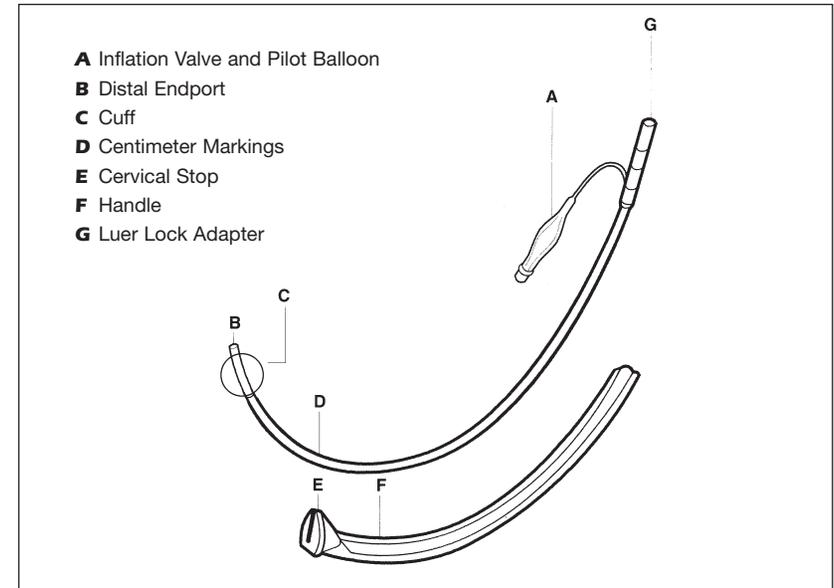


ZUMI 4.5™

Zinnanti Uterine Manipulator-Injector

*For such procedures as Minilaparotomy,
Salpingoplasties and Fertility Examinations*

Directions For Use



REF # ZSI 1151
LENGTH 33cm (13")
OD SIZE 4.5mm

PACKAGED 12 Individually packaged sterile disposable **latex-free** devices per box.

STERILE Unless package has been opened or damaged.
Ethylene Oxide Gas Sterilized.

DISPOSABLE Discard after single use.

CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician.

-  See Instructions for Use
-  Single Use Only/Do Not Reuse
-  Batch Code/Lot
-  Expiration Date (e.g. YYYY-MM)
-  Ethylene Oxide Sterilized
-  Irradiation Sterilized
-  Latex-Free

Rx ONLY **Caution:** Federal law restricts this device to sale by or on the order of a physician.

SN Serial Number

REF Catalog/Reorder Number

 Date of Manufacture (e.g. 2002-09)



Trumbull, CT 06611
 Phone: (203) 601-5200
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   **Rx ONLY**



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DESCRIPTION

ZUMI 4.5 (Zinnanti Uterine Manipulator-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 10cc intrauterine cuff and the other for injection of fluid through a distal endpoint. The product is slightly curved to facilitate forward uterine manipulation. The product features an inflation valve and pilot balloon assembly (A), an endport (B), an inflatable cuff (C), centimeter depth markings (D), a cervical stop (E), a removable rigid plastic handle (F) and a luer fitting to accommodate a syringe (G). The device has a length of 33cm and an outer diameter of 4.5mm.

INDICATIONS FOR USE

ZUMI 4.5 (Zinnanti Uterine Manipulator-Injector) is indicated in diagnostic laparoscopy, minilaparotomy, fertility examinations and salpingoplastic procedures where manipulation of the uterus is required. This product also facilitates the sealing of the cervical OS while providing a fluid or air injection port.

CONTRAINDICATIONS

ZUMI 4.5 should not be used in pregnant patients, in patients suspected of being pregnant or in the case of uterine or tubal infection.

WARNINGS

Insure that the handle (F) is secured to the catheter with the flat face of the cervical stop well fixed on the tube at the 6cm mark. (It is possible that the handle may become loosened from shipment or improper handling. It is easy to snap back on at the 6cm mark before usage.) To avoid uterine trauma, insertion of the cuff before manipulation is essential. Insert the ZUMI 4.5 along the proper axis to avoid trauma to the uterus.

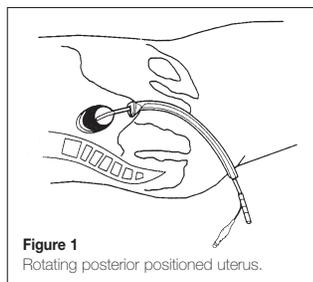
PRECAUTIONS

Lubricate catheter tip before insertion. Test inflatable uterine cuff (C) to check for leakage before insertion. Check for necessity to dilate cervix **before** insertion to avoid tearing inflatable cuff. Observe manufacturer's directions and precautions pertaining to any liquid media or gas that is being injected into the patient. After insertion and inflation, insure that the cuff (C) is properly inflated by squeezing the pilot balloon (A) and check for tautness. A device with a deflated cuff may injure or perforate the uterine wall. 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



DIRECTION FOR USE

- 1** Check to see that the sterile pouch containing the ZUMI 4.5 Uterine Manipulator-Injector has not been punctured or damaged thus compromising sterility.
- 2** Be sure handle (F) is securely in place with the flat side of stop at the 6cm mark.
- 3** Using a standard plastic syringe, test the inflatable cuff (C) by inserting 3-10cc of air into valve assembly (A).
- 4** After checking inflatability, evacuate all the air from the cuff for insertion of the manipulator. With the patient in the lithotomy position, expose the cervical OS. Then grasp the anterior lip of the cervix with a single tooth tenaculum.
- 5** Sound the uterus for depth and direction. Unless the uterus sounds to less than 6cm, insert the ZUMI 4.5 as is with the face of the cervical stop securely attached at the 6cm mark on the tube. The handle is removable for adjustment.
- 6** Ascertain if the cervix needs dilation. Dilate to #14 Hank size using appropriate surgical techniques or use a closed standard uterine dressing forceps to dilate cervix. The inflatable cuff (C) of the ZUMI 4.5 may tear if a wide enough passage is not afforded.
- 7** Lubricate the distal endpoint (B) and cuff (C) for easy insertion. Carefully guide the instrument along the natural axis of the cervix to avoid injury.
- 8** Insert the ZUMI 4.5 into the uterus until the face of the cervical stop (E) abuts the external cervix. Slowly inflate the cuff with 3-10cc 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** To ensue that the cuff (C) has not ruptured during the procedure, check the tautness of the pilot balloon (A). A soft balloon indicates a ruptured or leaking cuff.
- 10** Pull on the instrument gently to see if the inflation of the cuff is adequate to prevent expulsion of the inflated cuff during injection procedures. Excessive cuff inflation may cause utero-tubal spasm or a "foreign body" like reaction and physiologically close patent tubes. Rapid injection of fluid or gas, or injection of cold fluid may also cause utero-tubal spasms.
- 11** The speculum and tenaculum may be removed once the uterus is secured and sealed. The patient may be repositioned in the dorsorecumbent position with the proximal end of the ZUMI 4.5 available between the legs.
- 12** Posterior positioned uteri (Figure 1) can be rotated to the anterior position by placing the ZUMI 4.5 into the uterus posteriorly and carefully rotating it anteriorly before or after cuff inflation.
- 13** Before manipulating or injecting, check that the cuff (C) is inflated by observing pilot balloon inflation. The cervical seal will be lost should the cuff break. A deflated cuff increases the danger of uterine wall perforation.
- 14** To remove the ZUMI 4.5 Uterine Manipulator-Injector, insert a syringe deeply into the air valve (A) and deflate cuff. Carefully remove the instrument, checking carefully to be sure the device is intact and that no parts remain in the vaginal canal.