Preparation, Loading & Placement, Postplacement, and Removal

Paragard® intrauterine copper contraceptive
by CooperSurgical®

1

REVIEW
Review the placement guide.

2

VIEW
View the training video and access resources online by scanning the QR code or visiting **ParagardTraining.com.**

3

PRACTICE
Practice using the demo units and uterine model. **Demo units are not intended for human use – they are for educational purposes only.**

Paragard® (intrauterine copper contraceptive)

Single-Hand Inserter with Built-In Loading Tip

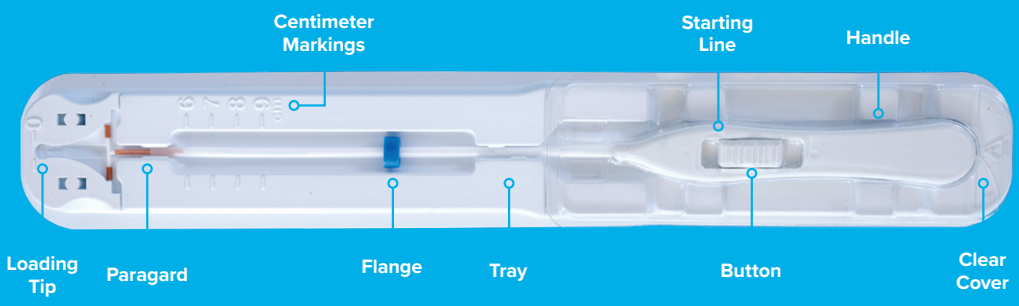
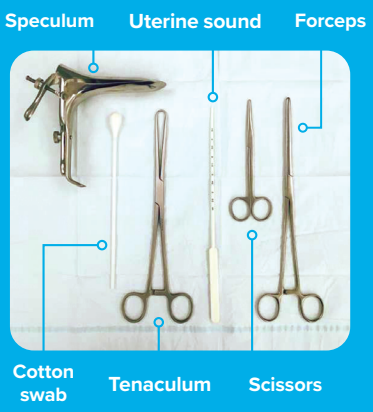


Fig. 1

Placement & Removal Tools



Dosage and Administration

Important Dosage and Administration Instructions

- Paragard® (Intrauterine copper contraceptive) should only be inserted by a healthcare provider trained in Paragard's insertion procedures, because insertion for Paragard is different from that used for other intrauterine systems. Healthcare providers should become thoroughly familiar with the product, product educational materials, product insertion instructions, and prescribing information before attempting insertion of Paragard.
- Insert one Paragard at the fundus of the uterine cavity.
- Remove Paragard on or before 10 years from the date of insertion.
- May replace Paragard at the time of removal with a new Paragard if continued contraceptive protection is desired.
- Before considering use of Paragard, make sure that the female is an appropriate candidate for Paragard. Exclude pregnancy (consider the possibility of ovulation and conception) prior to use.

INDICATIONS AND USAGE

Paragard is a copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 10 years.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

The use of Paragard is contraindicated when one or more of the following conditions exist:

- Pregnancy or suspicion of pregnancy, abnormalities of the uterus resulting in distortion of the uterine cavity, acute pelvic inflammatory disease (PID), postpartum or postabortal endometritis in the past 3 months, known or suspected uterine or cervical malignancy, uterine bleeding of unknown etiology, untreated acute cervicitis or vaginitis or other lower genital tract infection, conditions associated with increased susceptibility to pelvic infections, Wilson's disease, a previously placed IUS that has not been removed, hypersensitivity to any component of Paragard including to copper or any of the trace elements present in the copper component of Paragard.

Please see additional important safety information on back and accompanying full Prescribing Information or visit PI.Paragard.com.

