Dilapan-S® is a fast acting synthetic osmotic cervical dilator made of patented AQUACRYL® hydrogel specifically developed and approved for cervical ripening. Its mode of action is based mainly on its hydrophilic properties; after being inserted into the cervix, it absorbs fluids from surrounding tissue expanding in size and resulting in progressive cervical dilation. In addition to its mechanical effects, other mechanisms include the release of endogenous prostaglandins, collagen degradation and tissue softening due to a partial reversible dehydration of the cervical tissue.

The physiological process of labor is mimicked by multiple modes of action

- 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® does not contain pharmacologically active substances.

One 4 mm rod has the capability of increasing its volume by reaching a diameter of up to 15mm. To ensure adequate Bishop score increase, multiple rods are used for cervical ripening prior to labor induction.

Health care professionals and their patients can enjoy many benefits while using Dilapan-S® for cervical ripening:

- Safety for the mother and fetus thanks to non-pharmacological approach.
- Highly effective procedure with a successful cervical ripening achieved in 94% of cases and vaginal delivery rate in up to 80% of women.
- Gentle and predictable ripening.
- Time and money saved thanks to a single application and no need for monitoring during the ripening process.
- Possibility of outpatient cervical ripening

Insertion / extraction guide

1 | It is recommended to take 20 minutes of continuous CTG monitoring before device placement.

The recommended instruments for the procedure are two sponge forceps, speculum, gel, gloves and Dilapan-S® 4mm size rods.

The patient can remain on her bed with her legs folded upwards. Special stirrups or the lithotomy position are not usually necessary.

The procedure can be a bit uncomfortable, but generally it is well tolerated by most patients. No local anesthesia is necessary.

2 | The cervix is visualized with a sterile vaginal speculum. Appropriate cleaning solution (e.g iodine) is recommended, but not necessary to clean the cervix.
Using a second sponge forceps, the rod is inserted through the external cervical os gradually and without undue force. It is essential that the tip of the rod goes through the internal os. Do not insert the Dilapan-S® past the handle.

Insert as many pieces as possible (usually 3-5) of Dilapan-S® into the cervical canal. The number of pieces inserted varies, as patients have different pelvic or cervical/dilation. Each rod can act as a guide for subsequent rods to be inserted.

The mother should be informed that some minor bleeding can occur during insertion; this is common and should not be a concern. Insert a gauze pad to help keep the Dilapan-S® in place, if needed.

Another 20 minute CTG is recommended after the insertion procedure is completed.

The Patient could be sent home for the cervical ripening period and can shower and perform regular activities. Bathing, douching and sexual intercourse should be avoided while the rods are in place. The patient is instructed to report any excessive bleeding, pain, frequent contractions or other concerns to their clinician immediately. Under no circumstances should the patient try to remove the rods herself.

The rods should be left in place for approximately 12 hours. This is the optimal amount of time to adequately increase the Bishop score. Do not leave the rods in place for longer than 24 hours.

Reasons for examining or removing the dilators prematurely include:

- Spontaneous onset of labor (defined as regular, firm uterine contractions with an effaced cervix > 80% and a cervical dilation > 3cm)
- Category III fetal heart rate tracing
- Spontaneous rupture of membranes or need for amniotomy
- Spontaneous expulsion of dilators

While removing the rods, use sponge forceps to grasp a handle of the rod. They usually come out as a clump. Please ensure all inserted rods are removed.

The Bishop score can be determined at the end of removal procedure during the same vaginal examination. If the cervix remains unfavorable after the first series of dilators, a second series can be inserted to continue the cervical ripening for up to an additional 24 hours (but this is usually not necessary, the cervical ripening success rate is over 94%).

After the removal of Dilapan-S®, use ARM and oxytocin administration to promote uterine contractions and reach vaginal delivery.

<table>
<thead>
<tr>
<th>Cervical ripening</th>
<th>Labor induction (promotion of uterine contraction)</th>
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<tbody>
<tr>
<td>3-5 pieces of Dilapan-S® 4x55mm for 12 hours*</td>
<td>ARM** + uterotonic***</td>
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</table>

* Number of pieces can differ depending 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 independent of uterine contractions. After the cervical ripening, a uterotonic such as oxytocin is recommended to promote adequate uterine contractions. If cervical ripening does not develop into spontaneous vaginal birth.

References:

Dilapan-S® rods are intended for single use. The device is approved in more than 40 countries worldwide for use whenever cervical softening and dilation are desired. incl. USA (510(k), Class II) and EU (CE mark, Class IIa). Hydrogel rods are packed individually and distributed in boxes of 10 and 25 pieces. The shelf life of Dilapan-S® is 36 months. The device should be stored at room temperature. Manufactured at an ISO 13485 certified facility. Sterilized by gamma-irradiation. Please refer to Instruction for use for complete information on product usage, indications and contraindications.