

E. **Never** force dilator into your vagina. When you are relaxed, it should slide forward only with slight pressure. You will know the dilator is in fully when it will not move further in upon relaxation.

F. **For pain associated with sexual intercourse:** Leave dilator in place a moment or two to experience the “feel” of the dilator inside your vagina. Now slide it out gently.

**For post-reconstructive surgery or post - radiation:**

Withdraw dilator then reinsert several times for about 5 to 10 minutes.

G. Wash dilator with mild soap and water and rinse thoroughly.

If you have accomplished Step 1 with little difficulty, go on to Step 2 (otherwise, practice Step 1 once or twice a day until you are more relaxed).

### Step 2

A. Insert smallest size lubricated dilator and hold it in vagina for several minutes.

B. Repeat until you are able to keep the dilator in for 10 minutes without discomfort. It may take several tries over several days to reach a goal of 10 minutes. Proceed to Step 3.

Note: You may have to hold the dilator in place with one hand so that it doesn't slip out.

### Step 3

A. Insert smallest size (lubricated) dilator. Hold it still a moment - then try moving it around. Wiggle it gently side to side. Slide it in and out.

B. When Step 3 has been accomplished, start over with Step 1 using the next size dilator.

### Medications: Post-Reconstructive Surgery

If there are no contraindications, estrogen vaginal cream may be recommended for women without ovaries. The estrogen cream is inserted vaginally once a week.

### Medications: Post-Radiation Therapy

Your doctor will determine if you should use an estrogen cream, depending on the type of condition you have. Apply lubricant as directed.

### Important Notes Regarding Intercourse

- **Post-reconstructive surgery:** Intercourse may begin 10 to 14 days following surgery - if no bleeding or infection is present.

- **Post-radiation:** Intercourse is recommended during radiation treatments only when no bleeding or infection is present.

Intercourse on a regular basis may decrease the frequency of mechanical dilation needed.

Check with your doctor if you have any questions about these recommendations.

### Important Notes Regarding Bleeding

- Spotting after surgery or radiation treatment is normal. If heavy bleeding occurs, contact your physician.

### Special Instructions Before Return Visit

- Do **not** use vaginal dilators for 3 days before your next scheduled appointment.

### Explanation of Symbols

**REF** Catalog number

**LOT** Batch code

 Consult instructions for use

 Caution

 Non-sterile

 Not made with natural rubber latex

 Do not use if package is damaged

 Manufacturer

**R<sub>x</sub> Only** **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.

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## Instructions for Use Milex<sup>™</sup> Vaginal Dilators



### Set of 4 Dilators (Sm/Med/Lg/X-Lg):

**MX20-CA:** Vaginal-Hymenal Dilator Set

**MX25-CA:** Vaginal-Rectal Dilator Set

**MX23-CA:** Pediatric Size Vaginal Dilator Set

### Individual Dilators:

P/N	Size	Inches	mm
<b>MX20I</b>	Small	5-1/8 x 15/16	130 x 24
<b>MX20IM</b>	Medium	5-1/2 x 1-1/16	140 x 28
<b>MX20IL</b>	Large	5-3/4 x 1-1/4	146 x 32
<b>MX20IXL</b>	X-Large	6-1/8 x 1-1/2	157 x 38
<b>MX23I</b>	Small	2-1/16 x 1/2 x 3/8	52 x 13 x 10
<b>MX23IM</b>	Medium	2-5/16 x 9/16 x 7/16	63 x 14 x 11
<b>MX23IL</b>	Large	2-11/16 x 5/8 x 1/2	68 x 16 x 13
<b>MX23IXL</b>	X-Large	3 x 11/16 x 9/16	76 x 18 x 14
<b>MX25IS</b>	Small	3 x 11/16	76 x 17
<b>MX25IM</b>	Medium	3-1/8 x 15/16	80 x 24
<b>MX25IL</b>	Large	3-9/16 x 1-1/8	90 x 28
<b>MX25IXL</b>	X-Large	3-15/16 x 1-5/16	100 x 34

### Device Description

- Dilators can help overcome the pain of intercourse by teaching patients how to relax the vaginal muscles.
- Dilators are recommended following radiation therapy and reconstructive vaginal surgery to help restore elasticity of vaginal tissue.

### Warnings

- Never force dilator into your vagina. When you are relaxed it should slide forward only with slight pressure.
- DO NOT USE oil-based lubricants. Oil-based lubricants are not water-soluble and can be irritating to the vaginal walls.

### Indications for Use

Vaginal dilators are devices developed for progressive vaginal dilation therapy in the treatment of vaginismus (muscular spasm of the vagina) and the conditions that result in constriction of the vaginal and/or rectal orifice. Such conditions may be the result of vaginal and/or rectal reconstruction surgery or radiation therapy.

## Contraindications

- Pregnant patients should not use dilators.
- Patients suspected of vaginal infection

## Use of Dilators for Pain Associated with Sexual Intercourse

You have been prescribed a set of vaginal dilators which, when used as instructed, can help overcome pain associated with intercourse. Such pain is often caused, at least in part, by a spasm of the muscles around the vaginal entrance. This muscle tension is called vaginismus.