Timing of Placement

Clinical Situation	Recommended Timing of Paragard Placement
1. Start Paragard in females not currently using contraception.	At any time during the menstrual cycle.
2. Switch to Paragard from an oral, transdermal, or vaginal form of hormonal contraception or an injectable progestin contraceptive.	At any time during the menstrual cycle; discontinue the previous method.
3. Switch to Paragard from a contraceptive implant or other intrauterine system.	Same day the implant or IUS is removed (place Paragard at any time during the menstrual cycle).
4. Paragard placement after abortion or miscarriage.	Immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after a first trimester abortion.
5. Paragard placement after childbirth. *Note: The inserter provided with Paragard (see Figure 1) and the Insertion Procedure described in the Placement Guide are not applicable for immediate insertion after childbirth. For immediate insertion post childbirth, remove the inserter and Paragard from the tray, move the button forward and then completely back to release the Paragard unit from the inserter and insert Paragard.*	May place immediately postpartum. Placement before uterine involution is complete, which may not occur until the second postpartum month, has been associated with increased risk of expulsion. There appears to be an increased risk of perforation in lactating women.

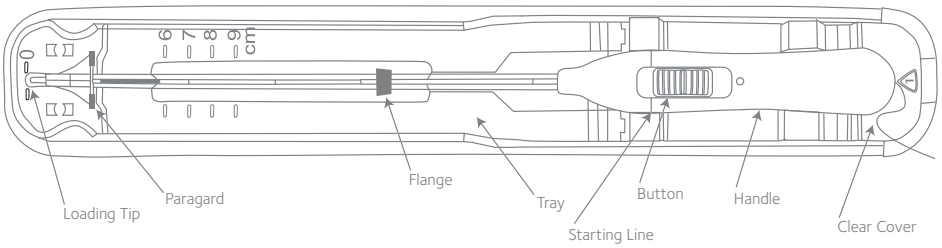
Preparation

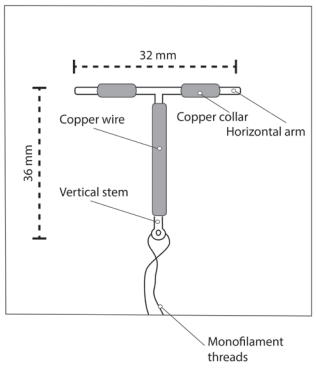
Before insertion:

- Do NOT remove the inserter from the tray before the arms are loaded into the insertion tube. The tray will be used to fold the Paragard arms down and load the IUS into the inserter.
- Use strict aseptic techniques throughout preparation.
- Prepare placement tools (e.g., speculum, cotton swab, tenaculum, uterine sound, scissors, and forceps).
- Consider use of an analgesic.
- Establish the size and position of the uterus by performing a bi-manual examination.
- Insert a speculum and, using a cotton swab, cleanse the cervix and vagina with an antiseptic solution.
- Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterine cavity.
- Gently insert a sterile uterine sound to measure the depth of the uterine cavity. The uterus should sound to a depth of 6 to 9 cm except when inserting Paragard immediately postabortion or immediately postpartum.
  - Insertion of Paragard may be associated with pain and/or bleeding, vasovagal reactions (e.g. syncope, bradycardia), or seizure, especially in patients with a predisposition to these conditions.
  - Insertion into a uterine cavity measuring less than 6 cm may increase the incidence of expulsion, bleeding, pain, and perforation.
  - If cervical stenosis is encountered, avoid undue force. Dilators and analgesia/local anesthesia may be helpful in this situation.

Loading and Insertion Procedure

When loading Paragard, use strict aseptic techniques throughout the procedure.

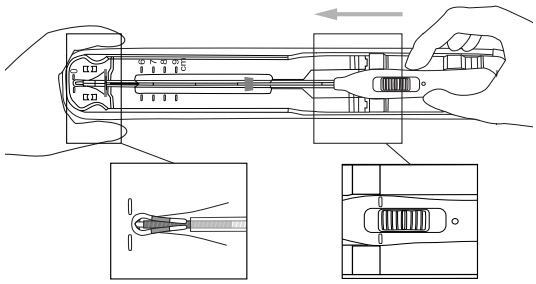




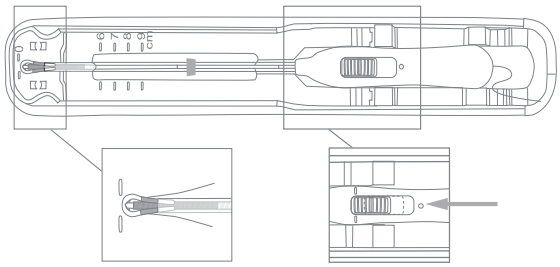
STEP 1: Opening the Sterile Paragard Package

