Protocol

Dilapan-S®

USE OF DILAPAN-S®

FOR CERVICAL RIPENING DURING INDUCTION OF LABOR

Dilapan-S is a firm hygroscopic cervical dilator rod composed of Aquacryl®, a synthetic patented hydrogel. Each rod absorbs fluid from the surrounding cervical tissue and expands to several times its original diameter, gradually softening and dilating the cervix.[1-3]

Dilapan-S is for use by healthcare professionals trained in OB/GYN whenever cervical softening and dilation are desired, such as for cervical ripening during term labor induction or gynecological procedures that require cervical preparation.[2]

Dilapan-S is contraindicated in the presence of clinically apparent genital tract infection.[2]

For additional information, see the full **Dilapan-S Instructions for Use**.[2]

Note: This document is not intended to provide medical advice. It is only an example of how your practice or institution may develop guidelines/protocols for the incorporation of Dilapan-S as a cervical ripening option in the induction of labor.

Appropriate Patient Types When Choosing Dilapan-S® for Cervical Ripening

As always, good clinical judgment should be used when determining a course of action for any patient. When choosing appropriate candidates for the use of Dilapan-S for cervical ripening, consider patients who require induction of labor and have the need for cervical ripening.

Dilapan-S is appropriate for a broad range of patient types.[1,3,4] Some examples are:

- Nulliparous
- Multiparous
- Elective Inductions at Term (≥39 weeks)
- Post-date Pregnancies (>41 weeks)
- Obese
- Diabetes
- Preeclampsia
- Previous Cesarean Delivery (TOLAC)
- Oligohydramnios

Induction of labor would not be appropriate for patients who have indications for delivering by cesarean section. Examples of such patients include but are not limited to patients with the following conditions[5,6]:

- Non-Reassuring Fetal Status
- Fetal Malpresentation
- Placenta Previa
- Prior "Classical" Vertical Uterine/ Myomectomy Scar
- Vasa Previa
- Placental Abruption

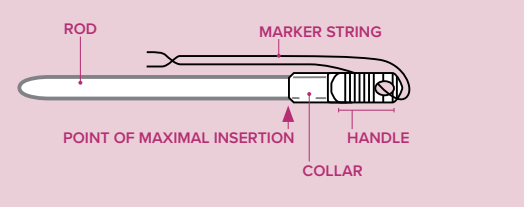
Dilapan-S can be inserted in a variety of healthcare settings, such as a hospital, outpatient clinic, or HCP office.[1,3,7] See below for examples of both inpatient and outpatient protocols.

Once an appropriate candidate for cervical ripening with Dilapan-S has been chosen, follow the insertion guide below. Treatment options and potential risks associated with using Dilapan-S for a planned procedure should be discussed with the patient before the procedure.

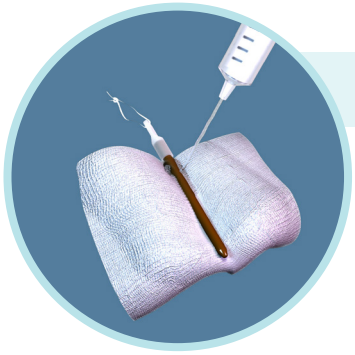
Recommended Equipment

- Two (2) sponge forceps
- Bivalve vaginal speculum
- Sterile water or saline
- Source of light
- Sterile gauze pads
- Antiseptic solution
- Gloves
- Dilapan-S rods (typically 3-5)

DILAPAN-S® SCHEMATIC DIAGRAM



Only grab the handle and not the collar with forceps.

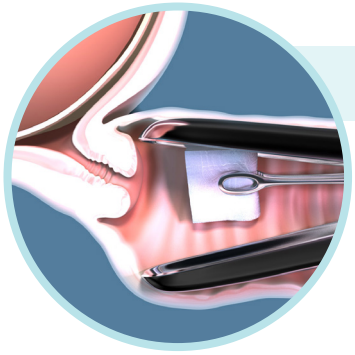


DILAPAN-S PREPARATION

Remove the Dilapan-S rods from their pouch using sterile technique. Moisten the Dilapan-S rods with sterile water or saline to lubricate the surface.

PATIENT POSITIONING

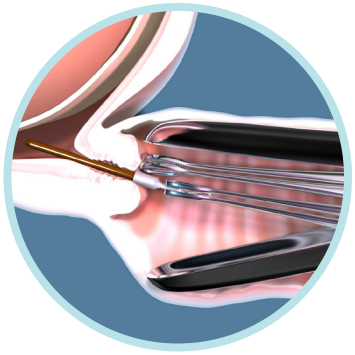
The patient may remain on the bed or exam table with her legs folded upward. The use of stirrups or the lithotomy position is not necessary.



