BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02)	19	10 December 2024, Tuesday 11:00 AM
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=m4e0b7ccf9576bdea015740a54b263d72 **Meeting Number**: 2514 834 8934 **Password**: Mhd02@19		
Chairperson	**Dr Sudhir Kumar** (*In Personal capacity*)	
Member Secretary	Vinit Vidyadhar Bansod Scientist-C/Deputy Director, MHD, BIS	

ITEM 0 GENERAL

0.1 Welcome Address by Member Secretary

0.2 Opening Remarks by Chairperson

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 18th meeting of Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02) held on 09 August 2024 approved by the Chairperson was circulated to the members through BIS portal as well as email vide letter no: MHD02/A2.18 dated 07 September 2024.

1.2 No comments have been received so far.

The Committee may kindly formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02) is as follows:

a) *To formulate Indian Standards for instruments used in orthopaedic surgery and*

orthopaedic implants (excluding cardio-vascular and neuro-surgical implants) such as bone holding forceps, bone nail, bone cutting saws and bone drills, etc.

b) *Liaison with the ISO Technical and Sub-committees:*

i) *ISO/TC 150 'Implants for surgery' (P-member)*

ii) *ISO/TC 150/SC 1 'Materials' (P-member)*

iii) *ISO/TC 150/SC 4 'Bone and joint replacements' (P-member)*

iv) *ISO/TC 150/SC 5 'Osteosynthesis and spinal devices' (P-member)*

The Committee may please note.

2.2 The present composition of Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02) is enclosed at ***Annexure A***.

2.3 The attendance of members in Sectional Committee meetings is essential for its efficient and effective functioning. Accordingly, any member remaining absent from two consecutive meetings and/or fifty percent or more meetings of the Sectional Committee in a year will become automatically disqualified to continue as the member of the Sectional Committee.

The Committee may please note.

2.4 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned considering that non-industry representation should not be less than two-third of the committee composition, as far as possible.

The committee may please note and review the composition.

ITEM 3 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

3.1 The following draft Indian Standards / Amendments have been sent for wide circulation:

Sl. No.	Document No.	Title	Technical Comments received (Yes/No)
1.	MHD 2 (26402)	Kuntscher Diamond Pointed Awl Specification First Revision	No*

2.	MHD 2 (26401)	Pin Chuck for Introducing Steinman Pins Specification First Revision	No*
3.	MHD 2 (26417)	Drivers for Kuntscher Nail Specification First Revision	No*
4.	MHD 2 (26447)	Orthopaedic Staple Punch Specification First Revision	No*
5.	MHD 2 (26446)	Hammer for Kuntscher Nail Extractor Specification First Revision	No*
6.	MHD 2 (26444)	Orthopaedic Staple Extractor — Specification First Revision	No*
7.	MHD 2 (26442)	Extractor for Kuntscher Nail Specification Part 2 Striker Type First Revision	No*
8.	MHD 2 (26437)	Extractor for Kuntscher Nail Specification Part 1 Handle Type First Revision	No*
9.	MHD 2 (26450)	Orthopaedic Staple Inserter Specification First Revision	No*
10.	MHD 2 (26449)	Orthopaedic Staple Starter Specification First Revision	No*
* *Commentors agree with the draft*			

The Committee may consider finalizing the documents as no technical comments have been received.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 There are no draft Indian Standards/amendments are ready for wide circulation.

The Committee may kindly note.

4.2 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user-friendly interface and helps faster compilation and analysis of comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.

The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 List of approved subjects for which working drafts are under preparation.

