**DILAPAN-S® Hygroscopic Cervical Dilator**

**Instructions for Use**

**GENERAL INFORMATION**

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

The DILAPAN-S® is available in a box of 25 dilators and in the following dimensions: 4x65mm, 4x55mm, 3x55mm.

**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.

![Diagram of DILAPAN-S®](image)

1. Dilating part made of hydrogel
2. Collar
3. Marker string
4. Handle
5. Point of maximal insertion

**Handling, transport, storage and waste management**
Store between +15 °C and +30 °C. Keep away from direct sunlight and high humidity. Do not freeze.

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

**Sterilization and expiration**
The sterility of each device is guaranteed only when the primary packaging is unopened and undamaged.

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

**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 cautery 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.

Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus and to avoid migration of the device either upward into the uterus or downward into the vagina.

The DILAPAN-S® may fragment during removal using incorrect technique. Fragmentation may result in pieces of the device being retained in the uterus. Carefully follow the Removal instructions.

**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®.
When M
Do not insert the DIL
V aginal packing is first removed, if used during the insertion procedure. I
Car
I nsert the DILAPAN-S® in the cervical canal gradually and without undue force. It is 282x163
The amount of dilation achieved depends on the amount of time in situ. The following 282x672
1.
TESTING OUTCOMES

2.
INTERACTIONS

In very rare cases the ballooning of the inserted DILAPAN-S® above and/or below the 282x436
If the DILAPAN-S® has somehow migrated or been placed in a false passage, it may 282x348
Within clinical investigations with the DILAPAN-S®, a broad range of licenced medications 282x382
DILAPAN-S® removal. This is corrected by sliding a sequence of graduated sizes of metal 282x478
Moisten the DILAPAN-S® with sterile water or saline thoroughly during removal, if the 282x594
The manufacturer holds no liability for any side effects or resulting damages, losses or 282x807
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).

Manufacturer:
MEDICEM Technology s.r.o.
Karlovarska trida 20, Kamenne Zehrovice
273 01, Czech Republic
Tel.: +420 317 070 370
e-mail: technology@medicem.com
http://www.medicem.com

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.

TABLE OF USED SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>R</td>
<td>Sterile, Sterilized using irradiation</td>
</tr>
<tr>
<td>C</td>
<td>Degrees of Celsius</td>
</tr>
<tr>
<td>ster</td>
<td>Caution, Consult accompanying documents</td>
</tr>
<tr>
<td>lot</td>
<td>Batch number</td>
</tr>
<tr>
<td>exp</td>
<td>Expiration date</td>
</tr>
<tr>
<td>man</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>qty</td>
<td>Quantity</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeter</td>
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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>
</tr>
<tr>
<td></td>
<td>(3 mm)</td>
</tr>
<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>
</tr>
</tbody>
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