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भारतीय मानक मसौदा

वक्ष शल्य चिकित्सा उपकरण - श्वसनीका प्रतिबंधक – विशिष्टि

(IS 8890 का दूसरा पुनरीक्षण)

Draft Indian Standard

Thoracic Surgery Instruments -Bronchus Clamps – Specification

(Second Revision of IS 8890)

ICS 11.040.55

Medical and Surgical Cardiology Equipment
Sectional Committee, MHD 06

Last Date of Comments: 17 Dec 2024

FOREWORD

(Formal Clauses, will be added later)

This standard was first published in 1978. 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. 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 shapes and dimensions for Lee's, Price Thomas and Sorb's Pattern Bronchus clamps for use in thoracic surgery.

2 REFERENCES

The standard given below contains 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: 2001	Stainless Steel Bars and Flats – Specification (<i>First Revision</i>)
IS 7531: 1990	Methods for Testing of Corrosion Resistance of Stainless Steel Surgical Instruments (<i>First Revision</i>)

3 MATERIAL

The clamps shall be made of stainless-steel conforming to Designation X20Cr13 or X30Cr13 of IS 6603.

4 SHAPES AND DIMENSIONS

- 4.1 The shapes and dimensions for three patterns of Bronchus clamps shall be as shown in Fig. 1, 2 and 3.
- 4.2 The joint shall be box type conforming to IS 3642 (Part 1) : 1990.
- 4.3 The serrations shall be provided as shown in Fig.1.
- 4.4 The ratchet teeth shall conform to IS 3642 (Part 1) : 1990 with the combination as shown in Fig. 1, 2 and 3.
- 4.5 The finger loop shall conform to size number 3 of IS 3642 (Part 1): 1990.
- 4.6 Permissible tolerances on linear and angular dimension shall be in accordance with Table 1.

5 WORKMANSHIP

- 5.1 The movement of the instrument shall be smooth and free from jerks.
- 5.2 The serrations shall match perfectly.
- 5.3 All edges and corners shall be rounded.

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

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

6 SURFACE CONDITION

6.1 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.

6.2 Surface Finish

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

- a) Mirror polished; and
- b) 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.

6.3 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.