5.1.1 WG for Surgical Power tools

Title of WG: MHD 02 : P3 : WG1 - Surgical Power Tools Working Group

Scope of WG: Standardization in the field of Orthopedic Surgical Power Tools

Task 1: Preparation of working draft of,

a. Battery Operated Saw
b. High-Speed Pneumatic Drill
c. Cannulated Battery Drill
d. Battery Operated Drill
e. Micromotor Drill, &
f. Oscillating Saw with Drill

Composition:

Sl. No.	*Experts*
1.	Dr. V. Koteswara Rao, CSIR-NCL – Project Leader
2.	Healthium Medtech (*for components related to drill*) - *(nomination awaited)*
3.	Manman Manufacturing Company Ltd. (*Manufacturer*) - *(nomination awaited)*

5.1.2 WG for Reconstruction Sets

Title of WG: MHD 02 : P2 : WG1-Reconstruction Sets Working Group

Scope of WG: Standardization in the field of Orthopedic Reconstruction and Repair Sets

Task 1: Preparation of working draft of,

a. Single/ Double Bundle ACL Reconstruction Set + PCL Reconstruction Set
b. Meniscal repair Set
c. Bankart repair Set, and
d. Rotator Cuff repair Set

Composition:

Sl. No.	*Experts*
1.	Chetan Meditech Pvt. Ltd. (BioTekortho), Gujarat - *(nomination awaited)*
2.	GESCO Healthcare, Chennai, Tamil Nadu - *(nomination awaited)*
3.	Dr. Vamsi Krishna Balla, CSIR-CGCRI, Kolkata

The Committee may kindly note.

5.2 Commenting on P-Drafts by Members of Technical Committee

5.2.1 P-Draft is the stage where members of the concerned technical committee can support or reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the Technical Committee in a year will automatically be disqualified to continue as a member.

5.2.2 The members may examine the P-Draft document(s) whenever under circulation and

offer comments as per the following options:

(a) Agree

(b) Agree (with comments*)

(c) Don't agree (with comments*)

(d) No Comments, as it is not related to my area of expertise.

5.2.3 The comments on P- Drafts shall be made only through the Standardization Portal.

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

7.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also define thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental and economic consideration.

The Committee may kindly deliberate.

7.2 New subject for standards formulation, received from DGHS, GoI.

1) Arthroscopy Work Station

The Committee may kindly deliberate.

ITEM 8 TECHNICAL ISSUES

8.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization. The details of membership held in various Technical

Committees/Subcommittees of ISO are given below:

Sl. No.	Liaison Committee of ISO	Type of Membership
1.	ISO TC 150 - Implants for surgery	Participating Member
2.	ISO TC 150 / SC 1 - Materials	Participating Member
3.	ISO TC 150 / SC 4 - Bone and joint replacements	Participating Member
4.	ISO TC 150 / SC 5 - Osteosynthesis and spinal devices	Participating Member

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO seeking votes/comments. The members should carefully examine the documents taking into consideration nation's interests and send the comments to BIS keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation. The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

The Committee may kindly note.

9.1.3 The Indian Delegation comprising of the following delegates attended the WG and Plenary meetings of **ISO TC 150** - Implants for surgery, **ISO TC 150 / SC 1** – Materials, and **ISO TC 150 / SC 4** - Bone and joint replacements held at Berlin, Germany from 09-13 September 2024.

1) Dr. Kantesh Balani, IIT Kanpur (MHD-02)

2) Dr. Vamsi K. Balla, CSIR-CGCRI, Kolkata (MHD-02)

3) Shri Vinit Vidyadhar Bansod, Sc-C/DD, (MS, MHD-02)

4) Ms Gayathri Nair, Meril Lifesciences, (MHD-06)

5) Shri Pawan Kumar, Sc-B/AD, (MS, MHD-06)

Delegates may present their report and share their key takeaways with the Committee

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 Participation of the experts on WGs of ISO TCs will be on Project basis. The Sectional Committee will review, establish and indicate the **Level of Interest** [Level H (High) and M(Medium)] in respect of each of the NWIPs or draft standard ballots received from ISO.

It is envisaged that the projects of standards development or revisions are to be identified at the nascent stages (as mentioned below) while assigning priorities.

- Preliminary stage = Preliminary work item (PWI)
- Proposal stage = New work item proposal (NP)
- Preparatory stage = Approved work item (AWI)
- Committee stage = Committee draft (CD)

- Review of Existing Standard = Systematic Review (SR)

Experts for the subjects will be identified from the committee or outside the committee and will be the **designated experts** who will later act as face and voice of BIS for that project at the international level.

