

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
सर्जरी के लिए प्रत्यारोपण — कुल इंटरवर्टेब्रल स्पाइनल डिस्क
प्रोस्थेसिस का घिसाव

भाग 1 घिसाव के परीक्षण के लिए लोडिंग और विस्थापन मापदंड और
परीक्षण के लिए संबंधित पर्यावरणीय स्थितियां

Draft Indian Standard

**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**

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)

Amendment 1 published in 2018, to 18192-1: 2011 will be given at the end of this publication.

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:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
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

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 18192-1: 2011 or kindly contact:

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SCOPE

This part of ISO 18192 defines a test procedure for the relative angular movement between articulating components, and specifies the pattern of the applied force, speed and duration of testing, sample configuration and test environment for use for the wear testing of total intervertebral spinal disc prostheses.

Both lumbar and cervical prostheses are addressed. This part of ISO 18192 is not applicable to partial disc replacements, such as nucleus replacements or facet joint replacements. The test method focuses on wear testing. Additional mechanical tests, such as fatigue testing, can be required.

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