भारतीय मानक

Indian Standard

IS 6466 : 2024

वक्ष शल्य चिकित्सा उपकरण — सुई धारक — विशिष्टि

(दूसरा पुनरीक्षण)

Thoracic Surgery Instruments — Needle Holder — Specification

(Second Revision)

ICS 11.040.30

भारतीय मानक ब्यूरो
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June 2024 **Price Group 5**

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 originally published as IS 6466 : 1972 ‘Thoracic Surgery Instruments Needle Holder 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 — NEEDLE HOLDER — SPECIFICATION

(Second Revision)

1 SCOPE

This standard prescribes requirements and tests for Gerbode's pattern and De Backey's pattern (3 mm jaw) needle holders 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 encouraged to investigate the possibility of applying the most recent edition of these standards:

IS No.	*Title*
IS 1501 (Part 1) : 2020/ISO 6507-1 : 2018	Metallic materials — Vickers hardness test: Part 1 Test method (*fifth revision*)
IS 3642 (Part 1) : 1990	Surgical instruments — Specification: Part 1 Non-cutting, articulated instruments (*second revision*)
IS 6528 : 1995	Stainless steel wire — Specification *(first 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 of tests (*first revision*)

3 MATERIAL

3.1 The instrument shall be made of stainless steel conforming to designation X30Cr13 of IS 6603.

3.2 Pin

The pin in the instruments shall be made of stainless steel conforming to designation X20Cr13 or X30Cr13 of IS 6603.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the instrument shall be as shown in Fig. 1 and Fig. 2.

4.2 Tolerances

Permissible tolerance on various dimensions are as given below:

a) ± 0.5 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 100.0 mm; and
f) ± 2.0 mm on dimensions above 100.0 mm.

The two halves of the instruments shall, however, not differ at any dimension and shall match with each other perfectly.

5 MASS

The mass of the instrument of Gerbode's pattern shall be 35 g to 45 g and that of the De Backey's pattern (3 mm Jaw) shall be 45 g to 55 g.

6 HEAT TREATMENT

6.1 The instruments shall be uniformly hardened and tempered to a hardness of 400 HV to 460 HV, when tested in accordance with IS 1501 (Part 1).

6.2 Mating surfaces on the same instrument, such as opposite jaws and shanks shall not vary in hardness by more than 40 HV.

7 WORKMANSHIP

7.1 The needle holder shall be symmetrical and balanced. The opening and closing movement shall be smooth and jerk free.

7.2 The joint shall conform to the relevant requirements of **6** of IS 3642 (Part 1).

7.3 The serrations on the jaws shall conform to the relevant requirements of Section 2 of IS 3642 (Part 1).

7.4 The ratchet teeth shall conform to Section 4 of IS 3642 (Part 1). The arms shall be symmetrical about the axis at every ratchet engagement.

7.5 The finger loops shall be in accordance with the relevant requirements of Section 6 of IS 3642 (Part 1).

7.6 All edges shall be smooth and even.

8 SURFACE CONDITION

8.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instrument shall be applied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

