissures and Their Derivative Utilized in the Manufacture of Medical Devices—Part 2: Controls on Sourcing, Collection and Handling
BSI BS EN 22442-3 Animal Tissures and Their Derivative Utilized in the Manufacture of Medical Devices—Part 3: Validation of the Elimination and/or Inactivation of Virus and Transmissible Agents

2.4 *Food and Drug Administration Documents:*
Code of Federal Regulations, Title 21, Parts 610 (General Biological Products Standards), 820 (Quality system regulation), 1270 and 1271 (Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient) or other of Parts 1-1499 [7]
Additional FDA Guidance Documents[8]
Selected Guidance Documents Applicable to Combination Products[9]

3. Summary of Guide

3.1 Novel materials that do not yet have standards associated with them are being created for use in tissue-engineering applications. The lack of standardized specifications for the physical and chemical properties of these new materials may lead to variation between lots, which could create variation in observed biological performance of the final product. It is the intent of this guide to provide a compendium of existing medical product materials specifications and test methods to serve as a guide for specifying the important chemical and physical properties of new raw or starting materials. Tables of commonly specified chemical, physical, and mechanical requirements are provided for each type of material (for example, ceramic, metal, polymer, composite, natural product) to assist with the development of a specification for a new material to be utilized for tissue engineering.

3.2 This guide is focused on providing a characterization template for raw or starting materials prior to their fabrication into a scaffold or tissue-engineered medical product. Guidance for the characterization and testing of materials after they have been formulated into three-dimensional scaffolds can be found in Guide F2150.

4. Significance and Use

4.1 The physico-chemical characteristics of the raw or starting material used in regenerative medicine scaffolds carries significant potential to affect product performance by influencing cell behavior and/or the release of bioactive molecules or drugs. This guide describes recommended specifications or characterizations of raw or starting materials to ensure reproducibility prior to their fabrication into implantable tissue-engineering scaffolds and/or controlled release matrices.

5. Classification of Materials

5.1 The properties of tissue-engineering scaffolds or cell delivery vehicles are, in part, a function of the type of material from which they are made. All materials can be classified according to their atomic content and bonding as either a ceramic, polymer, metal, or composite. Ceramics consist of ionically or covalently bonded metallic and non-metallic elements such as calcium phosphate or aluminum phosphate and include minerals and glasses, sintered or unsintered. Polymers consist of a repeating backbone structure. Metals are made of metallic elements bonded together by metallic bonds. Composites are blends of any of the three main types of materials. Even materials derived from natural sources such as anorganic bone or chitosan fall into one of these basic types; anorganic bone is a ceramic and chitosan is a polymer.

5.2 To use this guide, first classify the material into one of the basic material types listed in 5.1. Important properties that should be specified are listed and tabulated according to material type in Table 1 and Table 2. ISO 10993-18 also provides a framework for the identification of a material and the identification and quantification of its chemical constituents.

6. Chemical Requirements

6.1 *Chemical Requirements for Ceramics*—The raw or starting material shall have specifications for relevant chemical properties such as, but not limited to, those listed within Table 1, Col. 1. This includes, for ceramics: chemical formula or composition, requirements for the major and minor elemental constituents, phase content, and processing aids.

6.2 *Chemical Requirements for Metals*—The raw or starting material shall have specifications for relevant chemical properties such as, but not limited to, those listed within Table 1, Col. 2. The composition, trace elements analysis, phase content, and any surface modification (for example, pickled, ground, polished, acid-etched) should be specified quantitatively. Corrosion susceptibility should be tested.

6.3 *Chemical Requirements for Polymers*—The raw or starting material shall have specifications for relevant chemical properties such as, but not limited to, those listed within Table 1, Col. 3. In addition to specifying the chemical formula or composition, and requirements for the major and minor elemental constituents, the following aspects should be expressed quantitatively: viscosity (molecular weight), copolymer ratio (if appropriate), synthesis method, source (if naturally harvested), additives, fillers, unreacted monomer content, curing agents, catalysts, accelerators, initiators, concentration (if supplied in solution), stability, extractables, and degradation products, mechanism and kinetics. ISO 10993-9 provides guidance on identification and quantification of potential degradation products and ISO 10993-17 provides guidance on allowable limits for leachable substances. Tests for

[7] Available through this searchable database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm.
[8] Searchable through this website: http://www.fda.gov/opacom/morechoices/industry/guidedc.htm.
[9] Available at this wesite http://www.fda.gov/oc/combination/guidance.html.

