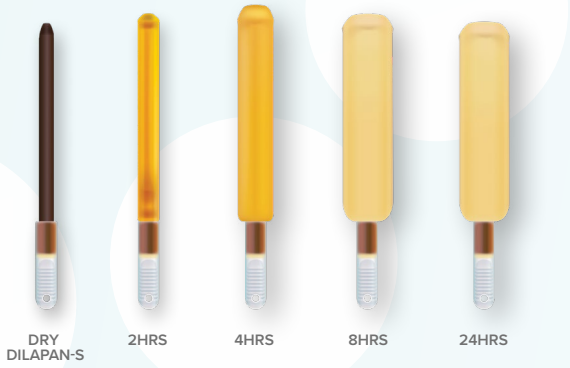
Dilapan-S®
CERVICAL DILATOR

PRODUCT GUIDE

An introduction to Dilapan-S®

The versatile, non-pharmacologic choice for predictable cervical ripening



Dilapan-S is an FDA-cleared mechanical cervical dilator designed for predictable and gentle cervical ripening prior to induction of labor.[1-4]

Indication 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.

Please see Instructions for Use on pages 20-21.

medicem

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INTRODUCTION

A fresh look at Induction of Labor (IoL)

Changing attitudes aim to lower C-section rates

In the US, concerns about the overuse of cesarean deliveries (C-sections) are increasing. In 2018, there were 3.79 million births in the US, with almost one-third of these occurring via C-section.[5] Entities such as the World Health Organization and the US Department of Health and Human Services are aiming to lower the rate of C-sections to 10-15%.[5-7]

Rates of IoL expected to increase

Historically, induction of labor (IoL) represents a small portion of all deliveries in the US.[8] However, this number is expected to increase due to changing attitudes which aim to lower C-section rates.[3,9] Additionally, data from the ARRIVE* trial published in 2018 showed that low-risk, nulliparous women who were induced at 39 weeks had a lower risk of C-section, furthering the case for IoL.[9]

Ideal cervical ripening agent: versatile and predictable

Response to these changing attitudes suggests new emphasis on practical induction practices as both hospitals and healthcare providers look for ways to reduce C-section rates. As a vaginal delivery is more likely in a woman with a favorable cervix, approximately 70% of IoLs will require cervical dilation and ripening.[8] Pharmacologic or mechanical cervical ripening agents can assist in a successful vaginal delivery by softening and opening the cervix.[4]

Dilapan-S® as your standard of care cervical ripening agent

Dilapan-S is an FDA-cleared mechanical cervical dilator designed for predictable and gentle cervical ripening prior to induction of labor.[1-4] Dilapan-S contains no pharmacologic agents, and only has one contraindication, clinically apparent genital tract infection.[1,2,10] As such, it can be readily administered as your standard of care cervical ripening device that offers flexibility in patient application and pre-labor induction settings.[1-4]

*__A R__andomized T__r__ial of __I__nduction __V__ersus __E__xpectant Management. (Grobman WA, Rice MM, Reddy UM, et al. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med.* 2018;379:513-23.)

Indication 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.

Dilapan-S® benefits

MULTIPLE MODES OF ACTION

- Patented design produces biophysical, mechanical, physiological changes to gradually ripen the cervix[2,10]

PREDICTABLE

- First round cervical ripening in up to 93% of patients[4]
- Vaginal delivery rates as high as 81%[3]

HIGH IN PATIENT COMFORT

- Allows for better sleep[11]
- Patients can shower, walk, use the toilet, and perform other daily activities[3]

ACCEPTED WORLDWIDE

- Available in over 40 countries[13]

BROAD UTILITY ACROSS PATIENT TYPES

- Predictable in nulliparous, multiparous, elective induction at term (≥39 weeks), post-date pregnancies (>41 weeks), obesity, diabetes, preeclampsia, TOLAC, and oligohydramnios[3,4,12]

DESIGNED WITH SAFETY IN MIND

- No pharmacologically active substances[1,2,10]
- No uterine tachysystole[2,11]
- Non-serious adverse events[1,4]

  In a clinical trial of 444 women treated with Dilapan-S during induction of labor[4]:

  - <1% reported cramping or pain
  - 2.7% experienced bleeding during Dilapan-S insertion or removal
  - No maternal infections (including chorioamnionitis, urinary tract infections, endometritis, and wound infections) were attributed to use of Dilapan-S by the investigating physicians
  - No serious adverse neonatal outcomes were attributed to use of Dilapan-S
- No observed device malfunctions, such as retraction, retention, or fragmentation with Dilapan-S use[13]

FLEXIBLE

- Results achieved overnight[1,11]
- 80% of rod swelling occurs within 4-6 hours[1,2]

CONVENIENT CARE SETTING

- Flexible cervical ripening window can be beneficial to L & D units[1,2,4]
- No additional fetal monitoring required

