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भारतीय मानक मसौदा
**वक्ष शल्य चिकित्सा उपकरण - एनास्टोमोसिस के लिए चिमटी एवं
प्रतिबंधक - विशिष्टि**
(IS 7345 का तीसरा पुनरीक्षण)

Draft Indian Standard
**Thoracic Surgery Instruments - Anastomosis forceps and Clamps
- Specification**
(Third Revision of IS 7345)

ICS 11.040.30

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 1974. The standard was revised in 1985 to incorporate tolerances for various dimensions and certain other modifications. The standard was again revised in 1994 to merge the requirements of anastomosis clamps, which were covered earlier in two separate Indian Standards, IS 8898 : 1988 'Clamp, anastomosis, Cooley's pattern' and IS 9927 : 1981 'Clamps, anastomosis, Dale-Femoral Popliteal's pattern'. The third 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 the requirements for anastomosis forceps and clamps used in cardiovascular 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: 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 anastomosis forceps and clamps shall be of the following patterns:

- 1) Anastomosis forceps, curved, Pott's pattern
- 2) Anastomosis forceps, right angle, Pott's pattern
- 3) Anastomosis forceps, spoon shape, Pott's pattern
- 4) Anastomosis clamps, Cooley's pattern
- 5) Anastomosis clamps, Dale-Femoral Popliteal's pattern

4.2 The shape and dimensions of the anastomosis forceps and clamps shall be as shown in Fig. 1 to 5.

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

4.4 Joints of the instrument shall be box type conforming to **13.2.2** of IS 3642 (Part 1) : 1990.

4.5 Serrations of the anastomosis forceps shall be non-truncated 60° profile. The serrations for anastomosis clamps shall be atraugrip type as shown in Fig. 4 and 5. The serrations shall satisfy the relevant requirements given in Section 2 of IS 3642 (Part 1): 1990.

**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	$\pm 0.2^\circ$

4.6 The ratchet teeth shall be provided in various combinations as indicated in Fig. 1 to 5. The force required to perform the load test in accordance with 14.2 of IS 3642 (Part 1): 1990 shall be as given in Table 2.

**TABLE 2 FORCE TO BE APPLIED FOR LOAD TEST OF ANASTOMOSIS
(Clause 4.6)**

<i>Position of Ratchet Teeth Engagement</i>	<i>Forceps N</i>	<i>Clamps N</i>
First Ratchet	2.5 ± 1	4.5 ± 2
Second Ratchet	5 ± 2	11 ± 2.5
Third Ratchet	7.5 ± 2	18 ± 4
Fourth Ratchet	---	32 ± 4
Sixth Ratchet	---	40 ± 7
Seventh Ratchet	---	40 ± 7

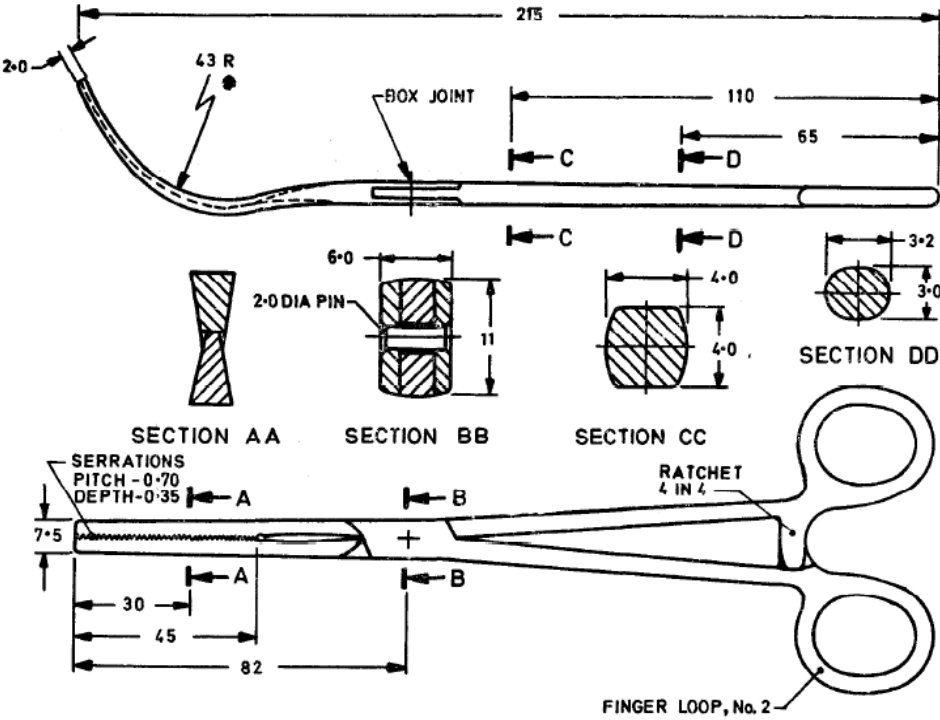
4.7 Finger Loops: The finger loops provided shall be of Size No. 2 conforming to Section 6 of IS 3642 (Part 1): 1990.

