



Standard Guide for Characterization and Testing of Raw or Starting Materials for Tissue-Engineered Medical Products¹

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D1898 Practice for Sampling of Plastics (Withdrawn 1998)³

E1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products (Withdrawn 2014)³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

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.