BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07)	18th	17 December 2024 10 : 00 AM Tuesday
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=m1606533434d42212ea1fb9787446bba9 **Meeting Number**: 2512 621 4725 **Password**: Mhd@07		

Chairperson	Dr. Daljit Singh Director, Professor & Head, Department of Neurosurgery B Pant Hospital, New Delhi
Member Secretary	Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards

ITEM 0 GENERAL

0.1 WELCOME ADDRES BY MEMBER SECERTARY

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the Seventeenth meeting of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) held on 26 September 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email vide letter no: : MHD 07/A2.17 dated 18-October-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 Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) is as follows:

• To formulate Indian Standards for Neurosurgery instruments, implants and accessories (cranial & spinal) and monitoring devices.

The Committee may please note.

2.2 The present composition of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) along with participation status of members is enclosed at ***Annexure A***

The Committee may please note.

2.3 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.

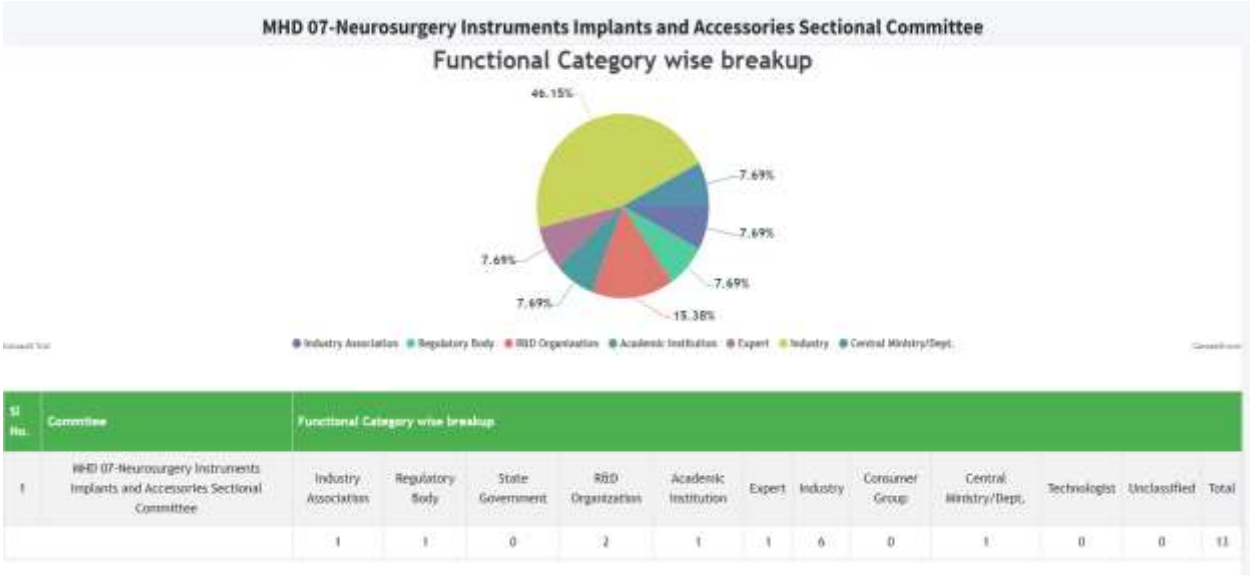
2.4 The following organization request received for removal from committee. ***Annexure B***

Sl. No.	**Organization Name**	**Name**	**Attendance**
1.	Abbott Healthcare India Private Limited, Mumbai	Ms. Lipi Chakhaiyar	1/2
		Ms. Shweta Sharma	2/2

The committee may please note and review the composition.

2.5 The following organization co-option request received for Committee

Sr.No	Organization Name	Nominated experts
1	Stryker India Pvt Ltd	1. Ms. Prachi Pal 2. Mr. Nadeem Ahmad



Sl No.	Committee	Functional Category wise breakup											
1	MHD 07-Neurosurgery Instruments Implants and Accessories Sectional Committee	Industry Association	Regulatory Body	State Government	R&D Organization	Academic Institution	Expert	Industry	Consumer Group	Central Ministry/Dept.	Technologist	Unclassified	Total
		1	1	0	2	1	1	6	0	1	0	0	13

Committee Composition

Sr. No	Functional Category	No of co-opted organizations	Percentage
1	Industry Association	7	53.86%
2	Regulatory Body	1	7.69%
3	R&D Organization	**2**	15.38%
4	Academic Institution	**1**	7.69%
5	Expert/ In-personal Capacity	**1**	7.69%
6	Central Ministry/Dept.	**1**	7.69%
7	State Government	**0**	0
8	Consumer Group	**0**	0
9	Technologist	**0**	0

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 There are currently no indigenous standard for finalization drafts.

