**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) and 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.

**EXPLANATION OF SYMBOLS**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Reorder Number</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch Code</td>
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<tr>
<td></td>
<td>Use-by date</td>
</tr>
<tr>
<td></td>
<td>Do not re sterilize</td>
</tr>
<tr>
<td></td>
<td>Do not reuse</td>
</tr>
<tr>
<td></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td></td>
<td>Not made with natural rubber latex</td>
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<tr>
<td></td>
<td>Caution</td>
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<tr>
<td></td>
<td>Rx Only</td>
</tr>
<tr>
<td></td>
<td>Sterilized using Ethylene Oxide</td>
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<tr>
<td></td>
<td>Manufacturer</td>
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</tbody>
</table>

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Infection
Cramping
does not indicate frequency or severity.
The following adverse reactions have been suspected or reported. The order of listing
ADVERSE REACTIONS
When injecting any liquid media, closely follow the manufacturer’s directions for use
PRECAUTIONS
See separate package insert for HUMI or Kronner instructions.
WARNINGS
HUI should not be used in pregnant patients or in patients suspected of being pregnant.

• Infection

• Cramping
does not indicate frequency or severity.
The following adverse reactions have been suspected or reported. The order of listing
ADVERSE REACTIONS
• When injecting any liquid media, closely follow the manufacturer’s directions for use
• 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 HUMIB (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 occultional 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, reinset 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. 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.
6. Do not inflate the intrauterine balloon at this time.

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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.
6. Do not inflate the intrauterine balloon at this time.

7. Continue insertion until the cervical disk is properly inflating. Then draw 4-5 cc of air into
the cervical canal as pressure builds during injection. Underinflation also defeats the “air
cushion” protective function 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” protective function of the intrauterine balloon.) See Figure 3.

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
grass and cervical seal will not be disturbed. The patient can now assume the
dorsorecumbent position for the injection of depth and direction. It is 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 should be used to build high intrauterine fluid or gas pressure. Rapid injection
can cause expulsion of the instrument, create vascular extravasation, or produce
uterine and fallopian tube spasms which 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
inflation tube. 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.

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 HUI rotated 180° to the normal position.

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

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