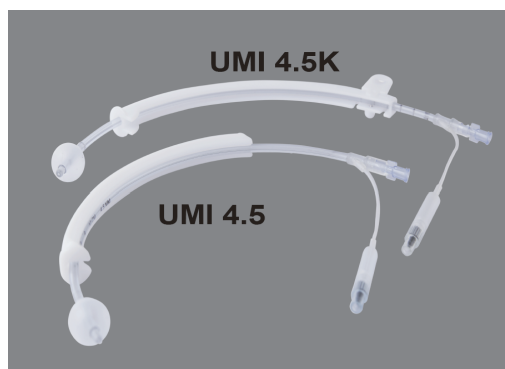




Description

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

Product Model

- HM6002 REF
- HM6003 REF

Indications

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

Cautions

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.
5. Use of oil-based contrast media may have the potential to affect the UMI device material. To minimize the possibility of material weakening or device breakage. Use water-based or aqueous contrast media whenever clinically appropriate.

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)

Potential Side Effects

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

Precautions

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 the manufacturer's instructions.
5. After insertion and inflation ensure 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.

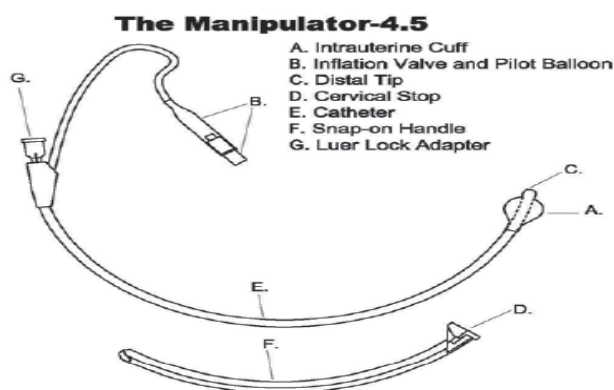
Warnings

1. Uterine Manipulator Injector is intended for single use only. DO NOT REUSE.
2. Do not use if the sterile packaging is compromised.
3. 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.
4. Inflate the cuff before manipulation is essential to avoid trauma to the uterus.
5. Insert Manipulator along the proper axis to avoid uterine trauma.
6. Dispose of medical waste properly in accordance with regulations after using.

Instructions for Use

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.



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.

Disposal Instructions

- Dispose of the used device in an approved biohazard container.
- Dispose of the device as a single-use medical device in accordance with local regulations for biohazardous or medical waste.
- Do not attempt to clean, reuse, or recycle the device.

Storage & Transportation Conditions

- The shelf life of this device is 3 years from the date of manufacture.
- Store in a clean, dry environment with a temperature between 10–40°C and relative humidity between 30–80% RH.
- The device contains no sensitive materials, liquids, or gases, and is not considered precision machinery.
- It should be transported under normal atmospheric conditions in accordance with the manufacturer's recommendations to prevent damage.
- The transportation methods for export include truck, ship, and airplane, while inland transportation is primarily conducted by truck.

Glossary of Symbols

	Batch code
	Manufacturer
	Temperature limit 10-40°C
	Humidity limitation 30-80%RH
	Not made with Natural Rubber Latex
	Consult instructions for use
	Expiry Date (YYYY/MM/DD)
	Caution
	Do not use if package is damaged and consult instructions for use
	Catalogue number
	Medical device
	Biological Risks
	Do not re-use
	Single sterile barrier system and using ethylene oxide

Rx ONLY Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner

Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to Hayden Medical and to the applicable competent authority having jurisdiction in their locale.