Doc: MHD 04 (26684) WC
October 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

ईएनटी शल्य चिकित्सा उपकरण — सक्शन इरिगेशन कैनुला — विशिष्टि

(IS 8825 का पहला पुनरीक्षण)

Draft Indian Standard

ENT Surgery Instruments – Suction Irrigation Cannula — Specification

(First Revision of IS 8825)

[ICS 11.040.30]

Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee, MHD 04	Last date for comments: **07 December 2024**

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1978. 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.

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.

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Indian Standard

ENT SURGERY INSTRUMENTS – SUCTION IRRIGATION CANNULA — SPECIFICATION

1 SCOPE

This standard specifies dimensional and other requirements for suction irrigation cannula with locking device used in microlaryngeal surgical operation.

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.

IS No.	*Title*
IS 1570 (Part 5) : 1985	Schedules for wrought steels: Part 5 stainless and heat – Resisting steels *(Second Revision)*
IS 410 : 1977	Specification for cold rolled brass sheet, strip and foil *(Third Revision)*
IS 1068 : 1993	Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium – Specification *(Third Revision)*
IS 7531 : 1990	Surgical instruments – Corrosion resistance of stainless steel surgical instruments – Methods of tests *(First Revision)*

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 ± 2.5˚ shall be allowed on all angles.

4 MATERIAL

Stainless steel conforming to Designation X04Cr18NilO or 07Crl8Ni19 of Schedule V of IS 1570 (Part V) or brass conforming to Designation CuZn37 or CuZn40 of IS 410.

5 WORKMANSHIP AND FINISH

5.1 The cannula shall be free from scales, pits, burrs and other surface defects.

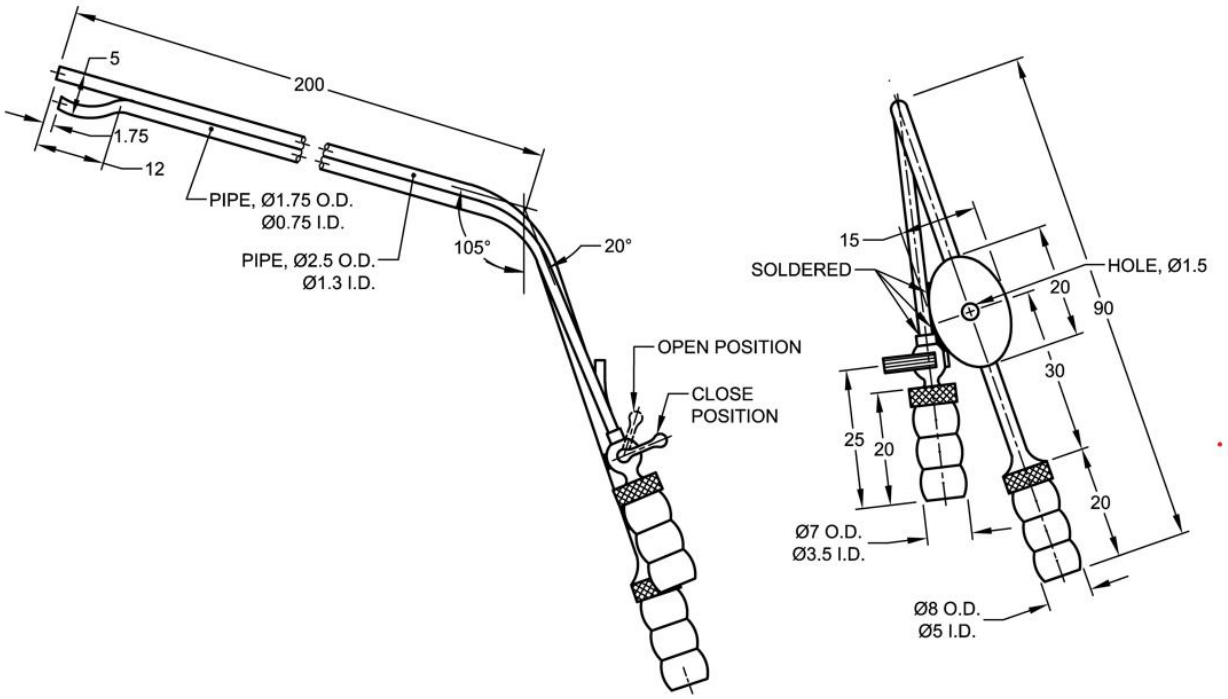
5.2 The hole in the cannula shall be well formed.

5.3 The brazing or soldering shall be neat and sound and shall be free from holes when tested as mentioned in **5.1.**

5.4 The locking device shall operate accurately.

5.5 The cannula if made of stainless steel shall be dull matt finished and passivated.

5.6 The cannula if made of brass shall be coated nickel and chromium conforming to IS 4827.



All dimensions in millimeters.

FIG. 1 SUCTION IRRIGATION CANNULA WITH LOCKING DEVICE

6 TESTS

6.1 Leakage Test

The brazed or soldered portion of the cannula shall be immersed in boiling paraffin wax for 2 minutes. There shall not be any air bubble visible on the surface of the liquid.

6.2 The cannula if made of stainless steel shall be subjected to any one of the tests given in **6.2.1** or **6.2.2.**

6.2.1 Copper Sulphate test

The cannula shall be scrubbed with soap and warm water, rinsed in hot water, followed by a dip in 95 percent ethyl alcohol and dried. The cannula shall be completely immersed in copper

sulphate solution at room temperature for 6 minutes and then washed off with fresh water. The copper sulphate solution shall be made up as follows:

Copper sulphate ($CuSO_4SH_2O$)	4.0 g
Sulphuric acid (H_2SO_4) (sp gr 1.84)	10.0 g
Water (H_2O)	90 ml

There shall not be any red stains or spot on the cannula after the test.

6.2.2 *Corrosion resistance Test*
Test the suction irrigation cannula in accordance with IS 7531. There shall not be any sign of corrosion visible after the completion of the test.

7 MARKING

7.1 The suction irrigation cannula shall be marked with the manufacturer's name, initials or recognized trade-mark, size, the country of manufacture and the words 'SS' if made of stainless steel.

7.2 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.

8 PACKING
The suction irrigation cannula shall be wrapped in moisture-proof paper or packed in polyethylene bags avoiding contact with one another. The suction irrigation cannula may also be packed as agreed to between the purchaser and the supplier.