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भारतीय मानक मसौदा

वक्ष शल्य चिकित्सा उपकरण - पसली विस्तारक - विशिष्टि

(IS 6436 का दूसरा पुनरीक्षण)

Draft Indian Standard

Thoracic Surgery Instruments – Rib Spreader – Specification

(Second Revision of IS 6436)

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 1977. The standard was revised in 1989 by altering material requirements, specifying dimensional tolerances, and adding requirements of surface conditions, packing and marking. 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 the requirements for adult size, Finochietto's pattern rib spreader 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 investigate the possibility of applying the most recent editions of these standards.

IS No.	Title

IS 1501 (Part 1): 2020/ ISO 6507-1: 2018 IS 6603: 2001	Metallic Materials — Vickers Hardness Test Part 1 Test Method (Fifth Revision) Stainless Steel Bars and Flats — Specification (First Revision)
IS 7531: 1990	Methods for Testing of Corrosion Resistance of Stainless Steel Surgical Instruments (<i>First Revision</i>)

3 MATERIAL

The materials of various components of the rib spreader shall be as given below:

Components	Material
Jaws	Stainless steel conforming to DesignationX20Cr13 of IS 6603.
Rack, propelling stud and handle	Stainless steel conforming to DesignationX30Cr13 of IS 6603.

4 SHAPES AND DIMENSIONS

- **4.1** The shape and dimensions of the rib spreader shall be as shown in Fig. 1.
- **4.2** With the movable jaw end flush with the end of the rack, the gap between the jaws shall be 160 mm.
- **4.3** Permissible tolerances on linear and angular dimension shall be in accordance with Table 1.

5 HEAT TREATMENT

5.1 The rack, propelling stud and jaws of the rib spreader shall be suitably heat treated. When testedin accordance with IS 1501 (Part 1), the hardness of various components shall be as given below:

- **5.2.1** The hardness of Jaws should be 380 to 420 HV
- **5.2.2** The hardness of Rack, propelling stud and handle 420 to 470 HV

TABLE 1 PERMISSIBLE TOLERANCES ON LINEAR

(Clause 4.2)

Dimension type	Dimension range	Permissible Tolerances
Dimension type	mm	mm
	Up to 2.0 mm	± 0.05
	Above 2.0 mm	± 0.1
Linear Dimensions	Above 5.0 mm	± 0.2
Linear Dimensions	Above 20.0 mm	± 0.5
	Above 50.0 mm	± 1.0
	Above 100.0 mm	± 2.0

6 WORKMANSHIP

- **6.1** The movement at the rack shall be smooth and free from jerks.
- **6.2** With the movable jaw fixed at any position, there shall be no play at the rack.
- **6.3** The faces of the jaws shall be true.
- **6.4** All edges and corners shall be rounded.

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.
- 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.

7.3 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.

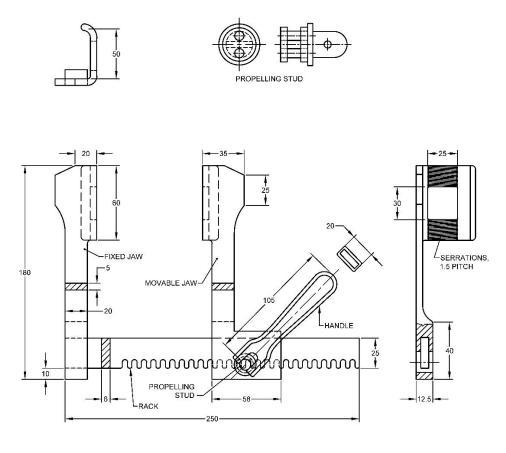
8 TESTS

8.1 Performance Test

With the movable jaw fixed at five different positions along the rack, a force of 50 N shall be applied each time at the jaw ends, tending to bring the jaws together. The distance between the jaws shall remain unchanged on the application of the force.

8.2 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 SPREADER, RIB, FINOCHIETTO'S PATTERN, ADULT SIZE

9 MARKING AND PACKING

9.1 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.

- **9.2** 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.
- **9.3** 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.

9.4 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.