



Standard Classification for Tissue Engineered Medical Products (TEMPs)¹

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1. Scope

1.1 This classification outlines the aspects of tissue engineered medical products that will be developed as standards. This classification excludes traditional transplantation of organs and tissues as well as transplantation of living cells alone as cellular therapies.

1.2 This classification does not apply to any medical products of human origin regulated by the U.S. Food and Drug Administration under 21 CFR Parts 16 and 1270 and 21 CFR Parts 207, 807, and 1271.

1.3 This standard does not purport to address specific components covered in other standards. Any safety areas associated with the medical product's use will not be addressed in this standard. *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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

F 2027 Guide for Characterization and Testing of Substrate Materials for Tissue-Engineered Medical Products²

F 2064 Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application²

F 2103 Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications²

F 2131 Test Method for *In Vitro* Biological Activity of Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) Using the W-20 Mouse Stromal Cell Line²

F 2150 Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products²

2.2 Federal Documents:³

Code of Federal Regulations (CFR) US FDA CFR 21, Part

3 [3.2(e)], Product Jurisdiction

21 CFR Parts 16 and 1270 Human Tissues, Intended for Transplantation

21 CFR Parts 207, 807, and 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing

2.3 ISO Standard:

ISO 10993 Biological Evaluation of Medical Devices⁴

2.4

International Standards—There are no known standards developed by the international community specifically for TEMPs; however, ASTM International has an effort initiated in 1997 and several colleagues of the international community (IEC, CEN, ISO) have been coordinating and contributing to the ASTM TEMPs standards. Also, the international community is in the process of formulating a direction for their standards and regulations for this area. Recently, several draft documents have been circulated for input regarding code of practice for Products using Material of Human Origin, from the U.K., EU-COMED position paper concerning the need for future regulation of human tissue products for Europe and “Pre-clinical Safety Assessment of Tissue Engineered Medical Products (TEMPs): An Investigation on Assays and Guidelines for Biocompatibility Testing.”⁵

3. Terminology

3.1 *tissue engineering, n*—the application, *in vivo* and *in vitro*, of scientific principles and technologies to form tissue engineered medical products (TEMPs) used for medical treatments and as diagnostics. The various technologies and principles are common practices and methods in engineering and biomedical sciences such as cell, gene, or drug therapy, embryology or other forms of developmental biology, surgical methods and technologies used to create traditional devices and biologics. Tissue engineering could be applied to create products for non-human use as well.

3.2 *tissue engineered medical products (TEMPs), n*—medical products that repair, modify, or regenerate the

¹ This classification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.41 on Classification and Terminology for TEMPs.

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² *Annual ASTM Book of Standards*, Vol 13.01.

³ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

⁴ Available from International Organization for Standardization (ISO), 1 rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland.

⁵ Available from Rijksinstituut voor Volksgezondheid en Milieu, (National Institute of Public Health and the Environment) The Netherlands.