The Committee may kindly note.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The following draft document had been circulated as a preliminary draft:

Note: As per the 17th meeting, discussion following documents are circulated for the period of 30 days.

Sl. No.	Document No./ Standard No.	Title	Mailing Date	Last date for comments	Comment s received (Yes/No)
1.	MHD/07/26392	Specification for Single Channel Physiological Recorder	13-Nov- 2024	13-Dec- 2024	**No**
2.	MHD/07/26388	Specification For Algometer	13-Nov- 2024	13-Dec- 2024	**No**

The committee may kindly approved.

4.2 As per the 17th meeting discussion the committee suggested to take inputs but no input received from Medtronic's Pvt Ltd and Johnson & Johnson. So kindly suggested the relevant field experts.

Sl. No.	Document No./ Standard No.	Title	Remarks
1.	MHD/07/26390	Specification for Intracranial Pressure Monitors	Email sent to J&J and Medtronics Pvt Ltd regarding inputs for the subject, but reply received from J& J and Medtronics they don't have experts on this subject
2.	MHD/07/26391	Specification for	BIS Secretariat Remarks : Dr. Raghul Ganesh , psychiatrist

		Electroconvulsive Therapy Machine	

The Committee may kindly deliberate.

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

The Committee may kindly discus.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The following indigenous subject drafts are under preparation.

Sl. No	Project Title	Remarks
1.	Computer Assisted Surgical Systems - Surgical Navigation System or Surgery	Draft received for Neuro navigation system working group
2.	Stereotactic System	The committee deliberated and requested to member Secretary to take inputs from stereotactic system stakeholder
3.	Endoscopic Brain System	The Medtronic and Karl Storz is not working for Endoscopic Brain System product and they didn't have expertise for this product
4.	Spine Implant	The J &J is not working for spine Implant product and they didn't have expertise for this product
5.	Intracranial Stents	The Medtronic and Karl Storz is not working for Intracranial Stents product and they didn't have expertise for this product
6.	Bipolar Cautery	Draft under preparation with Eclipse Prism Medical Devices Pvt. Ltd.
7.	Vagal Nerve Stimulator	Member Secretary trying to find the vagal nerve stimulator stakeholder
8.	IONM -Intra operative neuro monitoring system	The Medtronic and Karl Storz is not working for IONM product and they didn't have expertise for this product
9.	Coil for aneurysm	Draft under preparation with Johnson & Johnson Pvt Ltd

10	Flow Diverters

The committee may kindly deliberate

5.2 The following indigenous subject draft comments are received.

Sl. No	Project Title	Remarks Comments Received	Commenter Name	Comments Received
1.	Leyla retractor	Yes	Asok Kumar Raghavan Nair	1. Clause 4. The material of construction has been stipulated as Stainless steel. In my view specifying g a specific material will stifle innovation. I would recommend that the same should be specified as biocompatible material with specified tensile strength. 2. It was also noted that clause 6.1 specifies a compression strength of 110N. What is the basis of fixing this strength? If this could be addressed then the standard is fine.
2.	Leyla retractor	Yes	Dr. Ajay Chaudhary	1. In clause 4 the mentioned gr of stainless steel 304 & 316, Need to secure if it can be lighter one. 2. Is the compressive force of 110N actually translating over the retractor blade, then it needs to rectify 3. Clause 4.1 mechanism to ensure the holding arm remain fixed

Note: - Draft documents of Leyla retractor attached with ***Annexure C***

5.3 **Structure of Technical Committee Group.**

a) Neuro navigation system Working Group

Sl. No	Name	Organization	Role
1.	Mr. Naveen Khanna	AIMED	**Convener**
2.	Dr.Harsh Deora	SBSSI	**Expert**
3.	Mr.K. Puhazhendi	AIMED	**Expert**
4.	Mr. Asok Kumar Raghavan Nair	IN PERSONAL CAPACITY	**Expert**
5	Mr. Sanjeev Gautam	HRS Navigation	**Expert**
6	Mr. Himanshu Makhija	Medtronics	**Expert**

The Committee may kindly note.

