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)	17	17 May 2024, Friday 11 AM

via Webex platform

Meeting Link:
https://bismanak.webex.com/bismanak/j.php?MTID=m6703b1c15ce98e01f931789dc721176c

Meeting Number: 2517 549 4780
Password: Mhd02@17

Chairperson	Member Secretary
Dr Sudhir Kumar (*In-Personal capacity*)	Mr. Vinit Vidyadhar Bansod Scientist-C/Deputy Director

ITEM 0 GENERAL

0.1 WELCOME ADDRESS

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 16th meeting of the Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02) held on 28 February 2024 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD02/A2.16 dated 13 March 2024.

1.2 No comments have been received so far.

The Committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

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

2.3 Requests have been received from the following for representation on the Committee:

Sl. No.	Organisation	Nomination
1)	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong	Dr Bhaskar Borgohain, Professor & HoD, Department of Orthopaedics and Trauma (Refer ***Annexure B)***

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

There are no draft standards/amendments pending for finalization.

The Committee may kindly note.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

There are no draft standards/amendments pending for approval for wide circulation.

The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 There are currently no indigenous subject drafts under preparation.

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 deliberate.

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 Following new subjects have been received from the DGHS, GoI, for formulation of Indian Standards on priority.

Sr. No.	Name of Equipment
1)	Battery Operated Saw
2)	High Speed Pneumatic Drill
3)	Cannulated Battery Drill
4)	Automatic Tourniquet
5)	Battery Operated Drill
6)	Arthroscopy Work Station
7)	Single/ Double Bundle **ACL Reconstruction Set** + **PCL Reconstruction**
8)	Meniscal repair Set
9)	Bankart repair Set
10)	Rotator Cuff repair Set

The Committee may kindly deliberate.

ITEM 8 TECHNICAL ISSUES

There are no specific technical issues to be discussed.

ITEM 9 INTERNATIONAL ACTIVITIES

9.1 Committee may consider enhancing ISO participation by nominating experts on the relevant ISO working groups. The current status participation is given below.

TC No.	WG No	WG Title
ISO TC 150	ISO/TC 150/JWG 1	Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications

TC No.	WG No	WG Title
Implants for surgery	ISO/TC 150/WG 7	Fundamental standards ***Nominated Members*** *1) Dr Kantesh Balani, IIT, Kanpur* *2) Dr. Bhushan P. Chaudhari, CSIR - National Chemical Laboratory, Pune* *3) Mr. Deepak Gupta, Association of Indian Medical Device Industry, New Delhi* *4) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD02*
	ISO/TC 150/WG 8	Breast implants
	ISO/TC 150/WG 10	Use and retrieval of surgical implants
	ISO/TC 150/WG 12	Implant coatings
	ISO/TC 150/WG 13	Absorbable implants
	ISO/TC 150/WG 14	Models of tissues for mechanical testing of implants
	ISO/TC 150/WG 15	Neurosurgical implants (*Under the purview of MHD07*)
	ISO/TC 150/WG 16	Antimicrobial properties of implants ***Nominated Members*** *1) Dr. V. Koteswara Rao, CSIR - National Chemical Laboratory, Pune* *2) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD02*
ISO/TC 150/SC 1 Materials	ISO/TC 150/SC 1/WG 3	Ceramics ***Nominated Members*** *1) Dr Kantesh Balani, IIT, Kanpur* *2) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD02*
	ISO/TC 150/SC 1/WG 4	Metals ***Nominated Members*** *1) Mr. Deepak Gupta,Association of Indian Medical Device Industry, New Delhi* *2) Dr. Vamsi K. Balla,CSIR-Central Glass and Ceramic Research Institute, Kolkata* *3) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD02*
	ISO/TC 150/SC 1/WG 5	Plastics

TC No.	WG No	WG Title
		Nominated Members *1) Dr Kantesh Balani, IIT, Kanpur* *2) Mr. Deepak Gupta, Association of Indian Medical Device Industry, New Delhi* *3) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD02*
ISO/TC 150/SC 4 Bone and joint replacements	ISO/TC 150/SC 4/WG 1	Mechanical testing ***Nominated Members*** *1) Mr. Deepak Gupta, Association of Indian Medical Device Industry, New Delhi* *2) Dr. V. Koteswara Rao, CSIR - National Chemical Laboratory, Pune* *3) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD 02*
	ISO/TC 150/SC 4/WG 3	Wear ***Nominated Members*** *1) Mr. Deepak Gupta, Association of Indian Medical Device Industry, New Delhi* *2) Mr. Vinit Vidyadhar Bansod, Member Secretary, MHD 02*
	ISO/TC 150/SC 4/WG 4	General requirements
ISO/TC 150/SC 5 Osteosynthesis and spinal devices	ISO/TC 150/SC 5/WG 1	Osteosynthesis devices
	ISO/TC 150/SC 5/WG 2	Spinal devices

9.2 Appointed Working Group Experts are obliged to inform the National Mirror Committee (i.e. the concerned BIS Technical Committee) of their contribution and progress of technical work carried out by them at the ISO level.

