Dilapan-S® is an osmotic hygroscopic dilator produced from a patented Aquacryl hydrogel that guarantees consistency of action. It is a rigid gel rod that increases in volume by absorbing fluids so gradually dilating the cervix. After 2–6 hours, the 3 mm rod will have expanded to 8.3–10 mm and the 4 mm rod up to 10–12.5 mm. Simultaneously, Dilapan-S® initiates endogenous prostaglandin release causing collagen degradation which softens the cervix.

Dilapan-S® is sterilized by irradiation. It is manufactured in an ISO 9001 Certified facility and is fully CE Certified under the Medical Device Directive (EN46002). Approved by FDA for sale in the United States.

**Indications for use:**
- cervical ripening prior to the induction of labour
- cervical dilation prior to instrumentation of the uterine cavity, eg. termination of pregnancy, ERPC, fetal demise, etc.

**Contra-Indications:**
- clinically evident genital infection
- menstruation

**Recommendation for use:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 mm x 55 mm</td>
<td>Cervical ripening prior to the induction of labour</td>
</tr>
<tr>
<td>4 mm x 65 mm</td>
<td>Cervical preparation prior to the termination of pregnancy</td>
</tr>
<tr>
<td>3 mm x 55 mm</td>
<td>When Dilapan-S® 4 mm can not be inserted in early pregnancy, or when removal is to be accomplished in less then 4 hours</td>
</tr>
</tbody>
</table>
Tips for insertion:

- Moisten Dilapan–S® with sterile water or saline to lubricate the surface prior to insertion.
- A tenaculum may be used to stabilise the cervix and to straighten the cervical canal.
- Grasp Dilapan–S® at the handle. Gradually and without undue force, insert Dilapan–S® until it traverses the external and internal os.
- Do not insert Dilapan–S® past the handle. The border of the handle should rest at the external os.
- If inserting multiple Dilapan–S®, repeat the above steps for each one.
- Do not leave Dilapan–S® in place more than 24 hours.
- To remove Dilapan–S®, grasp the handle only with forceps and apply steady downward traction, in line with the long axis of the dilator. Do not twist excessively and do not use the marker string.
- For detailed instructions for use, please read the leaflet in each pack.
Successful labour induction is clearly related to the state of the cervix. Women with an unfavorable cervix who have not experienced cervical ripening phase before labor present the greatest challenge with regard to labor induction. 

“Labour should only be induced if the Bishop Score is 5 or higher — this indicates sufficient cervical ripening.”

Hygroscopic dilators (like Dilapan–S®) significantly enhance cervical ripening and increase the Bishop Score enabling smoother labour induction.

Comparison with control group:

<table>
<thead>
<tr>
<th>Initial Bishop score</th>
<th>Bishop score after 12 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilator group (N = 112)</td>
<td>4.0</td>
</tr>
<tr>
<td>Control group (N = 128)</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Comparison with PGE$_2$:

<table>
<thead>
<tr>
<th>Admission cervical score</th>
<th>Post-ripening cervical score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilator group (N = 214)</td>
<td>4.1</td>
</tr>
<tr>
<td>PGE$_2$ group (N = 202)</td>
<td>4.2</td>
</tr>
</tbody>
</table>

Non-significant difference.
Gentle and predictable cervical ripening prior to the labour induction

“Onset of regular uterine activity as a result of preinduction is negative and unwanted side effect”¹

“The principal role of the agents used for cervical ripening is to soften an unripe cervix independent of uterine activity”³

Hygroscopic dilators produce minimal uterine activity during the ripening process⁵,⁷

**Uterine contraction during ripening phase**⁵

<table>
<thead>
<tr>
<th></th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilator group (N = 214)</td>
<td>44.0</td>
</tr>
<tr>
<td>PGE₂ group (N = 202)</td>
<td>47.1</td>
</tr>
</tbody>
</table>

p = 0.001

**Uterine hyperstimulation and abnormal fetal heart rate changes**¹⁰

<table>
<thead>
<tr>
<th></th>
<th>Uterine hyperstimulation (%)</th>
<th>Deceleration of fetal heart rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilapan (N = 90)</td>
<td>0 %</td>
<td>0 %</td>
</tr>
<tr>
<td>PGE₂ gel (N = 95)</td>
<td>5.2%</td>
<td>3.1%</td>
</tr>
</tbody>
</table>

