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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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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.