

Disposable Sound - Dilator

For use in Uterine Sounding and Dilation of the Cervical Os
in Laparoscopic and Hysteroscopic procedures

Description

The Clinical Innovations' Disposable Sound - Dilator is used to find the cervical os, sound the uterus for depth and direction, and provide for comfortable dilation of the stenotic os. It is a sterile product made of soft, flexible molded plastic material, which meets USP recommendations. The product is designed for single use in the physician's office or in the operating room. The Sound- Dilator is ready for use as it comes from the package. The curved design allows the device to follow the natural shape of the cervical canal. One end of the device is used for sounding the uterus for depth and direction and is marked at 1 cm intervals, beginning at 4 cm and ending at 10 cm. The other end is used as a cervical dilator and is also marked at 1 cm intervals to ensure it is not inserted farther than the depth of the uterus. The instrument has an overall length of 27.5 cm (10.9 inches) and a maximum outer diameter of 5.5 mm (.022 inches) (see Figure).

Indications

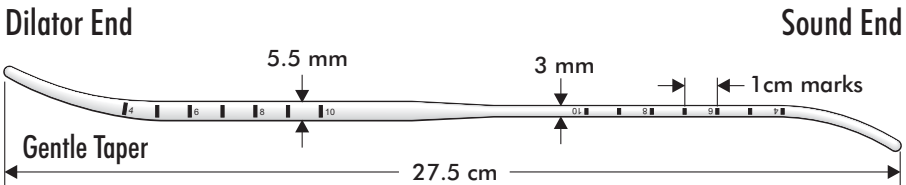
The Sound - Dilator is for use in laparoscopy or hysteroscopy involving the female pelvic organs when sounding of the uterus or dilation of the cervical canal is indicated.

Contraindications

Pregnancy or suspicion of pregnancy
Uterine or tubal infection
Uterine anomaly (associated with a small cavity or irregular cervical canal)
DES exposed uterus with small uterine cavity or cervical irregularity.
Cases in which the surgeon deems it inadvisable or finds it difficult to insert

WARNINGS

Avoid excessive force if resistance is encountered during



Instructions for Use

1. Check the sterile pouch for integrity. Remove the instrument using sterile procedure.
2. Perform a bimanual examination to determine the uterine position.
3. Sound the uterus using the sound end of the device to determine its depth and direction using standard techniques. Remove device.
4. If dilation is desired, use the dilation end of the device to go through and expand the cervical canal. Do NOT insert beyond the sounded depth of the Uterus in step 3.
5. Remove and dispose of the device as appropriate for medical products contaminated by human use.



Product No.
DSD-1000

Packaging: 50 units per box

LATEX FREE



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