Doc: MHD02 (28421) WC
August 2025

BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण — प्रत्यारोपण योग्य स्पाइनल उपकरणों का यांत्रिक परीक्षण — पूर्वकाल समर्थन का उपयोग करके स्पाइनल इम्प्लांट असेंबली के लिए थकान परीक्षण विधि

Draft Indian Standard

Implants for Surgery — Mechanical Testing of Implantable Spinal Devices — Fatigue Test Method for Spinal Implant Assemblies Using an Anterior Support

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: **05 September 2025**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

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International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10243, Tools for pressing — Compression springs with rectangular section — Housing dimensions and colour coding	IS 16796 : 2022/ ISO 10243:2019, Tools for pressing – Compression springs with rectangular section – Housing dimensions and colour coding (First Revision)	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ASTM F1717	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (Second Revision)'.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 12189: 2008 or kindly contact:

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SCOPE

This International Standard specifies methods for fatigue testing of spinal implant assemblies (for fusion or motion preservation) using an anterior support. It is intended to provide a basis for the assessment of intrinsic static and dynamic strength of spinal implants.