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**BUREAU OF INDIAN STANDARDS**

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*भारतीय मानक मसौदा*

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

## भाग 2 नाभिक प्रतिस्थापन

*Draft Indian Standard*

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

## Part 2 Nucleus Replacements

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.

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 14242-2, Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement | IS 19066 (Part 2) : 2025**,** Implants for Surgery — Wear of Total Hip-Joint Prostheses Part 2: Methods of Measurement | 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 |

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 18192-2: 2010 or kindly contact:

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**Bureau of Indian Standards**
**Manak Bhawan**
**9 Bahadur Shah Zafar Marg**
**New Delhi 110002**
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## SCOPE

This part of ISO 18192 defines a test procedure for spinal nucleus prostheses under the relative angular movement conditions specified by ISO 18192-1.

This part of ISO 18192 is applicable to both lumbar and cervical prostheses. It is not applicable to total disc replacements and facet joint replacements. The method includes wear and fatigue testing. Additional mechanical tests such as creep tests can be required.

This part of ISO 18192 does not reproduce the complex in vivo loads and motions. The wear and fatigue data obtained with this test method will enable comparison between different types of implant but can differ from the clinical wear performance. The user of this part of ISO 18192 should consider running additional tests addressing specific safety issues of the individual implant design to be tested.