

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

Sectional Committee	Meeting No:	Date, Day & Time
Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee, (MHD 04)	18	18 December 2024 Wednesday, 3:00PM
<i>Via Webex platform</i> Meeting Link: URL: https://bismanak.webex.com/bismanak/j.php?MTID=m8953820d4f5971e7fefe91db45ec2993 Meeting Number: 2517 680 8591 Password: MHD04@18		
Chairperson	Dr. Rakesh Kumar, Professor, Dept. of Otorhinolaryngology and HNS, AIIMS New Delhi	
Member Secretary	Karthik Reddy Katipally Scientist B/Assistant Director Bureau of Indian Standards.	

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the last meeting of Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee (MHD 04) held on 25th September 2024 approved by the Chairperson was circulated to all members through the BIS portal vide letter no: MHD 04/A2.17 dated 28 October 2024.

1.2 No comments have been received so far.

The Committee may formally confirm the minutes.

ITEM 2 SCOPES AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee (MHD 04) is as follows:

- To formulate Indian Standards for diagnostic, examining, surgical instruments, devices and implants used in Ear, Nose, Throat and Head & Neck Surgery.
- Excluding specific instruments under the scope of MHD 01 “Surgical Instruments” and MHD 08 “Dentistry”

The Committee may please note.

2.2 The present composition Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee (MHD 04) along with participation status of members is enclosed at [Annexure-A](#).

2.3 Structure of Technical Committee

a) MHD04/P7, Otology (Ear) Panel

Sr. No	Organization	Name
1.	PGIMER, Chandigarh	Dr Jaimanti Bakshi (Convener)
2.	Ex-PGIMS, Rohtak	Dr Vikas Kakkar
3.	ALPS International, New Delhi	Mr. Alok Narang Mr. Karan Narang

b) MHD04/P4, Rhinology (Nose) Panel

Sr. No	Organization	Name
1.	AIIMS, New Delhi	Dr Rakesh Kumar (Convener) Dr Prem Sagar Dr Arvind Kumar
2.	Government Medical College & Hospital, Chandigarh	Dr Surinder Singhal

c) MHD04/P5, Head and Neck Surgery (HNS) Panel

Sr. No	Organization	Name
1.	Maulana Azad Medical College, New Delhi	Dr Ravi Meher (Convener)
2.	PGIMER, Chandigarh	Dr Jaimanti Bakshi
3.	AIIMS, New Delhi	Dr Kapil Sikka

4.	GTB Hospital, New Delhi	Dr. Vipin Arora
5.	Tata Memorial Hospital, Mumbai	Dr. Richa Vaish

D) MHD04/P6, Laryngology (Throat) Panel

Sr. No	Organization	Name
1.	All India Institute of Medical Sciences, Bhopal	Dr Vikas Gupta (Convener)
2.	Government Medical College & Hospital, Chandigarh	Dr Nitin Gupta

2.4 The following organizations have requested BIS for representation in the Committee:

Sl. No.	Organisation	Nomination
1.	Stryker India Pvt. Ltd.	1) Dr Prachi Pal, Associate Manager 2) Nadeem Ahmed, Senior Manager

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

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

The committee may please note and review the composition.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

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

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1.	MHD/04/26670 Revision of (IS 8316: 1977)	ENT Surgery Instruments – Retractor – Hajek’s Pattern Specification (First Revision)	07 December, 2024	Yes (<i>placed at Annexure-B</i>)

2.	MHD/04/26669 Revision of (IS 8327: 1977)	Chevalier Jacksons Pattern Vocal Nodule Forceps Specification (First Revision)	30 November, 2024	Yes (<i>placed at Annexure-B</i>)
3.	MHD/04/26674 Revision of (IS 8734: 1978)	Ent Surgery Instruments – Removing and Cutting Forceps — Chevalier Jackson’s Pattern – Specification (First Revision)	06 December, 2024	Yes (<i>placed at Annexure-B</i>)
4.	MHD/04/26675 Revision of (IS 8735: 1978)	ENT Surgery Instruments — Suction Tube — Yankauer's pattern — Specification (First Revision)	07 December, 2024	Yes (<i>placed at Annexure-B</i>)
5.	MHD/04/26683 Revision of (IS 8743: 1994)	ENT Surgery Instruments – Direct Bronchoscopy Forceps — Irwin Moore's Pattern — Specification (Second Revision)	07 December, 2024	Yes (<i>placed at Annexure-B</i>)
6.	MHD/04/26684 Revision of (IS 8825: 1978)	ENT Surgery Instruments – Suction Irrigation Cannula — Specification (First Revision)	07 December, 2024	No
7.	MHD/04/26685 Revision of (IS 8837: 1978)	ENT Surgery Instruments — Suction Tube with Stylet — Specification (First Revision)	07 December, 2024	No
8.	MHD/04/26686 Revision of (IS 8838: 1978)	ENT Surgery Instruments — Straight Cup Forceps — Specification (First Revision)	07 December, 2024	Yes (<i>placed at Annexure-B</i>)
9.	MHD/04/26687 Revision of (IS 8839: 1978)	ENT Surgery Instruments — Upwards Cup Forceps — Specification (First Revision)	07 December, 2024	Yes (<i>placed at Annexure-B</i>)
10.	MHD/04/26688 Revision of (IS 8840: 1978)	ENT Surgery Instruments — Scissors — Specification (First Revision)	07 December, 2024	Yes (<i>placed at Annexure-B</i>)

