Specifications for

Copper Intra Uterine Contraceptive Device 375

1. Scope

1.1 The standard covers the shape, dimensions and other requirements for Copper intra-uterine contraceptive device, 375 and its components.

2. Normative references

The following Indian and international standards are necessary adjunct to this standard. However subsequent amendments have been made to the contents of the following references as per the requirements of this standard.

- *IS 3395: 1984, Low density polyethylene materials for moulding and extrusion (First revision)*
- *IS 12418 (Part 3):1987, Intra Uterine Contraceptive device: Part 3 Packaging and labeling*
- *The Cu 375 Intra Uterine Contraceptive Device (IUD) WHO/UNFPA Specification, 2011 (UNFPA/CPH/09/31)*
- *ASTM D638: 2010, 10 Standard Test Method for Tensile Properties of Plastics*
- *ASTM D790 - 10 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*
- *ISO 10993: Standards for evaluating the biocompatibility of a medical device prior to a clinical study. Special reference to ISO 10993:1; ISO:10993: 5; ISO 10993:18*

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3. Shapes and Dimensions

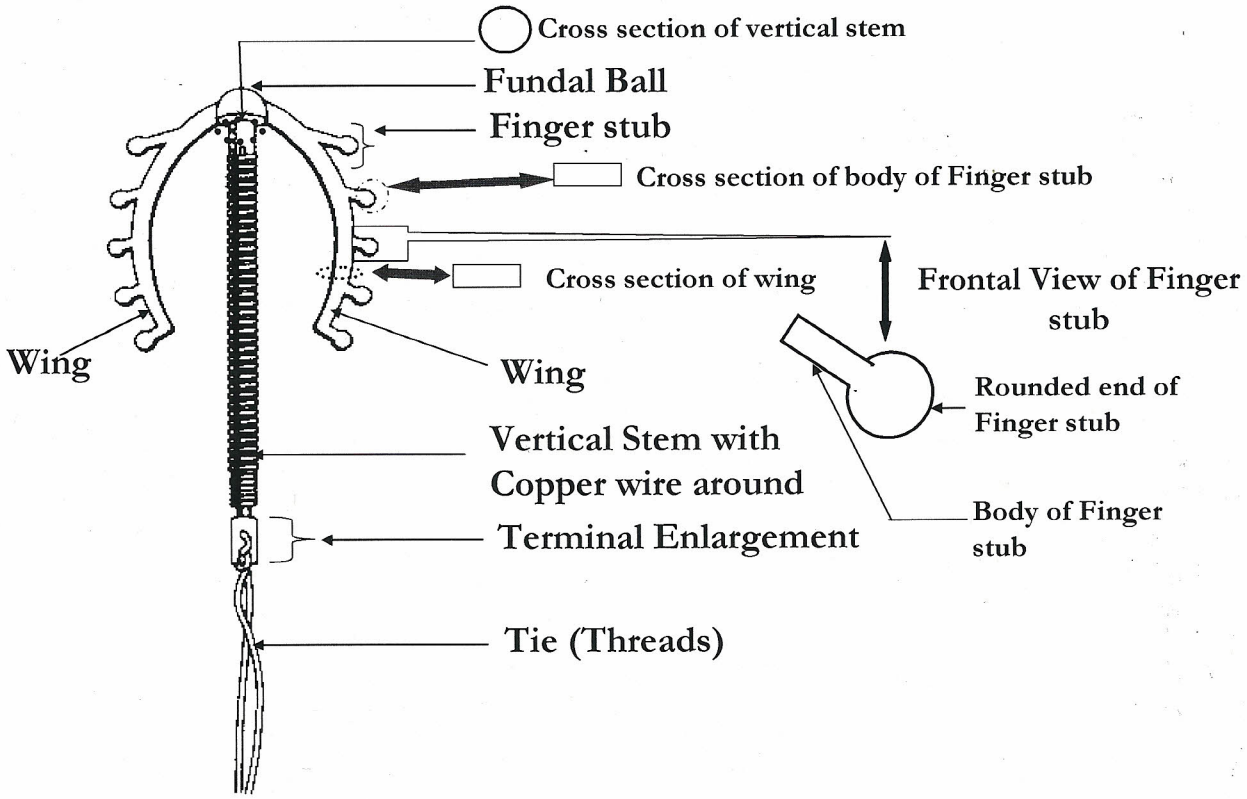
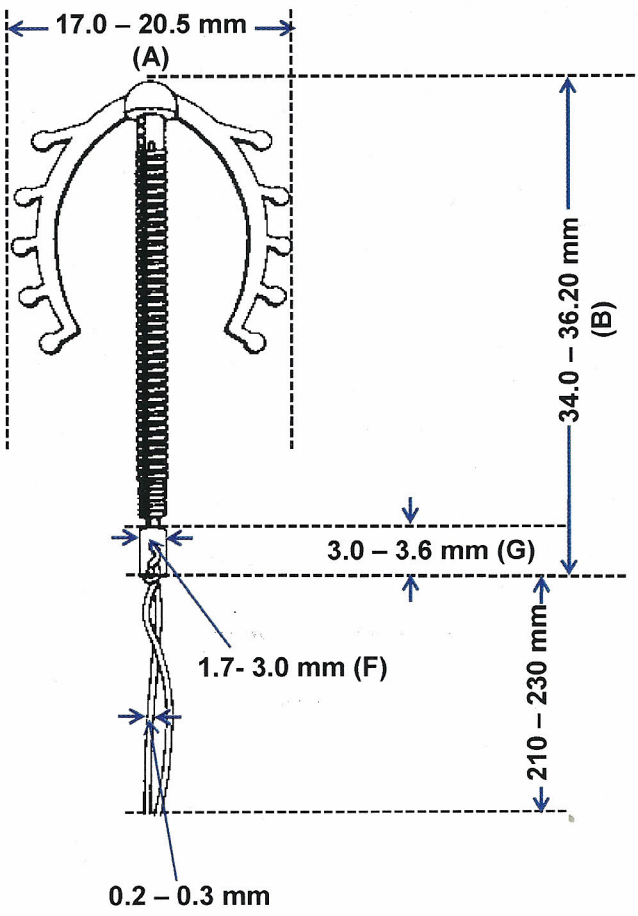
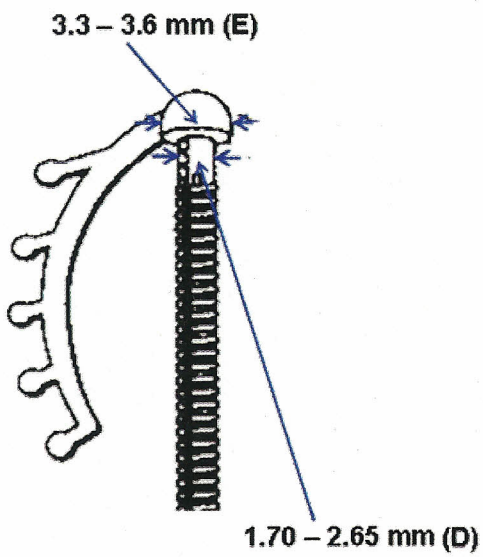


Figure1 Copper IUCD 375 (FRONTAL VIEW)





