



Standard Guide for Tissue Engineered Medical Products (TEMPs) for Reinforcement of Tendon and Ligament Surgical Repair¹

This standard is issued under the fixed designation F2903; 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 is intended as a resource for individuals and organizations involved in the development, production, and delivery of tissue engineered medical products (TEMPs) intended to provide a mechanical (functional) reinforcement of the surgical repair of tendons and ligaments.

1.2 Surgical repair can include procedures that repair tendon to tendon, tendon to bone, tendon to muscle, ligament to ligament, and ligament to bone. In the context of this guide, a tendon is a fibrous cord or band that connects a muscle to a bone or other structure and consists of both dense collagenous fibers and rows of elongated tendon cells. In contrast, a ligament is a band or sheet of fibrous tissue connecting two or more bones, or cartilagenous structures.

1.3 Examples of TEMPs for use in reinforcement of tendon or ligament repairs include extracellular matrices (including allograft tissue, xenograft tissue, and tissue engineered extracellular matrix), polymeric matrices, membranes, or combinations of two or more of these, with or without cells and/or molecular mediators, where the function is to reinforce the surgical repair of tendon to tendon, tendon to bone, tendon to muscle, ligament to ligament, or ligament to bone.

1.4 The products may be rapidly degrading, slowly degrading, or non-degrading.

1.5 The guide is not intended to apply to TEMPs that have a primary function to induce a biological repair through cell or molecular action, although biologic activity may be a feature of the TEMPs. Examples of products or product concepts that are not included are (a) growth factors or cytokines applied to a biologic or synthetic scaffold, and (b) platelet-enriched plasma applied to or within a biologic or polymeric scaffold, where the primary function of the product is biologic.

1.6 The guide is not intended to apply to TEMPs that have a primary function to induce a chemical repair. An example of a product or product concept that would not be included would

be a polymeric matrix containing reagents that glue collagenous tissues together.

1.7 The guide is not intended to apply to TEMPs that are designed to be used to achieve primary surgical repair of injured tendons and ligaments.

1.8 The guide is not intended to apply to TEMPs that are designed to replace tendons or ligaments.

1.9 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.10 *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

- D1004 Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheet
- D2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics
- D3786 Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method
- D3787 Test Method for Bursting Strength of Textiles—Constant-Rate-of-Traverse (CRT) Ball Burst Test
- D5035 Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method)
- E139 Test Methods for Conducting Creep, Creep-Rupture, and Stress-Rupture Tests of Metallic Materials
- F1635 Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants
- F1978 Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser

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 F04.44 on Assessment for TEMPs.

Current edition approved March 1, 2011. Published April 2011. DOI: 10.1520/F2903-11.

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.