3.2 The documents where no comments have been received may be taken up for finalization.

The Committee may kindly consider.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The following draft Indian Standards may be considered for wide circulation. For drafts where there is still scope for improvement, we can form working groups to further vet them. The committee may also recommend timelines for the submission of these drafts.

Sl. No.	Document No./ Standard No.	Title	Remarks
1	MHD/04/26136	Ossicular Reconstruction Prosthesis- General Requirements	The scope is not clear, there are different prosthesis for different applications. Functional requirements and test methods are not clearly mentioned
2	MHD/04/26141	Computer-Assisted Surgical Systems Surgical ENT Navigation System General and Safety Requirements	Practice, instruction manual clauses can be rewritten and few more test methods can be added.
3	MHD/04/26919	Audiometric Test Room Specification	May be proceeded for Wide circulation
4	MHD/04/25256 (completed WC once)	ENT Workstation	The scope is not clear. Functional requirements and test methods are not clearly mentioned
5	MHD/04/25258 (completed WC once)	Otology Drill	May be proceeded for Wide circulation
6	MHD/04(21279)	Fibrin Glue	The scope is not clear, terminology of glue and sealant is not clear . Functional requirements and test methods are not clearly mentioned
7	MHD/04(21280)	Grommets	The scope is not clear, there are different type of grommets. Functional requirements and test methods are not clearly mentioned

The Committee may kindly deliberate and approve.

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

The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The indigenous subjects under preparation are given in [Annexure-C](#).

The Committee may Deliberate and Decide.

5.2 Commenting on P-Drafts by Members of Technical Committee

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

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

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

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

The Committee may kindly note.

5.3 meeting Minutes of Otology panel and laryngology panel is can be accessed using [this link](#).

5.4 Progress on Sustainability of Steel Surgical Instruments

The panel under the convenorship of Dr. Vikas Gupta has convened three times and deliberated on the subject. Considering the vastness of the topic, the timelines could not be met. The panel requests the committee to extend the deadline for the preliminary draft to February 2025.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

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 a 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.

ITEM 8 TECHNICAL ISSUES

There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9 INTERNATIONAL ACTIVITIES

The Committee has no liaison with international standards organization.

The Committee may kindly note.

ITEM 10 PROGRAMME OF WORK

The present Programme of Work of Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee, (MHD 04) is available at BIS website www.bis.gov.in and the same is placed at [Annexure-D](#).

The Committee may kindly note.

ITEM 11 REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

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. The details in this regard are given below:

Total as per PoW	Under Development	Under Print	Remaining	Under Progress (out of the remaining)	Pending
37	15	6	16	4 - to be withdrawn 10- WC stage 1- IS 8343 : 1977	1- IS 11319 : 1985, Oesophago scope, Negus' Pattern

11.2 Amendment 1 to IS 8343:1977, ENT Surgery Instruments – Biopsy Forceps – Peterson's Pattern – Specification, was issued. Amendment 1 states that Figure 1 should be substituted for the existing figure. However, Figure 1 is not available in the amendment. Members are requested to review the figure provided and share their inputs or concurrence for wide circulating the draft placed at [Annexure-E](#).

The Committee may kindly review.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

There are no specific issues to be discussed.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 04 is scheduled on 19 March 2025.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

Annexure-A

Sl. No.	Organization	Member Name	15th meeting 20/03/2024	16th meeting 26/06/2024	17th meeting 25/09/2024	Attendance (x/3)
1.	All India Institute of Medical Sciences, New Delhi	Dr. Rakesh Kumar	P	A	P	2/3
		Dr Arvind Kumar	A	A	A	0/3
		Dr. Kapil Sikka	NA	P	P	2/2
		Dr. Prem Sagar	A	P	A	1/3
2.	ALPS International, New Delhi	Mr. Karan Narang	NA	P	P	2/2
		Mr. Alok Narang	NA	P	P	2/2
3.	All India Institute of Medical Sciences, Bhopal	Dr. Vikas Gupta	P	P	P	3/3
		Dr. Ganakalyan Behera	A	A	P	1/3
4.	Association of Indian Medical Device Industry, New Delhi	Dr. C.S.Prasad	P	P	A	2/3
		Mr. Ankur Bhargava	A	A	A	0/3
		Mr. Tarlochan Dev	A	A	P	1/3
5.	Directorate General of Health Services, New Delhi	Dr. Pallika Kumar	NA	NA	NA	
6.	Government Medical College & Hospital, Chandigarh	Dr. Nitin Gupta	P	A	A	1/3
		Dr. Surinder K Singhal	P	P	P	3/3

