Gynecath Catheter
For Hysterosonography and Hysterosalpingography
Instructions

Device Description:

The Gynecath Catheter consists of a latex-free balloon catheter, insertion sheath and a 1.5cc syringe (5F catheter) or 3.0cc syringe (7F catheter). The catheter can be used with saline or aqueous based contrast media. *See Figure 1.*

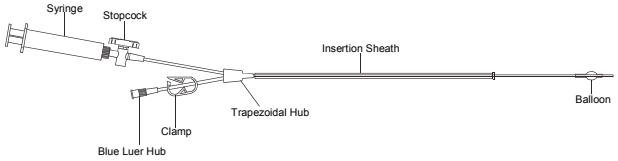

Figure 1

Warnings

Contents supplied sterile. Do not use if sterile barrier is damaged. For single use only.

Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State and local Medical/Hazardous waste practices

Intended Use/Indications:

For administering contrast media during Hysterosalping-ography 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 1.5cc (5F catheter) or 3.0cc (7F 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 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

Step 1: Grasp the translucent insertion sheath connected to the trapezoidal hub.

Step 2: Remove and discard the crimped yellow protective cover, exposing the balloon catheter tip.

Step 3: Test the balloon integrity by inflating with air, saline or water using the syringe in the set. If performing Hystero-sonography remove as much air as possible from the balloon. Deflate *completely* by pulling back on the syringe plunger and closing the stopcock.

Step 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

Step 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.

Step 6: Hold the sheath stationary and advance the catheter into the cervical canal and into the uterine cavity.

Step 7: Open the stopcock and **slowly** inflate the balloon with up to 1.5cc (5F catheter) or 3.0cc (7F catheter) of air, saline or water. Turn the stopcock off allowing the balloon to remain inflated.

Step 8: Withdraw the catheter until it occludes the internal os of the cervix.

Injection of Contrast Media

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

Step 10: Occasionally, when access to the uterine cavity is difficult the balloon must be inflated within the endo-cervical canal.

Catheter Removal

Step 11: Open the stopcock and deflate the balloon by pulling back on the syringe plunger. Withdraw the catheter.

Explanation of Symbols

REF	Reorder number	R_x Only	**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.
LOT	Batch code		Consult instructions for use
	Use-by date	STERILE EO	Sterilized Using Ethylene Oxide
	Caution		Do not use if package is damaged or opened.
	Do not re-use	LATEX	Not made with natural rubber latex
	Do not resterilize		Manufacturer

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