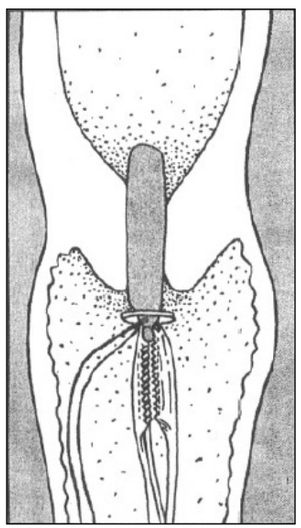
DILATERIA REMOVAL INSTRUCTIONS

NOTE: Not to be removed by patient.

To avoid breaking the top of the Dilateria (visible outside the cervical canal), apply gentle force using forceps to grasp the tip of the Dilateria.

1. Have patient empty bladder.
2. Depress the posterior vaginal wall with one or two fingers to allow for the removal of vaginal packing with forceps.

   Do not use the string to remove the device.
3. To prevent breakage, carefully remove Dilateria by forcep traction on tip of Dilateria visible in the cervical canal.
4. For the occasional spastic internal os it may be necessary to use forceps to grasp the Dilateria and exert steady traction for several minutes while the uterus is stabilized by placing an atraumatic tenaculum through the anterior lip of the cervix.



5. In very rare cases the ballooning of the inserted Dilateria above and/or below the internal cervical os has been known to cause a “tight cervix” and make for difficult Dilateria removal.

   This is corrected by sliding a sequence of graduated sizes of metal dilators along side the Dilateria and through the internal os until sufficient dilation takes place to permit easy withdrawal.

   If the Dilateria has somehow migrated or been placed in a false passage, it may be located using ultrasound. **NOTE:** the Dilateria is not radiopaque.
6. In the very rare instances where the Dilateria breaks inside and it is difficult to remove, insert an additional Dilateria to obtain greater dilation. This will facilitate the removal of broken parts with narrow forceps or by suction aspiration.

DILATERIA POST REMOVAL INSTRUCTIONS

1. Calibrate cervical canal for adequacy of dilation. Examine removed Dilateria for abnormal constrictions. They may indicate areas difficult to traverse with other instruments.
2. If additional dilation is required:
   - Remove plastic collars on Dilateria and insert an increased number of the same size of fresh Dilateria on successive days
   - OR insert increasingly larger sizes of fresh Dilateria on successive days
   - OR insert metal dilators in the standard manner

   NOTE: Dispose of in accordance with all applicable Federal, State, and local Medical / Hazardous waste practices.

Special Situations

The occasionally rigid internal os may require a preinsertion sedative or a paracervical block to enable placement of Dilateria.

Another technique is to place a Dilateria in the cervical canal up to the internal os or as far as possible on one day and replace with a fresh Dilateria on the next day at which time sufficient softening and dilation may have occurred in order to allow passage through restricted area.

FOLLOW-UP INSTRUCTIONS TO PATIENT

Patient should immediately report any bleeding heavier than menstrual flow, and any unusual pain or fever over 100°F (38°C).

EXPLANATION OF SYMBOLS

REF Reorder Number

LOT Batch Code

Expiration Date

Non-Sterile

Do Not Reuse

Latex Free

See Instructions for use.

ETHYLENE OXIDE PROCESSED: Device may have viable spores present after processing.

CooperSurgical

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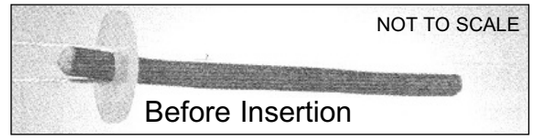
36999 • Rev. A • 9/09

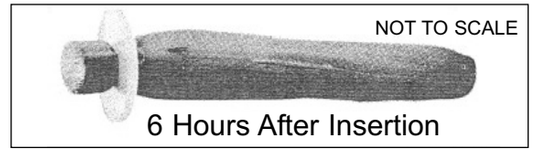
Dilateria
(Laminaria Hyperborea) Cervical Dilator

DILATERIA PART NUMBERS & SIZES (all sizes approximately 60 mm long)		
Product Number	**Diameter at Middle**	**Size**
MX210	3+mm	Thin
MX220	4+mm	Medium
MX230	5+mm	Thick
MX240	6+mm	Extra Thick

DEVICE DESCRIPTION

Dilateria is derived from Laminaria Hyperborea, a seaweed that grows in the waters of northern Europe. The stipe, or stem, is dried, sized and subsequently hand-processed to assure a proper rounding of the tip and a uniform diameter.
A string is attached for ease in location, and a disc is placed on the end to control migration further into the cervical canal.





A Dilateria is capable of absorbing fluids from the uterine cervix.

Gradual swelling of the Dilateria (up to four times its diameter) results in a simultaneous gradual symmetrical dilation of the cervical canal and softening of cervical tissue.

The Dilateria diameter swells most within the first 4 to 6 hours after insertion and may continue to swell for 12 hours or more. Swelling can be accelerated when saturated gauze squares are used to hold the Dilateria in place immediately after insertion.