8.2 Surface Finish

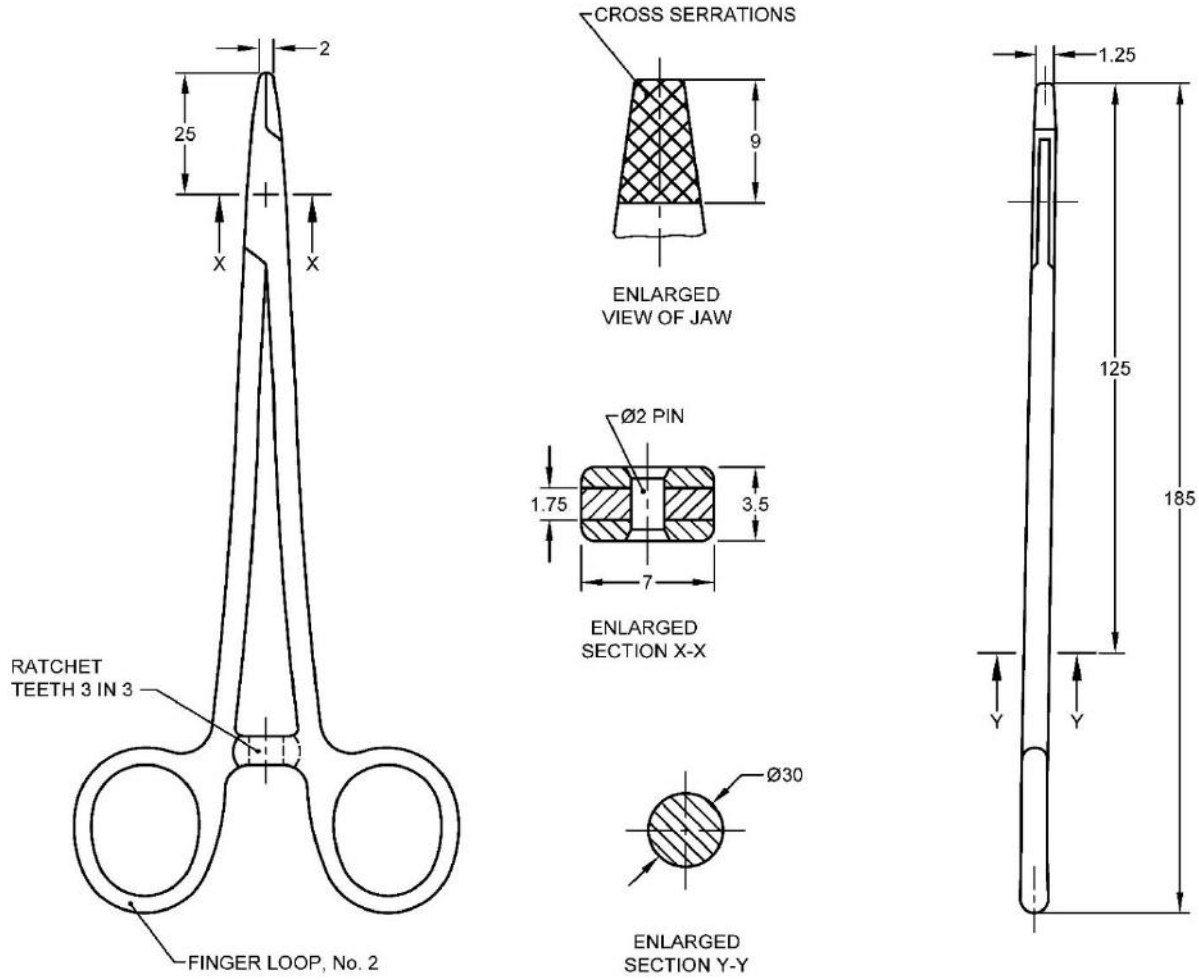
The surface finish of the instrument shall be reflection-reducing, for example satin finish, matt black finish.

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

8.3 Passivation and Final Treatment

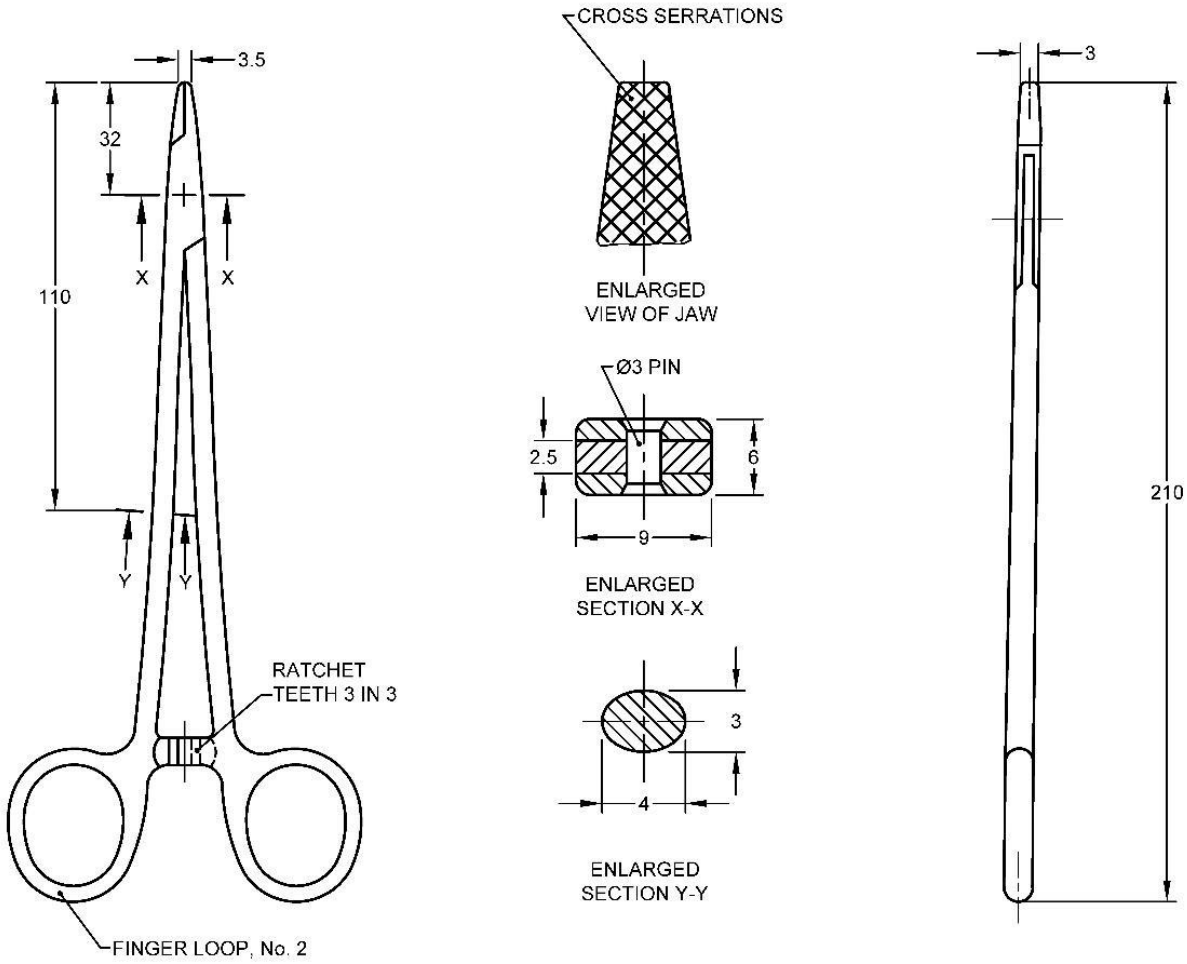
The instruments shall be treated by a suitable passivation process, for example by electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature not less than 10 °C and not exceeding 60 °C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.



