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.

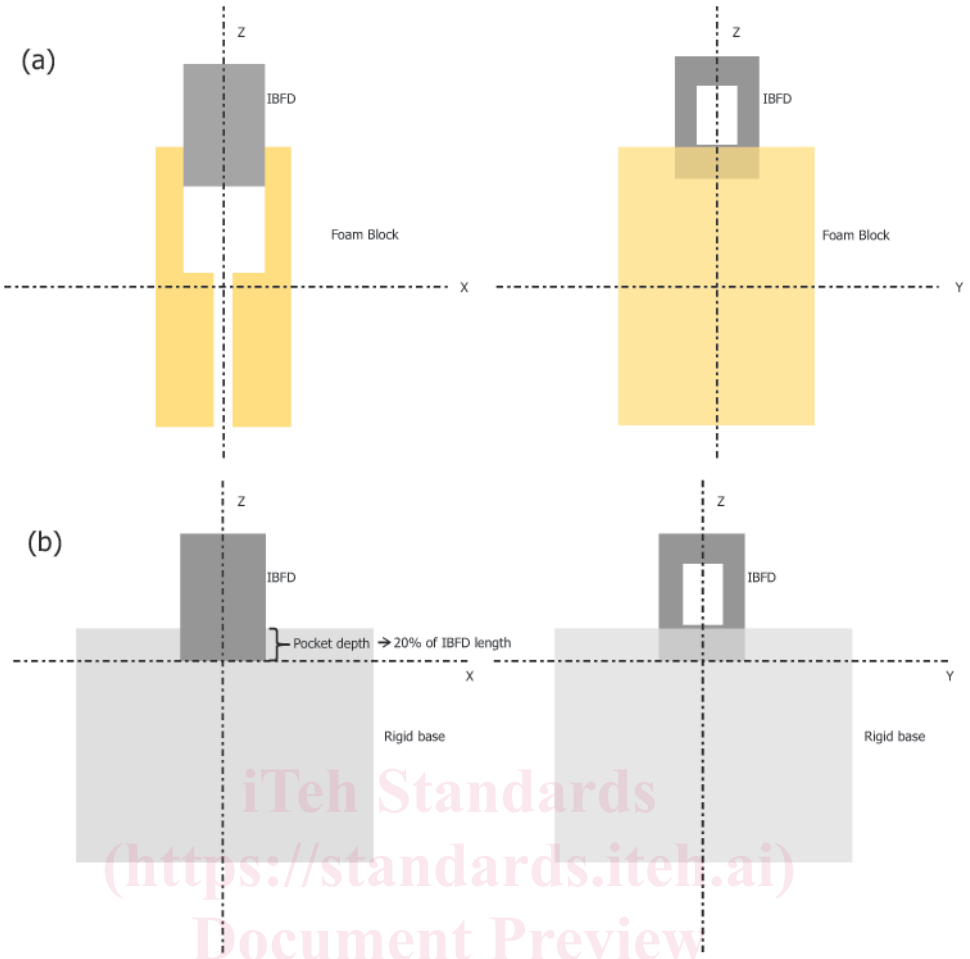

FIG. 1 Coordinate System with Lateral (Left) and Frontal (Right) Views for (a) Insertion Between Foam Blocks Method (Annex A1) Coordinate System; (b) Static Rigid Block Method (Annex A2) Coordinate System

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.

3.2.14 *test block, n*—the component of the test apparatus for mounting the intervertebral body fusion device assembly for the intended test configuration.

4. Summary of Test Method

4.1 This standard contains two options for impact testing of IBFD assemblies. The user of this test method must decide which of these two impact tests is most appropriate to evaluate the impact resistance of the IBFD assembly in question. The user of this test method may choose to use either or both of the tests described in this test method for testing a particular intervertebral body fusion device assembly.

4.2 Annex A1 describes an impact test method that can be used to evaluate both the insertion phase and impact resistance of the IBFD assembly. Intra-operative insertion is simulated using two Grade 40 polyurethane foam (per Specification F1839) test blocks with a simulated preload to represent two adjacent vertebral bodies. A hard stop ("lip") is incorporated into the polyurethane test blocks to allow for continued impact loading until failure or completion of a 40 impact test regimen.

4.3 Annex A2 describes an impact test method that evaluates the impact resistance of the IBFD assembly against a stainless steel block.

