Doc: MHD02(25897)WC

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण - घुटने के संपूर्ण कृत्रिम अंग का घिसाव

भाग 5: पेटेलोफेमोरल जोड़ का टिकाव

Draft Indian Standard

Implants for Surgery — Wear of Total Knee Prostheses

Part 5: Durability Performance of the Patellofemoral Joint

ICS 11.040.40

Orthopaedic Instruments, Implants and Last date for comments: **18 July 2024**Accessories Sectional Committee, MHD 02

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:

Doc: MHD02(25897)WC

June 2024

International Standard	Corresponding Indian Standard	Degree of Equivalence
ISO 5833, Implants for surgery — Acrylic resin cements	IS 8641 : 2015 ISO 5833 : 2002 Implants for	Identical
Activité résin écinents	surgery - Acrylic resin cements	
	(Third Revision)	
ISO 7207-1, Implants for surgery	IS 12376 (Part 1): 2015	Identical
— Components for partial and	ISO 7207-1 : 2007 Implants for	
total knee joint prostheses —	surgery - Components for partial	
Part 1: Classification, definitions	and total knee joint prostheses:	
and designation of dimensions	Part 1 classification, definitions	
	and designation of dimensions	
	(Second Revision)	
ISO 14243-1, Implants for	IS 18075 (Part 1): 2023	Identical
surgery — Wear of total knee-	ISO 14243-1:2009 Implants for	
joint prostheses — Part 1:	surgery – Wear of total knee-	
Loading and displacement	joint prostheses – Part 1: Loading	
parameters for wear-testing	and displacement parameters for	
machines with load control and	wear-testing machines with load	
corresponding environmental	control and corresponding	
conditions for test	environmental conditions for test	
ISO 14243-2, Implants for	IS 18075 (Part 2): 2023	Identical
surgery — Wear of total knee-	ISO 14243-2: 2016 Implants for	
joint prostheses — Part 2:	surgery – Wear of total knee-	
Methods of measurement	joint prostheses – Part 2:	
XGO 14040 0 X 1 1 1 6	Methods of measurement	*1
ISO 14243-3, Implants for	IS 18075 (Part 3): 2023	Identical
surgery — Wear of total knee-	ISO 14243-3:2014 Implants for	
joint prostheses — Part 3:	surgery Wear of total knee-joint	
Loading and displacement	prostheses Part 3 Loading and	
parameters for wear-testing	displacement parameters for	
machines with displacement	wear-testing machines with	
control and corresponding environmental conditions for test	displacement control and	
environmental conditions for test	corresponding environmental conditions for test	
	conditions for test	

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 14243-5: 2019 or kindly contact:

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Doc: MHD02(25897)WC June 2024

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Doc: MHD02(25897)WC

June 2024

SCOPE

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