**HUI® Harris Uterine Injector**

For such procedures as Hysterosalpingograms, Salpingoplasties and Hydrotubation

**Directions For Use**

- **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 underinflated HUI.**
- **If posterior insertion is made rotate HUI to normal position after intrauterine balloon inflation.**
- **Always**
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- **Don’t underinflated HUI.**
- **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.**

<table>
<thead>
<tr>
<th>REF</th>
<th>6002</th>
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<tbody>
<tr>
<td>LENGTH</td>
<td>22.9cm (9&quot;)</td>
</tr>
<tr>
<td>OD SIZE</td>
<td>4.5mm</td>
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</tbody>
</table>

**STERILE**

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

**DISPOSABLE**

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

**CAUTION**

- **Follow the instructions for use.**
- **Single Use Only/Do Not Reuse.**
- **Batch Code/Lot.**
- **Expiration Date (e.g. 2002-09).**
- **Ethylene Oxide Sterilized.**
- **Latex-Free.**
- **Caution: Federal law restricts this device to sale by or on the order of a physician.**

**LEGAL COMMUNITY REPRESENTATIVE—**

Leisegang Feinmechanik GmbH
Leibnizstraße 32
D-10625, Berlin GERMANY

**PACKAGE**

- 12 Individually sterile disposable latex-free devices per box.

**REVIEWED**

- 9/02

- 5/00

- 15/00

- 12/00

- 12/01

- 12/02

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DESCRIPTION
HU I (Harris Uterine Inflator) 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 22.0mm (9T) long and has an OD (Outside Diameter) of 4.5mm. Surrounding the distal end, but not covering the tip is an inflatable intratubal 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). A O-ring (not included) is used to ensure an assembly consisting of a rigid cylindrical disk (E), a compression spring (F), and a permanently fixed stop (G) presents the instrument's anterior disk beyond the head stop and acts to pull the intratubal balloon backwards to occlude the internal cervical os as its inflation and subsequent relaxation of forward insertion pressure.

INDICATIONS FOR USE
HU I (Harris Uterine Inflator) is indicated for in-office or hospital use when efficient sealing of the uterine cavity is required for the injection of liquid or gas such as hydrotubation, salpingoplasties, hydrotubation and Rubin’s Test. HU I can be used without cervical dilation or anesthesia and can often be introduced without the use of a tenaculum.

CONTRAINDICATIONS
HU I should not be used in pregnant patients or in patients suspected of being pregnant.

WARNINGS
■ HU I 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 HU I to determine both the direction and depth of the uterus.
■ Do not underinflate the intratubal 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 intratubal pressure builds during injection. Inflation with a 5 to 6cc of air is recommended since approximately 2cc will be consumed in the pilot balloon and inflation tube.
■ The use of HU I 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 HU I’s larger companion instrument HUM I (Harris-Kronner Uterine Manipulator-Injector) or Kronner Uterine Manipulator Injector should be considered.

See separate package insert for HUM I or Kronner instructions.

As with all occlusive balloon injection devices, HU I can create high intratubal pressures which could be accompanied by vascular extravasation. Do not inject fluid or gas rapidly.

PRECAUTIONS
■ Test inflate intratubal balloon prior to insertion.
■ Lubricate distal end of tube and intratubal balloon before insertion.
■ When injecting any liquid media, closely follow the manufacturer’s directions for use that accompany the product.
■ After removal of HU I 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
■ Infarction

DIRECTION FOR USE
1. Remove the sterile HU I from its protective package. Draw 4-5cc of air into a standard plastic syringe and then insert syringe into the inflation valve assembly and test inflate the intratubal balloon by injection of the air. Remove the syringe and check that the balloon remains inflated.
2. Following test inflation, insert the syringe firmly into the inflation valve assembly to open the valve and then completely evaluate 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. HU I 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 uterine lumen for depth and direction with a uterine sound. Do not use HU I as a uterine sound. HU I can be used without anesthesia or cervical dilation. It has an OD (outside diameter) of 4.5mm and has a rounded distal tip which makes it gently self-dilating upon insertion. However, no attempt should be made to force HU I into too tight a cervix since doing so may cause pain and may tear the intratubal balloon rendering it ineffective, and may produce cervical trauma.
5. Now lubricate the instrument’s distal tip and intratubal balloon lightly with the water soluble gel of your choice. Then draw 4-5cc of air into a standard plastic syringe and insert the syringe firmly into the inflation valve assembly.
6. Do not inflate the intratubal balloon as yet. Insert the lubricated instrument, with the balloon deflated, into the cervix in the direction of the curve of the uterine cavity. See Figure 1. 2. 3.
7. Continue insertion until the cervical disk compresses the spring completely to the fixed stop; an insertion depth of approximately 10 cm (if an unusually short uterine cavity has been determined) or until the tip of the device is visualized. The distal tip of the instrument is flexible. A tight feeling pilot balloon indicates lack of inflation of the intratubal balloon. Do not underinflate. Under-inflation may allow spontaneous expulsion of the device through the cervical canal as pressure builds during injection. Under-inflation also deactivates the “air cushion” protective valve of the intratubal balloon. See Figure 3.
8. Remove the syringe immediately following inflation of the intratubal balloon. (Relieving the syringe while it is still attached to the inflation valve assembly will allow the intratubal balloon to deflate due to back pressure.)
9. If insertion was made in the posterior direction due to retroflection of the uterus, HU I should now be rotated 180° to the normal position. (This action will rotate the uterus. The balloon will simply slide within the uterine cavity.)

Now HU I is properly positioned with the internal cervical os occluded to prevent reflux during the introduction of fluid or gas as required.

10. 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 enter the uterine cavity from the distal tip.
Do not exert forward pressure on HU I during this stage of the procedure since doing so may displace the intratubal balloon from its occlusive position at the internal cervical OS and could allow reflux to occur.

Do not inject fluid or gas too rapidly. HU I is a superb occlusive injector and as such can build high intratubal fluid or gas pressure. Rapid injection may cause expulsion of media, 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.

12. To remove HU I, insert a plastic syringe firmly into the inflation valve assembly to open the valve and then draw off the air contained in the plastic syringe. Note that the pilot balloon is expanded. It indicates that the intratubal balloon is properly inflated. A limp feeling pilot balloon indicates lack of inflation of the intratubal balloon. Do not underinflate. Under-inflation may allow spontaneous expulsion of the device through the cervical canal as pressure builds during injection. Under-inflation also deactivates the “air cushion” protective valve of the intratubal balloon. See Figure 3.

13. To remove HU I, insert a plastic syringe firmly into the inflation valve assembly to open the valve and then draw off the air contained in the plastic syringe. This releases HU I from the uterus. Now carefully remove HU I from the vagina. Do not use excessive force since the cervical disc may traumatize the vaginal canal. Two fingers can be used to keep the cervical disc from becoming lodged in the vagina.

14. After removal be sure to inspect HU I for intactness.

For directions, see continued