4.4 Two options for stair-step loading schemes are provided that can each be used for either method described in Annex A1 or Annex A2.

4.5 Each of these impact test methods should be performed using an IBFD assembly with acceptable clinical performance as a comparator.[3]

5. Significance and Use

5.1 IBFDs can be single-piece or multicomponent designs and can be porous or hollow in nature. Their function is to support the anterior column of the spine to facilitate arthrodesis of the motion segment.

5.2 Intra-operative IBFD assembly failures can result in significant clinical consequences.[4] This test method outlines materials and methods for the comparative characterization and evaluation of the intra-operative impact performance of IBFD assemblies.

5.3 The impact forces applied during a surgical procedure may be highly variable and, therefore, the results from these tests may not directly predict *in vivo* performance. The results, however, can be used to compare mechanical performance of different IBFD assemblies. The tests may also identify the weakest, most likely to fail points in particular IBFD-inserter combinations, thus enabling design improvements.

5.4 Intra-operative clinical failures may be due to several factors, some of which may not be simulated in the current method. For example, off-axis impact loads applied to the IBFD assembly are not simulated in the current method yet may contribute to intra-operative clinical failures in some designs. The user of this standard should consider incorporating such factors into their evaluations.

6. Apparatus

6.1 For apparatus descriptions, see Annex A1 for the Insertion Between Foam Blocks Test Method and Annex A2 for the Static Rigid Block Test Method.

7. Procedure

7.1 For procedures, see Annex A1 for the Insertion Between Foam Blocks Test Method and Annex A2 for the Static Rigid Block Test Method.

8. Report

8.1 For reporting requirements, see Annex A1 for the Insertion Between Foam Blocks Test Method and Annex A2 for the Static Rigid Block Test Method.

9. Precision and Bias

9.1 For precision and bias statements, see Annex A1 for the Insertion Between Foam Blocks Test Method and Annex A2 for the Static Rigid Block Test Method.

10. Keywords

10.1 IBFD; impact; insertion; spinal cage fracture; spinal implants

[3] Palepu, V., et al., "Development of an In Vitro Test Method to Simulate Intra-operative Impaction Loading on Lumbar Intervertebral Body Fusion Devices," *Journal of Biomechanics*, Vol 121, 2021, 110412.

[4] Piple, A. S., et al., "An Analysis of a Decade of Lumbar Interbody Cage Failures in the United States: A MAUDE Database Study," *Spine*, Vol 48, No. 23, 2023, pp. 1652–1657.

ANNEXES

(Mandatory Information)

A1. IMPACT TEST METHOD VIA INSERTION BETWEEN FOAM BLOCKS

A1.1 Scope for Insertion Between Foam Blocks Method

A1.1.1 The Insertion Between Foam Blocks test method can be used to evaluate lumbar IBFDs with parallel endplates.

A1.2 Apparatus

A1.2.1 The test machines will conform to the requirements of Practices E4.

A1.2.2 *Insertion Between Foam Blocks Test Apparatus*—An example schematic of Insertion Between Foam Blocks test setup can be referenced in Fig. A1.1. The test apparatus consists of: (*1*) a preload apparatus which consists of a mechanism for applying a constant axial preload on the foam test blocks and IBFD throughout testing, (*2*) a drop weight apparatus which consists of a drop weight, a guiding rod, an impact platform, and a frame, (*3*) the test specimen which consists of an IBFD and an inserter instrument, and (*4*) polyurethane foam test blocks simulating vertebral body endplates.

A1.2.2.1 *Preload Apparatus*—Two custom Grade 40 polyurethane foam blocks are rigidly mounted to metal pockets for rigid support. A constant preload is required to be transmitted and verified across the IBFD/foam block assembly. A pneumatic cylinder rigidly connected to a horizontal gimbal can be employed for applying intraspinal preload (axial) to the polyurethane foam blocks and implant assembly (X, 0, 0). The metal pockets housing the polyurethane foam blocks are attached to the horizontal gimbals. A compression load cell attached to a digital indicator is housed rigidly in a custom fixture at the opposite end of the pneumatic cylinder to monitor the preload applied to the polyurethane foam blocks. The mass of the moving parts (horizontal gimbal and the foam block pocket) of the preload apparatus should be 2.5 kg ± 2 % (see X1.4 for the rationale). Any displacements or rotations of the fixtures in any degree of freedom other than the horizontal axis (X-axis) should be minimized in order to ensure uniform preload is applied to the IBFD throughout the test. The user of this standard may choose to use an alternative method to apply preload to the test blocks and IBFD that achieves the same result.