Enlarged part of Copper IUCD 375

Figure2 Copper IUCD 375 with dimensions

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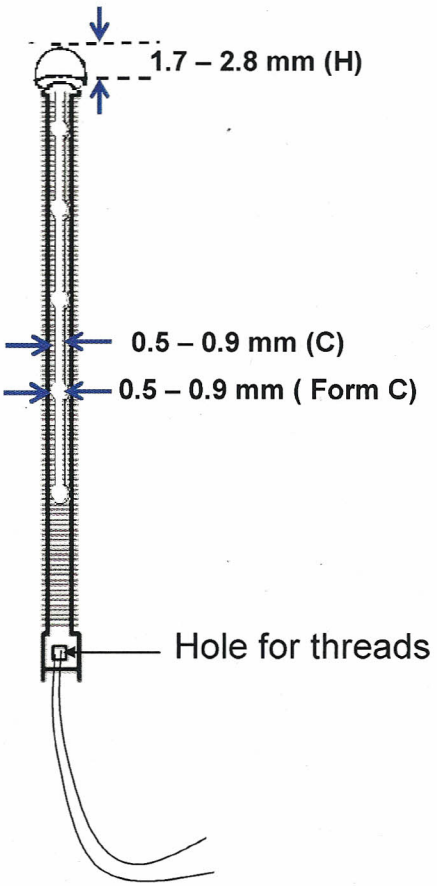
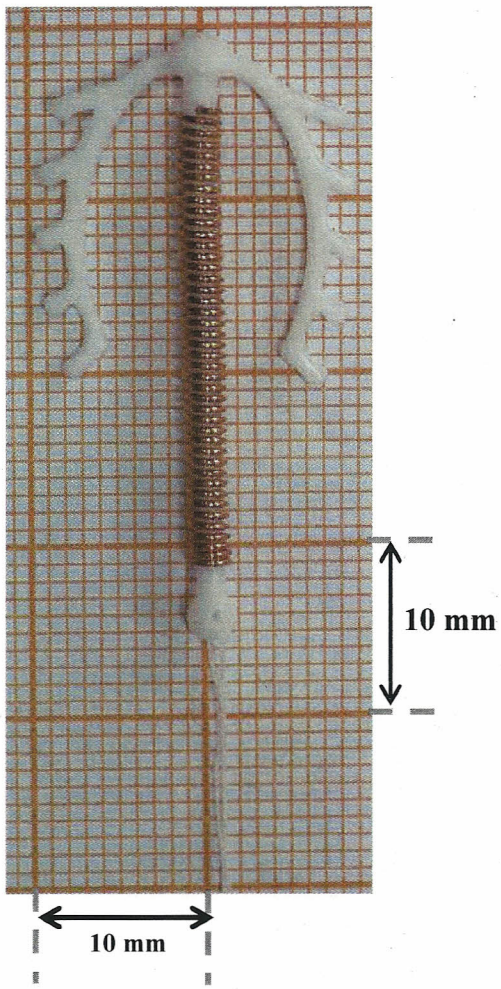


Figure3 Copper IUCD 375 (CORONAL VIEW)



Copper IUCD 375 (FRONTAL VIEW)

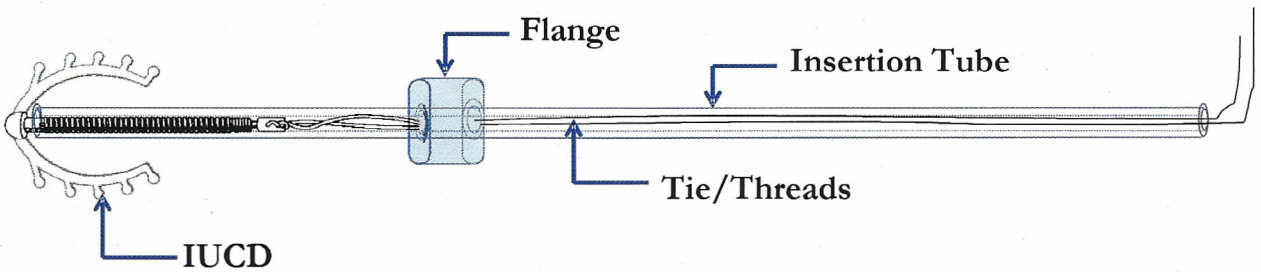


Figure 4 Copper IUCD 375 with Insertion Tube

3.1 General Description

The IUCD as shown in Figure 1 represents the IUCD in the "Frontal plane" and IUCD as shown in Figure 3 is in the "Coronal plane".

