Standards for PPIUCD Insertion forceps

(IIT KHARAGPUR MDS 05)

1. Introduction

Every specialty instrument in the obstetrics and gynecology 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 specification document covers the general measurements of the PPIUCD insertion forceps instrument fabricated from stainless steel and intended for reuse during surgery.

2. Scope

Because 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

3. Terms and Definitions

Box lock - the junction where the female member and the male member are secured, forming the pivoting feature.

Ratchets - the portion of both the female and male members at the proximal end possessing inclined teeth and that form the locking mechanism.

Serrations or teeth - the gripping or clamping surfaces of the jaws or ratchets

4. Surface finish, workmanship and appearance

4.1 Surfaces of the instruments shall be uniformly finished and free of burrs, sharp edges, cracks, coarse marks and processing materials.

4.2 The final surface visual appearance of the instrument should be classified as matte and have reduced reflected surfaces.

4.3 *Symmetry*: Excluding functional differences, both halves of the forceps shall be symmetrical.

4.4 *Handle serrations:* they shall be uniform in depth and spacing.

4.5 *Joints*: the instrument shall have a smooth moving joint and should close and open easily.

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

5. Dimensional Specification

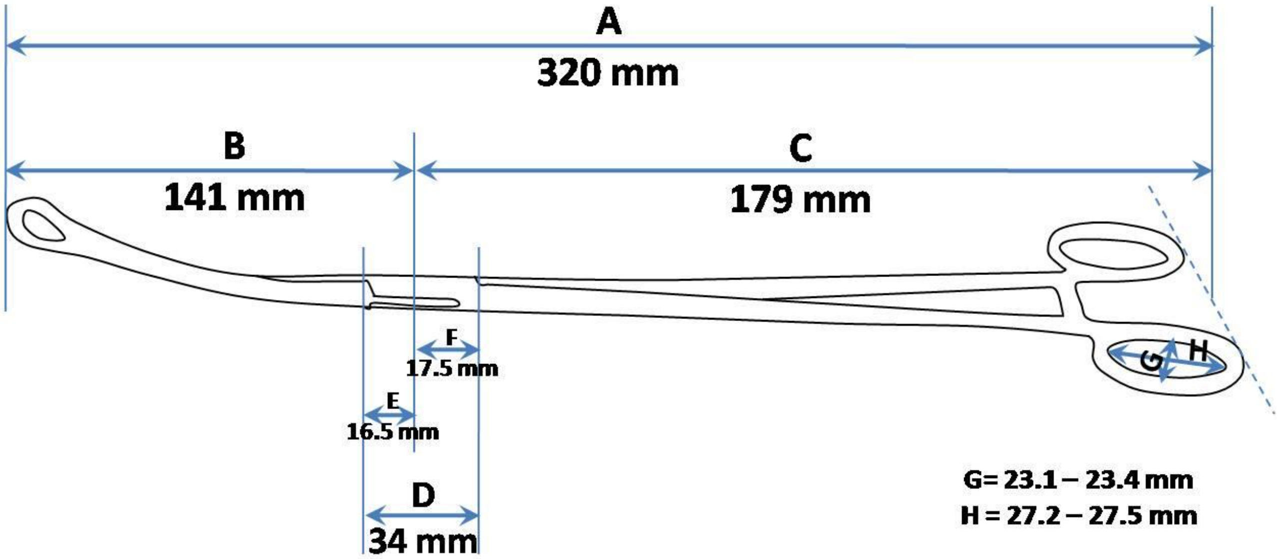
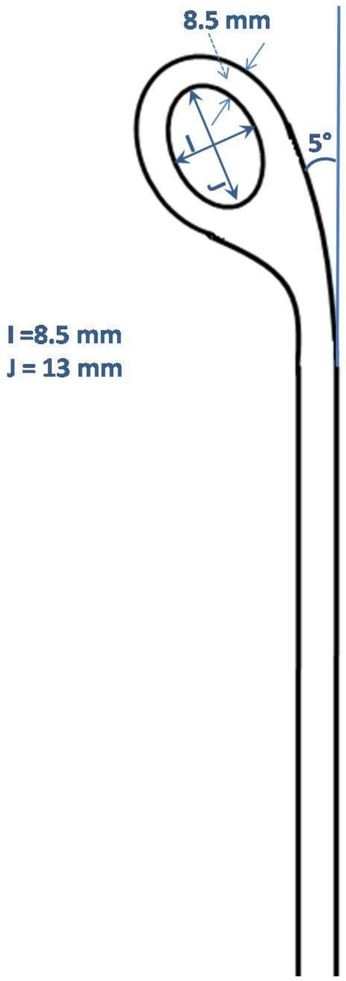
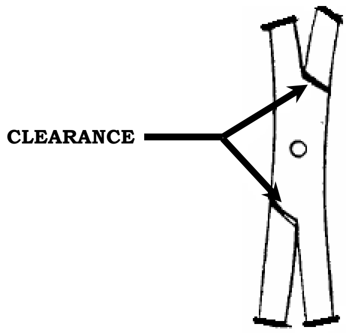


