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Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements —

Part 2:
Spinal intervertebral body fusion devices

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Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Mechanical requirements **1**
4.1 General 1
4.2 Test Methods 2
4.3 Comparative mechanical performance data 2
4.4 Other considerations 3
Bibliography **5**

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Foreword

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The committee responsible for this document is Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

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Introduction

Spinal intervertebral body fusion devices (IBFDs) are used in the treatment of various spinal pathologies. IBFDs are intended to be placed in between two adjacent vertebral bodies after removal of the interverbal disc to maintain the disc height and provide mechanical stability to the spine until fusion (arthrodesis) occurs.

This standard intends to establish a minimum battery of performance testing necessary during the development of IBFDs. However, certain IBFDs have design features that warrant additional evaluations, and the user of the standard is advised to consider if additional tests/evaluations are necessary.

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Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements —

Part 2: Spinal intervertebral body fusion devices

1 Scope

This document provides requirements for the mechanical assessment of spinal IBFDs used in spinal arthrodesis procedures. This document focuses on mechanical requirements and does not intend to cover all assessments that may be necessary for various types of IBFDs. Additional assessments may be necessary to assess technical aspects of the device not completely covered by the assessments outlined in this document such as, but not limited to, coating characterization, impact testing, expulsion testing, and additive manufacturing process validations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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ASTM F2077, *Test Methods For Intervertebral Body Fusion Devices*

ISO/DIS 23089-2
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ASTM F2267, *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*

ISO 14630:2012, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630:2012 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

4 Mechanical requirements

4.1 General

IBFDs function as load bearing implants that are subjected to the mechanical loads associated with the region of the spine in which the device is implanted. IBDF mechanical assessments shall consider the device's performance under the following loading modes:

– Axial compression: Axial compression loads are the primary mechanical load that IBFDs are subjected to in the body.

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– Compression-shear: IBFDs experience shear loads generated in the spine during activities of daily living and due to compression loads being applied across spinal curvatures (e.g., lumbar and cervical lordosis).

– Torsion: Torsional moments are generated in the spine during activities of daily living, (Torsional properties are most commonly assessed for devices intended to be implanted in the cervical spine).

The user of the standard shall justify not evaluating an IBFD under the loading modes prescribed above in situations where the evaluation is deemed unnecessary.

4.2 Test Methods

The intervertebral body fusion device shall be evaluated using the following test methods unless adequate justification is provided that a particular assessment is unnecessary:

- Axial compression testing: Static and fatigue characteristics (i.e., yield strength, stiffness, and runout load) shall be assessed in accordance with ASTM F2077.

- Compression-shear testing: Static and fatigue characteristics (i.e., yield strength, stiffness, and runout load) shall be assessed in accordance with ASTM F2077.

- Torsion testing: Static and fatigue characteristics (i.e., yield strength, stiffness, and runout torque) shall be assessed in accordance with ASTM F2077. In general, axial rotations are not as high in magnitude in the lumbar spine as in the cervical spine; therefore, a justification may be provided for not subjecting lumbar IBFDs to torsion tests. However, axial rotation still exists in the lumbar spine and lumbar devices that are particularly susceptible to failure in torsion should be evaluated in this loading mode.

- Subsidence testing: Assessment of the resistance to subsidence under axial compression loading shall be conducted in accordance with ASTM F2267.

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Testing should be performed on final, finished versions of the device, or justification should be provided that certain processing steps (e.g., sterilization) do not impact the mechanical performance of the IBFD. The user should perform testing on the worst-case device models/sizes that are determined to present the lowest results (i.e., stiffness, yield strength, runout load) for each test. An engineering justification or an adequately validated computational model can be used to justify this selection of worst-case device(s). See ASTM F2077 and F2267 for the particular reporting requirements for each test.