The following drafts Documents (Agenda and Minutes) given. ***Annexure D***

b) Bipolar Cautery Working Group

Sl. No	Name	Role
1.	Medtronics Pvt Ltd	**Convener**
2.	Johnson & Johnson Pvt Ltd	**Expert**
3.	Eclips Pvt Ltd	**Expert**

5.4 **Structure of Technical Committee – Panel in TC**

a) Neurosurgical instruments

Sl. No	Name	Organization	Role
1.	Mr. Kailash Khatod	Medtronic's Pvt Ltd	Convener
2.	Dr. Harsh Deora	SBSSI	Expert

b) Neurosurgical implants

Sl. No	Name	Organization	Role
1.	Mr. Naveen Khanna	AIMED	Convener

2.	Dr. Harsh Deora	SBSSI	Expert
3.	Mr. Kailash Khatod	Medtronic's Pvt Ltd	Expert

c) Neurosurgical Accessories

Sl. No	**Name**	**Organization**	**Role**
1.	Mr. Kailash Khatod	Medtronic's Pvt Ltd	Convener
2.	Dr. Harsh Deora	SBSSI	Expert

d) Neurosurgical monitoring devices

Sl. No	**Name**	**Organization**	**Role**
1.	Mr. Hemant	HRS Navigation	Convener
2.	Mr. Kailash Khatod	Medtronic's Pvt Ltd	Expert
3.	Dr. Harsh Deora	SBSSI	Expert

The Committee may kindly note the of Panels in TC.

Note: - Medtronic Request for Removal as Convener from **Working Group A and C**

5.5 **Commenting on P-Drafts by Members of Technical Committee**

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

5.5.2 The members may examine the P-Draft document(s) whenever under circulation and offer comments as per the following options:

(a) Agree
(b) Agree (with comments*)
(c) Don't agree (with comments*)
(d) No Comments, as it is not related to my area of expertise.

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

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

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

The Committee may kindly note.

7.2 The Department of Pharmaceuticals (DoP) is the nodal department for the strategic Implementation of National Medical Devices Policy (NMDP), 2023. One of the action points under the roadmap for implementation of strategies under the NMDP include adoption and Expansion of Indian Standards for Medical Devices. In this regard, DoP had constituted a Committee for prioritizing the setting of Indian Standards for Medical Devices and deliberated on the list of Medical Devices where Indian Standards need to be formulated.

The list of Subject taken up for the standard formulation:

Sl. No	**DOP Topics**
1.	Intra Operative Neuro Monitoring System
2.	Transcranial Magnetic Stimulation
3.	Epilepsy monitoring stimulator
4.	Electronic balances

The Committee may kindly note

ITEM 8 TECHNICAL ISSUES

8.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

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

Sl. No.	Liaison Committee of ISO	Type of Membership
1.	ISO TC 150/WG 15 - Neurosurgical implants	Participating Member
2.	ISO/TC 150/ SC 6/WG 5 - Implantable neuro stimulators	Participating Member

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

The Committee may kindly note.

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 Working Groups (WGs) are established by ISO/IEC Technical Committees for specific tasks. The Experts are nominated in these WGs by BIS ('P' Member National Standards Body – NSB) to deal with specific tasks allocated to the Working Group. Persistently Inactive Experts, meaning the absence of contributions through attendance to WG meetings or by correspondence, will be

removed from the Working Groups by ISO Technical Committee. This removal of Inactive Experts would also reflect badly on the 'P' Member NSB. Therefore, participation of nominated Indian Experts at the Working Group level of ISO is of critical importance while being a part of BIS for Standards Development.

ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) is available at BIS website **Program of work (bis.gov.in)**

The Committee may kindly note.

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

Stage		**No. of Documents**
Under Print		**07**
Sl. No.	**Document No**	**Title**
1.	MHD/07/25865	Specification For Forceps Dressing Bayonet Shape Gushing's Pattern
2.	MHD/07/25836	Neurosurgical Instruments - Needle Holder - Shape and Dimensions
3.	MHD/07/25834	Neurosurgical Instruments- Forceps Artery Dandy's Pattern-Shape and Dimensions
4.	MHD/07/25867	Specification For brain cannula
5.	MHD/07/25835	Neurosurgical Instruments -Forceps Artery Straight and Curved on Flat Hugh Cairns Pattern - Shape and Dimensions
6.	MHD/07/25866	Specification For Guide Saw De Martels Pattern
7.	MHD/07/25864	Rongeur, Cranial, Dahlgren's Pattern Specification

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 All Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archiving in the light of technological developments that have happened so far in relation to these standards. This exercise has to be completed in a time bound manner. In this regard, there are **7** documents under printing. There are no other Pre. 2000 standard remaining.

The Committee may kindly note.

11.2 Review of Standards as per 5-year cycle

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

11.2.2 With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document in respect of each of the Indian Standards, which are due for revision.

