Designation: F 1717 – 04

Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model[1]

This standard is issued under the fixed designation F 1717; 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 These test methods cover the materials and methods for the static and fatigue testing of spinal implant assemblies in a vertebrectomy model. The test materials for most combinations of spinal implant components can be specific depending on the intended spinal location and intended method of application to the spine.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future spinal implant assemblies. They allow comparison of spinal implant constructs with different intended spinal locations and methods of application to the spine. These test methods are not intended to define levels of performance, since sufficient knowledge is not available to predict the consequences of the use of a particular device.

1.3 These test methods set out guidelines for load types and methods of applying loads. Methods for three static load types and one fatigue test are defined for the comparative evaluation of spinal implant assemblies.

1.4 These test methods establish guidelines for measuring displacements, determining the yield load, and evaluating the stiffness and strength of the spinal implant assembly.

1.5 Some spinal constructs may not be testable in all test configurations.

1.6 Values stated in SI units are to be regarded as standard.

1.7 *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]

D 638 Test Method for Tensile Properties of Plastic

E 4 Practices for Force Verification of Testing Machines

E 6 Terminology Relating to Methods of Mechanical Testing

E 739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (S-N) and Strain-Life (ϵ-N) Fatigue Data

E 1150 Definitions of Terms Relating to Fatigue[3]

F 1582 Terminology Relating to Spinal Implants

F 2077 Test Methods For Intervertebral Body Fusion Devices

3. Terminology

3.1 *Definitions:*

3.1.1 For definitions of terms relating to these test methods, see Terminology E 6, Terminology F 1582, and Definitions E 1150.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *active length of the longitudinal element*—the straight line distance between the center of attachment of the superior anchor and the center of attachment of the inferior anchor.

3.2.2 *angular displacement at 2 % offset yield (degrees)*—the angular displacement of a construct measured via the actuator that produces a permanent angular displacement in the *X-Y* plane equal to 0.020 times the torsional aspect ratio (see Point A in Fig. 1).

3.2.3 *block moment arm*—the perpendicular to the applied load between the insertion point of an anchor and the axis of the hinge pin.

3.2.4 *compressive or tensile bending stiffness (N/mm)*—the compressive or tensile bending yield force divided by elastic displacement (see the initial slope of line *BC* in Fig. 1).

3.2.5 *compressive or tensile bending ultimate load (N)*—the maximum compressive or tensile force in *X-Z* plane applied to a spinal implant assembly (see the force at Point E in Fig. 1). The ultimate load should be a function of the device and not of the load cell or testing machine.

3.2.6 *compressive or tensile bending yield load (N)*—the compressive or tensile bending force in *X-Z* plane necessary to produce a permanent deformation equal to 0.020 times the active length of the longitudinal element (see the force at Point D in Fig. 1).

3.2.7 *coordinate system/axes*—three orthogonal axes are defined in Fig. 2 and Fig. 3. The anterior-posterior axis is *X* with positive being anterior. The medial-lateral axis is *Y* with

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.25 on Spinal Devices.

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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] Withdrawn.

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