EXPLANATION OF SYMBOLS

REF Reorder Number

LOT Batch Code

Use-by date

Do not resterilize

Do not reuse

Consult instructions for use

Do not use if package is damaged

LATEX Contains or presence of natural rubber latex

Caution

R_x Only U.S. Federal Law restricts this device to sale by on the order of of a physician

STERILE EO Sterilized using Ethylene Oxide

Manufacturer

CooperSurgical
95 Corporate Drive • Trumbull, CT 06611 USA
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ZSI1153-IFU • Rev. A • 05/16

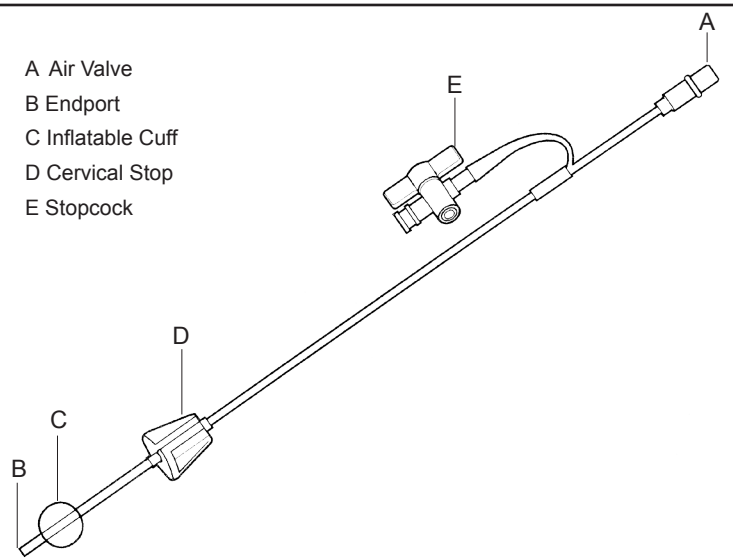
ZUI 2.0™

Zinnanti Uterine Injector

For such procedures as Hysterosalpingograms, Salpingoplasties and Hydrotubation

REF ZSI1153

Instructions For Use



LENGTH: 23 cm (9”)
OD SIZE: 2.0 mm

This product contains or has presence of natural rubber latex which may cause allergic reactions.

DESCRIPTION

ZUI 2.0 (Zinnanti Uterine Injector) is a single-use, sterile/disposable, clear polyvinyl chloride uterine injector which meets USP recommendations for implant testing.
This product is designed with a double-lumen, one for inflation of a 2 cc intrauterine cuff and the other for injection of fluid through a distal endport. The product is slightly curved to facilitate easy entrance into the uterus through the cervical canal. The product features an inflation valve **(A)**, an endport **(B)**, an inflatable cuff **(C)**, a removable cervical stop **(D)**, and a stopcock **(E)** to accommodate a syringe. The device has a length of 23 cm and an outer diameter of 2.0 mm.

INDICATIONS FOR USE

ZUI 2.0 (Zinnanti Uterine Injector) is indicated for in-office or hospital use when efficient sealing of the uterine cervix is required for the injection of liquid or gas such as hysterosalpingography, salpingoplasties, hydrotubation and Rubin's Test. ZUI 2.0 can be used without cervical dilation or anesthesia if the uterus can be sounded easily with a standard uterine sound

CONTRAINDICATIONS

- ZUI 2.0 should not be used in pregnant patients, in patients suspected of being pregnant or in the case of uterine or tubal infection.
- ZUI 2.0™ should not be used in patients with a known sensitivity or allergy to latex rubber.

WARNINGS

- Insure that the snap-on cervical stop **(D)** is secured to the catheter with the flat face of the cervical stop well fixed on the tube (see Figure 1). (It is possible that the stop may become loosened from shipment or improper handling. It is easy to snap back on before usage.) To avoid uterine trauma, thread the ZUI 2.0 along the natural axis of the cervical canal. To reduce the possibility of missing the natural axis of the cervical canal, be sure to sound the uterus prior to using this device.
- Contents supplied sterile. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.
- This product contains natural rubber latex which may cause allergic reactions.

PRECAUTIONS

Inflate uterine cuff **(C)** to check for leakage before insertion. Lubricate distal end (cuff and catheter) for easy insertion. Observe manufacturer's directions and precautions pertaining to any liquid media or gas that is being injected into the patient.

