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भारतीय मानक मसौदा

वक्ष शल्य चिकित्सा उपकरण - अलिंद उपांग प्रतिबंधक, ग्लोवर स्वरूप – विशिष्टि

(IS 10540 का दूसरा पुनरीक्षण)

Draft Indian Standard

Thoracic Surgery Instruments - Atrial Appendage Clamps, Glover's Pattern – Specification

(Second Revision of IS 10540)

ICS 11.040.30

Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

Last Date of Comments: **19 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 prescribes shape and dimensions for Atrial Appendage Clamps, Glover's Patterns for use 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 encouragedto investigate the possibility of applying the most recent editions of these standards.

IS No.	*Title*
IS 6603	Stainless Steel Bars and Flats – Specification *(First Revision)*
IS 7531	Methods for Testing of Corrosion Resistance of Stainless Steel Surgical Instruments *(First Revision)*
IS 3642 (Part 1)	Surgical instruments : Part 1 Non- cutting, articulated type instruments

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 Atria1 Appendage Clamps 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 serrations shall be atraugrip type and shall conform to **12.5** of IS 3642 (Part 1).
4.4 Ratchets shall conform to Section 4 of IS 3642 (Part 1) with a combination of 1 in 9.
4.5 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.
4.6 The finger loop shall conform to Size No. 3 of Section 6 of IS 3642 (Part 1).
4.7 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 DIMENSIONS
(Clause 4.2)

Dimension type	*Dimension range mm*	*Permissible Tolerances mm*
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^{o}

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

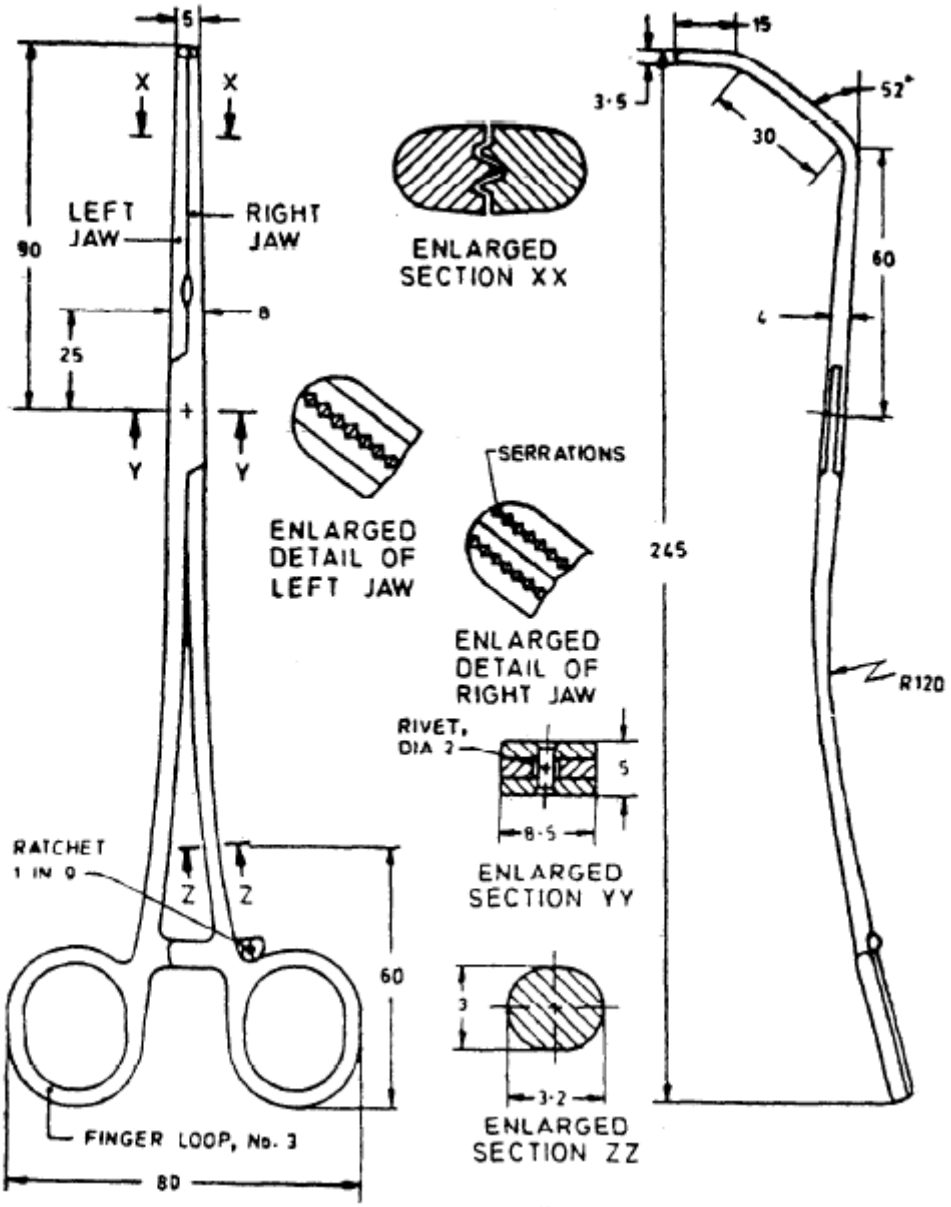
1 The satin finish should be achieved by an appropriate procedure such as, grinding, brushing electro polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform, smooth and it should reduce glare.

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 electropolishingor 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 CLAMP, ATRIAL PRRENDAGE, GLOVER'S PATTERN

7 TESTS

7.1 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 instrumentsshall 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.