



Standard Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses¹

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1. Scope

1.1 This practice provides guidance for the static and dynamic testing of Lumbar Total Facet Prostheses (FP). These implants are intended to allow motion and lend support to one or more functional spinal unit(s) through replacement of the natural facets.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future non-biologic FP. These test methods allow comparison of devices with different methods of application to the lumbar spine. These test methods are intended to enable the user to mechanically compare devices and do not purport to provide performance standards for them.

1.3 These test methods describe static and dynamic tests by specifying load types and specific methods of applying these loads.

1.4 These test methods do not purport to address all clinically relevant failure modes for FP, some of which will be device specific. For example, these test methods do not address implant wear resistance under expected *in vivo* loads and motions. In addition, the biologic response to wear debris is not addressed in these test methods.

1.5 Requirements are established for measuring displacements and evaluating the stiffness of FP.

1.6 Some devices may not be testable in all test configurations.

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

1.8 *The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.*

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

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2. Referenced Documents

2.1 ASTM Standards:²

- D638 Test Method for Tensile Properties of Plastics
- E4 Practices for Force Verification of Testing Machines
- E6 Terminology Relating to Methods of Mechanical Testing
- E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials
- E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life ($S-N$) and Strain-Life ($\epsilon-N$) Fatigue Data
- F1582 Terminology Relating to Spinal Implants

3. Terminology

3.1 All functional and kinematic testing terminology is consistent with the referenced standards (including Terminology E6 and Terminology F1582), unless otherwise stated.

3.2 Definitions:

3.2.1 *coordinate systems/axes*—Global XYZ orthogonal axes are defined following a right-handed Cartesian coordinate system in which the XY plane is parallel to and co-planar with the superior endplate of the inferior vertebral body. Alternative coordinate systems may be used with justification. The global axes are fixed relative to the inferior vertebral body. Lower case letters, xyz, denote a local moving orthogonal coordinate system attached to the superior vertebral body with directions initially coincident with those of the global XYZ axes, respectively. The 3D motion of the superior relative to inferior vertebra is specified and is to be measured in terms of sequential Eulerian angular rotations about the xyz axes, respectively (z axial rotation, x lateral bend, and y flexion-extension).

3.2.1.1 *origin*—center of the global coordinate system that is located at the posterior medial position on the superior endplate of the inferior vertebral body.

3.2.1.2 *X-axis*—positive X-axis is to be directed anteriorly relative to the specimen's initial unloaded position.

3.2.1.3 *Y-axis*—positive Y-axis is directed laterally (toward the left) relative to the specimen's initial unloaded position.

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.