INDICATIONS FOR USE

Dilapan-S is for use whenever cervical softening and dilation are desired, such as cervical ripening during labor induction.

Dilapan-S is for use by healthcare professionals trained in OB/GYN.

Patient types

Dilapan-S has demonstrated safety and efficacy in a broad range of maternal medical situations, including:[2,3]

- *Nulliparae*
- *Multiparae*
- *Post-dates (>41 wks)*
- *Obesity*
- *Pre-labor rupture of membranes*
- *Diabetes*
- *Preeclampsia*
- *TOLAC*
- *Oligohydraminos*

Mode of action[5]

BIOPHYSICAL The Aquacryl® gel rod promotes cellular dehydration by absorbing moisture, softening the surrounding cervical tissue, and increasing the rod volume.

MECHANICAL The rods expand in diameter and dilate the cervical canal by exerting a radial pressure.

PHYSIOLOGICAL This mechanical stretch leads to the release of endogenous prostaglandins initiating collagen degradation and cervical softening and ripening.

Dilapan-S does not contain any pharmacologically active substance.

Document based on DILAPAN-S Instructions for Use. DSPlenus-Rev018/2020-04. Plus the following where noted: [1]Hruban L, et al. XXIV European Congress of Perinatal Medicine. 2014; [2]Saad AF, et al. Am J Obstet Gynecol. 2019; [3]Gupta J, et al. Eur J Obstet Gynecol Reprod Biol. 2018; [4]Zahumensky, J, et al. 13th World Congress in Fetal Medicine, The Fetal Medicine Foundation. 2014; [5]Dilapan-S Issuance of Substantial Equivalence Determination. US FDA. 2015.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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 re-use, re-sterilize, 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). Do not leave in place > 24 hours. **Instruct patients to:** Report any excessive bleeding, pain, temperature elevation, 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 to not attempt self-removal under any circumstances.

POTENTIAL COMPLICATIONS/RISK

Twisting of device during its 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.

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Medicem, Inc. 125 High St.
STE 1704 Boston, MA 02110

The product information provided herein is intended for residents of the United States.

Dilapan-S®

DEVICE INSERTION & REMOVAL

Dilapan-S is an FDA-cleared, non-pharmacologic, mechanical cervical dilator designed for gentle, safe, and predictable cervical ripening during induction of term labor.

PROCEDURE PREPARATION

Equipment recommended for insertion and removal

- ☐ Two (2) sponge forceps
- ☐ Bivalve vaginal speculum
- ☐ Sterile water or saline
- ☐ Antiseptic Solution
- ☐ Gloves
- ☐ Dilapan-S rods (typically 3-5)

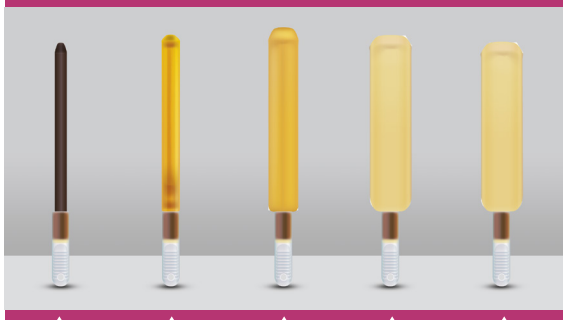
Device preparation

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

Patient positioning

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

ROD EXPANSION TIMELINE



Although Dilapan-S may remain in situ for up to 24 hours, the majority of rod expansion occurs in 4-6 hours, and is the minimum insertion time.[1] In clinical studies, the mean time for successful cervical ripening was 12-15 hours.[2,3]

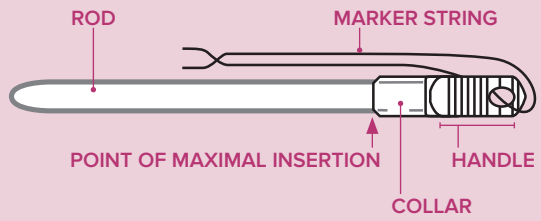
INSERTION

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

2 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 Dilapan-S rod past the handle. The border of the collar should rest at the external os.

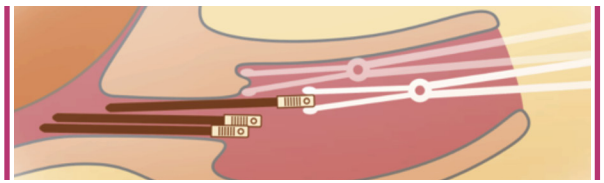
DILAPAN-S SCHEMATIC DIAGRAM



Only grab the handle and not the collar or string with forceps.

3 More than one Dilapan-S rod may be inserted into the cervical canal to achieve the desired effect. The specific number of rods will depend on the clinical judgement of the treating physician (typically 3-5 rods).[2,3,4] Note 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.



REMOVAL

PATIENT ADVISORY & PRECAUTION

Advise the patient that some minor bleeding can occur. The patient should be instructed that it is necessary to return for removal of Dilapan-S at the indicated time. Rod(s) should not be left in place more than 24 hours.

1 Remove any gauze in vaginal canal from insertion procedure.

2 Grasp the handle or marker string of the rod(s), and carefully remove. Do not twist or grasp the collar. For easy visualization, a speculum may be used and the handle grasped with forceps for removal.

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

3 Ensure all inserted rods are removed.

4 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.

Precautions

Instruct patients to: Report any excessive bleeding, pain, temperature elevation, 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 to not attempt self-removal under any circumstances.

For additional information, see full Dilapan-S IFU.

Adverse events

Report side effects from the use of this or any medical device to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088. See full Prescribing Information.