9.3 The meetings of ISO/TC 150 'Implants for Surgery' and its Sub-committees and Working Groups are scheduled to be held from **09** to **13 September 2024** in Berlin, Germany. Nominations were sought from the MHD 02 Committee members vide our email dated 09 May 2024. The last date for submitting nominations was 15 May 2024.

9.3.1 The following nominations have been received from member MHD02.

1) Dr. Kantesh Balani, IIT Kanpur
2) Dr. Vamshi K. Balla, CSIR-CGCRI, Kolkata

9.3.2 In addition to above, representing BIS Secretariat, the Member Secretary, Mr Vinit Vidyadhar Bansod, Sc-C/DD has also been proposed to be a part of the Indian delegation.

9.3.3 In addition to the meeetings of ISO/TC 150, ISO/TC 150/SC 1, ISO/TC 150/ SC 4, and ISO/TC 150/SC 5, the meetings of **ISO/TC 150/SC 2** 'Cardiovascular implants and extracorporeal systems' and **ISO/TC 150/SC 6** 'Active implants' are also scheduled.

In this regard the committee may please note that the *MHD06 - Medical and Surgical Cardiology Equipment Sectional Committee* is the National Mirror Committee for the ISO/TC 150/SC 2 and ISO/TC 150/SC 6.

9.3.4 Accordingly, MHD06, with the approval of Chairperson MHD 06, have nominated the following to be part of the Indian delegation for attending the meetings of ISO/TC 150/SC 2 and ISO/TC 150/SC 6.

1) Shri Pawan Kumar, Sc-B/AD (Member Secretary, MHD06)
2) Ms Gayathi Nair, Meril Lifesciences

The Committee may kindly consider.

9.4 The list of standards published by ISO/TC 150, ISO/TC 150/SC 1, ISO/TC 150/SC 4, and ISO/TC 150/SC 5 are given at ***Annexure C***.

9.5 Given that BIS holds a Participating Membership in these technical committees, it is crucial for its members to vote on the notified ballots. An updated list of ballots received since the previous meeting, along with the votes cast by us as the national mirror committee, is enclosed at ***Annexure D***.

ITEM 10 PROGRAMME OF WORK

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

The Committee may kindly note.

ITEM 11 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

There are no specific issues to be discussed from the previous meeting.

ITEM 12 DATE AND PLACE OF NEXT MEETING

As per the approved meeting calendar for **FY 2024-25,** the next meeting of the Hospital Planning Sectional Committee is tentatively scheduled for August 09, 2024, Friday.

The Committee may kindly note.

ITEM 13 ANY OTHER BUSINESS

Annexure A

(*Item 2.2*)

Composition of the Committee

Sl No.	Organization	Member Name
1	IN INDIVIDUAL CAPACITY	Dr. Sudhir Kumar
2	Artificial Limbs Manufacturing Corporation of India, Kanpur	Mr. A K Singh
		Mr. Vishal Shukla
3	Association of Indian Medical Device Industry, New Delhi	Mr. Anuj Dureja
		Mr. Ankur Bhargava
		Mr. Deepak Gupta
4	CSIR - Central Glass and Ceramic Research Institute, Kolkata	Dr. Biswanath Kundu
		Dr. Vamsi K Balla
5	CSIR - National Chemical Laboratory, Pune	Dr. Mahesh J Kulkarni
		Dr. Bhushan P. Chaudhari
		Dr. V. Koteswara Rao
6	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu
		Mr. Vinod Kumar Naik Mude
		Mr. Ajai Basil
7	Consumer Coordination Council, New Delhi	Dr. P. Ramarao
		Ms. Neetu Chauhan
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
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
		Mr. Sreeraj Pallath Rajan
12	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak	Dr. Roop Singh
13	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr. Manoj Komath
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

Resume

Name: Dr Bhaskar Borgohain
Father's Name: Jibon Ch Borgohain
Current Designation: Professor & HoD
Current Affiliation: Department of Orthopaedics and Trauma
NEIGRIHMS Shillong. www.neigrihms.gov.in

Address and Contact details

A-21, NEIGRIHMS Campus, Shillong-793018
Email: bhaskarneigrihms@gmail.com
Mobile: 9436706397 / 8837275614 (WhatsApp)

Educational Qualification:

MBBS (Assam Medical College)
MS (Delhi University)
DNB (National Academy of Medical Sciences)