TABLE 1 Typically Specified Chemical Requirements for Each Type of Material

NOTE 1—Natural materials made of proteins, nucleic acids, or polysaccharides are classified as polymers, so the chemical requirements listed for polymers apply. Anorganic bone and other naturally occurring inorganic substances are classified as ceramics, so the chemical requirements listed for ceramics apply.

Ceramics	Metals	Polymers	Composites
Chemical formula or composition	Chemical formula or composition	Chemical formula or composition	Chemical formula or composition
Phase content	Phase content	Unreacted monomer content	Phase content
Purity	Purity	Synthesis method	Characterization of the bonding process between phases
Major and minor elemental constituents	Major and minor elemental constituents	Source, if naturally harvested	Chemical content at the interface
Processing aids (dispersing agents, binders)	Corrosion susceptibility	Viscosity (molar mass)	All other properties listed in this table that may apply based on the type of materials used in the composite material.
Allowable % of foreign material contaminants	Surface modification	Additives, fillers, contaminants	
		Curing agents, catalysts, initiators, accelerators	
		Co-polymer ratio, if appropriate	
		Extractables	
		Degradation products, mechanism and kinetics	
		Residual moisture or solvent content	
		Contact angle—surface tension	

TABLE 2 Typically Specified Physical and Mechanical Requirements for Each Type of Material

NOTE 1—Natural materials made of proteins, nucleic acids, or polysaccharides are classified as polymers, so the physical and mechanical requirements listed for polymers apply. Anorganic bone and other naturally occurring inorganic substances are classified as ceramics, so the chemical requirements listed for ceramics apply.

Ceramics	Metals	Polymers	Composites
Particle size distribution	Material microstructure (grain size and orientation)	Structure—primary, secondary	Shape and dimensions of other phases
Crystal size distribution	Condition (hot-worked, annealed or cold-worked)	Powder size distribution	Bond strength between phases
Density	Melting point	Water absorption or swelling %	All other properties listed in this table that may apply based on the type of materials used in the composite material.
Specific surface area	Hardness	Glass transition temperature, melting point	
Crystallinity	Elastic modulus	Crystallinity	
Particle porosity	Yield strength	Density (true, bulk, or apparent)	
	Ultimate tensile strength	Elastic modulus[A]	
	Compressive strength	Ultimate tensile strength[A]	
		Compressive strength[A]	

[A] If polymer is in bulk solid form such as a rod or sheet, then mechanical testing may apply.

residual moisture or solvent content should be performed. Acceptable sterilization methods should be determined.

6.4 *Chemical Requirements for Composites*—Each raw or starting material within the composite shall have specifications for relevant chemical properties, depending on the type of material. The amount of each phase shall be specified. A characterization of the bonding process or bond strength between the various phases and the chemical content at the interface of the two or more materials should be completed.

6.5 *Chemical Requirements for Natural Materials*—Natural materials can be classified into one of the three materials types and are typically polymers, ceramics, or composites. Natural materials made of proteins, nucleic acids, polysaccharides, or lipids are classified as polymers, so the chemical requirements listed for polymers apply. Anorganic bone is a ceramic. The raw or starting natural material shall have specifications for relevant chemical properties such as, but not limited to, those listed within Table 1, based on how the natural material is classified. The source material shall be specified and handled and processed in such a manner as to avoid contamination of the final product. Natural materials have more variable chemical content than synthetically produced materials. Therefore, it may not be possible to have the exact same chemical composition for each lot produced and wider ranges of chemical requirements will need to be used.

