



Standard Guide for Classification of Therapeutic Skin Substitutes¹

This standard is issued under the fixed designation F2311; 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 and provides classification for products that can be substituted for tissue grafts of human or animal tissue in medical and surgical therapies of skin lesions.

1.2 This guide provides a classification method for skin substitutes by comparing their clinical uses with those of conventional tissue grafts. However, skin substitutes may also have equivalent, superior, or inferior clinical properties in comparison to conventional tissue grafts. Clinical classification is independent of the materials and technology used to make a skin substitute, or whether its components include human or animal tissue or other biological or non-biological materials.

1.3 This guide also describes a nomenclature for systematic description of the technologies and components of skin substitutes that is independent of their clinical utilities. This systematic nomenclature is not intended to be prescriptive for product labeling, and it describes only the most salient characteristics of skin substitutes; the actual biological and clinical functions of skin substitutes 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.

1.4 This guide does not provide a correspondence between the skin substitute composition and the clinical classification. Also, more than one product may be suitable for each clinical use, and one product may have more than one clinical use.

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 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

F2210 Guide for Processing Cells, Tissues, and Organs for Use in Tissue Engineered Medical Products

F2312 Terminology Relating to Tissue Engineered Medical Products

2.2 Other Reference:

Dorland's Illustrated Medical Dictionary, 29th Ed., W. B. Saunders Company, Philadelphia, 2000.

3. Terminology

3.1 Skin Tissue Definitions:

3.1.1 *dermal, adj*—pertaining to the dermis. **Dorland's**

3.1.1.1 *Discussion*—In this guide, to avoid confusion, “dermal” is preferred to be used to refer only to a patient’s existing or regenerated tissue and not to dermal tissue when used as a component of a skin substitute. Exceptions are “dermal autograft” and “dermal autograft substitute.”

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

Dorland's

3.1.3 *epidermal, adj*—pertaining to or resembling epidermis. **Dorland's**

3.1.3.1 *Discussion*—In this guide, to avoid confusion, “epidermal” is used to refer only to the patient’s existing or regenerated tissue and not to epidermal tissue used as a component of a skin substitute. Exceptions are “epidermal autograft” and “epidermal autograft substitute.”

3.1.4 *epidermis, n*—the outermost and nonvascular layer of the skin. **Dorland's**

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 Oct. 1, 2008. Published November 2008. Originally approved in 2003. Last previous edition approved in 2006 as F2311 – 06. DOI: 10.1520/F2311-08.

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.