MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
Bureau of Indian Standards

AGENDA

14TH MEETING OF ORTHOPAEDIC INSTRUMENTS, IMPLANTS AND ACCESSORIES SECTIONAL COMMITTEE, MHD 02

Date: 08th August 2023	Time: 11 AM
Venue: Online (BIS WebEx Platform)	
Meeting No: 2510 403 0579	Password: Mhd2@14
Link:	
https://bismanak.webex.com/bismanak/j.php?MTID=m725bb8be55edd53aa04d52789786e2a8	
Chairman:	Member Secretary:
Dr Sudhir Kumar (In-Personal capacity)	Ms Gurpreet Kaur (Scientist-B)

ITEM 0 WELCOME ADDRESS AND OPENING REMARKS

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The minutes of the last (13th) meeting were circulated to all the members after approval of the Chairperson vide email dated 29.08.2022. No comments have been received.

The Committee may formally confirm the minutes.

ITEM 2 PROCESS REFORMS IN STANDARDIZATION

2.1 BIS has instituted several process reforms in respect of formulation of Indian Standards. The process reforms introduced in the Standardization activities have been outlined in **Annex-A.**

2.2 Annual Meeting Calendar

As per guidelines, every Sectional Committee is required to meet once per quarter. In this regard, each committee needs to approve the annual meeting calendar in the beginning of the year. The annual calendar for MHD-02 is mentioned below.

Quarter	Q1	Q2	Q3	Q4
Date	*8th August, 2023 (Tuesday)*	20th Sept, 2023 (Wednesday)	30th Nov, 2023 (Thursday)	28th Feb, 2024 (Wednesday)

The Committee may kindly note.

ITEM 3 SCOPE AND COMPOSITION OF COMMITTEE

3.1 Scope

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:
    1) ISO/TC 150 'Implants for surgery' (P-member)
    2) ISO/TC 150/SC 1 'Materials' (P-member)
    3) ISO/TC 150/SC 4 'Bone and joint replacements' (O-member)
    4) ISO/TC 150/SC 5 'Osteosynthesis and spinal devices' (P-member)
    5) ISO/TC 150/SC 6 'Active implants' (O-member)

The Committee may kindly examine the scope.

3.2 Composition

The present composition of MHD-02 is given in **Annex-B** (Page 5 - 6). The Committee may review the composition according to following BIS guidelines:

a. Consumer interests shall, as far as possible, predominate. In case, non-industry interests are less than two third, it may be reviewed to ensure that 2/3rd of the total representation on the committee is from non-industry.
b. Only relevant organizations/government departments/consumer organizations and regulatory bodies that are related to the subject may be offered representation.
c. Non-active members to be withdrawn.
d. Young professionals who can contribute in the working of the committee may be co-opted. The committee may deliberate on the same and advice.

The Committee may please note.

3.3 Co-option request has been received from Mr Mayank Rohatgi, Head- Government Affairs, **Healthium Medtech, Bangalore.**

3.4 Members are also requested to provide their latest details like e-mail, phone no, enabling secretariat to make correspondence and send documents/Agenda/Minutes etc. through e-mail.

ITEM 4 DRAFT STANDARDS FOR FINALIZATION

The wide circulation stages for the following draft Indian Standards are complete.

Sr No.	Document No.	Title	Doc Type
1	MHD/02/19659	Orthopaedic Gouge Forceps Lanes Pattern Specification (*First Revision*)	Revision
2	MHD/02/21085	Specification for Stirrup Bohlers (*First Revision*)	Revision

The Committee may please note.

ITEM 5 DRAFT STANDARDS FOR APPROVAL FOR WIDE CIRCULATION

ISO standards to be considered for adoption are further given in **Item 7.3.** (Annex-C)

ITEM 6 DRAFTS UNDER PREPARATION

6.1 Under the BIS-Internship Program, 15 Interns were engaged under MHD. The scope of their project work involves *preparation of pre-standardisation document for New Work Item proposals for standard formulation*. The following new subjects under MHD-02 were assigned to the Interns:

a. Battery Operated Dermatome

b. Arthroscopy System

6.2 The following subjects have been taken up for formulation:

a. Battery Operated Drill

b. Pneumatic Drill

The Committee may please note.