The designated expert shall have the responsibilities of sharing detailed comments on the Drafts/documents received from ISO/IEC for the assigned projects, helping the SC in putting together the rationale for proposing NWIPs and firming up proposals for leadership positions and secretariats, and briefing the SC on the deliberations at ISO level.

9.3 The Committee may review the list of ballots received since the last meeting and kindly accord the priority as Level H or Level M on the open ballots at PWI, NP, AWI, CD & SR stages. The Committee may also find the list of ballots that concluded since the last SC meeting and the vote casted by MHD02 as the National Mirror Committee.

9.4 Harmonization of Indian Standards with International Standards

9.4.1 ISO comprising of global experts on various subjects regularly bring out International Standards. The Sectional Committees on a regular basis needs to review the ISO Standards published against the existing National Standards, current trade practices, consumer expectations, global trends, etc and decide for review of the published National Standards. In the process, Sectional Committees after a close scrutiny of the ISO Standards, may decide on adoption/adaptation of the ISO Standards keeping in view the technical relevance of the subject to the national conditions. Harmonization is not undertaken in case the ISO Standards are not relevant to Indian conditions or would put the Indian industry at disadvantage. The Sectional Committees while reviewing such ISO Standards also explore the possibility of adopting such ISO Standards on which no Indian Standards exist.

9.4.2 The list of Standards published by the ISO/TC 150, ISO/TC 150/SC 1, ISO/TC 150/SC 4, and ISO/TC 150/SC 5 along with their status of adoption is given at ***Annexure B***.

The Committee may kindly deliberate and recommend the Standards to be adopted as Indian Standards.

ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

10.2 The progress of development of Indian Standards at various stages is given below:

Stage	No. of Documents
Under Print	16
Under Development	22

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 All Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archiving in the light of technological developments that have happened so far in relation to these standards. This exercise has to be completed in a time bound manner.

11.1.2 The list of the above Indian Standards at various stages is given at ***Annexure C***.

The Committee may kindly review.

11.2 Review of Standards as per 5-year cycle

11.2.1 As per the policy of BIS, the Indian Standards which have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

The Committee may kindly note.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 There are currently no issues related to the previous meeting.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 02 is scheduled on 21 February 2025.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

Annexure A

(*Item 2.2*)

Composition of MHD02

Sl.No.	Organization	Member Name
1.	IN INDIVIDUAL CAPACITY	Dr. Sudhir Kumar
2.	Artificial Limbs Manufacturing Corporation of India, Kanpur	Mr. Chandra Kishor
		Mr. Vishal Shukla
		Mr. Prashant Thakur
3.	Association of Indian Medical Device Industry, New Delhi	Mr. Harvinder Singh
		Mr. Anuj Dureja
		Mr. Ankur Bhargava
		Mr. Deepak Gupta
4.	Chetan Meditech Pvt. Ltd., Ahmedabad, Gujarat	Ms Rashmi Godeshwer *Alternate Member Nomination Awaited*
5.	CSIR - Central Glass and Ceramic Research Institute, Kolkata	Dr. Biswanath Kundu
		Dr. Vamsi K Balla
6.	CSIR - National Chemical Laboratory, Pune	Dr. Mahesh J Kulkarni
		Dr. Bhushan P. Chaudhari
		Dr. V. Koteswara Rao
7.	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu
		Mr. Vinod Kumar Naik Mude
		Mr. Ajai Basil
8.	Healthium Medtech Limited, Noida	Mr. Raajjhesh R Kulkarni
		Mr. Pankaj Dawar
		Dr. Deepak TS
9.	Indian Institute of Technology Kanpur, Kanpur	Dr. Kantesh Balani
		Dr. Niraj Sinha
10.	Johnson and Johnson Private Limited, Mumbai	Ms. Himani Gupta
		Mr. Hemant Sonawane
11.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Amit Sharma
		Mr. Santosh Kumar Balivada
12.	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak	Dr. Roop Singh *Alternate Member Nomination Awaited*
13.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr. Manoj Komath *Alternate Member Nomination Awaited*
14.	Stryker India Private Limited, Gurugram	Mr. Gajender Sharma
		Mr. Deepak Sharma
		Ms. Ishani Mondal
15.	Sunways Inor Medical Devices Private Limited, Gundlav	Mr. Sorab R. Patel
		Mr. Aatish Anupam Shroff

