



Standard Terminology Relating to Tissue Engineered Medical Products¹

This standard is issued under the fixed designation F 2312; 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 terminology defines basic terms and presents the relationships of the scientific fields related to Tissue Engineered Medical Products (TEMPs). Committee F04 has defined these terms for the specific purpose of unifying the language used in standards for TEMP.

1.2 The terms and relationships defined here are limited to TEMP. They do 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 The terms and nomenclature presented in this standard are for the specific purposes of unifying the language used in TEMP standards and are not intended for labeling of regulated medical products.

1.4 *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.*

2. Referenced Documents

2.1 ASTM Standards:²

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

F 2311 Guide for Classification of Therapeutic Skin Substitutes

2.2 Government Documents:³

21 CFR Parts 16 and 1270, Human Tissues, Intended for Transplantation (July 29, 1997)

21 CFR Parts 207, 807, and 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing (January 19, 2001)

3. Significance and Use

3.1 The need for standards regarding TEMP has also prompted a need for definitions. This terminology sets forth definitions of the most commonly used terms and specifies the relationship among the sciences and components applied in tissue engineering to develop TEMP. Use of these terms and an understanding of these relationships will unify the ASTM TEMP standards with a common language such that the users of these standards can understand and interpret the standards more precisely. Terms specific to a TEMP standard will also be defined within the respective standard as appropriate.

3.2 *Defining Terms*—Terms are defined with a broad scope to encompass these new products known as TEMP. For instance, the definition for somatic cell therapy as stated in the “Guidance for Human Somatic Cell Therapy and Gene Therapy” (5)⁴ is recognized in this terminology. However, for the purposes of TEMP that contain cells, we have added the definition of “cell” which is much broader and not limited to the use of living cells.

3.3 *Clinical Effects of TEMP*—The users of this terminology should note that terms used regarding the clinical effects of TEMP, for instance, “modify or modification” of the patient’s condition, may also be interpreted to “enhance, augment, transform, alter, improve, or supplement.” Similarly, “repair” may also serve to mean “restore.”

3.4 The diagram in Fig. 1 shows the relationships of components of TEMP and of the fields of science (for example, technologies and principles) used in tissue engineering to create TEMP. Certain TEMP may be tissue engineered or produced *in vitro* by using specific components and sciences to create an off-the-shelf TEMP for the users. Other TEMP may by design require the users to place the components inside the patient, (that is, *in vivo*) to rely upon the patient’s regenerative potential to achieve the product’s primary intended purpose. The expectation of a TEMP used for therapeutic clinical applications is to have a therapeutic effect, specifically to repair, modify or regenerate the recipient’s cells, tissues, and organs or their structure and function. Such a TEMP may be used for human and non-human applications. In

¹ This terminology 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 TEMP.

Current edition approved Sept. 10, 2003. Published November 2003.

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

⁴ The boldface numbers in parentheses refer to this list of references at the end of this standard.