**DILAPAN-S® Hygroscopic Cervical Dilator**

**Instructions for Use**

**GENERAL INFORMATION**

**Content**
A sterile hygroscopic cervical dilator packed in a printed composite primary peel-open pouch, a piece of Instructions for use.

The DILAPAN-S® is available in a box of 25 dilators. Product samples for evaluation are provided in a box of 10 dilators. The following dimensions are available: 4×65 mm, 4×55 mm, 3×55 mm.

**Device description and performance**
Synthetic hydrogel cervical dilator consists of the dilating part, the polypropylene handle and the marker string (see the figure below). The dilating part is manufactured from an anisotropic xerogel of AQUACRYL. The dilator is capable of increasing in diameter as it absorbs moisture from the genital tract. The marker string is tied securely to the handle of the DILAPAN-S®, and is provided to indicate its location.

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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</thead>
<tbody>
<tr>
<td>Dilating part made of hydrogel</td>
<td>Collar</td>
<td>Marker string</td>
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</table>

**Handling, transport, storage and waste management**

Store between +15 °C and +30 °C. Keep away from direct sunlight and high humidity.

Do not freeze.

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Sterilization and expiration

The sterilization procedure that has been applied is marked on the label of the device – using irradiation.

The product, its waste materials and other consumables used during the procedure, should be disposed in accordance with local/national regulations.

**INTENDED PURPOSE**

**Indications**
The DILAPAN-S® is to be used wherever cervical softening and dilation is desired, some examples are:
- Cervical stenosis
  - Related to dysmenorrhea
  - Considered a possible cause of infertility
  - Resulting from cauterization or conization
- Placement and removal of intrauterine devices
- Induction of labor
- Radium placement
- Drainage of uterine cavity
- Endometrial biopsy
- Uterine curettage
- Suction aspiration cannula
- Operative hysteroscopy

**Patient target group**
The DILAPAN-S® is targeted for women indicated to labor induction or intrauterine procedure with necessary cervical ripening and/or dilation.

**Intended users**
The DILAPAN-S® is for use by healthcare professionals trained in obstetrics and gynecology only.

**Contraindications**
The DILAPAN-S® is contraindicated in the presence of clinically apparent genital tract infection.

**WARNINGS**
The DILAPAN-S® is intended for one-time use. Instructions for its use and handling are attached to minimize exposure to conditions that may jeopardise the product, patient or user.

Re-use / re-sterilization / reprocessing of the DILAPAN-S® single-use medical device may result in physical damage to the medical device, failure of intended use of the medical device, and illness or injury to the patient as a result of infection, inflammation and / or disease due to product contamination, infections and insufficient sterility of the product.

1) A process carried out on a used device in order to allow its safe reuse including cleaning.

**Use**
Examine the label of the unopened pouch and expiry date of the dilator.

**Instructions for insertion**

1. Insert a bivalve speculum and prepare the vagina and cervix with an antiseptic solution.
2. Remove the DILAPAN-S® from the pouch using sterile technique.
3. Moisten the DILAPAN-S® with sterile water or saline to lubricate the surface prior to insertion.
4. If necessary, use an appropriate technique to visualize the cervix and straighten the cervical canal for easier insertion of the DILAPAN-S®.
5. Insert the DILAPAN-S® in the cervical canal gradually and without undue force. It is important that the DILAPAN-S® traverses the internal os. Do not touch the dilating part with a sharp instrument.

6. Do not insert the DILAPAN-S® past the handle. The border of the collar should rest at the external os. Do not insert the DILAPAN-S® into cervix further than the arrow indicates (see the figure above – 5. Point of maximal insertion).

7. More than one DILAPAN-S® may be inserted into the cervical canal as determined to be appropriate by the physician.

8. When using several dilators, repeat steps 2 to 4. As many dilators as needed to achieve the desired effect should be inserted. Specific number of pieces always depends on decision and clinical judgement of physician and indications.

9. Insert a gauze pad moistened with sterile water or saline to help keep the DILAPAN-S® in place, if needed.

Removal instructions

1. Vaginal packing is first removed, if used during the insertion procedure.

2. Carefully remove the DILAPAN-S® by grasping the handle or pulling the string. Do not twist the DILAPAN-S® during removal. Do not grasp the collar with forceps.

3. Do not grasp the marker string with a sharp-edged instrument.

2) Neither grasp the collar with forceps to remove the device nor twist handle when attempting to remove the device, as this may cause the device to break.