- Place the package containing Paragard (face-up) on a flat sterile field. Open the pouch from the handle end where the arrow on the Placement Guide says "OPEN."
- Remove the clear cover from the tray (not shown).
- Confirm that the top of the button is located at the starting line on the handle prior to loading Paragard.
- The inserter should remain in the tray until Paragard T-Arms are loaded.
- **Do not slide the button on the handle before folding the arms in the tray.**
- **Do not repeatedly slide the button forward and back as this may cause slack in the threads and may result in an unsuccessful placement.**

STEP 2: Loading Paragard into the Inserter



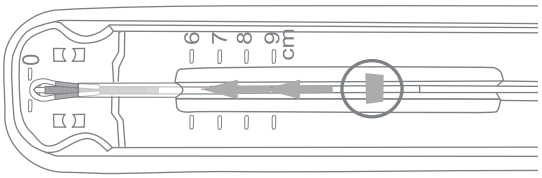
- Using sterile gloves, place one hand on the distal end of the tray and the other on the inserter handle. Slide the handle completely forward so that the Paragard advances into the Loading Tip folding the T-Arms of Paragard against the stem.



- Once the T-Arms are folded against the stem, slide the button on the handle completely forward to advance the insertion tube over the tips of the T-Arms. Only the tips of the T-Arms should be in the insertion tube. Do not advance beyond the copper collars.
- **IMPORTANT: Do not leave the T-Arms of Paragard bent for more than 5 minutes, as the arms may not open properly.**

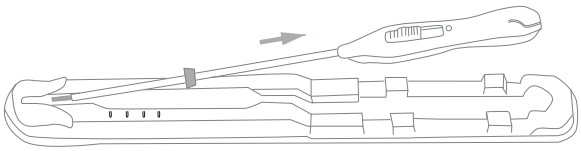
STEP 3: Adjusting the Flange

- Once the above steps are completed and Paragard is in the insertion tube, adjust the blue flange. The tray is marked with centimeters and can be used to set the flange to the correct depth.
- Adjust the flange so the distance from the top of Paragard (where it protrudes from the inserter) to the top of the flange is equal to the pre-measured uterine depth.



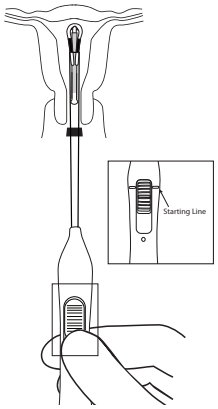
STEP 4: Removing Inserter from Tray

- Ensure the button remains in the forward position.
- To remove the inserter from the tray, gently lift the handle out of the tray, then gently slide the inserter back and lift out of the tray.
- Upon removal from the tray, verify and rotate the blue flange as needed so that the horizontal arms of Paragard and the long axis of the blue flange and handle lie in the same horizontal plane to ensure the arms open in the proper direction.
- Confirm that both T-Arms are captured within the insertion tube.



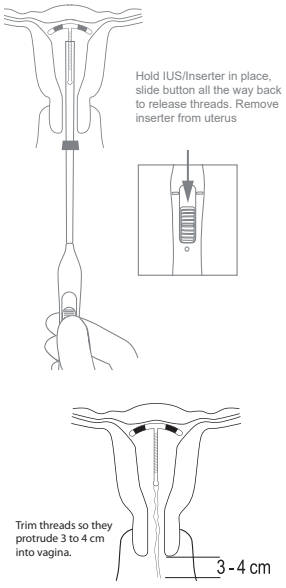
STEP 5: Inserting Paragard to the Fundus

- To orient the uterus in an axial position, apply gentle traction to the tenaculum. While holding the button forward, pass the loaded inserter through the cervical canal until the Paragard reaches the fundus of the uterus. This will ensure placement of Paragard at the highest possible position within the uterus.
- The blue flange should be at the cervix in the horizontal plane. The button should remain in the forward position.



