



Designation: F 2077 – 01

Test Methods For Intervertebral Body Fusion Devices¹

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1. Scope

1.1 This test method covers the materials and methods for the static and dynamic testing of intervertebral body fusion device assemblies, spinal implants designed to promote arthrodesis at a given spinal motion segment.

1.2 This test method is intended to provide a basis for the mechanical comparison among past, present, and future non-biologic intervertebral body fusion device assemblies. This test method allows comparison of intervertebral body fusion device assemblies with different intended spinal locations and methods of application to the intradiscal spaces. This test method is intended to enable the user to compare intervertebral body fusion device assemblies mechanically and does not purport to provide performance standards for intervertebral body fusion device assemblies.

1.3 The test method describes 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 intervertebral body fusion device assemblies.

1.4 This test method does not purport to address expulsion testing of intervertebral body fusion device assemblies. However, since expulsion is a potential clinical failure mode, the user should address the implant's resistance to expulsion.

1.5 Guidelines are established for measuring displacements, determining the yield load or moment, evaluating the stiffness, and strength of the intervertebral body fusion device assemblies.

1.6 Some intervertebral body fusion device assemblies 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 *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 1823 Terminology Relating to Fatigue and Fracture Testing²

F 1582 Terminology Relating to Spinal Implants³

3. Terminology

3.1 For definition of terms refer to Terminology E 6, E 1823, and F 1582.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *coordinate system/axes, n*—Three orthogonal axes are defined by Terminology F 1582. The center of the coordinate system is located at the geometric center of the intervertebral body fusion device assembly. The XY plane is to bisect the sagittal plane angle between superior and inferior lines (surfaces) that are intended to simulate the adjacent vertebral end plates. The positive Z axis is to be directed superiorly. Force components parallel to the XY plane are shear components of loading. The compressive axial force is defined to be the component in the negative Z direction. Torsional load is defined to be the component of moment parallel to the Z axis.

3.2.2 *fatigue life, n*—The number of cycles, *N*, that the intervertebral body fusion device assembly can sustain at a particular load or moment before mechanical or functional failure occurs.

3.2.3 *functional failure, n*—Permanent deformation that renders the intervertebral body fusion device assembly ineffective or unable to resist load and/or maintain attachment adequately.

3.2.4 *ideal insertion location, n*—The implant location with respect to the simulated inferior and superior vertebral bodies (polyacetal or metal blocks) dictated by the type, design, and manufacturer's surgical installation instructions.

3.2.5 *intended method of application, n*—Intervertebral body fusion device assemblies may contain different types of stabilizing anchors such as threads, spikes, and knurled surfaces. Each type of anchor has an intended method of application or attachment to the spine.

3.2.6 *intended spinal location, n*—The anatomic region of the spine intended for the intervertebral body fusion device assembly. Intervertebral body fusion device assemblies may be

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

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