

## 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.

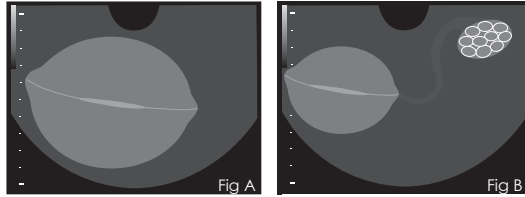
## PROCEDURAL GUIDELINES FOR FEMVUE SONO HSG

### 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**)



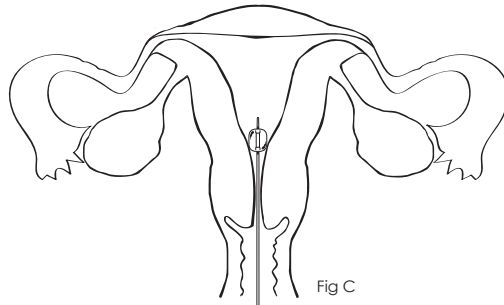
Take note of the probe position.

### 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**)

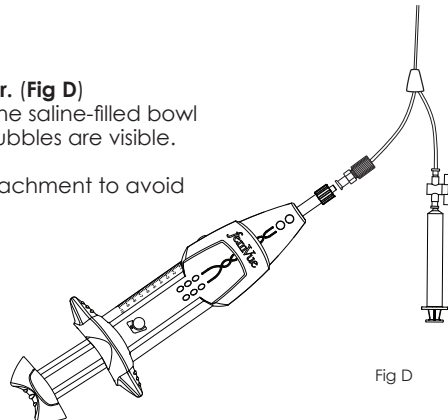


### 4. Prime FemVue and Connect to Catheter. (Fig D)

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.*

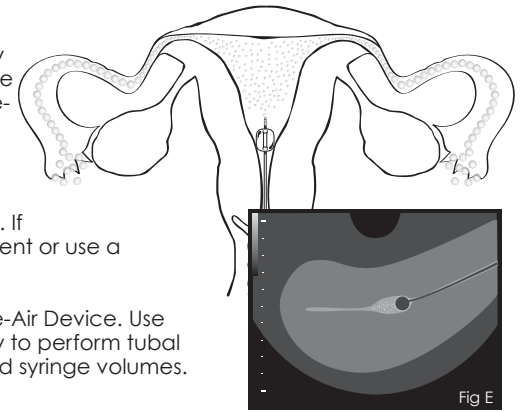


### 5. Deliver Contrast Slowly.

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.



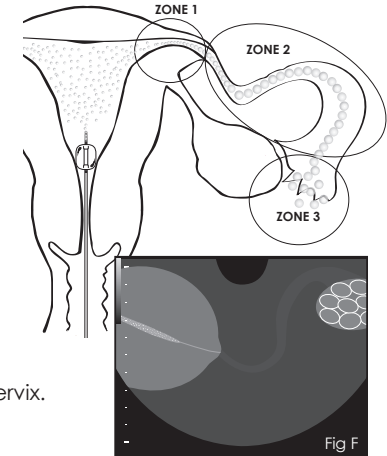
### Troubleshooting: No contrast exiting catheter and plunger resistance

- 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.

### 6. Make Tubal Assessment.

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).<sup>1,2</sup>
- **Zone 2** - Flow throughout course of tube (may not be seen).<sup>1</sup>
- **Zone 3** - Flow exiting tube (fimbrial turbulence, bubbles seen around ovary or in cul-de-sac).<sup>1,2,3</sup>

### References:

<sup>1</sup> Volpi, Ultrasound Obstetrics Gynecology. 1996;7:43-48.

<sup>2</sup> Exacoustos, The Journal of the American Association of Gynecologic Laparoscopists. 2003;10(3):367-372.

<sup>3</sup> Allahbadia, Fertility and Sterility. 1992;58(5):901-907.

## SYMBOL LEGEND



Single Use



Use by



Refer to Instructions for Use.



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



Do not use if pouch is damaged.

**femVue**  
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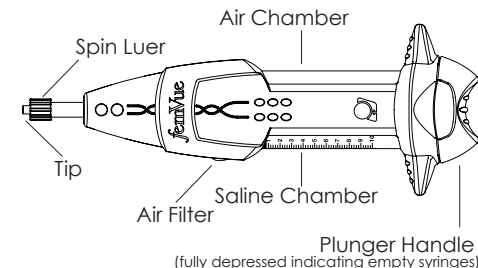
**femVue**

## 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.



### 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).

### 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.

### 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.

Reference	Number of Tubes	Sensitivity (%)	Specificity (%)	Concordance (%)
<b>Allahbadia</b> Fertility and Sterility. 1992;58(5):901-907.	134	Not reported		94
<b>Heikkinen et al.</b> Fertility and Sterility. 1995;64(2):293-298.	61	82	86	85
<b>Volpi et al.</b> Ultrasound Obstetrics Gynecology. 1996;7:43-48.	56	85	92	89
<b>Spalding et al.</b> Human Reproduction. 1997;12(11):2461-2464.	29	63	100	90
<b>Inki et al.</b> Acta Obstetrica et Gynecologica Scandinavica. 1998;77:978-982.	53	90	83	89
<b>Jeanly et al.</b> Journal Ultrasound Medicine. 2000;19:519-527.	29	86	77	79
<b>Exacoustos et al.</b> The Journal of the American Association of Gynecologic Laparoscopists. 2003;10(3):367-372.	30	75	91	87

### 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.