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Standard Guide 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 guide 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 guide 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 guide 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 guide 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.

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:

E 4 Practices for Force Verification of Testing Machines²

E 6 Terminology Relating to Methods of Mechanical Testing²

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

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

E 1150 Definitions of Terms Relating to Fatigue²

F 383 Practice for Static Bend and Torsion Testing of Intramedullary Rods³

F 1582 Terminology Relating to Spinal Implants³

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 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

¹ This guide is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices

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² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.