Dilapan-S®

DEVICE INSERTION & REMOVAL

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

medicem

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)

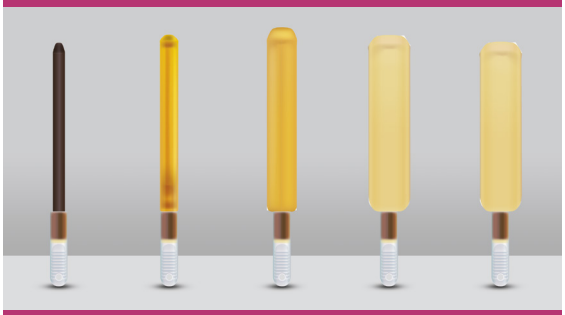
Device preparation

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]*

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.*

Dilapan-S®

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.

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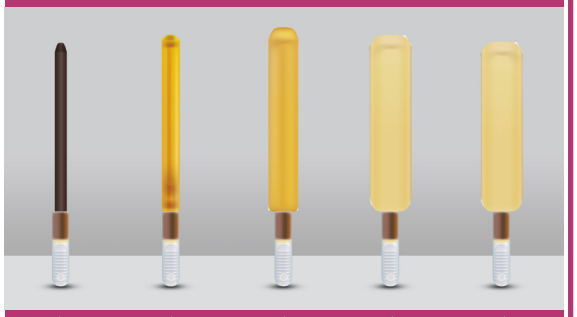

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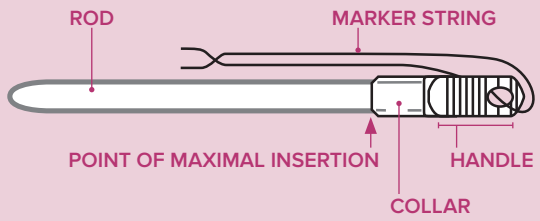
INSERTION

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.

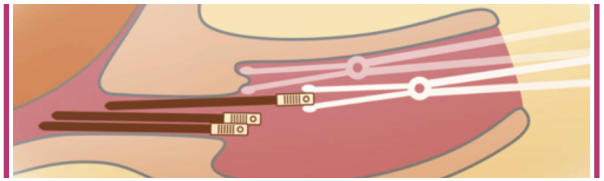
DILAPAN-S SCHEMATIC DIAGRAM



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.

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.

06/2020 – Printed in the USA **US-DS-2000008**

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STE 1704 Boston, MA 02110

DILAPAN-S® Hygroscopic Cervical Dilator

Instructions for Use

GENERAL INFORMATION

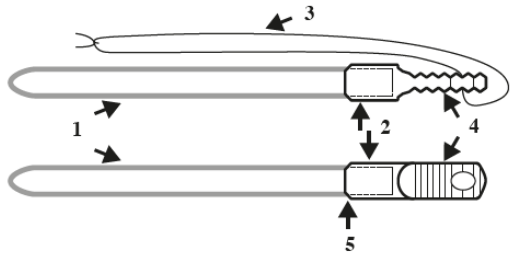
Content

A sterile hygroscopic cervical dilator packed in a printed composite primary peel-open pouch, a piece of Instructions for use.

The DILAPAN-S® is available in a box of 25 dilators and in the following dimensions: 4×65mm, 4×55mm, 3×55mm.

Device description and performance

Synthetic hydrogel cervical dilator consists of the dilating part, the polypropylene handle and the marker string (see the figure below). The dilating part is manufactured from an anisotropic xerogel of AQUACRYL. The dilator is capable of increasing in diameter as it absorbs moisture from the genital tract. The marker string is tied securely to the handle of the DILAPAN-S®, and is provided to indicate its location.



1. Dilating part made of hydrogel
2. Collar
3. Marker string
4. Handle
5. Point of maximal insertion

Handling, transport, storage and waste management

Store between +15 °C and +30 °C.
Keep away from direct sunlight and high humidity.
Do not freeze.

The product, its waste materials and other consumables used during the procedure, should be disposed in accordance with local/national regulations.

Sterilization and expiration

The sterility of each device is guaranteed only when the primary packaging is unopened and undamaged.

The sterilization procedure that has been applied is marked on the label of the device – using irradiation.

INTENDED PURPOSE

Indications

The DILAPAN-S® is to be used wherever cervical softening and dilation is desired, some examples are:

- Cervical stenosis
  - Related to dysmenorrhea
  - Considered a possible cause of infertility
  - Resulting from cauterization or conization
- Placement and removal of intrauterine devices
- Induction of labor
- Radium placement
- Drainage of uterine cavity
- Endometrial biopsy
- Uterine curettage
- Suction aspiration cannula
- Operative hysteroscopy

Patient target group

The DILAPAN-S® is targeted for women indicated to labor induction or intrauterine procedure with necessary cervical ripening and/or dilation.