For more than a century, laminaria has been preferred by many physicians, who have found its gradual dilation far less traumatic than rapid dilation. Today, Laminaria Hyperborea is commonly used as a dilation aid.

Dilateria is visible on ultrasound.

WARNINGS

- Laminaria is a sea-grown plant that may have viable spores present even after processing with Ethylene Oxide.
- Dilateria should only be used in absence of infections or in “clean cases.” Acute cervicitis or gonococcal infection should be treated with a test of cure before Dilateria insertion is attempted.
- Any cervical manipulation may cause a vaso-vagal reaction. Patient should be watched for evidence of unusual pallor, nausea, vertigo or weakness. By remaining recumbent for 3 to 10 minutes these symptoms usually disappear.
- Single use only. (Dilateria becomes brittle if reused, and may break.)
- Do not use for more than 24 hours. Follow sterility and medication routines at each insertion.
- Unusual heavy bleeding must not be present prior to patient release.
- Do not force Dilateria into a seemingly obstructed cervix. Probe gently. If cervix is obstructed, you my have to predilate.
- **DO NOT pull string to remove Dilateria.**
- If Dilateria is being used for abortion, and patient changes her mind after insertion, advise patient that long-term effects on the pregnancy and the fetus are unknown. Fetal and maternal well-being in this situation cannot be assured.

CAUTIONS

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

INDICATIONS FOR USE

- Cervical dilation
- Softening of the cervix
- Cervical stenosis
  a. related to dysmenorrhea
  b. considered a possible cause of infertility
  c. resulting from cauterization or conization
- Placement and removal of intrauterine devices
- Induction of labor
- Improving visualization at colposcopy
- Drainage of uterine cavity
- Endometrical biopsy
- Uterine curettage
- Suction cannula aspiration

CONTRAINDICATIONS

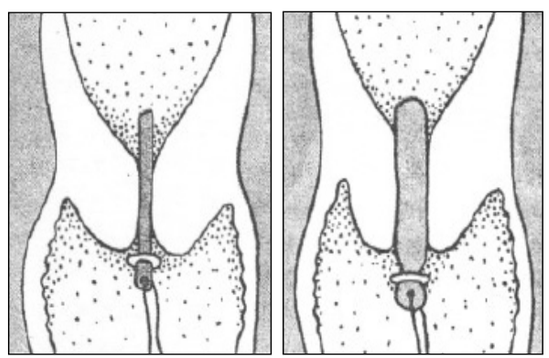
- Dilateria should not be used in the presence of a vaginal, cervical or pelvic infection. The infection must be treated before Dilateria insertion is attempted.
- A “non-compliant” patient - patient must return within 24 hours for removal of Dilateria.
- Incidence of infectious complication is possible.

PRIOR TO INSERTION OF DILATERIA, INFORM PATIENT OF:

- Purpose of Dilateria insertion
- Advantages of Dilateria over traditional means of cervical dilation
- Risk of infection if patient does not return as instructed
- Other risks if Dilateria is left in place over 24 hours
- Patient may feel discomfort similar to a menstrual cramp while Dilateria is in place.
- Patient is to call her physician immediately should she develop a fever over 100°F (38°C), chills, pain, or vaginal bleeding while Dilateria is in place.
- Report if Dilateria falls out.
- **Under no circumstances should patient try to remove Dilateria herself**

DILATERIA INSERTION INSTRUCTIONS

1. Note size and position of uterus while doing a pelvic examination. An empty bladder increases accuracy of this examination.
2. With vaginal speculum in place, thoroughly cleanse vagina and cervix with antiseptic solution.
3. Sound cervical canal for patency; sound should pass easily through internal os. Note the direction of canal, spasticity of the internal os and the presence of false passages.
4. Grasp the Dilateria with long forceps for placement in the endocervical canal. The string indicates the proximal end of the device (see diagram).



Dilateria Upon Insertion **Dilateria Expanded**

IMPORTANT: It is recommended that if multiple Dilateria are inserted together, the plastic collars (discs) should be removed.

If using Dilateria without disc, be sure to have Dilateria extending outside of the cervical canal a minimum of 10mm (approximately 1/4") so that the end of the Dilateria can be grasped with a forcep for removal.

5. Gradually insert Dilateria until plastic disc contacts external os. **Do not force insertion.** Attached string should rest in the vaginal vault for easy identification of the Dilateria. It is important that the Dilateria traverses the internal and external os for proper dilation at these sites.
6. If uterus moves upward in the pelvis during Dilateria insertion, stabilization can be accomplished by placing an atraumatic tenaculum through the anterior lip of the cervix. The patient should be warned of a transient sharp pain when placing tenaculum.
7. To avoid expulsion during uterine contractions and/or dilation, pack Dilateria with the provided 4"x4" gauze squares. Place the first square like a blanket over the cervical canal and Dilateria. Remaining gauze squares should be placed in the fornices to hold the first gauze square in place.
8. To avoid infection and to keep Dilateria intact, Dilateria should never be left in place for more than 24 hours. Maximum dilation and softening occurs within approximately 12 hours.
9. Patient should be instructed to avoid bathing, douching and refrain from intercourse while Dilateria is in place.