

Comfort-Flex Dilator™ Set

Uterine Dilators

DIRECTIONS FOR USE

PRODUCT # 64-376



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DESCRIPTION

The Comfort-Flex Dilator Set includes three separate instruments made of Teflon that are designed for superb tactile sensation. The set, which are used to locate the external os, dilate the endocervical canal and identify the location of the uterine fundus, are all 21.5cm total length. The shaft has a blunt distal tip, which gradually tapers from a 1.7mm outer diameter to a maximum of 3.8mm. Each device is unique in its range to maximum dilation and varies according to purpose. The OS Locator (one ring) has the shallowest depth of dilation at 2.3cm, followed by the Canal Dilator (two rings) at 4.5cm. The Fundus Finder™ (three rings) provides the greatest length of dilation to 8.5cm.

INDICATIONS FOR USE

- Cervical os location
- Gradual cervical canal dilation
- Location of uterine fundus

CONTRAINDICATIONS FOR USE

The Comfort-Flex Dilators should not be used:

- In patients who are absent a uterus
- In patients who are pregnant or are suspected of being pregnant
- In patients with existing pelvic inflammatory inflammatory disease (PID)
- In patients whose clinical condition and/or anatomy otherwise deem its use to be inadvisable in the opinion of the physician

WARNINGS

The Comfort-Flex Dilator instruments should be used only by trained and qualified physicians. As with other devices intended for intrauterine insertion, a potential for uterine perforation and/or trauma always exists. Use extreme caution when probing the uterus for depth and direction. An anteriorly or posteriorly directed curved device may cause perforation of an oppositely directed uterus. Never use force to

Canal Dilator™ Set

Canal Dilator

WARNINGS continued

advance the instruments against resistance. The blunt 1.75mm distal tip of the Comfort-Flex Dilator will frequently permit its easy passage through the internal cervical os. Therefore, resistance felt beyond the external os should be treated with extreme caution.

DIRECTION FOR USE

- 1** Once an estimation of the size and direction of the uterus has been determined, prepare the cervix for the insertion of a device according to your normal protocol for such procedures.
- 2** Grasp the Comfort-Flex Dilator instrument in one hand with a comfortable grip.
- 3** Position the distal tip of the shaft against the cervical face and gently probe until the opening of the external os is located.
- 4** Slowly advance the shaft to gradually dilate the endocervical canal. Some resistance will be felt as the distal tip of the shaft encounters the internal cervical os. Maximum dilation should be accomplished using the Canal Dilator but limited according to each patient's uterine anatomy.
- 5** Slowly retract the Canal Dilator and carefully insert the Fundus Finder™. Advance the device to gently follow the curvature of the patient's uterus.
- 6** The fundus of the uterine cavity is determined to have been reached when resistance that cannot be overcome when very gentle probing is applied. This is the uterine depth. (Note: An abnormally shallow uterine depth may indicate a medical abnormality).
- 7** Completely remove the device.

CARE

Thorough maintenance will ensure proper function of these instruments. It is important to clean and sterilize each instrument according to instructions. Proper maintenance will extend the life of the instrument. Do not allow this device to come into contact with harsh chemicals. Handle each instrument carefully. Do not handle in groups or stack with other instruments.

CLEANING

Rinse and clean instruments immediately following use. Remove adherent particles which may cause staining. Enzymatic cleaning agents may help reduce organic matter and facilitate its removal. Foreign organic matter may reduce sterilization effectiveness. Follow the instructions under "Care" for proper handling of instruments. Wear protective gloves during the cleaning procedure. Never use corrosive cleaning agents (i.e. bleach). Fully immerse instruments in cleaning agent. (Warm water and a mild detergent are preferred). Neutral pH cleaning agents are recommended (if unknown check MSDS or with distributor). A soft bristle brush (toothbrush type) should be used to remove difficult matter from the device. A final rinse of distilled or softened water is recommended.

STORAGE

Store instruments in a dry, moisture-free area.

STERILIZATION *Steam Autoclave Sterilization*

- Follow the manufacturer's instructions for operation and loading of steam autoclave.
- There must be direct steam exposure to all surfaces of the instrument being sterilized.
- Autoclave temperatures should not exceed 280°F (137°C); pressure should not exceed 32 p.s.i. (2.2 atmospheres).
- Standard cycle of 270°F (132°C) for 10 minutes will vary depending on autoclave model, autoclave size, load size, and load configuration.

RECOMMENDED AUTOCLAVE CYCLES

Allow longer times for lower temperatures. Allow instruments to cool down from autoclave to room temperature. Do not immerse in any fluid until the instrument has been allowed to cool.

Gravity Displacement Cycles

270°—275°F for 10-15 minutes **or**
250°F / 15 for 30 minutes

Prevacuum Cycles

270°—275°F for 3-4 minutes