

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
सर्जरी के लिए प्रत्यारोपण — आर्थोपेडिक संयुक्त कृत्रिम अंग
भाग 1 घुटने के CT डेटा से पैरामीट्रिक 3D हड्डी मॉडल बनाने की प्रक्रिया

Draft Indian Standard

Implants for Surgery — Orthopaedic Joint Prosthesis
Part 1 Procedure for Producing Parametric 3D Bone Models
from CT Data of the Knee

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:

- 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 7207-1, Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions	IS 12376 (Part 1): 2015, Implants for surgery - Components for partial and total knee joint prostheses: Part 1 classification, definitions and designation of dimensions (Second Revision)	Identical
ISO 14971, Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019, Medical devices - Application of risk management to medical devices First Revision	Identical
ISO 21536, Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants	IS 19180 : 2025, Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint Replacement implants	Identical
IEC/TR 60788, Medical electrical equipment — Glossary of defined terms	IS/IEC/TR 60788 : 2004, Medical electrical equipment - Glossary of defined terms	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>
IEC 61223-2-6	Evaluation and routine testing in medical imaging departments — Part 26: Constancy tests — Imaging performance of computed tomography X-ray equipment

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 19233-1: 2017 or kindly contact:

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SCOPE

This document provides requirements for capturing necessary bone geometries, when using a medical X-ray computed tomography apparatus, to provide the information for applications such as preoperative planning, surgical navigation, robotic surgeries, patient matched instruments and personalized total knee joint prosthesis. The conditions to scan images of bones and the conditions to reconstruct three-dimensional bone models are provided.

NOTE — Requirements for the competence of testing laboratories appropriate to help to ensure the reliability and accuracy of the computational measurements can be found in ISO/IEC 17025.