A1.2.2.2 *Drop Weight Apparatus*—A vertical drop weight apparatus is used for applying the impact loads on the IBFD/inserter instrument combination. A stainless steel drop weight is used to apply the impact loads. The drop weight shall weigh 1 ± 0.02 kg and can be entirely spherical but shall at least be spherical on the side that contacts the impact platform. The intention behind designing a spherical drop weight is to facilitate a consistent contact of the drop weight with the platform upon impact and minimize any errors related to applying bending moment at the implant-inserter interface caused by off-axis loading. The drop weight should have a hole through the center to sleeve onto the guiding rod. The difference between the internal diameter of the drop weight

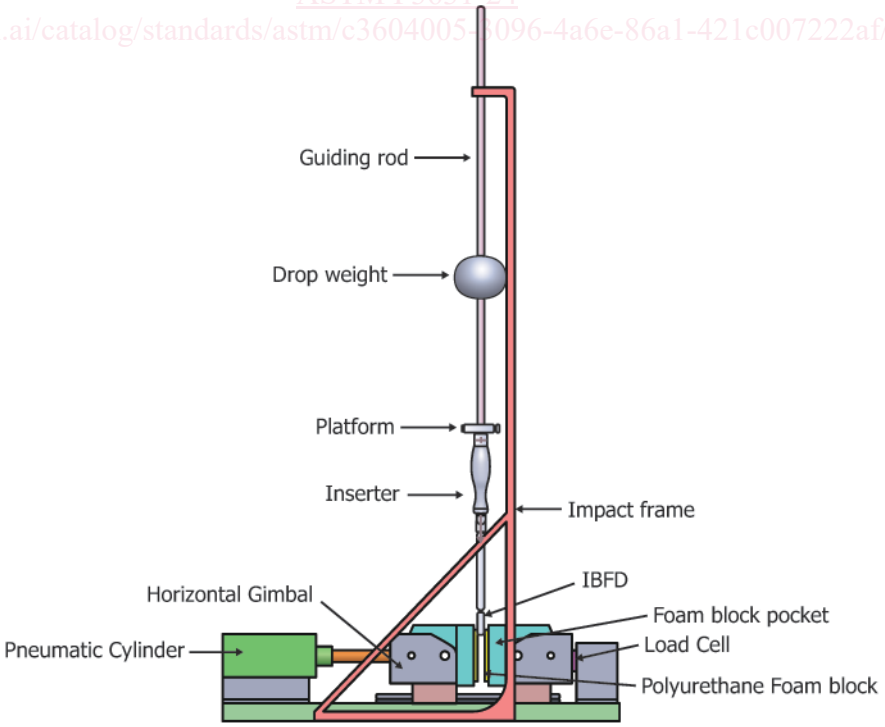

FIG. A1.1 Schematic of the Example Insertion Between Foam Blocks Test Apparatus

center hole and outer diameter of the guiding rod should be 0.25 mm. The drop weight travels along a guiding rod that is long enough to achieve the drop heights specified and pass through the drop weight frame with sufficient overlap. The inferior end of the guiding rod can be rigidly attached to an impact platform made of stainless steel. The impact platform is intended to act as a stop for the drop weight and is rigidly fixed between the guiding rod and the inserter instrument. The weight of the impact platform and guiding rod (if connected) shall be recorded and provided in the test report. The impact platform is not mandatory and direct contact with the inserter can also be considered in the apparatus. Furthermore, the guide rod is not required to be rigidly attached to the inserter as long as vertical drop vector (direction and distance) is maintained. The top end of the guiding rod passes through a circular slotted hole in the impact frame and is unconstrained (0, 0, Z) in the Z-axis to allow vertical movement of the IBFD-inserter combination upon impact loading. Furthermore, the difference in internal diameter of the circular slotted hole and diameter of the guiding rod should be such that sufficient stability is provided to the guiding rod during impact testing and the IBFD as well as inserter are not pre-stressed when the intraspinal load is transmitted across the IBFD. The user of this standard may use an alternate design that achieves the same result. However, care should be taken to center the impact area of the drop weight with the center of the inserter to avoid off-axis impact loading.