ITEM 7 INTERNATIONAL ACTIVITIES

7.1 The membership status of India in the ISO/TC & SC's is given below:

a. ISO/TC 150 'Implants for Surgery': *(P-member)*
b. ISO/TC 150/SC 1 'Materials': *(P-member)*
c. ISO/TC 150/SC 4 'Bone and Joints Replacements': *(O-member)*
d. ISO/TC 150/SC 5 'Osteosynthesis and spinal devices': *(P-member)* and
e. ISO/TC 150/SC 6 'Active implants': *(O-member)*

The Committee may please note.

7.2 As per the new process reforms being undertaken by BIS, it is important to ensure increased participation in the international activities. For MHD-02, the upgradation from O-membership to P-membership in ISO/TC 150/SC 4 can increase the contribution of Indian experts at ISO. The scope of ISO/TC 150/SC 4 'Bone and joint replacements' is:

'Standardization of prostheses and their components used for the repair or replacement of bones and joints of the body.'

7.3 A list of ISO Standards published by ISO/TC 150 and its Sub Committees (corresponding to MHD-02 as National Mirror Committee) is given in **Annex-C** (Page 7-16). Present status of adoption of such ISO Standards has been provided.

The Committee may examine, identify, and recommend action for adoption of the ISO Standard(s) as Indian Standard(s), keeping in view India's national interest.

ITEM 8 REVIEW OF STANDARDS & PROGRAMME OF WORK

The status of Indian Standards under MHD-02 that were published before the year 2000 and taken up for revision are placed at **Annex-D** (Page 17 -20).

Sr No.	Status of Pre 2000 standards	
1	Revision drafts under wide circulation	10
2	Drafts for Finalization	2
3	Standards under print	12
4	No. of standards superseded	3
5	No. of IS Withdrawn	5
6	No. of Pre 2000 standards remaining	63
7	Total	95

ITEM 9 TECHNICAL ISSUES

The scope of ISO/TC 150/SC 6 is 'Standardization of active implantable medical devices that rely for their functioning on a source of energy or any source of power other than that directly generated by the human body or gravity.' BIS is P-member and the National Mirror Committee is MHD-06 Medical and Surgical Cardiology Equipment Sectional Committee.

The Committee may please note.

ITEM 9 ISSUES ARISING OUT OF PREVIOUS MEETINGS

9.1 Battery Operated Dermatome: In the last meeting, it was decided that the draft is to be prepared by panel consisting of one member from SCTIMST-Thiruvananthapuram, stakeholder from industry and one orthopaedic surgeon.

9.2 Arthroscopy System: In the last meeting, it was decided that the draft is to be prepared by panel consisting of Dr. V Bhasin (Sir Ganga Ram Hospital, New Delhi), Dr. Sumit Sural (MAMC, New Delhi) and one stakeholder from industry.