**Dilapan-S® key benefits:**

- significant increase in cervical ripening and Bishop score⁴,⁵
- high predictability due to material and mode of action
- minimal risk of uterine hyperstimulation and impact on the fetal heart rate⁵,⁶
- no pharmacological side effects
- effective and safe even in women with Caesarean section in medical history¹²
- accentuates the physiological processes of labour
- very high patient acceptability
Gentle and predictable cervical preparation prior to the termination of pregnancy

Dilapan-S® represents one of the most preferred methods for cervical preparation prior D&E procedure in second trimester thanks to its predictability, efficacy and safety.

Society for Family Planning Clinical Guidelines, 2013

Conclusions and Recommendations:

Level A:

- When osmotic dilator placement and D&E are to be performed on the same day, Dilapan-S® is preferred over laminaria tents to achieve adequate priming more quickly.
- Osmotic dilators achieve more preoperative dilation than mifepristone or misoprostol.
- Dilapan-S® is safe and effective for cervical preparation prior to D&E.
- Use of osmotic dilators does not increase infectious morbidity.

Level B:

- Prior to 20 weeks' gestation, adequate cervical preparation may be achieved with a single set of osmotic dilators.
- Dilapan-S® placed 3–4 h prior to D&E is a safe alternative to overnight dilator placement up to 18 weeks' gestation.

Level C:

- Use of misoprostol or mifepristone as an alternative to osmotic tents increases risk of inadequate cervical dilation.
- Routine use of adjunctive buccal misoprostol in addition to osmotic dilators is not recommended before 16 weeks' gestation but may be considered when difficult cervical dilation is anticipated or at later gestational ages.
- Only experienced providers capable of managing difficult cervical dilation should use protocols omitting osmotic tent placement prior to D&E.
- Overnight placement of osmotic dilators is recommended after 18 weeks' gestation. Highly experienced D&E providers may consider same-day procedures at later gestations utilizing a combination of osmotic and pharmacologic agents or serial doses of misoprostol.

RCOG Evidence-based Clinical Guidelines, No 7, Nov 2011

- After 14 weeks of gestation, osmotic dilators provide superior dilatation to medical methods (grade B)
Dilapan-S®

Fast acting synthetic osmotic cervical dilator

Developed to enable same-day D&E procedure in late first and second trimester

Cervical dilation over the course of the 3–4 hours period

<table>
<thead>
<tr>
<th></th>
<th>diameter in mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilapan-S® group (N = 60)</td>
<td>9.8</td>
</tr>
<tr>
<td>Misoprostol group (N = 62)</td>
<td>10.2</td>
</tr>
</tbody>
</table>

Treatment with Dilapan-S® demonstrated statistically improved dilation over misoprostol, when analysis was controlled for the inequity of cesarean deliveries between the two arms (P = 0.049), and when the five participants misclassified according to strata were removed in a per-protocol analysis (P = 0.047) respectively.

The ease of further mechanical dilation (% of patients)

<table>
<thead>
<tr>
<th></th>
<th>Not needed / very easy</th>
<th>Moderate</th>
<th>Very difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilapan-S®</td>
<td>10.0</td>
<td>40.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>62.0</td>
<td>19.0</td>
<td>29.0</td>
</tr>
</tbody>
</table>

Dilapan-S® key benefits:

- in comparison with misoprostol, Dilapan-S® offers higher efficacy and better predictability helping to avoid challenging situations
- efficacy enables same-day D&E procedure in late 1st and 2nd trimester
- gradual atraumatic dilation
  - significantly reduces the risk of cervical injury and suture repair
  - preserves full functionality of the cervix for future pregnancy
- no pharmacological side effects
- minimising risk of uncontrolled abortions, eg. during the night
- evaluated by SFP Guidelines as the best product in its class of osmotic cervical dilators
Gentle and predictable cervical ripening prior to the labour induction

- significant increase in cervical ripening\(^4,5\)
- high predictability due to material and mode of action
- minimal risk of uterine hyperstimulation and impact on the fetal heart rate\(^5,6\)
- no pharmacological side effects
- effective and safe even in women with C. section* in medical history\(^12\)
- accentuates the physiological processes
- very high patient acceptability

\(* C. section = Caesarean section*

Sources: