Dilapan-S®

HYGROSCOPIC CERVICAL DILATOR

Instruction guide
Induction of labor

medicem

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 release of endogenous prostaglandins, collagen degradation and tissue softening due to partial reversible dehydration of the cervical tissue.

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.

One 4 mm rod has the capability of increasing its volume by reaching diameter up to 15 mm. 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:[2]

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

Insertion / extraction guide

A/ It is recommended to take 20 minutes of continuous CTG monitoring before device placement.

The usually required equipment is two sponge forceps, speculum, gel, gloves and DILAPAN-S® 4 mm size rods.

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

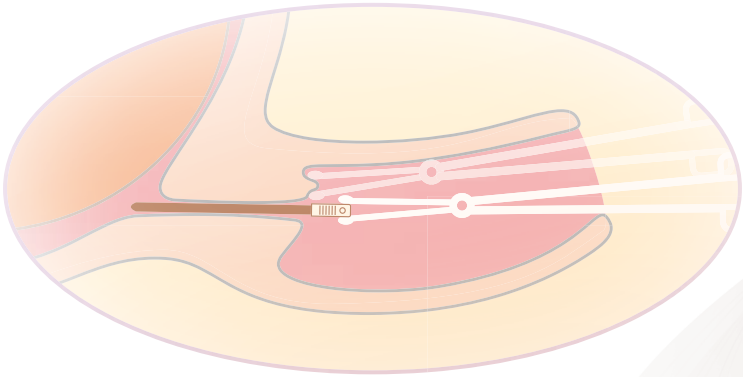
Insertion is usually fully acceptable by women, so there is no need of any local anesthesia.

B/ The cervix is visualized with a sterile vaginal speculum. Appropriate cleaning solution (e. g. iodine) is recommended, but not necessary to clean the cervix.

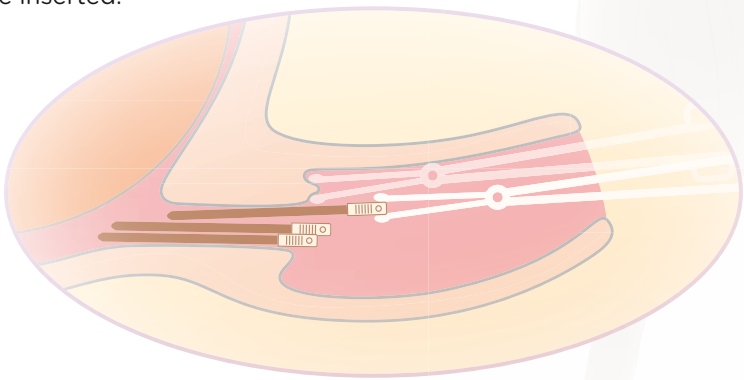
Sponge forceps rather than a tenaculum should be used to stabilize the anterior lip of the cervix and to straighten the cervical canal for easier insertion of the rods. It can be beneficial especially in case of highly unmatured cervix.

DILAPAN-S® rod can be moistened with sterile water or saline to lubricate the surface prior to insertion.

C/ 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.



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



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 to keep the DILAPAN-S® in place, if needed.

D/ Another 20 minutes CTG is recommended to be performed after completion and the patient could be offered to leave the hospital and spend the ripening period at home.

The patient is instructed to report any excessive bleeding, pain or other concerns. Under no circumstances should the woman try to remove the rods herself.

The patient is allowed to shower and perform regular activities, but should avoid bathing, douching and sexual intercourse while the rods are in place.

E/ The rods should be left in place up to 12 hours, which is usually sufficient time for increasing the Bishop score adequately. Do not leave the rods in place for longer than 24 hours.

Reasons for examining or removing the dilators prematuraly include:

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

F/ 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 unfavourable after the first series of dilators, a second series can be inserted to continue the cervical ripening for up to additional 24 hours (but this is usually not necessary, the cervical ripening success rate is over 94 %).

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

Cervical ripening	Labor induction (promotion of uterine contraction)
3–5 pieces of DILAPAN-S® 4 x 55 mm for 12 hours*	ARM** + uterotonic***

* 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.

References:
1. Drunecky, T. et al: Experimental comparison of properties of natural and synthetic osmotic dilators. Arch Gynecol. Obst., Published online: 25 Jan 2015. 2. Gupta, J.: Synthetic osmotic dilator prior to induction of labor: outocmes from international observational e-registry. Oral presentation, EBCOG 2017, Turkey. 3. Instruction for use

DILAPAN-S® rods are intended for single use.
The device is approved in more then 40 countries worldwide for use wherever 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.

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