POINTS TO REMEMBER (REFER TO EARLIER PAGES FOR COMPLETE DETAILS)

- Sound uterus for depth and direction before use of HUMI.
- ALWAYS set HUMI to correct uterine depth before use and NEVER use HUM without properly attaching the rigid handle or properly inflating the intrauterine balloon.
- Lubricate distal tip and intrauterine balloon before insertion of HUMI.
- Be sure to insert HUMI along the correct uterine axis as determined by sounding. If posterior insertion is made rotate HUMI to normal position after intrauterine balloon inflation.
- ALWAYS maintain full forward insertion pressure on HUMI while inflating intrauterine balloon. Relaxing on this pressure before balloon inflation will allow the instrument to self retract from the uterus and may cause the balloon to be inflated within the cervical canal from which it will be easily expelled.
- ALWAYS remove the syringe used for inflation of the intrauterine balloon immediately after inflation. Letting go of this syringe while it is still in the inflation valve following inflation will allow the intrauterine balloon to spontaneously deflate due to back pressure. This can lead to easy expulsion of the instrument and defeats the manipulatory control and safety advantages of HUMI.
- DON'T UNDERINFLATE HUMI. Remember 2 cc of air will be trapped in the pilot balloon and inflation tube. Use up to a total of 10 cc of air.
- Though not recommended, some physicians use saline to inflate the intrauterine balloon. If you elect to do so, remember that saline is NOT as compressible as air, and, therefore, a potential for balloon rupture exists.
- Following a procedure ALWAYS check HUMI for intactness upon removal.

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

Not made with 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
Phone: (800) 243-2974 • Fax: (800) 262-0105
International Phone: (203) 601-9818 • Fax: (203) 601-4747
www.coopersurgical.com

6001-IFU • Rev. A • 05/16

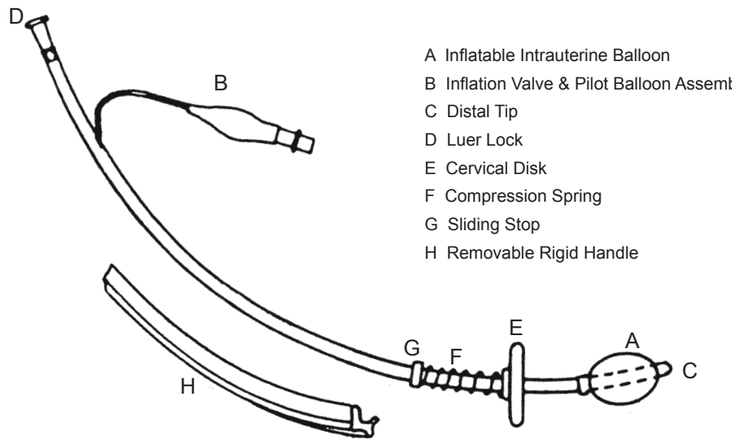
HUMI®

Harris-Kronner Uterine Manipulator-Injector

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

REF 6001

Instructions For Use



A Inflatable Intrauterine Balloon
B Inflation Valve & Pilot Balloon Assembly
C Distal Tip
D Luer Lock
E Cervical Disk
F Compression Spring
G Sliding Stop
H Removable Rigid Handle

LENGTH: 33 cm (13")
OD SIZE: 5 mm

DESCRIPTION

HUMI (Harris-Kronner Uterine Manipulator-Injector) is a gently curved, single-use, sterile/disposable, double lumen device made of clear polyvinyl chloride which meets USP requirements for implant testing. The double-lumen tube is 33 cm (13") long; has an OD (Outside Diameter) of 5 mm; and is marked along its distal segment from 6-12 cm to establish the depth of insertion. 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 which can be passed through the inner injection lumen via a luer lock connector (D) with a syringe (not included). A movable assembly consisting of a rigid cervical disk (E) a compression spring (F) and a sliding stop (G) can be positioned along the tube at the desired depth of insertion. A rigid snap-on handle (H) provides both purchase and rigidity and prevents backward movement of the sliding stop when positioned against it.

