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भारतीय मानक मसौदा
**वक्ष शल्य चिकित्सा उपकरण - सीधा एवं वक्री संकुचन प्रतिबंधक,
पॉट्स स्वरूप - विशिष्टि**
(IS 7367 का दूसरा पुनरीक्षण)

Draft Indian Standard
**Thoracic Surgery Instruments - Straight and Angular
Coarctation Clamps, Potts' Pattern - Specification**
(Second Revision of IS 7367)

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 1983. The standard was revised in 1991 to retain the requirements in respect of shape and dimensions. 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 specifies requirements for Potts' pattern, straight and angular coarctation clamps 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 (<i>Second Revision</i>)
IS 1501 (Part 1)/ ISO 6507-1	Metallic Materials — Vickers Hardness Test Part 1 Test Method (<i>Fifth 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 shape and dimensions of the clamps shall be as shown in Fig. 1

4.2 Permissible tolerances on linear and angular dimension shall be in accordance with Table 1.

4.3 The mass shall be 30 to 50 g.

5 WORKMANSHIP

5.1 The opening and closing of the jaws shall be smooth and jerk free.

5.2 The joint shall conform to the relevant requirements of **13.2** of IS 3642(Part 1).

5.3 The serrations on the jaws shall be transverse with non-truncated 60° profile and shall conform to the relevant requirements of Sec 2 of IS 3642(Part 1) except that the test for engagement of the jaws shall be as in **11.5.2** of IS 3642(Part 1).

5.4 The ratchet teeth shall be in accordance with Section 4 of IS 3642(Part 1).

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

5.6 All edges and corners shall be rounded and there shall be no sharp edges.

6 HEAT TREATMENT

6.1 The instruments shall be uniformly hardened and tempered to a 400 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 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
Angular Dimensions	Above 100.0 mm	± 2.0
	All dimensions	± 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

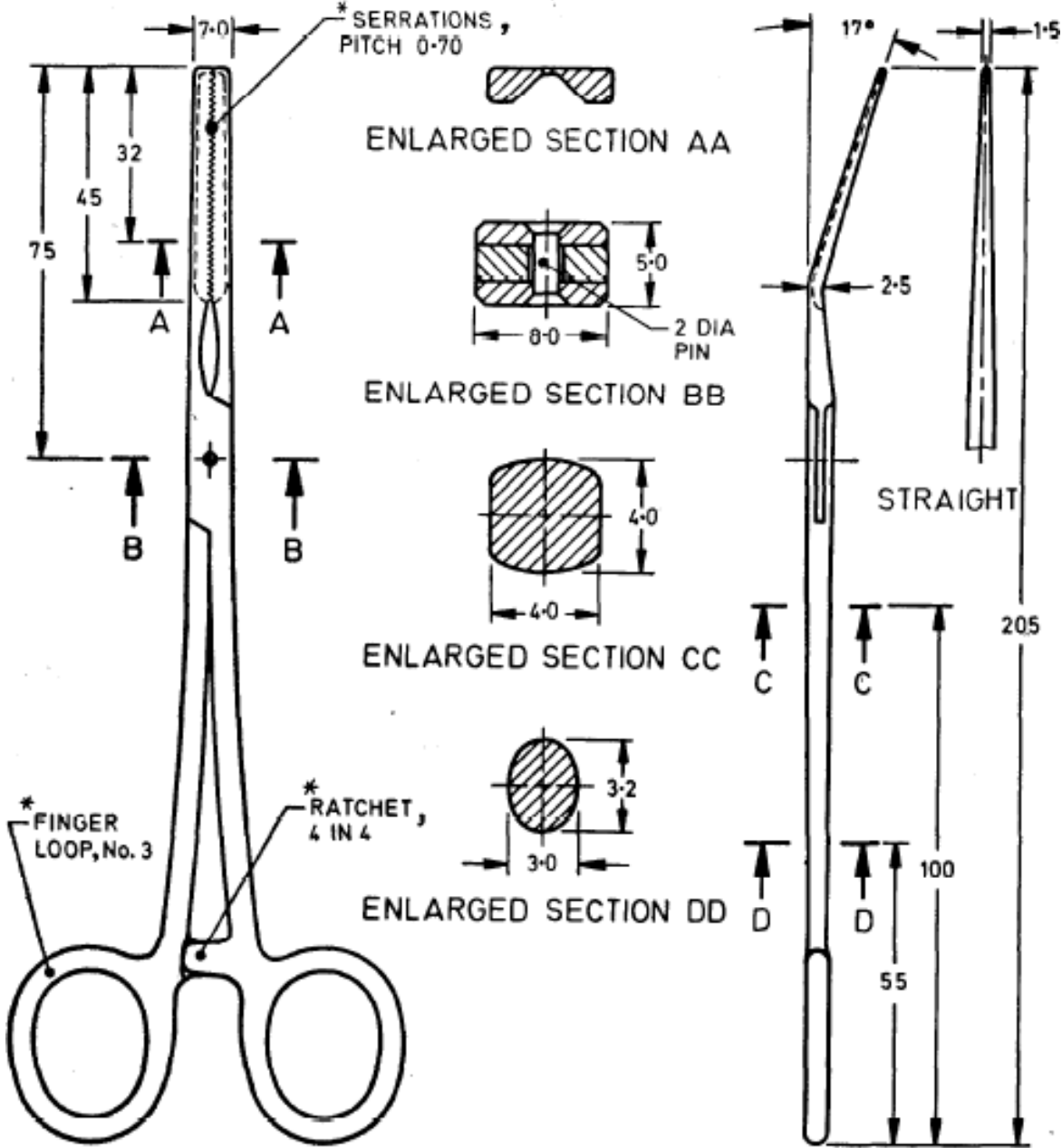
1 The satin finish should be achieved by an appropriate procedure such as, grinding, brushing electro polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform, smooth and it should reduce glare.

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.



All dimensions in millimetres.

FIG. 1 STRAIGHT AND ANGULAR COARCTATION CLAMPS

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 Test for Engagement of Jaws

When the first ratchet is engaged, the serrations shall approximate to a gap of 2 mm at the extreme end of the tip. The serrations shall become parallel and ready for engagement when the second ratchet engages. Partial engagement of all serrations shall occur when the third step of the ratchet is engaged. On engaging the fourth ratchet, the serrations shall engage fully along the entire length. The serrations shall engage perfectly and truly. The load required to close the clamps on the first step of the ratchet shall be 2.5 N, for the second step the load shall be 5 N, for the third step 7.5 N and for the fourth step 10N.

7.3 Flexibility Test

Each arm of the clamps shall be fixed in a vice so that the entire arm projects above the vice. By gradual application of force on the finger loop, the arm shall be deflected by 15mm in the same plane as that of the finger loop. The arm shall not take a permanent set or break.

7.4 Gripping Test

A piece of fresh goat or pig aorta shall be placed between the jaws of the instrument. The instrument shall then be closed to the last ratchet position and kept under this strain for 3 hours at a temperature of $25 \pm 2^{\circ}\text{C}$. After or during this test, no distortion, cracks or any other permanent deformation of the instrument shall be visible. The aorta shall not get crushed, pierced or damaged.

7.5 Drop Test

The instrument shall be dropped from a height of 150 cm on a hard surface 5 times and shall then be examined visually. There shall be no damage or distortion or malfunctioning of the instrument. After this test, the clamps shall again satisfy the requirements of the flexibility test.

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.