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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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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

A list of all parts in the ISO 23089 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 document 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 this document is advised to consider if additional tests/evaluations are necessary.

Additional assessments can 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.

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

Part 2: Spinal intervertebral body fusion devices

1 Scope

This document specifies requirements for the mechanical assessment of spinal intervertebral body fusion devices (IBFDs) used in spinal arthrodesis procedures.

This document focuses on mechanical requirements and does not intend to cover all assessments for various types of IBFDs.

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.

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

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

ASTM F2267, *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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 to which IBFDs are subjected in the body.

— Compression-shear: IBFDs experience shear loads generated in the spine during activities of daily life 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 life (torsional properties are most commonly assessed for devices intended to be implanted in the cervical spine).

In situations where the evaluation of an IBFD under the loading modes prescribed in this clause is deemed unnecessary, the user of this document choosing not to carry out the evaluation shall provide justification for this decision.

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. In general, compression-shear testing on an IBFD should be conducted in the posterior-to-anterior direction. Additional compression-shear testing in other device orientations can be appropriate if the device is particularly susceptible to failure in an alternate shear direction.

— 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.

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 and 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 ASTM 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 [4] and [5]) 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 do 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.

Table 1 — Optional acceptance criteria for cervical and lumbar IBFDs

Test mode	Comparative parameter	Cervical device	Lumbar device intended to be implanted in pairs[a]	Lumbar device intended to be implanted individually[b]
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[c] (N/mm)	257	289	428

[a] For example, posterior lumbar interbody fusion (PLIF) devices.

[b] For example, transforaminal, anterior, and lateral lumbar interbody fusion (TLIF, ALIF, LLIF) devices.

[c] Kp is a symbol for block stiffness as defined in ASTM F2267.

b) Mechanical performance of an IBFD with a successful clinical history as justified by the user of this document: Acceptance criteria can be based on the mechanical performance assessment of a similarly designed 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.

c) Scientific literature review: scientific literature review can be conducted in order to determine the load levels to which the IBFD is subjected 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[3].

If device performance does not meet acceptance criteria derived from the options above, clinical data can be provided to demonstrate successful clinical outcomes of the IBFD under development.

Example acceptance criteria**:** A manufacturer might develop an IBFD whose performance exceeds all of the optional acceptance criteria listed in Table 1, with the exception of subsidence block stiffness (Kp). However, the manufacturer might be aware of a marketed IBFD with a successful clinical history with a lower subsidence block stiffness. The sponsor can 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 that their IBFD exceeds the subsidence testing results of a marketed predicate device as the acceptance criteria for subsidence (option B).

4.4 Other considerations

4.4.1 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 dependent on device geometry, in which case testing of the coating strength and abrasion resistance should potentially be performed on the final, finished device rather than test coupons. Useful information can be found in ISO 17327-1.

The mechanical strength of the IBFD can be impaired by the coating processes itself (related to the techniques involved, use of heat processes). Therefore, the mechanical testing should be performed on the coated IBFD.

4.4.2 Migration/expulsion

An assessment of the risk of migration and expulsion should be performed as compared to devices with successful clinical histories. If the risk assessment concludes that migration/expulsion should be assessed through mechanical testing, a standardized test method should be utilized if available. However, no standardized test method for IBFD migration/expulsion testing was available when this document was published.

4.4.3 Corrosion

If the IBFD is manufactured from raw materials that are susceptible to corrosion, the user of this document should consider this and perform applicable evaluations, such as but not limited to ASTM F2129[1]. Fretting corrosion resistance testing can be applicable in cases when the IBFD consists of two or more metallic parts that contact one another.

4.4.4 Impaction

Failure of IBFDs under the impaction loads that occur during surgical implantation is common (see References [4] and [5]). The user should consider assessment of the risk of IBFD failure under clinically relevant impaction loads that simulate surgical implantation. In addition, the user should consider performing the mechanical testing outlined in this document on IBFD specimens that have undergone clinically relevant impaction loading.

4.4.5 Additive manufacturing

If the IBFD is manufactured via additive manufacturing, the user of this document should take into account the variability and technology specific challenges of the additive manufacturing process when assessing the IBFD. Of specific concern is ensuring that the worst-case build conditions are captured in the performance testing of the device (i.e. build location, build parameters, and material re-use), as well as the impact of any post-processing steps. Additionally, for IBFDs incorporating a lattice structure, the following elements shall be assessed: residual manufacturing material removal, orientation of the lattice structure, and ensuring the chosen AM technology can accurately make the lattice structure.