

# GYNEX®

## Instructions For Use:

### Century UMI™ Uterine Manipulator Injector

STERILE EO Single-Use

Not made with natural rubber latex.

#### DESCRIPTION

The Manipulator is a simple, safe and effective device for Diagnostic Laparoscopy, Mini-laparotomy, Fertility Exams, and Salpingoplasty. It also helps the sealing of the cervical os while providing a fluid or air to the cuff. Designed for single patient use only.

#### INDICATIONS

Use of the Manipulator is indicated in Diagnostic Laparoscopy, Mini-laparotomy, Fertility Exams, and Salpingoplastic procedures where manipulation of the uterus is required.

#### PRECAUTION

- Test inflatable cuff before insertion for possible leakage.
- Lubricate catheter tip before use.
- Check for necessity to dilate cervix before insertion to avoid tearing inflatable cuff.
- When using any liquid media, be sure to follow manufacturer instruction.
- After insertion and inflation insure the cuff is properly inflated. (Squeeze pilot balloon and check its tautness.)
- A deflated cuff may cause injury and trauma to the uterus.
- Inspect the device for its integrity after use to ensure no parts are left inside.

#### CONTRAINDICATIONS

- Pregnancy or suspected pregnancy
- Uterine or tubal infection
- Media allergy
- Gynecological malignancy
- During assisted reproduction technology (ART) procedure related to in vitro fertilization (IVF)

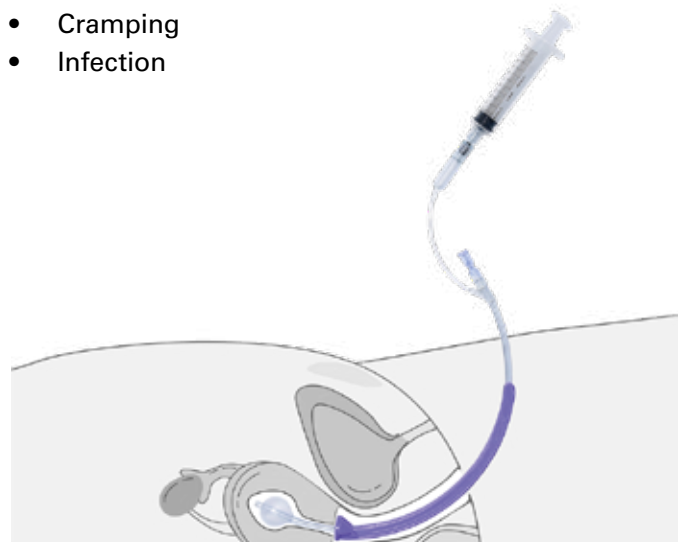


#### ⚠ WARNINGS

- Ensure the catheter is secured to the handle. It's possible that the handle may be loosened during transportation. Snap it back on at the 6cm mark before use.
- Inflate the cuff before manipulation is essential to avoid trauma to the uterus.
- Insert Manipulator along the proper axis to avoid uterine trauma.
- Do not reuse for avoiding user may be infected by the microorganism
- Federal law requires that these devices be ordered by a physician.
- If the sterile package is damaged or unintentionally opened before use, do not use.
- Store in a dark, cool, dry place.
- Dispose of medical waste properly in accordance with regulations after using.

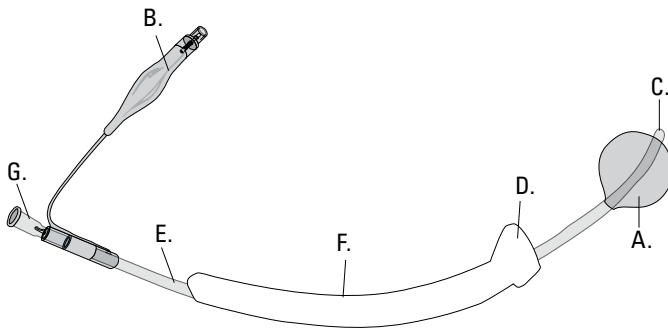
#### ADVERSE REACTIONS

- Perforation of the uterine wall
- Cramping
- Infection



## DIRECTIONS FOR USE

1. Check the sterile pouch has not been opened or damaged.
2. Be sure the catheter is securely snapped in the handle.
3. Test the inflatable cuff by injecting 6 to 7 cc of air into valve (B).
4. After testing, evacuate all air from the cuff for insertion.
5. Sound the uterus for depth and direction, adjust the Manipulator depth accordingly. Century UMI Manipulator is pre-set at 6cm in depth.
6. Ascertain if the cervix needs dilation. The inflatable cuff may tear if the passage is not wide enough.
7. Lubricate the distal tip (C) and cuff (A) for easy insertion.
8. Guide the manipulator carefully along the natural axis of the cervix to avoid injury.
9. Insert the manipulator into the uterus until the face of cervical stop (D) touches the external cervix.
10. Inflate the cuff slowly with 3 to 10 cc of air until the cervical stop being pulled up tightly against the cervix. When detach the syringe, hold the plunger to prevent reflux of air back into the syringe.
11. Pull gently on the manipulator to be sure cuff inflation is adequate. Excessive cuff inflation may cause utero-tubal spasm and physiologic closure of patent tubes.
12. To insure the cuff has not ruptured during procedure, check the tautness of the pilot balloon. A soft balloon indicates a ruptured or leaking cuff.
13. To remove the manipulator, insert a syringe in the valve and deflate the cuff, then remove the manipulator carefully.



- A. Intrauterine Cuff
- B. Inflation Valve and Pilot Balloon
- C. Distal Tip
- D. Cervical Stop
- E. Catheter
- F. Snap-on Handle
- G. Luer Lock Adapter

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