



Provisional Standard Test Method for Static and Dynamic Spinal Implants Assembly in a Corpectomy Model¹

This provisional standard is issued by ASTM in accordance with a special procedure to meet the demand for rapid issuance of specific documents.²

1. Scope

1.1 This provisional test method covers the materials and methods for the static and dynamic testing of spinal implant assemblies in a corpectomy 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 This provisional test method is intended to provide a basis for the mechanical comparison among past, present and future spinal implant assemblies. This provisional test method allows comparison of spinal implant constructs with different intended spinal locations and methods of application to the spine. This provisional test method is 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 This provisional test method sets out guidelines for load types and methods of applying loads. Methods for four static load types and one dynamic test are defined for the comparative evaluation of spinal implant assemblies.

1.4 This provisional test method establishes guidelines for measuring displacements, determining the yield load, 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 The 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:

E 4 Practices for Force Verification of Testing Machines²

E 6 Terminology Relating to Methods of Mechanical Testing²

E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process³

E 468 Practices for the Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials²

E 739 Practice for Statistical Analysis of Linear or Linearized Stress-Life ($S-N$) and Strain-Life ($\epsilon-N$) Fatigue Data²

E 1150 Definitions of Terms Relating to Fatigue²

F 648 Specification for Ultra-high-molecular-weight Polyethylene Powder and Fabricated Form for Surgical Implants⁴

3. Terminology

3.1 Definitions:

3.1.1 For definitions of terms relating to this provisional test method, see Terminology E 6 and Definitions E 1150.

3.2 Descriptions 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*—The angular displacement (degrees) when an assembly has 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 *anchor*—components that are directly attached to bony elements of the spine (sacrum, lamina, pedicle, vertebral body, spinous process, transverse process, the pelvis, or ribs).

3.2.3.1 *band*—a flexible anchor component with a non-circular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components using knot or similar tying mechanism, forming a locked, closed loop.

3.2.3.2 *bolt*—an anchor component that connects to the bony elements of the spine, pelvis or ribs by means of threads with the lead threads accommodating a nut thus sandwiching the bony elements or implant component between the nut or washer and bolt head or other fixed stop.

3.2.3.3 *hook*—an anchor component that fastens to the spine by means of a curved blade passed under or over lamina, transverse or spinous processes or into an anatomic or surgically created notch or opening.

(1) *hook blade*—that portion of a spinal hook that is placed under, over or into a bony structure to provide attachment.

(2) *hook body*—that portion of a spinal hook that connects the hook blade to the longitudinal element.

3.2.3.4 *post*—a non-threaded anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of a non-threaded hole in the bony element.

3.2.3.5 *screw*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads.

¹ This provisional test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee on F04.35 on Constructs.

Current edition approved July 20 1994. Published October 1994.

² See Section 13 of the *Regulations Governing ASTM Technical Committees*.

³ *Annual Book of ASTM Standards*, Vol 03.01.

⁴ *Annual Book of ASTM Standards*, Vol 14.02.