5 WORKMANSHIP

5.1 The movement of the forceps and clamps shall be smooth and free from jerks.

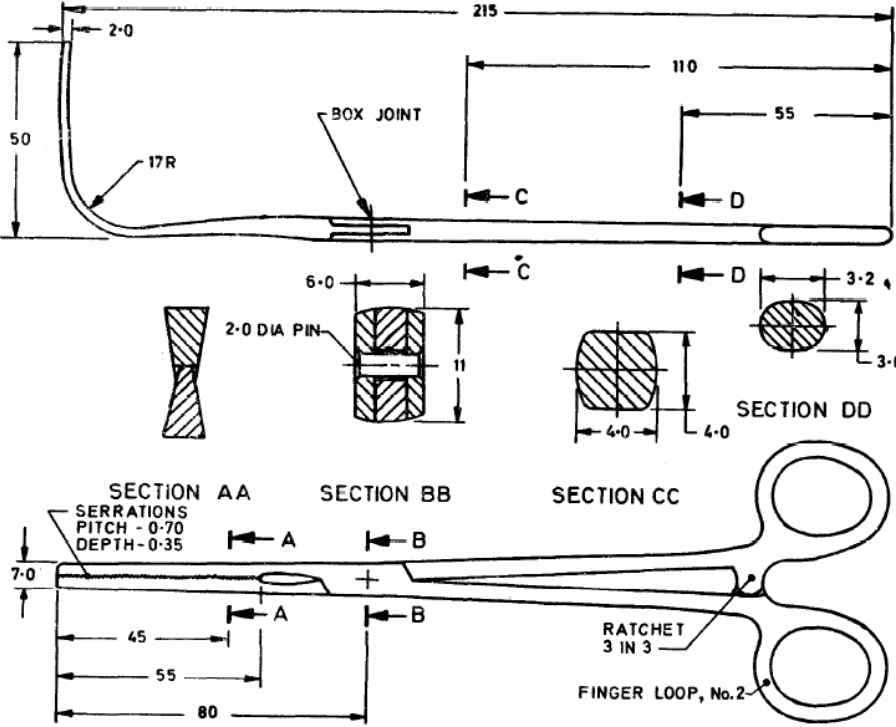
5.2 The serrations shall match perfectly.