International Fellowships

AO Trauma Fellow (Germany)
Trauma Disaster Management Fellow (Israel)

National Fellowship

J & J Fellowship (Joint Replacement)

Academic Appointments

2002-2005: Academic Senior Resident: Dr. Ram Manohar Lohia Hospital, New Delhi
2005-2006: Jr. Consultant, JCI -Accredited Indraprastha Apollo Hospital, New Delhi
2006-2013: Asst. Professor i/c HoD, Department of Orthopaedics at NEIGRIHMS
2013-2019: Associate Professor i/c HoD, Orthopaedics NEIGRIHMS, Shillong
2019-till date: Professor and HoD, Department of Orthopaedics at NEIGRIHMS, Shillong

Teaching Experience (as on 19-03-2024)

Postgraduate period in M.S. Orthopaedics: 03 years
Senior Residency in Orthopedics: 03 years
Assistant Professor, Shillong: 06 years 02 months 10 days
Associate professor, Shillong: 06 years 27 days
Professor and HoD, Shillong: 04 year 11 months 12 days

Total Teaching experience = 23 years 2 months

Administrative and corporate activities

1. Expert member, Ethics and Appeal Board (Registration), National Medical Commission
2. Expert member, Undergraduate orthopaedics education, National Medical Commission
3. Member National Committee on student ethics and responsibility, National Medical Commission
4. Member, State allied healthcare professionals' council Meghalaya (under National Commission for Allied and Healthcare professions act 2021)

5. Member, Board of Studies: NEHU Central University Shillong
6. Member, School of Technology, NEHU Central University Shillong
7. Member, State task force for control of tuberculosis (under RNTCP)

Scholarly affiliations

1. Editorial Board Member, Indian Journal of Orthopaedics, Indian Orthopaedic Association
2. Editorial Board Member, Journal of Clinical Orthopaedics & Traumatology (Pubmed), Delhi Orthopaedic Association
3. Thesis examiner, MCh Orthopaedics, Edinburgh University (UK)
4. External Examiner: MD Sports Medicine GGS IP University, Delhi
5. External Examiner, MS Orthopaedic Surgery, Patna Medical College
6. Thesis examiner, MS Orthopaedics, Manipur University
7. Thesis examiner, MS Orthopaedics, S. S. University of Health Sciences, Assam
8. National Faculty, AO trauma Courses, India for the years 2013, 2015, 2018, 2021, 2022
9. National Faculty, Biomaterials Courses, Coimbatore Institute of Technology, Tamil Nadu
10. National Faculty, QIP Biomaterials Courses, Indian Institute of Technology, Guwahati

Awards

1. Vocational Excellence Award of Rotary Club Shillong at Raj Bhawan 2022
2. Balu Sankaran Oration: 66th Annual Conference (Goa), Indian Orthopaedic Association 2021
3. 7th Dr Bhupen Hazarika Pillar of Humanity Award 2021-22
4. Best Researcher Award in Science-Engineering-Medicine, VD Good Professional Association (Chennai, India): 2020
5. Academic Excellence Awards 2015-16, NEIGRIHMS (For the second time)
6. Academic Excellence Awards 2014-15: NEIGRIHMS (The Highest Award of the Institute)
7. R.C. Rallan Gold Medal Nomination on Basic Science Research: 66th Annual Conference (Goa), Indian Orthopaedic Association Goa 2021
8. P. Kanabar Gold Medal Nomination on Sports Research: 64th Annual Conference (Kolkata)Indian Orthopaedic Association Kolkata 2019
9. National President's Award as the Best State Secretary, Indian Medical Association: 2020
10. Certificate of distinguished services as Medical Board Member, South Asian Games -2016
11. Certificate of distinguished services From District Commissioner, Charaideo, Assam 2018
12. Chaired scientific session in 9th world Biomaterials Congress held first time in Asia-2012

Research work and Journal Publications

Published over 70 research papers on Advanced Biomaterials, Trauma (including sports injuries) and diseases of musculoskeletal system in reputed International, National journals and peer reviewed publications. Collaborative Research work with Harvard Medical School, University of Colorado, IIT Guwahati and NIT Patna. PhD Thesis submission on fat embolism syndrome. Thesis guidance to several MD Students of Radiology, Microbiology and Gynecology having multidisciplinary research thesis. Currently Editorial Borad member of four reputed Journals of Orthopaedics.