The Copper IUCD 375 consists of a ∩ shaped frame comprising of two 'Wings' joined to an enlargement of the Vertical Stem termed the "Fundal Ball". The shape is loosely described as inverted 'U' shape. The shape shall be as shown in Figure 1.
The vertical stem has a terminal enlargement at the bottom to guard against cervical penetration. A small hole is located on the vertical stem to act as an anchor for the

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copper wire which is wound over vertical stem. A filament is tied in a knot through a small hole in the terminal enlargement to provide two equal length marker threads (termed as "Tie"), as a means to locate and remove the device. There will be 5 'Finger stubs' on both wings.

The device is supplied with a tubular insertion instrument as shown in Figure 4. A moveable plastic flange is positioned on the insertion tube to assist in positioning the IUCD correctly in relation to the uterine fundus during insertion thus minimizing risk of perforation of the uterus.
The IUCD device with the insertion instrument is pre-positioned ready for insertion as shown in Figure 5 is supplied sterile within a sealed primary pack.

The IUCD and associated components are made up of:

- **Frame** - Low-density polyethylene(LDPE) or High Density Polyethylene (HDPE) + ethylene vinyl acetate copolymer
- **Wire wound around Vertical stem** - Copper
- **Tie** – Nylon
- **Insertion Tube** - HDPE (High Density Polyethylene) or gamma radiation resistant Polypropylene
- **Flange** – Polyvinyl chloride
- **Package** – Polyester and polyethylene

FRAME

Material
The Frame shall be made from Low-Density polyethylene (LDPE) or Gamma Radiation resistant High Density Polyethylene (HDPE) + ethylene vinyl acetate copolymer free of stabilizers having a minimum tensile strength of 15 MPa and a 2% secant flexural modulus in the range 133.5 MPa to 180.6 MPa.
The material shall be blended with 20% to 24% barium sulphate with a particle size of 95% less than 10 micron. The implant material shall pass the cytotoxicity tests, implantation test and extractables test as per the international standards.
The finger stubs shall be moulded together with the wings and have the same material as that of the frame.

Dimensions and Form

- Dimension A: Width of horizontal wings shall lie between 17.00 to 20.5 mm
- Dimension B: Vertical stem length shall lie between 34.00 to 36.20 mm
- Dimension C: Thickness of wings shall lie between 0.5 to 0.9 mm
- Dimension D: Diameter of vertical stem (before winding) shall lie between 1.70 to 2.65 mm, a uniform over the length of the stem between fundal ball and terminal enlargement.
- Dimension E: Fundal ball should be solid hemisphere with diameter 3.3 to 3.6 mm
- The size of the terminal enlargement should be in the range of:
  Dimension F: Lateral – 1.7 to 3.0 mm
  Dimension G: Vertical - 3.0 to 3.6 mm
- Dimension H: Height of the fundal ball shall lie between 1.7 to 2.8 mm
- Form A: Hole for anchoring an end of the copper wire may be provided.
- Form B: Cross section of the wings should be rectangular.

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- Form C:
  - ✓ There will be 5 finger stubs on the either side.
  - ✓ The stubs will be knob shaped as shown in Figure 1 and the thickness of the stubs will be 0.5 to 0.9 mm as shown in figure 3.
  - ✓ Cross sections of the finger stubs should be rectangular.
  - ✓ Finger Stubs will be sloping downwards in the frontal view.
  - ✓ Slope angle as shown in figure 5 is to be in the range of 40° to 70°