ITEM 10 DATE AND PLACE OF NEXT MEETING

ITEM 11 ANY OTHER BUSINESS

ANNEX-B
(Item 3.2)
Composition

Sr No	Name of Organization	Represented by	Attendance in last 3 meetings
1	In Personal Capacity, Greater Noida	Dr. Sudhir Kumar **(Chairperson)**	3/3
2	All India Institute of Medical Sciences, New Delhi	Prof. H.L. Nag	0/3
		Prof. Ravi Mittal	
3	Artificial Limbs Manufacturing Corporation of India (ALIMCO), Kanpur	Shri A.K. Singh	0/3
		Shri Vishal Shukla	
4	Association of Indian Medical Device Industry (AIIMED), New Delhi	Shri. Vivek Mangalwedhekar	0/3
		Shri. Anuj Dureja	
5	BBraun Medical (India) Pvt. Ltd., Delhi	Dr. Anmol Kumar Ray	1/3
		Ms. Gayatri Garg	
6	Bhabha Atomic Research Centre, Mumbai	Dr. Pravin P. Bande	0/3
		Dr. Sagar S. Wajekar	
7	Central Drugs Standards Control Organisation (CDSCO), New Delhi	Dr. Ravi Kant Sharma	0/3
8	Centre for Cellular and molecular platform (C- Camp), Bengaluru	Dr. Niranjan Joshi	3/3
9	Central Manufacturing Technology Institute (CMTI), Bengaluru	Shri Ankit K	0/3
10	Consumer Co Ordination Council, Delhi	Mr. Abhishek Srivastava	0/3
		Mrs. Neetu Chauhan	
11	CSIR-Central Glass & Ceramic Research Institute (CGCRI), Kolkata	Dr. Biswanath Kundu	1/3
		Dr. Vamsi K. Balla	
		Dr. Subhadip Bodhak	
12	CSIR- National Chemical Laboratory	Dr. Mahesh J Kulkarni	2/3
		Dr. Bhushan P Chaudhari	
		Dr. V Koteswara Rao	
13	Department of Orthopaedics, Institute of Medical Science, Varanasi	Dr. Anil Kumar Rai	0/3
		Dr. Saurabh Singh	
14	Directorate General of Armed Forces Medical Services, New Delhi	Col. Barun Datta	0/3
		Lt. Col. Mikhil Sood	
15	Directorate General of Health Services, New Delhi	Dr. V.P. Bansal	0/3
16	Food & Drug Administration (M.S.), Mumbai	Shri V.K. Biyani	0/3
		Shri K.G. Gadewar	
17	Food & Drugs Laboratory, Vadodara	Mrs. Dipika R. Chauhan	0/3
		Shri Y.D. Chauhan	
18	Government Medical College and Hospital, Chandigarh	Dr. Sudhir Kumar	1/3
		Dr. Ravi K. Gupta	
19	Green Surgicals (P) Ltd., Vadodara	Dr. Vinay Kumar	1/3
20	India Medtronic Pvt. Ltd., Gurugram	Shri Priyanshu Garg	0/3
		Ms Sumukhi Sabbarwal	

21	Indian Institute of Technology Bombay, Mumbai	Prof. B. Ravi	1/3
22	Indian Institute of Technology Delhi, New Delhi	Dr. Dinesh Kalyanasundaram	0/3
23	Indian Institute of Technology, Kanpur	Dr. Kantesh Balani	3/3
24	Indian Institute of Technology, Roorkee	Prof. Debrupa Lahiri	1/3
		Prof. Inderdeep Singh	
25	Indian Orthopaedic Association, Delhi	Dr. Rajiv Jain	0/3
		Dr. Sharad K. Agarwal	
26	Johnson & Johnson Pvt. Ltd., New Delhi	Mr Aaditya Vats	3/3
		Mr. Yateen Shah	
		Ms Himani Gupta	
27	K.E.M Hospital & G.S. Medical College, Mumbai	Prof. Bibhas Das Gupta	0/3
28	Kalam Institute of Health Technology,	Dr. Jitendar Sharma	3/3
		Shri Dilip Kumar Chekuri	
29	Lady Hardinge Medical College, New Delhi	Prof. Mukesh Kalra	0/3
		Dr. Sanjay Meena	
30	Maulana Azad Medical College, New Delhi	Dr. Sumit Sural	3/3
31	Mishra Dhatu Nigam Ltd, Hyderabad	Dr. P. Krishna Mohan	0/3
		Shri Shashi Kumar Dwivedi	
32	National Medical Commission, New Delhi	Dr. Anilbhai Jaydev Nayak	0/3
33	Orthopaedics Implants Manufacturer Association India	Shri Hemkumar Patel	2/3
		Dr. Vinay Kumar	
34	Pt. B.D. Sharma PGIMS, Rohtak	Dr. Rakesh Kumar Gupta	0/3
		Dr. Roop Singh	
35	Premier Surgicals, Delhi	Shri A.L. Saigal	0/3
		Shri Vijay Sehgal	
36	RCH Orthopaedics, Vasai (East)	Shri Hem Kumar Patel	2/3
37	S.H. Pitkar Orthotools Pvt. Ltd., Pune	Shri Vivek Mangalwedhekar	0/3
		Shri Bhushan H. Pitkar	
38	Sir Ganga Ram Hospital, New Delhi	Dr. V B Bhasin (Reply awaited)	0/3
		Dr. R.S. Chahal	
39	SMITH & Nephew Healthcare Pvt Ltd., Mumbai	Leena Jeswani	2/3
		Devaleena Goswami	
		Shri Ravi Sarangapani	
40	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram	Dr. Manoj Komath	3/3
41	Stryker India Pvt. Ltd	Shri Shivkumar Hurdale	3/3
		Shri Gajender Sharma	
42	Sunways Inor Orthopaedics, Mumbai	Mr. S. R. Patel	2/3
		Shri A.D. Surekha	
43	University College of Medical Sciences & G.T.B. Hospital, Delhi	Dr. A.K. Jain	0/3
		Dr. Aditya Agarwal	