Sl. No.	Organization	Member Name	15th meeting 20/03/2024	16th meeting 26/06/2024	17th meeting 25/09/2024	Attendance (x/3)
7.	Happy Reliable Surgeries Private Limited, Bangalore	Mr. Sanjeev Gautam	P	A	A	1/3
		Mr. Hemant Savale	P	P	P	3/3
8.	India Medtronic Private Limited, Gurugram	Ms.Latika Vats	P	A	A	1/3
		Mr. Saurabh Sable	A	A	P	1/3
		Mr. Sandeep Verma	A	P	P	2/3
9.	Indian Institute of Technology Kanpur, Kanpur	Dr. A. R. Harish	P	P	P	3/3
10.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Amit Sharma	P	P	P	3/3
		Dr. Arjun Thimmaiah	A	A	P	1/3
11.	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Kapil Rana	NA	A	P	1/2
		Mr. Sandeep Sethi	NA	P	P	2/2
12.	Serwell MediEquip, Chennai	Mr. T. Jebin Samuel	P	P	P	3/3
		Mr. R. Radhakrishnan	P	A	A	1/3
		Mr. G. Sathish	A	A	A	0/3
13.	Tata Memorial Center (Hospital), Mumbai	Dr. Richa Vaish	NA	P	P	2/2

Sl. No.	Organization	Member Name	15th meeting 20/03/2024	16th meeting 26/06/2024	17th meeting 25/09/2024	Attendance (x/3)
		Mr. Vijay Yashwant Mestri	NA	A	P	1/2
		Dr Arjun Singh	NA	A	A	0/2
14.	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Jaimanti Bakshi	NA	A	P	1/2

Annexure-B

MHD 4(26669)/ Chevalier Jacksons Pattern Vocal Nodule Forceps Specification First Revision				
Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
1	Mr. Abhishek singh	General	The name mention Chevalier Jackson should be changed, it should be kept as “vocal nodule forceps for Laryngeal surgeries” The name Chevalier Jackson is used by only one company, Karl Storz Endoscopy do have similar forceps with different name.	The name should be kept as “vocal nodule forceps for Laryngeal surgeries” The name Chevalier Jackson is used by only one company, we do have similar forceps with different name.
		Technical	The sizes mentioned in the draft are 25-55 cm which is not at all required in any ENT procedure including laryngeal surgeries, Instead of that they should mention the range from 16-25 cm it will cover all the forceps	The size range should be from 16-25 cm,it will cover all the forceps used for ENT procedure.
MHD 4(26670)/ ENT Surgery Instruments – Retractor – Hajek’s Pattern – Specification First Revision				
Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
1	Mr. Abhishek singh	General	The title should be ENT SURGERY INSTRUMENTS – RETRACTOR. HAJEK’S PATTERN should be removed.	The title should be ENT SURGERY INSTRUMENTS – RETRACTOR. HAJEK’S PATTERN should be removed.
				Karl Storz do have ENTretractor with differenet name.

2		General	Instrument should follow IS or ISO 7531.	Instrument should follow ISO 7531 Surgical instruments - Materials - Part 1: Metals.
MHD 4(26674)/ Ent Surgery Instruments – Removing and Cutting Forceps — Chevalier Jackson’s Pattern – Specification First Revision				
Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
1	Mr. Abhishek singh	General	Chevalier Jacksons Pattern should be mentioned in the shape instead of mentioning in the product name/Title	Chevalier Jacksons Pattern should be mentioned in the shape instead of mentioning in the product name.
2		Technical	The maximum length for ENT surgery should be 23CM , but the length mentioned in the draft is 550, 400, 350 & 300 which is way high for ENT surgeries.The sizes (550, 400, 350 & 300) and the name (Chevalier Jacksons Forceps) mentioned in draft is usually being used in bronchial and esophagoscopy procedures.Please specify this.	The maximum length for ENT surgery should be 23CM , but the length mentioned in the draft is 550, 400, 350 & 300 which is way high for ENT surgeries.
MHD 4(26675)/ ENT Surgery Instruments — Suction Tube — Yankauer's pattern — Specification (First Revision)				
Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
1	Mr. Abhishek singh	Technical	Instrument should comply IS or ISO 7153.	Instrument should comply ISO 7153-1:Surgical instruments - Materials - Part 1: Metals.
2		Technical	The working length which is mention is 300-500mm, but for ENT maximum 300mm length is enough.	The working length should be 300mm.

