

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
**वक्ष शल्य चिकित्सा उपकरण - फेफड़ों के लिए विच्छेदक चिमटी -
विशिष्टि**

(IS 6777 का दूसरा पुनरीक्षण)

Draft Indian Standard

**Thoracic Surgery Instruments - Dissecting Forceps for lungs -
Specification**

(Second Revision of IS 6777)

ICS 11.040.30

Medical and Surgical Cardiology Equipment
Sectional Committee, MHD 06

Last Date of Comments: **23 Dec 2024**

FOREWORD

(Formal Clauses, will be added later)

This standard was first published in 1972. The standard was revised in 1989 altering material requirements, specifying dimensional tolerances, and adding requirements of surface conditions, packing and marking. The second revision of this standard has been brought out to align the cross references to latest 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.

1 SCOPE

This standard prescribes requirements for lung dissecting forceps used in thoracic surgery.

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.

<i>IS No.</i>	<i>Title</i>
IS 6603	Stainless Steel Bars and Flats — Specification (<i>First Revision</i>)
IS 7531	Methods for Testing of Corrosion Resistance of Stainless Steel Surgical Instruments (<i>First Revision</i>)
IS 3642 (Part 1)	Surgical instruments — Specification: Part 1 non - Cutting, articulated instruments
IS 1501 (Part 1):2020/ ISO 6507-1 : 2018	Metallic Materials — Vickers Hardness Test Part 1 Test Method (<i>Fifth Revision</i>)

3 MATERIAL

The instrument shall be made of stainless-steel conforming to Designation X20 Cr13 or X30Cr13 of IS 6603.

4 SHAPES AND DIMENSIONS

- 4.1** The shape and dimensions of the instrument shall be as shown in Fig. 1.
4.2 Permissible tolerances on linear dimension shall be in accordance with Table 1.

5 WORKMANSHIP

- 5.1** The two halves of the instrument shall, however, not differ at any dimension and shall match with each other perfectly.
5.2 The forceps shall be symmetrical and balanced, and the opening and closing shall be true and in one plane. The teeth shall register accurately without sticking or locking. The registration shall correspond to that of the guide pin with the guide hole.
5.3 The teeth shall be with combination of 6 in 7, and rounded, conforming to the relevant requirements of 5 of IS 3642(Part 1).
5.4 The joint shall be in accordance with the relevant requirements of 3 of IS 3642(Part 1).
5.5 There shall be no sharp edges. All edges and corners shall be rounded.

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.

**TABLE 1 PERMISSIBLE TOLERANCES ON LINEAR AND ANGULAR DIMENSIONS
(Clause 4.2)**

<i>Dimension type</i>	<i>Dimension range mm</i>	<i>Permissible Tolerances mm</i>
Linear Dimensions	Up to 2.0	± 0.05
	Above 2.0	± 0.1
	Above 5.0	± 0.2
	Above 20.0	± 0.5
	Above 50.0	± 1.0
	Above 100.0	± 2.0

7 SURFACE CONDITION

7.1 General

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

7.2 Surface Finish

The surface finish shall be one of, or a combination of, the following:

- Mirror polished; and
- Reflection-reducing, for example, satin finish, matt black finish