3) Do not grasp the marker string with a sharp-edged instrument to remove the device, as this may cause the string to tear.

When difficulties occur during removal of the device by pulling the string, do not use excessive force on the string to remove the dilator. Use a visualization technique to identify the cause of these difficulties and remove the dilator by grasping the handle.

Occasionally, it may be necessary to use forceps to grasp the DILAPAN-S® by the handle and exert steady traction for several minutes, while the uterus is stabilized by placing an atraumatic tenaculum through the anterior lip of the cervix.

Moisten the DILAPAN-S® with sterile water or saline thoroughly during removal, if the dilator has stuck to the tissue, or more dilators have stuck together.

In very rare cases the ballooning of the inserted DILAPAN-S® above and/or below the internal cervical os has been known to cause a “tight cervix” and make for difficult DILAPAN-S® removal. This is corrected by sliding a sequence of graduated sizes of metal dilators alongside the DILAPAN-S® and through the internal os until sufficient dilation takes place to allow easy withdrawal.

If the DILAPAN-S® has somehow migrated or been placed in a false passage, it may be identified using ultrasound.

NOTE: The DILAPAN-S® is not radiopaque.

INTERACTIONS

Within clinical investigations with the DILAPAN-S®, a broad range of licenced medications have been administered during indicated procedures. No specific interactions between drugs / medical devices and the DILAPAN-S® have been identified to date. Using the DILAPAN-S® does not impose any specific limitations on standard medication administered in the context of the DILAPAN-S® indications. Information provided to particular medications should be followed properly.

External influences

No negative interactions between the DILAPAN-S® and external influences were observed. Desired interference include ultrasound waves that can be used for location of the inserted dilator.

TESTING OUTCOMES

Clinical

Clinical trials have not demonstrated any allergic reactions to the device. However, an allergic reaction could result from hypersensitivity to the components.

Clinical trials have not demonstrated any infections causally related to the DILAPAN-S®. However, in the presence of pathogens, contamination of the device during insertion is possible. Administration of antibiotic for infection prophylaxis should be considered prior to insertion of DILAPAN-S®.

Mechanical

The amount of dilation achieved depends on the amount of time in situ. The following is provided as a guide.

<table>
<thead>
<tr>
<th>Time in situ (hours)</th>
<th>Expected Dilation (in mm)</th>
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<tbody>
<tr>
<td></td>
<td>One DILAPAN-S®</td>
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<tr>
<td></td>
<td>(3 mm)</td>
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<tr>
<td>2</td>
<td>7.2 – 8.3</td>
</tr>
<tr>
<td>4</td>
<td>8.4 – 9.5</td>
</tr>
<tr>
<td>6</td>
<td>9.0 – 10.0</td>
</tr>
<tr>
<td>24</td>
<td>9.6 – 11.3</td>
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TABLE OF USED SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>M</td>
<td>Millimeter</td>
</tr>
<tr>
<td>&amp;</td>
<td>Degrees of Celsius</td>
</tr>
<tr>
<td>R</td>
<td>Sterile, Sterilized using irradiation</td>
</tr>
<tr>
<td>☇</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>☑</td>
<td>Do not re-sterilize</td>
</tr>
<tr>
<td>☐</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>☑️</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>📑</td>
<td>Batch number</td>
</tr>
<tr>
<td>🕋</td>
<td>Expiration date</td>
</tr>
<tr>
<td>🟢</td>
<td>Date of manufacture</td>
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<tr>
<td>⏰</td>
<td>Manufacturer</td>
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<tr>
<td>⏰</td>
<td>Quantity</td>
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CONTACTS AND VIGILANCE

Please report incidents of death to the FDA or serious injury to your distributor (USRegulatory@medicem.com) or to the manufacturer (technology@medicem.com) in relation to the DILAPAN-S®.

Please report any potential or actual product deficiencies, and product quality issues associated with the use of the DILAPAN-S® directly to your distributor (USRegulatory@medicem.com) or to the manufacturer (technology@medicem.com).

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Initial Importer, Distributor and US Agent:
Medicem Inc. 125 High Street, Suite 1704 Boston, MA 02110 Tel.: +1 973-534-2396 e-mail: USRegulatory@medicem.com

Liability

The manufacturer holds no liability for any side effects or resulting damages, losses or costs that may arise as a result of the incorrect handling or use of the device.

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