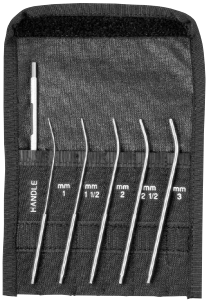
Cervical Dilator Sets

INSTRUCTIONS FOR USE

PRODUCT #'s

Hank Cervical
Dilator Set
#64-370

Small Cervical
Dilator Set
#64-372



Mini Cervical
Dilator Set
#64-374

R_xOnly **CAUTION U.S.** Federal Law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Euro-Med Cervical Dilators are designed to dilate the cervical canal to allow entry into the uterus for evaluation of the cervical canal or uterine cavity. The stainless steel reusable dilators are comfortable to hold and allow the physician to dilate the cervix and endocervical canal with excellent control.

The Euro-Med Hank Cervical Dilator Set contains 6 dilators in half-millimeter increments from 4.5mm to 10mm. Each dilator has a full millimeter size and a half millimeter size and comes in a custom fitted numbered pouch.

The Euro-Med Small Cervical Dilator Set contains 6 dilators in 1mm increments from 1mm to 6mm and comes in a fitted carrying pouch. These are designed for patients with a tight cervical os.

The Euro-Med Mini Cervical Dilator Set includes a universal handle that holds any of five dilators in half-millimeter increments from 1mm to 3mm. A rounded tip on each dilator helps prevent puncture of the uterine wall.

INDICATIONS FOR USE

Cervical dilatation is indicated whenever there is a need to insert an instrument through the cervical canal and the canal is not dilated enough to allow free passage of that instrument.

CONTRAINDICATIONS

Absolute contraindications include hypovolemic shock, cardiac decompensation (Class IV) and coagulapothy/blood dyscrasia. Cervical biopsy performed during active local infections, especially those caused by Herpes Simplex, Chlamydia or Gonococcus, may increase the risk of pelvic inflammatory disease (PID), and should be avoided.

WARNINGS

Bleeding after dilation may occur but can usually be controlled by direct pressure with cotton swabs. Silver nitrate or Monsel's solution (AstrinGyn®) may be helpful in controlling persistent oozing. The patient should be informed that there may be some vaginal discharge/spotting and that intercourse should be avoided for at least 72 hours after the procedure.

PRECAUTION

Adequate local anesthesia and visualization should be achieved before initiation of the procedure in an informed patient. Adequate visualization of the entire cervix with sufficient lighting should be achieved to assure proper placement of cervical dilator.

It may be necessary to manipulate the cervix toward the introitus to make the os accessible or to straighten the cervical canal. The cervix should be stabilized with a tenaculum to the anterior cervical lip to allow visualization of the os and entry into the canal.

One must take care not to perforate the uterine cavity by exerting too much pressure with the dilator if resistance is felt. If perforation does occur the patient must be observed to ascertain whether laparoscopy or laparotomy needs to be performed.

INSTRUCTIONS FOR USE • Sterilize Dilators Before 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 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 shafts 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 plain on the handles 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.
- 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 a protective tray with partitions. Protect with cloth or gauze if stored in drawers.

EXPLANATION OF SYMBOLS

REF Reorder number

LOT Lot number

Consult instructions for use

Caution

NON STERILE Nonsterile 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

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