भारतीय मानक **IS 9911 : 2024**

Indian Standard

मस्तिष्क कैनुला — विशिष्टि

(पहला पुनरीक्षण)

Brain Cannula — Specification

(First Revision)

ICS 11.040.30

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI - 110002
www.bis.gov.in www.standardsbis.in

August 2024 **Price Group 3**

Neurosurgery Instruments, Implants & Accessories Sectional Committee, MHD 07

FOREWORD

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

This standard was first published as IS 9911 : 1981 ‘Specification for cannula brain’. This 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.

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

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

BRAIN CANNULA — SPECIFICATION

(First Revision)

1 SCOPE

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

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 edition of these standards.

IS No.	*Title*
IS 319 : 2007	Free cutting brass bars, rods and section — Specification (*fifth revision*)
IS 1068 : 1993	Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium — Specification (*third revision*)
IS 2112 : 2014	Silver and silver alloys, jewellery/artefacts- fineness and marking — Specification (*third revision*)
IS 6528 : 1995	Stainless steel wire — Specification (*first revision*)
IS 6911 : 2017	Stainless steel plate, sheet and strip — Specification (*second revision*)
IS 7531 : 1990	Methods for testing of corrosion resistance of stainless-steel surgical instruments (*first revision*)
IS/ISO 80369-7 : 2016	Small-bore connectors for liquids and gases in healthcare applications: Part 7 Connectors for intravascular or hypodermic applications

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 IS 6911 : 2017 or fine silver conforming to IS 2112.

4.2 Hub

Free cutting brass rod or bar conforming to IS 319.

4.3 Stillette

Hard drawn stainless steel wire conforming to IS 6528.

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 (Part 7).

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 Stillette supplied with the cannula shall be finished smooth and free from nicks and kinks. Its hall 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.

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 h. It shall then be boiled in distilled water for 30 min, and cooled while immersed in the same for 48 h. 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.

7 MARKING

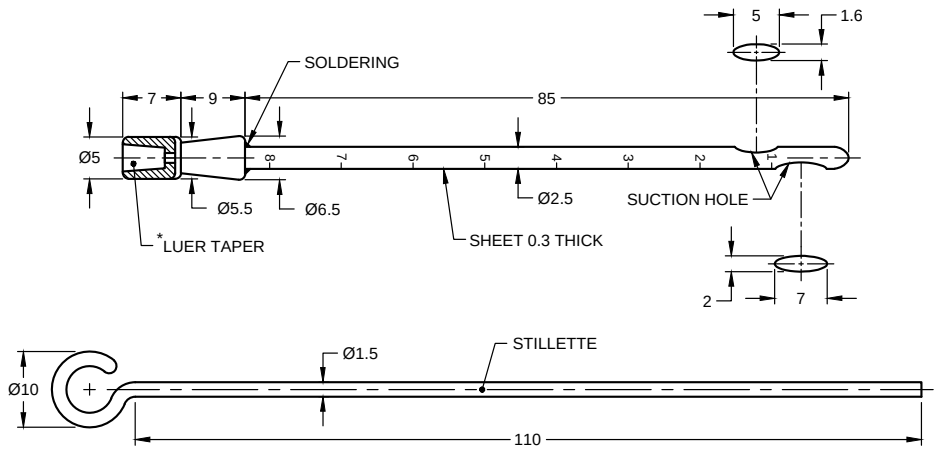
The hub of the cannula shall be marked with the manufacturer's name, initials or recognized trademark. The cannula shall be graduated lengthwise from 1 to 8, each graduation being marked at a distance of 10 mm from the other as shown in Fig. 1.

8 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 PACKAGING

Each cannula with a 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.



All dimensions in millimetres.

FIG.1 CANNULA, BRAIN

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

Neurosurgery Instruments Implants and Accessories Sectional Committee, MHD 07

Organization	*Representative*(*s*)
G B Pant Hospital, New Delhi	DR DALJIT SINGH **(*Chairperson*)**
Abbott Healthcare India Private Limited, Mumbai	SHRI LIPI CHAKHAIYAR SHRIMATI SHWETA SHARMA (*Alternate*)
Association of Indian Medical Device Industry, New Delhi	SHRI NAVEEN KHANNA SHRI PUHAZHENDI KALIYAPPAN (*Alternate* I) SHRI ANKUR BHARGAVA (*Alternate* II)
Boston Scientific India Private Limited, Gurugram	SHRI DEV CHOPRA SHRI PRASHANTH PRABHAKAR (*Alternate*)
Central Drugs Standard Control Organization, New Delhi	SHRI ASEEM SAHU MS SHYAMNI SASIDHARAN (*Alternate*)
Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru	SHRI JAYANT DANIEL SHRI G. SRIPATHY (*Alternate*)
Directorate General of Health Services, New Delhi	SHRI AJAY CHOUDHARY SHRI K. B. SHANKER (*Alternate*)
Happy Reliable Surgeries Private Limited, Bengaluru	SHRI HEMANT SAVALE SHRI SANJEEV GAUTAM (*Alternate*)
Indian Institute of Technology Hyderabad, Hyderabad	SHRI AVINASH ERANKI SHRI KOUSIK SARATHY S. (*Alternate*)
Kalam Institute of Health Technology, Vishakhapatnam	SHRI SANTOSH KUMAR BALIVADA SHRIMATI DIVYA ANIL PATIL (*Alternate* I) SHRI PURVA SUHAS PHALKE(*Alternate* II)
Skull Base Surgery Society of India, Chennai	SHRI HARSH DEORA
In Personal Capacity	SHRI ASOK KUMAR RAGHAVAN NAIR
BIS Directorate General	SHRI A. R. UNNIKRISHNAN, SCIENTIST 'G' AND HEAD (MEDICAL EQUIPMENT AND HOSPITAL PLANNING) [REPRESENTING DIRECTOR GENERAL (*Ex-officio*)]

Member Secretary
MS HARSHADA GANESH KADAM
SCIENTIST 'B'/ASSISTANT DIRECTOR
(MEDICAL EQUIPMENT AND HOSPITAL PLANNING), BIS

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	: 601/A, Konnectus Tower -1, 6th Floor, DMRC Building, Bhavbhuti Marg, New Delhi 110002	2323 7617
Eastern	: 8th Floor, Plot No 7/7 & 7/8, CP Block, Sector V, Salt Lake, Kolkata, West Bengal 700091	2367 0012 2320 9474
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg, Chandigarh 160019	265 9930
Southern	: C.I.T. Campus, IV Cross Road, Taramani, Chennai 600113	2254 1442 2254 1216
Western	: Manakalya, 5th Floor/MTNL CETTM, Technology Street, Hiranandani Gardens, Powai Mumbai 400076	25700030 25702715

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