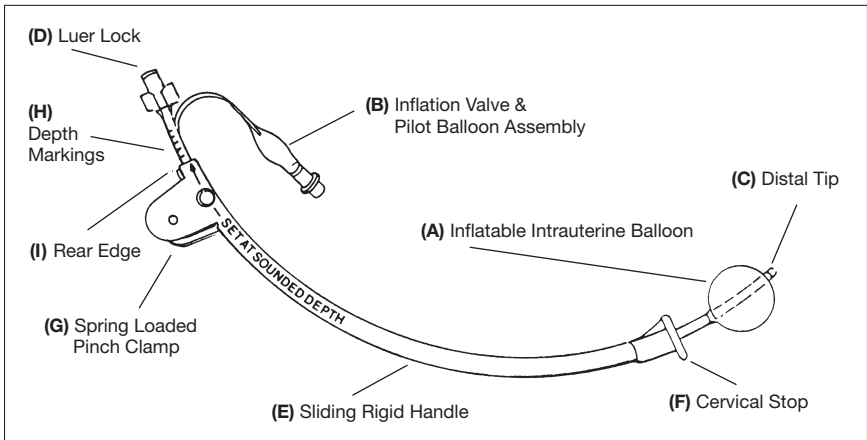


Kronner Manipujector®

Uterine Manipulator-Injector

*For such procedures as Diagnostic Laparoscopy Minilaps,
Laparoscopic Tubal Occlusion and Fertility Studies*

DIRECTIONS FOR USE



REF	6003
LENGTH	33cm (13")
O.D. SIZE	5.0mm
PACKAGED	12 Individual 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.



CooperSurgical

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DESCRIPTION

The Kronner Manipujector® (Uterine Manipulator-Injector) is a gently curved, single-use, sterile, disposable, latex-free double lumen device made of clear polyvinyl chloride which meets USP requirements for implant testing. The double-lumen tube is 33cm (13") long; has an OD (Outside Diameter) of 5mm, and is marked along the tube segment from the rear of the handle. The insertion depth (H) is marked from 5-10cm in 1cm increments. Surrounding the distal end but not covering the tip is an inflatable balloon (A) which is inflated using a standard syringe (not included) via an inflation valve and pilot balloon assembly (B). The distal tip (C) is open to allow the introduction of appropriate media into the uterus. The media can be passed through the inner injection lumen via a luer lock connector (D) with a syringe (not included). The curved non-removable sliding rigid handle (E) has a molded cervical stop (F) at the distal end and a spring loaded pinch clamp (G) on the proximal end.

Firmly squeezing the pinch clamp allows the cervical stop to be positioned at the desired measured depth. When released, the spring loaded pinch clamp forces a pin into the hard wall of the catheter preventing any movement of the handle once it is in the desired position. The balloon is inflated in the uterus and is retracted against the internal os. By advancing the cervical stop firmly against the cervix, the instrument will maintain a secure, trauma-free hold on the uterus. The operator can then safely manipulate the uterus and inject media into the uterus without reflux through the cervical canal.

INDICATIONS FOR USE

The Kronner Manipujector (Uterine Manipulator-Injector) is indicated for use during those procedures requiring manipulation of the uterus such as minilap tubal ligation, laparoscopic tubal occlusion, diagnostic laparoscopy or operative laparoscopy. It is also an efficient intrauterine injector that effectively seals the internal cervical os against the cervical back-flow of fluid or gas during its injection through the device's central lumen. As such it can be used in laparoscopic tubal patency studies such as chromotubation and in selected patients for such a procedure as hysterosalpingography.

CONTRAINDICATIONS

The Kronner Manipujector (Uterine Manipulator-Injector) should not be used in patients who are pregnant or in patients suspected of being pregnant.

WARNINGS

- The Kronner Manipujector (Uterine Manipulator-Injector) should be inserted along the correct axis, (which depends upon the position of the uterus), to reduce the possibility of uterine trauma. Sound the uterus prior to using the Kronner Manipujector (Uterine Manipulator-Injector) to determine both the direction and depth of the uterus.
- Always set the sliding handle cervical stop at the uterine sounded depth, e.g., if sounded depth is 7cm, set cervical stop at 7cm. The cervical stop should be set using the cm markings on the catheter.
- **NEVER** use the device with the intrauterine balloon deflated.
- **DO NOT** underinflate the intrauterine balloon. Underinflation will defeat the purpose of the balloon; that is to provide a gentle "air cushion" against the uterine wall for safer manipulatory control. Underinflation may also result in spontaneous expulsion of the devices as intrauterine pressure builds during its use as a fluid or gas injector. The use of 10cc of air is recommended since approximately 2cc will be consumed in the pilot balloon and inflation tube.
- **NEVER** use fluid to inflate the distal balloon. Use of fluid will not effectively inflate the distal balloon due to the small diameter of the inflation channel lumen and failure of the device may occur. Moreover, the use of fluid could potentially cause the balloon to burst since fluid is not compressible and the balloon will over-distend.