MHD 4(26683)/ ENT Surgery Instruments – Direct Bronchoscopy Forceps – Irwin Moore's Pattern – Specification (Second Revision)				
Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
	Mr. Abhishek singh	General	The Title should be ENT Surgery Instruments – Direct Bronchoscopy Forceps.	The Title should be ENT Surgery Instruments – Direct Bronchoscopy Forceps.
		Technical	The length which is mentioned in draft is 550, 400, 350 & 300 mm but for Micro Laryngeal Surgery the maximum length should be 230mm.	The length which is mentioned in draft is 550, 400, 350 & 300 mm but for Micro Laryngeal Surgery the maximum length should be 230mm.
		General	Instrument should comply IS or ISO 7153.	Instrument should comply IS or ISO 7153-1:Surgical instruments - Materials - Part 1: Metals
MHD 4(26686)/ ENT Surgery Instruments – Straight Cup Forceps – Specification (First Revision)				
Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
1	Mr. Abhishek singh	Technical	The scissors should be with cleaning connector , cleaning connector is useful for the proper cleaning , sterilization and helpful in increasing the life span of the instruments.	The scissors should be with cleaning connector , cleaning connector is useful for the proper cleaning , sterilization and helpful in increasing the life span of the instruments.
2		Technical	Draft has shown one screw (M0.75 screw) at length of 125 mm in drawing, it should not be there ideally as instruments shaft should be single shaft from handle to tip there should not be any joint in between	Draft has shown one screw (M0.75 screw) at length of 125 mm in drawing, it should not be there ideally as instruments shaft should be single shaft from handle to tip there should not be any joint in between.

3		Technical	In product drawing it is mentioned that working length is 275 mm which is not required in Micro Laryngeal surgeries, ideal length of the instrument should be 22-24cm only	In product drawing it is mentioned that working length is 275 mm which is not required in Micro Laryngeal surgeries, ideal length of the instrument should be 22-24cm only.
4		General	Instrument should comply IS or ISO 7153.	Instrument should comply IS or ISO 7153-1 :Surgical instruments - Materials - Part 1: Metals.

MHD 4(26687)/ENT Surgery Instruments — Upwards Cup Forceps — Specification (First Revision)

Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
1	Mr. Abhishek singh	Technical	The length which is mentioned in draft is 275 mm, which is way high as per the need of the MLS procedure. It should be maximum 230mm.	The length which is mentioned in draft is 275 mm, which is way high as per the need of the MLS procedure. It should be maximum 230mm.
2		Technical	In the shape please add the point that all the forceps should be with cleaning connector , cleaning connector is useful for the proper cleaning , sterilization and helpful in increasing the life span of the instruments.	In the shape please add the point that all the forceps should be with cleaning connector.
3		Technical	The forceps shall be made of stainless steel conforming to IS/ISO 7153 Surgical instruments - Materials - Part 1: Metals	The forceps shall be made of stainless steel conforming to IS/ISO 7153 Surgical instruments - Materials - Part 1: Metals.

MHD 4(26688)/ ENT Surgery Instruments — Scissors — Specification (First Revision)

Sl.No	Comment by	Type of Comment	Comment	Change /Modified Comment
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1	Mr. Abhishek singh	Technical	The working length which is mentioned in draft is 275 mm which should be 230mm(maximum) for MICROLARYNGEAL SURGERY.	The working length which is mentioned in draft is 275 mm which should be 230mm(maximum) for MICROLARYNGEAL SURGERY.
2		Technical	The scissors should be with cleaning connector ,cleaning connector is useful for the proper cleaning , sterilization and helpful in increasing the life span of the instruments and the working length surface should be symmetrical. 7153.	The scissors should be with cleaning connector ,cleaning connector is useful for the proper cleaning ,sterilization and helpful in increasing the life span of the instruments and the working length surface should be symmetrical. Materials - Part 1: Metals
3		Technical	The instrument should follow IS or ISO 7153.	The instrument should follow IS or ISO 7153-1:Surgical instruments - Materials - Part 1: Metals

Annexure-C

Sr. No.	Name of Equipment	Origin	Panel	Progress
1	Micro debrider	DOP List	Nose	Accepted by the committee
2	Otology Drill	Committee decision	Ear	WC draft
3	Nasal Endoscopes	DOP List	Throat	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment
4	Flexible Video-Rhino-Laryngoscope (FOL)	DOP List	Throat	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment
5	Otoendoscopes	DOP List	Ear	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment
6	Flexible Fibre optic bronchoscope	DOP List	Throat	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment
7	Oesophagoscope	DOP List	Throat	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment

