**IS 6465 : 2024**

***भारतीय मानक***

***Indian Standard***

**ईएनटी शल्य चिकित्सा उपकरण — कैनुला के साथ एंट्रल ट्रोकार — टिली लिचविट्ज़ पैटर्न — विशिष्टि**

*(*पहला पुनरीक्षण)

**ENT Surgery Instruments — Antral Trocar with Cannula — Tilley Lichtwitz's Pattern — Specification**

)*First Revision )*

ICS 11.040.30

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भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDARDS

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**XXXXXX Price Group**

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

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards after the draft Finalized by the Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

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. This revision incorporates the Amendment 1 issued in 1979 and test on hardness.

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 — ANTRAL TROCAR WITH CANNULA — TILLEY LICHTWITZ'S PATTERN — SPECIFICATION

**1 SCOPE**

This standard specifies dimensional and other requirements of Tilley Lichtwitz's 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/ISO 80369-7 : 2016 | Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications |
| IS 1570 (Part 5): 1985 | Schedules for wrought steels: Part 5 stainless and heat -Resisting steels *(second revision).* |
| IS 1068: 1993 | Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium – Specification *(third revision).* |
| IS 1501 (Part 1) : 2020 ISO 6507-1 : 2018 | Metallic Materials — Vickers Hardness Test Part 1 Test Method *( fifth revision )* |

**3 SHAPE AND DIMENSIONS**

**3.1** The shape and dimensions of Tilley Lichtwitz's Pattern Antral Trocar with Cannula shall be as shown in **Fig. 1.**

**4 MATERIAL**

**4.1** The Materials used to manufacture Trocar shank shall be stainless steel conforming to designation X30Crl3 of IS 1570(Part 5).

**4.2** The Materials used to manufacture Cannula and Adapter Handle shall be stainless steel conforming to designation X04Crl9Ni9 or X07Crl9Ni9 of IS 1570(Part 5).

Ø6

Ø2

10

12

100

KNURLED

Ø7.5

Ø7

1

3.5

13

24.5

\*LUER TAPER

.5

16

16

DETAILS OF CANNULA ADAPTER SECTION X-X

Ø1.5

5

105

Ø6

X

X

15

60

\*SEE IS 3234. IS/ISO 80369-7

**All dimensions in millimeters.**

**FIG. 1 Antral Trocar With Cannula (Tilley Lichtwitz' Pattern)**

**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 AND HARDNESS**

**6.1 General**

The trocar portion shall be heat treated using hardening and tempering procedures to produce specified hardness

**6.2 Hardness**

The Vickers hardness of the finished instrument shall be within the range of 400 to 500 HV, when tested in accordance with IS 1501 (Part 1).

**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 the 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.

**8 MARKING**

**8.1 Mark with the following:**

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

**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 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.

**ANNEX A**

(*Foreword*)

**COMMITTEE COMPOSITION**

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

Committee, MHD 04

| ***Organization*** | ***Representative(S)*** |
| --- | --- |
| All India Institute of Medical Sciences, New Delhi | Dr. Rakesh Kumar *(Chairperson)* |
| ALPS International, New Delhi | Shri.Alok Narang,  |
| Shri. Karan Narang (*Alternate*) |
| All India Institute of Medical Sciences, New Delhi | Dr. Prem Sagar  |
| Dr. Arvind Kumar (*Alternate*) |
| All India Institute of Medical Sciences, Bhopal | Dr. Vikas Gupta  |
| Dr. Ganakalyan Behera (*Alternate*) |
| Association of Indian Medical Device Industry, New Delhi | Shri. Tarlochan Dev  |
| Shri. Ankur Bhargava (*Alternate* I*)* |
| Dr. C.S. Prasad (*Alternate* II) |
| Directorate General of Health Services, New Delhi Central | Ms. Dr. Pallika Kumar |
| Government Medical College & Hospital, Chandigarh | Dr. Surinder K Singhal  |
| Shri. Nitin Gupta (*Alternate*) |
| Happy Reliable Surgeries Private Limited, Bangalore | Shri. Hemant Savale  |
| Shri. Sanjeev Gautam (*Alternate*) |
| India Medtronic Private Limited, Gurugram | Smt. Latika Vats  |
| Shri. Saurabh Sable (*Alternate* I*)* |
| Shri. Sandeep Verma (*Alternate* II) |
| Indian Institute of Technology Kanpur, Kanpur | Dr. A. R. Harish  |
| Kalam Institute of Health Technology, Vishakhapatnam | Dr. Arjun Thimmaiah  |
| Shri. Amit Sharma (*Alternate*) |
| Karl Storz Endoscopy India Private Limited, New Delhi | Shri. Sandeep Sethi |
| Shri. Kapil Rana (*Alternate*) |
| Serwell MediEquip, Chennai | Shri. T. Jebin Samuel  |
| Shri. R. Radhakrishnan (*Alternate* I*)* |
| Shri. G. Sathish (*Alternate* II) |
| Tata Memorial Center (Hospital), Mumbai | Dr. RICHA VAISH  |
| Shri. Vijay Yashwant Mestri (*Alternate* I*)* |
| Dr. Arjun Singh (*Alternate* II) |
| Postgraduate Institute of Medical Education and Research, Chandigarh | Smt. Dr Jaimanti Bakshi |
| In Personal Capacity , D-2 ,Tower 7, Type 5, East Kidwai Nagar, New Delhi-110023 | Dr. Kapil Sikka |
| BIS Directorate General | Shri A. R. Unnikrishnan Scientist ‘G’ And Head (Medical Equipment And Hospital Planning) [Representing Director General (Ex-Officio)] |

*Member Secretary*

Mr. Karthik Reddy Katipally

Scientist ‘B’/Assistant Director

(Medical Equipment And Hospital Planning). Bis