List of Important Publications

1. Nag P, **Borgohain B**, Ahmed KA, Phukan P, Kumar N, Borjali A, Varadarajan KM, Chanda S. The Influence of Static Load and Sideways Impact Fall on Extramedullary Bone Plates Used to Treat Intertrochanteric Femoral Fracture: A Preclinical Strength Assessment. Ann Biomed Eng. 2022 Jul 12 PMID: 35821164
2. Nag P., **Borgohain B.**, Chanda S. Novel Design of Minimal Incision Double Oblique Device for Osteosynthesis (DODO) of Hip: Results of an In-silico Study Based on the Femur Morphometrics of the North-East (NE) Indian population. *Indian Journal of Orthopaedics* 2021; **55,** 385–94 PMID: 34306552
3. Khonglah TG, **Borgohain B**, Khongwir W, Ahmed KA. Clinical outcome and cost analysis of negative pressure wound therapy in extremity wounds: a comparison to conventional wound management. *Int J Res Orthop* 2021; 7: 97-102
4. Arun S, Marbaniang B, **Borgohain B**, Kanagaraj S. Rehabilitation evaluation of the newly developed polymeric based passive polycentric knee joint. *Disability and Rehabilitation: Assistive Technology.* 2019 Jun 5:1-7
5. Davis, R., Singh, A., Debnath, K., Sabino, R. M., Popat, K., Soares, P., Keshri, A. K., and **Borgohain B**. Enhanced Micro-Electric Discharge Machining-Induced Surface Modification on Biomedical Ti-6Al-4V Alloy. *ASME J Manuf Sci Eng* 2021; 144(7): 071002
6. da Silva L R R, Sales W F, Campos F D A, de Sousa J A G, Davis R, Singh A, Coelho R T**, Borgohain B.** A comprehensive review on additive manufacturing of medical devices. *Progress in Additive Manufacturing* 2021; 3 DOI:10.1007/S40964-021-00188-0
7. Sharma D, **Borgohain B,** Saikia B (2021). Mucormycosis and diabetes: Lessons from the COVID pandemic. Assam J Intern Med 2021; 11:60-1
8. **Borgohain B,** Tariang C, J P Darjee, et al. A Report on injuries and illnesses among Athletes and Games Officials during XII South Asian Games (SAG-2016), Shillong, India. Submitted to *Int J Res Orthop*. 2017; Vol 3 (5) :1-7
9. V. Singh, A.C.Phukan, **Borgohain B**. Importance of Ultrasonographic guided aspirated sample in early diagnosis of Musculoskeletal tuberculosis among the patients attending tertiary health care centre. British Journal of Medical and Health Research. 2018; 5(5)
10. T. Khonglah, **Borgohain B**, Khongwir W, Kashif Ahmed. Extremity chronic osteomyelitis in a population of North East India: epidemiology, clinical characteristics and management. International Journal of Research in Orthopaedics. Int J Res Orthop. 2020 Jul;6(4):754-9
11. B. Saikia, Samarjit Dey, **Borgohain B** et al. Medical Research in India - Comprehending Challenges and Quest for Renaissance. Annals of International Medical and Dental Research. 2017; 3 (6): 3-7
12. **Borgohain B**, T. Khonglah: Developing and organizing a trauma system and mass casualty management: Some useful observations from the Israeli trauma model. ***Ann Med Health Sci Res***. 2013; 3(1): 85–9
13. **Borgohain B**, Kumar B, S. Balasubramanian et al. Risks of concomitant trauma to the knee in lower limb long bone shaft fractures: A retrospective analysis from a prospective study population. **Adv Biomed Res**. 2013; 3:49
14. **Borgohain B.** Ethical issues in Orthopaedic Surgery: A perspective. Global Bioethics Enquiry (Scholarly publication of UNESCO Chair of Bioethics: 2018; Special supplementary issue :S-33
15. Khongwir WK, Khonglah TG, **Borgohain B**, Ahmed K. Traumatic anterior hip dislocation in 4- year-old child with polytrauma and flail chest. Journal of Orthopedics,

