

BUREAU OF INDIAN STANDARD

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भारतीय मानक मसौदा
कैनुला, मस्तिष्क के लिए विशिष्टता
(IS 9911 पहला पुनरीक्षण)

Draft Indian Standard
Specification For Cannula, Brain
(First Revision of IS 9911)

[ICS 11.040.30]

Neurosurgery Instruments, Implants and
Accessories Sectional Committee, MHD-07

Last date for comments: **17 July 2024**

FOREWORD

(Formal clause will be added later)

This standard was originally published as IS 9911: 1981 'Specification for cannula brain'. This first revision includes minor changes in references to incorporate the updated designation of steel, brass bars, plate, strip and the currently used methods of test for hardness and corrosion resistance.

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.

1 SCOPE

This standard covers materials, dimensions and other requirements for brain cannula, used in neurosurgery.

2 REFERENCES

The standard 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 6911: 2017	Stainless Steel Plate, Sheet and Strip — Specification (<i>Second Revision</i>)
IS 2112: 2014	Silver and Silver Alloys, Jewellery/Artefacts- Fineness and Marking – Specification (<i>Third Revision</i>)
IS 319:2007	Free cutting Brass Bars, Rods and Section – Specification (<i>Fifth Revision</i>)
IS 6528: 1995	Stainless steel wire – Specification (<i>First Revision</i>)
IS/ISO 80369-7: 2016	Small-Bore Connectors for Liquids and Gases in Healthcare Applications (Part 7) Connectors for Intravascular or Hypodermic Applications
IS 1068: 1993	Electroplated coatings of Nickel plus Chromium and Copper plus Nickel plus Chromium – Specification (<i>Third Revision</i>)
IS 7531: 1990	Methods for testing of corrosion resistance of stainless-steel surgical instruments (<i>First Revision</i>)

3 SHAPE AND DIMENSIONS

Shall be as shown in Fig. 1.

A deviation of ± 2.5 percent is permissible on all dimensions.

4 MATERIAL

4.1 Cannula

The cannula shall be made of stainless steel conforming to designation X07Cr18Ni9 of IS6911:2017 or fine silver conforming to IS 2112: 2014.

4.2 Hub - Free cutting brass rod or bar conforming to IS 319: 2007.

4.3 Stilette - Hard drawn stainless steel wire conforming to IS 6528: 1995.

5 WORKMANSHIP AND FINISH

5.1 All surfaces shall be free from pits, dents, burs, scales and other surface defects.

5.2 The hub of the cannula shall have a female luer taper which shall conform to IS/ISO 80369-7: 2016.

5.3 The cannula shall be pushed well into the cavity of the hub and securely swaged. The cannula and the hub shall be concentric and well aligned.

5.4 Stilette supplied with the cannula shall be finished smooth and free from nicks and kinks. It shall slide smoothly into the cannula.

5.5 The tip of the cannula shall be of round shape with two suction holes suitably formed and situated as shown in Fig. 1.

5.6 The hub shall be free from sharp edges and other defects. It shall be plated both inside and outside, chromium over nickel conforming to IS 1068: 1993.

6 TESTS

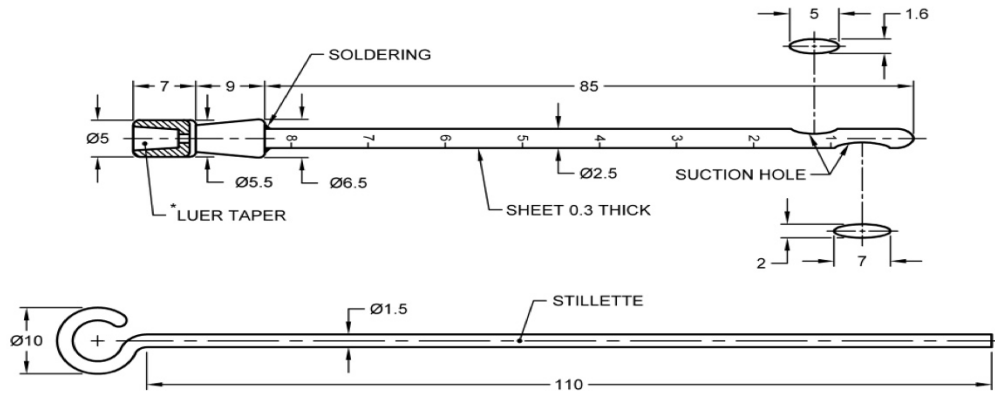
6.1 Leakage Test - Connect the cannula to the barrel of a syringe and the open end of the barrel to an air pump, delivering air at a pressure of 100 kPa. Block the cannula outlet by suitable means and start the air pump. Check for any leakage at the joint between the cannula and syringe and other parts of the cannula by dipping into water and observing for leakage in the form of any bubbles. There shall be no leakage during the test.

6.2 Security of swaging - The swaging of the cannula with the hub shall be tested by applying a pull of 90 N for one minute. The cannula shall not come out of the hub and it shall not become loose.

6.3 Corrosion Resistance Test

6.3.1 For Cannula Made of Silver — The cannula shall be immersed in a 10 percent solution of citric acid at room temperature for 5 hours. It shall then be boiled in distilled water for 30 minutes, and cooled while immersed in the same for 48 hours. The cannula or hub shall show no corrosion. The test shall be conducted in a glass container.

6.3.2 For Cannula Made of Stainless Steel — The cannula shall not show any sign of corrosion when tested as per IS 7531: 1990.



All dimensions in millimetres.

FIG. 1 CANNULA, BRAIN

7 MARKING

7.1 The hub of the cannula shall be marked with the manufacturer's name, initials or recognized trade-mark. The cannula shall be graduated lengthwise from 1 to 8, each graduation being marked at a distance of 10 mm from the other as shown in Fig. 1.

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

Each cannula with stiletto shall be packed in accordance with the best trade practices. Alternatively, packing may be done as agreed to between the purchaser and the supplier. On the package of the product batch Number, Lot Number, and Serial Number shall be mentioned.