ID4 FemVue Saline-Air Device Instructions for Use

Caution: Federal (USA) law restricts the device to sale by or on the order of a physician.

DEVICE DESCRIPTION
The FemVue Saline-Air Device (FemVue) is a dual-barrel contrast media syringe that can be connected to an intrauterine catheter to instill saline-air contrast media during sono-hysterosalpingogram (Sono HSG) procedures. Sono HSG consists of an ultrasound evaluation of the fallopian tubes with or without assessment of the uterine cavity.

CLINICAL USE
The table below presents reported sensitivity, specificity, and concordance of saline-air sono-hysterosalpingography to assess tubal patency compared to laparoscopic chromopertubation. The FemVue Saline-Air Device has not been evaluated in a clinical study.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of Tubes</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Concordance (%)</th>
</tr>
</thead>
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<td>Allahbodja</td>
<td>134</td>
<td>Not reported</td>
<td></td>
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<tr>
<td>Heikkinen et al.</td>
<td>61</td>
<td>82</td>
<td>86</td>
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<td>Volpi et al.</td>
<td>56</td>
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<td>Spalding et al.</td>
<td>29</td>
<td>63</td>
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<td>Inki et al.</td>
<td>53</td>
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<td>Jeanty et al.</td>
<td>29</td>
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<td>Exacoustos et al.</td>
<td>30</td>
<td>75</td>
<td>91</td>
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</table>

WARNINGS/PRECAUTIONS
- Do not use oil-based contrast media. Saline-air is the recommended contrast media for this device.
- In order to minimize the risk of air embolism, do not exceed delivery of six (6) filled syringe volumes to the patient. Air embolism has not been reported with saline-air contrast volumes below 70 mL.
- Sono HSG with FemVue should be performed after completion of the menstrual cycle and before the onset of ovulation.
- Intended for single patient use only.
- Reuse creates a potential risk of patient or user infections.
- Do not use if pouch is damaged.

STORAGE
Store in a cool, dry place.

CONTRAINDICATIONS
The FemVue Saline-Air Device should not be used in any woman who has a contraindication to hysterosalpingography, including women who are pregnant or who have been pregnant in the previous 6 weeks (including miscarriage). These women may be at increased risk for air embolism.

HOW SUPPLIED
Sterile for single use only.

INDICATIONS FOR USE
The FemVue Saline-Air Device instills a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

SYMBOLE LEGEND
- Single Use
- Use by
- Refer to Instructions for Use.
- Only Federal (USA) law restricts the device to sale by or on the order of a physician.
- Do not use if pouch is damaged.

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FEMVUE PREPARATION

1. Completely submerge tip into a saline-filled bowl.
2. Fully pull back the plunger handle and hold until the saline chamber completely fills. Do not squeeze the air and saline chambers.

PROCEDURAL GUIDELINES FOR FEMVUE SONO HSG

1. Sonographic Landmarking.
   Conduct your standard ultrasound evaluation per your practice guidelines.

   Attempt to locate the following in the transverse view:
   • Endometrial stripe and utero-tubal junctions (Fig A)
   • Position of each ovary relative to the uterus (Fig B)
   
   Take note of the probe position.

2. Insert Intrauterine Catheter per the Catheter Instructions for Use.
   If desired, first perform Saline Infusion Sonography with a saline-filled syringe per your practice protocol, because bubbles in the uterus from the FemVue may cause artifact.

3. Inflate Balloon, if applicable.
   Inflation of the balloon with subsequent placement over the internal cervical os is recommended to prevent retrograde flow. (Fig C)

4. Prime FemVue and Connect to Catheter. (Fig D)
   To prime FemVue, submerge the tip in the saline-filled bowl and depress the plunger handle until bubbles are visible.

   Ensure FemVue is primed just before attachment to avoid delay in contrast visualization.

   Do not overtighten FemVue’s spin luer to the catheter. This prevents catheter kinking and luer detachment while ensuring easy device removal for refilling, if necessary.

5. Deliver Contrast Slowly.
   With ultrasound probe in place, slowly and steadily depress the plunger handle to deliver the contrast. Visualize saline-air contrast (bubbles) entering the cavity (distention is not necessary).

   Confirm in the sagittal view there is no retrograde flow through the cervix. If needed, adjust the balloon’s placement or use a balloon to block the flow. (Fig E)

   Start with one fill of the FemVue Saline-Air Device. Use the minimum number of fills necessary to perform tubal assessment. Do not exceed six (6) filled syringe volumes.

Troubleshooting: No contrast exiting catheter and plunger resistance
   • Make certain that catheter clamp is open, if applicable.
   • Confirm the catheter is patent.
   • Ensure FemVue has not been over tightened to catheter luer.
   • Replace catheter if kinking is suspected.

   In the transverse view orient the probe to observe the uterotubal junction to assess contrast flow in one tube. Although flow may be seen bilaterally, evaluate each tube individually. (Fig F)

   • Locate flow in Zone 1 and hold view to observe.
   • Slowly and methodically scan to possibly observe tubal flow in the remaining zones.

   Evaluate contralateral tube.

Troubleshooting: No contrast flow visible in Zone 1
   • Ensure there is no retrograde flow through the cervix.
   • Consider repositioning ultrasound probe.
   • Hold probe, maintain plunger handle position, and wait for resolution of possible tubal spasm.
   • After extensive observation, trace laterally to Zone 3 and observe.

Troubleshooting: Inadequate visualization of tube
   • Consider pulling back with probe if tube is viewed anteriorly.
   • Consider adjusting ultrasound equipment settings.

SONO HSG: DEMONSTRATING TUBAL PATENCY

Guidelines from published literature using saline and air are as follows:

   • Zone 1 - Flow in the interstitial part of the tube (minimum criterion). 1, 2
   • Zone 2 - Flow throughout course of tube (may not be seen). 1
   • Zone 3 - Flow exiting tube (fimbrial turbulence, bubbles seen around ovary or in cul-de-sac). 1, 2, 3

References: