Doc: MHD02 (25875)WC
June 2024

BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

गैर-सक्रिय सर्जिकल प्रत्यारोपण - संयुक्त प्रतिस्थापन प्रत्यारोपण - घुटने के जोड़ प्रतिस्थापन प्रत्यारोपण के लिए विशिष्ट आवश्यकताएं

(IS/ISO 21536 : 2007 का पहला पुनरीक्षण)

Draft Indian Standard

Non-Active Surgical Implants — Joint Replacement Implants — Specific Requirements for Knee-Joint Replacement Implants

(First Revision of IS/ISO 21536 : 2007)

ICS 11.040.10

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: **17 July 2024**

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 7207-2, Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials	MHD02 (25841), IS 12376 (Part 2) : 20XX, Implants for surgery — Components for partial and total knee joint prostheses: Part 2 Articulating surfaces made of metal, ceramic and plastics materials	Modified
ISO 5834-1, Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form	IS/ISO 5834-1 : 2005, Implants for surgery - Ultra – High Molecular - Weight polyethylene: Part 1 powder form	Identical
ISO 7207-1:2007, Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions	IS 12376 (Part 1) : 2015/ISO 7207-1 : 2007, Implants for surgery - Components for partial and total knee joint prostheses: Part 1 classification, definitions and designation of dimensions (Second Revision)	Identical
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 12572 (Part 1) : 1994/ISO 10993-1, Biological Evaluation of Medical Devices - Part 1 : Guidance on Selection of Tests	Identical
ISO 14243-1, Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test	IS 18075 (Part 1) : 2023/ ISO 14243-1:2009, Implants for surgery— Wear of total knee-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test	Identical
ISO 14243-2, Implants for surgery — Wear	IS 18075 (Part 2) : 2023/ ISO 14243-1:2016, Implants for	Identical

of total knee-joint prostheses — Part 2: Methods of measurement	surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement	
ISO 14243-3, Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	IS 18075 (Part 3) : 2023/ISO 14243-3:2014, Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	Identical
ISO 14630, Non-active surgical implants — General requirements	IS 18076 : 2023/ ISO 14630: 2012, Non-active surgical implants - General requirements	Identical
ISO 14879-1, Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays	IS 18125 (Part 1) : 2023/ISO 14879-1: 2020, Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays	Identical
ISO 21534:2007, Non-active surgical implants — Joint replacement implants — Particular requirements	IS/ISO 21534 : 2007, Non - Active surgical implants - Joint replacement implants - Particular 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:

International Standard/ Other Publication	*Title*
ISO 14243-5	Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint
ASTM F648	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
ASTM F1223	Standard Test Method for Determination of Total Knee Replacement Constraint
ASTM F2722	Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops
ASTM F2723	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
ASTM F2724	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation
ASTM F2777	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion

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ASTM F3210	Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions

In reporting the result of a test or analysis made in accordance with this standard, is to be rounded off, its shall be done 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 21536 : 2023 or kindly contact:

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SCOPE

This document specifies requirements for knee-joint replacement implants. Regarding safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer and methods of test.

This document applies to both total and partial knee joint replacement implants. It applies to these replacements both with and without the replacement of the patella-femoral joint. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of knee replacement implants, but for some specific knee replacement implant types, some considerations, not specifically covered in this document, can be applicable. Further details are given in 7.2.1.2.

The requirements which are specified in this document are not intended to require the re-design or re-testing of implants which have been legally marketed and for which there is a history of sufficient and safe clinical use. For such implants, compliance with this document can be demonstrated by providing evidence of the implant’s sufficient and safe clinical use.