Designation: F3631 – 24

Standard Test Method for Assessment of Intra-operative Durability of Intervertebral Body Fusion Devices[1]

This standard is issued under the fixed designation F3631; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the materials and methods for impact testing of lumbar intervertebral body fusion devices (IBFD).

1.2 This test method is intended to provide a basis for the mechanical comparison among nonbiologic IBFD assemblies (the IBFD and associated inserter tool). This test method is intended to enable the user to compare these IBFD assemblies under impact loads to simulate the intra-operative surgical technique used to insert the IBFD.

1.3 The test method describes the impact test by specifying impact energies and specific methods for applying these energies. The tests are designed to allow for the comparative evaluation of IBFD assemblies.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Calibration and Verification of Testing Machines

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F1582 Terminology Relating to Spinal Implants

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

F2077 Test Methods for Intervertebral Body Fusion Devices

F2267 Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

F3292 Practice for Inspection of Spinal Implants Undergoing Testing

3. Terminology

3.1 For definitions of terms, refer to terminology in Practices E4, Terminology F1582, Specification F1839, and Practice F3292.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *coordinate system/axes, n*—for the Insertion Between Foam Blocks method (Annex A1), the center of the coordinate system is located at the geometric center of the foam block assembly. The XY plane is to bisect the sagittal plane angle across the foam blocks that are intended to simulate the adjacent vertebral end plates. The positive Z-axis is to be directed superiorly and should be collinear with the long axis of the inserter instrument and the guide rod. The compressive intraspinal force is defined to be the component in the positive X direction. Impact force is defined to be the force along the negative Z-axis, Fig. 1(a). For the Static Rigid Block method (Annex A2), the XY plane is coplanar with the bottom surface of the pocket that mates with the tip of the IBFD. The positive Z-axis is to be directed superiorly and should be collinear with the long axis of the inserter instrument and the guide rod, Fig. 1(b).

3.2.2 *crack, n*—an externally visible physical discontinuity in the form of a narrow opening that arises from mechanical impact forces.

[1] This test method 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] 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.

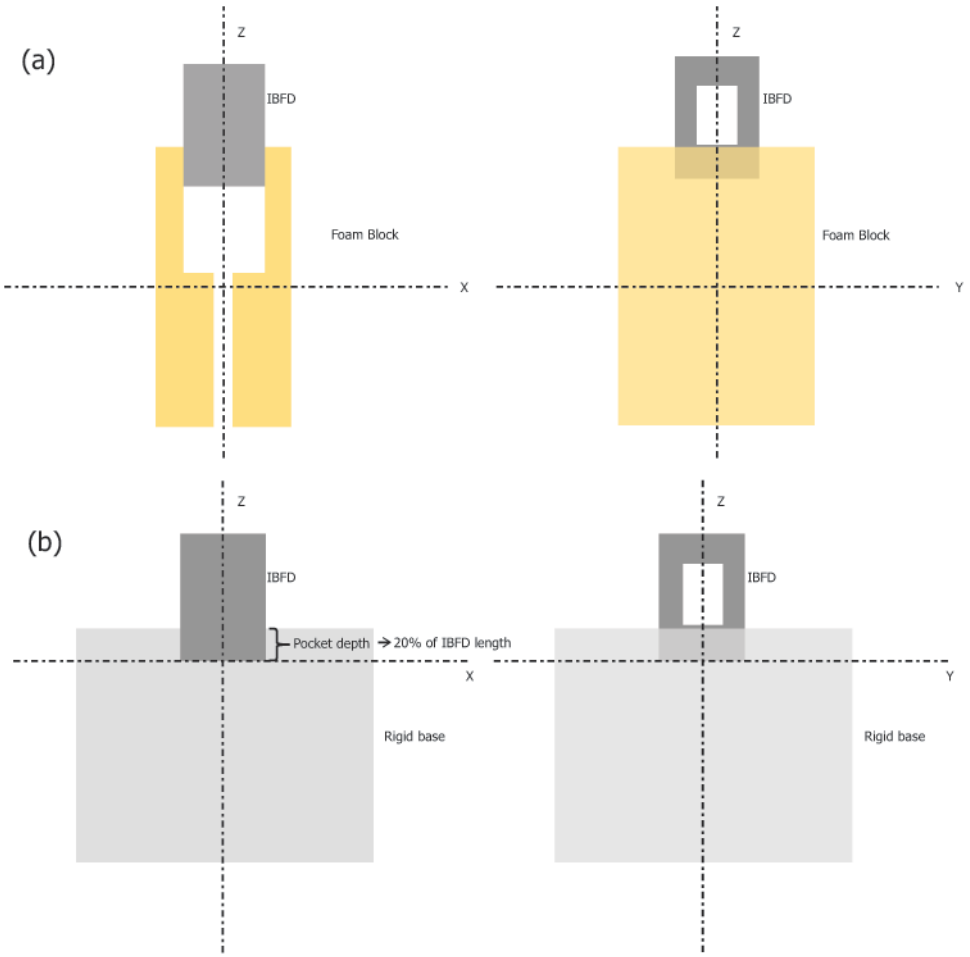

FIG. 1 Coordinate System with Lateral (Left) and Frontal (Right) Views for (a) Insertion Between Foam Blocks Method (Annex A1) Coordinate System; (b) Static Rigid Block Method (Annex A2) Coordinate System

3.2.3 *drop weight, n*—a 1 kg stainless steel structure (similar in weight to a surgical mallet) that is dropped from the appropriate height to simulate an impact hit.

3.2.4 *functional failure, n*—permanent deformation that renders the intervertebral body fusion device assembly ineffective or unable to resist impact force and/or maintain attachment adequately.

3.2.5 *impact energy, n*—the product of the weight of the drop weight and the vertical distance it travels before touching the specimen.

3.2.6 *impact resistance, n*—the number of hits, N, and associated impact energy step level that the intervertebral body fusion device assembly can sustain before mechanical or functional failure occurs.

3.2.7 *inserter, n*—a surgical instrument used to implant the IBFD *in situ* (within the intervertebral disc space) between the two adjacent vertebral bodies. This instrument is attached to the IBFD and then impacted with a mallet during the implantation procedure.

3.2.8 *intervertebral body fusion device (IBFD), n*—a structure that is placed in the disc space between two adjacent vertebral bodies to provide support for eventual arthrodesis of the two adjacent vertebral bodies.

3.2.9 *intervertebral body fusion device (IBFD) assembly, n*—the IBFD and associated inserter instrument.

3.2.10 *intervertebral body fusion device (IBFD) leading portion, n*—the distal section of the IBFD that is initially inserted into the disc space during surgery. This section often contains an IBFD nose.

3.2.11 *intervertebral body fusion device (IBFD) nose, n*—a wedge-shaped feature on the leading portion of certain IBFDs that is intended to assist with insertion during surgery.

3.2.12 *lip, n*—a structure in the foam blocks that is defined at a distance from top surface of the polyurethane foam blocks to act as a hard stop. The hard stop allows for continued impact on the device even after insertion is completed to simulate impact to failure or reach a relevant number of impact hits.

3.2.13 *mechanical failure, n*—that associated with the onset of a new defect in the material (for example, initiation of crack) or breakage.