Traumatology and Rehabilitation. 2018 Jan 1;10(1):83

16. T. Khonglah, **Borgohain B**, Wanlam K. Khongwir, Kashif A Ahmed. Salvage of segmental defect of tibia using the Huntington's procedure: A case report. National Journal of Clinical Orthopaedics. 2018; 2(3):87-9
17. Ahmed KA, Khonglah T, **Borgohain B**, Khongwir W, Magu D. An Uncommon Presentation of Chronic Osteomyelitis of the Fibula in an 11-Year-Old Child: A Case Report. Journal of Diagnostic and Clinical Research. 2019 June; 13(6): RD01-RD03
18. **Borgohain B**, Kashif A, Khonglah T. Endoscopy assisted extended curettage in a rare case of aneurysmal bone cyst involving the 2nd metatarsal of a child. Int J Res Orthop. 2020 May;6(3):638-42
19. **Borgohain B**, Kashif Akhtar Ahmed, Tashi Galen Khonglah, Wanlam K. Khongwir. A case report on survival of a polytrauma patient with Fat Embolism Syndrome treated by principles of damage control orthopaedics and intensive care, Indian Journal of Applied Research. 2020 April; 10(4):1-2
20. T. Khonglah, **Borgohain B**, Kashif Ahmd. Arthroscopic assisted evacuation of a rare Brodie's abscess in the femoral head of an adolescent girl – A case report. Indian Journal of Orthopaedics Surgery. April 2020; 6(1):50-3
21. T. Khonglah, Kashif A. Ahmed, **Borgohain B**. A rare case report of bilateral distal radius fractures including bilateral isolated metacarpophalangeal joint dislocations in a piano artist. International Journal of Orthopaedics Sciences 2020; 6(2): 104-6
22. **Borgohain B,** T.Khonglah, J. Bareh**:** Tuberculous dactylitis (spina ventosa) with concomitant ipsilateral axillary scrofuloderma in an immunocompetent child: A rare presentation of skeletal tuberculosis. ***Adv Biomed Res***. 2013, 2:29
23. **Borgohain B**: Commentry: Role of MRI in spinal tuberculosis. ***J Neurosc. Rur Prac***. 2013; 4:128-31
24. **Borgohain B,** N. Borgohain, T. Khonglah et al. Occult renal cell carcinoma with acrometastasis and ipsilateral juxta-articular knee lesions mimicking acute inflammation: A case report. ***Adv Biomed Res***. 2012, 1:48
25. **Borgohain B**, N. Borgohain, T. Khonglah et al. Complete incorporation of long diaphyseal sequestrum without surgical intervention in chronic haematogenous osteomyelitis of tibia in an immunocompetent child: a case report. ***Adv Biomed Res***. 2012. 1(4) 49-51
26. **Borgohain B,** N. Borgohain, A. Handique et al. Case report and brief review of literature on sonographic detection of accidentally implanted wooden foreign body causing persistent sinus. ***Crit Ultrasound J*** 2012, 4:10
26. **Borgohain B**: Prompt restoration of airway along with rapid neurological recovery following ultrasound guided needle aspiration of tubercular retro-pharyngeal abscess causing airway obstruction: A case report. ***Singapore Med J.*** 2011; 52(11): e229-31
27. **Borgohain B,** Tashi G Khonglah, Cherry M Tariang. Profile of rare disabling musculoskeletal diseases in the North-Eastern Region of India: A hospital-based study. **Indian Journal of Orthopaedic Surgery**. July-Dec 2017; 3(2): 209-16
28. **Borgohain B**, Tashi G Khonglah, B.Marbaniang. A Brief Report on Amputees from North East India: A tertiary care hospital-based study. Accepted for publication in ***Journal of Orthopaedics*** 2018; 5 (1): 12-7
29. **Borgohain B,** P. Phukan, K. Sarma. Prevalence of osteoporosis among vulnerable adults residing in the North-Eastern Region of India: a preliminary report from a tertiary care referral hospital. Accepted for publication by ***Journal of Orthopedics, Traumatology and Rehabilitation***: July-Dec 2017; 9 (2): 84-7
30. **Borgohain B,** Barman**.** Clinico-epidemiological profile and treatment outcome (DAS28-ESR) in Adult Rheumatoid Arthritis: Early results of intensive treatment in a tertiary care institute from North-East India. ***Journal of Indian Orthopaedic Rheumatology Association***. July-Dec 2017;3 (2):29-34

31. **Borgohain B,** T.G. Khonglah, N. Borgohain**.** Chronic recurrent multifocal osteomyelitis (CRMO) presenting as nonhealing wound: Case report and brief review of literature: ***Journal of Indian Orthopaedic Rheumatology Association*** Jan-June 2017; 3(1): 27-31
32. **Borgohain B**, Saikia B, Sarma A. Proximal tibiofibular joint: Rendezvous with a forgotten articulation. Indian J Orthop. 2015; 49(5): 489-95
33. **Borgohain B**, Saikia B, Sarma A. Cultivate…. research an attitude and learning a passion. Indian J Orthop. 2014 Nov; 48(6):631-2
34. **Borgohain B**, N.Borgohain, P. Tittal: ***Original article***: "Double parabolic K-Wires for definitive treatment of unstable intra-articular phalangeal fractures of hand". ***Indian J Orthop.*** 2012; 46 (6): 680-4
35. **Borgohain B**. Salvage of infected total knee arthroplasty with ilizarov external fixator: Letter to the editor. ***Indian J Orthop***. 2012; 48 (4):470
36. **Borgohain B.** (Editorial) treatment evolution and evidence Based practices in managing thoraco- lumbar spine injuries. ***North East Orthoscan*** 7 (3); 2011: 5-9
37. K B Attri, **Borgohain B**: "Total knee replacement in severe varus deformity: A brief insight". ***North East Orthoscan*** 2011; 7(3) 104-8
38. M. Kapoor, **Borgohain B**, A. Mishra et al. Peroperative management in orthopaedic surgery: Patients with coronary artery disease. ***North East Orthoscan*** 2011; 7(3): 61-7