INDICATIONS FOR USE

HUMI (Harris-Kronner Uterine Manipulator-Injector) is indicated for use during those procedures requiring manipulation of the uterus such as a minilap tubal ligation, laparoscopic tubal occlusion or diagnostic 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 and in selected patients, for such procedures as hysterosalpingography and Rubin's Test.

CONTRAINDICATIONS

HUMI should not be used in patients who are pregnant or in patients suspected of being pregnant.

WARNINGS

- HUMI 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 HUMI to determine both the direction and depth of the uterus.
- ALWAYS set the sliding stop at the depth of intended insertion as determined by uterine sounding then attach the rigid handle so that it approximates the sliding stop and prevents its movement.
- NEVER use the device with the rigid handle detached or 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 device as intrauterine pressure builds during its use as a fluid or gas injector. Between 5 to 10 cc of air is recommended since approximately 2 cc will be consumed in the pilot balloon and inflation tube.
- HUMI has an OD (Outside Diameter) of 5 mm. 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 HUMI's companion instrument HUI® (Harris Uterine Injector) be used (see separate package insert for HUI® instructions).
- As with all occlusive balloon devices, when used as an injector, HUMI can create high intrauterine pressures which could be accompanied by vascular intravasation. DO NOT inject fluid or gas rapidly.
- 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.

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 HUMI insertion 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.
- After removal of HUMI following a procedure ALWAYS inspect the device for intactness.

ADVERSE REACTIONS

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

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

INSTRUCTIONS FOR USE

1. Remove the sterile HUMI from its protective package. Draw 5-10 cc 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 and then completely evacuate all the air in the balloon with the syringe. Then remove the syringe.
3. With the patient in the lithotomy position, expose the uterine cervix and grasp the anterior lip with a single tooth tenaculum.
4. Probe the uterus for depth and direction with a uterine sound. DO NOT use HUMI as a uterine sound. If necessary, dilate the cervix to #13-14 Hank size following currently accepted surgical techniques. If HUMI is forced into too tight a cervix the intrauterine balloon may tear, rendering it ineffective, and may produce some cervical trauma.
5. Now set the device for effective uterine depth as indicated by sounding. To do this (a) remove the rigid handle by simply pulling it away from the instrument's shaft, (b) adjust the plastic sliding stop (along with its attached compression spring and cervical disk) to the cm setting marked on the instrument's shaft that corresponds to the uterine depth finding, (c) replace the rigid handle by placing one end of it flush against the sliding stop and then pressing the instrument's shaft into the handle until it snaps snugly into place. This results in an effective intrauterine shaft length of approximately 1 cm less than the sounded depth. NEVER USE HUMI WITHOUT PERFORMING THESE ADJUSTMENTS OR WITHOUT THE RIGID HANDLE PROPERLY ATTACHED.
6. Lubricate the instrument's distal tip and intrauterine balloon lightly with the water soluble gel of your choice. Then draw 5-10 cc 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.
7. Insert the lubricated instrument, with the balloon deflated, into the cervix in the direction of the curve of the uterine cavity. (See Figures 1 & 2)
8. Continue insertion until the cervical disk compresses the spring completely to the previously adjusted depth setting. Then, WHILE STILL MAINTAINING FORWARD INSERTION PRESSURE, inflate the intrauterine balloon with the 5-10 cc of air contained in the plastic syringe. Note that the pilot balloon is expanded. It indicates that the intrauterine balloon is properly inflated. (The amount of inflation should be determined by clinical judgment as to the size of the uterus. Underinflation should be avoided since it reduces the degree of manipulatory control and defeats the air cushion protectiveness of the balloon. It may also allow spontaneous expulsion of the device through a large cervix). (See Figure 3)

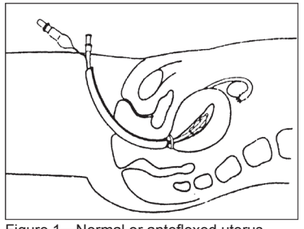


Figure 1—Normal or anteflexed uterus. Initial insertion, balloon deflated.

