



Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs¹

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1. Scope

1.1 These test methods specify the materials and methods for the static and dynamic testing of artificial intervertebral discs.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future non-biologic artificial intervertebral discs. These test methods allow comparison of artificial intervertebral discs with different intended spinal locations (cervical, thoracic, and lumbar) and methods of application to the intervertebral spaces. These test methods are intended to enable the user to mechanically compare artificial intervertebral discs and do not purport to provide performance standards for artificial intervertebral discs.

1.3 These test methods describe static and dynamic tests by specifying load types and specific methods of applying these loads. These tests are designed to allow for the comparative evaluation of artificial intervertebral discs.

1.4 These test methods do not purport to address all clinically relevant failure modes for artificial intervertebral discs, some of which will be device specific. For example, these test methods do not address the implant's resistance to expulsion or 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, determining the yield load or moment, and evaluating the stiffness of artificial intervertebral discs.

1.6 Some artificial intervertebral discs 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 use of this standard may involve the operation of potentially hazardous equipment. 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
E6 Terminology Relating to Methods of Mechanical Testing
E466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System
E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials
E1823 Terminology Relating to Fatigue and Fracture Testing
F1582 Terminology Relating to Spinal Implants
F2077 Test Methods For Intervertebral Body Fusion Devices

3. Terminology

3.1 All definitions below supersede definitions contained within Terminologies E6, E1823, F1582, and Practices E466, E467.

3.2 *Definitions:*

3.2.1 *artificial intervertebral disc*—a synthetic structure that is permanently implanted in the disc space between two adjacent vertebral bodies to provide spinal column support and allow intervertebral motion.

3.2.2 *coordinate system/axes*—three orthogonal axes are defined by Terminology F1582. The center of the coordinate system is located at the geometric center of the artificial intervertebral disc. Alternative coordinate systems may be used with justification. The XY-plane is to bisect the superior and inferior surfaces that are intended to simulate the adjacent

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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.