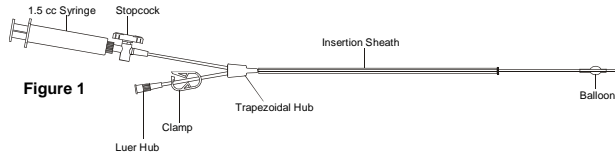


Model 61-4005S Instructions • H/S Elliptosphere™ Catheter with Integrated Stylet for Hysterosonography and Hysterosalpingography

DEVICE DESCRIPTION

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



CAUTIONS

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

PRECAUTIONS

Do not exceed the recommended balloon inflation volume of 1.5 cc or the balloon may burst.

INDICATIONS FOR USE

For administering contrast media during Hysterosonography or Hysterosalpingography 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.

ADVERSE EVENTS

Some patients may have a hypersensitivity to contrast media.

INSTRUCTIONS FOR USE

Catheter Preparation

1. Grasp the insertion sheath connected to the trapezoidal hub.
2. Remove and discard the crimped protective cover, exposing the balloon catheter tip.
3. Test the balloon integrity by inflating with air, saline, or contrast media using the supplied syringe. Deflate *completely* by pulling back on the syringe plunger and closing the stopcock.
4. Attach a contrast media-filled syringe (not supplied) to the 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

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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. The catheter may be shaped / curved to facilitate insertion.
7. Hold the sheath stationary and advance the catheter into the cervical canal 1-2 cm.
8. 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

9. Inject the contrast media, close the clamp and complete the study in a routine manner.
10. 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

11. Open the stopcock and deflate the balloon by pulling back on the syringe plunger. Withdraw the catheter.
12. Dispose of in accordance with all applicable Federal, State, and local Medical / Hazardous waste practices.

EXPLANATION OF SYMBOLS



Reorder Number



Batch Code



Use By



Irradiation Sterilization



Latex Free



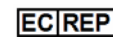
Do Not Reuse



ATTENTION: See instructions for use.

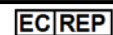


Product conforms to the Medical Device Directive 93/42/EEC



Authorized Representative in the European Community

Made in the USA



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