STEP 6: Releasing Paragard and Withdrawing Inserter

- Release the arms of Paragard by holding the handle steady and sliding the button all the way down (and you may feel a click). Do not stop at the starting line as it is not used for deployment.
- This releases the threads and the T-Arms of Paragard high in the uterine fundus.
- Gently and slowly withdraw the inserter from the uterus and cervical canal.
- Only the threads should be visibly protruding from the cervix. Trim the threads so that 3 to 4 cm protrude into the vagina.
- Measure and note the length of threads, date of placement and Paragard lot number.
- Discard the used inserter – do not attempt to re-use the inserter because it is a single use device.
- If you suspect that Paragard is not in the correct position, check placement (with ultrasound, if necessary). If Paragard is not positioned completely within the uterus, remove it and replace it with a new Paragard. Do not reinsert an expelled or partially expelled Paragard.



Visit Us Online for More Training Resources

Placement Training Video

Watch our step-by-step instructional video on Paragard preparation, loading, placement, and removal.

Live or Virtual Training Session

Request a Live or Virtual training for your office using our virtual IUS simulation technology or three-dimensional models.

You may obtain additional demo units by contacting your Paragard® (intrauterine copper contraceptive) Sales Representative, or by calling 1-877-PARAGARD (1-877-727-2427)

IMPORTANT SAFETY INFORMATION CONTINUED

WARNINGS AND PRECAUTIONS

Ectopic Pregnancy: Evaluate for possible ectopic pregnancy in any female who becomes pregnant while using Paragard.
Intrauterine Pregnancy: Failure to remove Paragard increases the risk of miscarriage, sepsis, premature labor, and premature delivery.
Sepsis: Severe infection or sepsis, including Group A Streptococcal Sepsis (GAS), have been reported following insertion of IUSs, including Paragard.
Pelvic Inflammatory Disease and Endometritis: Remove Paragard in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.
Embedment: Partial penetration or embedment of Paragard in the myometrium can make removal difficult; surgical removal may be necessary. Breakage of an embedded Paragard during non-surgical removal has been reported.
Perforation: Partial or total perforation of the uterine wall or cervix may reduce contraceptive efficacy and result in pregnancy. Delayed detection or removal of Paragard may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal penetration, intestinal obstruction, abscesses and/or damage to adjacent organs. Increased risk when the uterus is fixed, retroverted or not completely involuted during the postpartum period. If perforation does occur, locate and remove Paragard promptly.
Expulsion: Partial or complete expulsion of Paragard has been reported, resulting in the loss of contraceptive protection. The risk of expulsion may be increased when the uterus is not completely involuted at the time of insertion. Remove a partially expelled Paragard.
Wilson's Disease: Paragard may exacerbate Wilson's disease.
Bleeding Pattern Alterations: Paragard can alter the bleeding pattern and result in heavier and longer menstrual cycles with intermenstrual spotting.
Magnetic Resonance Imaging (MRI) Safety Information:
Non-clinical testing has demonstrated that Paragard is MR Conditional.
Medical Diathermy: Avoid using high medical RF transmitter devices in females with Paragard.

ADVERSE REACTIONS

Adverse reactions reported in clinical trials include anemia, backache, dysmenorrhea, dyspareunia, expulsion (complete or partial), prolonged menstrual flow, menstrual spotting, pain and cramping, and vaginitis.

Please see Important Safety Information and accompanying full Prescribing Information or visit PI.Paragard.com.

References

Paragard Package Insert, Trumbull CT CooperSurgical Inc 2024.