Designation: F3163 – 22

Standard Guide for Categories and Terminology of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds[1]

This standard is issued under the fixed designation F3163; 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 defines terminology for description of cellular and/or tissue-based products (CTPs) for skin wounds. CTPs are TEMPs (tissue-engineered medical products) that are primarily defined by their composition and comprise viable and/or nonviable human or animal cells, viable and/or nonviable tissues, and may include extracellular matrix components. CTPs may additionally include synthetic components.

1.2 This guide also describes categories and terminology for CTPs based on their composition. This systematic categorization 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 categorization and it should be understood that two products that can be described identically by the categorization 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 guide 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 involved in the development of said products in accordance with applicable regulatory guidance documents and in implementing this guide to evaluate the cellular and/or tissue-based products for wounds.

1.5 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *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]

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

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

F2311 Guide for Classification of Therapeutic Skin Substitutes (Withdrawn 2017)[3]

F2312 Terminology Relating to Tissue Engineered Medical Products

F2739 Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds

3. Terminology

3.1 *Skin Tissue Definitions:*

3.1.1 *dermal, adj*—pertaining to the dermis (**1**).[4]

3.1.2 *dermis, n*—the layer of the skin underneath 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**).

[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 F04.41 on Classification and Terminology for TEMPs.

Current edition approved Feb. 15, 2022. Published March 2022. Originally approved in 2016. Last previous edition approved in 2016 as F3163 – 16. DOI: 10.1520/F3163-22.

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

*A Summary of Changes section appears at the end of this standard

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 regulates cell communication. Typical components are collagens, adhesive glycoproteins, glycosaminoglycans, and proteoglycans (**3**).

3.1.7 *skin, n*—the outer integument or covering of the body, consisting of the dermis and the epidermis, and resting upon the subcutaneous tissue.

3.1.8 *tissue, n*—a level of organization in multicellular organisms consisting of a group of structurally and functionally related cells and extracellular matrix. (**F2312**)

3.2 *Skin Wound and Ulcer Definitions:*[5]

3.2.1 *acute wound, n*—a wound that normally proceeds through an orderly and timely reparative/regenerative process that results in sustained restoration of anatomic and functional integrity (**4**).

3.2.2 *arterial ulcer, n*—also referred to as *ischemic ulcer*, is caused by poor perfusion (delivery of nutrient-rich blood) to the lower extremities (**5, 6**).

3.2.3 *burn, n*—injury to tissues caused by contact with heat, chemicals, electricity, friction, or radiant and electromagnetic energy (**1**).

3.2.4 *chronic wound, n*—a wound that has failed to proceed through an orderly and timely process to produce anatomic and functional integrity, or proceeded through the repair process without establishing a sustained anatomic and functional result (**4**).

3.2.5 *diabetic leg or foot ulcer, n*—a break of the skin of the foot that includes minimally the epidermis and part of the dermis and involves infection, ulceration, or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of a person with (a history of) diabetes mellitus (**5, 6**).

3.2.6 *full-thickness skin wound, n*—a skin wound with the loss of or penetration through the epidermis and all the dermis, or at least the depth of dermis that includes most or all sources of epidermal cells from epidermal adnexae (glands and follicles).

3.2.7 *ischemic ulcer, n*—see *arterial ulcer*.

3.2.8 *lesion, n*—any pathological or traumatic discontinuity of tissue or loss of function of a tissue part.

3.2.9 *mixed arterial-venous ulcer, n*—an ulceration due to a combination of chronic venous insufficiency and arterial disease (**7**).

3.2.10 *partial thickness skin wound, n*—a skin wound with the loss of the epidermis and part of the dermis, but retaining a layer of viable dermal tissue that includes the sources of epidermal cells from which the wound can heal spontaneously by epidermal tissue regeneration.

3.2.11 *pressure injury/ulcer, n*—localized injury to the skin and/or underlying tissue usually over a bony prominence as a result of pressure, or pressure in combination with shear. Also known as *decubital ulcer*, *decubitus ulcer*, *pressure sore*, or *bed sore* (**8**).

3.2.12 *scar, n*—fibrous tissue replacing normal tissues destroyed by injury or disease.

3.2.13 *surgical wound, n*—a wound created as the result of a surgical procedure.

3.2.14 *ulcer, n*—a local defect, or excavation of the surface of an organ or tissue, which is produced by the sloughing of inflammatory necrotic tissue.

3.2.15 *venous leg ulcer, n*—a local defect on the leg due to chronic venous insufficiency. Also known as a venous stasis ulcer or a venous insufficiency ulcer (**5, 6**).

3.2.16 *wound, n*—an acquired disruption of normal anatomic structure and function of a tissue or organ. Also known as *injury* or *trauma* (**4**).

3.3 *Wound Healing Physiology Definitions:*

3.3.1 Acute wound healing of skin typically proceeds in a sequential series of steps that overlap in time: hemostasis, inflammation, new tissue formation (re-epithelialization, granulation tissue formation, neovascularization), and tissue remodeling (wound contraction and extracellular matrix reorganization). Each of these steps is characterized by dynamic, reciprocal interactions among cells, extracellular matrix, and the cellular microenvironment. In contrast, chronic wounds do not proceed normally through these healing steps but instead exhibit numerous abnormalities as a result of underlying pathobiology (**9, 10**).

3.3.2 *granulation tissue, n*—the newly formed vascular tissue normally produced in the healing of wounds of soft tissue and ultimately forming the cicatrix (scar); it consists of small, translucent, red, nodular masses or granulations that have a velvety appearance.

3.3.3 *heal, v*—to restore wounded parts or to make healthy.

3.3.4 *healing, n*—the restoration of integrity to injured tissue.

3.3.5 *necrotic, adj*—characterized by the sum of the morphological changes indicative of cell death and caused by the progressive degradative action of enzymes (**1**).

3.3.6 *scar, n*—fibrous tissue replacing normal tissues destroyed by injury or disease.

3.3.7 *tissue regeneration, n*—healing in which lost tissue is replaced by migration, differentiation, and proliferation of cells that deposit new extracellular matrix with normal architecture, function, and appearance.

3.3.8 *tissue repair, n*—healing in which lost tissue is replaced by a fibrous scar, which is produced from granulation tissue.

3.3.9 *wound contraction, n*—the shrinkage and spontaneous closure of open skin wounds.

[5] In this guide, skin wounds include those caused by burns, trauma, surgical incision, or surgical excision, in addition to ulcers associated with underlying chronic conditions. This guide makes no distinction among different types of ulcers, which are a result of differing pathologies or conditions and for which different procedures and different types of CTPs may be appropriate.