11.2.3 The list of such Indian Standards, which are due for review in FY 2025- 2026, is given at ***Annexure E***

The Committee may kindly note.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 There are no specific issues to be discussed.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 07 is scheduled on 3th March 2025.

Quarter	Q1 Apr-June 2024	Q2 July-Sept 2024	Q3 Oct-Dec 2024	Q4 Jan-Mar 2025
Date	27 June 2024 , Thursday	26 Sep 2024, Thursday	19 Dec 2024, Thursday	3March 2025, Monday

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

Sr. No	Organization name	Project	Purposed
1.	NIT Jalandhar	RTMS	Dr. Jay deep Kaur NIT Jalandhar

The Committee may kindly note.

Annexure A

(Agenda Item 2.2)

Composition of Neurosurgery Instruments, Implants & Accessories Sectional Committee

Sr. No	Organization	Member Name	Role	Attendance
1.	G B Pant Hospital, New Delhi	Dr. Daljit Singh	**Chairperson**	2/2
2.	Abbott Healthcare India Private Limited, Mumbai	Ms. Lipi Chakhaiyar	Principal Member	2/2
		Ms. Shweta Sharma	Alternate Member	
3.	Association of Indian Medical Device Industry, New Delhi	Mr. Puhazhendi Kaliyappan	Alternate Member	2/2
		Mr. Naveen Khanna	Principal Member	
		Mr. Ankur Bhargava	Alternate Member	
4.	Boston Scientific India Private Limited, Gurugram	Mr. Prashanth Prabhakar	Alternate Member	2/2
		Mr. Dev Chopra	Principal Member	
5.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu	Principal Member	2/2
		Ms. Shyamni Sasidharan	Alternate Member	
7.	Directorate General of Health Services, New Delhi	Dr. Ajay Choudhary	Principal Member	1/2
		Dr. K. B. Shanker	Alternate Member	
8.	Happy Reliable Surgeries Private Limited, Bangalore	Mr. Hemant Savale	Principal Member	2/2
		Mr. Sanjeev Gautam	Alternate Member	
9.	Indian Institute of Technology Hyderabad, Hyderabad	Dr. Avinash Eranki	Alternate Member	2/2
		Dr. Kousik Sarathy S	Alternate Member	
10.	Johnson and Johnson Pvt Ltd	Ms. Meenakshi Goal	Principal Member	1/2

		Ms. Aishwarya Chaudran	Alternate Member	
		Ms. Bhuwan Singla	Alternate Member	
11.	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Manish Thakore	Alternate Member	1/2
		Mr. Kapil Rana	Principal Member	
12.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Santosh Kumar Balivada	Principal Member	2/2
		Ms. Divya Anil Patil	Alternate Member	
		Ms. Purva Suhas Phalke	Alternate Member	
13.	Medtronic's India Private Limited , Gurugram	Mr. Himanshu Makhija	Principal Member	1/2
		Mr. Sandeep Verma	Alternate Member	
14.	Skull Base Surgery Society of India, Chennai	Mr. Harsh Deora	Principal Member	2/2
15.	In Personal Capacity	Mr. Asok Kumar Raghavan Nair	Personal Capacity	2/2

Annexure B

(Agenda Item 2.4)

Organization request received for removal from committee.

RE: 17th technical committee meeting agenda

lipi.chakhaiyar@abbott.com

Thu, 26 Sep 2024 2:41:12 PM +0530 •

To "MHDtcSEVEN Medical Equipment Department"<mhd7@bis.gov.in>

Cc "asokkumar.raghavannair"<asokkumar.raghavannair@abbott.com>, "shweta.sharma1" <shweta.sharma1@abbott.com>

Tags Not in Contacts

Dear Sir/Madam

Thank you for including us in MHD 07 technical commi ee. I would like to share that we are restric ng our domain of business from Neurosurgery in India therefore, I will request that myself and my colleague Shweta Sharma may not be able to con nue contribu ng to MHD 07.

You may discon nue us from the member list.