DILAPAN-S INSERTION

Insert a vaginal bivalve speculum and prepare the vagina and cervix with antiseptic solution. If necessary, use appropriate technique to visualize the cervix and straighten the cervical canal for insertion of Dilapan-S.

Use sponge forceps to grasp the handle of the Dilapan-S rod and insert the rod through the external cervical os gradually and without undue force. It is important that the rod traverses the internal os. Do not insert the Dilapan-S rod past the handle. The border of the collar should rest at the external os.



More than one Dilapan-S rod may be inserted into the cervical canal to achieve the desired effect. Insert only one rod at a time. The specific number of rods will depend on the clinical judgment of the treating physician (typically 3-5 rods are used).[1,3,8] Record the number of rods placed.

Gauze pads moistened with sterile water or saline may be inserted to assist in keeping Dilapan-S rods in place, if needed. If using gauze, record the number of gauze pads placed.

Patient should be advised that some minor bleeding can occur.[6]

Provider may choose to use the Patient Care card to record the number of Dilapan-S rods and gauze pads placed. These cards can be obtained through your Dilapan-S Sales Representative.

Patient Instructions

Dilapan-S®

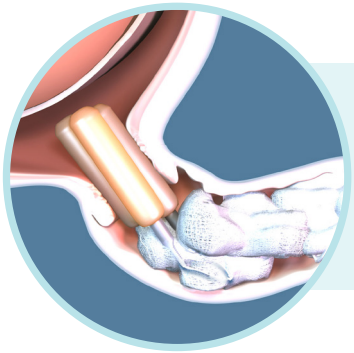
Instruct your patients:

Report any excessive bleeding, pain, or temperature elevation, and to avoid bathing, douching, and intercourse. Patient should return to the physician for removal of the Dilapan-S® at the indicated time and should be instructed not to attempt self-removal under any circumstances.[6] Dilapan-S should not be left in place for more than 24 hours.[6]

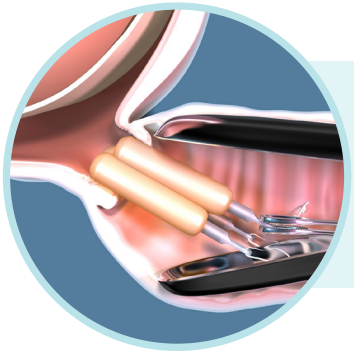
Although Dilapan-S may remain in situ for up to 24 hours, the majority of rod expansion occurs in the first 4-6 hours, which is the minimum insertion time.[6] In clinical studies, the mean time for successful cervical ripening with Dilapan-S rods was 12-15 hours.[2,3,9]

Patient information brochures can be obtained from your Dilapan-S sales representative, or email usinfo@medicem.com

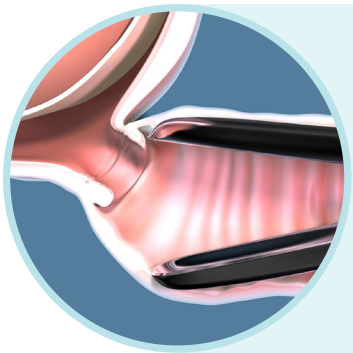
Removal Instructions



Remove any gauze in vaginal canal placed during insertion procedure, if used.



Remove Dilapan-S rods by grasping the handle or carefully pulling the marker string (occasionally it may be necessary to use forceps). Do not twist Dilapan-S rods. Do not grasp the collar with forceps. Do not grasp the marker string with a sharp instrument.



If the rod has stuck to the tissue, moisten with sterile water or saline thoroughly during removal. Rods usually come out as a clump.

Ensure all inserted rods are removed.

Determine Bishop Score.

If the cervix remains unfavorable, a second series of rods can be inserted to continue cervical ripening for up to an additional 24 hours at the provider's discretion.

1

DETERMINE if patient is appropriate for vaginal delivery and induction of labor. Confirm cervical ripening is required and patient is a candidate for Dilapan-S®.

2

INSERT Dilapan-S as per insertion instructions in hospital setting. No additional fetal monitoring is required per provider's discretion.

3

PATIENT REMAINS in hospital, and is given appropriate instructions (see Patient Instructions above). At the provider's discretion, patient may ambulate, shower, use the toilet, and perform daily activities.

The patient should be instructed to report any excessive bleeding, pain, or temperature elevation. The patient should be instructed to avoid bathing, douching and refrain from intercourse while Dilapan-S is in place.

The device **SHOULD NOT** be left in place more than 24 hours.

4

AT THE APPROPRIATE TIME, the Dilapan-S will be removed as per removal instructions and Bishop Score will be determined.

5

IF THE BISHOP SCORE IS FAVORABLE, proceed as per provider's discretion.

5

IF THE CERVIX REMAINS UNFAVORABLE,

a second series of rods can be inserted to continue cervical ripening for up to an additional 24 hours at the provider's discretion.

