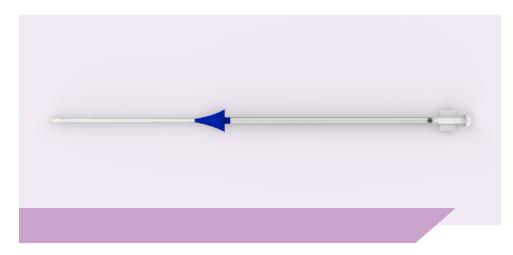


BELLOTA SONOHYSTEROGRAPHY CATHER WITH CERVICAL CONE

7272026 Rev. 0



STERILE EO

The catheter is to be used for sonohysterography procedure 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.

The Bellota Sonohysterography Cather with Cervical Cone is available in a 5 (f) size and is 296mm in length.

PRODUCT NUMBER

HBI-UIC5FA - 25 sterile catheters per box

NOT MADE WITH NATURAL RUBBER LATEX

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

Do not reuse for avoiding user may be infected by the microorganism.

INDICATIONS

The Bellota Sonohysterography Catheter with Cervical Cone Catheter is used to access the uterine cavity for saline infusion Sonohysterography procedure.

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.

PROCEDURE

- Remove the catheter from the sterile pouch.
- Attach the saline source to the open luer and allow the saline to flow through the catheter removing air and flushing the saline channel.
- Adjust the protective sheath so that just 1/2 to 1 cm of the

catheter protrudes beyond the sheath.

- Expose the cervix using a speculum and clean it with an antiseptic solution.
- 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.
- 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 is advanced and placing the acorn to avoid any fluid reflux.
- Attach saline to open syringe and introduce through catheter slowly.
- Remove the speculum and insert the transvaginal transducer into its proper position adjacent to the catheter.
- Now activate the ultrasound system and inject saline as required by the procedure. Usually, 3cc to 20cc is sufficient saline for a proper diagnosis.
- Perform Sonohysterography in the usual way.
- 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.
- Upon completion of Sonohysterography, remove the catheter carefully from uterine cavity

STORAGE

Store at room temperature.



20855 NE 16th Ave, Suite C15,





HNM is committed in providing improved surgical outcomes for surgeons and healthcare professionals.

T: 1.866.291.8498 F: 305.513.5740

Miami, FL 33179