


POINTS TO REMEMBER (Refer to earlier pages for complete details)

- Sound uterus for depth and direction before use of HUI.
- Lubricate distal tip and intrauterine balloon before insertion of HUI.
- Be sure to insert HUI along the correct uterine axis as determined by sounding. If posterior insertion is made rotate HUI to normal position after intrauterine balloon inflation.
- **Always** maintain forward insertion pressure on HUI 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.
- **Never** use HUI without properly inflating the intrauterine balloon after insertion.
- **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.
- **Don't underinflate HUI.** Remember 2 cc of air will be trapped in the pilot balloon and inflation tube. Use up to a total of 5 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** compressible as is air, and, therefore, a potential for balloon rupture exists.
- Following a procedure **always** check HUI 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
- Rx Only** U.S. Federal Law restricts this device to sale by on the order of a physician
- STERILE EO** Sterilized using Ethylene Oxide
-  Manufacturer

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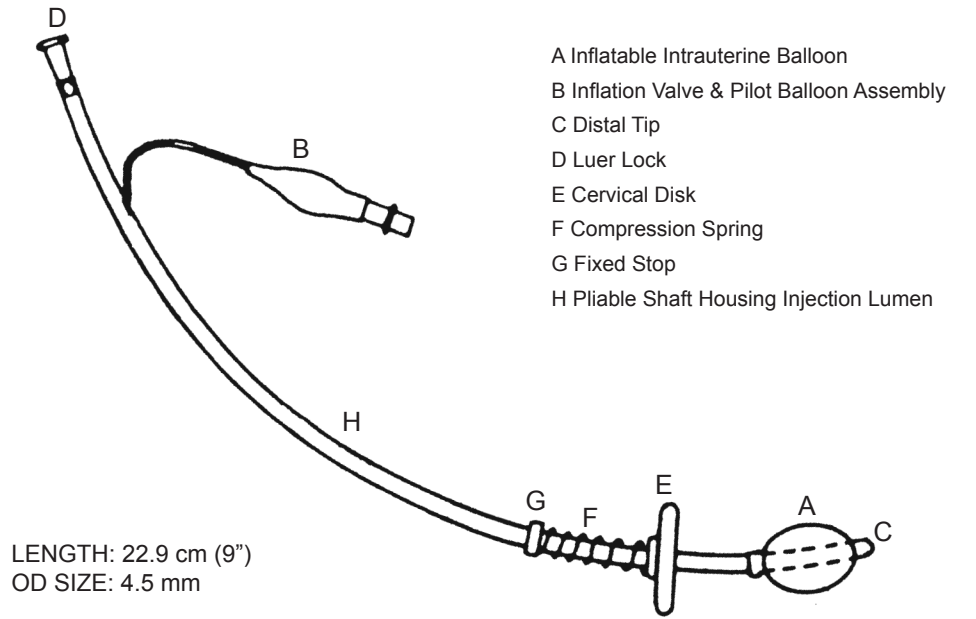
HUI®

Harris Uterine Injector

For such procedures as Hysterosalpingograms
Salpingoplasties and Hydrotubation

REF 6002

Instructions For Use



DESCRIPTION

HUI (Harris Uterine Injector) is a single-use, sterile/disposable, double lumen device made of clear polyvinyl chloride which meets USP requirements for implant testing. The double-lumen tube is 22.9 cm (9") long and has an OD (Outside Diameter) of 4.5 mm. Surrounding the distal end, but not covering the tip is an inflatable intrauterine 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). An assembly consisting of a rigid cervical disk (**E**) a compression spring (**F**) and a permanently fixed stop (**G**) prevents the instruments' insertion beyond the fixed stop depth and acts to pull the intrauterine balloon backwards to occlude the internal cervical os following its inflation and subsequent relaxation of forward insertion pressure.

INDICATIONS FOR USE

HUI (Harris 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. HUI can be used without cervical dilation or anesthesia and can often be introduced without the use of a tenaculum.

CONTRAINDICATIONS

HUI should not be used in pregnant patients or in patients suspected of being pregnant.

WARNINGS

- HUI 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 HUI to determine both the direction and depth of the uterus.
- **Do not** underinflate the intrauterine balloon. Underinflation will defeat the purpose of the balloon; which is to effectively occlude the internal cervical os to the backflow of liquid or gas being injected and to provide a gentle protective "air cushion" against the uterine wall. Underinflation may also result in spontaneous expulsion of the device as intrauterine pressure builds during injection. Inflation with 4 to 5 cc of air is recommended since approximately 2 cc will be consumed in the pilot balloon and inflation tube.
- The use of HUI in a patient with an exceptionally large uterus (post-abortal, etc.) may be ineffective due to spontaneous expulsion of the device. In such cases the use of HUI's larger companion instrument HUMI® (Harris-Kronner Uterine Manipulator-Injector) or Kronner Uterine Manipulator Injector should be considered.

See separate package insert for HUMI or Kronner instructions.

