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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण — कूल्हे के जोड़ के कृत्रिम अंगों के लिए सिरेमिक ऊरु सिर के प्रभाव प्रतिरोध का निर्धारण

Draft Indian Standard

Implants for Surgery — Determination of Impact Resistance of Ceramic Femoral Heads for Hip Joint Prostheses

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: **05 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 7206-10, Implants for surgery — Partial and total hip-	IS 12375 (Part 10) :2023 ISO 7206-10: 2018, Implants for	Identical

joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads	surgery - Partial and total hip-joint prostheses Part 10 Determination of resistance to static load of modular femoral heads	

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 197-1	Copper and copper alloys — Terms and definitions — Part 1: Materials
ISO 4288	Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture

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 11491: 2017 or kindly contact:

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SCOPE

This document specifies two alternative test methods for determining the impact resistance of ceramic femoral heads for hip joint prostheses.