



PRODUCT LITERATURE | GYNECOLOGICAL INSTRUMENTS

Uterine Manipulator Injector - Instructions for Use

Official Manufacturer IFU | English

The following pages reproduce the manufacturer's official document without alteration. For availability, quotations and support in Canada, please contact Beauray Inc.

CANADIAN SALES & SUPPORT

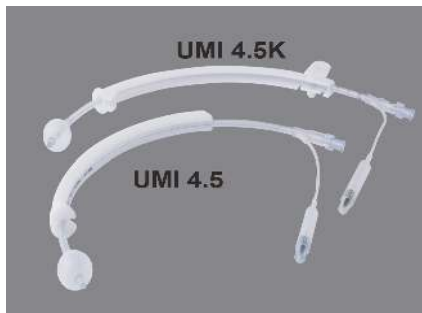
Beauray Inc.

info@beauray.co

+1 437 607 5116 | Thornhill, Ontario, Canada

For Canadian product inquiries, contact Beauray Inc.

Uterine Manipulator Injector



Uterine Manipulator Injector
Product Name: THE MANIPULATOR -4.5
Product No. UMI 4.5
 UMI 4.5K (Adjustable)
OD Size: 4.5mm

Not made with natural rubber latex

DESCRIPTION:

The Manipulator is a simple, safe and effective device for Diagnostic Laparoscopy, Minilaparotomy, Fertility Exams, and Salpingo-plasty. It also helps the sealing of the cervical os while providing air to the cuff. It is designed for single patient use only.

INDICATIONS:

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

CAUTION:

1. Sterile product unless package is opened or damaged.
2. Do not reuse for avoiding user may be infected by the microorganism.
3. This device is sold by or on the order of a physician.
4. If the sterile package is damaged or unintentionally opened before use, do not use.

CONTRAINDICATIONS:

1. Pregnancy or suspected pregnancy
2. Uterine or tubal infection
3. Media allergy
4. Gynecological malignancy
5. During assisted reproduction technology (ART) procedure related to in vitro fertilization (IVF)

ADVERSE REACTIONS:

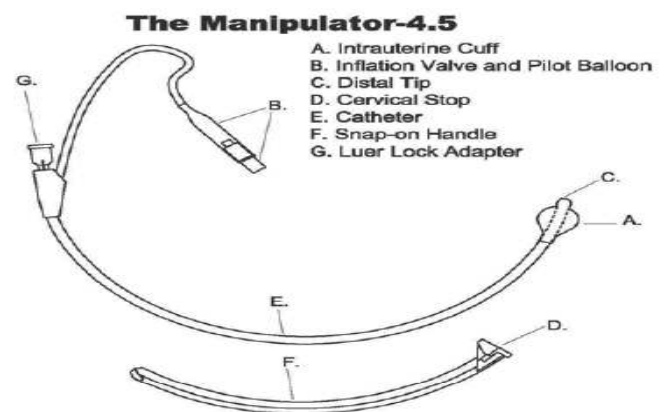
1. Perforation of the uterine wall
2. Cramping
3. Infection

PRECAUTION:

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

WARNINGS:

1. 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.
2. Inflate the cuff before manipulation is essential to avoid trauma to the uterus.
3. Insert Manipulator along the proper axis to avoid uterine trauma.
4. Dispose of medical waste properly in accordance with regulations after using.



The double-lumen tube is 33.7cm in length. Encircling the proximal end but not covering the Distal tip (C) is an Intrauterine Cuff (A) which is inflated using a standard syringe via an Inflation Valve and Pilot Balloon (B).

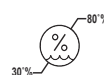
The Luer lock adapter (G) fitting to accommodate a syringe to introduce contrast media through the inner lumen to reach the Distal tip (C). A Detachable rigid snap-on plastic handle (F) provides a Cervical stop (D) that can be positioned along the catheter (E) at the desired depth of insertion. The double lumen was designed to one for air inflation of a 10 cc Intrauterine Cuff, and the other for injection of contrast media through the distal tip.

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 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.



Warehouse temperature 10~40°C



Warehouse humidity 30~80%RH.



Not Made With Natural Rubber Latex



Do not reuse



Batch code



Expiry date



Attention



Biological risks



Consult instructions for use



Sterile EO



Bioteque Taiwan Ltd.

7F., No. 431, 433, Baozhang Rd., Xizhi Dist., New Taipei City 22103, Taiwan