8	Stroboscope	DOP List	Throat	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment
9	Microalaryngoscope	DOP List	Throat	IS 15732 series, Endoscopes - Medical Endoscopes and Endotherapy Devices IS 13450 (Part 2/Sec 18) : 2014 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment
10	Plasma Ablation System (Coblation System)	DOP List	Nose	Recomended to transfer to MHD 15
11	LED head light	DOP List	Nose	IS 13450 (Part 2/Sec 41) : 2020/IEC 60601-2-41 : 2009 Medical electrical equipment — Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis, already covers Requirements for light source used for diagnosis.
12	Navigation system	DOP List	Nose	P draft stage completed
13	Camera monitor system for endoscopic sinus surgery	DOP List	Nose	IS/IEC 62563-1:2016 Medical Electrical Equipment Medical Image Display System Part 1 Evaluation Method IS 15732 (Part 1): 2018 / ISO 8600-1 : 2015 Endoscopes — Medical Endoscopes and Endotherapy Devices Part 1 General Requirements (First Revision)"
14	Pure Tone Audiometer with Speech audiometers	DOP List	Ear	IS/IEC 60645-1:2017 Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry
15	Tympanometer	DOP List	Ear	IS/IEC 60645-5 : 2004 Electroacoustics Audiometric equipment Part 5: Instruments for the measurement of aural acoustic impedance / admittance

16	Automated otoacoustic emission recorder	DOP List	Ear	IS/IEC 60645-6:2022 Electroacoustics - Audiometric equipment - Part 6: Instruments for the measurement of otoacoustic emissions
17	Automated auditory brain stem recorder	DOP List	Ear	IS/IEC 60645-7 : 2009 Electroacoustics - Audiometric equipment: Part 7 instruments for the measurement of auditory brainstem responses
18	Evoked Potential system (for Brain Stem Evoked Response audiometry and Auditory steady state responses and vestibular evoked myogenic potentials)	DOP List	Ear	IS/IEC 60645-7 : 2009 Electroacoustics - Audiometric equipment: Part 7 instruments for the measurement of auditory brainstem responses
19	Videonystagmography system	DOP List	Ear	Accepted by the committee
20	Tracheostomy tubes (cuffed and plain)	DOP List	Throat	IS 18377 : 2024/ ISO 5366:2016 Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors
21	Fibrin Glue	Committee decision	Head and neck surgery	WC draft stage completed, comments under resolution
22	Grommet Specification	Committee decision	Ear	WC draft stage completed, comments under resolution
23	ENT treatment unit (ENT Workstation)	DOP List	Ear	WC draft stage completed, comments under resolution
24	Oscillating Saw	Committee decision	Head and neck surgery	already under-developemnt in MHD02. Commitee may consider to drop this subject.
25	External Nasal Splint	Committee decision	Nose	Accepted by the committee
26	Audiometry Room	Committee decision	Ear	P draft stage completed
27	Ossicular Reconstruction Prosthesis	Committee decision	Ear	P draft stage completed, The

28	ENT operating Microscope	Committee decision	Ear	recommended to adopt " ISO 10936-1:2017 Optics and photonics — Operation microscopesPart 1: Requirements and test methods"
29	Voice prosthesis	Committee decision	Head and neck surgery	Transferred from MHD 11 Anaesthetic, Resuscitation and Allied Equipment

Annexure-D

Sl. No.	IS No.	TITLE	Remarks
1.	IS 10344 : 2024	Davis-Boyle Gag Frame and Tongue Plates Specification First Revision	Revised
2.	IS 10725 : 2024	Myringotomy Knife Specification (First Revision)	Revised
3.	IS 10726 : 2024	Meatal Skin Incision Knife Specification (First Revision)	Revised
4.	IS 10786 : 2024	St. Clair Thomsons Rhinoscopic Mirror Specification (First Revision)	Revised
5.	IS 10846 : 2024	Killian's Pattern Nasal Speculum - Specification (First Revision)	Revised
6.	IS 12901 (Part 1) : 2024	Laryngeal Forceps Part 1 Fine Grasping Crocodile Jaws Straight Specification (First Revision)	Revised
7.	IS 12901 (Part 2) : 2024	Laryngeal Forceps Part 2 Oval Cup Specification (First Revision)	Revised
8.	IS 17407 : 2020	Digital Otoscope " Handheld Type	Revised
9.	IS 17750 (Part 7): 2021 ISO 14708-7:2019	Implants for surgery Active implantable medical devices Part 7: Particular requirements for cochlear and auditory brainstem Implant Systems(First Revision)	
10.	IS 3758 : 2018	Hooks, aural - Specification (First Revision)	Revised
11.	IS 3760 : 2021	Probe, Aural, Jobson Horne's Pattern " Specification (First Revision of IS 3760)	Revised