1. Lipi Chakhaiyar
2. Shweta Sharma

Regards
Lipi

Abbott

Lipi Chakhaiyar
Director - Regulatory Affairs

Abbott Healthcare Pvt. Ltd

The Suryaa
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From: MHDtcSEVEN Medical Equipment Department <mhd7@bis.gov.in>
Sent: Thursday, September 26, 2024 9:35 AM
To: drdaljit <drdaljit@hotmail.com>; Chakhaiyar, Lipi <lipi.chakhaiyar@abbo .com>; Sharma, Shweta <shweta.sharma1@abbo .com>; pugal <pugal@perfinthealthcare.com>; khanna, naveen <naveen.khanna@inmito.com>; Ankur.jupiter <ankur.jupiter@gmail.com>; prashanth prabhakar <prashanth.prabhakar@bsci.com>; dev chopra <dev.chopra@bsci.com>; Shri Aseem Sahu <aseem.sahu@cdsco.nic.in>; Shyamni Sasidharan <shyamni.sasidharan@cdsco.nic.in>; Jayanth Daniel <jayanth.daniel.debel@gov.in>; SRIPATHY G <sripathyg@debel.drdo.in>; choudhary, ajay7 <ajay7.choudhary@gmail.com>; nitushank <nitushank@yahoo.co.in>; sanjeevgautam13 <sanjeevgautam13@gmail.com>; hemant <hemant@hrsnaviga on.com>; aeranki <aeranki@bme.iith.ac.in>; kousiksarathy <kousiksarathy@bme.iith.ac.in>; bsingla <bsingla@its.jnj.com>; Achand42 <Achand42@ITS.JNJ.com>; mgoel11 <mgoel11@its.jnj.com>; santosh <santosh.b@amtz.in>; divya <divya.p@amtz.in>; purva <purva.p@amtz.in>; kapilrana <kapil.rana@karlstorz.com>; manishthakore <manish.thakore@karlstorz.com>; sandeepverma2 <sandeep.verma2@medtronic.com>; himanshumakhija <himanshu.makhija@medtronic.com>; demo5601 <demo5601@gmail.com>; Raghavan Nair, Asok Kumar <asokkumar.raghavannair@abbo .com>
Subject: 17th technical commi ee mee ng agenda

To all Committee members,
I hope this email finds you well. This is a reminder for our 17th technical committee meeting scheduled as follows:

Date: 26 Sep 24
Time: 11:00 am
Duration: 1hr

Meeting Platform: Webex
Video Conference Link: https://bismanak.webex.com/bismanak/j.php?MTID=md93ee6ee25542457eaf8c747a511a420
Meeting ID: 2518 599 6943
Passcode: Mhd@07

Enclosed: Agenda of the 17th technical committee meeting

Annexure C
(Agenda Item 5.2)

भारतीय मानक **IS: 2024**

Indian Standard

न्यूरोसर्जरी के लिए लेयला रिट्रैक्टर

(सेल्फ रिटेनिंग ब्रेन रिट्रेक्टर)

Leyla Retractor for Neurosurgery

(Self-Retaining Brain Retractor)

ICS 11.040.30

Neurosurgery Instruments, Implants and Accessories Sectional Committee, MHD 07

FOREWORD

This Indian Standard was framed by the Bureau of Indian Standards after the draft finalized by the Neurosurgery Instruments, Implants and Accessories Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

The composition of the Committee responsible for formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard complies with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (second revision)’. The number of significant places retained in the rounded-off value should be the same as that of the specified value in this standard

INTRODUCTION

This standard outlines the essential requirements for the Leyla Retractor, a critical instrument in neurosurgical procedures, particularly those involving the ear and middle skull. It encompasses dimensional, material, and technical specifications necessary for the manufacturing and application of the retractor. Key components, including the flexible arm, coupling head, and fixation base, are detailed, ensuring their construction, materials,

and surface conditions meet rigorous quality standards. Additionally, the standard prescribes the necessary tests for biocompatibility, tensile strength, and corrosion resistance to guarantee the retractor's safety and functionality. Compliance with established protocols for cleaning, sterilization, and maintenance is also mandated, providing a comprehensive framework to ensure the device's optimal performance in clinical setting

1. SCOPE

This standard specifies dimensional, material, and other requirements for the Leyla Retractor used in neurosurgery involving the ear and middle skull.

This document does not recommend which type of Leyla Retractor is most suitable for any specific use context.

This document specifies the mechanical and technical requirements to manufacture Leyla Retractors and the technical information of the Leyla Retractor to be supplied by the manufacturer.

2. NOMINATIVE REFERENCES

The standard given below contains provisions, which, through reference in this text, constitute provisions of this standard.