NOTES

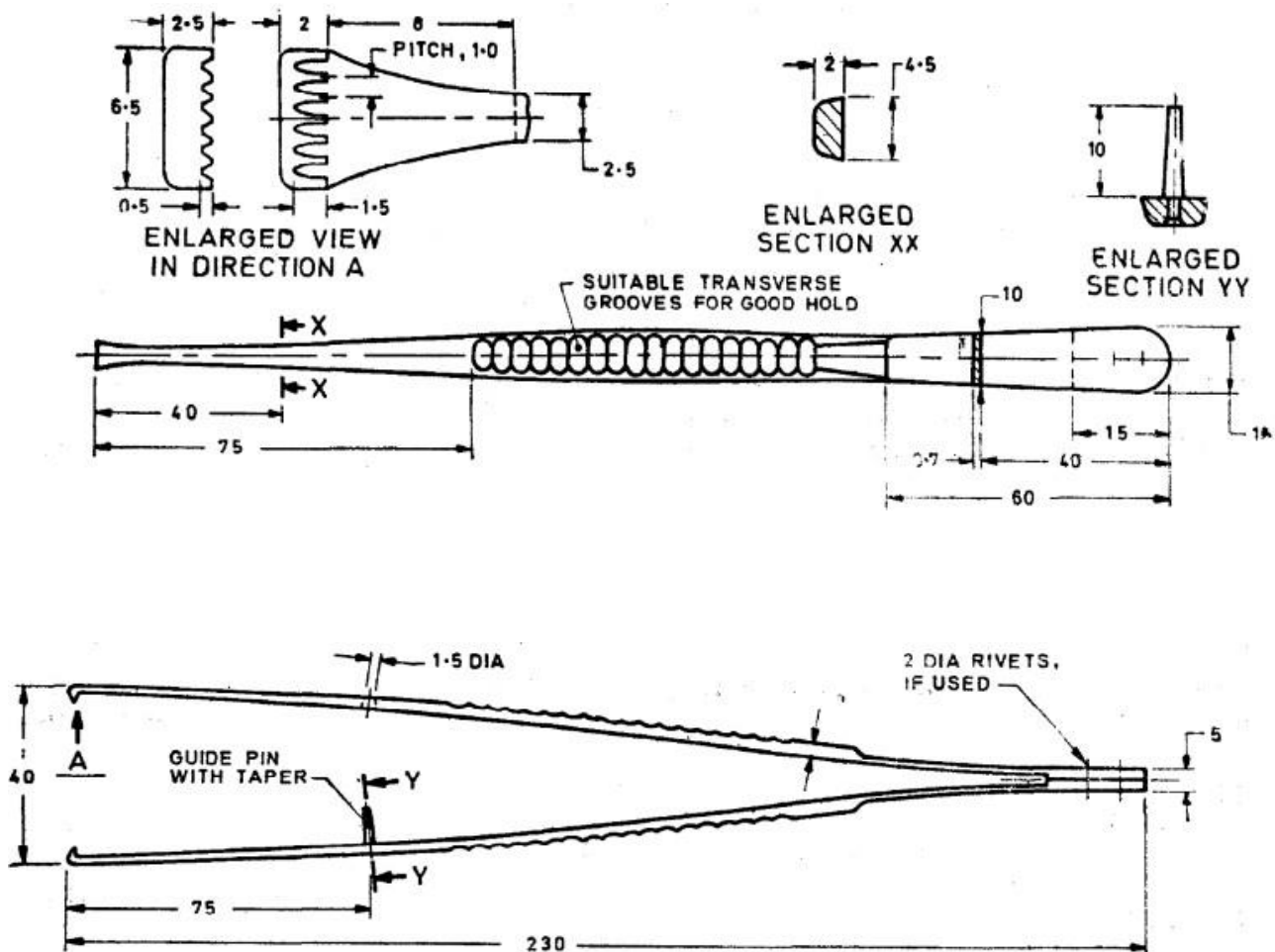
1 The satin finish should be achieved by an appropriate procedure such as, grinding, brushing electro polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform, smooth and it should reduce glare.

2 Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. -The mirror finish should be achieved by an appropriate procedure, such as, polishing, brushing, electropolishing and mirrorbuffing.

7.3 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.



All dimensions in millimetres

FIG. 1 LUNG DISSECTING FORCEPS

7 TESTS

7.1 Corrosion Resistance Test The rib spreader shall show no sign of corrosion when tested in accordance with IS 7531.

7.2 Load Closure Test The teeth of the forceps shall just close when a force of 1.7 ± 0.1 N is applied at the first finger groove from the tip. When a sheep or goat intestine is held with moderate force applied on the grooves of the forceps, the intestine shall be held firmly and shall not slip when a slight pull is applied.

7.3 Flexibility Test

7.3.1 The arms of the forceps after maximum closure by manual compression shall not take a permanent set and the teeth shall continue to engage or disengage accurately without sticking or locking.

7.3.2 The joint end of the forceps shall be clamped in a vice so that the riveted or welded joint is gripped firmly. By the application of force at the tip of the arm, one arm of the forceps shall be deflected in a plane at right angles to the plane of the arm' by a distance of 50 mm measured at the tip of the forceps. On release of the force, no permanent set shall be observed. The test shall be repeated on the other arm.

8 MARKING AND PACKING

8.1 The instruments shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trademark, the words 'Stainless Steel' or letters 'SS', and the country of manufacture.

8.2 Each instrument shall be wrapped in a suitable cushioning material 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 between the purchaser and the supplier.

8.3 The packages shall be marked with the name of the instrument, the manufacturer's name, initials or recognized trademark, the words 'Stainless Steel', and the country of manufacture.

8.4 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.