12.	IS 3788 : 2024	Aural Specula Specification First Revision	Revised
13.	IS 3799 : 2019	Forceps, aural and nasal, crocodile action - Specification (First Revision)	Revised
14.	IS 3807 : 2024	Aural and Nasal Dressing Forceps Specification (Second Revision)	Revised
15.	IS 4488 : 2018	Forceps, Tonsil Holding (Muck's and White's Patterns) Specification (First Revision)	Revised
16.	IS 4489 : 2018	Forceps, Nasal Turbinate, Lucâ€™s â€™ Specification (First Revision)	Revised
17.	IS 4504 : 2018	Forceps, peritonsillar - Specification (First Revision)	Revised
18.	IS 4514 : 2018	Forceps, Tonsil Dissecting (Waugh's Pattern) - Specification (First Revision)	Revised
19.	IS 4520 : 2018	Forceps, Punch, Nasal Citelli's Antrum and Hajek's Sphenoidalâ€™ Specification (First Revision)	Revised
20.	IS 4959 : 2018	Raspatory, Nasal, Howarth'sâ€™ Specification (First Revision)	Revised
21.	IS 5338 : 2024	Eustachian Catheter Specification First Revision	Revised
22.	IS 5720 : 2024	Mollison's Pattern Self-Retaining Mastoid Retractor Specification (First Revision)	Revised
23.	IS 8094 : 2024	Cawthornes Pattern Cerumen Hook Specification First Revision	Revised
24.	IS 8128 : 2024	Farabeuf's Pattern Elevator Specification (First Revision)	Revised

25.	IS 8129 : 2024	Forceps - Tonsil Artery, Curved (Scotts Pattern) - Specification (First Revision)	Revised
26.	IS 8136 : 2024	Dundas Grant's Pattern Seeker Specification (First Revision)	Revised
27.	IS 8157 : 2024	Heath's Pattern Granulation Forceps Specification (First Revision)	Revised
28.	IS 9058 : 2024	Zoellner's Pattern Upward Cutting Knife Specification - (First Revision)	Revised
29.	IS 9059 : 2024	Zoellner's Pattern Downward Cutting Knife Specification (First Revision)	Revised
30.	IS 9479 : 2024	Shea's Pattern 25, 45, and 90 Angle Fenestra Hook for Ear Surgery - Specification (First Revision)	Revised
31.	IS 9480 : 2024	Shea's Pattern Left and Right Elevators For Ear Surgery - Specification (First Revision)	Revised
32.	IS 9526 : 2024	Crocodile Jaw Stapedectomy Scissors - Specification (First Revision)	Revised
33.	IS 9544 : 2024	Round Cup, Elongated Cup and Oval Cup Jaws Stapedectomy Forceps - Specification (First Revision)	Revised
34.	IS 9564 : 2024	Serrated, Smooth and Mc Gee Wire Closing Jaws Stapedectomy Forceps - Specification (First Revision)	Revised
35.	IS 10272 : 1982	Specification for draffin suspension apparatus	MHD/04/25980.(WC completed)
36.	IS 10308 : 1982	Tracheostomy Tubes and Guides, Cubley's Pattern	MHD/04/25984 (WC completed)
37.	IS 11318 : 1985	Bronchoscope, Aspirating, Negus' Pattern	To be withdrawn

38.	IS 11319 : 1985	Oesophagoscope, Negus' Pattern	Decision to be taken for WC
39.	IS 13169 : 1991	Ent surgery instruments head mirror - Specification	MHD/04/25979(WC completed)
40.	IS 13179 : 1991	Ent Surgery Instruments - Tracheostomy Tubes, Chevaliar Jackson's Pattern	MHD/04/25987 (WC completed)
41.	IS 4487 : 2000	ENT Surgery Instruments - Forceps, Tonsil Artery (Birkett's Pattern)	MHD/04/25394 (under print)
42.	IS 4994 : 1968	Specification for Forceps, Redressing, Walsham's Right, Left and Straightening	MHD/04/25923 (WC completed)
43.	IS 5147 : 1969	Examination Lamp with Bull's Eye Condenser (Floor Model)	To be withdrawn
44.	IS 5377 : 1969	Speculum, Nasal, Thudichum's	MHD/04/25925 (WC completed)
45.	IS 5412 : 1969	Saws, Nasal, Joseph's Pattern	MHD/04/25922 (WC completed)
46.	IS 5723 : 1970	Specification for mallet with fluted handle for ENT surgery	MHD/04/21654 (under print)
47.	IS 5732 : 1970	Gouge, Mastoid (Jenkins' Pattern)	To be withdrawn
48.	IS 5747 : 1970	Retractor, Endaural (Lempert's Pattern)	MHD/04/21736 (under print)
49.	IS 6464 : 2000	ENT Diagnostic Instruments - Tuning Forks (Gardiner Brown's Pattern)	MHD/04/21743 (under print)