5.3 All edges and corners shall be rounded.



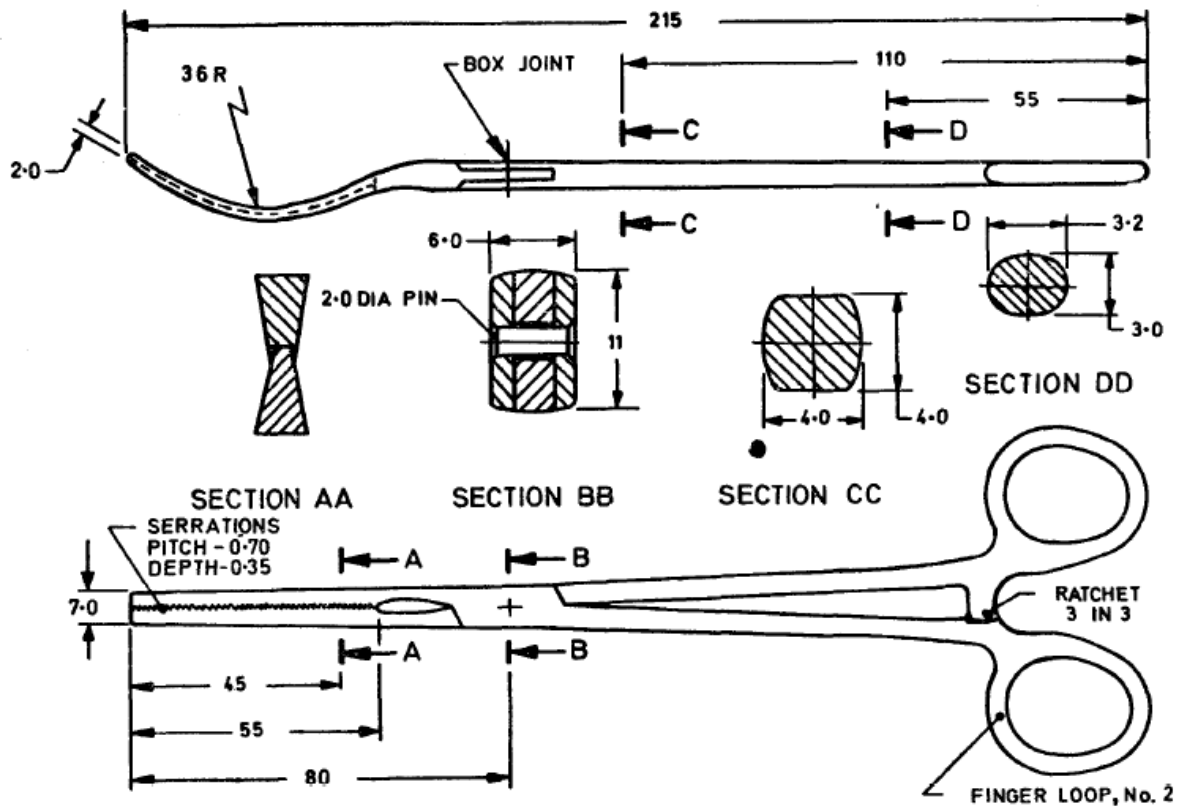
All dimensions in millimetres.

FIG. 1 ANASTOMOSIS FORCEPS, CURVED (POTT'S PATTERN)



