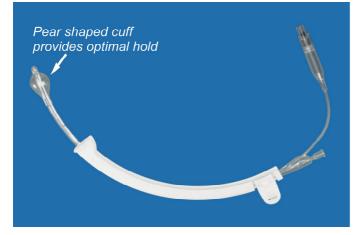


# Uterine Manipulator Injector (Adjustable)

U.A.Medical Products, Inc. Dedicated to quality surgical Instruments...



### NOT MADE WITH NATURAL RUBBER LATEX

UA Medical Manipulator is a simple, safe and effective device for Diagnostic Laparoscopy, Minilaparotomy, Fertility Exams, and Salpingoplasty. It also helps the sealing of the cervical os while providing a fluid or air to the cuff.

# PRODUCT NO. UA6003 (Adjustable)

# **INDICATION**

Use of the UA Medical Manipulator is indicated in Diagnostic Laparoscopy, Minilaparotomy, Fertility Exams, and Salpingoplastic procedures where manipulation of the uterus is required.

# CAUTION

Federal law restricts this device to sale by or on the order of a physician.

Do not reuse for avoiding user may be infected by the microorganism.

#### 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.

Distributed by: U.A.Medical Products, Inc. P.O.Box 472205 Charlotte, NC 28247

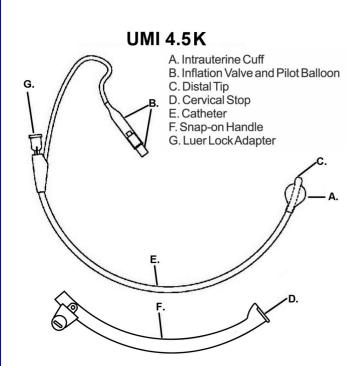
- Inflate the cuff before manipulation is essential to avoid trauma to the uterus.
- Insert Manipulator along the proper axis to avoid uterine trauma.

# PRECAUTIONS

- 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.

#### **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 UA Medical 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 detaching 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.

# **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)