



Standard Guide for Classification of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds¹

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1. Scope

1.1 This guide defines terminology for description of cellular and/or tissue-based products (CTPs) for skin wounds. CTPs are defined primarily by their composition and comprise cells and/or the extracellular components of tissue. CTPs may contain cells (viable or nonviable), tissues, proteins, and other materials for which there is a rationale for benefit beyond that achievable with conventional wound coverings. CTPs may additionally include synthetic components. Whether an individual CTP is capable of promoting wound healing must be determined by adequate evidence and is beyond the scope of this standard.

1.2 This guide also describes a classification and nomenclature for CTPs based on their composition. This systematic nomenclature is not intended to be prescriptive for product labeling, and it describes only the most salient characteristics of these products; the actual biological and clinical functions can depend on characteristics not recognized in the nomenclature, and it should be understood that two products that can be described identically by the nomenclature should not be presumed to be identical or have the same clinical utility.

1.3 This guide defines CTP-related terminology in the context of skin wounds. However, this guide does not provide a correspondence between the CTP composition and its clinical use(s). More than one product may be suitable for each clinical use, and one product may have more than one clinical use.

1.4 *This standard does not purport to address safety concerns with the use of CTPs. 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

F2027 Guide for Characterization and Testing of Raw or Starting Biomaterials for Tissue-Engineered Medical Products

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

F2311 Guide for Classification of Therapeutic Skin Substitutes

F2312 Terminology Relating to Tissue Engineered Medical Products

F2739 Guide for Quantitating Cell Viability Within Biomaterial Scaffolds

3. Terminology

3.1 Skin Tissue Definitions:

3.1.1 *dermal*, *adj*—pertaining to the dermis (**1**).³

3.1.2 *dermis*, *n*—the layer of the skin deep to the epidermis, consisting of a dense bed of vascularized connective tissue (**1**).

3.1.3 *dermoepidermal junction (DEJ)*, *n*—distinct anatomic zone between the epidermis and dermis that facilitates adherence between the two layers; contains laminin, collagen type VII, collagen type IV, and tenascin C (**2**).

3.1.4 *epidermal*, *adj*—pertaining to or resembling epidermis (**1**).

3.1.5 *epidermis*, *n*—the outermost and nonvascularized layer of the skin (**1**).

3.1.6 *extracellular matrix*, *n*—a structural and functional entity produced by cells that surrounds and supports cells and

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 F04.41 on Classification and Terminology for TEMPs.

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