1

DETERMINE if patient is appropriate for vaginal delivery and induction of labor. Confirm cervical ripening is required and patient is a candidate for Dilapan-S®.

2

INSERT Dilapan-S as per insertion instructions in outpatient clinic or HCP office. No additional fetal monitoring is required per provider's discretion.

3

PATIENT MAY BE SENT HOME per provider discretion with appropriate instructions (see Patient Instructions above). At the provider's discretion, patient may ambulate, shower, use the toilet, and perform daily activities.

4

PATIENT SHOULD BE INSTRUCTED that it is necessary to return for removal of Dilapan-S at the indicated time. Under no circumstances should the patient try to remove Dilapan-S herself.

The patient should be instructed to report any excessive bleeding, pain, or temperature elevation. The patient should be instructed to avoid bathing, douching and refrain from intercourse while Dilapan-S is in place.

The device **SHOULD NOT** be left in place more than 24 hours.

Instruct patient to bring patient care card, if used.

5

AT THE APPROPRIATE TIME, the Dilapan-S will be removed as per removal instructions and Bishop Score will be determined.

6

IF THE BISHOP SCORE IS FAVORABLE, proceed as per provider's discretion.

6

IF THE CERVIX REMAINS UNFAVORABLE,

a second series of rods can be inserted to continue cervical ripening for up to an additional 24 hours at the provider's discretion.

Indications for Use

Dilapan-S® is for use by healthcare professionals trained in OB/GYN whenever cervical softening and dilation are desired, such as for cervical ripening during term labor induction or gynecological procedures that require cervical preparation.

Contraindication: Dilapan-S® is contraindicated in the presence of clinically apparent genital tract infection.

Warnings & Precautions:

- Dilapan-S® is intended for single use only. **Do not** reuse, resterilize, reprocess, or use if primary packaging has been opened or damaged. Discard after use.
- Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus (see Instructions for Use—Insertion). The device should not be left in place more than 24 hours **Instruct patients to:** Report any excessive bleeding, pain, or temperature elevation, and to avoid bathing, douching, and intercourse. Patients should return to the physician for removal of Dilapan-S® at the indicated time and should be instructed not to attempt self-removal under any circumstances.
- Potential Complications/Risks: Twisting of device during removal may cause the device to break (see Instructions for Use—Removal). Complications may include: device entrapment and/or fragmentation, expulsion, or retraction; patient discomfort or bleeding; spontaneous rupture of membranes; spontaneous onset of labor; cervical laceration.

Storage & Handling: Store between +15°C and +30°C and keep away from direct sunlight and high humidity.

Please see Instructions for Use.

ADVERSE EVENT REPORTING

You may report a product complaint or adverse event related to the use of Dilapan-S by calling **1 (888) 257-9676** (United States Only).

REFERENCES: 1. Saad AF, Villarreal J, Eid J, et al. A randomized controlled trial of Dilapan-S® vs Foley balloon for preinduction cervical ripening (DILAFOL trial). *Am J Obstet Gynecol.* 2019;220(3):275.e1-275.e9. **2.** DILAPAN-S® Instructions for Use. DSPIenus-Rev018/2020-04. **3.** Gupta J, Chodankar R, Baev O, et al. Synthetic osmotic dilators in the induction of labour. An international multicentre observational study. *Eur J Obstet Gynecol Reprod Biol.* 2018; 229:70-75. **4.** Maier JT, Metz M, Watermann N, et al. Induction of labor in patients with an unfavorable cervix after a cesarean using an osmotic dilator versus vaginal prostaglandin. *J Perinat Med.* 2018;46(3):299-307. **5.** Cunningham FG, Leveno KJ, Bloom SL, et al. *Williams Obstetrics.* 24th ed. McGraw Hill Education: New York; 2014. **6.** Maier JT, Schalinski E, Gauger U, Hellmeyer L. Cervical ripening with an osmotic dilator (Dilapan-S®) in term pregnancies. An observational study. *J Gynecol Neonatal Biol.* 2015;1(3):1-6. **7.** Dilapan-S® Issuance of Substantial Equivalence Determination. US Food and Drug Administration. 2015. https://www. accessdata.fda.gov/cdrh_docs/pdf13/K133898.pdf. Accessed February 24, 2020. **8.** Vlk R, Hruban L, Janků P, et al. Efficacy and safety of the osmotic dilator Dilapan-S® for cervical ripening in women with/without Caesarean section. Poster presented at the 13th World Congress in Fetal Medicine, The Fetal Medicine Foundation. June 29-July 3, 2014. Nice, France. **9.** Dilapan-S® Issuance of Substantial Equivalence Determination. US Food and Drug Administration. 2015. https://www. accessdata.fda.gov/cdrh_docs/pdf13/K133898.pdf. Accessed February 24, 2020.

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