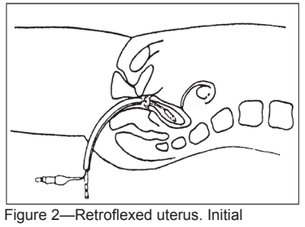


Figure 2—Retroflexed uterus. Initial insertion, balloon deflated. Balloon is then inflated, syringe removed and the HUMI rotated 180o to the normal position.

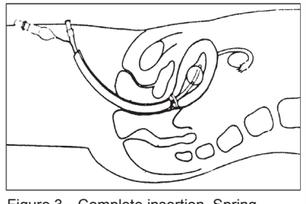


Figure 3—Complete insertion. Spring compressed and balloon inflated. Uterus manipulated toward anterior abdominal wall.

9. Remove the syringe IMMEDIATELY following inflation of the intrauterine balloon. (Releasing the syringe while it is still attached to the inflation valve assembly will allow the intrauterine balloon to deflate due to back pressure).
10. If insertion was made in the posterior direction due to retroflextion of the uterus, HUMI should not be rotated 180° to the normal position. This action will not rotate the uterus. The balloon will simply slide within the uterine cavity.
11. Now, by applying gentle traction on the device, check that HUMI is secure and that the uterus is grasped.
12. The speculum and single tooth tenaculum may now be removed and the uterine grasp will not be disturbed. The patient can now assume the dorsorecumbent position with the end of the HUMI available to the operator for manipulation.
    HUMI IS NOW READY FOR UTERINE MANIPULATION AND THE INTERNAL CERVICAL OS OCCLUDED TO PREVENT REFLUX DURING THE INTRODUCTION OF FLUID OR GAS AS REQUIRED.
13. To inject fluid or gas into the uterus to demonstrate tubal patency, use a standard plastic syringe inserted into the Luer Lock at the proximal end of the shaft. A plastic stop cock and extension tube can be interposed, allowing the injection syringe to be brought under the operators complete control. The selected media will pass through the instrument's inner lumen and will exit into the uterine cavity from the distal tip.
    BE SURE NOT to exert forward pressure on HUMI during this stage of the procedure since doing so may displace the intrauterine balloon form its occlusive position at the internal cervical os and could allow reflux to occur. DO NOT INJECT FLUID OR GAS TOO RAPIDLY. HUMI 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 INTRAVASATION 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.
14. Careful medical judgment must be used when a clinical situation requires the manipulation of a large boggy post-abortal uterus. Any manipulator including HUMI must be used with great care. In such situations the uterus may well have a universal joint at the uterocervical junction and HUMI 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 and adjustable stop proximally. Make sure that the intrauterine balloon is fully inflated with 10 cc of air and frequently check the pilot balloon assembly connected to the inflation valve. Should the intrauterine balloon rupture during use, the pilot balloon will not feel taut when compressed between the fingers. If the intrauterine balloon had ruptured, the cervical seal will be lost, and the rigid tip without the inflated balloon could more easily damage the soft uterine wall during manipulative attempts. Should this occur, cease manipulation immediately and remove the device.
15. To remove HUMI, insert a plastic syringe FIRMLY into the inflation valve assembly to open the valve then draw off the air completely from the intrauterine balloon with the syringe. This releases HUMI from the uterus. Now carefully remove HUMI from the vagina. DO NOT use excessive force since the cervical disk may traumatize the vaginal canal. Two fingers can be used to help keep the cervical disk from becoming lodged in the vagina.
16. AFTER REMOVAL BE SURE TO INSPECT HUMI FOR INTACTNESS.