A1.2.2.3 *Test Specimen*—The test specimen consists of an IBFD and inserter combination. The inserter should be rigidly attached to the inferior side of the impact platform. The inserter can consist of the actual IBFD inserter designed for the intended use of the implant. If this final design is not used, a worst-case inserter connection should be considered that can be customized to be connected to the impact platform (for example, a threaded connection) or an alternate design for achieving the same result. The weight of the customized impactor should be identical to the impactor used clinically or the difference shall be justified. At the beginning of testing, the IBFD leading portion is placed between the test blocks in the axial preload apparatus, Fig. A1.2.

A1.2.2.4 *Test Blocks*—Grade 40 PCF polyurethane foam blocks per Specification F1839 are machined to a rectangular shape with a flat surface. Grade 40 polyurethane foam is commonly used to simulate dense bone such as that on the vertebral endplates. The foam blocks are machined to have a lip approximately the depth of the implant from the top of the blocks to act as a hard stop for the IBFD. The test blocks are then mounted in the custom metal pocket fixture of the preload apparatus. This design allows the IBFD to be inserted a defined distance while maintaining a constant axial load on the IBFD. The hard stop allows for continued impact loading on the device even after insertion is completed to test the IBFD until failure. Fig. A1.3 describes the foam block design in this example test setup. The foam block should have a sufficient length of foam underneath the lip (hard stop) to ensure the failure of the lip does not occur during the test. The lip thickness should be sufficient to prohibit the device from advancing further. The user may design the setup so that the IBFD is centered along the axis of horizontal preload when it reaches the final insertion depth. The test setup should be designed such that the inserter does not interfere with the foam blocks at any point during the test. The width of the foam block is designed to have at least the width of the device plus 10 mm on either side. The minimum thickness of each foam block