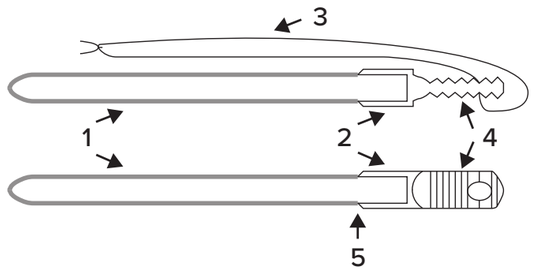
USING DILAPAN-S®

Product description

Dilapan-S is a hygroscopic rod made of a patented Aquacryl® hydrogel. Dilapan-S does not contain latex.[13] The thin (3 or 4 mm) rod is inserted into the cervical canal, where it absorbs fluid from the cervical tissue, and can expand up to ~15 mm in diameter (for the 4 mm rod) over a 12-24 hour period. Typically, 3 to 5 rods are inserted in a single procedure, with the rods inserted one at a time.[1,2,4,11]

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.

FIGURE 1. SCHEMATIC DIAGRAM OF DILAPAN-S



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

How Dilapan-S is supplied

Each Dilapan-S rod (Figure 1) is a sterile cervical dilator packed in a printed composite primary peel-open pouch. Dilapan-S is available in boxes of 25 dilators and in the following dimensions:

- 4 mm x 65 mm (25 ea/bx)
- 4 mm x 55 mm (25 ea/bx)
- 3 mm x 55 mm (25 ea/bx)

Handling, transport, storage and waste management

Store Dilapan-S® between +15°C and +30°C. Keep away from direct sunlight and humidity. No refrigeration needed. Do not freeze.

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.

Equipment recommended for insertion and removal

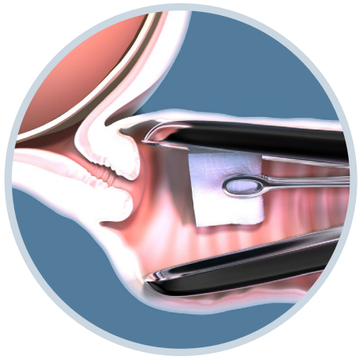
- Two sponge forceps
- Bivalve vaginal speculum
- Sterile water or saline
- Sterile gauze pads
- Source of light
- Antiseptic solution
- Gloves
- Dilapan-S rods (typically 3-5)

Patient positioning

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

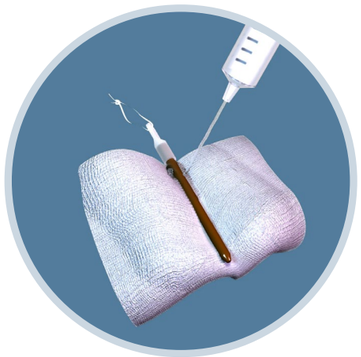
INSTRUCTIONS FOR INSERTION[1,4,6]

Dilapan-S® rods are smooth and firm to allow ease of insertion.
Typically, 3-5 Dilapan-S rods are used.



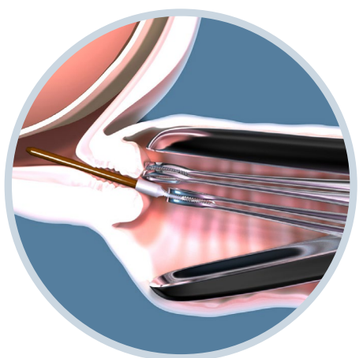
1 **Insert a vaginal bivalve speculum** and prepare the vagina and cervix with an antiseptic solution.

Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus (see Instructions for Use—Insertion).



2 **Moisten the Dilapan-S rods** with sterile water or saline to lubricate the surface.

4 mm x 65 mm actual size



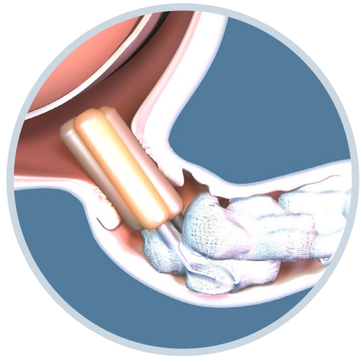
3 **Place Dilapan-S rods** by using forceps to grasp the handle of the Dilapan-S rod. Insert the rods one at a time through the external cervical os, so that the border of the collar rests at the external os.

Record the number of rods placed.

Insert a gauze pad moistened with sterile water or saline to help keep the rod(s) in place, if needed.

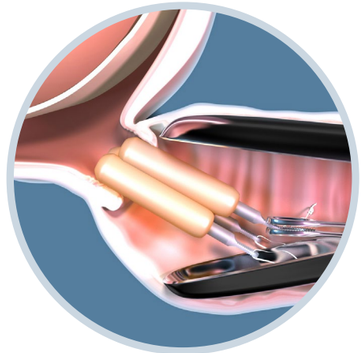
INSTRUCTIONS FOR REMOVAL[1]

Dilapan-S® should not be left in place more than 24 hours.