Book Chapters

1. **Borgohain B**, S.Lahkar. Ankylosing Spondylitis and other seronegative spondyloarthropathies. Textbook of Orthopaedics and Trauma. 3rd Edition. (Editor: Kulkarni GS, Jaypee publication, India)
2. **Borgohain B**. Other spondyloarthropathies.Textbook of Orthopaedic Rheumatology. 1st Edition, Delhi; Jaypee 2021
3. **Borgohain B.** Otherspondyloarthropathies. TextbookofOrthopaedicRheumatology.1st Edition, Delhi; Jaypee 2021
4. **Borgohain B**, S. Arun, P. S. Rama Sreekanth, S. Kanagaraj. Biomaterials in Total Hip Replacements: Evolution of basic concepts, trends and current limitations, Trends in Biomaterials. (Editors: G.P. Kothiyal, A. Srinivasan), Pam Stanford, Hong Kong

Pioneering Work in Orthopaedics

1. Performed the first successful Total hip and Total knee Replacement, spine surgery under operating microscope and heads the Sports injury clinic since 2010 at NEIGRIHMS
2. Developed nanotechnology based Indigenous artificial limb with IIT Guwahati 2012-2015
3. Developed New Hip Fixation Device with IIT Guwahati 2020-2022 (Patent awaited)
4. Regularly performs Arthroscopic Sports Surgery of Knee and Ankle joint on sportspersons
5. Delivered over 100 invited lectures at Regional, National and International Conferences on Orthopaedic injuries, Joint Replacements, Sports injuries, Spine diseases, Joint diseases, hand surgery, Rehabilitation Engineering and Biomaterials
6. Trained in Computer navigated Total Knee Replacement during 2005 and 2006

Research Projects with Harvard Medical School

1. The Influence of Static Load and Sideways Impact Fall on Extramedullary Bone Plates Used to Treat Intertrochanteric Femoral Fracture: A Preclinical Strength Assessment

Funded Research Projects with IIT Guwahati

1. Title of the project: Feasibility studies on Carbon Nanotubes- UHMWPE Nanocomposite for Total Joint Replacements. Deptt. of Science & Technology. Govt. of India. Project completed in May, 2012. Grant: Rs 24,64 Lakhs.
2. Title of the project: Developing light weight, durable and user-friendly artificial limbs through Nanotechnology-based modification of conventional materials and optimizing mechanical component design for enhancing their functional performance. Funding agency. Deptt. of Biotechnology (2012-2015). Project completed in 2016. Grant: Rs 33.69 Lakhs.

Annexure C

(*Item 9.4*)

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

ISO/TC 150		MHD 02		
Published standards	17	**Adopted**	**Under Development**	**To be adopted**
Under Development	4	10	1	6

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

Sl 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 on MHD 07 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	IS 14139 : 2008 ISO 9713	Published on 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 on May-2018
5	ISO 12891-2: 2020	Retrieval and analysis of surgical implants — Part 2: Analysis of retrieved surgical implants	MHD/02/23713	***Under Print***
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		**To be adopted**

Sl No.	ISO	Title	Existing IS	Status of adoption
9	ISO 14630:2012	Non-active surgical implants — General requirements	IS 18076 : 2023 ISO 14630: 2012	Published Aug-2023
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		**To be 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		**To be adopted**
14	ISO 19213: 2017	Implants for surgery — Test methods of material for use as a cortical bone model		**To be 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		**To be adopted**
17	ISO 22926:2023	Implants for surgery — Specification and verification of synthetic anatomical bone models for testing		**To be adopted**

ISO/TC 150/SC 1		MHD 02		
Published standards	38	**Adopted**	**Under Development**	**To be adopted**
Under Development	6	24	7	7

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

Sl 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	IS 18261 (Part 3) : 2023 ISO 5832-3: 2021	Published Aug-2023
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	IS 18261 (Part 6) : 2023 ISO 5832-6: 2022	Published Aug-2023
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	MHD/02/23696	***Under Print***
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	MHD/02/23983	**Under WC**

Sl No.	ISO	Title	Existing IS	Status of adoption
11	ISO 5832-14: 2019	Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy	MHD/02/23984	**Under WC**
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	MHD/02/24239	**Under WC**
16	ISO 5834-4:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 4: Oxidation index measurement method	MHD/02/24240	**Under WC**
17	ISO 5834-5:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 5: Morphology assessment method	MHD/02/24241	**Under WC**
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	MHD/02/23712	***F-Draft***
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	IS/ISO 13175-3: 2012	Published Mar-2019