IS No.	*Title*
IS 7531: 1990	Surgical instruments - Corrosion resistance of stainless steel surgical instruments - Methods of tests (First Revision)
IS 6603: 2024	Stainless Steel Semi-Finished Products, Bars, Wire Rods, and Bright Bars Specification (Second Revision)
IS 9933: 2023	Brain Retractors (first revision)
ISO 17665:2024	Sterilization of Health Care Products– Moist Heat— Requirements for the development, validation, and routine control of a sterilization process for medical devices
IS/ISO 10993-5:2009	Biological evaluation of medical devices Part 5 Tests for in vitro cytotoxicity
IS 17932 (Part 6): 2023	Biological Evaluation of Medical Devices Part 6 Tests for skin sensitization (ISO

	10993-10: 2021, MOD)
IS 6528: 1995	Stainless steel wire - Specification (First Revision)

3 TERMINOLOGIES

3.1 Leyla Retractor — A self-retaining surgical instrument designed for use in neurosurgery, comprising a flexible arm and blade attachment, utilized to hold tissues or organs away from the surgical site during procedures on the brain or spinal cord.

3.2 Self-Retaining Retractor — A surgical device capable of maintaining tissue retraction without continuous manual assistance, typically employed to secure tissues or organs in a desired position during operative interventions

3.3 Flexible Arm — A component of the Leyla Retractor allowing for adjustable positioning and orientation, facilitating customized retraction based on the specific anatomical requirements of the surgical site.

3.4 Coupling Head — A connecting component that joins different parts of the retractor system, providing a secure and adjustable connection.

3.5 Ball and Socket Joint — A mechanical joint consisting of a spherical ball (head) fitting into a corresponding socket, allowing multidirectional movement and rotation.

3.6 Blade Attachment — The part of the Leyla Retractor's flexible arm is designed to accommodate various blade types, such as spatulas, to gently retract tissues or organs while minimizing tissue trauma.

3.7 Mounting System — The mechanism employed by the Leyla Retractor to secure the instrument in place during neurosurgical procedures, which may include skull-mounted, table-mounted, or headrest-mounted configurations to ensure stability and precise positioning.

3.8 Malleable Ribbon Retractors — Thin, flexible blades or ribbons of variable widths that are attached to the the flexible arm of the Leyla Retractor. These retractors are designed to gently hold tissues aside during neurosurgical procedures, providing access to the operating area while minimizing trauma to surrounding tissues.

3.9 Neurosurgery — The medical specialty concerned with the diagnosis, treatment, and surgical management of disorders affecting the brain, spinal cord, and nervous system, wherein the Leyla Retractor plays a crucial role in facilitating access and visualization of critical anatomical structures.

3.10 Fraction Vacuum — The fractionated (pulsed) vacuum process is deemed to represent the state of the art for the steam sterilizers used for medical devices. In a fractionated vacuum process steam is admitted into the sterilizer chamber after evacuation and immediately afterward the steam- the residual-air mixture is removed again.

4 MATERIAL & DIMENSIONS

The Leyla Retractor shall be manufactured from grade> 304L (X02Cr19Ni10) or grade> 316 (X04Cr17Ni12Mo2) stainless steel to ensure enhanced corrosion resistance. The material shall comply with the guidelines specified in IS 6603.

4.1 Fixation Base

The fixation base shall be used for skull mounting, capable of holding 1-2 arms. It is also suitable for mounting bars up to 16 mm in diameter, holding 1 arm.

4.2 Malleable Ribbon Retractor

The retractors shall be made in accordance with IS 9933.

4.3 Screws

The screw shall be made of stainless steel conforming to X20Cr13 of IS 6603.

4.4 Ball and Socket Joint

The Ball and Socket joint for fixing the holding rod to the pole of the operating table shall have dimensions of 10 x 25 mm, with a maximum size of 9 x 32 mm.

4.5 Holding Rod

The Holding Rod for fixation in the Ball and Socket joint and to take coupling head lengths ranging from around 20 cm to 50 cm.

4.6 Coupling Head

The coupling head shall accommodate 1-5 flexible arms. It can be of the following types:

a) Rotatable: Can be fixed in any position to take one arm. If necessary, multiple coupling heads can be attached.

b) Laterally open: Can be subsequently fixed at any position on the holding rod.

4.7 Flexible Arm

The length of Leyla retractor arms shall vary from 20 cm to 50 cm, selected based on surgical requirements and the anatomy involved.

5 REQUIREMENTS

5.1 Workmanship

The Leyla Retractor shall be of a well-balanced and precise construction. All screws shall exhibit consistent and accurate threading. The joints must operate seamlessly, and the overall movement should be fluid without any rigidity or excessive looseness. The retractor's working edges shall be sharp and consistently uniform, ensuring they align perfectly during use. The handles shall be designed with a matte finish or a knurled texture to provide a secure grip. Any grooves on the handle's outer surface shall be shallow and smoothly rounded to prevent discomfort.

