

HSG-Sono Catheter

CAUTION: Federal law requires the sale of this device by or on the order of a physician only.

Device Description:

The HSG-Sono Catheter is a latex-free balloon catheter with a rigid insertion sheath. A syringe is included for balloon inflation.

Intended Use/Indications:

For administering contrast media or sterile saline during Hysterosalpingography and Sonohysterography procedures to detect uterine pathology such as polyps, fibroids, adhesions or endometrial thickening, and/or patency of fallopian tubes.

Contraindications:

Suspected infection, suspected pregnancy, profuse bleeding or sexually transmitted disease.

Precautions:


- Do not exceed the preset recommended balloon inflation volume (2 cc for the 5 French catheter and 3.5 cc for the 7 French catheter) or the balloon may burst.
- The use of OIL-BASED contrast media such as ethyl esters may interact with the balloon of the catheter, causing possible balloon rupture. The use of aqueous contrast media is recommended.

Adverse Events:

Some patients may have a hypersensitivity to contrast media.

How Supplied:

STERILE EO Sterile via Ethylene Oxide

 Single Use Only

Instructions for Use:

1. Remove catheter from pouch.
2. Remove and discard the protective sleeve.
3. Test balloon inflation with air using the supplied preset syringe, check for leaks, and deflate.
4. Attach a contrast media or saline filled syringe (not supplied) to the luer connector. Inject contrast media or saline through catheter to remove air. Advance the insertion sheath so that the distal end of the catheter protrudes slightly from the distal end of the sheath.
5. View the cervix and advance the sheath and catheter so that the tip of the catheter enters the cervix.
6. Advance the catheter through the cervical canal and into the uterus.
7. Open the stopcock and slowly inflate the balloon with up to 2 cc for the 5 French catheters and 3.5 cc for the 7 French catheter of either air or saline.
8. Close the stopcock allowing the balloon to remain inflated. Gently withdraw catheter so balloon will rest against internal os.
9. Inject contrast media or saline into the uterus and complete the examination.
10. Open the stopcock to deflate the balloon. Withdraw the catheter.

Manufactured in Taiwan by the Panpac Medical Corporation



Distributed by Femasys Inc.
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02686 Rev 02 01.June.2016