Annexure B

(*Item 9.4.2*)

List of ISO Standards Published by ISO/TC 150 Secretariat and its SCs

ISO/TC 150		MHD 02		
Published standards	16	**Adopted/Revision needed**	**Under Development**	**To be adopted**
Under Development	5	10/2	6	0

Standards published under the direct responsibility of ISO/TC 150 Secretariat

Sl No.	ISO	Title	Existing IS	Status of adoption
1.	ISO 7197:2006 (Withdrawn)	Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components	IS/ISO 7197:2006	Published on MHD 07 Jan-2010
	ISO 7197:2024 (Revised)	Neurosurgical implants — Sterile, single-use hydrocephalus shunts		(Revision needed)
2.	ISO 9713:2022	Neurosurgical implants — Self-closing intracranial aneurysm clips	IS 14139 : 2008 ISO 9713	Published on MHD-07 (21710)
3.	ISO 12891-1: 2015	Retrieval and analysis of surgical implants — Part 1: Retrieval and handling	IS/ISO 12891-1: 2015	Published on May-2018
4.	ISO 12891-2: 2020	Retrieval and analysis of surgical implants — Part 2: Analysis of retrieved surgical implants First Revision	IS 18537-2: 2024	Published July-2024
5.	ISO 13179-1: 2021	Implants for surgery — Coatings on metallic surgical implants — Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders	MHD/02/25843	***Under development***
6.	ISO/TR 14283: 2018	Implants for surgery — Essential principles of safety and performance	IS/ISO/TR 14283: 2018	Published Jan-2021

7.	ISO 14607:2018	Non-active surgical implants — Mammary implants — Particular requirements	MHD/02/25918	***Under development***
8.	ISO 14630:2012 (Withdrawn)	Non-active surgical implants — General requirements	IS 18076 : 2023 ISO 14630: 2012	Published Aug-2023
	ISO 14630:2024			(Revision needed)
9.	ISO 16054:2019	Implants for surgery — Minimum data sets for surgical implants	IS 17744: 2021/ ISO 16054:2019	Published Dec-2021
10.	ISO 16061:2021	Instruments for use in association with non-active surgical implants — General requirements	MHD/02/25919	***Under development***
11.	ISO 17327-1: 2018	Non-active surgical implants — Implant coating — Part 1: General requirements	IS/ISO 17327-1: 2018	Published Jan-2021
12.	ISO/TR 17327-2: 2021	Non-active surgical implants — Implant coating — Part 2: Reference standards related to coatings	IS 18592-2: 2024	Published Jul-2024
13.	ISO 19213: 2017	Implants for surgery — Test methods of material for use as a cortical bone model	MHD/02/25920	***Under development***
14.	ISO 19227:2018	Implants for surgery — Cleanliness of orthopedic implants — General requirements	IS/ISO 19227: 2018	Published Jan-2021
15.	ISO/TS 20721: 2020	Implants for surgery — General guidelines and requirements for assessment of absorbable metallic implants	MHD/02/25942	***Under development***
16.	ISO 22926:2023	Implants for surgery — Specification and verification of synthetic anatomical bone models for testing	MHD/02/25943	***Under development***

ISO/TC 150/SC 1		MHD 02		
Published standards	38	**Adopted/Revision needed**	**Under Development**	**To be adopted**
Under Development	10	29/5	6	3

ISO/TC 150/SC 1 Materials (P member)

Sl No.	ISO	Title	Existing IS	Status of adoption
1	ISO 5832-1:2024	Implants for surgery — Metallic materials — Part 1: Wrought stainless steel	IS/ISO 5832-1: 2016	Published Jan-2019 (Revision needed)
2	ISO 5832-2:2018	Implants for surgery — Metallic materials — Part 2: Unalloyed titanium	IS/ISO 5832-2: 2018	Published Jan-2019
3	ISO 5832-3: 2021	Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	IS 18261 (Part 3): 2023 ISO 5832-3: 2021	Published Aug-2023
4	ISO 5832-4:2024	Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy	IS/ISO 5832-4: 2014	Published Feb-2018 (Revision needed
5	ISO 5832-5:2022	Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel	IS 18261 (Part 5): 2023/ISO 5832-5: 2022	Published Jul-2023
6	ISO 5832-6:2022	Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	IS 18261 (Part 6): 2023 ISO 5832-6: 2022	Published Aug-2023
7	ISO 5832-7:2024	Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy	IS/ISO 5832-7: 2016	Published Jan-2019 (Revision needed
8	ISO 5832-9:2019	Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel First Revision	IS 18261-9: 2024	Published July-2024
9	ISO 5832-11: 2014 (Withdrawn) ISO 5832-11:2024	Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy	IS/ISO 5832-11: 2014	Published May-2018 (Revision needed

10	ISO 5832-12: 2019	Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy	IS 18555-12: 2024	Published Feb-2024
11	ISO 5832-14: 2019	Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy	IS 18555-14: 2024	Published Feb-2024
12	ISO 5833:2002	Implants for surgery — Acrylic resin cements	IS 8641: 2015/ ISO 5833: 2002	Published Dec-2015
13	ISO 5834-1:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form	IS 18074 (Part 1): 2023/ISO 5834-1: 2019	Published Aug-2023
14	ISO 5834-2:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms	IS 18074 (Part 2): 2023/ISO 5834-2: 2019	Published Oct-2023
15	ISO 5834-3:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 3: Accelerated ageing methods	IS 18074 (Part 3): 2024	Published June-2024
16	ISO 5834-4:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 4: Oxidation index measurement method	IS 18074 (Part 4): 2024	Published May-2024
17	ISO 5834-5:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 5: Morphology assessment method	IS 18074 (Part 5): 2024 ISO 5834-5:2019	Published June-2024
18	ISO 6474-1:2019	Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina	MHD/02/25842	***Under development***
19	ISO 6474-2:2019	Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement (First Revision)	IS 18530 (Part 2): 2024 ISO 6474-2:2019	Published June-2024
20	ISO 9583:1993	Implants for surgery — Non-destructive testing — Liquid penetrant inspection of metallic surgical implants	IS/ISO 9583: 1993	Published Jan-2021
21	ISO 9584:2023	Implants for surgery — Non-destructive testing — Radiographic examination of	IS/ISO 9584: 2021	Published Jan-2021 (Revision

		cast metallic surgical implants		needed)
22	ISO 13175-3: 2012	Implants for surgery — Calcium phosphates — Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes	IS/ISO 13175-3: 2012	Published Mar-2019
23	ISO 13356:2015	Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	IS/ISO 13356: 2015	Published Feb-2018
24	ISO 13779-2: 2018	Implants for surgery — Hydroxyapatite — Part 2: Thermally sprayed coatings of hydroxyapatite	IS 18359: 2023 ISO 13779-2:2018	Published Aug-2023
25	ISO 13779-3: 2018	Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity	IS/ISO 13779-3: 2018	Published Mar-2019
26	ISO 13779-3:2018/AMD 1: 2021	Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity — Amendment 1		**To be adopted**
27	ISO 13779-4: 2018	Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength	IS/ISO 13779-4: 2018	Published Mar-2019
28	ISO 13779-6:2015	Implants for surgery — Hydroxyapatite — Part 6: Powders	IS/ISO 13779-6: 2015	Published Mar-2019
29	ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing	IS/ISO 13781: 2017	Published Jan-2019
30	ISO 13782:2019	Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications	MHD/02/25874	***Under development***
31	ISO 14949:2001	Implants for surgery — Two-part addition-cure silicone elastomers	MHD/02/25944	***Under development***
32	ISO 15309:2013	Implants for surgery — Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices		Published Mar-2019
33	ISO	Implants for surgery —	MHD/02/25945	***Under***

