• Fast acting hygroscopic cervical dilator made of patented AQUACRYL hydrogel specifically developed for obstetrics and gynaecology.¹

• Approved in more than 40 countries worldwide* for labor induction, including USA [510(k), Class II] and EU [CE mark, Class IIa].

• Manufactured at an ISO 13485 certified facility. Sterilized by gamma irradiation.

Sources/References:

* The date of January 2016 it is 44 countries. Worldwide registrations including premarket notifications, no objection letters and other types governmental approval and EEA incl. Switzerland and Turkey.
**Multiple mode of action**

Mimics physiological processes of the labor

- **Mechanical:** Controlled pressure on the cervical wall dilates the cervix
- **Biophysical:** Partial reversible osmotic dehydration softens the tissue
- **Physiological:** Promotion of endogenous prostaglandins release causing collagen degradation and tissue restructuring

**Dilapan-S®** doesn’t contain any pharmacologically active substance, which could be released during its use.

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**Efficacy and safety confirmed by**

- **International observational e-registry on the use of Dilapan-S® osmotic dilator for cervical ripening prior to labor induction (ongoing)**
  - 11 study sites from 7 countries participate in the project to collect induction of labor clinical data
  - Data from 6 centers / 214 patients included in the 1st interim analysis in Q4/2015

- **Prospective clinical study comparing Dilapan-S® with PGE, gel and Estradiol gel**
  - 247 patients randomized, 82 treated by Dilapan-S®

- **Prospective, observational, multicentre data collection on the use of osmotic dilator Dilapan-S® in labor pre-induction in females with/without Caesarean section in medical history**
  - 6 study sites collected data from 96 patients, incl. women with previous Caesarean section

- **Prospective observational study evaluating Dilapan-S® efficacy and safety**
  - 92 patients

- **Retrospective study evaluating efficacy and safety of Dilapan-S® in labor pre-induction**
  - 68 patients, incl. women with previous Caesarean section

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**General recommendation for the treatment regimen:**

<table>
<thead>
<tr>
<th>Cervical ripening</th>
<th>Labor induction (promotion of uterine contraction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-4 pieces of Dilapan-S® 4 x 55 mm for 12-15 hours*</td>
<td>ARM** + uterotonic***</td>
</tr>
</tbody>
</table>

* Number of pieces can differ depends on initial Bishop score.

** Artificial rupture of membranes can be proceeded if beneficial and in line with local clinical protocol.

*** Dilapan-S® ripens the cervix independently on uterine contractions. After the cervical ripening, uterotonic such as oxytocin is recommended to promote adequate uterine contractions. If cervical ripening does not develop into spontaneous vaginal birth.

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**Efficacy**

- Significant Bishop score increase 2, 3, 4 and vaginal delivery rate up to 80 %. 2, 3, 4
- Spontaneous vaginal delivery with no pharmacological intervention up to 20 %. 2, 3, 5–8, 10
- Suitable for VBAC 2, 3, 6, 10

**Safety**

- No hyperstimulation or fetal pathology during cervical ripening
- No infectious complications related to the use of Dilapan-S®
- No limitation related to mother’s gestational age and/or comorbidities

**Cost-effectiveness**

- Potential prevention of C. sections in high-risk groups of patients 2, 3, 5–8, 10, 11
- Out-patient regimen (home cervical ripening) for low-risk groups of patients 2, 3, 4
- Saving time of health care professionals thanks to one-time application and no need of continuous CTG monitoring 2

**Patient satisfaction**

- Low rate of uterine contractions during cervical ripening 2, 3, 5–8, 10, 11
- Up to 90 % of women can relax or sleep during cervical ripening 2, 3, 4
- Minimising of vaginal examination during cervical ripening

**Unique combination of efficacy, safety and patient satisfaction**

- For clinicians helps to minimise safety risks while maintaining high efficiency 2, 3, 5
- For mothers ensures gentle and predictable cervical ripening and promotes natural vaginal delivery 2, 3, 4
- For health care providers offers reduction of overall healthcare cost 2, 3, 4

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**Dilapan-S®**

Gentle. Predictable.