ANNEX-C

(Item 7.3)

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

ISO/TC 150		**MHD-02**		
Published standards	16	**Adopted**	**Under Development**	**Not adopted**
Under Development	5	8	2	6

ISO/TC 150/SC 1		**MHD-02**		
Published standards	38	**Adopted**	**Under Development**	**Not adopted**
Under Development	7	19	6	13

ISO/TC 150/SC 4		**MHD-02**		
Published standards	36	**Adopted**	**Under Development**	**Not adopted**
Under Development	10	13	0	23

ISO/TC 150/SC 5		**MHD-02**		
Published standards	26	**Adopted**	**Under Development**	**Not adopted**
Under Development	1	13	0	13

ISO/TC 150/SC 6		**MHD-02**		
Published standards	16	**Adopted**	**Under Development**	**Not adopted**
Under Development	3	14	0	2

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

Sr. no	ISO	Title	Existing IS	Status of adoption
1	ISO 7197:2006	Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components	IS/ISO 7197:2006	Published Jan-2010
2	ISO 7197:2006/ COR 1:2007	Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components — Technical Corrigendum 1		
3	ISO 9713:2022	Neurosurgical implants — Self-closing intracranial aneurysm clips		WC under MHD-07 (21710)
4	ISO 12891-1: 2015	Retrieval and analysis of surgical implants — Part 1: Retrieval and handling	IS/ISO 12891-1: 2015	Published May-2018
5	ISO 12891-2: 2020	Retrieval and analysis of surgical implants — Part 2: Analysis of retrieved surgical implants	IS/ISO 12891-2: 2014	***Revision Needed***
6	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	IS/ISO 13179-1: 2014	***Revision Needed***
7	ISO/TR 14283: 2018	Implants for surgery — Essential principles of safety and performance	IS/ISO/TR 14283: 2018	Published Jan-2021
8	ISO 14607:2018	Non-active surgical implants — Mammary implants — Particular requirements		**Not adopted**
9	ISO 14630:2012	Non-active surgical implants — General requirements	MHD/02/18608	*Under print*
10	ISO 16054:2019	Implants for surgery — Minimum data sets for surgical implants	IS 17744: 2021/ ISO 16054:2019	Published Dec-2021
11	ISO 16061:2021	Instruments for use in association with non-active surgical implants — General requirements		**Not adopted**
12	ISO 17327-1: 2018	Non-active surgical implants — Implant coating — Part 1: General requirements	IS/ISO 17327-1: 2018	Published Jan-2021
13	ISO/TR 17327-2: 2021	Non-active surgical implants — Implant coating — Part 2: Reference standards related to coatings		**Not adopted**
14	ISO 19213: 2017	Implants for surgery — Test methods of material for use as a cortical bone model		**Not adopted**
15	ISO 19227:2018	Implants for surgery — Cleanliness of orthopedic implants — General requirements	IS/ISO 19227: 2018	Published Jan-2021
16	ISO/TS 20721: 2020	Implants for surgery — General guidelines and requirements for assessment of absorbable metallic implants		**Not adopted**

