भारतीय मानक

Indian Standard

IS 18562 : 2024

पीपीआईयूसीडी सम्मिलन संदंश — विशिष्टि

PPIUCD Insertion Forceps — Specification

ICS 11.200

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May 2024 **Price Group 5**

Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD 03

FOREWORD

This Indian Standard was adopted by Bureau of Indian Standards, after the draft finalized by the Obstetric and Gynaecological Instruments and Appliances Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

Every specialty instrument in the obstetrics and gynaecology section combines old world craftsmanship with modern manufacturing processes to make certain that the instrument has the correct feel which is rendered vital to the various procedures undertaken and surgeries done. This standard covers the general measurements of PPIUCD insertions forceps instrument fabricated from stainless steel and intended for reuse during surgery.

As there is a clinical need for a variety of instruments for general and surgical procedures, they are manufactured in various configurations and from various types of stainless steel. For practical purposes and patient safety, these devices supplied by different manufacturers necessitate a defined system of specification, materials and performance requirements.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

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.

Indian Standard

PPIUCD INSERTION FORCEPS — SPECIFICATION

1 SCOPE

This standard specifies the dimensions and requirements of PPIUCD insertion forceps for use in hospitals.

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.

IS No.	*Title*
IS 1586 (Part 1) : 2018/ISO 6508-1 : 2016	Metallic materials — Rockwell hardness test: Part 1 Test method (*fifth revision*)
IS 7531: 1990	Surgical instruments — Corrosion resistance of stainless steel surgical instruments — Methods of tests (*first revision*)

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following terms and definitions shall apply:

3.1 Box Lock — The junction where the female members and male members are secured, forming the pivoting feature.

3.2 Ratchets — The portion of both female and male members at the proximal end inclined teeth which forms the locking mechanism.

3.3 Serration or Teeth — The gripping or clamping surfaces of the jaws or ratchets.

4 MATERIAL

4.1 PPIUCD insertion forceps shall be made of metal. The metal shall be light-weight surgical alloy, non-staining, corrosion free, non-rusting and shall be able to withstand the temperature of autoclaving. The metal shall be non-light reflecting (surface shall not be shiny) with a buff coating. The metal shall not be brittle.

4.2 The material used for forceps shall be Stainless steel. The chemical composition (weight percentage) and mechanical properties shall conform to the values given in Table 1 and Table 2 respectively.

4.3 Hardness when determined in accordance to IS 1586 (Part 1) shall be 40 HRC to 45 HRC.

Table 1 Chemical Composition

(*Clause* 4.2)

Sl No.	Constituent	Percent
(1)	(2)	(3)
i)	Carbon	0.15 *Max*
ii)	Silicon	1.0 *Max*
iii)	Manganese	1.0 *Max*
iv)	Nickel	0.50 *Max*
v)	Chromium	11.5 to 13.5
vi)	Sulphur	0.03 *Max*
vii)	Phosphorus	0.04 *Max*

Table 2 Mechanical Properties

(*Clause* 4.2)

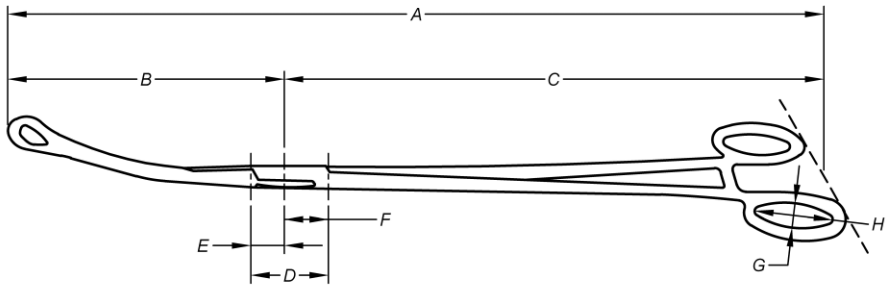
Sl No.	0.2 Percent Proof Stress, *Min, MPa*	Tensile Strength, *Min, MPa*	Elongation, *Min*, Percent
(1)	(2)	(3)	(4)
i)	290	510	34

