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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण — कुल टखने के जोड़ के कृत्रिम अंग का घिसाव — भार या विस्थापन नियंत्रण के साथ घिसाव-परीक्षण मशीनों के लिए लोडिंग और विस्थापन मापदंड और परीक्षण के लिए संबंधित पर्यावरणीय स्थितियाँ

Draft Indian Standard

Implants for Surgery — Wear of Total Ankle-Joint Prostheses — Loading and Displacement Parameters for Wear-Testing Machines with Load or Displacement Control and Corresponding Environmental Conditions for Test

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:

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 14243-2, Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement	IS 18075 (Part 2): 2023 Implants for surgery – Wear of total knee-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 22622: 2019 or kindly contact:

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SCOPE

This document specifies the relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total ankle-joint prostheses in wear-testing machines with load or displacement control.

NOTE — This document is based on the method described by ISO 14243-1 and ISO 14243-3 and allows for the use of the same test equipment as for total knee replacement wear testing.