



Designation: F3223 – 17

Standard Guide for Characterization and Assessment of Tissue Engineered Medical Products (TEMPs) for Knee Meniscus Surgical Repair and/or Reconstruction¹

This standard is issued under the fixed designation F3223; 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 guide is intended as a resource for individuals and organizations involved in the production, delivery, and regulation of tissue engineered medical products (TEMPs) and other tissues intended for use in the surgical repair, replacement, and/or reconstruction of the knee meniscus.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

D570 Test Method for Water Absorption of Plastics

F1635 Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants

F2150 Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products

F2210 Guide for Processing Cells, Tissues, and Organs for Use in Tissue Engineered Medical Products (Withdrawn 2015)³

F2211 Classification for Tissue Engineered Medical Products (TEMPs)

F2212 Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)

F2312 Terminology Relating to Tissue Engineered Medical Products

F2386 Guide for Preservation of Tissue Engineered Medical Products (TEMPs) (Withdrawn 2013)³

F2739 Guide for Quantifying Cell Viability within Biomaterial Scaffolds

2.2 ISO Standards:⁴

ISO 10993-1 Biological evaluation of medical devices

ISO 13022:2012 Medical products containing viable human cells—Application of risk management and requirements for processing practices

ISO 18362:2016 Manufacture of cell-based health care products—Control of microbial risks during processing

2.3 Code of Federal Regulations⁵

CFR 610.12 General Biological Products Standards—Sterility

CFR 820 Current Good Manufacturing Practice for Quality System Regulation

CFR 1270 Current Good Manufacturing Practice for Human Tissue Intended for Transplantation

CFR 1271 Current Good Manufacturing Practice for Human Cells, Tissues, and Cellular and Tissue-Based Products

3. Terminology

3.1 Unless provided otherwise in 3.2, terminology shall be in conformance with Terminology **F2312**.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *ECM, n*—extracellular matrix.

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.44 on Assessment for TEMP.

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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.

⁴ Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <http://www.iso.org>.

⁵ Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.