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

Sr. no	ISO	Title	Existing IS	Status of adoption
1	ISO 5832-1:2016	Implants for surgery — Metallic materials — Part 1: Wrought stainless steel	IS/ISO 5832-1 : 2016	Published Jan-2019
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	MHD/02/22137	*Under print*
4	ISO 5832-4:2014	Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy	IS/ISO 5832-4: 2014	Published Feb-2018
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	MHD/02/22143	*Under print*
7	ISO 5832-7:2016	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
8	ISO 5832-9:2019	Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel	IS/ISO 5832-9 : 2007	***Revision Needed***
9	ISO 5832-11: 2014	Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy	IS/ISO 5832-11 : 2014	Published May-2018
10	ISO 5832-12: 2019	Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy		**Not Adopted**
11	ISO 5832-14: 2019	Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy		**Not Adopted**
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	MHD/02/17310	*Under print*
14	ISO 5834-2:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms	MHD/02/17336	*Under print*
15	ISO 5834-3:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 3: Accelerated ageing methods		**Not Adopted**
16	ISO 5834-4:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 4: Oxidation index measurement method		**Not Adopted**
17	ISO 5834-5:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 5: Morphology assessment method		**Not Adopted**
18	ISO 6474-1:2019	Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina	IS/ISO 6474-1: 2010	***Revision Needed***

19	ISO 6474-2:2019	Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement	IS/ISO 6474-2: 2012	***Revision Needed***
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 9584:1993	Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants	IS/ISO 9584: 2021	Published Jan-2021
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	MHD/02/17598	*Under print*
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		**Not 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**	**IS 5347(Part 17): 2002/ISO 13782: 1996**	***Revision Needed***
31	ISO 14949:2001	Implants for surgery — Two-part addition-cure silicone elastomers		**Not Adopted**
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 15374:1998	Implants for surgery — Requirements for production of forgings		**Not Adopted**
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		**Not Adopted**
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		**Not Adopted**

37	ISO 20160:2006	Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars		**Not Adopted**
38	ISO 23317:2014	Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials		**Not Adopted**

ISO/TC 150/SC 5 Osteosynthesis and spinal devices (P member)

Sr. 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**	**To be revised**
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**	**To be revised**
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		**Not 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		**Not adopted**
18	ISO 14602:2010	Non-active surgical implants — Implants for osteosynthesis — Particular requirements		**Not adopted**
19	ISO 15142-1: 2003	Implants for surgery — Metal intramedullary nailing systems — Part 1: Intramedullary nails		**Not adopted**
20	ISO 15142-2: 2003	Implants for surgery — Metal intramedullary nailing systems — Part 2: Locking components		**Not adopted**
21	ISO 15142-3: 2003	Implants for surgery — Metal intramedullary nailing systems — Part 3: Connection devices and reamer diameter measurements		**Not 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		**Not 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 testing and corresponding environmental conditions for test — Amendment 1		**Not adopted**
24	ISO 18192-2: 2010	Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 2: Nucleus replacements		**Not 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		**Not 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		**Not adopted**

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

Sr. 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		**Not Adopted**

		made of metallic, ceramic and plastics materials — Amendment 1		
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 resistance to static load of modular femoral heads	IS 12375 (Part 10): 2023	Published May-2023
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		
9	ISO 7206-12: 2016	Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells		**Not Adopted**
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		**Not Adopted**
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		**Not 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		**Not Adopted**
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		**Not Adopted**
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		**Not Adopted**
16	ISO 11491:2017	Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses		**Not Adopted**
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		**Not Adopted**