5.2 Surface Condition

All surfaces shall be free from pores, crevices, and grinding marks. The retractor shall be supplied free from residual scale, acid, grease, grinding, and polishing materials. Compliance with these requirements shall be checked by visual inspection. Components of Leyla Retractor shall be passivated.

5.3 Surface Finish

The surface finish shall be Reflection-reducing, eg Matt finish.

5.4 Treatment of Brand New Instrument

Leyla Retractor must undergo cleaning and disinfection before their initial sterilization or use. All protective caps and films must be completely removed from each instrument.

After Each Use

a) Contaminated instruments should be cleaned promptly.

b) Instruments with joints should be opened to a 90-degree angle.

c) For machine cleaning, place the instrument in a wire basket suitable for the cleaning process, ensuring the cleaning solution and rinse water contact all surfaces.

d) Completely dismantle any instruments designed for disassembly.

e) Preferably remove instruments from the operating room (OR) in a dry condition.

f) For wet removal, always use an active cleaning disinfectant. Rinse the instrument thoroughly with clear, flowing water before machine cleaning and disinfection.

g) Whether cleaning manually or with a machine, always adhere to the manufacturer's instructions regarding detergents and cleaning solutions.

5.5 Manual Cleaning/Disinfection

a) Place instruments into a suitable disinfectant with active cleaning

properties so that all surfaces, inner cavities, lumens, and openings come into contact with the solution. Always follow the disinfectant manufacturer's instructions.

b) After chemical disinfection, always rinse thoroughly with clear, flowing water.

c) Always follow the instructions provided by the manufacturer of the disinfectant.

d) Remove any contaminants still clinging to the instrument with a soft synthetic brush. Do not use a scouring or metal brush.

e) Clean any lumens and conduits with soft, round, synthetic brushes. Ensure that the diameter of the brush matches that of the lumen.

f) Final rinsing should be done with demineralized water.

g) Dry the instrument with an absorbent, soft, and lint-free cloth.

h) Dry lumens and conduits with compressed air. Use this method cautiously.

5.6 Machine Cleaning/Disinfection

Clean the instrument according to the material of the instrument (eg. stainless steel, aluminum) to be cleaned. Always follow the machine manufacturer's instructions. Leave sufficient time for drying

5.7 Care/Maintenance

Allow instruments to cool down to room temperature.

Lubricate movable parts (eg joints and ends) with special sterilization-capable, steam-permeable lubricant.

After each cleaning-disinfection process, inspect the instrument to make sure it is clean, that it functions properly, and that it has not suffered any damage, eg bent, broken, fractured, or worn parts.

Remove any damaged and defective Instruments replace them with functional items and send away any product that is damaged for repair.

5.8 Sterilization

Procedure

a) Validation:
Steam sterilization must be performed using a validated process in compliance with standard ISO 17665.

b) Sterilization Program:
For the fractional vacuum method, use a program at 134°C and 2 bar pressure with a minimum hold time of 5 minutes.

c) Load Capacity:

When sterilizing multiple products simultaneously, ensure that the maximum permitted loading of the steam sterilizer, as specified by the manufacturer, is not exceeded.

Note:
Always follow the manufacturer's instructions for steam sterilization procedures.

5.9 Storage

Place components with the fine working end in a suitable storage rack, Always secure the instrument properly.

5.10 Repairs

Personnel authorized by manufacturers must carry out repairs to the product. Only in this way will warranties and guarantees remain valid.

6 TESTS

6.1 Compressive Force Test

A compressive force of 110 N shall be applied to the arms at a distance of 75 mm from free ends in such a manner that it tends to press the arms together. The maximum force shall be attained gradually and shall act for two minutes. On completion of the test, the retractor shall show no sign of damage.

6.2 Corrosion Test

The Leyla Retractor shall show no sign of corrosion or staining when tested in accordance with IS 7531.

7.2 Tensile Test

The Leyla Retractor steel wire (X04Cr17Ni12Mo2) shall show no sign of damage when tested per Clauses 10.1 and 12.2 Table 7 of IS 6528.

6.3 Biocompatibility test

The Leyla Retractor shall show not cause cytotoxicity, sensitization, and irritation when tested per Clause 6, 7, 8, and 9 of IS/ISO 10993-5 and Clause 5, 6, 7, and 8 of IS 17932 (Part 6).

7 MARKING

7.1 Each Leyla Retractor component shall be suitably marked by etching or otherwise with the following:

a) Company name and logo.

b) The word ‘Stainless steel’ or the Letter “SS”.

c) Article number to be referred to the company's catalog of products.

d) Year and month of manufacturing.

e) Batch Lot and Number.

