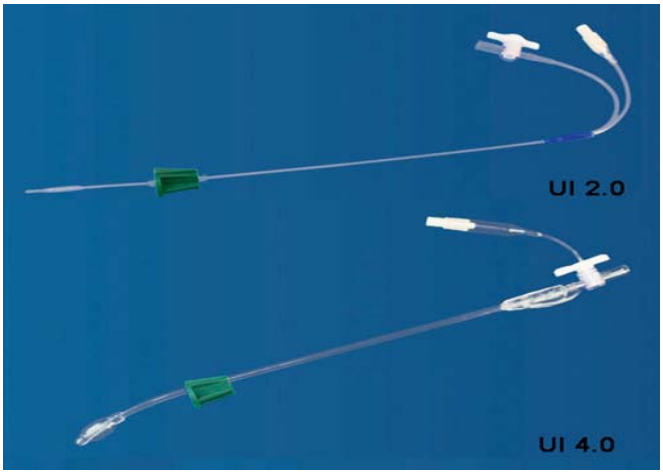
PAN PAC®

Uterine Injector



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STERILE EO

LATEX FREE

CE 0434 EC REP Wellkang Ltd (www.CE-marking.eu)
29 Harley St., London W1G 9QR, UK

Panpac 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 which meets the USP recommendation for class VI testing.

PRODUCT NAME

THE INJECTOR-4.0 / THE INJECTOR-2.0

PRODUCT NO.

UI 2.0 / UI 4.0

SPECIFICATION

Product No.	Length	OD size
UI 2.0	28cm (11.0”)	2.0mm
UI 4.0	26.2cm (10.3”)	4.0mm

INDICATIONS

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

WARNINGS

1. The safety and effectiveness of Panpac Uterine injectors have not been demonstrated in the setting of uterine bleeding.
2. DO NOT use this device when the sterile pouch has been punctured or damaged.
3. Test inflatable cuff before insertion for possible leakage. DO NOT use the device while the Cuff is malfunction.
4. Inject 5cc of air (UI-4.0) / 3cc of air (UI-2.0) 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.
5. NEVER introduce fluid such as contrast media or water to inflate the Intrauterine Cuff (A). Such act will impair Intrauterine Cuff.
6. Do not reuse for avoiding user may be infected by the microorganism.

PRECAURTIONS

1. Sound the depth and direction of uterus prior to using the Injector-4.0 or the Injector-2.0. 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.

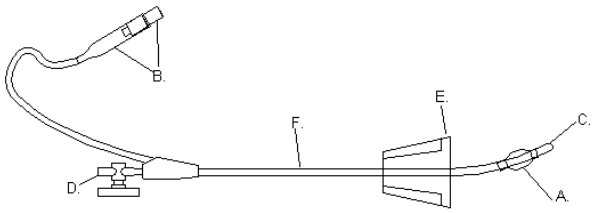
Version 3.0 2010-12

ADVERSE REACTIONS

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

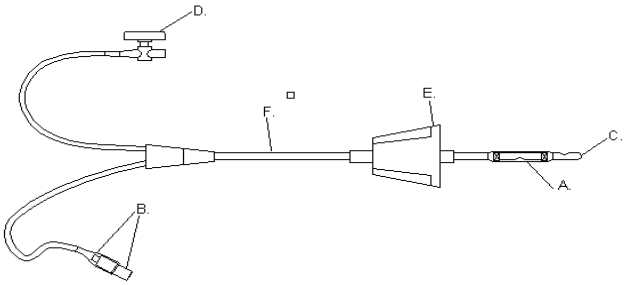
The Injector-4.0

A. Intrauterine Cuff
B. Inflation Valve and Pilot Balloon
C. Distal Tip
D. Stopcock
E. Cervial Stop
F. The rigid tubing with centimeter depth markings



The Injector-2.0

A. Intrauterine Cuff
B. Inflation Valve and Pilot Balloon
C. Distal Tip
D. Stopcock
E. Cervial Stop
F. The rigid tubing with centimeter depth markings



DIRECTIONS FOR USE

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 (UI-4.0) / 3 cc of air (UI-2.0) 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 INJNETOR-2.0 as a uterine sound is forbidden. Set the 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 along the 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 (UI-4.0) / 3 cc of air (UI-2.0) 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.

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)