Sl No.	ISO	Title	Existing IS	Status of adoption
		substitutes		
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**	**IS 5347(Part 17): 2002/ISO 13782: 1996**	***Revision Needed***
31	ISO 14949:2001	Implants for surgery — Two-part addition-cure silicone elastomers		**To be 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		**To be adopted**
34	ISO 16402:2008	Implants for surgery — Acrylic resin cement — Flexural fatigue	IS/ISO 16402: 2008	Published Mar-2019

Sl No.	ISO	Title	Existing IS	Status of adoption
		testing of acrylic resin cements used in orthopaedics		
35	ISO 16428:2005	Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices		**To be 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		**To be adopted**
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	1	15	0	11

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**	**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

Sl No.	ISO	Title	Existing IS	Status of adoption
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		**To be adopted**
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**

Sl No.	ISO	Title	Existing IS	Status of adoption
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		**To be adopted**
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	12	17	2	17

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 resistance to static load of modular femoral heads	IS 12375 (Part 10): 2023	Published May-2023

Sl No.	ISO	Title	Existing IS	Status of adoption
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	MHD/02/24243	**Under WC**
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	MHD/02/24242	**Under WC**
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		**To be 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		**To be 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		**To be adopted**
16	ISO 11491:2017	Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses		**To be adopted**

Sl No.	ISO	Title	Existing IS	Status of adoption
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		**To be 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		**To be adopted**
19	ISO 14242-2: 2016	Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement		**To be 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		**To be 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		**To be 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		**To be 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		

Sl No.	ISO	Title	Existing IS	Status of adoption
		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		**To be 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		**To be adopted**
31	ISO 17853:2011	Wear of implant materials — Polymer and metal wear particles — Isolation and characterization		**To be adopted**
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		**To be adopted**
33	ISO 21534:2007	Non-active surgical implants — Joint replacement implants — Particular requirements	IS/ISO 21534: 2007	Published Jun-2018
34	**ISO**	**Non-active surgical implants —**	**IS/ISO 21535:**	**Revision**

Sl No.	ISO	Title	Existing IS	Status of adoption
	21535:2023	**Joint replacement implants — Specific requirements for hip-joint replacement implants**	**2007**	**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		**To be adopted**

Annexure D

(*Item 9.5*)

Ballots - ISO/TC 150 - Implants for surgery

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
1)	Revision of ISO 19227	2024-03-03	Closed	1) Do you approve Draft Resolution 920? 2) Do you have any comments to be considered during the revision of ISO 19227?	1) Yes 2) No
2)	Revision of ISO/TS 20721	2024-03-03	Closed	1) Do you approve Draft Resolution 921? 2) Do you have any comments to be considered during the revision of ISO 20721?	1) Yes 2) No
3)	Transfer of ISO 13781 and initiation of PWI	2024-03-03	Closed	1) Do you approve Draft Resolution 922? 2) Do you approve Draft Resolution 923? 3) Do you have any comments to be considered for the revision of ISO 13781?	1) Yes 2) Yes 3) No
4)	ISO/FDIS 14630 (Ed 5) Non-active surgical implants — General requirements	2024-06-14	Open	Do you approve the technical content of the final draft?	
5)	ISO/FDIS 7197 (Ed 4) Neurosurgical implants — Sterile, single-use hydrocephalus shunts	2024-06-27	Open	Do you approve the technical content of the final draft?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
6)	ISO/NP TR 4234	2024-06-28	Open	Do you approve draft resolution 924?	
7)	ISO/DIS 5092 Additive manufacturing for medical — General principles — Additive manufacturing of non-active implants	2024-07-05	Open	Do you approve the technical content of the draft?	
8)	ISO 16054:2019 (Ed 2) Implants for surgery — Minimum data sets for surgical implants	2024-09-02	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				project leader for the development of that project?	

Ballots - ISO/TC 150/SC 1 - Materials

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
1)	ISO/CD 5834-1 Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form	2024-02-29	Closed	Do you have any comments related to the Committee Draft?	No
2)	ISO/CD 5834-2 Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms	2024-02-29	Closed	Do you have any comments related to the Committee Draft?	No
3)	ISO/CD 5834-3 Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 3: Accelerated ageing methods	2024-02-29	Closed	Do you have any comments related to the Committee Draft?	No
4)	ISO/CD 5834-4 Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 4: Oxidation index measurement method	2024-02-29	Closed	Do you have any comments related to the Committee Draft?	No
5)	ISO/CD 5834-5 Implants for surgery — Ultra-high-molecular-weight	2024-02-29	Closed	Do you have any comments related to the Committee Draft?	No