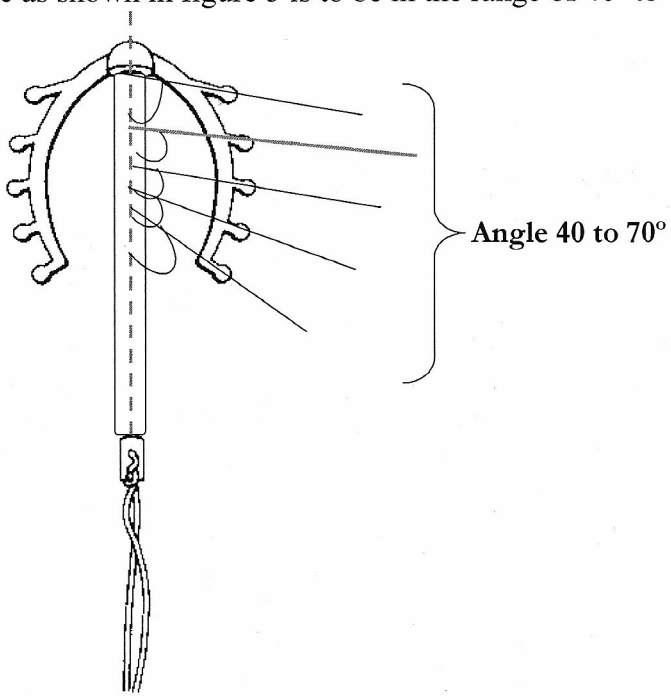

Figure 5 Measurement of slope angle of finger stubs

Requirements and Tests

The material of the frame to meet the ISO 10993 standards for chronic biomedical implants Specifically the ISO 10993: 5 Cytotoxicity test, 10993:18 Implantation and extractables test must give comparable biocompatibity as USP grade negative control.

Memory test

Memory is measured in terms of recovery after acute flexion quantified by restoration of width of the horizontal wings (Dimension A). On removal and observation after 1 minute of the frame following an insertion into 6 mm internal diameter tubing for 2 minutes. Dimension A to be no less than 25% less than the original pre stressed width of the wings (Provisional).

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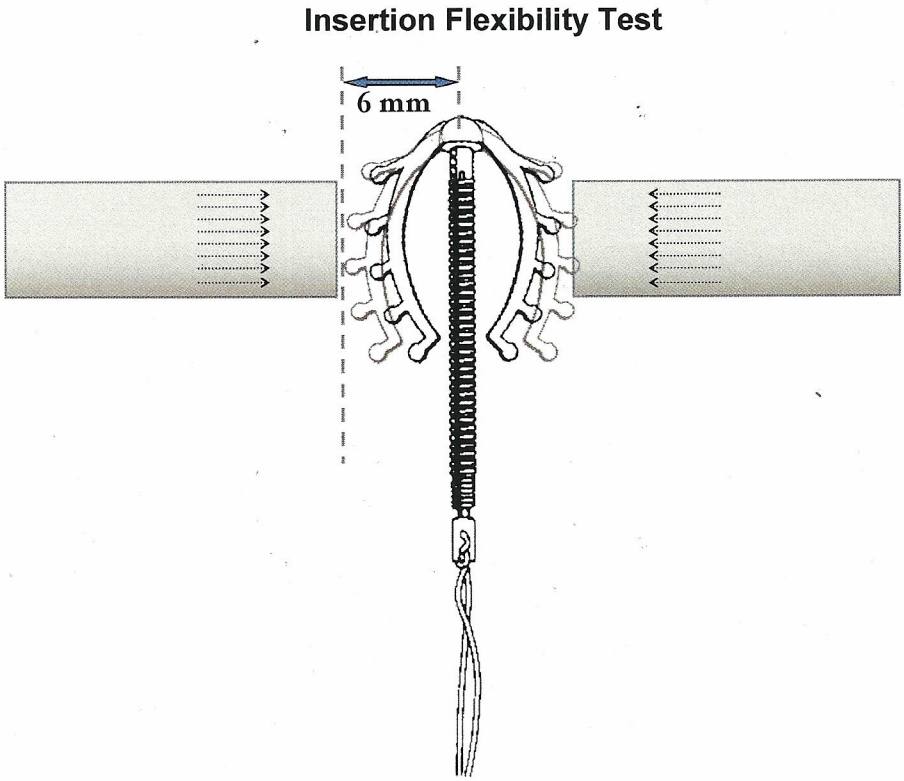
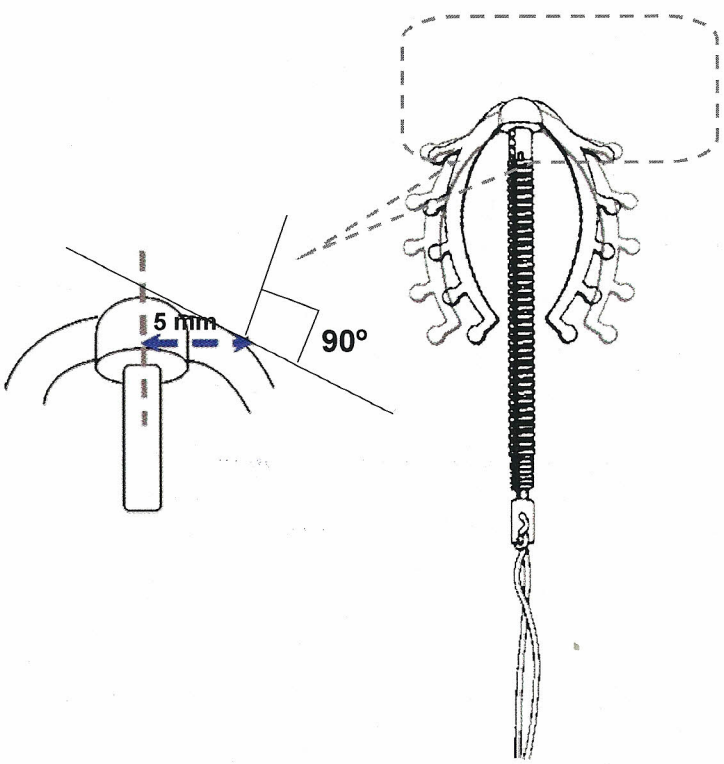
Insertion Flexibility test



Insertion flexibility relates to the recoiled force exerted by the wings onto the inner wall of the uterine cervix at the time of insertion of IUCD. The force to compress the wings to bring the width of the wings to 6 mm should not exceed 1 N (Provisional)

Implant Flexibility test



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Implant flexibility relates to the recoiled force when the wings are compressed by uterine contractions under normal placement of the IUCD within the uterus. The force is quantified by the bending of the wings on application of the bilateral force perpendicular to the wings at a point where a horizontal line of length 6 mm is calculated from the base of the first finger stub to the centre of the fundal ball.The force required to displace the point towards the vertical stem by 1.5 mm is to be in the range of 7-12 N (Provisional)

Frame shall be radio-opaque and shall have two ties for easy removal

Ash Content

Ash Content (as barium sulphate) of moulded frame shall be between 20-24 percent when tested in accordance with the method specified in latest Indian Pharmacopoeia.

Sterility Test

When Copper 375 is distributed as sterile, it shall be capable of meeting the requirements of any suitable sterility test specified in latest Indian Pharmacopoeia

WIRE

The copper wire should be wound tightly around the vertical stem with the loops even spaced. "Single" or "Double"wounding format may be used. The two ends of the copper wire are so closely positioned on the vertical stem surface that there are no projections of the wire end.

Material

The wire shall be made from 99.99% pure copper.

Dimensions

Copper wire of should be of 349 - 392 mm^2 surface area and of diameter 0.38 to 0.41mm

The mass of copper wire wound shall be 310 to 360 mg.

TIE (THREADS)

Material

The thread shall be made from Polyamide Nylon 6 or polyamide nylon 66 monofilament thread. The material shall pass ISO 10993 test as applicable for chronic implantation.

Dimension

Thread Length

Thread Length shall be 210 to 230 mm.

Colour of the thread should be medical grade green.

Thread Knot

The knot shall be secure and not promote breakage under normal use.

Thread dimension

The thread shall be made of Nylon of diameter 0.20 to 0.30mm.

Tensile strength of the thread shall be more than 9.5 N for a force applied for 30 S.

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Extractables test
The thread shall pass currently applicable USP extractable test class II and shall be evaluated for biological safety in accordance with ISO 10993-1: 2003 requirements for mucosal membrane contact devices intended for permanent contact.