Intended users

The DILAPAN-S® is for use by healthcare professionals trained in obstetrics and gynecology only.

Contraindications

The DILAPAN-S® is contraindicated in the presence of clinically apparent genital tract infection.

WARNINGS

The DILAPAN-S® is intended for one-time use. Instructions for its use and handling are attached to minimize exposure to conditions that may jeopardise the product, patient or user.

Re-use / re-sterilization / reprocessing[1)] of the DILAPAN-S® single-use medical device may result in physical damage to the medical device, failure of intended use of the medical device, and illness or injury to the patient as a result of infection, inflammation and / or disease due to product contamination, infections and insufficient sterility of the product.

[1)] A process carried out on a used device in order to allow its safe reuse including cleaning.

Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus and to avoid migration of the device either upward into the uterus or downward into the vagina.

The DILAPAN-S® may fragment during removal using incorrect technique. Fragmentation may result in pieces of the device being retained in the uterus. Carefully follow the Removal instructions.

Do not use if primary packaging has been opened or damaged.

Do not re-use, intended for one-time use.

Do not re-sterilize this device by any method.

Do not store at a temperature lower than +15 °C and higher than +30 °C.

Keep away from direct sunlight and high humidity.

Disposable, discard after use.

All instructions must be carefully read **prior to** using the DILAPAN-S®.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

PRECAUTIONS

As with the use of any medical device, a careful evaluation and clinical judgement should be made by the healthcare professional before using the device for the procedure to decide on the benefit/risk ratio. Alternative treatment should be considered for patients with a pre-existing condition listed under contraindications above.

Treatment options and potential risks associated with using the DILAPAN-S® for planned procedure should be discussed with the patient before the procedure.
The patient should be instructed to report any excessive bleeding, pain, temperature elevation. The patient should be instructed to avoid bathing, douching and refrain from intercourse while the DILAPAN-S® is in place.

The patient should be instructed that it is necessary to return for removal of the DILAPAN-S® at the indicated time. Under no circumstances should the patient try to remove the DILAPAN-S® herself.

The device **should not** be left in place more than 24 hours.

When the dilator has been inserted during a procedure for termination of pregnancy, the procedure of termination of pregnancy should always be completed. Effect of termination the procedure on the fetus has not been clinically investigated.

Risks associated with the procedure

Twisting the device during its removal may cause the device to break.

In case of breakage, every attempt must be made to remove all fragments from the uterus. All fragments removed should be checked to ensure complete evacuation of the cavity. If in doubt, a hysteroscopy or ultrasound scan should be performed. The clinical effects of fragments retained in the genital tract are unknown.

Any cervical manipulation may cause a vaso-vagal reaction. The patient should be watched for evidence of any unusual pallor, nausea, vertigo or weakness. By remaining recumbent for 3 to 10 minutes these symptoms usually disappear.

Complications

The following complications may be associated with use of the DILAPAN-S® device, or may occur during the indicated procedure:

- Device entrapment
- Fragmentation or detachment of the handle
- Device expulsion
- Device retraction into the uterus
- Patient discomfort or bleeding during and/or after insertion
- Spontaneous rupture of membranes
- Spontaneous onset of labor
- Cervical laceration

USE

Examine the label of the unopened pouch and expiry date of the dilator.

Instructions for insertion

1. Insert a bivalve speculum and prepare the vagina and cervix with an antiseptic solution.
2. Remove the DILAPAN-S® from the pouch using sterile technique.
3. Moisten the DILAPAN-S® with sterile water or saline to lubricate the surface prior to insertion.
4. If necessary, use an appropriate technique to visualize the cervix and straighten the cervical canal for easier insertion of the DILAPAN-S®.

FDA approved text_DSPIenus-Rev019/2021-04

5. Insert the DILAPAN-S® in the cervical canal gradually and without undue force. It is important that the DILAPAN-S® traverses the internal os. Do not touch the dilating part with a sharp instrument.
6. Do not insert the DILAPAN-S® past the handle. The border of the collar should rest at the external os. Do not insert the DILAPAN-S® into cervix further than the arrow indicates (see the figure above – 5. Point of maximal insertion).
7. More than one DILAPAN-S® may be inserted into the cervical canal as determined to be appropriate by the physician.
8. When using several dilators, repeat steps 2 to 4. As many dilators as needed to achieve the desired effect should be inserted. Specific number of pieces always depends on decision and clinical judgement of physician and indications.
9. Insert a gauze pad moistened with sterile water or saline to help keep the DILAPAN-S® in place, if needed.