7.2 Marking Durability:

Laser marking shall be employed to ensure the durability and legibility of the markings in compliance with the specified standards. The markings on the Leyla retractor shall remain clear and readable throughout the device's lifespan, even after usage, cleaning, disinfection, sterilization, and storage as per the instruction manual.

7.3 Alternative Marking:

If it is impractical to mark the Leyla Retractor components due to size or design constraints, the required information should be included on the packaging or within the instruction manual

7.4 BIS **Certification Marking**

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

8 PACKING

Each component of the Leyla retractor shall be packaged separately with appropriate cushions, as agreed upon between the purchaser and the supplier. The manufacturer shall provide an instruction manual to the end user.

A typical instruction manual content is given in ANNEX A (Informative).

ANNEX A
Informative

INSTRUCTION MANUAL

a) Manufacturers or distributor's name and address.
b) Article number and name.
c) Batch Lot and Number.
d) Detailed description of the intended clinical applications of the retractor.
e) Length and Dimensions of the Component.
f) Comprehensive guidance on operating the retractor.
g) Diagrams to identify pertinent parts and characteristics, consistent with the device specifications.
h) Step-by-step instructions for assembling the Leyla Retractor for use, and disassembling and reassembling it after cleaning, disinfection, and sterilization.
i) List of permitted liquids for use with the retractor (e.g., contrast medium, sclerosing therapy medium, lubricant, and anesthetic medium) and warnings against using unspecified liquids.
j) Procedures to ensure the Leyla Retractor is in working order before use.
k) Detailed instructions for cleaning Leyla Retractor components, including identification of specific cleaning tools or equipment.
l) Specific environments in which the equipment can be disinfected and sterilized.
m) Recommended procedures for storage before use and, for reusable equipment, between uses.
n) Identification of any parts that the user can replace, along with instructions for their replacement.
o) Information on where the user can obtain authorized service.
p) All information must be in English, Hindi, and other required languages.

Annexure E

Due for review in 2025-2026

Sl. No	IS	Title	Remark
1.	IS 17744 : 2021 ISO 16054:2019	Implants for surgery Minimum data sets for surgical implants	Reaffirm Due to Base standard is not updated .

Annexure D

(Agenda Item 5.3)

Neuro Navigation System Working Group

BUREAU OF INDIAN STANDARDS
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
(MHD)

AGENDA

Working Group	***Meeting No:***	***Date, Day & Time***
Neuro navigation system	3rd	06 November 2024 3 : 00 PM Thursday
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=mfc7aa7c258e0d50a8bff560b07406b0a		
Meeting Number: 2513 454 5544 **Password**: Mhd07@WG1		
Convener Mr. Naveen Khanna , AIMED	**Member Secretary** Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards	

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY CONVENER

0.2 OPENING REMARKS BY MEMBER SECRETARY

ITEM 1 PURPOSE (Discussion Points of Agenda)

1.1 Discussion on the draft document of Surgical Neuro navigation system.

BUREAU OF INDIAN STANDARDS
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
(MHD)

Minutes

Working Group	*Meeting No:*	*Date, Day & Time*
Neuro navigation system	3rd	06 November 2024 3: 00 PM Wednesday
via Webex platform **MeetingLink**: https://bismanak.webex.com/bismanak/j.php?MTID=mfc7aa7c258e0d50a8bff560b07406b0a		
Meeting Number: 2513 454 5544 **Password**: Mhd07@WG1		
Convener Mr. Naveen Khanna , AIMED **Convenered by** Mr. Puhazhendi Kaliyappan, AIMED	**Member Secretary** Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards	

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY CONVENER

Mr. Puhazhendi Kaliyappan, welcomed the members present in the meeting. The list of participants is given in ANNEX A

0.2 OPENING REMARKS BY MEMBER SECRETARY

Member Secretary extended his greetings to all the members present in the meeting. The meeting commenced with the introduction of the members

ITEM 1 PURPOSE (Discussion Points of Agenda)

1.1 The committee deliberated and circulated (14 days time period) the draft document in Working group for the further technical comments

The committee requested to Mr. Puhazhendi Kaliyappan to submit the final draft of Neuronavigation System.

ANNEX A

List of Participants:

Sr. No	Name	Organization
1	Mr. Puhazhendi Kaliyappan	Association of Indian Medical Device Industry, New Delhi
2	Mr.Sanjeev Gautam	HRS Navigation, Bangalore
3	Mr. Himanshu Makhija	Medtronic India Private Limited, Gurugram
4	Mr. Asok Kumar Raghavan Nair	In- Personal Capacity