Figure: Dimensions of the PPIUCD insertion forceps



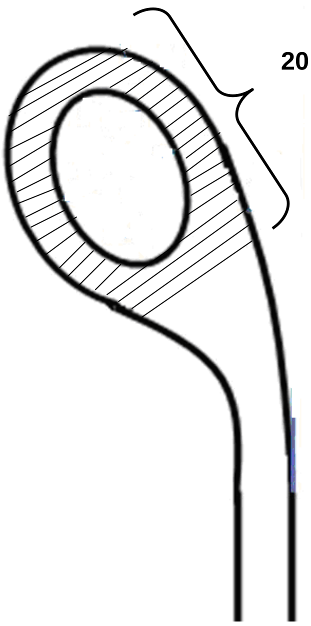


Name of specification parameter		*Range*
a. Weight of forceps	:	110 -115 g
b. Diameter of inner ring (J)	:	11 to 15 mm (major diameter)
c. Diameter of inner ring (I)	:	8.0 to 8.8 mm (minor diameter)
d. Thickness of ring	:	3.5 to 4 .00 mm
e. Length of the clearance of forcep (D)	:	33 to 35 mm
f. Tip to box joint length (B)	:	141 to145 mm
g. Box joint to end of grip length (C)	:	177 to181 mm
h. Tip to end of grip length (A)	:	315 to 325 mm (Overall length)
i. Diameter of the finger rings(G)	:	27.2 - 27.5 mm (major diameter)
j. Diameter of the finger rings (H)	:	23.1 - 23.4 mm (minor diameter)
k. Thickness of the finger rings	:	3.5 – 3.8 mm

l. Angle of the forcep tip on plane : 5º

Serration in the jaws

Serrated ring jaws, slightly curved at the tip



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

Metal Specifications

The metal should be lightweight surgical alloy, non-staining, corrosion free, non-rusting and should be able to withstand the temperature of autoclaving. It should be non light reflecting (surface should not be shiny) with a buff coating. It should not be brittle.

Mechanical property requirements, heat treating requirements, hardness requirements and all other requirements are governed by the appropriate material/metal standards.

Classes—Stainless steel material requirements for surgical instruments shall conform to one of the following classes, as specified:

Class 3—Austenitic Stainless Steel.

Class 4—Martensitic Stainless Steel.

Class 5—Precipitation Hardening Stainless Steel.

Class 6—Ferritic Stainless Steel.

Class 4 Use of Martensitic stainless steel type 410 for the PPIUCD insertion forceps. Is recommended.

1. Test methods for corrosion

This test method provides a methodology and means of evaluation consistent to both producers and users alike. Corrosion on blades and box locks is an indication of one or more of the following situations:

- Inadequate cleaning and drying after use
- Either corrosive sterilizing solutions or excess exposure to the sterilizing solutions, or both
- Incorrect detergent and hard water for cleansing. Deionized, distilled, or otherwise demineralized water should be used.
- Autoclave contaminated (steam)
- Coarse surfaces
- Knurled or grooved surfaces may rust while polished surfaces may not be affected.