Removal instructions

1. Vaginal packing is first removed, if used during the insertion procedure.
2. Carefully remove the DILAPAN-S® by grasping the handle or pulling the string. Do not twist[2)] the DILAPAN-S® during removal. Do not grasp the collar with forceps. Do not grasp the marker string with a sharp-edged instrument[3)].

[2)] Neither grasp the collar with forceps to remove the device nor twist handle when attempting to remove the device, as this may cause the device to break.

[3)] Do not grasp the marker string with a sharp-edged instrument to remove the device, as this may cause the string to tear.

When difficulties occur during removal of the device by pulling the string, do not use excessive force on the string to remove the dilator. Use a visualization technique to identify the cause of these difficulties and remove the dilator by grasping the handle.

Occasionally, it may be necessary to use forceps to grasp the DILAPAN-S® by the handle and exert steady traction for several minutes, while the uterus is stabilized by placing an atraumatic tenaculum through the anterior lip of the cervix.

Moisten the DILAPAN-S® with sterile water or saline thoroughly during removal, if the dilator has stuck to the tissue, or more dilators have stuck together.

In very rare cases the ballooning of the inserted DILAPAN-S® above and/or below the internal cervical os has been known to cause a "tight cervix" and make for difficult DILAPAN-S® removal. This is corrected by sliding a sequence of graduated sizes of metal dilators alongside the DILAPAN-S® and through the internal os until sufficient dilation takes place to allow easy withdrawal.

If the DILAPAN-S® has somehow migrated or been placed in a false passage, it may be located using ultrasound.

NOTE: The DILAPAN-S® is not radiopaque.

INTERACTIONS

Within clinical investigations with the DILAPAN-S®, a broad range of licenced medications have been administered during indicated procedures. No specific interactions between drugs / medical devices and the DILAPAN-S® have been identified to date. Using the DILAPAN-S® does not impose any specific limitations on standard medication administered in the context of the DILAPAN-S® indications. Information provided to particular medications should be followed properly.

External influences

No negative interactions between the DILAPAN-S® and external influences were observed. Desired interference include ultrasound waves that can be used for location of the inserted dilator.

TESTING OUTCOMES

Clinical

Clinical trials have not demonstrated any allergic reactions to the device. However, an allergic reaction could result from hypersensitivity to the components.

Clinical trials have not demonstrated any infections causally related to the DILAPAN-S®. However, in the presence of pathogens, contamination of the device during insertion is possible. Administration of antibiotic for infection prophylaxis should be considered prior to insertion of DILAPAN-S®.

Mechanical

The amount of dilation achieved depends on the amount of time in situ. The following is provided as a guide.

Time in situ (hours)	Expected Dilation (in mm)	
	One DILAPAN-S® (3 mm)	One DILAPAN-S® (4 mm)
2	7.2 – 8.3	7.8 – 10.0
4	8.4 – 9.5	10.0 – 11.2
6	9.0 – 10.0	10.1 – 12.5
24	9.6 – 11.3	12.7 – 14.6

CONTACTS AND VIGILANCE

Please report incidents of death to the FDA or serious injury to your distributor (USRegulatory@medicem.com) or to the manufacturer (technology@medicem.com) in relation to the DILAPAN-S®.

Please report any potential or actual product deficiencies, and product quality issues associated with the use of the DILAPAN-S® directly to your distributor (USRegulatory@medicem.com) or to the manufacturer (technology@medicem.com).

Manufacturer:
MEDICEM Technology s.r.o.
Karlovarska trida 20, Kamenne Zehrovice
273 01, Czech Republic
Tel.: +420 317 070 370
e-mail: technology@medicem.com
http://www.medicem.com

Initial Importer, Distributor and US Agent:
Medicem Inc.
125 High Street, Suite 1704
Boston, MA 02110
Tel.: +1 973-534-2396
e-mail: USRegulatory@medicem.com

Liability

The manufacturer holds no liability for any side effects or resulting damages, losses or costs that may arise as a result of the incorrect handling or use of the device.

CE 2797

TABLE OF USED SYMBOLS

	Keep in a dry place
	Keep away from sun
	Store at 15 – 30 °C
STERILE R	Sterile, Sterilized using irradiation
	Do not re-use
°C	Degrees of Celsius
	Caution, Consult accompanying documents
	Do not resterilize
	Do not use if package is damaged
	Consult instructions for use
mm	Millimeter
LOT	Batch number
	Expiration date
	Date of manufacture
	Manufacturer
QTY	Quantity
pc / pcs	Piece(s)