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		**Not Adopted**
19	ISO 14242-2: 2016	Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement		**Not Adopted**
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		**Not Adopted**
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		**Not Adopted**
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		**Not Adopted**
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 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		
28	ISO 14243-5: 2019	Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint		**Not Adopted**
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		**Not Adopted**
31	ISO 17853:2011	Wear of implant materials — Polymer and metal wear particles — Isolation and characterization		**Not Adopted**
32	ISO 19233-1:2017	Implants for surgery — Orthopaedic joint prosthesis — Part 1: Procedure for producing		**Not Adopted**

		parametric 3D bone models from CT data of the knee		
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**	**IS/ISO 21535: 2007**	**Revision needed**
35	**ISO 21536:2023**	**Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants**	**IS/ISO 21536: 2007**	**Revision needed**
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		**Not Adopted**

ISO/TC 150/SC 6 Active implants (O Member)

Sr. no	ISO	Title	Existing IS	Status of adoption
1	ISO 5841-2: 2014	Implants for surgery — Cardiac pacemakers — Part 2: Reporting of clinical performance of populations of pulse generators or leads	IS 17712 (Part 2): 2021/ ISO 5841-2:2014	Published Nov-2021
2	ISO 5841-3: 2013	Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers	IS 17712 (Part 3): 2021/ ISO 5841-3:2013	Published Dec-2021
3	ISO/TS 10974:2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	IS/ISO/TS 10974: 2018	Published Aug-2019
4	ISO 11318:2002	Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements	IS 17709: 2022 ISO 11318:2002	Published Feb-2022
5	ISO 14117:2019	Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices	IS 17842: 2022/ ISO 14117:2019	Published Apr-2022
6	ISO 14708-1: 2014	Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	IS/ISO 14708-1: 2014	Published Jun-2019
7	ISO 14708-2: 2019	Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers	IS/ISO 14708-2: 2019	Published Sept-2021
8	ISO 14708-3: 2017	Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators	IS/ISO 14708-3: 2017	Published Mar-2019

9	ISO 14708-4: 2022	Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pump systems		**Not adopted**
10	ISO 14708-5: 2020	Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices	IS 17750 (Part 5): 2021/ ISO 14708-5:2020	Published Dec-2021
11	ISO 14708-6: 2019	Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)	IS 17750 (Part 6): 2022/ ISO 14708-6:2019	Published Oct-2022
12	ISO 14708-7: 2019	Implants for surgery — Active implantable medical devices — Part 7: Particular requirements for cochlear and auditory brainstem implant systems	IS 17750 (Part 7): 2021/ISO 14708-7: 2019	Published Dec-2021
13	ISO/TR 21900: 2018	Guidance for uncertainty analysis regarding the application of ISO/TS 10974		**Not adopted**
14	ISO 27185:2012	Cardiac rhythm management devices — Symbols to be used with cardiac rhythm management device labels, and information to be supplied — General requirements	IS 17710: 2021/ ISO 27185:2012	Published Dec-2021
15	ISO 27186:2020	Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements	IS 17746: 2021	Published Nov-2021
16	IEC 60601-2-31: 2020	Medical electrical equipment — Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	IS 13450 (Part 2/Sec 31): 2021/IEC 60601-2-3: 2020	Published Sept-21

ANNEX-D

(Item 8)

