

Insertion Instructions for ParaGard

A single ParaGard® should be placed at the fundus of the uterine cavity. ParaGard® should be removed on or before 10 years from the date of insertion.

Before Placement:

1. Make sure that the patient is an appropriate candidate for ParaGard® and that she has read the Patient Package Insert.
2. Use of an analgesic before insertion is at the discretion of the patient and the clinician.
3. Establish the size and position of the uterus by pelvic examination.
4. Insert a speculum and cleanse the vagina and cervix with an antiseptic solution.
5. Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterine cavity.
6. Gently insert a sterile sound to measure the depth of the uterine cavity.
7. The uterus should sound to a depth of 6 to 9 cm except when inserting ParaGard® immediately post-abortion or post-partum. Insertion of ParaGard® into a uterine cavity measuring less than 6 cm may increase the incidence of expulsion, bleeding, pain, and perforation. If you encounter cervical stenosis, avoid undue force. Dilators may be helpful in this situation.

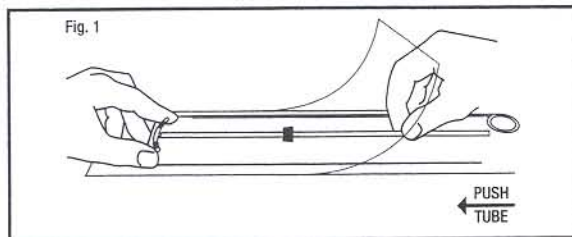
How to Load and Place ParaGard®:

Do not bend the arms of ParaGard® earlier than 5 minutes before it is to be placed in the uterus. Use aseptic technique when handling ParaGard® and the part of the insertion tube that will enter the uterus.

STEP 1

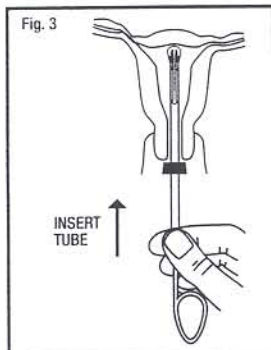
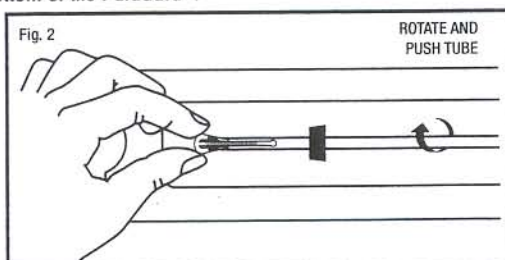
Load ParaGard into the insertion tube by folding the two horizontal arms of ParaGard® against the stem and push the tips of the arms securely into the inserter tube.

If you do not have sterile gloves, you can do STEPS 1 and 2 while ParaGard® is in the sterile package. First, place the package face up on a clean surface. Next, open at the bottom end (where arrow says OPEN). Pull the solid white rod partially from the package so it will not interfere with assembly. Place thumb and index finger on top of package on ends of the horizontal arms. Use other hand to push insertion tube against arms of ParaGard® (shown by arrow in Fig. 1). This will start bending the T arms.



STEP 2

Bring the thumb and index finger closer together to continue bending the arms until they are alongside the stem. Use the other hand to withdraw the insertion tube just enough so that the insertion tube can be pushed and rotated onto the tips of the arms. Your goal is to secure the tips of the arms inside the tube (Fig. 2). Insert the arms no further than necessary to insure retention. Introduce the solid white rod into the insertion tube from the bottom, alongside the threads, **until it touches the bottom of the ParaGard®**.

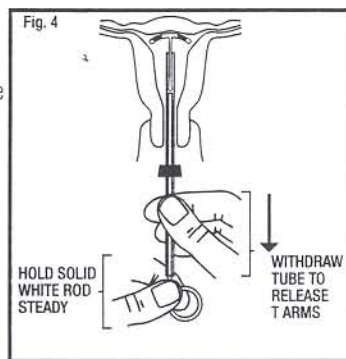


STEP 3

Grasp the insertion tube at the open end of the package; adjust the blue flange so that the distance from the top of the ParaGard® (where it protrudes from the inserter) to the blue flange is the same as the uterine depth that you measured with the sound. Rotate the insertion tube so that the horizontal arms of the T and the long axis of the blue flange lie in the same horizontal plane (Fig. 3). Now pass the loaded insertion tube through the cervical canal until ParaGard® just touches the fundus of the uterus. The blue flange should be at the cervix in the horizontal plane.

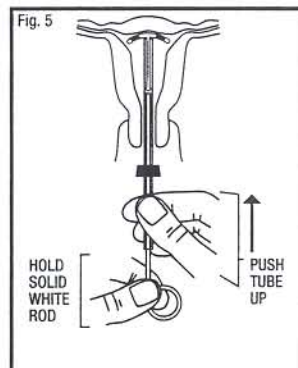
STEP 4

To release the arms of ParaGard®, hold the solid white rod steady and withdraw the insertion tube no more than one centimeter. This releases the arms of ParaGard® high in the uterine fundus (Fig. 4).



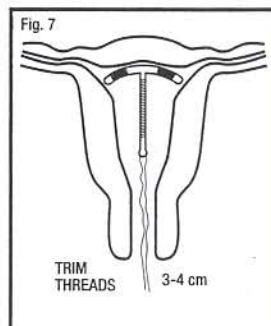
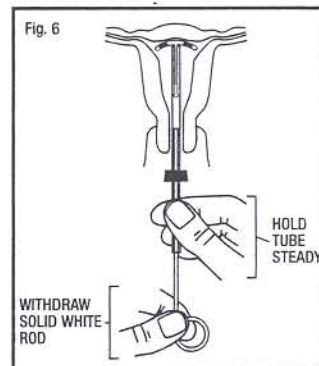
STEP 5

Gently and carefully move the insertion tube upward toward the top of the uterus, until slight resistance is felt. This will ensure placement of the T at the highest possible position within the uterus (Fig. 5).



STEP 6

Hold the insertion tube steady and withdraw the solid white rod (Fig. 6).



STEP 7

Gently and slowly withdraw the insertion tube from the cervical canal. Only the threads should be visible protruding from the cervix (Fig. 7). Trim the threads so that 3 to 4 cm protrude into the vagina. Note the length of the threads in the patient's records.

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®.

CAUTION

Instrumentation of the cervical os may result in vasovagal reactions, including fainting. Have the patient remain supine until she feels well, and have her get up with caution.

Continuing Care:

Following placement, examine the patient after her first menses to confirm that ParaGard® is still in place. **You should be able to see or feel only the threads.** If ParaGard® has been partially or completely expelled, remove it. You can place a new ParaGard® if the patient desires and if she is not pregnant. Do not reinsert a used ParaGard®.

Evaluate the patient promptly if she complains of any of the following:

- Abdominal or pelvic pain, cramping, or tenderness; malodorous discharge; bleeding; fever
- A missed period