INSTRUCTIONS FOR USE:

1. Remove the catheter from pouch.
2. Remove and discard the protective sleeve.
3. Test balloon inflation with air using the supplied syringe, check for leaks, and if satisfactory, deflate balloon.
4. Attach contrast media or saline (not supplied) filled syringe to the luer connector. Inject contrast media or saline through catheter to remove air. Advance insertion sheath so distal end of catheter protrudes slightly from distal end of sheath.
5. View cervix and advance sheath and catheter so tip of catheter enters cervix.
6. Advance catheter through cervical canal and into uterus.
7. Open stopcock and slowly inflate balloon with up to 1.5cc for the 5F catheter and 3cc for the 7F catheter of either air or saline.
8. Close stopcock allowing balloon to remain inflated. Gently withdraw catheter so balloon will rest against internal os.
9. Inject contrast media or saline into uterus through the second port using another syringe and complete examination.
10. Open stopcock to deflate balloon. Withdraw catheter.

SEE PRODUCT LABEL FOR:

REF Catalog Number
LOT Lot Number
Date of Manufactor
Use By Date

EC REP
ADVENA LTD,
Tower Business Centre,
2nd Flr., Tower Street,
Swatar, BKR 4013, Malta

/

UK REP
RB Medical
Alton Road, Industrial Estate,
Unit 2. Ross-on-Wye,
Herefordshire, HR9 5NS, UK

MEDGYN INTERNATIONAL, INC.
800 Pasquinelli Dr. Westmont, IL 60559 USA
e: info@medgyn.com ; www.medgyn.com
t: 630.627.4105
f: 630.627.0127
toll-free: 800.451.9667

HSG IFU - English
HSGINSML-IF5

MedGyn

HSG CATHETERS (5F AND 7F)

DEVICE DESCRIPTION:

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

INDICATIONS FOR USE:

Diagnostic device to detect uterine pathology such as polyps,fibroids,adhesions or endometrial thickening and /or patency of fallopian tubes.

INTENDED USE:

The device is meant for administering contrast media or saline during Hysterosalpingography and Sonohysterography procedures to

CONTRAINDICATIONS:

- Patients with suspected pelvic infection
- Patients with suspected pregnancy
- Patients with profuse uterine bleeding
- Patients with a sexually transmitted disease
- Patients with suspected allergy to contrast media

CAUTION:

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

PRECAUTIONS:

- Do not exceed recommended balloon inflation volume (1.5cc for the 5F catheter and 3cc for the 7F catheter) or balloon may burst.
- The use of oil-based contrast media such as ethyl esters may interact with balloon of catheter, causing possible balloon rupture. The use of aqueous contrast media is recommended.

ADVERSE REACTIONS:

Adverse reactions include hypersensitivity to contrast media.

WARNINGS:

- CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGE.
- SINGLE USE ONLY. DO NOT REUSE.
- DISPOSABLE - DISCARD AFTER USE.
- STERILIZED BY ETHYLENE OXIDE.