5 SHAPE AND DIMENSIONS

5.1 PPIUCD Insertion Forceps shall be as per Fig. 1A and Fig. 1B.

5.2 The dimensions shall be as per following requirements:

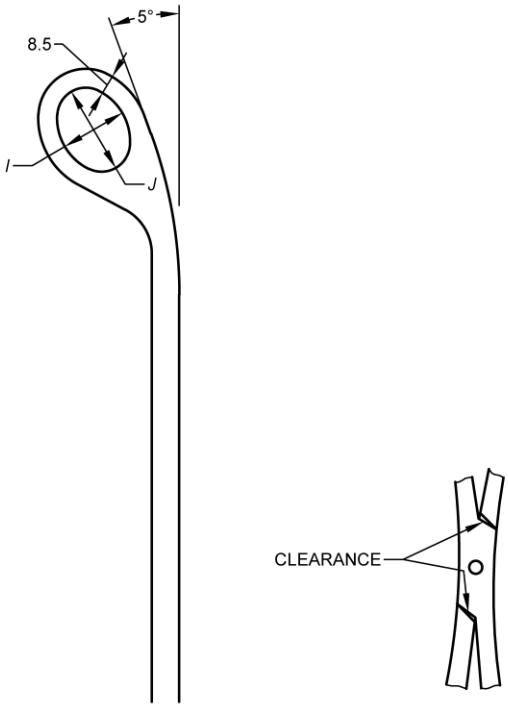
Sl No.	*Name of the Parameter of Instrument*	*Requirements*
(1)	(2)	(3)
i)	Weight of forceps	110 g to 115 g
ii)	Diameter of inner ring (J)	11 mm to 15 mm
iii)	Diameter of inner ring (I)	8.0 mm to 8.8 mm
iv)	Thickness of ring	3.5 mm to 4.0 mm
v)	Length of the clearance of forceps (D)	33 mm to 35 mm
vi)	Tip to box joint length (B)	141 mm to 145 mm
vii)	Box joint to end of grip length (C)	177 mm to 181 mm
viii)	Tip to end of grip length (A)	315 mm to 325 mm
ix)	Diameter of the finger rings (G)	27.2 mm to 27.5 mm
x)	Diameter of the finger rings (H)	23.1 mm to 23.4 mm
xi)	Thickness of the finger ring	3.5 mm to 3.8 mm
xii)	Angle of the forceps tip on plane	5°



A = 320
B = 141
C = 179
D = 34
E = 16.5
F = 17.5
G = 23.1 - 23.4
H = 27.2 - 27.5

All dimensions in millimetres.

1A



I = 8.5
J = 13

All dimensions in millimetres.

1B

FIG. 1 PPIUCD INSERTION FORCEPS

5.3 Jaws

Jaws of the insertion forceps shall have serration rings (*see* Fig. 2). Serration rings shall be slightly curved at the tip.

Number of serrations	20
Distance between the serrations	0.65 mm to 0.75 mm
Depth of serration	0.9 mm to 1.08 mm

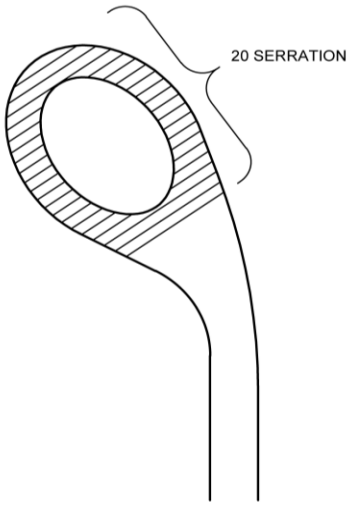


FIG. 2 SERRATIONS IN THE JAWS

6 SURFACE FINISH, WORKMANSHIP AND APPEARANCE

6.1 Surfaces of the instrument shall be uniformly finished and free from burrs, sharp edges, cracks, coarse marks and processing materials.

6.2 The visual appearance of final surface of the instrument may be classified as matte and reduced reflected surface.

6.3 Symmetry

Excluding functional differences, both halves of the forceps shall be symmetrical.

6.4 Handle Serration

Handles shall be uniform in depth and spacing.

6.5 Joints

The instrument shall have a smooth joint and shall close and open easily.

6.6 The inside surface of the PPIUCD insertion forceps shall be well rounded and polished and no sharp cutting edges or cracks shall be present.

7 HEAT TREATMENT

The forceps shall be heat treated to give a hardness of 430 HV to 490 HV at the tips.

8 CORROSION RESISTANCE

The instrument shall satisfy the boiling and autoclaving test as specified in IS 7531.

9 MARKING

9.1 The product shall be clearly and legibly marked with the manufacturer's name, initials or trade-mark and the country of manufacture.

9.2 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 there under, and the product(s) may be marked with the Standard Mark.

10 PACKAGING

The product shall be wrapped in wax paper and then shall be packed in polyethylene bag or cardboard. Non-biodegradable material used for packaging shall be recyclable and shall indelibly marked with the universal recycling symbol and applicable recycling code.

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD 03

Organization	*Representative(s)*
In Personal Capacity (*890, Sector 15, Part 2, Gurugram - 12001*)	DR SUNEETA MITTAL **(*Chairperson*)**
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This Indian Standard has been developed from Doc No.: MHD 03 (21503).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi