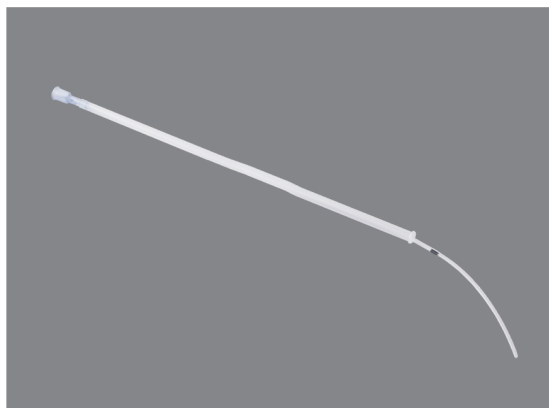




Not made with natural rubber latex

Description

The catheter is to be used for sonohysterography procedures that aid in the analysis of uterine pathology. A placement sheath eliminates the need for a tenaculum. This catheter is designed for single patient use.

Product Model

UIC 5F (without Cervical Cone) **REF**

Each 25 sterile catheters per box.

Indications

The Bellota Sonohysterography Catheter without Cervical Cone (Model: UIC 5F) is used to access the uterine cavity for saline infusion Sonohysterography procedure.

Caution

1. The product is sterile unless the package is opened or damaged.
2. Do not reuse the device to avoid the risk of infection caused by microorganisms.
3. This device is sold by or on the order of a physician.
4. Do not use the device if the sterile package is damaged or unintentionally opened before use.

Warnings

After use, dispose of the device as medical waste in accordance with applicable regulations.

Contraindications

The catheter type procedures are contraindicated in pregnancies, suspected pregnancies, active pelvic infections, or recent pelvic infections, severe uterine bleeding, gynecologic malignancies. This device should not be used for intrafallopian or intratubal procedure or for in-vitro fertilization.

Instructions for Use

1. Remove the catheter from the sterile pouch.
2. Attach the saline source to the open luer and allow the saline to flow through the catheter to remove air and flush the saline channel.
3. Adjust the protective sheath so that approximately 1/2 to 1 cm of the catheter protrudes beyond the sheath.

4. Expose the cervix using a speculum and clean it with an antiseptic solution.
5. Carefully advance the 5F catheter through the cervical canal and past the internal cervical os until the catheter is positioned within the uterine cavity.
6. The 7 cm marking on the catheter is helpful for proper catheter placement.
7. Attach saline to open syringe and introduce through catheter slowly.
8. Remove the speculum and insert the transvaginal transducer into the proper position adjacent to the catheter.
9. Activate the ultrasound system and inject saline as required for the procedure. Usually, 3 cc to 20 cc of saline is sufficient for proper diagnosis.
10. Perform sonohysterography in the usual manner.
11. Endometrial distention can usually be maintained throughout the procedure. If uterine distention is not visualized by ultrasound while saline is being injected through the catheter, or if leakage from the vagina is observed, verify that the catheter is correctly positioned within the uterine cavity before continuing.
12. Upon completion of the sonohysterography procedure, carefully remove the catheter from the uterine cavity.

Glossary of Symbols

LOT	Batch code
	Manufacturer
MD	Medical device
	Temperature limit 10-40°C
	Humidity limitation 30-80%RH
	Biological Risks
	Do not re-use
	Consult instructions for use
	Expiry Date (YYYY/MM/DD)
	Caution
	Do not use if package is damaged and consult instructions for use
	Single sterile barrier system and using ethylene oxide
REF	Catalogue number
	Not made with Natural Rubber Latex

Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to Bioteque Taiwan Ltd. and to the applicable competent authority having jurisdiction in their locale.



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