भारतीय मानक

Indian Standard

IS 6468 : 2024

वक्ष शल्य चिकित्सा उपकरण — प्रदहन विदारक, नेल्सन स्वरूप — विशिष्टि

(दूसरा पुनरीक्षण)

Thoracic Surgery Instruments — Empyema Trocar, Nelson's Pattern — Specification

(Second Revision)

ICS 11.040.30

भारतीय मानक ब्यूरो
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June 2024 **Price Group 4**

Medical and Surgical Cardiology Equipment Sectional Committee MHD 06

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Medical and Surgical Cardiology Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in IS 6468 : 1972 ‘Thoracic surgery instruments trocar empyema nelsons pattern specification’. The standard was revised in 1989 by altering material requirements, specifying dimensional tolerances, and adding requirements of surface conditions, packing, marking, and recommended sampling plan. This revision aligns the cross references to the latest standards, incorporates the revised designation for stainless steel, includes certification clause and removes the optional sampling requirements.

The composition of the Committee responsible for the 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*)’.

Indian Standard

THORACIC SURGERY INSTRUMENTS — EMPYEMA TROCAR, NELSON'S PATTERN — SPECIFICATION

(Second Revision)

1 SCOPE

This standard prescribes requirements and tests for Nelson's pattern empyema trocars used in thoracic surgery.

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 encouragedto investigate the possibility of applying the most recent edition of these standard:

IS No.	*Title*
IS 1501 (Part 1) : 2020/ISO 6507 -1 : 2018	Metallic materials — Vickers hardness test: Part 1 Test method (*fifth revision*)
IS 1570 (Part 5) : 1985	Schedules for wrought steels: Part 5 Stainless and heat-resisting steels (*second revision*)
IS 6603 : 2001	Stainless steel bars and flats — Specification (*first revision*)
IS 7531 : 1990	Surgical instruments — Corrosion resistance of stainless steel surgical instruments — Methods for tests (*first revision*)

3 MATERIALS

3.1 Trocar Shank and Handle

The trocar shank and handle shall be made of stainless steel conforming to designation X30Cr13 or X40Cr13 of IS 6603.

3.2 Cannula

The cannula shall be made of X04Cr19Ni9 or X07Cr18Ni9 of IS 1570 (Part 5).

4 SHAPE AND DIMENSIONS

4.1 The shape and dimension of the instrument shall be as shown in Fig. 1.

4.2 Tolerances

Permissible tolerance on various dimensions is as given below:

a) ± 0.05 mm on dimensions up to 2.0 mm;

b) ± 0.1 mm on dimensions above 2.0 mm and up to 5.0 mm;

c) ± 0.2 mm on dimensions above 5.0 mm and up to 20.0 mm;

d) ± 0.5 mm on dimensions above 20.0 mm and up to 50.0 mm;

e) ± 1.0 mm on dimensions above 50.0 mm and up to 1000 mm; and

f) ± 2.0 mm on dimensions above 100.0 mm.

5 HEAT TREATMENT

The trocar tip shall be hardened and tempered to 400 HV to 500 HV, when tested in accordance with IS 1501 (Part 1).

6 WORKMANSHIP

6.1 The trocar may be of one-piece or two-piece construction. In case of two-piece construction, the shank shall be attached securely and permanently to the handle.

6.2 The handle shall be knurled.

6.3 The trocar point shall be central and sharp. The cannula shall snugly fit on the trocar. The tip of the cannula shall be sprung in to snap on the tapered portion of the neck of the trocar. The trocar shall be capable of fitting into the cannula easily and shall be removable without undue forcerequired to pull it out.