50.	IS 6465 : 1972	Trocar, Antral, with Cannula (Tilley Lichtwitz' Pattern)	MHD/04/25933 (WC completed)
51.	IS 6514 : 1972	Nasal Cartilage Knife (Ballenger's Pattern)	MHD/04/25934 (WC completed)
52.	IS 7710 : 1975	Snare, Tonsil, Eve's Pattern	MHD/04/26089 (WC completed)
53.	IS 7712 : 1975	Curette, Adenoid, St. Clair Thomson's Pattern	MHD/04/26103 (WC completed)
54.	IS 7713 : 1975	Retractor, Light Model, Weislander's Pattern	MHD/04/25494 (WC completed)
55.	IS 7756 : 1975	Depressor, Tongue, Lack's Pattern	MHD/04/25938 (WC completed)
56.	IS 8093 : 1976	Curette, Ballance's pattern	MHD/04/25927 (WC completed)
57.	IS 8199 : 1976	Tracheostomy Tubes, Fuller's Pattern	To be withdrawn
58.	IS 8315 : 1977	Forceps, Redressing, Asch's Pattern	MHD/04/25929 (WC completed)
59.	IS 8316 : 1977	Retractor, Hajek's Pattern	MHD/04/26670 (WC)
60.	IS 8327 : 1977	Forceps, Nodule, Vocal, Chevalier Jackson's Pattern	MHD/04/26669 (WC)
61.	IS 8343 : 1977	Forceps, Biopsy, Peterson's Pattern	MHD/04/26681 (WC)
62.	IS 8734 : 1978	Forceps, Cutting and Removing Large Specimens, Chevalier Jackson's Pattern	MHD/04/26674 (WC)
63.	IS 8735 : 1978	Tube, Suction, Yankauer's Pattern	MHD/04/26675 (WC)

64.	IS 8743 : 1994	ENT surgery instruments - Forceps, direct bronchoscopy, with alligator jaws and tenaculum points, Irwin Moore's pattern	MHD/04/26683 (WC)
65.	IS 8825 : 1978	Specification for cannula, suction irrigation with locking device, microlaryngeal	MHD/04/26684 (WC)
66.	IS 8837 : 1978	Specification for suction tubes with stylet microlaryngeal surgery	MHD/04/26685 (WC)
67.	IS 8838 : 1978	Specification for forceps, cup, straight, microlaryngeal surgery	MHD/04/26686 (WC)
68.	IS 8839 : 1978	Specification for forceps, cup upwards, microlaryngeal surgery	MHD/04/26687 (WC)
69.	IS 8840 : 1978	Specification for scissors, microlaryngeal surgery	MHD/04/26688 (WC)
70.	IS 9558 : 1980	Specification for gauge, depth, ptfе (Teflon) piston	MHD/04/21830 (under print)
71.	IS 9718 : 1981	Specification for jig, cutting, ptfе piston	MHD/04/21659 (under print)

Annexure-E

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
ईएनटी शल्यचिकित्सा उपकरण – बायोप्सी संदंश –
पीटरसन पैटर्न — विशिष्टि
(IS 8343 का पहला पुनरीक्षण)

Draft Indian Standard
**ENT Surgery Instruments – Biopsy Forceps –
Paterson's Pattern — Specification**
(*First Revision of IS 8343*)

[ICS 11.040.30]

Ear, Nose, Throat and Head & Neck Surgery (ENT -
H&N) Instruments Sectional Committee, MHD 04

Last date for comments:

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1977 and Amendment No. 1 to the standard was published in 1984. The first revision of this standard has been brought out to align it with the recent developments and to bring the standard in line with the latest style and format of Indian Standards.

Amendment No. 1 published in 1984 is incorporated in the standard.

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

Indian Standard
**ENT SURGERY INSTRUMENTS – BIOPSY FORCEPS –
PATERSON'S PATTERN — SPECIFICATION**

1 SCOPE

This standard covers dimensional and other requirements for Paterson's pattern biopsy forceps of sizes 20, 25, 30, 35, 40, 45, 50, 55 and 60 cm used in ENT surgery.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

<i>IS No.</i>	<i>Title</i>
IS 3642 (Part 1): 1990	Surgical Instruments – Specification Part 1 Non-Cutting, Articulated Instruments (<i>Second Revision</i>)
IS 6603: 2024	Stainless Steel Semi-Finished Products, Bars, Wire Rods and Bright Bars — Specification (<i>Second Revision</i>)
IS 7531: 1990	Surgical Instruments – Corrosion Resistance of Stainless-Steel Surgical Instruments -Methods of Tests (<i>First Revision</i>)

