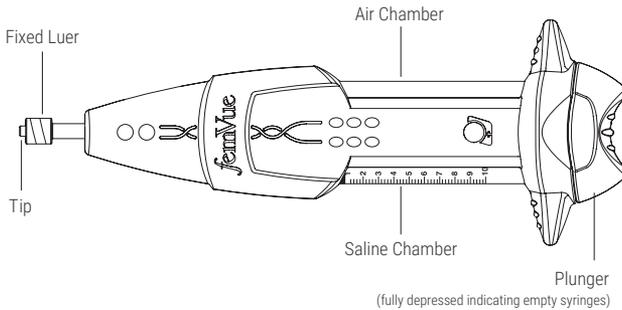


CAUTION – Federal (USA) law restricts this device to sale by or on the order of a physician.

Instructions for Use



DEVICE DESCRIPTION

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

FemVue is intended to instill 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

- Any condition that is a contraindication to hysterosalpingography.
- Current or recent pregnancy (previous 6 weeks) including miscarriage which may increase risk of air embolism.

WARNINGS & PRECAUTIONS

- Sterile device. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize.
- Do not use oil-based contrast medium.
- To minimize risk of air embolism, do not exceed delivery of six (6) filled device volumes (max 60 mL of air) to the patient. Air embolism has not been reported in the literature with air volumes below 70 mL.
- FemVue should be performed after completion of the menstrual cycle and before the onset of ovulation.

INSTRUCTIONS FOR USE

Ensure use of aseptic technique throughout procedure.

I. DEVICE PREPARATION

1. Completely submerge device tip in sterile saline-filled bowl.
2. Fully pull back plunger and keep tip submerged until saline chamber is completely filled to the 10 mL mark, as confirmed visually.
NOTE: FemVue fills with a delay. Keep tip submerged in saline during the entire filling process.
NOTE: FemVue fills the air chamber simultaneously through an internal 0.2 micron air filter.
3. Prime FemVue by depressing plunger with tip submerged in bowl until bubble visible.

Refilling FemVue

- a. Disconnect FemVue from catheter
- b. Fill FemVue
- c. Prime FemVue
- d. Reconnect FemVue to catheter

NOTE: If using intrauterine catheter with clamp, engage clamp prior to disconnecting FemVue and disengage clamp after reconnecting FemVue prior to contrast delivery.

II. DEVICE USE

NOTE: Transvaginal ultrasound pre-scan can provide baseline assessment for location of endometrial stripe and cornua, left and right adnexa/ovary and tubal course.

NOTE: Uterine cavity assessment (saline infusion sonogram) can be performed with saline-filled syringe per practice guidelines.

1. After intrauterine catheter placement, connect FemVue to catheter luer.
NOTE: Avoid overtightening FemVue's luer to catheter luer to ensure easy device disconnection for refilling.

2. Deliver Contrast Slowly

- a. With ultrasound probe in place, slowly depress plunger to deliver contrast.

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

NOTE: Consider adjusting balloon if backflow of contrast is observed.

3. Complete Tubal Assessment

- NOTE:** Probe must be held steady to observe and confirm contrast flowing.

- a. Orient ultrasound probe to assess contrast flow in one tube. Hold probe steady while focusing on: cornu, tubal course and adnexa/ovary.

NOTE: Contrast flow may be observed bilaterally.

- b. Orient ultrasound probe to assess contrast flow in contralateral tube. Hold probe steady while focusing on: cornu, tubal course and adnexa/ovary.

- c. Orient ultrasound probe to assess contrast presence in cul-de-sac.

NOTE: Tubal patency can be confirmed by: flow in the interstitial part of the tube (minimum criterion), or flow throughout tubal course, or contrast observed around adnexa/ovary or in cul-de-sac.

III. PATIENT POST CARE

1. Disconnect device from intrauterine catheter and discard.

NOTE: Patient should expect leaking of fluid after the procedure that may be blood-tinged.

