

# HYSTERO CATH SILICONE Hysterosalpingography Catheter

**Description:**

Device Name	Reference Number
HYSTERO CATH SILICONE Hysterosalpingography Catheter	HCSIL-HSG-7
HYSTERO CATH SILICONE Hysterosalpingography Catheter - Open Taper Tip	HCSIL-HSG-O7

**Intended use:**

HSG Catheter is used for injection of contrast media into the uterine cavity to evaluate patency of the fallopian tubes.

**Contraindications:**

- Suspected pregnancy
- suspected infection
- Profuse bleeding or sexually transmitted diseases.

**Complications:**

- Venous Intravasation
- Bleeding and pain

**Caution:**

Federal (USA) law restricts this device to sale by or on the order of a physician. This product contains natural rubber latex which may cause allergic reactions in some individuals.

**Warning / Precaution:**

- Do not use if package is opened or damaged.
- Only experienced surgeons should use this device.
- This device is supplied sterile and intended for single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Dispose in accordance with recognized medical practice and under observance of applicable law & regulation
- Storage temperature between 5°C to 30°C.

**Instruction for Use:**

1. Check balloon inflation with air using the supplied syringe, check for leaks, and deflate.
2. Attach a contrast medium or saline filled syringe to the luer connector. Inject contrast medium or saline through catheter to remove air. Proceed the insertion sheath so that the distal end of the catheter protrudes slightly from the distal end of the sheath.
3. View the cervix and move the sheath and catheter along, so that the tip of the catheter enters the cervix.
4. Move the catheter further ahead through the cervical canal and into the uterus.
5. Open the stopcock and slowly inflate the balloon with up to 3cc air or saline.
6. Close the stopcock, while allowing the balloon to remain inflated. Gently withdraw the catheter so balloon rests against internal OS.
7. Inject contrast media or saline into the uterus and complete the examination.
8. Open the stopcock to deflate the balloon. Take out the catheter.

**Do not reuse, reprocess & resterilize:**

Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

**Limited Express Warranty:**

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Catalogue Number	Batch Code	Date of Manufacture	Use By	Do not re-use	Do not Re-Sterilize	Rx only	Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.	
Consult Instruction for use	Do not use if Packing is damaged	Caution	Keep out of sunlight	Keep Dry	MD Medical Device	STERILE EO Sterilized using ethylene oxide	Not made with natural rubber latex	Temperature Limit
EU REP	CMC Medical Devices & Drugs S. L. C/Horacio Lengo N° 18, CP 29006, Malaga, Spain Tel.: +34 951 214 054 E-mail : info@cmcmedicaldevices.com		CE 0123	<p><b>Allwin Medical Devices, Inc.</b> 3305 E. Miraloma Ave., Suite 176 Anaheim, CA 92806 (USA) Tel. : +1 714-572-1709 Email : info@allwinmedical.com   www.allwinmedical.com</p>				