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.

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Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model[1]

This standard is issued under the fixed designation F2706; 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 occipital-cervical and occipital-cervical-thoracic spinal implant assemblies in a vertebrectomy model. The test materials for most combinations of occipital-cervical and occipital-cervical-thoracic spinal implant components can be specific depending on the intended location and intended method of attachment.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future occipital-cervical and occipital-cervical-thoracic spinal implant assemblies. They allow comparison of occipital-cervical and occipital-cervical-thoracic spinal implant constructs with different 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 two fatigue tests for the comparative evaluation of occipital-cervical and occipital-cervical-thoracic spinal implant assemblies are defined.

1.4 These test methods establish guidelines for measuring displacements, determining the yield load, and evaluating the stiffness and strength of occipital-cervical or occipital-cervical-thoracic spinal implant assemblies.

1.5 It may not be possible to test some occipital-cervical and some occipital-cervical-thoracic spinal constructs in all test configurations.

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

1.8 *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]

E4 Practices for Force Verification of Testing Machines
E6 Terminology Relating to Methods of Mechanical Testing
E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (***S-N***) and Strain-Life (ε-***N***) Fatigue Data
E1823 Terminology Relating to Fatigue and Fracture Testing
F1582 Terminology Relating to Spinal Implants
F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
F2077 Test Methods For Intervertebral Body Fusion Devices

3. Terminology

3.1 *Definitions*—For definitions of terms relating to these test methods, see Terminologies E6, F1582, and E1823.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *active length of the longitudinal element, n*—the straight line distance between the centers of rotation of the test blocks.

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

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

3.2.4 *compressive or tensile bending ultimate load (N), n*—the maximum compressive or tensile force in the *X-Z* plane

[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.

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