This test method covers general test procedures and evaluation criteria for the corrosion resistance of surgical instruments intended for reuse in surgery and fabricated from stainless steel as per *ASTM Standard F- 1089- 02*. This analysis provides a test methodology and means of evaluation consistent to both producers and users alike. The corrosion tests serve as an indicator of proper material processing selection by the manufacturers and proper care by the user.

1.1 *Boil Test*:

- The instrument(s) were washed with mild soap using a nonmetallic hard bristle brush and warm tap water, 26 to 51°C (80 to 125 °F).
- The instruments were rinsed thoroughly at room temperature in distilled water, 95 % ethyl alcohol, or isopropyl alcohol.
- The instruments were dried using paper towel or soft cloth.

Test procedure

- The instrument(s) were immersed into a nonreactive container of distilled water.
- The water was brought to a boil.

- Boiling temperature was maintained for 30 ± 1 min. It was ensured that the instrument(s) remains immersed.
- The heat source was removed and the instrument(s) were allowed to stand for 3 h ± 15 min.
- The instrument(s) were removed from the water and set on a towel to air dry for 3 h ± 10 min.

It is recommended that the pH level of test water is recorded before discarding. If the pH is outside the 6.5 to 7.0 range, the instrument was not cleaned thoroughly and should be retested accordingly.

1.2 *Copper Sulfate Corrosion Test*:

- The instrument(s) were washed with mild soap using a nonmetallic hard bristle brush and warm, 26 to 51°C (80 to 125 °F) tap water.
- The instruments were rinsed thoroughly at room temperature in distilled water followed by rinsing in 95 % ethyl alcohol or isopropyl alcohol.
- The instruments were air dried (ambient air).

Copper Sulfate Solution Preparation:

- A nonreactive container was filled with 22.5 ml of warm distilled water, 26 to 51°C (80 to 125 °F).
- 1 g of cupric sulfate crystals was added and stirred until the crystals are completely dissolved.
- 2.5 g of sulfuric acid was added and mixed thoroughly.

Test Procedure:

- The instrument(s) were submerged in a nonreactive container containing copper sulfate solution at a temperature of 17 to 20°C (63 to 67 °F).
- Instruments too large for complete immersion shall have partial immersion or test by drops of the solution
- The copper sulfate solution shall be allowed to remain in contact with the instrument for 6 min ± 30 s.
- The instrument(s) were rinsed thoroughly with tap water and vigorously cleaned with cloth or nonmetallic soft bristle brush to remove any nonadherent copper plating.

Interpretation of Results

Boil Test:

- All surfaces shall show no signs of corrosion (without magnification).
- A slight evidence of rust (ferrous oxide) in serrations, teeth, locks, ratchets, inserts (brazed or soldered junctions), and so forth, shall be cause for rejection.

Copper Sulfate Corrosion Test:

- All surfaces shall show no visual signs of copper plating (without magnification) with the following exceptions:
  - ❖ Copper plating in serrations, teeth, locks, ratchets, braze junctions, solder junctions, or dulling of polished surfaces shall be cause for rejection.
  - ❖ Copper plating at the periphery of the copper sulfate solution drops shall be cause for rejection.

2. Test methods for hardness

Hardness is the property of a material that enables it to resist plastic deformation, usually by penetration. However, the term hardness may also refer to resistance to bending, scratching, abrasion or cutting. Hardness is a characteristic and not a fundamental physical property. It is an empirical value seen in conjunction with the experimental methods and hardness scale used. Hardness being defined as the resistance to indentation is determined by measuring the permanent depth of the indentation. More simply put, when using a fixed force (load) and a given indenter, the smaller the indentation, the harder the material. There are several methods to measure hardness like

1) Rockwell Hardness Test.
2) Vickers Hardness.
3) Brinell Hardness
4) Knoop Hardness.

and 5) Shore (Durometer) Hardness Test.