	15374:1998	Requirements for production of forgings		***development***
34	ISO 16402:2008	Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics	IS/ISO 16402: 2008	Published Mar-2019
35	ISO 16428:2005	Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices	MHD/02/26001	***Under development***
36	ISO 16429:2004	Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods	MHD/02/26002	***Under development***
37	ISO 20160:2006	Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars		**To be adopted**
38	ISO 23317:2014	Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials		**To be adopted**

ISO/TC 150/SC 5		MHD 02		
Published standards	26	**Adopted**	**Under Development**	**To be adopted**
Under Development	3	15	1	10

ISO/TC 150/SC 5 Osteosynthesis and Spinal Devices (P member)

Sl No.	ISO	Title	Existing IS	Status of adoption
1	ISO 5835:1991	Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions	IS 9829 (Part 1): 1996	Published Jun-1996
2	ISO 5836:1988	Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical thread and spherical under-surface	IS 18078: 2023/ ISO 5836: 1988	Published Apr-2023
3	ISO 5837-1:1985	Implants for surgery — Intramedullary nailing systems — Part 1: Intramedullary nails with cloverleaf or V-shaped cross-section	IS 5395(Part 1): 1989	Published Aug-1990
4	ISO 5838-1:2013	Implants for surgery — Metallic skeletal pins and wires — Part 1: General requirements	IS/ISO 5838-1: 2013	Published Mar-2018
5	ISO 5838-2:1991	Implants for surgery — Skeletal pins and wires — Part 2: Steinmann skeletal pins — Dimensions	IS 5848: 1996/ ISO 5838-2: 1991	Published Feb-1996
6	ISO 5838-3:1993	Implants for surgery — Skeletal pins and wires — Part 3: Kirschner skeletal wires	IS 8261 (Part 1): 1976	Published Feb-1977
7	ISO 6475:1989	Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods	IS 10121 (Part 1): 1982 & IS 10121 (Part 2): 1982	Published Apr-1982 Published Dec-1982
8	ISO 8319-1:1996	Orthopaedic instruments — Drive connections — Part 1: Keys for use with screws with hexagon socket heads	IS 6801 (Part 1): 1999	Published Dec-1999
9	ISO 8319-2:1986	Orthopaedic instruments — Drive connections — Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws	IS 6801 (Part 2): 1987	Published Jul-1989

10	ISO 8615:1991	Implants for surgery — Fixation devices for use in the ends of the femur in adults	IS 14227: 1995/ ISO 8615: 1991	Published Jan-1995
11	ISO 8827:1988	Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements	IS 14228: 1996/ ISO 8827: 1988	Published Mar-1996
12	ISO 9268:1988	Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions	IS 9829 (Part 2): 1996/ ISO 9268: 1988	Published June-1996
13	ISO 9269:1988	Implants for surgery — Metal bone plates — Holes and slots corresponding to screws with conical under-surface	IS 18079: 2023/ ISO 9269: 1988	Published May-2023
14	ISO 9585:1990	Implants for surgery — Determination of bending strength and stiffness of bone plates	IS 14229:1995/ ISO 9585: 1990	Published July-1995
15	ISO 9714-1:2012	Orthopaedic drilling instruments — Part 1: Drill bits, taps and countersink cutters	IS 14239 (Part 1): 2018	Published June-2018
16	ISO 10334:1994	Implants for surgery — Malleable wires for use as sutures and other surgical applications		**To be adopted**
17	ISO 12189:2008	Implants for surgery — Mechanical testing of implantable spinal devices — Fatigue test method for spinal implant assemblies using an anterior support	MHD/02/26003	***Under development***
18	ISO 14602:2010	Non-active surgical implants — Implants for osteosynthesis — Particular requirements		**To be adopted**
19	ISO 15142-1: 2003	Implants for surgery — Metal intramedullary nailing systems — Part 1: Intramedullary nails		**To be adopted**
20	ISO 15142-2: 2003	Implants for surgery — Metal intramedullary nailing systems — Part 2: Locking components		**To be adopted**
21	ISO 15142-3: 2003	Implants for surgery — Metal intramedullary nailing systems — Part 3: Connection devices and reamer diameter measurements		**To be adopted**
22	ISO 18192-1: 2011	Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test		**To be adopted**
23	ISO 18192-1:2011/AMD 1: 2018	Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 1: Loading and displacement parameters for wear		**To be adopted**

		testing and corresponding environmental conditions for test — Amendment 1		
24	ISO 18192-2: 2010	Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 2: Nucleus replacements		**To be adopted**
25	ISO 18192-3: 2017	Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 3: Impingement-wear testing and corresponding environmental conditions for test of lumbar prostheses under adverse kinematic conditions		**To be adopted**
26	ISO 23089-2: 2021	Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements — Part 2: Spinal intervertebral body fusion devices		**To be adopted**