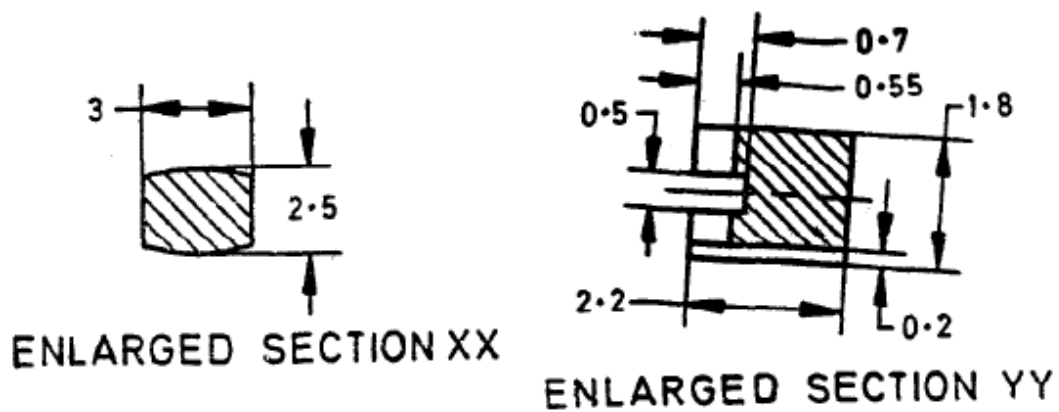
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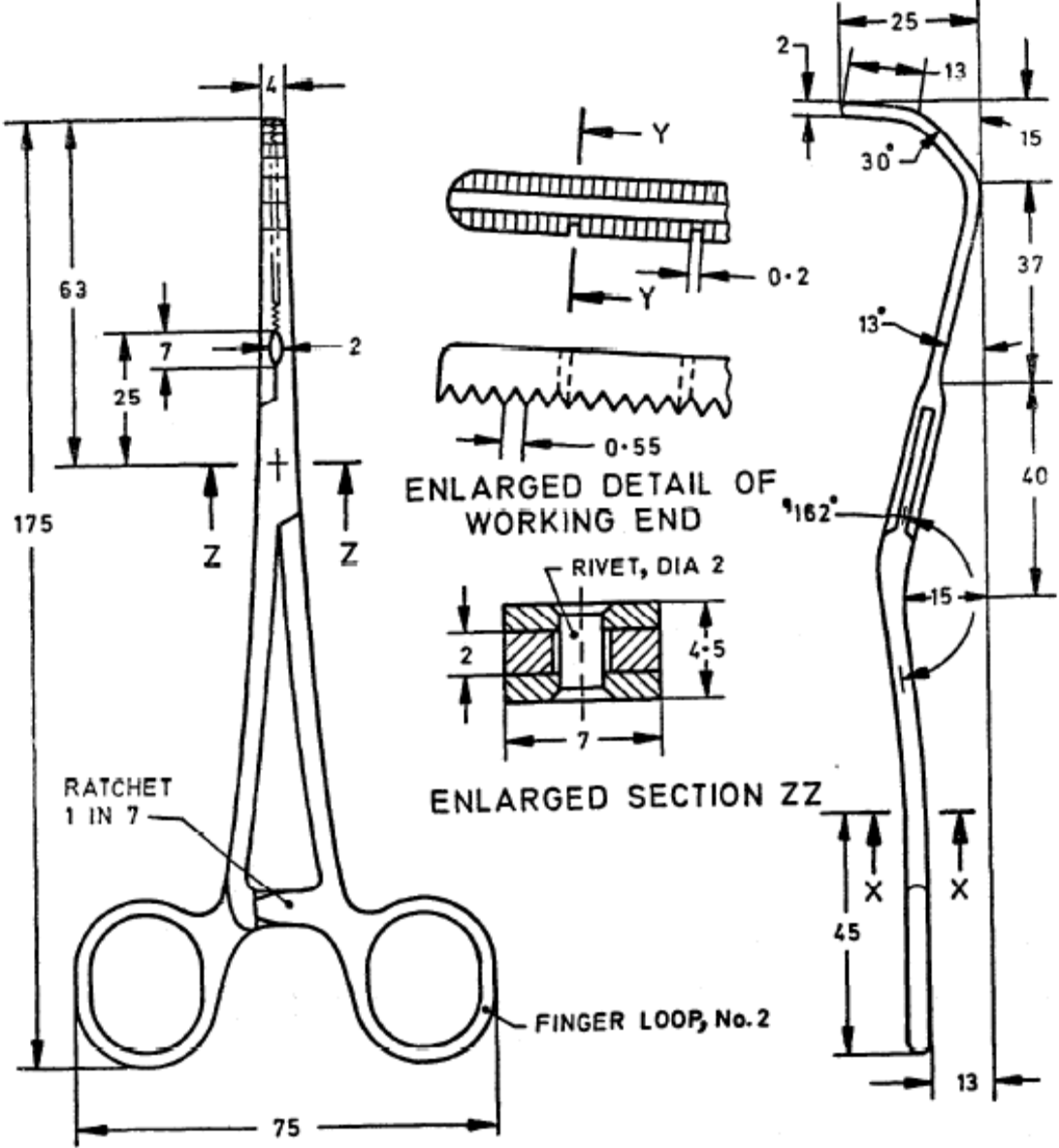
FIG. 2 ANASTOMOSIS FORCEPS, RIGHT ANGLED POTT'S PATTERN



All dimensions in millimetres.

