

Thurmond-Rösch Movable Cup Hysterocath®

Instructions for Use



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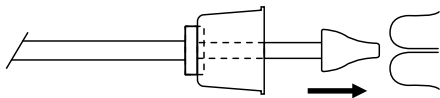


Fig. 1

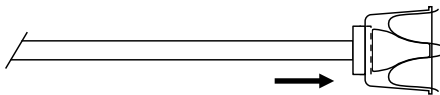


Fig. 2

THURMOND-RÖSCH

MOVABLE CUP HYSTEROCATH®

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

The Thurmond-Rösch Movable Cup HysteroCath is a 28 French polyvinylchloride catheter with a distal acorn tip for engagement with the external cervical os, and a sliding cup. Apposition of the cup to the cervix is obtained by suction applied to the HysteroCath's vacuum port.

INTENDED USE

The Thurmond-Rösch Movable Cup HysteroCath is intended to access the uterine cavity for hysterosalpingography and other diagnostic studies.

CONTRAINDICATIONS

Do not use in a patient with an active vaginal or intrauterine infection, a recent uterine perforation, a recent pregnancy (or is currently pregnant), or if the patient currently has an intrauterine device.

WARNINGS

None known

PRECAUTIONS

This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for hysterosalpingography should be employed.

INSTRUCTIONS FOR USE

1. Remove the metal obturator from the HysteroCath.
2. With the movable cup in withdrawn position (**Fig. 1**) and the central lumen of the HysteroCath filled with contrast medium, position the acorn tip in the external os of the cervix.
3. Maintaining tip position, advance the movable cup until it is positioned over the outer surface of the cervix. (**Fig. 2**)
4. Apply suction to the vacuum port of the HysteroCath to create a seal between the cup and the surface of the cervix.

NOTE: If leakage of contrast medium occurs, carefully advance the central shaft of the HysteroCath until proper seal is achieved.

5. Proceed with hysterosalpingography or other diagnostic study.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.



Keep dry



Keep away from sunlight



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