

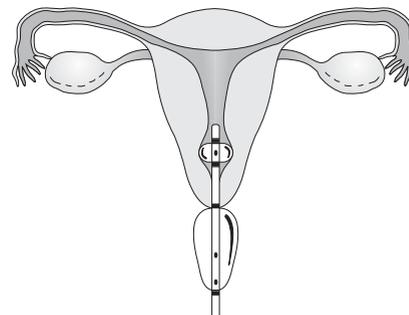
Figure 2

- Inflate the proximal balloon with 10-25 cc's of saline or contrast. (Figure 2) The portion of the balloon not constricted by the cervical canal will be inflated, sealing the external cervical os.
- For hysterosalpingography studies, **slowly** inject contrast medium through the stopcock and side-arm adapter of the Check-Flo® adapter. The Check-Flo® valve helps prevent fluid reflux. Due to the sealing of the balloons around the cervix, rapid injection of contrast medium could cause high intrauterine pressure resulting in extravasation.

## ACKNOWLEDGEMENT

Raymond Mencini, M.D., Director, Interventional Radiology, St. Anthony Hospital Central, Denver, Colorado.

# Mencini Double Balloon Hysterosalpingography Catheter



Suggested Instructions for Use



MANUFACTURER

COOK INCORPORATED  
750 Daniels Way, P.O. Box 489  
Bloomington, IN 47402-0489 U.S.A.  
Phone: 812 339-2235  
Toll Free: 800 457-4500  
Toll Free FAX: 800 554-8335

[www.cookmedical.com](http://www.cookmedical.com)

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EC REPRESENTATIVE

WILLIAM COOK EUROPE ApS  
Sandet 6, DK-4632  
Bjaeverskov, DENMARK  
Phone: +45 56 86 86 86

# COOK®



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## MENCINI DOUBLE BALLOON HYSTEOSALPINGOGRAPHY CATHETER

**ORDER NUMBER: DBH-100**

### INTENDED USE

The Mencini Double Balloon Hysterosalpingography Catheter is used for diagnostic studies and/or to access the uterine cavity for fallopian tube catheterization procedures. A metal stiffening cannula with malleable tip is fitted inside the catheter for shaping and ease of introduction. The catheter is introduced and anchored securely into position with inflation of the distal balloon against the internal cervical os and a proximal balloon conforms to the cervical canal. The balloons provide sufficient pressure on the cervix for the contrast studies or platforming for introduction of various devices into the fallopian tubes. A side-arm adapter on the Check-Flo® Performer® valve facilitates introduction of contrast and eliminates fluid reflux. Supplied sterile in peel-open packages. Intended for one-time use.

### WARNINGS

The Mencini Double Balloon Hysterosalpingography Catheter should not be used in the presence of hemorrhage, active pelvic infection, profuse bleeding or pregnancy.

Do not exceed recommended balloon inflation volumes. Balloons may rupture if overinflated.

Do not use power injector for injection of contrast medium. Extravasation or tubal perforation may occur due to high pressure injections or rapid infusion of contrast medium.

This device should only be used by an experienced clinician.

### CONTRAINDICATIONS

- Pregnancy or suspected pregnancy
- Active or recent pelvic infection
- Known allergy to dye or contrast medium

### POSSIBLE ADVERSE EFFECTS

1. **Pain or Discomfort** – Some patients may experience cramping or other abdominal pain.
2. **Extravasation** – Dye or contrast medium that exceeds normal anatomic constraints of the fallopian tube(s).

### SUGGESTED INSTRUCTIONS FOR USE OF THE MENCINI DOUBLE BALLOON HYSTEOSALPINGOGRAPHY CATHETER

1. The cervix is exposed using a vaginal speculum. Prepare the cervix with povidone-iodine solution.
2. Introduce the catheter transcervically until the distal balloon is positioned in the lower portion of the uterus. **NOTE:** The stiffening cannula may be left in the catheter to enhance the rigidity of the shaft. The distal tip of the stiffening cannula is malleable and can be shaped with a slight curve to facilitate directional control.

**WARNING: Always inflate the balloon with a sterile saline or a 1:1 saline and contrast medium. Never inflate with air, carbon dioxide or any other gas.**

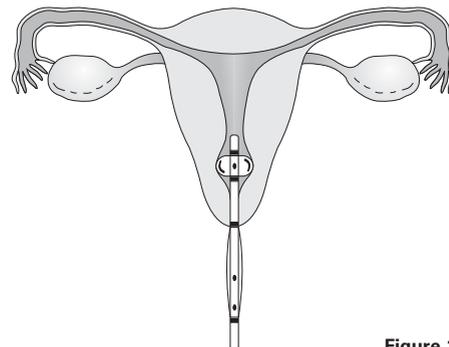


Figure 1

3. Inflate the distal balloon with 3-5 cc's using the saline or contrast medium. Gently pull back on the catheters shaft to seat the distal balloon in the internal cervical os. (Figure 1)

**WARNING: Do not exceed recommended balloon volume. Overinflation can cause the balloon to rupture.**

*Continued*