6.6 *Viral and Cellular Contaminants*—The number of viable and non-viable cell colonies (aerobic, anaerobic, and spore cells per gram of material) may be measured. Tests for pyrogenic substances (for example, endotoxins) may be performed and limits set. Because these properties may be significantly influenced by the exposure of the material to any non-sterile environment, such properties are not typically specified in the starting material, unless it is from a natural source. The specifications for and validation of the elimination

and/or inactivation of viruses and transmissible agents in natural products of human, animal or plant origin should be performed as described in EN ISO 22442-1, EN ISO 22442-2 and EN ISO 22442-3.

6.7 *General Chemical Requirements:*

6.7.1 Products shall be free of extraneous material except that which is unavoidable in the manufacturing process. A limit on the amount of foreign material contaminants should be set. Guidance on determining purity, impurities and contaminants can be found in Guide E1298.

6.7.2 All ingredients used, and any diluent provided as an aid in the administration or use of the product, shall meet generally accepted standards of purity and quality.

6.7.3 Handling of raw or starting materials should be conducted in a manner that effectively eliminates any risk of gross contamination and provides control of potential particulate contamination.

7. Physical and Mechanical Requirements

7.1 *Physical and Mechanical Requirements for Ceramics*—The raw or starting material shall have specifications for relevant physical and mechanical properties such as, but not limited to, those listed in Table 2 for ceramics. This includes, for ceramics: powder size distribution (ceramics are typically supplied in granular form), crystal size distribution (crystal size is often not the same as powder size), porosity, specific surface area, crystallinity, and density.

7.2 *Physical and Mechanical Requirements for Metals*—The raw or starting material shall have specifications for relevant physical and mechanical properties such as, but not limited to, those listed in Table 2 for metals. This includes material microstructure (for example, grain size, grain orientation), condition (for example, hot-worked, annealed or cold-worked), melting point, hardness, elongation %, elastic modulus, yield strength, and ultimate tensile strength. Photomicrographs of the microstructure of the material should be observed to confirm specified characteristics. In the case of shape memory alloys, transformation temperature and recoverable range of deformation should be specified. Magnetic materials require additional material specification not covered here.

7.3 *Physical and Mechanical Requirements for Polymers*—The raw or starting material shall have specifications for relevant physical and mechanical properties such as, but not limited to, those listed in Table 2 for polymers. In addition to specifying the powder size distribution (if in granular form), crystallinity, density, the polymer structure (primary and secondary), water absorption or swelling characteristics, and melting range or temperature should also be specified.

7.4 *Physical and Mechanical Requirements for Composites*—Each raw or starting material within the composite shall have specifications for relevant physical and mechanical properties as described above, depending on the material classification of the phases that make up the composite. Additionally, a characterization of the bonding strength between the phases should be completed.

7.5 *Physical and Mechanical Requirements for Natural Materials*—After classifying the natural material as either a polymer or a ceramic or a composite based on the type of atomic bonding or macromolecular content, the corresponding requirements can be found in Table 2.

7.6 *General Physical and Mechanical Requirements*—Typically mechanical properties of the raw or starting materials such as compressive and tensile strength will not be specified, but they might be if wires, blocks, or large samples of material from which smaller shapes/parts are cut are to be utilized.

8. Existing Standards for Materials

8.1 Table 3 summarizes existing AAMI, ISO, ASTM, and other recognized standards for each type of material, including specific techniques for determining the chemical and physical properties listed in Table 1. Appropriate selection from this list may provide an interim guide for raw materials without existing standards. The existing standards may be useful as templates for developing new standards.

8.2 The following US Food & Drug Administration web site link to Recognized Consensus Standards provides an additional resource for locating existing medical product related standards, (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm). Specifications for biologically derived materials may be found in The Code of Federal Regulations, Title 21, Parts 610, 1270, and 1271 or others of Parts 1-1499.

9. Sampling

9.1 It is suggested that fulfillment of requirements for each lot of the raw or starting material be determined by sampling sizes and procedures in accordance with Practice D1898 or equivalent.

10. Handling, Packaging, and Labeling

10.1 Recommendations for product handling and packaging are specified in USP 661 or ISO 11607 and BSI BS EN 22442-2. Products containing human donor derived material must be labeled in a manner that facilitates traceability back to the donor (21 CFR 1271.290 (c) and ISBT 128).

