

H/S Elliptosphere™ Catheter Set for Hysterosonography and Hysterosalpingography 61-4205 (5F) Instructions for Use

Device Description:

The H/S Elliptosphere Catheter Set consists of a latex-free balloon catheter, insertion sheath and a 1.5 cc syringe. The catheter can be used with aqueous based contrast media. See Figure 1.

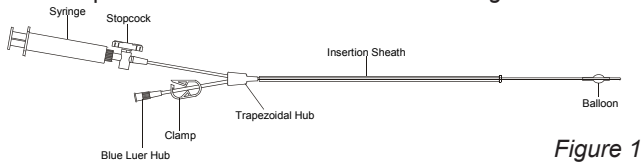


Figure 1

Intended Use/Indications: For administering contrast media during Hysterosalpingography or Hysterosonography procedures to detect uterine pathology such as polyps, fibroids, adhesions or endometrial thickening, or patency of fallopian tubes.

Contraindications:

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

Precautions:

Do not exceed the recommended balloon inflation volume of 1.5 cc 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 rupture. The use of oil-based contrast media is not recommended.

Adverse Events:

Some patients may have a hypersensitivity to contrast media.

Instructions for Use:

Catheter Preparation

1. Grasp the light blue insertion sheath connected to the trapezoidal hub.
2. Remove and discard the crimped yellow protective cover, exposing the balloon catheter tip.
3. Test the balloon integrity by inflating with air or contrast media using the syringe in the set. Deflate *completely* by pulling back on the syringe plunger and closing the stopcock.
4. Attach a contrast media-filled syringe (not supplied) to the blue luer hub and fill the catheter with contrast media to expel air. Advance the insertion sheath so that the distal end of the catheter protrudes slightly from the distal end of the sheath. See Figure 2.



Figure 2

Catheter Placement

5. Visualize the external cervical os with the aid of a speculum and advance the sheath and catheter so that the tip of the catheter enters the cervical canal.
6. Hold the sheath stationary and advance the catheter into the cervical canal 1-2 cm.
7. Open the stopcock and **slowly** inflate the balloon with up to 1.5 cc of either air or saline to provide occlusion without causing discomfort to the patient. Turn the stopcock off allowing the balloon to remain inflated.

Injection of Contrast Media

8. Inject the contrast media, close the clamp and complete the study in a routine manner.
9. If uterine placement is desired, deflate the balloon by opening the stopcock and pulling back on the syringe plunger. Advance the catheter into the uterus, fully inflate the balloon using the enclosed syringe, close the stopcock and withdraw the catheter until the balloon occludes the internal os.

Catheter Removal

10. Open the stopcock and deflate the balloon by pulling back on the syringe plunger. Withdraw the catheter.

EXPLANATION OF SYMBOLS

REF Reorder Number

LOT Batch Code

Use By

R_xOnly U.S. Federal law restricts this device to sale by or on the order of a physician.

STERILE EO Sterilized Using Ethylene Oxide

Do not re-use

Do not re-sterilize

Caution

Consult instructions for use

Do not use if package is damaged

Not made with natural rubber latex

Manufacturer

CooperSurgical

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974
Fax: (800) 262-0105

International
Phone: +1 (203) 601-9818
Fax: +1 (203) 601-4747
www.coopersurgical.com