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

This standard is issued under the fixed designation F 2027; 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.

ϵ^1 NOTE—Table 1 was editorially corrected in June 2001.

1. Scope

1.1 This guide addresses material characteristics of raw or virgin materials in a nonfabricated form that will ultimately undergo additional processing into growth, support, or delivery vehicles for cells or biomolecules. This guide does not apply to packaged, sterilized, and finished tissue-engineered medical products.

1.2 The purpose of the guide is to assist the developer of tissue-engineered medical products to locate relevant existing standards and test methods and to provide guidance for interim use of materials for which a standard does not exist.

2. Referenced Documents

2.1 *ASTM Standards:*

D 1763 Specification for Epoxy Resins[2]

D 1898 Practice for Sampling of Plastics[3]

E 1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products[4]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[5]

F 451 Specification for Acrylic Bone Cement[5]

F 560 Specification for Unalloyed Tantalum for Surgical Implant Applications[5]

F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application[5]

F 604 Specification for Silicone Elastomers Used in Medical Applications[5]

F 624 Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Biomedical Applications[5]

F 641 Specification for Implantable Epoxy Electronic Encapsulants[5]

F 665 Classification for Vinyl Chloride Plastics Used in Biomedical Application[5]

F 702 Specification for Polysulfone Resin for Medical Applications[5]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[5]

F 749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit[5]

F 755 Specification for Selection of Porous Polyethylene for Use in Surgical Implants[5]

F 756 Practice for Assessment of Hemolytic Properties of Materials[5]

F 763 Practice for Short-Term Screening of Implant Materials[5]

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[5]

F 895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity[5]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[5]

F 997 Specification for Polycarbonate Resin for Medical Applications[3]

F 1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation[5]

F 1185 Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants[5]

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices[5]

F 1425 Specification for Virgin Poly (L-lactic Acid) Resin for Surgical Implants[3]

F 1439 Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials[5]

F 1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications[5]

F 1579 Specification for Polyaryletherketone (PAEK) Resins for Surgical Implant Applications[5]

F 1581 Specification for Composition of Anorganic Bone for Surgical Implants[5]

[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 Tissue Characterization.

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

[3] Discontinued; see *1997 Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 11.05.

[5] *Annual Book of ASTM Standards*, Vol 13.01.