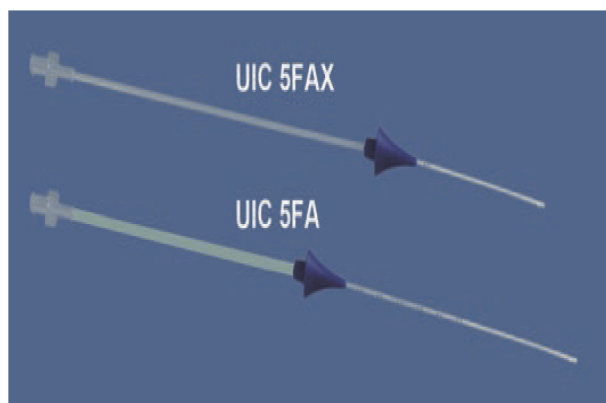




Not made with natural rubber latex

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 5FA (with Cervical Cone) 

UIC 5FAX (with Cervical Cone) 

Each 25 sterile catheters per box.

Indications

The Bellota Sonohysterography Catheter with Cervical Cone (Model: UIC 5FA) 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

Dispose of medical waste properly in accordance with regulations after using.

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 removing air and flushing the saline channel.
3. Adjust the protective sheath so that just 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. The single-lumen tube is featured with centimeter depth markings along its distal segment from 6-10cm to set the depth of insertion. It is helpful to place the catheter properly.
6. Carefully advance the 5f catheter through the cervical canal and past the internal cervical OS, so that the catheter is within the uterine cavity while the catheter advanced and placing the acorn to avoid any fluid reflux.
7. Attach saline to open syringe and introduce through catheter slowly.
8. Remove the speculum and insert the transvaginal transducer into its proper position adjacent to the catheter.
9. Now activate the ultrasound system and inject saline as required by the procedure. Usually, 3cc to 20cc is sufficient saline for a proper diagnosis.
10. Perform Sonohysterography in the usual way.
11. Endometrial distention usually can be maintained throughout the procedure. If uterine distention is not visualized with ultrasound while saline is injected into the catheter or leaking is observed from the vagina, verify that the catheter is positioned correctly in the uterine cavity before continuing.
12. Upon completion of Sonohysterography, remove the catheter carefully from uterine cavity.

Glossary of Symbols

	Batch code
	Manufacturer
	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
	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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