Among the following methods Rockwell and Vickers Hardness measurement are to be used since these are generally used for surgical instruments as per *ASTM Standard F- 18 -08* for Rockwell hardness and *ASTM Standard F- 92-82* for Vickers hardness test**.**

2.1 ***Rockwell hardness test***—an indentation hardness test using a verified machine to force a diamond spheroconical indenter with a cone of 120º angle and .2 mm tip radius, called 'Brale' or tungsten carbide (or steel) ball indenter of some specified diameter, into the surface of the material under test, and to measure the difference in depth of the indentation as the force on the indenter is increased from a specified preliminary test force to a specified total test force and then returned to the preliminary test force.

Principles of Test and Apparatus

Rockwell Hardness Test Principle

The general principle of the Rockwell indentation hardness test is illustrated in Fig. 2. The test is divided into three steps of force application and removal.

Step 1—The indenter is brought into contact with the test specimen, and the preliminary test force F_0 is applied. After holding the preliminary test force for a specified dwell time, the baseline depth of indentation is measured.

Step 2—The force on the indenter is increased at a controlled rate by the additional test force F_1 to achieve the total test force F. The total test force is held for a specified dwell time.

Step 3—The additional test force is removed, returning to the preliminary test force. After holding the preliminary test force for a specified dwell time, the final depth of indentation is measured. The Rockwell hardness value is derived from the difference H in the final and baseline indentation depths while under the preliminary test force.

$$H = E - e$$

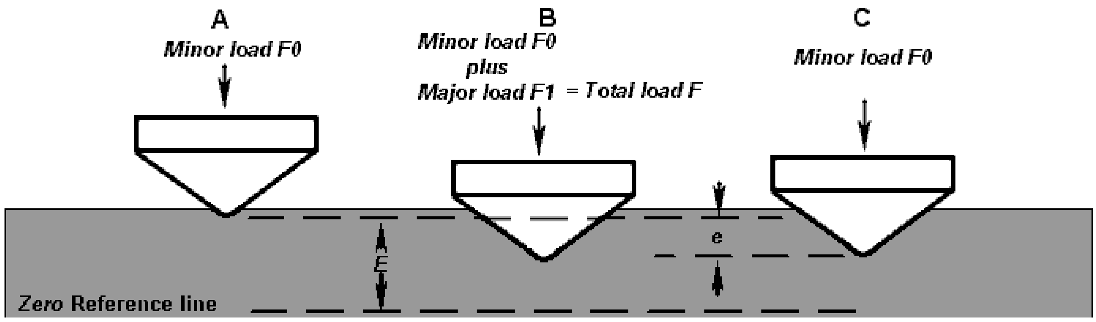


Figure 2. Principle of measuring Rockwell Hardness

For the Rockwell hardness test, the preliminary test force is 10 kgf (98 N) and the total test forces are 60 kgf (589 N), 100 kgf (981 N), and 150 kgf (1471 N).

2.2 *Vickers Hardness test-* Based on the principle that impressions made by this indenter are geometrically similar regardless of load. The Vickers test has 2 distinct force ranges, micro (10 to 1000g) and macro (1 to 1000 kg) to cover all testing requirements. The indenter is the same for both range therefore hardness values are continuous over the total range of hardness for metals. With exception of test forces below 200g Vickers value are generally considered test force independent. In other words if the material tested is uniform, the Vickers value will be same if tested using a 500g or a 50 kg force. Below 200g, caution must be used when trying to compare results. The Vickers hardness test method consists of indenting the test material with a diamond indenter, in the form of a right pyramid with a square base and an angle of 136 degrees between opposite faces and 22° between indenter face and the surface subjected to a load of 1 to 100 kgf. The full load is normally applied for 10 to 15 seconds.

