Doc: MHD 04 (25933) WC

June 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

(Not to be reproduced without permission of BIS or used as an Indian Standard)

भारतीय मानक मसौदा

ट्रोकार, एंट्रल, कैनुला के साथ (टिली लिचविट्ज़ पैटर्न) के लिए विशिष्टि

(IS 6465 का पहला पुनरीक्षण)

Draft Indian Standard

Specification for Trocar, Antral, With Cannula (Tilley Lichtwitz' Pattern)

(First Revision of IS 6465)

[ICS 11.040.30]

Ear, Nose, Throat, Head & Neck Surgery
Instruments Sectional Committee, MHD 04

Last date for comments: 22 July, 2024

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1972. The First revision of this standard has been brought out to align it with 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.

Doc: MHD 04 (25933) WC

June 2024

Indian Standard

SPECIFICATION FOR TROCAR, ANTRAL, WITH CANNULA (TILLEY LICHTWITZ' PATTERN)

1 SCOPE

Specifies dimensional and other requirements of Tilley Lichtwitz' antral trocar with cannula used by ENT surgeons.

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.

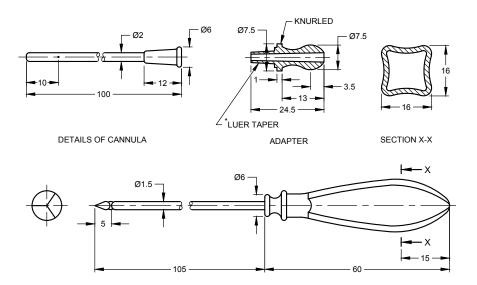
IS No.	Title	
IS 7531 : 1990	Surgical instruments - Corrosion resistance of stainless steel	
	surgical instruments - Methods of tests (First Revision)	
IS 1570 (Part 5): 1985	Schedules for wrought steels: Part 5 stainless and heat -	
	Resisting steels (Secoind Revision)	
IS 1068: 1993	Electroplated coatings of nickel plus chromium and copper plus	
	nickel plus chromium - Specification (Third Revision)	

3 SHAPE AND DIMENSIONS

As shown in Fig. 1.

4 MATERIAL

Component	Material	Conforming to
Trocar shank	Stainless steel	Designation 30Crl3 of IS: 1570(Part 5)
Cannula	Stainless steel	Designation 04Crl9Ni9 or 07 Crl9Ni9 of IS: 1570(Part 5)
Adapter Handle	Brass Stainless steel or Brass	Designation 04Crl9Ni9 or 07 Crl9Ni9 of IS: 1570(Part 5)



 * SEE IS 3234 : 1965 'SPECIFICATION FOR CONICAL FITTING FOR HYPODERMIC SYRINGES, NEEDLES AND OTHER MEDICAL EQUIPMENT, LUER TYPE'.

All dimesions in millimetres.

FIG. 1 ANTRAL TROCAR WITH CANNULA (TILLEY LICHTWITZ' PATTERN)

Doc: MHD 04 (25933) WC
June 2024

5 WORKMANSHIP AND FINISH

- **5.1** The trocar shank shall be central and its point shall lie on the axis.
- **5.2** The trocar edges shall be well-cut, clean, sharp and free from nicks, feathers and pits.
- **5.3** The handle shall be hollow and shall be fitted to the trocar shank by silver soldering. The silver soldering shall be sound and neat.
- **5.4** The cannula shall smoothly fit the trocar. The edge of the tip of the cannula shall be sharp and the tip shall be slit and sprung in to snap on the neck of the trocar. When the cannula is snapped onto the trocar neck, the cannula tip shall fit snugly to facilitate smooth entry of the trocar-cannula assembly.
- **5.5** The instrument shall be balanced and shall have a good feel.
- **5.6** All edges except the trocar point and cannula tip shall be even, rounded and nowhere sharp. All surfaces shall be smooth and free from burrs, pits, cracks and other surface flaws.
- **5.7** The trocar shank, cannula and handle when made of stainless steel shall be passivated and polished bright. The adapter and the handle when made of brass shall be plated chromium over nickel and the placing shall conform to Service Grade No. 2 of IS: 1068

6 HEAT TREATMENT

The trocar portion shall be hardened and tempered to a hardness of 400 to 500 HV.

7 TESTS

- **7.1 Performance Test** Take a piece of cardboard 1.5 mm thick. Hold the cardboard piece in such a way that, It is supported by thumb and first two fingers. The fingers shall support che cardboard piece to enable the trocar to punch through the cardboard. Keeping the trocar point against the cardboard, push the trocar by hand, to make a hole in the cardboard. The hole shall be cleanly made with a moderate push of the hand. The trocar tip and edges shall not get damaged during the test.
- **7.2 Flexibility Test** Hold the trocar, without the cannula, from the handle in a vice in such a way that the entire length of the trocar shank lies outside the vice. Apply a force at the tip of the trocar to deflect it through 25 mm from its original position. Release the force. The tip shall return to its original position and shall not have acquired a new set.
- **7.3 Corrosion Resistance** The instrument shall satisfy the boiling and autoclaving test as specified in IS: 7531.

Doc: MHD 04 (25933) WC June 2024

8 MARKING

Mark with the following:

- a) Manufacturer's name, initials or recognized trade-mark; and
- b) Words 'Stainless Steel' on the trocar shank and cannula.

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

As agreed, between the purchaser and the supplier ensure that the trocar and cannula tips are suitably protected. On the package of the product batch Number, Lot Number, and Serial Number shall be mentioned.