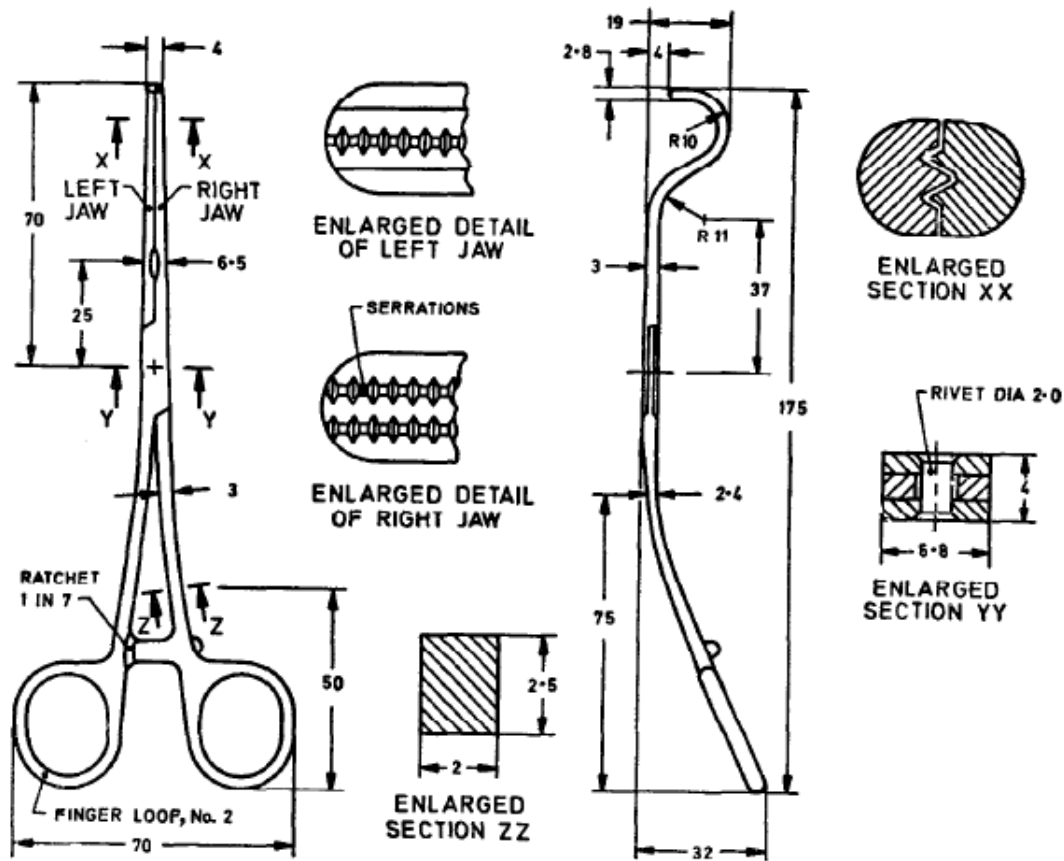
FIG. 3 ANASTOMOSIS FORCEPS, SPOON SHAPED (POTT'S PATTERN)





All dimensions in millimetres.

FIG. 4 CLAMP, ANASTOMOSIS, COOLEY'S PATTERN



All dimensions in millimetres

FIG. 5 CLAMP, ANASTOMOSIS, DALE FEMORAL – POPLITEAL'S PATTERN

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 Closure Test:

7.1.1 Closure Test for Clamps: 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.

7.1.2 Closure Test for Forceps

7.1.2.1 In case of 3 in 3 ratchet combination, when the first ratchet is engaged, the tips shall approximate to a gap of 1 mm and serrations shall not interdigitate. The serrations shall be just ready to be engaged at the second ratchet engagement. On engaging the third ratchet, all serrations shall fully engage along the entire length.

7.1.2.2 For 4 in 4 ratchet combination, the gap at the extreme end of the tip on first ratchet engagement shall be approximately 2 mm. The serrations shall be just ready to be engaged at the second ratchet engagement. Partial engagement of all serrations shall result when the third step of the ratchet is engaged. On engaging the fourth ratchet, all serrations shall fully engage along the entire length.

7.2 Corrosion Resistance Test

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

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.