## Use of Dilators Following Reconstructive Vaginal Surgery

You have just had reconstructive surgery of your vagina. The vaginal dilators you have been prescribed, when used as instructed, can help keep the vagina open and the tissue more supple, making intercourse and follow-up examinations more comfortable. Begin using the dilators as soon as possible after your surgery. Use dilators, as prescribed, for 5 to 10 minutes daily for 10 days. Leave dilator in place overnight if you are not having intercourse.

## Use of Dilators Following Radiation Treatments

Radiation of vaginal tissue results in a decrease in the blood supply in that area, this decrease helps shrink or slow the growth of a tumor. A potential side effect for this decreased blood supply is the loss of elasticity normally found in vaginal tissue. There may also be increased tenderness in the area. The use of vaginal dilators will help keep the vagina open and the tissue more supple, making intercourse and follow-up examinations more comfortable. Begin using the dilators 2 weeks after your radiation therapy. Use dilators, as directed, for 5 to 10 minutes daily for 10 days. On the 11th day, you can begin using the dilator every other day. You may need to do this for the rest of your life, to keep the vagina healthy. The vagina may be sore after the onset of radiation treatments. If it is too painful to use the dilators or to have intercourse, consult your doctor.

## Instructions Prior to Inserting Dilator

The first step in using a vaginal dilator is to learn how to relax the muscles that surround the vagina. Follow the steps below to practice relaxing those muscles, known as pubococcygeal (PC) muscles.

1. Squeeze by tensing the PC muscles (as if you were trying to stop urinating in midstream). Hold and count to 3.
2. Stop squeezing and relax. Let the PC muscles go loose.
3. Repeat steps 1 and 2 several times. These actions are called Kegel exercises.

Continue to do these exercises twice a day, doing 10 in a row each time.

## Patient and Physician Cleaning Instructions for Individual Dilators

### GENERAL CLEANING INSTRUCTIONS FOR INDIVIDUAL DILATORS

1. Prepare a cleaning solution by mixing a mild soap (such as Dawn<sup>®</sup> or equivalent) with tap water using the soap manufacturer's recommended concentration. Prepare this solution in a container large enough to fully submerge the device.
2. **Soak and Scrub**
  - A. Soak the device in the container of prepared soap solution for a minimum of 5 minutes.
  - B. Following the 5-minute soak period, scrub the device for a minimum of 15 seconds with a soft-bristled brush, such as a tooth brush and/or pipe brush. Scrub device below water line to prevent aerosolization of contaminants.
  - C. Following scrub, inspect device for visible soil residue.
3. **Rinse**
  - A. Remove the device from the soap solution and thoroughly rinse under flowing tap water for a minimum of 30 seconds.
  - B. Allow the device to dry.

### PHYSICIAN ONLY: HIGH LEVEL DISINFECTION AND STERILIZATION FOR DILATOR SETS MX20-CA, MX25-CA AND MX23-CA

#### High Level Disinfection

1. Prepare a container of Revital-Ox<sup>™</sup>, RESERT<sup>®</sup> STERIS, Cidex<sup>®</sup> OPA or equivalent disinfectant in a container large enough to fully submerge the device.
2. Transfer the device to the container to soak. Ensure that the device is completely immersed in the disinfecting solution. Soak the device for at least 9 minutes in RESERT or 12 minutes in Cidex OPA
3. Rinse the device thoroughly in sterile water.
4. Place the cleaned/disinfected device in an appropriate dry storage area.

#### Sterilization of Dilators

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

## Preparation for Use

You and your physician will determine which size vaginal dilator to use first. For pain associated with sexual intercourse, start with the smallest dilator.

Wash your hands prior to using dilators.

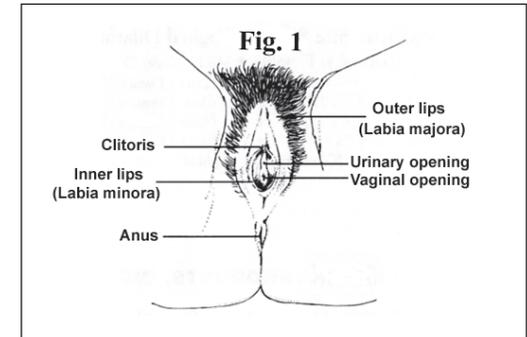
Apply water-base lubricant to the tip end of the dilator.

## Instructions to Insert Dilator

If you have problems during any of the following steps, call your physician.

### Step 1: Initial Insertion

- A. Lie down and bring your knees up and apart. You may find it easier to use a hand mirror to look at your genital area. (Refer to Figure 1.)
- B. If not already done, lubricate the entering end of the dilator to the rounded tip.
- C. Separate the labia (the lips, Figure 1). Now tense the PC muscles as practiced and relax.



- D. Slide lubricated dilator into vagina. You may have to slip it in a little at a time.

Note: Each time you squeeze the PC muscles, hold dilator in place so it isn't pushed out.

As soon as you relax, push dilator a little further into your vagina. (Refer to Figures 2 through 5.)