INSERTION TUBE

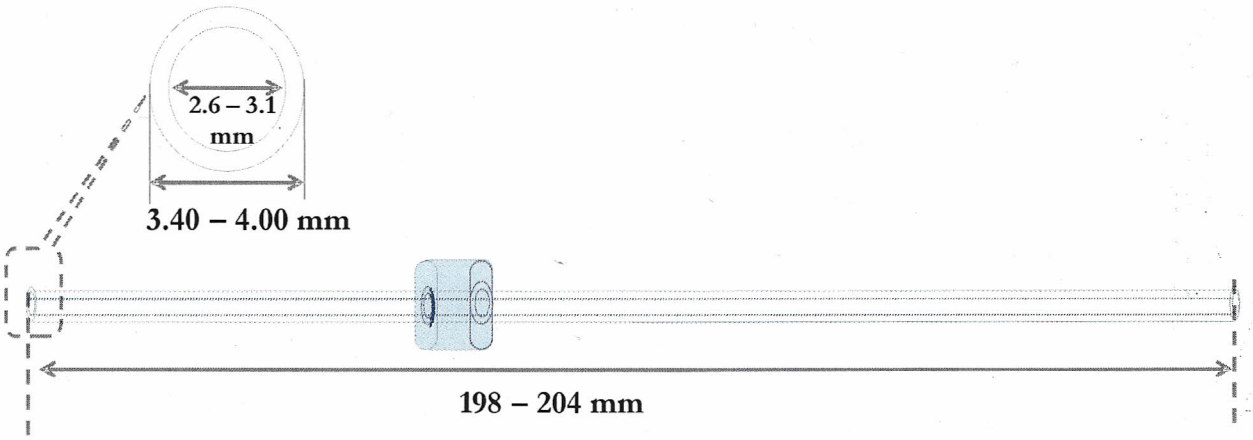

Figure 6 Insertion Tube Dimensions

Material
The insertion tube shall be made of HDPE (High Density Polyethylene) or gamma radiation resistant Polypropylene. The material shall pass the 10993:18 Implantation and extractables test and must give comparable biocompatibity as USP grade negative control

Dimensions
Length must lie between 198 to 204mm.
Internal Diameter must lie within 2.6 to 3.1mm.
Outside Diameter must lie within 3.40 to 4.00 mm (As shown in Figure 6)

Requirement
The insertion tube must slip out of the tie and vertical stem without exerting excessive drag force on the frame when the insertion tube is pulled in a direction axial to the vertical stem and away from the fundal ball.

Test
When gripping the fundal ball, the frame and insertion tube assembly is held in a position with the vertical stem being vertical and the fundal ball being topmost the insertion tube should slip out by virtue of its own weight.

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FLANGE

Material

The flange shall be made of polyvinyl chloride containing titanium dioxide.