11. Quality Program Requirements

11.1 The commercial manufacturer should conform to Quality Systems Regulations (see 21 CFR Part 820) or its equivalent. All equipment should be calibrated as described in ISO/IEC 17025 or its equivalent.

12. Biocompatibility

12.1 This guide does not include safety and biocompatibility requirements since safety and biocompatibility testing is typically done on materials fabricated into a final form to include all possible effects of fabrication and sterilization techniques. Guide F2150 and ISO 10993-1, -12 provide recommended biocompatibility testing for scaffolds for tissue engineering applications and includes descriptions of various biological tests and evaluations.

12.2 Pharmacological disposition (that is, fate, clearance, or lack thereof) of the material should be known or described.

TABLE 3 Existing Standards for Characterizing the Chemical and Physical Structure of Materials

Material Category	Specification or Test Method
Ceramics	F603 Specification for High-Purity Dense Aluminum Oxide for Medical Applications
	F1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation
	F1185 Specification for Composition of Hydroxyapatite for Surgical Implants
	F1538 Specification for Glass and Glass Ceramic Biomaterials for Implantation
	F1581 Specification for Composition of Anorganic Bone for Surgical Implants
	F1873 Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications
	ISO 6474 Implants for Surgery—Ceramic Materials Based on Alumina
	ISO 10993-14—Part 14 Identification and Quantification of Degradation Products from Ceramics
Metals	F67 Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
	F75 Specification for Cobalt-28, Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implant Applications (UNS R30075)
	F90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)
	F136 Specification for Wrought Titanium 6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
	F138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
	F139 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)
	F560 Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
	F562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications (UNS R30035)
	F1377 Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)
	F1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications (UNS R56400)
	F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
	F1713 Specification for Wrought Titanium-13, Niobium-13 Zirconium Alloy for Surgical Implant Applications (UNS R58130)
	ISO 10993-15—Part 15 Identification and Quantification of Potential Degradation Products from Metals and Alloys
	F3160 Guide for Metallurgical Characterization of Absorable Metallic Materials for Medical Implants
Polymers	D1763 Specification for Epoxy Resins
	F451 Specification for Acrylic Bone Cement
	F602 Criteria for Implantable Thermoset Epoxy Plastics
	F619 Practice for Extraction of Medical Plastics
	F624 Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Biomedical Applications
	F639 Specification for Polyethylene Plastics for Medical Applications
	F641 Specification for Implantable Epoxy Electronic Encapsulants
	F648 Specification for Ultra-High-Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants
	F665 Classification for Vinyl Chloride Plastics Used in Biomedical Application
	F702 Specification for Polysulfone Resin for Medical Applications
	F755 Specification for Selection of Porous Polyethylene for Use in Surgical Implants
	F997 Specification for Polycarbonate Resin for Medical Applications
	F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices
	F1579 Specification for Polyaryletherketone (PAEK) Resins for Surgical Implant Applications
	F1634 Practice for *In Vitro* Environmental Conditioning of Polymer Matrix Composite Materials and Implant Devices
	F1635 Test Method for *In Vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Form for Surgical Implants
	F1855 Specification for Polyoxymethylene (Acetal) for Medical Applications
	F1876 Specification for Polyetherketoneetherketoneketone (PEKEKK) Resins for Surgical Implant Applications
	F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants
	F2026 Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
	F2064 Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application
	F2103 Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications
	F2212 Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)
	F2259 Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (1H NMR) Spectroscopy
	F2260 Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance (1H NMR) Spectroscopy
	F2347 Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications
	F2313 Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide
	F2579 Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants
	F2848 Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
	USP-30, NF-19 Methacrylate acid copolymer Polyoxamer Polyethylene glycol Polysorbate 40,60,80 Polyvinyl acetate phthalate Propylene glycol-alginate Shellac Sodium alginate Xanthum gum
	ISO 10993-13—Part 13

13. Keywords

13.1 biomaterials; ceramics; composites; materials; metals; natural products; polymers; regenerative medicine; tissue-engineered medical products