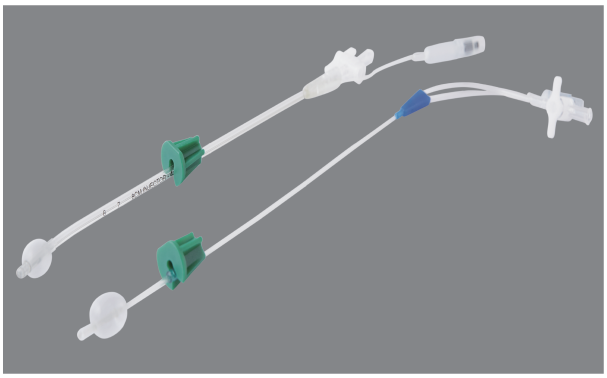
Instructions for Use
Uterine Injector

MD



Uterine Injector
Product Name: THE INJECTOR - 4.0
Product No. UI 4.0
OD Size: 4.0mm

Not made with natural rubber latex

Description

The Uterine Injectors are double lumen, slightly curved and designed for single use. It was developed to facilitate diagnostic procedures such as Laparoscopy, Minilaps, Salpingoplasties and Fertility Examinations. It is a sterile disposable product consisting of plastic tube, connector and other plastic components.

Product Model

UI 4.0 REF

Indications

The Uterine Injector is intended to be used during hysterosonography, hydrotubation,hysterosalpingogram, and salpingoplasties.

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)

Warnings

1. The safety and effectiveness of Uterine injectors have not been demonstrated in the setting of uterine bleeding.
2. Test inflatable cuff before insertion for possible leakage. DO NOT use the device while the Cuff is malfunction.
3. Inject 5cc of air via Pilot Balloon with syringe to Intrauterine Cuff (A). Also, DO NOT attempt to infuse additional air into cuff. Doing so may cause harm to the patient.
4. NEVER introduce fluid such as contrast media or water to inflate the Intrauterine Cuff (A). Such act will impair Intrauterine Cuff.
5. Dispose of medical waste properly in accordance with regulations after using.

Potential Side Effects

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

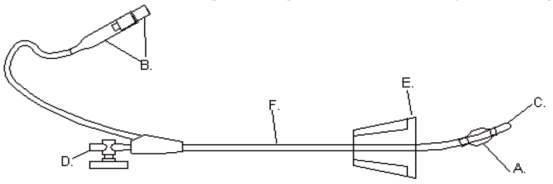
Precaution

1. Sound the depth and direction of uterus prior to using the Injector-4.0. Insert it along the proper axis to avoid uterine trauma.
2. Snap firmly in place for cervical stop (E) to the tubing (F) before use. The default setting is that the cervical stop is locked on the tubing at the 6 Centimeter Marking but not firmly. Snap it back on at the appropriate sounding depth marking before use.
3. Lubricate catheter tip before use.
4. Check for necessity to dilate cervix before insertion to avoid tearing inflatable cuff.
5. When using any liquid media, precisely follow manufacturer instruction.
6. After insertion and inflation insure the cuff is properly inflated. (Squeeze pilot balloon and check its tautness.)
7. A deflated cuff may cause injury and trauma to the uterus.
8. Exactly follow a procedure to remove this device; **INSPECT** the device for intactness.

Instructions for Use

The Injector 4.0

A. Intrauterine Cuff
B. Inflation Valve and Pilot Ballon
C. Distal Tip
D. Stopcock
E. Cervical Stop
F. The Rigid tubing with centimeter depth markings



The double-lumen tube of UI-4.0 is 26.2cm in length; has an OD of 4.0mm; and is featured with centimeter depth markings (F) along its distal segment from 6-10cm to set the depth of insertion.

Encircling the proximal end but not covering the Distal tip (C) is an Intrauterine Cuff (A) which is inflated using a standard syringe (not included) via an Inflation Valve and Pilot Balloon (B). The Luer lock adapter/Stop lock adapter (E) fitting to accommodate a syringe (not included) to introduce contrast media through the inner lumen to reach the Distal tip (C). A Cervical stop (E) can be positioned along the rigid tubing(F) at the desired depth of insertion. The double lumen was designed to one for air inflation of a 5 cc (UI-4.0) Intrauterine Cuff, and the other for injection of contrast media through the distal tip.

1. Take out instrument from the sterilized pouch, insert a standard syringe to air port of Inflation Valve (B) to inflate Intrauterine Cuff (A) by inserting 5 cc of air then remove syringe to ensure inflation integrity. After examining its function, reinsert syringe and completely release the residual air in the cuff.

2. Place the patient in lithotomy position, grip anterior cervical lip with tenaculum, visualize the uterine cervix. Determine the depth and direction of uterus with a uterine sound. Use of the INJECOTR-4.0 or as a uterine sound is forbidden. Setthe instrument for effective uterine depth according to the result of uterine sounding. If the depth of the uterus less 6cm, no needs to adjust cervical stop (E) but snap firmly in place. If exceeds, adjust cervical stop to appropriate marks and snap firmly in place. e.g., if the uterine depth measures 8cm, then slide and set Cervical Stop (E) at the 8cm mark.
   Note: The default value of centimeter depth marking for Cervical Stop is six.
3. If necessary, enlarge the uterine cervix to #13-14 hand size with proper existing surgical techniques. The inflatable cuff may tear if it is forced into a cervix too tight, leading to possibly ineffectiveness and injury of uterine cervix. Lubricate Intrauterine Cuff (A) and Distal Tip (C) for easy insertion. Guide the instrument carefully alongthe natural axis of the cervix to avoid injury. Insert the instrument into the endometrial cavity until the face of Cervical Stop (E) touches the external cervix. Insert a standard plastic syringe to air port of Inflation Valve (B) to inflate the Intrauterine Cuff (A) gradually with 5 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.
4. Pull gently on the instrument to be sure cuff inflation is adequate. Excessive cuff inflation may cause utero-tubal spasm and physiologic closure of patent tubes. 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. Remove speculum and tenaculum. Leave proximal end of instrument between patient's legs in order to operate.
   CAUTION: DO NOT inject cold fluid or fluid/gas rapidly that may cause utero-tubal spasms.
5. Attach contrast media to open syringe and introduce through injection port. Upon completion of operation, insert a syringe in the valve and deflate the cuff, then remove the instrument carefully, and inspect the device for its integrity after use to ensure no parts are left inside.

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

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

Reporting of Serious Incidents

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

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