- As with all occlusive balloon injection devices, HUI 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.
- When injecting any liquid media, closely follow the manufacturer's directions for use that accompany the product.
- After removal of HUI 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.

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

INSTRUCTIONS FOR USE

1. Remove the sterile HUI from its protective package. Draw 4-5 cc of air into a standard plastic syringe and then insert syringe into the inflation valve assembly and test inflate the intrauterine balloon by injection of the air. 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. A single tooth tenaculum may be used to grasp the anterior lip if necessary. HUI can often be inserted without the use of a tenaculum and the appropriateness of tenaculum use should be evaluated in each individual case.
4. Probe the uterus for depth and direction with a uterine sound. **Do not** use HUI as a uterine sound. (HUI can be used without anesthesia or cervical dilation. It has an OD (outside diameter) of 4.5 mm and has a rounded distal tip which makes it gently self-dilating upon insertion. However, no attempt should be made to force HUI into too tight a cervix since doing so may cause pain and may tear the intrauterine balloon rendering it ineffective, and may produce cervical trauma.)

5. Now lubricate the instrument's distal tip and intrauterine balloon lightly with the water soluble gel of your choice. Then draw 4-5 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.**

6. 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.*

7. Continue insertion until the cervical disk compresses the spring completely to the fixed stop; an insertion depth of approximately 6 cm (If an unusually short uterine cavity has been determined by sounding, insertion should be advanced only to the determined depth.) Then, **while still maintaining forward insertion pressure**, inflate the intrauterine balloon with the 4-5 cc of air contained in the plastic syringe. Note that the pilot balloon is expanded. It indicates that the intrauterine balloon is properly inflating. A limp feeling pilot balloon indicates lack of inflation of the intrauterine balloon.

(Do not underinflate. Under-inflation may allow spontaneous expulsion of the device through the cervical canal as pressure builds during injection. Underinflation also defeats the "air cushion" protectiveness of the intrauterine balloon). *See Figure 3.*

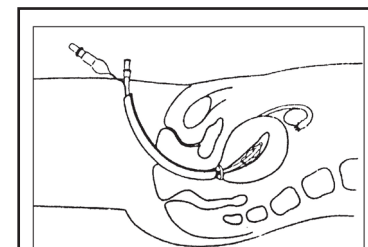


Figure 1—Normal or anteфлекted uterus. Initial insertion, balloon deflated.

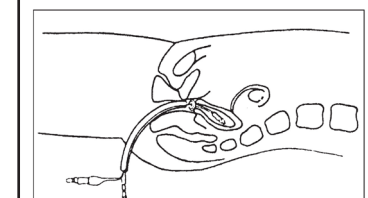


Figure 2—Retroflexed uterus. Initial insertion, balloon deflated. Balloon is then inflated, syringe removed and the HUI rotated 180 degrees to the normal position.

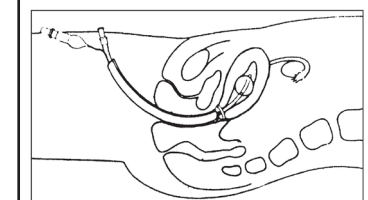


Figure 3—Complete insertion. Balloon inflated and sealing the internal cervical os; ready for liquid or gas injection.

8. 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).
9. If insertion was made in the posterior direction due to retroflexion of the uterus, HUI should now be rotated 180° to the normal position. (This action will not rotate the uterus. The balloon will simply slide within the uterine cavity.)
10. Now, by applying gentle traction on the device, check that HUI is secure and that the uterus is grasped.
11. The speculum and single tooth tenaculum may now be removed and the uterine grasp and cervical seal will not be disturbed. The patient can now assume the dorsorecumbent position with the end of the HUI available to the operator. If necessary, at this point the patient can be moved about or even stand up and walk without losing the device or breaking the cervical seal. The plastic shaft of the instrument is pliable enough to be bent in almost any direction desired.

HUI is now properly positioned with the internal cervical OS occluded to prevent reflux during the introduction of fluid or gas as required.

12. To inject fluid or gas into the uterus use a standard plastic syringe inserted into the Luer Lock at the proximal end of the shaft. A plastic stopcock and extension tube can be interposed, if desired, allowing a radiologist to step out of the field of radiation or to bring the injection syringe under a surgeon's complete control. The selected media will pass through the instrument's inner lumen and will exit into the uterine cavity from the distal tip.

Do not exert forward pressure on HUI during this stage of the procedure since doing so may displace the intrauterine balloon from its occlusive position at the internal cervical OS and could allow reflux to occur.

Do not inject fluid or gas too rapidly. HUI 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 temporary physiologic blockage to passage of media. Slow but steady injection has been shown to produce excellent results.

13. To remove HUI, 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 HUI from the uterus. Now carefully remove HUI from the vagina. **Do not use excessive force** since the cervical disk may traumatize the vaginal canal. Two fingers can be used to keep the cervical disk from becoming lodged in the vagina.
14. **After removal be sure to inspect HUI for intactness.**