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भारतीय मानक मसौदा

**वक्ष शल्य चिकित्सा उपकरण - उरोस्थि के लिए चाकू, लेब्सो स्वरूप -
विशिष्टि**

(IS 7399 का दूसरा पुनरीक्षण)

Draft Indian Standard

**Thoracic Surgery Instruments - Sternum Knife, Lebsche's
Pattern - Specification**

(Second Revision of IS 7399)

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 1974. The standard was revised in 1987 to alter material requirements, specifying dimensional tolerances, and adding requirements of surface conditions, packing, marking, and recommended sampling plan. 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 Lebsche's pattern sternum knife 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: 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>)
IS 1501 (Part 1):2020/ ISO 6507-1 : 2018	Metallic Materials — Vickers Hardness Test Part 1 Test Method (<i>Fifth Revision</i>)

3 MATERIAL

3.1 The sternum knife with integral handle shall be made from stainless steel of Designation X30Cr13 of IS 6603.

3.2 Where the handle of sternum knife is not made integral with the working part the material shall be as follows:

a) Working part

The working part shall be made from stainless steel conforming to Designation X40Cr13 of IS 6603.

b) Handle

The handle shall be made from stainless steel conforming to Designation X07Cr18Ni9 of IS 6603.

4 SHAPES AND DIMENSIONS

4.1 The shape and dimensions of the sternum knife shall be as shown in Fig. 1

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

5 WORKMANSHIP

5.1 The handle when net in integral part of the blade shall be secured to the shank by screwing in and brazing or soldering the brazing or soldering shall be neat and sound.

5.2 All edges shall be rounded except the cutting edge which shall be sharp and uniform. The cutting edge shall not have risks. Jags and waviness when examined under a magnification of 10x.

**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	± 0.05
	Above 2.0	± 0.1
	Above 5.0	± 0.2
	Above 20.0	± 0.5
	Above 50.0	± 1.0
	Above 100.0	± 2.0

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

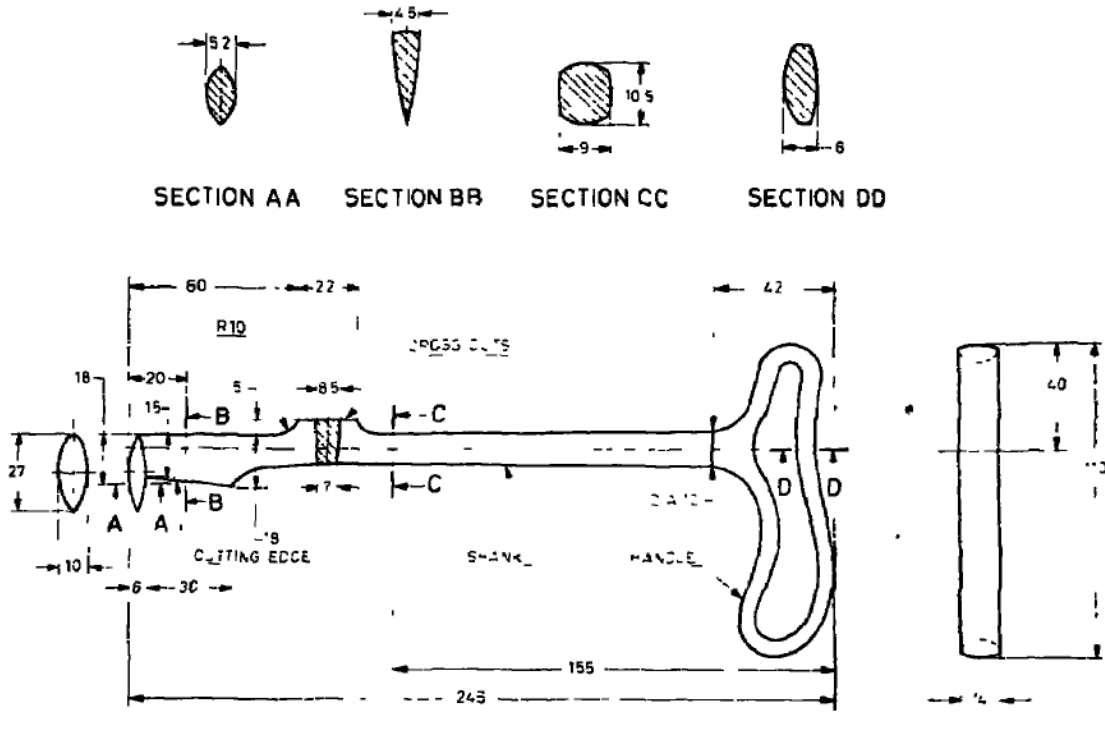
1 The satin finish should be achieved by an appropriate procedure such as, grinding, brushing electro polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform, smooth and it should reduce glare.

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 STERNUM KNIFE

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 Performance Test

A fresh piece of goat or sheep hip bone, 4 to 8 mm thick, shall be gripped at its end in a suitable vice. With the cutting edge of the instrument, the bone shall be cut vertically for about 25 mm length by striking with a hammer at the crosscuts. The bone shall be cleanly cut without splintering and the cutting edge of the knife shall not get damaged.

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.