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भारतीय मानक मसौदा
**वक्ष शल्य चिकित्सा उपकरण - आलिन्द प्रतिबंधक, डेबेकी स्वरूप -
विशिष्टि**

(IS 9928 का पहला पुनरीक्षण)

Draft Indian Standard

**Thoracic Surgery Instruments - Aortic Clamp, DeBakey's Pattern
- Specification**

(First Revision of IS 9928)

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 1981. The first 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 covers the requirements of DeBakey's pattern aortic clamp 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	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 clamp shall be as shown in Fig. 1.

4.2 The joints shall be of box type in accordance with **13.2.2** of IS 3642 (Part 1).

4.3 The clamp shall have non-cutting longitudinal jaw serrations with 60° profile and shall grasp the tissue delicately but firmly. In other respect the serrations shall be in accordance with Section 2 of IS 3642(Part 1).

4.4 Teeth used in ratchets of the clamp shall conform to Section 4 of IS 3642(Part 1). The load required to close the clamp on 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 N and soon. The ratchet teeth shall be designed such that the force required to close the clamp at first step of the ratchet shall be 2.5 N, for the second step 5 N and so on.

4.5 The finger loop shall conform to Size No. 2 of Section 6 of IS 3642 (Part 1).

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

5 WORKMANSHIP

- 5.1 The two halves of the instrument shall not differ at any specified dimension and shall match with each other perfectly.
- 5.2 The surface of the clamp shall be finished smooth and free from burrs, pits, cracks, scale and other surface defects.
- 5.3 The jaws shall open and close with even and balanced movement. The opening and closing movements of the jaws shall be smooth and jerk free.
- 5.4 The clamp shall be passivated and shall have a dull and non-glare finish.
- 5.5 The serrations shall match perfectly.
- 5.6 All the edges and corners, except serrations and teeth, shall be rounded.

**TABLE 1 PERMISSIBLE TOLERANCES ON LINEAR AND ANGULAR DIMENSIONS
(Clause 4.6)**

<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
Angular Dimensions	Above 100.0	± 2.0
	All dimensions	± 2°

6 HEAT TREATMENT

The different components of the clamp shall be hardened and tempered to give a hardness of 400 to 460 HV.

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:

- 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.

7 TESTS

7.1 Performance of Tips and Jaws

When the first step of the ratchet is engaged, the teeth shall approximate to a gap of 1 mm and not interdigitate; the tip shall bite when the second step of the ratchet engages. The jaws shall fully close when the last ratchet engages. The teeth shall match perfectly and truly. In other aspects, the jaws shall engage as stipulated in IS 3642 (Part 1).

7.2 Flexibility

Each arm of the clamp 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 15 mm in the same plane as the finger loop. The arm shall not take a permanent set or break.

7.3 Corrosion Resistance Test

The rib spreader 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.