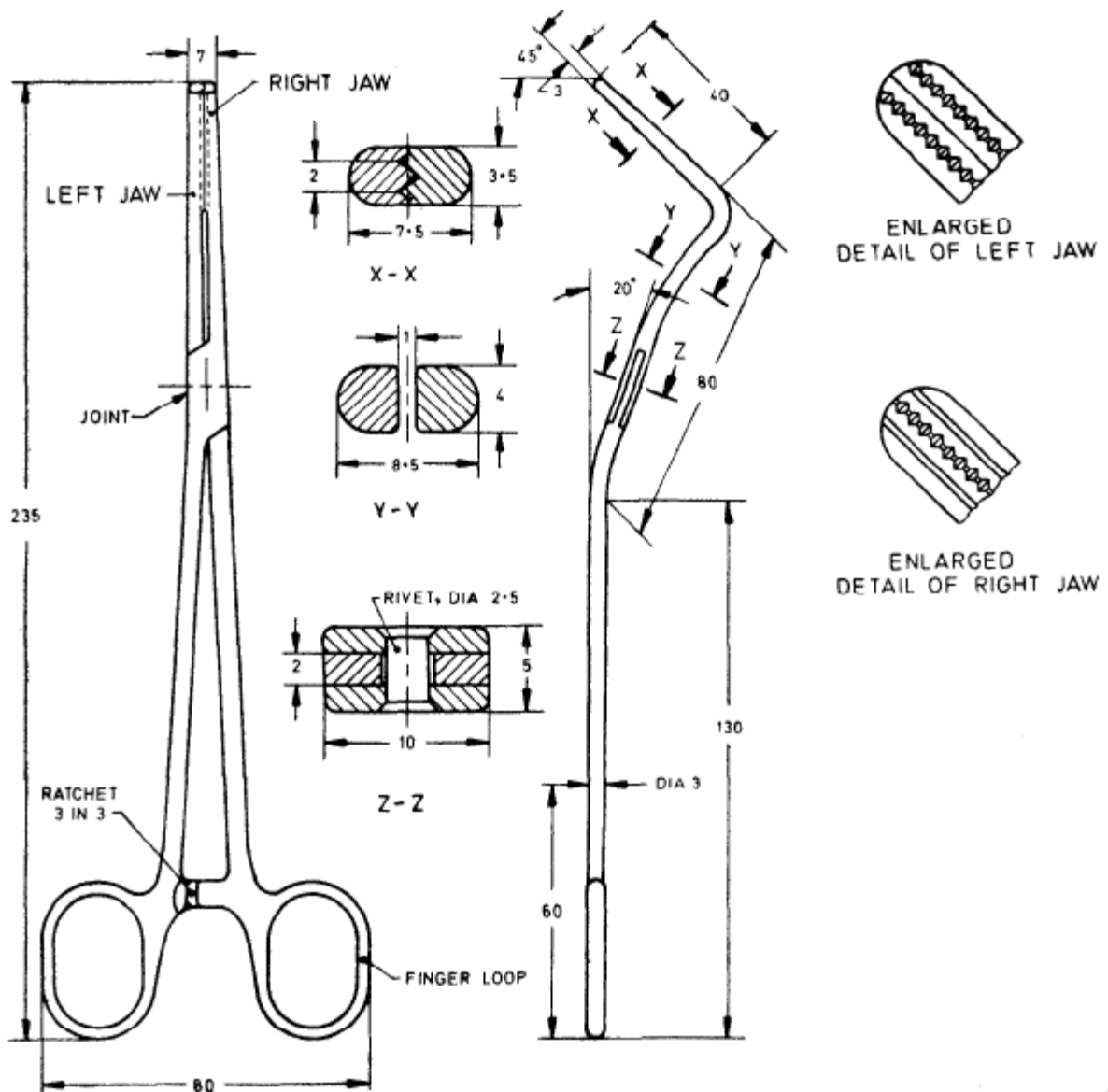
7 TESTS

7.1 Performance Test

When the first ratchet is engaged, the tips shall approximate a gap of 2 mm and serrations shall not interdigitate. The gap shall become 1 mm on engaging the second step. Tips shall bite when the third step of the ratchet engages. The jaws shall fully close when the last step engages. The serrations shall match perfectly.