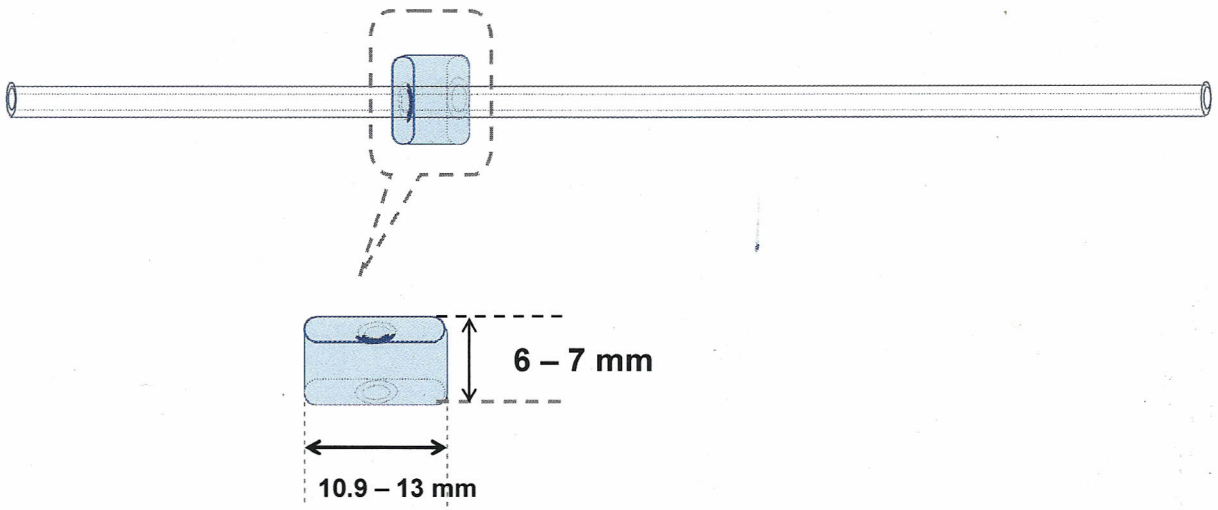

Figure 7 Insertion tube with Flange and Flange Dimensions

Dimension

The lateral length of the flange shall be in the range of 10.9 to 13 mm (as shown in Figure 7).
The vertical length of the flange shall be in the range of 6 to 7 mm.
Diameter of central hole shall be chosen and specified with a tolerance to achieve the flange displacement force. The shape and dimensions of the central hole may be changed to facilitate meeting the specified flange displacement force

Flange Displacement Force

Flange selected at random is placed on the insertion tube selected at random and allowed to age in place for minimum of 24 hours. The resistance to displace the flange by a steadily applied force shall be between 1.8-10 N.

PACKAGING AND LABELING

The packaging shall be done in film film pouch. Double cover packaging preferred for withstanding adverse storage conditions.
Continuous pin hole free Gamma radiation resistant polymer films shall be used. Manufacturers shall select films that reduce the risk of tarnishing the copper & withstand extremes of storage conditions. For optimum protection against tarnishing continuous pin hole free polyester-polyethylene laminate or other material giving equivalent or better protection may be used.

Sealed Pouch

IUCD shall be packed in individual sealed pouches.

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Sealed Pouch Integrity

Sealed pouch integrity shall be tested according to ASTM D3078:1994 (Standard test method for determination of leaks in flexible packaging by bubble emission).
The integrity is to be maintained under test exposure to an envoirnment of temperature 60 deg.and80% relative humidity for a period of 12 hrs.

Sealed Pouch Peel Strength

When tested according to ASTM F 88: 2000 (Standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4 N and not greater than 17 N. when a double cover packaging is used & the pealable inner cover is not the primary barrierthe peeling force of the inner packaging will be in the range of 4N-17 N.The outer cover of a double layer pouch is to be "tear open'.

Labelling and Inserts

Information required in accordance with ISO 7439: 2002 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the purchaser.
The Expiry Date is the date after which the product cannot be inserted.
The Expiry shall be printed on the sealed pouch/ID card and shall be based on the maximum product shelf-life from the date of sterilization.
The sterilization shall be completed within 30 days of sealing the finished device in the pouch.
In addition, the duration of the maximum period the device can remain *in utero* shall be printed on the primary container. This period shall not exceed 5 years from the date of insertion.

Printing

All printing shall be clear and readily legible.

Cleanliness

The device, insertion tube, flange and any insert such as instructions included in the pack shall be free of visible particulate matter and cuttings should be non-adherent.

Pouch Peeling Force

The packing pouch shall peel off when a force of 4 to 17 N is applied on both the edges of the pouch.

Product Shelf Life before Insertion

The maximum permitted shelf life for storage of the device prior to insertion is 4 years.

General Requirements

The materials of which the frame, insertion tube, flange and tie are made shall be sufficiently resistant to the unintended influence by body fluids and tissues, and shall be biologically compatible without causing undue/unacceptable allergic, toxic or inflammatory reaction.

The tie or thread attached to the frame shall be monofilament which is easily feelable after the insertion of the Copper IUCD375.

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Copper IUCD 375 shall be free from sharp edges, rough surfaces and shall be finished smooth.

Copper IUCD 375 when inserted shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

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