List of standards published prior to 2000

Sr No	IS No	IS Title	Remarks
1	IS 5089: 1969	Specification For Blade Plate, Blount Type	
2	IS 5347: Part 1:1986	Requirements for orthopaedic implants: Part 1 general requirements (Second Revision)	
3	IS 5395: Part 1:1989/ ISO 5837/1-1985	Specification for surgical implants - Intramedullary nailing systems for bone surgery Part 1 intramedullary nails with cloverleaf or v - Shaped cross - Section (Second Revision)	
4	IS 5396:1969	Specification for guide pin for kuntscher nail	
5	IS 5397:1969	Specification for reamer, flexible for kuntscher nail (Meddulary canal)	
6	IS 5574:1970	Specification for forceps, wire cutting, compound action, orthopaedic	
7	IS 5580:1970	Specification for chisels, stille pattern, orthopaedic	21087
8	IS 5581:1970	Stirrup, Bohler's	21085-Draft for finalization
9	IS 5583:1970	Specification for osteotomes, stille pattern, orthopaedic	21088
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 5848:1996	Implants for surgery - Skeletal pins and wires - Steinmann skeletal pins - Dimensions (First Revision)	
17	IS 6187:1971	Specification for saw, wire (Gigli Pattern)	
18	IS 6233:1971	Specification for forceps, bone cutting (Stille Liston Pattern)	First Revision under print
19	IS 6252:1971	Scissors Bandage, Lister's Pattern	21077
20	IS 6281:1971	Specification for Awl, bone	First Revision under print
21	IS 6289:1971	Specification for staple, epiphyseal, orthopaedic	21064
22	IS 6319:1971	Specification for clamp, bone, Lowman type	21063
23	IS 6371:1971	Forceps, Bone Holding, Lane's, Lane-fagge's and Fergusson's Patterns	First Revision under print
24	IS 6484:1972	Forceps, Gouge, Orthopaedic Fergusson's Pattern	First Revision under print
25	IS 6485:1972	Specification for forceps, gouge, angular, orthopaedic	First Revision under print
26	IS 6486:1972	Forceps, Gouge, Orthopaedic Lane's Pattern	19659-Draft for finalization
27	IS 6501:1972	Forceps, Gouge, Orthopaedic, Stille Luer's Pattern	First Revision under print
28	IS 6801: Part 1:1999	Orthopaedic instruments - Drive connections Part 1 keys for use with screws with hexagon socket heads (Second Revision)	

29	IS 6801: Part 2:1987	Specification for drive connections for orthopaedic instruments: Part 2 screw drivers for single slot head screws, screws with cruciate slot and cross - Recessed head screws (First Revision)	
30	IS 6975:1973	Specification for reamer, trochanteric, orthopaedic	
31	IS 6976:1973	Specification for awl, kuntscher, diamond pointed	
32	IS 6982:1973	Specification for gauge for intramedullary nails	
33	IS 7055:1973	Specification for drivers, kuntscher, nail, orthopaedic	
34	IS 7102:1973	Specification for screw, bone, leinbach, medullary	
35	IS 7105: Part 1:1973	Specification for extractor for kuntscher nail Part 1 handle type	
36	IS 7105: Part 2:1986	Specification for extractor for kuntscher nail Part 2 striker type	
37	IS 7106:1973	Specification for extractor, staple, orthopaedic	
38	IS 7107:1973	Specification for punch, staple, orthopaedic	
39	IS 7108:1973	Specification for hammer for kuntscher nail extractor	
40	IS 7109:1973	Specification for starter, staple, orthopaedic	
41	IS 7111:1973	Specification for inserter, staple, orthopaedic	
42	IS 7398:1974	Forceps, Bone Holding, Farabeuf's Pattern	22703
43	IS 7435:1974	Rongeur, Ruskin's Pattern	
44	IS 7442:1974	Forceps, Bone Cutting, Straight and Angular, Liston's Pattern	
45	IS 7629:1975	Specification for bender, plate, orthopaedic	
46	IS 7650:1975	Specification for drill, hand, bone, universal, micro and Kirschner	
47	IS 7817:1975	Specification for impactor for hip prosthesis	
48	IS 7818:1975	Specification for broach, moore type, for hip prosthesis	
49	IS 7819:1975	Specification for mallet, nylon headed, orthopaedic	22704
50	IS 7841:1975	Specification for compression plate, muller type	
51	IS 7846:1975	Specification for extractor for Hip Prosthesis	
52	IS 8261: Part 1:1976	Specification for pins and wires, skeletal, traction: Part 1 kirschner wires	
53	IS 8261: Part 2:1976	Specification for pins and wires, skeletal, traction: Part 2 guide wires	
54	IS 8261: Part 3:1976	Specification for pins and wires, skeletal, traction: Part 3 pins and wires, fixation and threaded	
55	IS 8332:1977	Specification for handle, saw, Gigli	22705
56	IS 8608:1977	Specification for countersinks, pilot type, for orthopaedic use	
57	IS 8755:1977	Method for testing biological compatibility of metals for surgical implants	
58	IS 8922:1978	Specification for depth gauge for orthopaedic use	
59	IS 8926:1978	Bone Skid, Murphy Lane's Pattern	First Revision under print
60	IS 9265:1979	Clamp, Compression, Muller's Pattern	First Revision under print
61	IS 9829: Part 1:1996/ ISO 5835	Implants for surgery - Metal bone screws Part 1 with hexagonal drive connection, spherical under surface of head, asymmetrical thread - Dimensions (First Revision)	
62	IS 9829: Part 2:1996/ ISO 9268	Implants for surgery - Metal bone screws: Part 2 with conical under - Surface of head - Dimensions (First Revision)	

