
**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	4
4.4.1 Coating characterization	4
4.4.2 Migration/expulsion	4
4.4.3 Corrosion	4
4.4.4 Impaction	4
4.4.5 Additive manufacturing	4
Bibliography	5

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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*.

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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 intervertebral 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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