Doc: MHD02 (28484) WC
August 2025

**BUREAU OF INDIAN STANDARDS**

**DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY**



*भारतीय मानक मसौदा*

# सर्जरी के लिए प्रत्यारोपण — कुल इंटरवर्टेब्रल स्पाइनल डिस्क प्रोस्थेसिस का घिसाव

## भाग 3 प्रतिकूल गतिज स्थितियों के तहत काठ कृत्रिम अंगों के परीक्षण के लिए प्रभाव-घिसाव परीक्षण और संबंधित पर्यावरणीय स्थितियां

*Draft Indian Standard*

# Implants for Surgery — Wear of Total Intervertebral Spinal Disc Prostheses

## Part 3 Impingement-Wear Testing and Corresponding Environmental Conditions for Test of Lumbar Prostheses Under Adverse Kinematic Conditions

ICS 11.040.40

| | |
|---|---|
| Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02 | Last date for comments: **24 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.

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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:

| *International Standard* | *Corresponding Indian Standard* | *Degree of Equivalence* |
|---|---|---|
| ISO 4965-1, Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 1: Testing systems | IS 17417 (Part 1):2020**,** Metallic Materials - Dynamic Force Calibration for Uniaxial Fatigue Testing Part 1: Testing Systems | Identical |
| ISO 18192-1, Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test | MHD02 (28482), Implants for Surgery — Wear of Total Intervertebral Spinal Disc Prostheses Part 1: Loading and Displacement Parameters for Wear Testing and Corresponding Environmental Conditions for Test | 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* |
|---|---|
| ISO 23788 | Metallic materials — Verification of the alignment of fatigue testing machines |

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 18192-3: 2017 or kindly contact:

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## SCOPE

This document defines a test procedure to simulate and evaluate lumbar spinal disc prostheses wear under adverse impingement conditions.