

ClearView[®] Total

Uterine Manipulator

INSTRUCTIONS FOR USE

UM750 & UM950



DESCRIPTION

The ClearView® Total uterine manipulator with ColpoCup and Occluder is intended to be a single-use, disposable device. It is a sterile device made of medical grade, molded plastic materials which meet USP/Class VI recommendations for implant testing. The device comes with three different sizes of ColpoCups which are all compatible with electrosurgical, harmonic and laser devices. The ClearView Total is designed to allow secure placement of the manipulator tip into the uterus and the ColpoCup into the vaginal fornices around the cervix. This product is designed as a single unit body with (a) a rotation control knob which controls tip, (b) a dual lumen obturating tip which pivots at the cervical os, (c) a soft inflatable uterine cavity balloon with external inflation tubing for securing the device in the uterine cavity (d) a spacer for reducing insertion depth by 1 cm.

INDICATIONS

The ClearView Total is intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices, and the surgeon intends to remove or access intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies or total laparoscopic hysterectomies while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.

WARNINGS

- Do not use the ClearView Total if it has been opened or damaged.
- Do not reuse. Discard after one procedure. Function may be impaired through reuse or cleaning. The device is difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Clinical Innovations will not be responsible for any direct, incidental, or consequential damages resulting from the reuse of this device.
- 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 or bleeding.
- Sound the uterus for depth and direction prior to use. Do not use the ClearView Total as a sound.
- Do not use a tip which is longer than the sounded depth. Apply a spacer, or use a shorter-tipped device, so insertion is 1 cm or less than sounded depth.
- **The spacer may detach if not twisted and snapped securely into place. If the spacer becomes detached and retained in the patient, it may lead to**

potential pain and or infection.

- Do not use the device without first testing the tip and Occluder balloons.
- The tip balloon is designed to hold up to 10 ml of inflation.
- The Occluder balloon is designed to hold up to 120 ml of inflation.
- **Do not inflate balloons with air.**
- Use of an incorrect sized ColpoCup could result in patient injury.
- Do not force the tip of the device into a cervical os that is insufficiently dilated.
- A non-inflated, or under-inflated, tip balloon may result in the expulsion of the device from the uterus during use.
- Do not attempt extensive uterine manipulation without a clear laparoscopic view.
- Do not employ extreme or excessive force when manipulating.
- Do not attempt to remove the device by pulling on any exposed tubing. Remove by pulling on the handle only.
- Do not allow prolonged contact between cutting instrument and ColpoCup.

CONTRAINDICATIONS

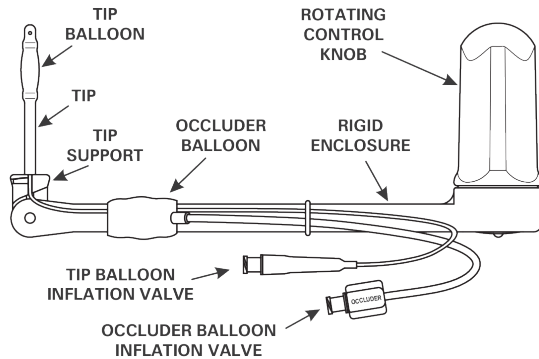
Pregnancy or suspicion of pregnancy, known or suspected uterine or tubal infection, an IUD in place, uterine anomaly especially anomalies with a small cavity, and cases in which the surgeon deems it inadvisable or finds it difficult to insert.

POSSIBLE ADVERSE REACTIONS

- Cervical laceration
- Uterine perforation
- Laceration of uterine vessels
- Retroperitoneal or intraperitoneal bleeding
- Perforation of the bowel or bladder infection
- Interruption of unsuspected intrauterine pregnancy and retention of part of the manipulator (spacer or cup) as a retained foreign body.

PRECAUTION

Confirm that the ColpoCup and/or spacer is locked into place prior to starting the procedure.




Instructions for Use

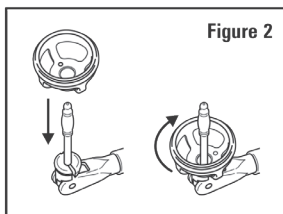
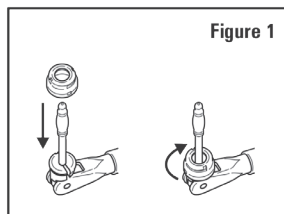
1. Check the sterile tray for integrity. Remove the device. Using the small syringe (included in package), inflate the tip balloon with sterile saline (10 ml maximum). Remove the syringe and make sure the balloon stays inflated. Reattach the syringe and remove the fluid, deflating the balloon, prior to patient insertion. Using the large syringe included in the package, test the integrity of the Occluder balloon by inflating with 30 – 60 ml of sterile saline (do not use air); then deflate prior to patient insertion.
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 9cm ClearView device; If the uterus sounds to less than 10 cm, attach a spacer.
3. To attach a spacer, with tip balloon deflated, position spacer with the larger open end facing towards the pivot and carefully slide the spacer over the tip until it touches the tip support; then twist the spacer clockwise until it snaps in place at the base of the tip (see Figure 1, Page 6). Tug on the spacer to make sure it is secured. The manipulator tip should be positioned 1 cm below the maximum sounded depth of the uterus.
4. If the spacer cannot be secured, do not proceed; Select another device.
5. Choose the correct size of ColpoCup to properly fit the patient and then carefully place the ColpoCup over the deflated ClearView Total tip until it touches the tip support or spacer (if used). Twist the ColpoCup clockwise until it snaps tightly in place (see Figure 2, Page 6).
6. If indicated, dilate the cervix using standard procedures, or use the combination Sound/Dilator provided.
7. Lubricate the distal manipulator tip and balloon. After placing a speculum, slowly insert the tip into the uterine cavity. Completely insert the tip into the uterus until the bottom of the ColpoCup abuts the external cervix. Confirm that the distal end of the ColpoCup is secured in the vaginal fornices.
8. Using the small syringe, slowly inflate the tip balloon with sterile saline until the base of the ColpoCup is pulled tight against the cervix (10 ml maximum). Continue to hold the plunger of the syringe as it is removed from the inflation valve, to prevent reflux of fluid back into the syringe. Do not over inflate the tip balloon.
9. Gently pull on the manipulator to test for proper engagement of the cuff in the uterus. Remove the speculum and rotate the manipulator clockwise to the anteverted position with the manipulator handle between the patient's legs.
10. The uterus can now be manipulated by rotating the ClearView Total's handle. Clockwise rotation elevates the uterus to the anteverted position, counterclockwise rotation retroverts the uterus. The uterus can also be moved laterally by directing the handle to one side or the other.
11. Just prior to making the colpotomy incisions, inflate the Occluder balloon

with 60 – 120 ml of sterile saline (do not use air).
















11. After completion of the procedure, deflate the Occluder balloon and remove the device, in its entirety, from the 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
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Latex Free
	Do not resterilize



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