All dimensions in millimetres.

FIG.1 NEEDLE HOLDER, GERBODE'S PATTERN



All dimensions in millimetres.

FIG. 2 NEEDLE HOLDER, DE BACKEY'S PATTERN (3 mm JAW)

9 TESTS

9.1 Performance Test

A plastics fiber (for example a suture filament) of maximum diameter 0.2 mm shall be placed between the jaws of the instrument at a point within one third of the length nearer to the tip. The instrument shall be fully closed and a tensile force of 20 N applied to the fiber. The fiber shall not slip out, irrespective of whether the direction of the load is longitudinal or transverse.

9.2 Load Closure Test

By fixing one finger loop of the needle holder in a vice, load shall be applied at the other finger loop by means of a pan or spring balance. The load at which the first ratchet just engages shall be noted. The load required to close the needle holder at the first step of the ratchet shall be 7 N to 12 N.

9.3 Flexibility Test

9.3.1 One arm of the needle holder shall be fixed in a vice at a point under the joint so that the arm protrudes from the upper surface of the vice jaws by an amount as follows:

Sl No.	*Type of Needle Holder*	*Distance of Pole of Finger Loop Point of Application of Load from Vice Jaws* (mm)	*Deflection* (mm)
(1)	(2)	(3)	(4)
i)	Gerbode's pattern	100	12
ii)	De Backey's pattern	125	15

By the application of gradual force at the upper pole of the finger loop the shank of the needle holder shall be deflected in a plane at right angle to that of the finger loop by the amount shown in col (3) above as measured at the upper extremity of the clamped arm (that is at the upper pole of the finger loop). On release of the force, no permanent set shall be observed. The test shall be repeated on the same arm with the finger loop fixed at its equator in the vice and the shank projecting above the vice. The deflecting force shall be applied to the shank at the point mentioned above and shah act in a plane at right angles to that of the finger loop. The shank shall be deflected by the amount shown above as measured at the level of the point where the force is applied. On release of the force, the forceps shall not take a permanent set. The complete test shall be repeated on the opposite arm.

9.3.2 A stainless steel wire of 1 mm dia, conforming to designation X04Crl8Ni10 of IS 6528 shall be placed between the tips of the instrument jaws. The instrument shall be fully closed to the last ratchet position and left in this position for 3 hours at room temperature. After the test, no distortion, cracks or any other permanent modification in the instrument shall be visible.

9.4 Corrosion Resistance Test

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

10 MARKING AND PACKING

10.1 The instruments shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel' or letters 'ss'; and the country of manufacture.

10.2 Each instrument shall be wrapped in a suitable cushioning materials like folded tissue paper. It 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. Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

10.3 The packages shall be marked with the name and pattern of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel', and the country of manufacture.

11 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 3rd 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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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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Amend No.	Date of Issue	Text Affected

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