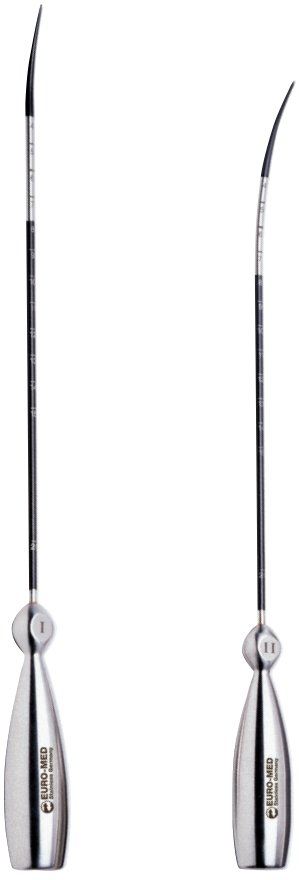
Dil-Os™
Uterine Sound/Dilators

Instructions For Use



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DEVICE DESCRIPTION

The Dil-Os™ Uterine Sound/Dilator instrument is a reusable stainless steel device with a 23 cm long rigid shaft attached to an ergonomically designed handle that rovides superb tactile sensation and instrument balance. The shaft has a blunt distal tip that gradually tapers from 1.5 mm outer diameter to a maximum of 4.0 mm outer diameter at the 4.0 cm mark. Graduation marks are shown in one centimeter increments on the anterior and posterior sides of the shaft. A color change in the shaft is readily apparent at the 4.0 cm depth mark and again at the 8.0 cm mark to afford rapid estimation of the device's depth of insertion. A visually observable and digitally felt flat surface located on the distal segment of the handle indicates the direction of the curve of the distal end of the shaft. The Dil-Os is available in two curvatures to accommodate a variety of uterine positions.

INDICATIONS FOR USE

- Cervical os location
- Gradual cervical canal dilation up to 4.0 mm
- Determination of uterine depth and direction

CONTRAINDICATIONS

The Dil-Os Uterine Sound/Dilator should not be used:

- in patients who no longer have a uterus
- in patients who are pregnant or are suspected of being pregnant
- in patients with existing pelvic 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 Dil-Os 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 sounding the uterus for depth and direction. An anteriorly or posteriorly directed curved sound may cause perforation of an oppositely directed uterus. Never use force to advance Dil-Os against resistance. The blunt 1.5 mm distal tip of the Dil-Os will frequently permit its easy passage through the internal cervical os. Therefore, resistance felt beyond the 3.5 cm insertion depth should be treated with extreme caution.

INSTRUCTIONS 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 handle of the Dil-Os in one hand with a grip that you find most comfortable and accommodating for your use of the device. Note the direction of the curvature of the distal end of the shaft in the direction of the uterus.
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 requires further insertion of the shaft which will be limited according to each patients uterine anatomy.
5. Slowly continue to advance the device while gently manipulating the curvature of the shaft's distal segment into the direction that follows the curvature of the patient's uterus.

6. When the fundus of the uterine cavity is determined to have been reached or resistance that cannot be overcome with very gentle probing, read the marking on the shaft that is at or closest to the external cervical os. This is the measured uterine depth. Also note the curvature direction of the patient's uterus by the position of the flat surface on the Dil-Os handle's distal segment.
7. Completely remove the device and confirm the initial uterine depth reading by observing the mark on the shaft at which the presence of mucus (moisture) ends.

CLEANING AND STERILIZATION

CARE

Thorough maintenance will ensure proper function of the Euro-Med instruments. It is important to clean and sterilize each instrument immediately after each procedure. Proper maintenance will also extend the life of the instrument.

- Handle each instrument individually. Do not handle in groups or stacks.
- Rinsing and cleaning must take place immediately following the instrument's use for decontamination. Adherent particles may resist cleaning or cause staining. Instruments are to be completely cleaned of all foreign matter with special attention focused on channels in contact with body tissue and fluid. Thorough cleaning is essential prior to sterilization.
- Wear protective gloves during the cleaning procedure

CLEANING

1. Prepare the neutral pH enzyme cleaning solution (Enzol®) at 75% concentration (11.7 mL/L) of that recommended by the cleaning agent manufacturer.
2. Soak the devices in the cleaning solution for 1 minute. Record the time.
3. Clean the devices by washing with a soft bristle brush in the cleaning solution until all soil has been visually removed. Record the total time spent brushing the device.
4. Remove from the cleaning solution and rinse the devices in tap water for 0.5 minute. Record the time.
5. Prepare another batch of the neutral pH enzyme cleaning solution (Enzol®) at 75% concentration (11.7 mL/L) of that recommended by the cleaning agent manufacturer.
6. Soak the devices for 1 minute. Record the time.
7. Remove the devices from the cleaning solution and rinse in tap water for 0.5 minute. Record the time.
8. Visually inspect the instruments for visible contamination or debris and then dry with a lint free wipe.

STERILIZATION

WARNING: Do not sterilize these instruments with Ethylene Oxide (EO), Liquid Chemical (Cold Soak) or Sterrad.

Recommended Steam Autoclave Sterilization Parameters

- The instrument(s) should be thoroughly cleaned of all foreign matter prior to sterilization following the steps above.

STERILIZATION PROCESS	EXPOSURE TEMPERATURE	EXPOSURE TIME	DRY TIME
Gravity Displacement	250° F / 121° C	30 minutes	30 minutes
Pre-vacuum	270° F / 132° C	4 minutes	30 minutes
Pre-vacuum	273° F / 134° C	3 minutes	30 minutes

STORAGE

Instruments should be stored dry in a moisture free area.

The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect from damage if stored in drawers.

EXPLANATION OF SYMBOLS

REF Reorder number

LOT Lot number

Consult instructions for use

Caution

Non-sterile
Sterilize before use

Do not use if package is damaged

Manufacturer

R_x Only **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Product of Germany

CooperSurgical

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974
Fax: (800) 262-0105
www.coopersurgical.com

International
Phone: +1 (203) 601-9818
Fax: +1 (203) 601-4747

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