7 SURFACE CONDITION

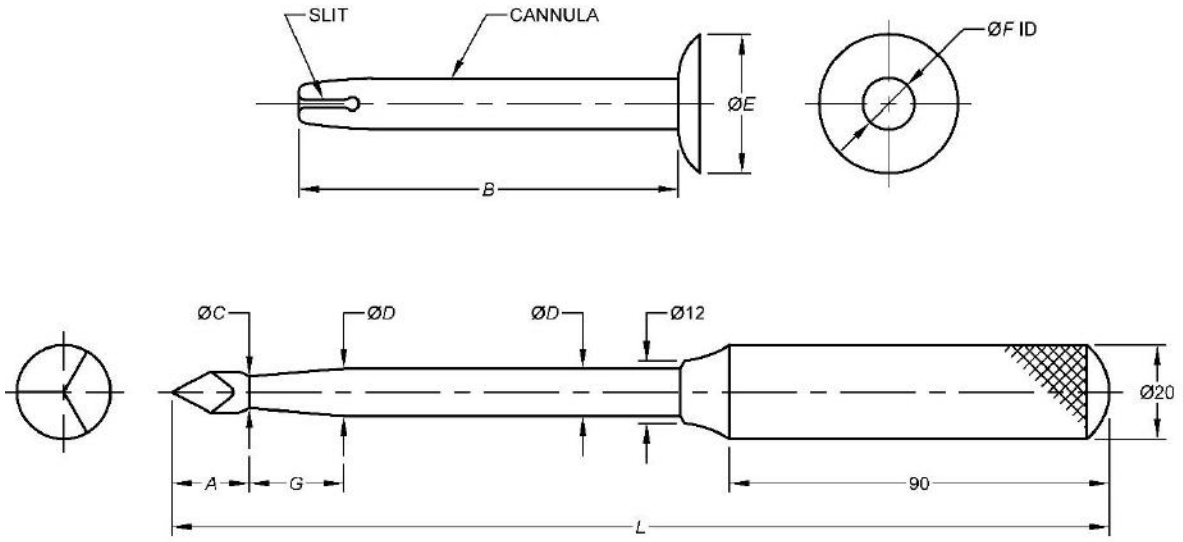
7.1 General

All surfaces shall he free from pares, crevices and grinding marks. The instruments shall be supplied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

7.2 Surface Finish

The surface finish of the instrument till be reflection-reducing, for example, satin finish, matt black finish.

NOTE — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and should reduce glare.



SIZE	L	A	B	C	D	E	F	G
SMALL	185	16	70	5	6.5	24	7.3	14
MEDIUM	190	17	75	6	8.0	26	8.7	17
LARGE	195	18	80	7	10.0	28	10.7	20

All dimensions in millimetres.
FIG. 1 TROCAR, EMPYEMA, NELSON'S PATTERN

7.3 Passivation and Final Treatment

The instruments shall, unless the metallurgical characteristics of the instrument (for examplethe presence of brazed or soldered joints) render it inappropriate, be treated by a suitable passivation process, for example by electro polishing or by treatment with 10 percent (*v/v*) nitric acid solution for not less than 30 minutes at a temperature not less than 10 °C and not exceeding 60 °C. The instruments shall then be rinsed in water and dried in hot air.

8 TESTS

8.1 Performance Test

8.1.1 When the trocar is rotated on a V-block, the tip shall remain at one point.

8.1.2 The trocar with the cannula shall be made to pierce through a piece of soft wood, 6 mm thick.The instrument shall do this easily and rapidly and in doing so, the point and the cutting edges shall not become blunt or distorted.

8.1.3 The trocar with the cannula on shall be made to pierce through a piece of leather, 3 mm thick, soaked in water for 2 hours. The instrument shall do this easily and rapidly and in doing sothe point and the cutting edges shall not become blunt or distorted.

8.2 Corrosion Resistance Test

The trocar shall show no sign of corrosion when tested in accordance with IS 7531.

9 MARKING AND PACKING

9.1 The instruments shall be legibly and indelibly marked with the indication of the source of manufacture, the words 'stainless steel' or letters 'SS'; and the country of manufacture.

9.2 After protecting the trocar point by a corrosion inhibiting plastic coating, the instruments shallbe individually wrapped in a suitable cushioning material like folded tissue paper. Each instrument shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

9.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

9.3 The packages shall be marked with the name and size of the instrument; the indication of the source of manufacture, the words 'stainless steel'; and the country of manufacture.

10 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.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

Organization	*Representative(s)*
In Personal Capacity (*B*-87, *Alpha* 1, *Greater Noida, Pilkhan Estate*, 3*rd Street*)	DR DEEPAK KUMAR SATSANGI **(*Chairperson*)**
All India Institute of Medical Sciences, Delhi	DR MILIND P HOTE DR PRADEEP RAMAKRISHNA REDDY (*Alternate*)
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Central Drugs Standard Control Organization, Delhi	DR RAVI KANT SHARMA
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Ministry of Electronics and Information Technology, Delhi	SHRIMATI SUNITA VERMA SHRI RASHID SHABAN (*Alternate*)
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Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	PROF VIVEK V. PILLAI PROF BINEESH K. R. (*Alternate*)
Stryker India Private Limited, Gurugram	SHRI SHIVKUMAR HURDALE
TTK Healthcare Limited (Heart Valve), Chennai	SHRI RAJIV K. NAIR MS INDU V. NAIR (*Alternate*)
BIS Directorate General	SHRI A. R. UNNIKRISHNAN, SCIENTIST 'G' AND HEAD (MEDICAL EQUIPMENT AND HOSPITAL PLANNING) [REPRESENTING DIRECTOR GENERAL (*Ex-officio*)]

Member Secretary
SHRI PAWAN KUMAR
SCIENTIST 'B'/ASSISTANT DIRECTOR
MEDICAL EQUIPMENT AND HOSPITAL PLANNING, BIS

Bureau of Indian Standards

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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