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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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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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).