WARNINGS (continued)

- The Kronner Manipujector (Uterine Manipulator-Injector) has an OD (Outside Diameter) of 5mm. Its use in hysterosalpingography and Rubin's Test should be reserved for the patient with a large uterus (multiparous, post-abortal, etc.) that will accept this size comfortably without anesthesia. Otherwise it is recommended that the Kronner Manipujector (Uterine Manipulator-Injector)'s companion instruments HUI® (Harris Uterine Injector) or HUI® Mini-Flex (Flexible Harris Uterine Injector) be used (see separate package insert for HUI® or HUI® Mini-Flex instructions).
- As with any occlusive balloon device when used as an injector, the Kronner Manipujector (Uterine Manipulator-Injector) can create high intrauterine pressures which could be accompanied by vascular extravasation. **DO NOT** inject fluid or gas rapidly.

PRECAUTIONS

- Test inflate intrauterine balloon prior to insertion.
- Lubricate distal end of tube and intrauterine balloon before insertion.
- The cervical os should be #13-14 Hank size before inserting the Kronner Manipujector (Uterine Manipulator-Injector) for easy passage and to prevent tearing the intrauterine balloon.
- When injecting any liquid media, closely follow the manufacturer's Directions for Use that accompany that product.

ADVERSE REACTIONS

The following adverse reaction have been suspected or reported, The order of listing does not indicate frequency or severity.

- Injury to uterus (perforation) ▪ Cramping ▪ Infection
- Uterine spasm with temporary physiologic blockage of patient fallopian tubes.

DIRECTION FOR USE

- 1** Remove the sterile Kronner Manipulator (Uterine Manipulator-Injector) from its protective peel-apart package. Draw 10cc of air into a standard plastic syringe and then insert syringe into the inflation valve assembly. Test inflate the intrauterine balloon by injection of the air in the syringe. Remove the syringe and check that the balloon remains inflated.
- 2** Following test inflation, reinsert the syringe firmly into the inflation valve assembly to open the valve. Completely evacuate all the air in the balloon with the syringe. Then remove the syringe.
- 3** With the patient in the lithotomy position, use a vaginal speculum to expose the uterine cervix and grasp the anterior cervical lip with a single tooth tenaculum.
- 4** Probe the uterus for depth and direction with a uterine sound. **DO NOT** use the Kronner Manipujector (Uterine Manipulator-Injector) as a uterine sound. Before inserting the Kronner Manipujector (Uterine Manipulator-Injector) into the uterus, determine its direction and set the device for effective uterine depth as indicated by sounding.

To Set the Depth—

- A** Locate the depth marks (5cm thru 10cm) at the rear underside of the catheter tube.
- B** Firmly squeeze the pinch clamp at the proximal end of the handle to reposition the catheter within the handle.
- C** With the pinch clamp compressed, slide the catheter until the selected depth mark aligns with the rear edge (I) of the handle marked by the arrow; e.g., if the uterine depth measures 7cm, then set the handle at the 7cm mark.
- D** Release the pinch clamp to secure the catheter within the handle.

DIRECTION FOR USE (continued)

NOTE When the handle is correctly set, the actual insertion depth of the catheter will be 1 cm less than indicated by the printed scale. Thus the intrauterine catheter shaft will be positioned in the uterus at 1 cm less than the sounded depth and minimize the possibility of over-inserting the instrument.

- 5 Lubricate the instrument's distal tip and intrauterine balloon lightly with a sterile, water soluble gel of your choice. Draw 10cc of air into a standard plastic syringe and insert the syringe firmly into the inflation valve assembly.
DO NOT INFLATE THE INTRAUTERINE BALLOON AS YET.
- 6 With the balloon deflated, insert the lubricated instrument into the cervix in the direction of the curve of the uterine cavity (**Figures 1 & 2**). If necessary, dilate the cervix to #13-14 Hank size following currently accepted surgical techniques. If the Uterine Manipulator-Injector is forced into too tight a cervix the intrauterine balloon may tear, rendering it ineffective, and may produce some cervical trauma.
- 7 Continue insertion until cervical stop rests firmly against the cervix.
WHILE STILL MAINTAINING SLIGHT FORWARD INSERTION PRESSURE, inflate the intrauterine balloon with the 10cc of air contained in the plastic syringe. Note that the pilot balloon is now expanded and taut indicating that the intrauterine balloon is properly inflated. Inflation with the full 10cc of air is recommended. (The amount of inflation should be determined by clinical judgment as to the size of the uterus. Underinflation should be avoided since it:
A Reduces the degree of manipulatory control.
B Defeats the air cushion protectiveness of the balloon.
C May allow spontaneous expulsion of the device through a large cervix.
D May allow reflux leakage of injected fluid through the cervix. (**Figure 3**)

Remove the syringe **IMMEDIATELY** following inflation of the intrauterine balloon. (If the syringe plunger is release while the syringe is still attached to the inflation valve assembly, the back pressure of the balloon will allow the air to return to the syringe resulting in deflation of the intrauterine balloon).