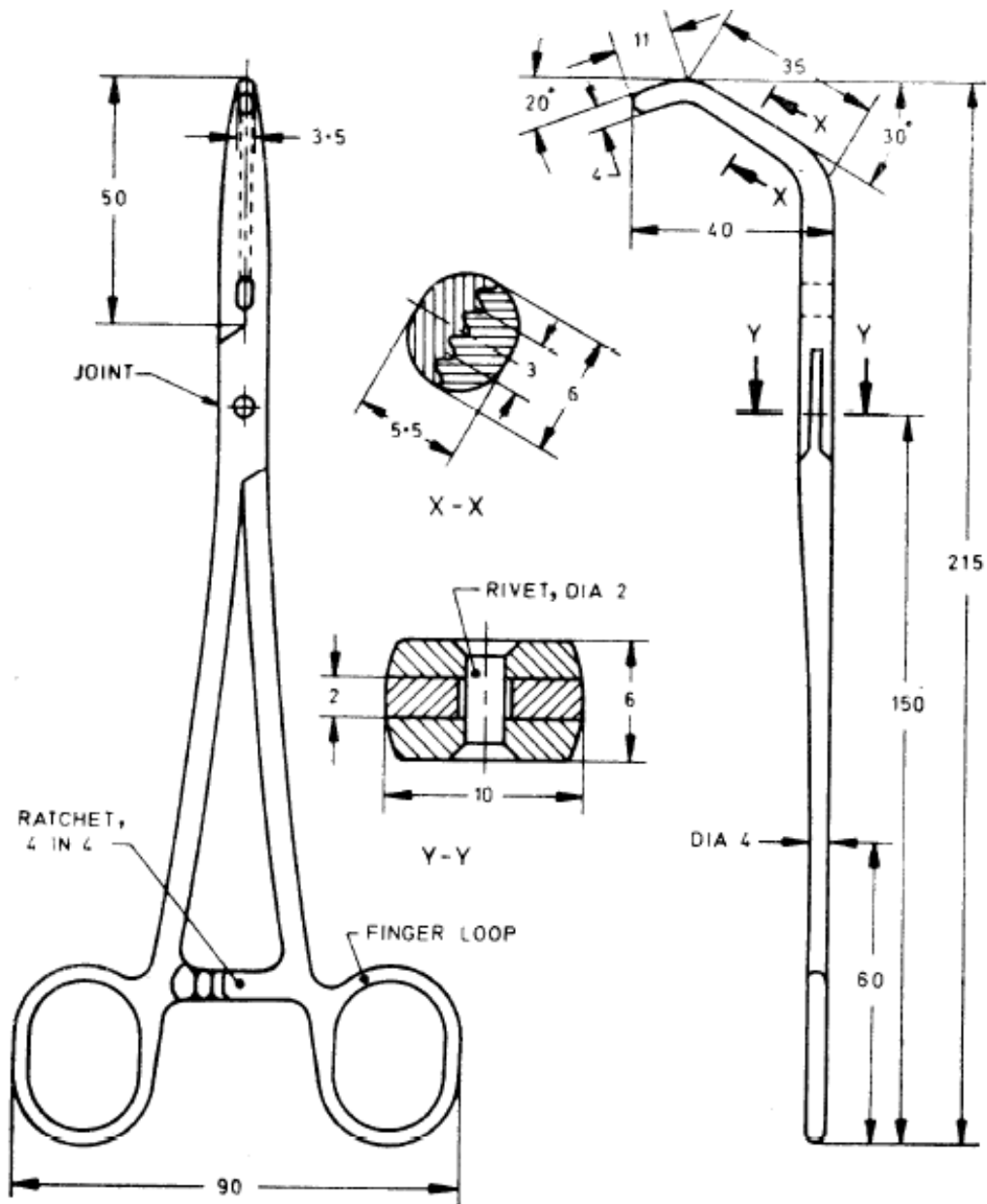
7.2 Corrosion Resistance Test

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



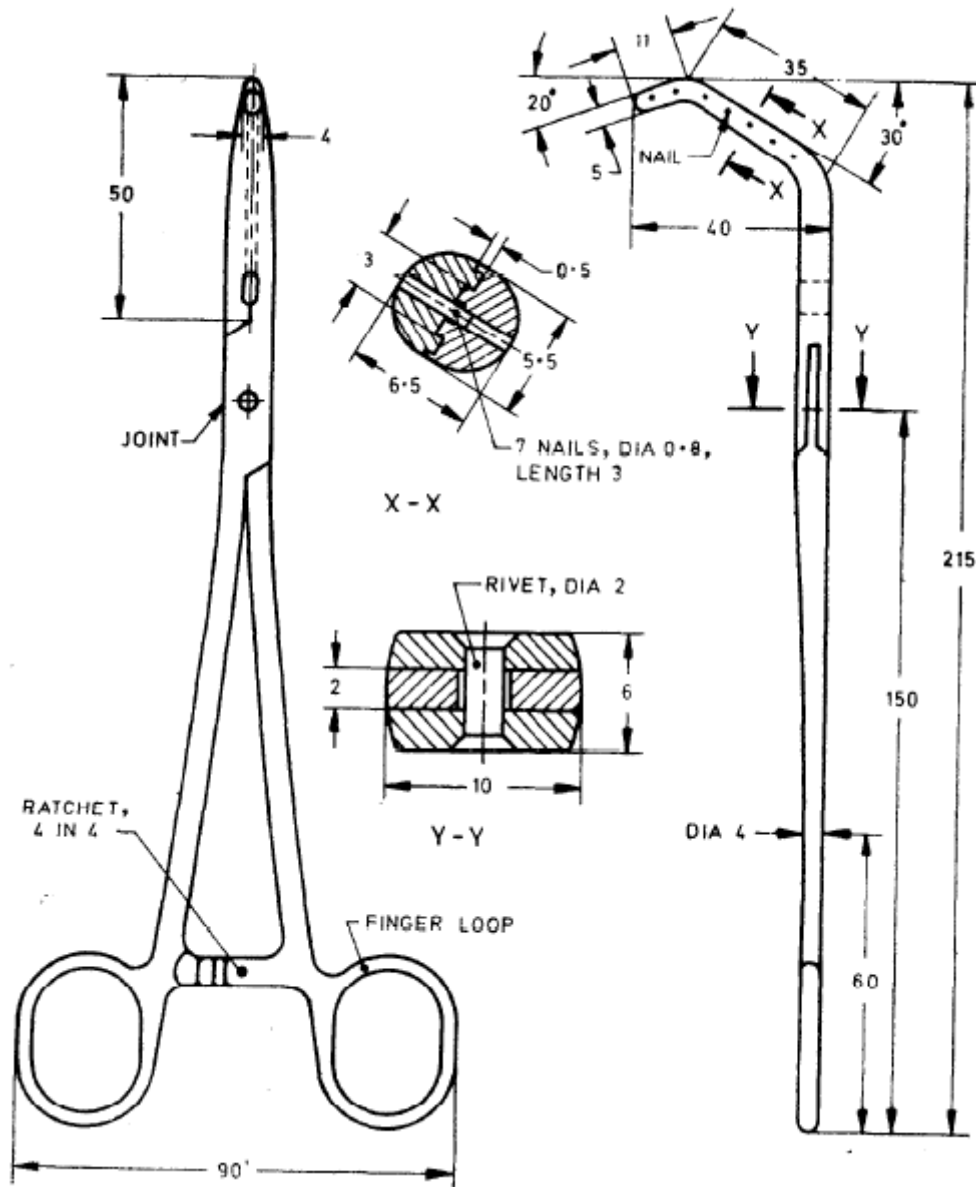
All dimensions in millimetres.

FIG. 1 CLAMP, BRONCHUS, LEE'S PATTERN



All dimensions in millimetres.

FIG. 2 CLAMP, BRONCHUS, PRICE THOMAS' PATTERN



All dimensions in millimetres.

FIG. 3 CLAMP, BRONCHUS, SORB'S PATTERN

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 put in a polyethylene bag or wrapped in wax paper. The instrument shall then 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.