4.3 Comparative mechanical performance data

Acceptance criteria shall be developed for each of the test methods described in 4.2. These acceptance criteria should be derived from any combination of the following three sources:

(A) ***Table 1:*** Table 1 (see references [3] and [4]) is comprised of optional acceptance criteria derived from aggregated mechanical test data from IBFDs previously cleared by the U.S. Food and Drug Administration through the 510(k) process. The values in Table 1 represent the 5th percentile of the range of devices surveyed. The published data summarized in Table 1 are derived from mechanical testing of single-piece PEEK and metallic designs and does not incorporate testing of more complex designs such as IBFDs with integrated fixation or expandable features. When evaluating more complex IBFDs, differences in test methods and failure modes should be considered to determine if appropriate comparisons can be made to the published mechanical performance values. In addition, the user should take into consideration the fact that posterior lumbar interbody fusion (PLIF) IBFDs are often used in pairs while other lumbar IBFD designs are typically used individually, which is why the optional acceptance criteria for these designs are stratified in Table 1.

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Table 1 — Optional acceptance criteria for cervical and lumbar IBFDs [3,4].

Test Mode	Comparative Parameter	Cervical Device	Lumbar device intended to be implanted in pairs[1]	Lumbar device intended to be implanted individually[2]
Static axial compression	Stiffness (N/mm)*	5 097	5 914	7 670
	Yield load (N)	5 450	6 371	10 799
Static compression-shear	Stiffness (N/mm)	1 492	1 435	2 219
	Yield load (N)	1 464	1 996	3 999
Static torsion	Stiffness (N-m/degree)	0,3	1,0	0,9
	Yield torque (N-m)	3,1	7,0	11,0
Dynamic axial compression	Runout load (N)	1 500	1 440	3 000
Dynamic compression-shear	Runout load (N)	679	972	1 225
Dynamic torsion	Runout torque (N-m)	±1,0	±2,0	±6,0
Subsidence	Block stiffness, Kp (N/mm)	257	289	428

1 For example, posterior lumbar interbody fusion (PLIF) devices

2 For example, transforaminal, anterior, and lateral lumbar interbody fusion (TLIF, ALIF, LLIF) devices

(B) ***Mechanical performance of a legally marketed IBFD with a successful clinical history:*** Acceptance criteria can be based on the mechanical performance assessment of a similarly designed legally marketed IBFD with a successful clinical history. When using predicate devices to establish an acceptance criterion, the similarity between the implant being developed and the similar implant shall be evaluated and demonstrated.

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(C) ***Scientific literature review:*** A scientific literature review can be conducted in order to determine the load levels that the IBFD will be subjected to when implanted. However, interpretation of physiologic load data in the literature is challenging due to the complex loading conditions in the spine and limitations associated with measuring spinal loads. Therefore, this method should be considered only if comparison cannot be made using the previous two options listed above or if the previous options are not accepted by the local regulatory authority. In addition, if literature is used to define acceptance criteria, the user of this document is encouraged to incorporate a safety factor into physiologic loading values determined. Be advised that use of this option can lead to a large variability in derived acceptance criteria.

NOTE Suitable appraisal method for scientific literature data can be found on MEDDEV 2.7/1 rev 4[5]

If device performance does not meet acceptance criteria derived from the options above, clinical data can be provided (and may be required by the local regulatory authority) to demonstrate successful clinical outcomes of the IBFD under development.

Example Acceptance Criteria: A manufacturer may develop an IBFD whose performance exceed all of the optional acceptance criteria listed in Table 1, with the exception of subsidence block stiffness (Kp). However, the manufacturer may be aware of a legally marketed IBFD with a successful clinical history with a lower subsidence block stiffness. The sponsor may then propose the values listed in Table 1 as the acceptance criteria for the majority of test results (Option A), and provide side-by-side testing demonstrating their IBFD exceeds the subsidence testing results of a legally marketed predicate device as the acceptance criteria for subsidence (Option B).

4.4 Other considerations

Coating Characterization: If the IBFD is coated, the strength (tensile and shear) and abrasion resistance of the coating on the device substrate material should be assessed and results should be justified. The user should consider that performance of the coating may be dependant on device geometry, in which

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