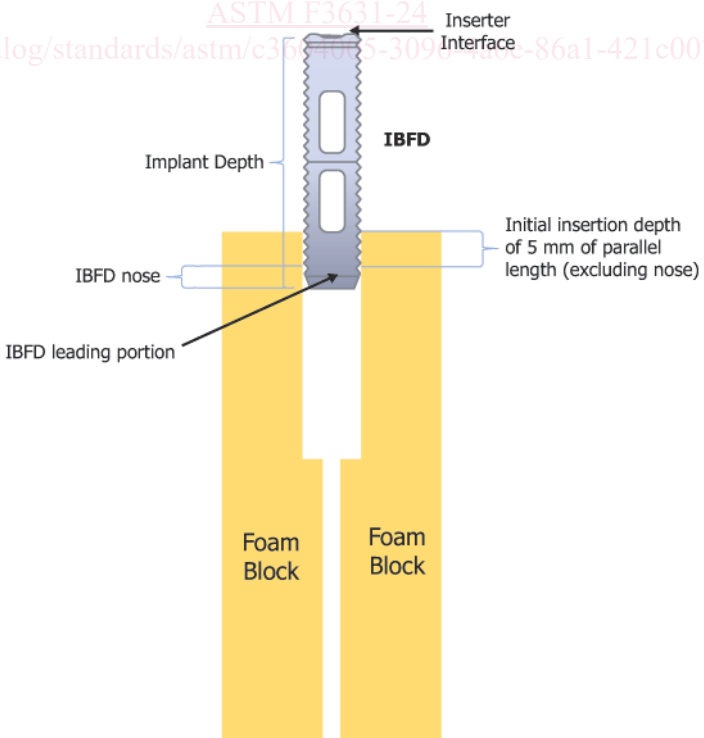

FIG. A1.2 Test Configuration

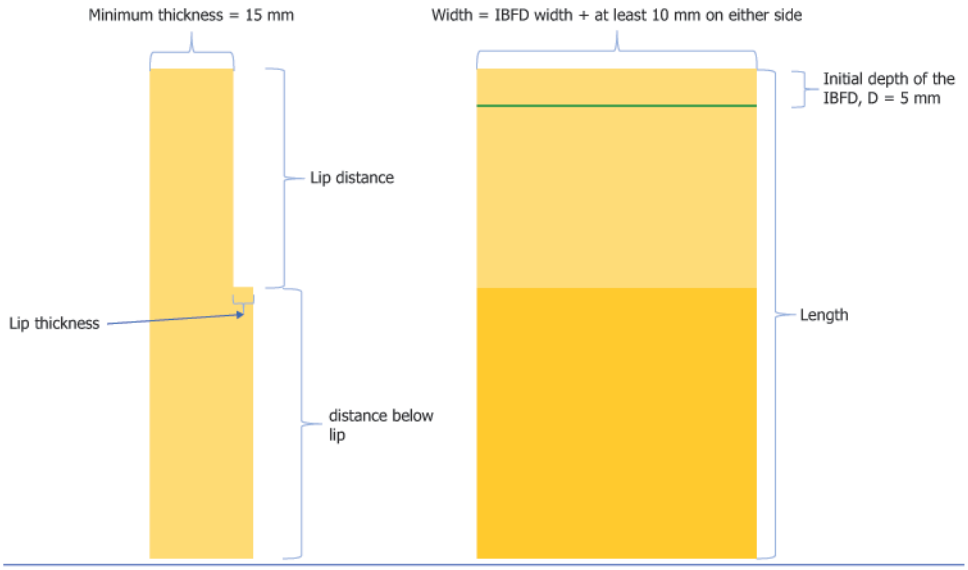

FIG. A1.3 Single Polyurethane Foam Block Design Schematic with Lateral And Frontal Views Respectively

shall be 15 mm. It is important to monitor that the two foam blocks are not touching each other when the intraspinal preload is transmitted across the foam/implant assembly, and throughout the impact testing.

A1.3 Hazards

A1.3.1 The user(s) should take precautions to protect themselves from any potential flying debris through the use of items such as, but not limited to, safety goggles and protective shields.

A1.3.2 The user(s) should protect themselves from any injury related to the drop weight and the preload apparatus.

A1.4 Sampling

A1.4.1 Each pair of polyurethane foam blocks shall be used for one specimen only.

A1.4.2 The test assemblies (that is, IBFD, inserter, and polyurethane blocks) shall be labeled, inspected (per Practice F3292 preferentially), and maintained according to good laboratory practice.

A1.4.3 All tests shall have a minimum of five test samples.

A1.5 Calibration and Standardization

A1.5.1 The load cell and the digital indicator to be used for monitoring intraspinal preload during the experiments shall be calibrated.

A1.6 Procedure

A1.6.1 The foam blocks are to be inserted into the custom fixture pockets so that the positions of the blocks are constrained in the Y and Z directions, and the preload constrains in the X direction.

A1.6.2 The IBFDs are to be placed in between the two prepared foam blocks. The IBFD should be positioned at the center (in axial plane view) of the foam blocks and the leading portion of the IBFD (Fig. A1.2) shall be placed into the foam blocks at the beginning of the testing such that 5 mm of the IBFD parallel endplates are inserted (excluding IBFD nose). This position shall be constant for all the IBFD test samples.

A1.6.3 An intraspinal preload of approximately 200 N shall be applied to the foam blocks throughout the testing using the pneumatic cylinder or other means of static compression. This force of 200 N was selected based on *in vivo* axial load values of subjects lying in a relaxed position.[5] The operator should monitor the consistency of the spikes in intraspinal preload that occur during impact loading to ensure that variability does not affect the repeatability and reproducibility of the test.

A1.6.4 An inserter is to be connected to the IBFD and then the inserter must be rigidly connected to the guiding rod on the opposite end. Furthermore, the alignment of both inserter and guiding rod must be vertical with a tolerance of ±3° (measured with the angle indicator) so that the load is applied along the vertical axis. Alternatively, the guiding rod is not required to be rigidly attached to the inserter as long as the vertical drop vector (direction and distance) is maintained. Impact testing will then be performed using a vertical drop weight apparatus. The inserter should not contact or share load with the foam blocks at any point during the testing.

A1.6.5 The drop weight (1 kg) is to be dropped on the device from the appropriate height (distance measured from bottom edge of drop weight to the impact platform, or top of inserter if platform is not used) that approximates the impact energy based on impact velocity data. Each device will be loaded according to a stair-step impact loading scheme. The user may decide whether they use stair-step impact loading scheme 1 (see Table A1.1) or scheme 2 (see Table A1.2). However, the user shall use the same loading scheme for all the specimens of the test. The tolerance of the drop heights (shown

[5] Kienle, A., Graf, N., and Wilke, H. J., "Does Impaction of Titanium-coated Interbody Fusion Cages into the Disc Space Cause Wear Debris or Delamination?" *The Spine Journal*, Vol 16, No. 2, 2016, pp. 235–242.