- 8 If the insertion is made in the posterior direction due to retroflexion of the uterus, after inflating the balloon the Kronner Manipjector (Uterine Manipulator-Injector) should be rotated 180° to place the uterus in the normal anteverted position. (This action will not rotate the uterus. The balloon will simply rotate within the uterine cavity).
- 9 After inserting the catheter into the uterus and inflating the balloon, place gentle outward traction on the proximal end of the catheter. The intrauterine balloon is thus retracted against the internal os of the uterus. While maintaining traction on the proximal end of the catheter with one hand, firmly squeeze the pinch clamp with the thumb and forefinger

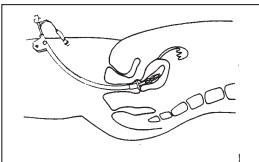


Figure 1
Normal or anteverted uterus. Initial insertion, balloon deflated.

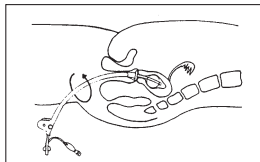


Figure 2
Retroflexed uterus. Initial insertion, balloon deflated. Balloon is then inflated, syringe removed and the **MANIPUJECTOR** rotated 180° to the normal position.

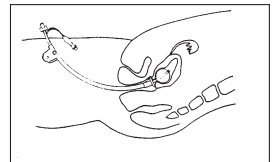


Figure 3
Completed insertion. With balloon inflated, place traction on catheter, advance handle. Manipulate uterus toward abdominal wall.

DIRECTION FOR USE (continued)

DIRECTION FOR USE (continued)

of the other hand. Advance the handle to snug the cervical stop against the cervix and release the pinch clamp. Observe that the depth setting changes when performing this step. The Uterine Manipulator-Injector is firmly in control of the uterus.

- 10** Test the placement of the instrument Uterine Manipulator-Injector by applying gentle traction on the instrument to insure that the uterus is properly grasped.
- 11** The speculum and single tooth tenaculum, if used, may be removed. The grasp of the uterus by the Uterine Manipulator-Injector will not be disturbed. The patient can assume the dorsorecumbent position with the end of the Kronner Manipujector (Uterine Manipulator-Injector) available to the operator for manipulation. The Kronner Manipujector (Uterine Manipulator-Injector) is ready for uterine manipulation and the internal cervical os is occluded to prevent reflux during the introduction of fluid or gas as required.
- 12** To demonstrate tubal patency, insert a standard plastic syringe filled with the appropriate media into the Luer Lock at the proximal end of the catheter and inject into the uterus. A plastic stopcock and extension tube can be interposed, allowing the injection syringe to be brought under the physician's complete control during the procedure. The injection of the selected media will pass through the instrument's inner lumen and will exit into the uterine cavity from the distal tip. **DO NOT** inject fluid or gas too rapidly. The Kronner Manipujector (Uterine Manipulator-Injector) is a superb occlusive injector and as such can build high intrauterine fluid or gas pressure. Rapid injection may cause expulsion of the instrument, create vascular extravasation or produce uterine and fallopian tube spasm that may result in a physiologic blockage to passage of media. Slow but steady injection has been shown to produce excellent results.
- 13** Careful medical judgement must be used when a clinical situation requires the manipulation of a large boggy, post-abortion uterus. Any manipulator including the Kronner Manipujector (Uterine Manipulator-Injector) must be used with great care. In such situations the uterus may well have a universal joint at the uterocervical junction and the Kronner Manipujector (Uterine Manipulator-Injector) may only manipulate the cervix. In this difficult situation you may elect to increase the intrauterine depth of the instrument's shaft by moving the rigid handle proximally, thereby placing the balloon at the distal end of the uterine cavity. Be aware that using the balloon at the fundus or in any other location within the uterine cavity other than at the internal os will not provide a seal against fluid reflux through the cervical canal. Make sure the intrauterine balloon is fully inflated with 10cc of air and frequently check the pilot balloon assembly connected to the inflation valve to insure adequacy of distal balloon inflation. Should the intrauterine balloon rupture during use, the pilot balloon will not feel taut when compressed between the fingers. If this has occurred, cease manipulation immediately, remove and replace the device. The rigid tip without the inflated balloon could more easily damage the soft uterine wall during manipulative attempts. If at any time the intrauterine balloon has ruptured, the cervical seal will be lost.
- 14** To replace and remove the Uterine Manipulator-Injector from the uterus, insert a plastic syringe firmly into the inflation valve assembly to open the valve. The air is then aspirated completely from the intrauterine balloon with the syringe. Carefully remove the Uterine Manipulator-Injector from the uterus and vagina. **DO NOT** use excessive force when removing the instrument since the cervical stop may traumatize the vagina, especially if the vaginal speculum has been previously removed.

Legal Community Representative—



Leisegang Feinmechanik GmbH
Leibnizstraße 32
D-10625, Berlin GERMANY



See Instructions for Use



Single Use Only/Do Not Reuse



Batch Code/Lot



Expiration Date (e.g. 2002-09)



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)

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