After removal of this product following a procedure, ALWAYS inspect the device for intactness.

ADVERSE REACTIONS

Uterine spasm with accompanying temporary physiologic blockage of patient's fallopian tubes.

- Cramping
- Infection
- Perforation of uterine wall

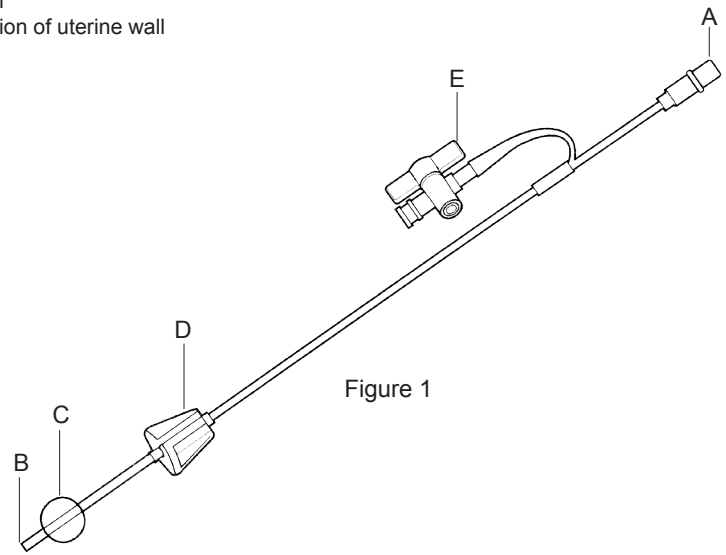


Figure 1

INSTRUCTIONS FOR USE

1. Check to see that the sterile pouch containing the ZUI 2.0 Uterine Injector has not been punctured or damaged thus compromising sterility.
2. Inspect carefully to ensure that the cervical stop **(D)** is securely in place. If the stop is not fixed and slides easily, snap it securely in place before using.
3. Using a plastic syringe, inflate the cuff **(C)** with 2 cc of air to check for leakage before inserting into patient. Air is injected through the valve assembly **(A)**.
4. After checking inflatability, evacuate all the air.
5. Using a speculum, expose cervix and grasp the anterior lip with a single tooth tenaculum.
6. Sound the uterus for depth and direction. If the sound does not slide easily or drags, **do not force the injector through.** The cuff may tear if the cervical opening is too narrow.
7. Lubricate the distal endport **(B)** and cuff **(C)** for easy insertion. Carefully glide the instrument along the natural axis of the cervix to avoid injury.
8. Insert the injector fully into the uterus until the face of the cervical stop **(D)** abuts the external cervix. Slowly inflate the cuff with 1.5-2 cc of air until you notice the cervical stop being pulled up tightly against the cervix. The inflating cuff grasps the lower uterus between itself and the fixed cervical stop. Hold thumb on plunger as you remove the syringe from the inflation valve to prevent reflux of air back into the syringe.
9. Pull on the instrument gently to see if the inflation of the cuff is adequate to prevent expulsion of the inflated cuff with normal intrauterine injection pressure. The less the cuff is inflated, the easier it can be expelled with excessive intrauterine injection pressure. If, however, the cuff is inflated beyond the amount of air needed to gently grasp the uterus, there will be more discomfort for the unanesthetized patient. This tense inflated cuff in the smaller uterus may also set up a "foreign body" like reaction causing utero-tubal spasm that may give the patient a physiological blockage of the tubes at the cornua.
10. The uterus is now grasped and the OS sealed. The speculum and tenaculum may be removed without disturbing the seal or losing the device. The patient may be repositioned in the dorsorecumbent position with easy access to the uterine cavity maintained. The plastic tube is pliable enough to be bent in the desired direction.
11. Injection media may be applied with a standard syringe and plastic stopcock or extenders as needed. Easy access to the uterus during Salpingoplasties may be achieved by attaching an extender to the stopcock **(E)**.
12. To remove the ZUI 2.0 Uterine Injector, insert the syringe deeply into the air valve **(A)** and deflate cuff. Carefully remove the instrument, checking carefully to be sure the device is intact and no parts remain in the vaginal canal.