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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

गैर-सक्रिय सर्जिकल प्रत्यारोपण - संयुक्त प्रतिस्थापन प्रत्यारोपण - कूल्हे-संयुक्त प्रतिस्थापन प्रत्यारोपण के लिए विशिष्ट आवश्यकताएं

(IS/ISO 21535 : 2007 का पहला पुनरीक्षण)

Draft Indian Standard

Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint Replacement implants

(First Revision of IS/ISO 21535 : 2007)

ICS 11.040.40

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 7206-12 Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells	MHD02 (24243), IS 12375 (Part 12) : 2024, Implants for Surgery — Partial and Total Hip Joint Prostheses Part 12 Deformation Test Method for Acetabular Shells (ISO 7206-12 : 2016, MOD)	Modified
ISO 7206-13, Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components	MHD02 (24242), IS 12375 (Part 13) : 2024, Implants for Surgery — Partial and Total Hip-Joint Prostheses Part 13 Determination of Resistance to Torque of Head Fixation of Stemmed Femoral Components (ISO 7206-13 : 2016, MOD)	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 7206-1 : 2008 Implants for surgery - Partial and total hip joint prostheses: Part 1 classification and designation of dimensions	IS 12375 (Part 1) : 2015/ISO 7206-1 : 2008 Implants for surgery - Partial and total hip joint prostheses: Part 1 classification and designation of dimensions (Second Revision)	Identical
ISO 7206-2, Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials	IS 12375 (Part 2) : 2018/ ISO 7206-2:2011 Implants for surgery - Partial and total hip joint prostheses: Part 2 articulating surfaces made of metallic, ceramic and plastics materials (First Revision)	Identical
ISO 7206-4, Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components	IS 12375 (Part 4) : 2016/ ISO 7206-4 : 2010 Implants for surgery - Partial and total hip joint prostheses: Part 4 determination of endurance properties and performance of stemmed femoral components (First Revision)	Identical
ISO 7206-6, Implants for surgery — Partial	IS 12375 (Part 6) : 2018/ISO 7206-6:2013	Identical

and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components	Implants for surgery - Partial and total hip joint prostheses: Part 6 endurance properties testing and performance requirements of neck region of stemmed femoral components (First Revision)	
ISO 7206-10, Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads	IS 12375 (Part 10) : 2023/ ISO 7206-10: 2018 Implants for surgery Partial and total hip-joint prostheses Part 10 Determination of resistance to static load of modular femoral heads	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 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
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:

International Standard/ Other Publication	*Title*
ISO 6475	Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods
ISO 11491	Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses
ISO 14242-1,	Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
ISO 14242-2,	Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement
ISO 14242-3,	Implants for surgery — Wear of total hip-joint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test
ISO 14242-4,	Implants for surgery — Wear of total hip-joint prostheses — Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading
ASTM F543	Standard Specification and Test Methods for Metallic Medical Bone Screws

ASTM F648	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
ASTM F1820	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F1875	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2009	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
ASTM F2033	Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials
ASTM F2345	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
ASTM F2580	Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis
ASTM F2582	Standard Test Method for Impingement of Acetabular Prostheses
ASTM F3018	Standard Guide for Assessment of Hard-on-Hard Articulation Total Hip Replacement and Hip Resurfacing Arthroplasty Devices
ASTM F3047M	Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations
ASTM F3090	Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement
ASTM F3143	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings Under Standard Conditions Using a Reciprocal Friction Simulator
ASTM F3446	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator

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 21535:2023 or kindly contact:

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SCOPE

This document specifies requirements for hip-joint replacement implants. With regard to 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 hip joint replacement implants. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of hip replacement implants, but for some specific hip 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 retesting 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.