



Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants¹

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1. Scope

1.1 This test method covers the measurement of uniaxial static and fatigue strength, and resistance to loosening of the component interconnection mechanisms of spinal arthrodesis implants.

1.2 The purpose of this test method is to provide a means of mechanically characterizing different designs of spinal implant interconnections. Ultimately, the various components and interconnections should be combined for static and fatigue testing of the spinal implant construct. It is not the intention of this test method to address the analysis of spinal implant constructs or subconstructs or to define levels of performance of spinal implants as insufficient knowledge is available to predict the consequences of the use of particular spinal implant designs.

1.3 This test method sets out definitions for use in measuring the strength of component interconnections of spinal implants, possible test methods themselves, and the reporting of test results.

1.4 The values stated in SI units are to be regarded as standard, with the exception of angular measurements, which may be reported in terms of either degrees or radians.

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

[E4 Practices for Force Verification of Testing Machines](#)

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and 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.

[F383 Practice for Static Bend and Torsion Testing of Intramedullary Rods](#) (Withdrawn 1996)³
[F1582 Terminology Relating to Spinal Implants](#)

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *active length of longitudinal element*—the span between rigid supports (for example, 50 mm is the active length in [Fig. 1](#), [Fig. 2](#), [Fig. 3\(a\)](#), [Fig. 3\(b\)](#), and [Fig. 4](#).

3.1.2 *global coordinate system*—spinal column motion has six degrees of freedom, having translational motion along, and rotational motion about three axes. The axes are labeled anterior-posterior or a-p (X), medial-lateral or transverse (Y), and caudal-cranial or axial (Z). This coordinate system is right handed with +X in the anterior direction, +Y towards the left side of the body, and +Z in the cranial direction. Positive rotations are defined by the right hand rule (see [Fig. 5\(a\)](#)).

3.1.3 *gripping capacity*—the maximum applied load or moment across an interconnection mechanism within the first 1.5 mm of permanent displacement or 5° of permanent rotation between the connected components.

3.1.4 *local coordinate system*—the spine's global coordinate system shall be applied locally at the position of the interconnection. The local direction, z, shall be centered through the longitudinal element of the x-y plane. The local direction, x, shall be defined as parallel to the axis of a screw or back of a hook. The local transverse axis, y, shall be parallel to a transverse element (See [Fig. 5\(b\)](#) and [Fig. 5\(c\)](#)).

3.1.5 *loosening torque*—the torque required to disconnect the various threaded fasteners that might comprise the implant's interconnection mechanism.

3.1.6 *major directions of loading*—directions of the predominant forces and moments (relative to the local axes) to which vertebral connection elements are subjected, (that is, axial load, F_z; A-P load, F_x; axial torsion, M_z; and flexion-extension moment, M_y).

³ The last approved version of this historical standard is referenced on www.astm.org.