ISO/TC 150/SC 4		MHD 02		
Published standards	36	**Adopted**	**Under Development**	**To be adopted**
Under Development	8	14	16	6

ISO/TC 150/SC 4 Bone and joint replacements (P Member)

Sl No.	ISO	Title	Existing IS	Status of adoption
1	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	Published Dec-2015
2	ISO 7206-2:2011	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	Published May-2018
3	ISO 7206-2: 2011/AMD 1: 2016	Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials — Amendment 1		**To be adopted**
4	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	IS 12375(Part 4): 2016	Published Mar-16
5	ISO 7206-4:2010/AMD 1:2016	Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components — Amendment 1	Amendment No. 1 February 2019 to IS 12375 (Part 4): 2016	Published Feb-2019
6	ISO 7206-6:2013	Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components	IS 12375 (Part 6): 2018	Published Jun-2018
7	ISO 7206-10: 2018	Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of	IS 12375 (Part 10): 2023	Published May-2023

		resistance to static load of modular femoral heads		
8	ISO 7206-10: 2018/AMD 1: 2021	Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads — Amendment 1		**To be adopted**
9	ISO 7206-12: 2016	Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells	IS 12375 (Part 12): 2024	Published Jun-2024
10	ISO 7206-13: 2016	Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components	IS 12375 (Part 13): 2024	Published Jun-2024
11	ISO 7206-13:2016/Amd 1:2022	Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components — Amendment 1		**To be adopted**
12	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	Published Dec-2015
13	ISO 7207-2:2011	Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials	MHD/02/25841	***Under development***
14	ISO 7207-2: 2011/AMD 1: 2016	Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials — Amendment 1	MHD/02/25841	***Under development***
15	ISO 7207-2: 2011/AMD 2: 2020	Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials — Amendment 2	MHD/02/25841	***Under development***
16	ISO 11491:2017	Implants for surgery — Determination of impact resistance of ceramic femoral		**To be adopted**

		heads for hip joint prostheses		
17	ISO 14242-1:2014	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	MHD/02/25893	***Under development***
18	ISO 14242-1: 2014/AMD 1: 2018	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 — Amendment 1	MHD/02/25893	***Under development***
19	ISO 14242-2: 2016	Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement	MHD/02/25894	***Under development***
20	ISO 14242-3: 2009	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	MHD/02/25895	***Under development***
21	ISO 14242-3: 2009/AMD 1: 2019	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 — Amendment 1	MHD/02/25895	***Under development***
22	ISO 14242-4: 2018	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	MHD/02/25896	***Under development***
23	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	IS 18075 (Part 1): 2023/ ISO 14243-1:2009	Published Feb-2023
24	ISO 14243-1: 2009/AMD 1: 2020	Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and		To be adopted

		displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test — Amendment 1		
25	ISO 14243-2: 2016	Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement	IS 18075 (Part 2): 2023/ISO 14243-2: 2016	Published Feb-2023
26	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	IS 18075 (Part 3): 2023/ISO 14243-3: 2014	Published Feb-2023
27	ISO 14243-3:2014/AMD 1:2020	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 — Amendment 1		To be adopted
28	ISO 14243-5: 2019	Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint	MHD/02/25897	***Under development***
29	ISO 14879-1: 2020	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	Published Feb-2023
30	ISO 16087:2013	Implants for surgery — Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants	MHD/02/25946	***Under development***
31	ISO 17853:2011	Wear of implant materials — Polymer and metal wear particles — Isolation and characterization	MHD/02/25947	***Under development***
32	ISO 19233-1:2017	Implants for surgery — Orthopaedic joint prosthesis — Part 1: Procedure for producing parametric 3D bone models from CT data of the knee	MHD/02/25948	***Under development***
33	ISO 21534:2007	Non-active surgical implants — Joint replacement implants — Particular requirements	IS/ISO 21534: 2007	Published Jun-2018