Principles of Test and Apparatus

Vickers Hardness Test Principle:

The general principle of the Vickers hardness test is illustrated in Fig. 3. The two diagonals of the indentation left in the surface of the material after removal of the load are measured using a microscope and their average calculated. The area of the sloping surface of the indentation is calculated. The Vickers hardness is the quotient obtained by dividing the kgf load by the square mm area of indentation. Vickers Pyramid number (**HV**) is the ratio of **F/A** where **F** is the test force applied to the diamond indenter and **A** is the surface area of the resulting indentation.

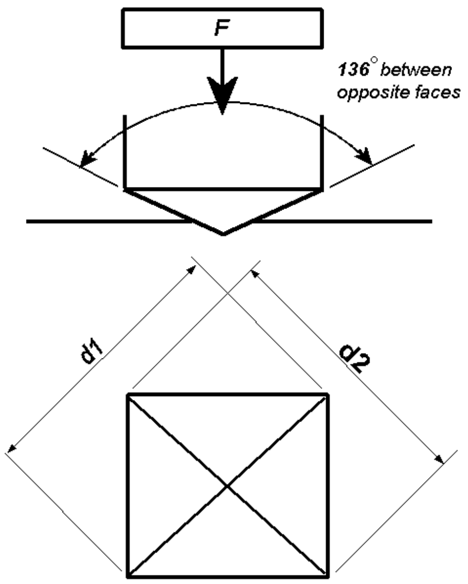


Figure 3 Principle of measuring Vickers Hardness

where F = Load in kgf and *d* = Arithmetic mean of the two diagonals, *d1* and *d2* in mm

$$HV = (2F\sin(136°/2))/d^2$$

$$HV = 1.854\ F/d^2 \quad \text{(approx)}$$

When the mean diagonal of the indentation has been determined the Vickers hardness may be calculated from the formula, but is more convenient to use conversion tables. The Vickers hardness is reported as 800 HV/10, which means a Vickers hardness of 800, was obtained using a 10 kgf force.

The chemical composition and the mechanical properties of the alloy should be as per Table 1 & 2.

Table 1: Chemical composition: Element in Weight Percent

Stainless Steel	**Carbon**	**Manganese**	**Silicon**	**Chromium**	**Nickel**	**Sulphur**	**Phosphorus**	**Iron**
Alloy 410	0.15 max	1.00 max	1.00 max	11.50 – 13.50	0.50 max	0.03 max	0.04 max	Balance

Table 2: Mechanical Properties of Martensitic stainless steel: Typical Specification

Stainless Steel	Typical Composition (Weight Percent)		Typical Annealed Properties				Hardening Response (HRC)
	C	Cr	HRB	0.2 % Offset Yield Strength Ksi (MPa)	Tensile Strength Ksi (MPa)	Elongation percent in 2” (51mm)	
Alloy 410	0.14	12.5	82	42 (290)	74 (510)	34	40-45

Table 3: Physical properties of Martensitic stainless steel: Typical specification

Property	Alloy 410
Specific Gravity	7.65
Density gm/cm^3	7.75-8.25
Specific Heat Btu/lb. * °F	0.11
Thermal Conductivity at 212°F (100°C) Btu/(hr * ft * °F) W/m * K	14.4 24.9
Electrical Resistivity Microhm-cm 68°F (20°C)	56
Coefficient of Thermal Expansion 68 - 392°F, in/in°F 20 - 200°C, cm/cm/°C 68 - 1112°F, in/in/°F 20 - 600°C, cm/cm/°C	5.9×10^{-6} 10.5×10^{-6} 6.5×10^{-6} 11.6×10^{-6}
Melting Range	2700 – 2790°F 1482 – 1532°C

Conclusion

The primary reason for this specification is to ensure consistency in the manufacture of this special type of obstetrics and gynecological instrument. The metal used should be lightweight surgical alloy, non-staining, corrosion free, non-rusting and should be able to withstand the temperature of autoclaving. It should be non light reflecting (surface should not be shiny) with a buff coating. It should not be brittle. The ends of the prongs of the tip should be smooth and non-piercing.