63	IS 10121: Part 1:1982	Specification for metal bone screws – Mechanical requirements and methods of test: Part 1 screws with asymmetrical thread, variable fitting	
64	IS 10121: Part 2:1982	Specification for metal bone screws - Mechanical requirements and methods of test: Part 2 screws with asymmetrical thread, constant fitting	
65	IS 10128: 1982	Specification for pin, Knowles	First Revision under print
66	IS 10155: 1982	Specification for blade plate, femoral, lower	20867
67	IS 10235: Part 1:1982	Glossary of terms: Part 1 general medical terms for surgical implants	
68	IS 10235: Part 2:1982	Glossary of terms in orthopaedics: Part 2 mechanics and materials for implants	
69	IS 10235: Part 3:1982	Glossary of terms in orthopaedics: Part 3 orthopaedic surgery	
70	IS 10326: 1982	Spreader, Plaster Cast, Henning's Pattern	
71	IS 10327: 1982	Bender, Plaster, Bohler's Pattern	
72	IS 10338: 1982	Specification for saw, plaster, hand	
73	IS 10349: 1982	Rasp for Hip Prothesis, Thompson's and Moore's Patterns	
74	IS 10727: 1983	Specification for nail, square, Ulna	First Revision under print
75	IS 10728: 1983	Specification for nail, square, radius	First Revision under print
76	IS 10729: 1983	Specification for nail set, kuntscher	
77	IS 10730: 1983	Osteotome, Whitchurch Howell's Pattern	
78	IS 11567: Part 1:1986	Specification for holes and slots for metal bone plates: Part 1 corresponding to screws with asymmetrical thread and spherical under – Surfaces	IS 18078: 2023/ ISO 5836: 1988
79	IS 11567: Part 3:1986	Specification for holes and slots in metal bone plates: Part 3 corresponding to screws with asymmetrical thread and conical under – Surfaces	IS 18079: 2023/ISO 9269: 1988
80	IS 11567: Part 4:1986	Specification for holes and slots in metal bone plates: Part 4 corresponding to screws with symmetrical thread and conical undersurfaces	IS 18079: 2023/ISO 9269: 1988
81	IS 11568: 1986	Forceps, Bone Holding, Semb's Pattern	Draft under preparation
82	IS 11569: 1986	Specification for cervical collar	First Revision under print
83	IS 11953: 1986	Specification for driver and bender for rush intramedullary pin	
84	IS 12088: 1987	Specification for bone plate, dynamic compression	
85	IS 12172: 1987	Specification for distraction cervical collar	
86	IS 12304: 1987	Specification for Plastic Cervical Collar	22677
87	IS 13423: 1992	Good manufacturing practices for orthopaedic implants - Guide	

88	IS 14227: 1995/ ISO 8615	Implants for surgery - Fixation devices for use in the ends of the femur in adults	
89	IS 14228: 1996/ ISO 8827	Implants for surgery - Staples with parallel legs for orthopaedic use - General requirements	
90	IS 14229: 1995/ ISO 9585	Implants for surgery - Determination of bending strength and stiffness of bone plates	