34	ISO 21535:2023	Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants	MHD/02/25876	***Under development***
35	ISO 21536:2023	Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants	MHD/02/25875	***Under development***
36	ISO 22622:2019	Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test	MHD/02/25949	***Under development***

Annexure C

(*Item 11.1.2*)

List of Pre-2000 standards to be reviewed

Sl.No.	IS No.	IS Title
1.	IS 11568: 1986	Forceps, Bone Holding, Semb's Pattern
2.	IS 11953: 1986	Specification for driver and bender for rush intramedullary pin
3.	IS 12088: 1987	Specification for bone plate, dynamic compression
4.	IS 12172: 1987	Specification for distraction cervical collar
5.	IS 5089: 1969	Specification for blade plate, blount type
6.	IS 5347(part 1): 1986	Requirements for orthopaedic implants: Part 1 general requirements (Second Revision)
7.	IS 5396: 1969	Specification for guide pin for kuntscher nail
8.	IS 5397: 1969	Specification for reamer, flexible for kuntscher nail (Meddulary canal)
9.	IS 5574: 1970	Specification for forceps, wire cutting, compound action, orthopaedic
10.	IS 5585: 1970	Specification for mallet, rubber-capped
11.	IS 5589: 1970	Specification for saw handle, bone amputation, orthopaedic
12.	IS 5590: 1970	Specification for saw blade, bone amputation
13.	IS 5601: 1970	Specification for gouges, stille pattern, orthopaedic
14.	IS 5803: 1970	Specification for twist drill used in orthopaedic surgery
15.	IS 5847: 1970	Specification for pin chuck for introducing steinman pins
16.	IS 6187: 1971	Specification for saw, wire (Gigli Pattern)
17.	IS 6976: 1973	Specification for awl, kuntscher, diamond pointed
18.	IS 6982: 1973	Specification for gauge for intramedullary nails
19.	IS 7055: 1973	Specification for drivers, kuntscher, nail, orthopaedic
20.	IS 7102: 1973	Specification for screw, bone, leinbach, medullary
21.	IS 7105(part 1): 1973	Specification for extractor for kuntscher nail: Part 1 handle type
22.	IS 7105(part 2): 1986	Specification for extractor for kuntscher nail: Part 2 striker type
23.	IS 7106: 1973	Specification for extractor, staple, orthopaedic
24.	IS 7107: 1973	Specification for punch, staple, orthopaedic
25.	IS 7108: 1973	Specification for hammer for kuntscher nail extractor
26.	IS 7109: 1973	Specification for starter, staple, orthopaedic
27.	IS 7111: 1973	Specification for inserter, staple, orthopaedic
28.	IS 7435: 1974	Rongeur, Ruskin's Pattern
29.	IS 7442: 1974	Forceps, Bone Cutting, Straight and Angular, Liston's Pattern
30.	IS 7629: 1975	Specification for bender, plate, orthopaedic
31.	IS 7650: 1975	Specification for drill, hand, bone, universal, micro and kirschner
32.	IS 7817: 1975	Specification for impactor for hip prosthesis
33.	IS 7818: 1975	Specification for broach, moore type, for hip prosthesis
34.	IS 7841: 1975	Specification for compression plate, muller type
35.	IS 7846: 1975	Specification for extractor for Hip Prosthesis
36.	IS 8608: 1977	Specification for countersinks, pilot type, for orthopaedic use
37.	IS 8922: 1978	Specification for depth gauge for orthopaedic use
38.	IS 8261(part-2):	Specification for pins and wires, skeletal, traction: Part 2 guide

	1976	wires
39.	IS 8261(part-3): 1976	Specification for pins and wires, skeletal, traction: Part 3 pins and wires, fixation and threaded