BEAURAY

PRODUCT LITERATURE | HSG AND SONOHYSTEROGRAPHY

HSG Catheter Set - Instructions for Use

Official Manufacturer IFU | English

The following pages reproduce the manufacturer's official document without alteration. For availability, quotations and support in Canada, please contact Beauray Inc.

CANADIAN SALES & SUPPORT

Beauray Inc.

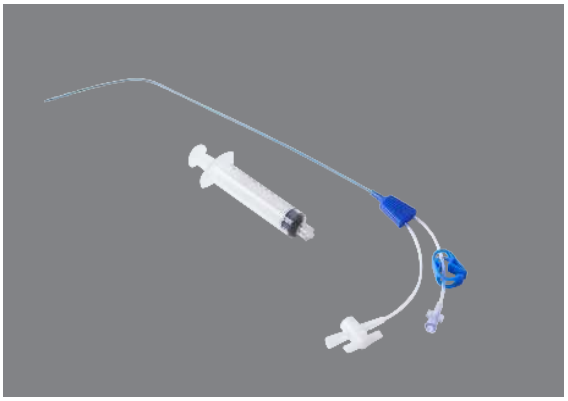
info@beauray.co

+1 437 607 5116 | Thornhill, Ontario, Canada

For Canadian product inquiries, contact Beauray Inc.

www.biotequetaiwan.com
TEL: +886-2-27160135

HSG Catheter Set



HSG Catheter Set
available in 5(fr) and 7(fr) size

Not made with natural rubber latex

DESCRIPTION:

HSG Catheter Sets can be used for sonohysterography and hysterosalpingography procedures that greatly enhance the analysis of uterine pathology. Using HSG balloon catheters, the procedures are simple and non-traumatic for your patients. A placement sheath eliminates the need for a tenaculum. HSG catheters are designed for single patient use only.

Product No.:

BA05F (5 french)
BA07F (7 french)
BA051F (5 french) SureFlex
BA071F (7 french) SureFlex
BA05F-ST (5 french) Malleable

INDICATIONS:

The HSG Catheter Sets are indicated to evaluate the causes of abnormal uterine bleeding, menstrual disorders, recurring pregnancy loss, or unexplained infertility. They can also be used to assess uterine pathology and patients on tamoxifan therapy. HSG type catheter sets are used to infuse a fluid (either a contrast media or a sterile saline) into the uterine cavity while blocking the external cervical OS to retain the fluid in the uterus during the procedure.

CAUTION:

1.Sterile product unless package is opened or damaged.
2.Do not reuse for avoiding user may be infected by the microorganism.
3.This device is sold by or on the order of a physician.
4.If the sterile package is damaged or unintentionally opened before use, do not use.

CONTRAINDICATIONS:

HSG procedures are contraindicated in pregnancies, suspected pregnancies, active pelvic infections, or recent pelvic infections, severe uterine bleeding, gynecologic malignancies, or if the patient is allergic to the contrast media. This device should not be used for intrafallopian procedures.

PROCEDURES:

Remove the HSG set from the sterile pouch and remove the balloon protective sleeve from the distal end of the catheter. Using the attached syringe, inflate the silicone balloon by opening the stopcock attached to the syringe luer. Then allow the silicone balloon to completely deflate. This procedure ensures the integrity of the HSG balloon. Attach the media source to the open luer and allow the contrast media to flow through the catheter removing air and clearing the media channel.

DIRECTIONS FOR USE:

With the guiding sheath, position the HSG catheter so that the tip of the catheter is at the entrance of the cervix external OS. Gently push the HSG catheter, with balloon, through the cervical canal and into the uterine cavity. Inflate the balloon within the uterine cavity and close the balloon stopcock to prevent the balloon from deflating. Carefully withdraw the catheter until the balloon is resting against the internal OS. Now inject the contrast media into the uterus and proceed with the examination.
In cases where the access to the uterus is difficult, the balloon may be inflated within the cervical canal.

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.

WARNINGS:

Dispose of medical waste properly in accordance with regulations after using.

STERILE EO	Sterile EO		Attention
LATEX	Not Made With Natural Rubber Latex		Biological risks
	Do not reuse	10°C 40°C	Warehouse temperature 10~40°C
LOT	Batch code	30% 80%	Warehouse humidity 30~80%RH.
	Expiry date		
	Consult instructions for use		

Bioteque Taiwan Ltd.
7F., No. 431, 433, Baozhang Rd., Xizhi Dist., New Taipei City 22103, Taiwan