

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
आर्थोपेडिक स्टेपल इंसर्टर — विशिष्टि

(IS 7111 का पहला पुनरीक्षण)

Draft Indian Standard

Orthopaedic Staple Inserter — Specification

(*First Revision of IS 7111*)

ICS 11.040.30

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02 Last date for comments: **28 November 2024**

FOREWORD

(*Formal clauses will be added later*)

This standard was first published in 1973. 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*)'.

1 SCOPE

This standard specifies dimensions and other requirements for staple inserter used for inserting the staples in the bone.

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.

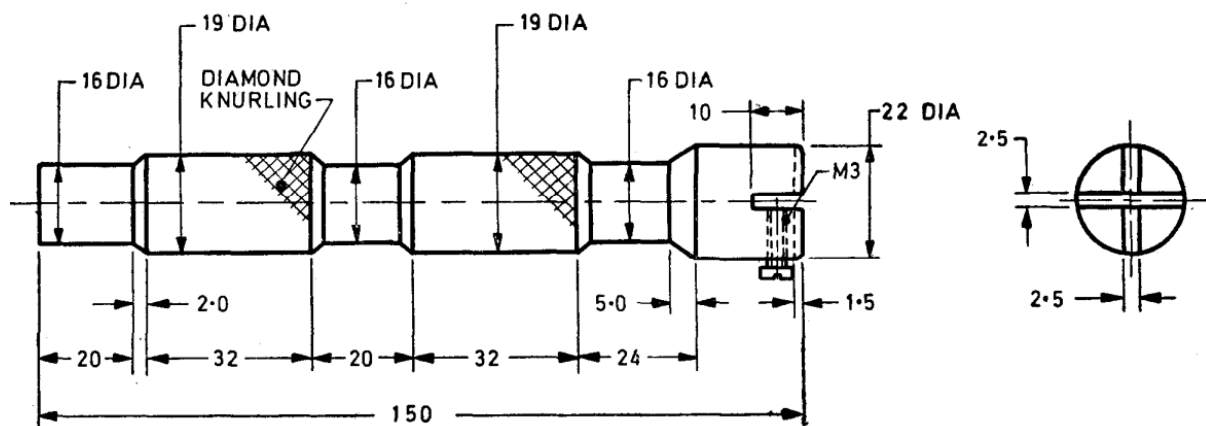
| <i>IS No.</i> | <i>Title</i> |
|----------------|--|
| IS 1070 : 2023 | Reagent Grade Water — Specification (<i>fourth revision</i>) |
| IS 6603 : 2024 | Stainless Steel Semi-Finished Products, Bars, Wire Rods and Bright Bars — Specification (<i>second revision</i>) |

3 MATERIAL

Stainless steel bars conforming to Designation 30Cr13 or 20Cr13 of IS 6603.

4 SHAPE AND DIMENSIONS

As shown in Fig. 1



All dimensions in millimeters.

FIG. 1 ORTHOPAEDIC STAPLE INSERTER

5 HEAT TREATMENT

The inserter shall be hardened and tempered to 400 to 450 HV.

6 WORKMANSHIP AND FINISH

6.1 The inserter shall have the recess to hold the staple.

6.2 It shall have a screw hole for flat head screw to keep the staple in position. A spare screw shall also be supplied.

6.3 The inserter shall be free from pits, burrs, draw-marks, cracks and other surface contaminations.

6.4 It shall be passivated and polished bright.

6.5 The screw threads shall be neat and clean.

7 TEST

7.1 CORROSION RESISTANCE TEST

7.1.1 Scrub the instrument with soap and warm water, rinse in hot water and then dip in 95 percent ethyl alcohol. Dry the instrument, immerse in copper sulphate solution at room temperature for 6 minutes and wash with fresh water or wet cotton wool.

7.1.2 The copper sulphate solution shall be made up as follows:

| | |
|---|---------|
| Copper sulphate (CuSO ₄ .5H ₂ O) | 4.0 g |
| Sulphuric acid (H ₂ SO ₄) (Sp gr 1.84) | 10.0 g |
| Distilled water (<i>see</i> IS 1070) | 90.0 ml |

7.1.3 There shall be no red stains or spots on the instrument, but dulling of the polished surface may be permitted.

8 MARKING

The inserter shall be marked with the manufacturer's name initials or recognized trade-mark.

8.1 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.

9 PACKING

As agreed to between the purchaser and the supplier.