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
	polyethylene — Part 5: Morphology assessment method				
6)	ISO 13779-2:2018 (Ed 3) Implants for surgery — Hydroxyapatite — Part 2: Thermally sprayed coatings of hydroxyapatite	2024-03-03	Closed	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	1) Confirm 2) Yes, The International Standard has been adopted as a national standard 3) Identical 4) Nationally adopted 5) No 6)Yes, Dr. Biswanath Kundu, Expert, kundu@cgcri.res.in
7)	ISO 13779-3:2018 (Ed 2)	2024-03-03	Closed	1) Recommended action	1) Confirm

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
	Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity			2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	2) Yes, The International Standard has been adopted as a national standard 3) Identical 4) Nationally adopted 5) No 6)Yes, Dr. Biswanath Kundu, Expert, kundu@cgcri.res.in
8)	ISO 13779-4:2018 (Ed 2) Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength	2024-03-03	Closed	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication?	1) Confirm 2) Yes, The International Standard has been adopted as a national standard

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	3) Identical 4) Nationally adopted 5) No 6)Yes, Dr. Biswanath Kundu, Expert, kundu@cgcri.res.in
9)	Draft resolution 779/2024 Draft resolution 779/2024: ISO CD 23317 Change of title and scope	2024-03-29	Closed	Do you agree to draft resolution 779/2024 to change the title and scope if ISO CD 23317	Yes
10)	ISO/CD 18368 Implants for surgery — Nitride ceramic materials — Monolithic materials made of beta silicon-nitride	2024-04-24	Closed	Do you have any comments related to the Committee Draft?	Yes

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
11)	ISO 5832-9:2019 (Ed 3) Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
12)	ISO 5832-12:2019 (Ed 3) Implants for surgery — Metallic materials — Part 12: Wrought	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
	cobalt-chromium-molybdenum alloy			the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
13)	ISO 5832-14:2019 (Ed 2) Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
14)	ISO 6474-1:2019 (Ed 2) Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
15)	ISO 6474-2:2019 (Ed 2) Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
16)	ISO 9583:1993 (vers 6) Implants for surgery — Non-destructive testing — Liquid penetrant inspection of metallic surgical implants	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard?	

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				5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
17)	ISO 13782:2019 (Ed 2) Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
18)	ISO 15309:2013 (vers 2) Implants for surgery — Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
19)	ISO 16402:2008 (vers 3) Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
20)	ISO 16428:2005 (vers 4) Implants for surgery — Test solutions and environmental conditions for static and dynamic	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in	

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	corrosion tests on implantable materials and medical devices			the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
21)	ISO 16429:2004 (vers 4) Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication?	

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				3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
22)	ISO/PWI 20014 Implants for surgery — Test method to evaluate delamination resistance of ultra-high molecular weight polyethylene materials used for orthopaedic implants	2024-07-15	Open	Do you approve, disapprove or abstain on this NWIP?	

Ballots - ISO/TC 150/SC 4 - Bone and joint replacements

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
1)	ISO 16087:2013 (vers 2) Implants for surgery — Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants	2024-06-03	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country? 6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	
2)	Approval ballot for 9 month extension - ISO 16436-2	2024-06-03	Open	Do you approve the 9 month extension for ISO 16436-2?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
3)	ISO/DIS 16436-1 Implants for surgery — Wear of total shoulder-joint prostheses — Part 1: Force and displacement parameters for wear-testing machines and corresponding environmental conditions for test of anatomic total shoulder-joint prostheses	2024-07-25	Open	Do you approve the technical content of the draft?	
4)	ISO 14243-5:2019 Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint	2024-09-02	Open	1) Recommended action 2) Has this International Standard been adopted or is it intended to be adopted in the future as a national standard or other publication? 3) Is the national publication identical to the International Standard or was it modified? 4) If this International Standard has not been nationally adopted, is it applied or used in your country without national adoption or are products/processes/services used in your country based on this standard? 5) Is this International Standard, or its national adoption, referenced in regulations in your country?	

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
				6) If the committee decides to revise or amend, do you propose an expert and/or project leader for the development of that project?	

Ballots - ISO/TC 150/SC 5 - Osteosynthesis and spinal devices

Sl. No.	Reference & title	End date	Status	Ballot Question	National View Point
1)	ISO/CD 18967-1 Implants for surgery — Bone anchoring systems — Part 1: Impact, expandable and threaded suture anchors requirements	2024-05-08	Closed	Do you have any comments related to the Committee Draft?	No
2)	ISO/PWI 23089-1.2 Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements — Part 1: Part 1: Thoracolumbar pedicle screw systems	2024-07-18	Open	Do you approve, disapprove or abstain on this NWIP?	