



US

INSTRUCTIONS FOR USE

Reusable Dilators

Gynecologic Instrumentation



Manufacturer:
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Intended Use:

Cervical Dilators are intended to be used in locating and dilating the external OS, the cervical canal and the internal OS. These instruments are particularly beneficial for use on postmenopausal patients with cervical stenosis.

Hegar Dilators are indicated to dilate the opening of the uterus, allowing sufficient space for instruments to conduct sampling and/or remove contents.

Device Description:

OS Dilator:

Premier® OS Dilators are malleable, warm and self-lubricating OB/GYN instruments. These instruments deliver excellent patient comfort and are distinguished as OS Locator, Canal Finder and Fundus Dilator based on their tapered length at working end.

Kleegman Dilator:

Premier® Kleegman Dilators are double-ended, narrow shaped OB/GYN instruments. The instrument tips are smooth, rounded and curved slightly in opposite directions. PTFE made Kleegman Dilator shows merit in situations where malleability is desired.

Hegar Dilator:

Premier® Hegar Dilators are smooth, double-ended and slightly curved along the longitudinal axis. These instruments are available in eight (8) different sizes as a set.

Contraindications:

Cervical dilators should not be used under the following conditions –

- Acute genital tract or bleeding diathesis.
- Acute inflammation of the lesser pelvis, sub-acute or chronic endocervicitis or active STDs (Sexually Transmitted Diseases).
- Noticed visible evidence of damage to the instrument.
- An Invasive cancer that is visible on examination.
- Re-use of device on different patient without recommended sterilization.
- During a confirmed or possible pregnancy.

PRECAUTIONS:

- Do not use if the package is damaged/broken, prior to use.
- Prior to first and subsequent use, examine the device for breaks, cracks and/or fractures.
- Discard the device, if any thinning breaks, cracks/fractures are noticed.
- Device must be cleaned and sterilized, prior to first and subsequent usage.
- Medical professionals and assistants should always wear surgical masks and other appropriate Personal Protective Equipment (PPE) when performing dilation procedure.
- Do not apply excessive force on dilator during surgical procedure, as this could cause temporary discomfort to the patient.

Prescription Device, Rx only.

WARNINGS:

- Use of excessive force should be avoided.
- Device should not be used for prolonged periods.
- Do not bend the PTFE made instruments more than 90° from its longitudinal axis.
- A pelvic examination should be performed on the patient prior to dilation to determine conditions present and risks of dilation.

ADVERSE EVENTS:

- Mild Cramping
- Spotting or light bleeding.

Contents and Setup:

| Item No. | Product name |
|----------|------------------------------------|
| 1030581 | Kleegman Dilator – Stainless steel |
| 1030582 | Kleegman Dilator – PTFE |
| 1030585 | OS Dilator Set, set of three (3) |
| 1030586 | OS Locator (Yellow Ring) |
| 1030587 | Canal Finder (Blue Ring) |
| 1030588 | Fundus Dilator (Green Ring) |
| 9030544 | Hegar Dilator – 3/4 |
| 9030546 | Hegar Dilator – 5/6 |
| 9030559 | Hegar Dilator, Set of eight (8) |

Materials:

| Dilators | Material |
|-------------------------|--|
| OS Dilator | ASTM A276/A269/A582 – 300 series Stainless Steel |
| | Teflon (PTFE –Polytetrafluoroethylene) |
| Kleegman Dilator | ASTM A276/A269/A582 – 300 series Stainless Steel |
| | Teflon (PTFE –Polytetrafluoroethylene) |
| Hegar Dilator | ASTM A276/A269/A582 – 300 series Stainless Steel |

Directions for Use:

- Ensure tapered working end of dilator has adequate amount of lubrication.
- Start the procedure with the smallest size dilator in clinical kit.
- Using gentle pressure, slowly insert smooth round working end of the dilator into patient’s cervix.
- Always insert it in the direction of the spine (back) straight or at a slightly downward angle.
- Continue to insert the dilator slowly until the patient experiences slight discomfort or exhibits muscle tension and then stop. The dilator should feel snug but not painful.
- Never use excessive force and stop if the patient is in pain. It is recommended to use the next larger sized dilator, if patient feels no pain or discomfort when inserted.
- Once the dilator is in place, it is recommended to add more lubricant if needed during the procedure.

- Gently push the dilator in and out to stretch the length of cervix.
- Gently rotate the dilator in wide circles to stretch the width of cervix. Repeat this at the back, middle and opening of the cervix.
- Never force dilator into the cervix. When the patient is relaxed, it should slide forward only with slight pressure. This indicates that the dilator went fully inserted will not move further upon patient relaxation.
- Dilator shall be removed after the procedure.

Cleaning:

- Place the instruments in a clean container filled with warm water and mild detergent (use per detergent manufacturers recommendation).
- Use soft nylon brush to remove stains or debris.
- Demineralized water is recommended for rinsing. Allow to dry completely prior to sterilization.

Sterilization/Reprocessing:

- Dilators can be sterilized by autoclave.
- Autoclave process carried out at temperature 273°F (134°C) for 5 minutes, 30 minutes of dry time.
- Dry heat sterilization not recommended.






Storage:

- Always store the device in original protective packaging, prior to first usage.
- Device storage and handling temperature should not exceed (37.7° C) 100° F.
- Extra care should be taken while handling and avoid the Dilators from coming in contact with aggressive and/or caustic solutions.

Shelf Life: Premier Dilators have indefinite shelf life.

Disposal: Dispose the instruments as biohazardous medical waste in accordance to facility or institutional guidelines/procedures.

For Further Information: Please visit premiermedicalco.com

| Symbols | Symbol Meaning |
|---|---|
|  | Manufacturer |
|  | Batch number |
|  | Caution: See instructions for use |
| Rx ONLY | CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician |
|  | Non-Sterile |
|  | Fragile, Handle with care |