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भारतीय मानक मसौदा

**सर्जरी के लिए प्रत्यारोपण — रीढ़ की हड्डी के प्रत्यारोपण का
पूर्व-नैदानिक यांत्रिक मूल्यांकन और विशेष अपेक्षाएँ
भाग 2 रीढ़ की हड्डी के कशेरुकाओं के बीच की हड्डी जोड़ने वाले उपकरण**

Draft Indian Standard

**Implants for Surgery — Pre-Clinical Mechanical
Assessment of Spinal Implants and Particular
Requirements**

Part 2 Spinal Intervertebral Body Fusion Devices

ICS 11.040.40

Orthopaedic Instruments, Implants and
Accessories Sectional Committee, MHD 02

Last date for comments: **19 October 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:

- Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’.
- 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 14630, Non-active surgical implants — General requirements	IS 18076:2023 Non-active surgical implants - General requirements	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:

<i>International Standard/ Other Publication</i>	<i>Title</i>
ASTM F2077	Test Methods For Intervertebral Body Fusion Devices
ASTM F2267	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

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 23089-2: 2021 or kindly contact:

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SCOPE

This document specifies requirements for the mechanical assessment of spinal intervertebral body fusion devices (IBFDs) used in spinal arthrodesis procedures.

This document focuses on mechanical requirements and does not intend to cover all assessments for various types of IBFDs.