3 SHAPE AND DIMENSIONS

3.1 The shape and dimensions shall be as shown in **Fig. 1**.

3.2 A deviation of ± 2.5 percent shall be allowed on all dimensions.

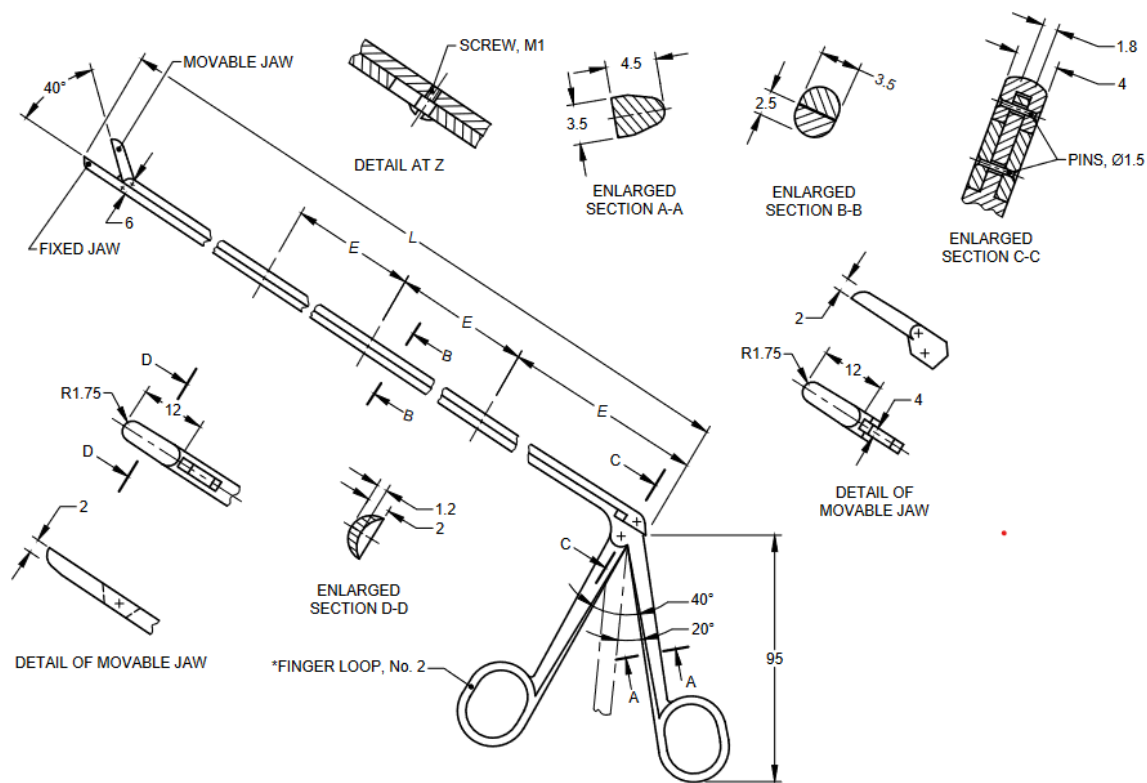
3.3 A deviation of $\pm 2^\circ$ shall be allowed on all angular dimensions.

4 MATERIAL

The forceps shall be made of stainless steel conforming to Designation X40Cr13 of IS 6603.

5 WORKMANSHIP AND FINISH

5.1 The forceps shall be free from scales, burrs, cracks, pits, tool marks and other surface defects.



E = 100, L = 200, 250, 300, 350, 400, 450, 500, 550 and 600. *See IS 3642

All dimensions in millimeters

FIG. 1 PETERSON'S PATTERN BIOPSY FORCEPS

5.2 All edges shall be smoothly rounded off except the cutting edge which shall be as shown in Fig. 1.

5.3 The jaws shall open and close fully and freely without any stiffness.

5.4 The forceps shall be passivated and shall have matt finish.

6 HEAT TREATMENT

The forceps shall be uniformly hardened and tempered to give a hardness of 540 to 600 HV.

7 TESTS

7.1 Performance

The forceps shall be made to punch a 1/2 mm thick card-board sheet. The forceps shall do this easily and cleanly. This shall be repeated 10 times. During or on completion of the test, the cutting edges of the forceps shall show no sign of damage.

7.2 Flexibility Test

The jaws shall be made to bite a piece of firm rubber about 3.00 mm thick and the finger loops closed as fully as possible. On release, the forceps shall not show any sign of damage or the upper jaw shall not become loose at the hinges.

7.3 Corrosion resistance

The scissors shall satisfy the boiling and autoclaving test as specified in IS 7531.

8 MARKING

8.1 The forceps shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark and the country of manufacture.

8.2 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.

9 PACKING

The forceps shall be wrapped in moisture-proof paper or packed in polyethylene bag. Each forceps shall then be packed in individual cartons. The forceps may also be packed as agreed to between the purchaser and the supplier.