ClearView

Uterine Manipulator

INSTRUCTIONS FOR USE

UM700 & UM900

DESCRIPTION

The Clinical Innovations ClearView® is both a uterine manipulator and a uterine injector designed for single use for complete uterine control by the attending laparoscopist. It is a sterile product made of molded plastic material which meets USP/Class VI recommendations for implant testing. This product is designed as a single unit body with (a) a rotation control knob which controls tip, (b) an enclosure, (c) a dual lumen obturating tip which pivots at the cervical os, (d) a soft inflatable uterine cavity balloon with external inflation tubing for securing the device in the uterine cavity, (e) a luer fitting to accommodate a syringe for contrast media injection through the distal tip assembly, and (f) a spacer for reducing insertion depth by 1 cm. Extended length is 32.5 cm (12.8 inches). Outer diameter of distal tip is 5.1 mm (0.20 inches).

INDICATIONS

Procedures in which uterine manipulators are used include tubal ligations, diagnostic laparoscopies for evaluating pelvic pain and infertility, treatment of endometriosis, removal of pelvic scars (adhesions) involving the uterus, fallopian tubes and ovaries, treatment of ectopic pregnancy, removal of uterine fibroids, removal of ovarian cysts, removal of ovaries, tubal repair, laparoscopic hysterectomy, laparoscopic repair of pelvic bowel or bladder, sampling of pelvic lymph nodes, and biopsy of pelvic masses minilaparotomy, fertility examinations, salpingoplasty, tubal reanastomosis and in procedures requiring chromotubation.

WARNINGS

- Sound uterus for depth and direction before use. NEVER use the ClearView as a sound.
- Never use a tip which is longer than the sounded depth. Apply spacer so depth of insertion is 1 cm less than sound depth.
- The spacer may detach if not securely snapped in place. If the spacer becomes detached and retained in the patient, it may lead to potential pain and or infection.
- Never attempt extensive uterine manipulation without a clear laparoscopic view of the uterus.
- Never use the device without testing cuff first.
- Do not employ extreme or excessive force when manipulating.
- Never force the tip into a cervical os that is insufficiently dilated.
- As with all uterine manipulators, a careful clinical examination should be

performed prior to use. Certain clinical conditions may present a uterus which is more prone to perforation and bleeding.
- A non-inflated or under-inflated cuff may result in the expulsion of the device from the uterus during use.
- Dye injection should be performed slowly. Rapid injection may cause uterine damage or result in fallopian tube spasm.
- If preferential flow is noted on chromotubation, occlude the side with free flow to assess contralateral flow.

ADVERSE REACTIONS

- Cramping
- Infection
- Perforation of uterine wall
- Uterine spasm with accompanying temporary physiologic blockage of patent fallopian tubes
- If the spacer is detached and retained in the patient, it may lead to potential pain and or infection.

Instructions for Use

1. Check the sterile tray for integrity. Remove the instrument. Using the included syringe, inflate cuff (balloon at distal tip) with fluid (10ml maximum). Remove the syringe and make sure that the cuff stays inflated. Reattach the syringe and remove the fluid, thus deflating the balloon.

2. Sound the uterus using the combination Sound-Dilator provided. For the 7cm ClearView device; if the uterus sounds to less than 8 cm, attach a spacer. For the 9 cm ClearView® device; if the uterus sounds to less than 10 cm, attach a spacer.

3. To attach a spacer, position spacer with the snap fingers towards the pivot and carefully slide the spacer over the tip (with balloon deflated) until it snaps in place at the base of the tip (see diagram). Tug on the spacer to make sure it is secured. The uterine manipulator tip with its injection ports should be positioned 1 cm below the maximum depth of the uterus by sounding. Dilate the cervix, if indicated, using standard procedures or utilize the combination Sound-Dilator provided.

   If the spacer cannot be secured, do not proceed; Select another device.

4. Lubricate the distal manipulator tip and cuff. After placing a speculum, slowly insert the tip into the uterine cavity. Completely insert the tip into the uterus until the face of the cervical stop abuts the external cervix.

5. Slowly inflate the cuff with fluid until the cervical stop is pulled tight against the cervix (10ml max.). Hold the plunger of the syringe as it is removed from the reflux valve to prevent the reflux of fluid back into the syringe. Do not over inflate the cuff.

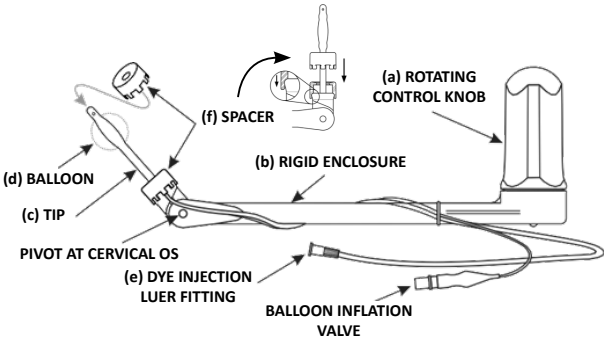
6. Gently pull on the manipulator to test for proper engagement of the cuff in the uterus. Remove the speculum, rotate the manipulator to the antevert position, with the manipulator handle between the patient's legs.

7. Manipulate the uterus by rotating the handle. Clockwise rotation elevates the uterus to the antevert position. Counterclockwise rotation retroverts the

uterus. The uterus can also be moved laterally by directing the handle to one side or the other.

8. If desired, inject media through the dye injection port to test patency of the fallopian tubes. When the procedure is complete, insert the syringe into the reflux valve and draw off the fluid from the cuff. Move the uterus to its natural position and remove from the uterus and vagina.

Note: Check to ensure that spacer is not detached and retained in the patient.



Used device should be disposed according to standard facility **biohazard** **procedure**

SYMBOLS GLOSSARY

Symbol	Symbol Description
	Indicates Device Manufacturer Includes name and address of the manufacturer
	Date of Manufacture
	Use By Date YYYY-MM-DD is generic placeholder for specified Use By Date
	Medical Device
	Lot Code
	Authorized EC Representative
	Catalog Number
	Do Not Re-use
	Sterilized by Irradiation
	Consult Instructions For Use
	Do not use if package is damaged
R_x ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Latex Free
	Do not resterilize

CLINICAL
INNOVATIONS
for**MOM**. for**BABY**. for**LIFE**.

CE 2797

EC REP

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