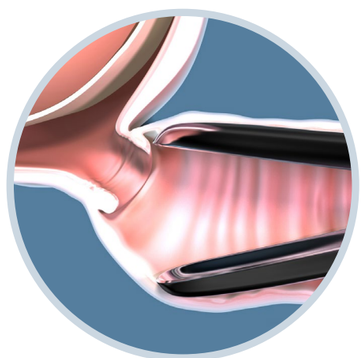
Instruct patients to: Report any excessive bleeding, pain, or temperature elevation, and to avoid bathing, douching, and intercourse. Patients should return to the physician for removal of Dilapan-S at the indicated time and should be instructed not to attempt self-removal under any circumstances.

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



2 **Remove Dilapan-S rods** by grasping the handle or carefully pulling the marker string (occasionally it may be necessary to use forceps).

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.

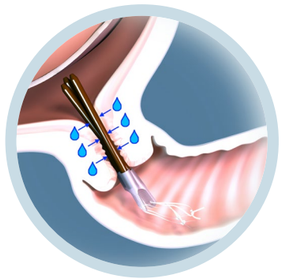


3 **Ensure all inserted rods are removed.**

For additional information, please see the Insertion and Removal Guide.

Multiple modes of action

After insertion, Dilapan-S® initiates a cascade of biophysical, mechanical, and physiological changes in the cervical tissue that continue until rod removal.[2,10]

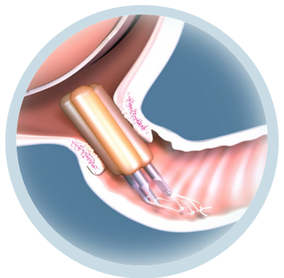


BIOPHYSICAL

- The biophysical mode of action occurs when the Dilapan-S rods are inserted into the cervical canal, where they ***absorb moisture from the cervix.***

MECHANICAL

- As the Dilapan-S rods expand, they exert ***controlled radial pressure*** on the cervical canal, which dilates the cervix.



PHYSIOLOGICAL

- Stretching of the cervical tissue promotes the release of local endogenous prostaglandins. These ***local prostaglandins initiate collagen degradation*** and cervical softening and ripening.

Dilapan-S works with a woman's body

Dilapan-S rods work by absorbing fluid from the adjacent cervical tissue. These rods then uniformly expand in diameter and gradually dilate the cervical canal by exerting radial pressure. This mechanical stretch leads to the release of endogenous prostaglandins, which initiates collagen degradation and cervical softening and ripening.

Through these 3 modes, the cervix gradually and predictably softens and dilates, preparing the patient for the next step in induction of labor.[2,10]

Flexible cervical ripening window

After insertion, the Dilapan-S® rod expands to several times its original diameter. The amount of dilation achieved depends on the amount of time in situ, but the majority, up to 80%, of rod expansion occurs in 4 to 6 hours, which is the minimum insertion time. Dilapan-S rods should not be left in place for more than 24 hours.[1,2,4] 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

FLEXIBLE CERVICAL RIPENING WINDOW[1,2]

80% of rod expansion occurs within 4-6 hours

Clinical studies have shown that the average time for successful cervical ripening was between 12-15 hours, allowing for flexibility in labor & delivery units.[1,2,4]

CLINICAL APPLICATION

Bishop score increases in multiple populations

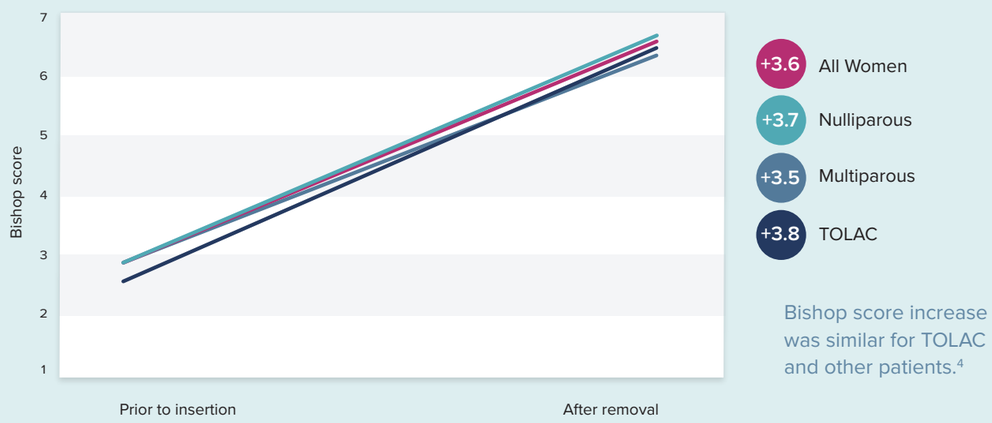
Clinical studies with Dilapan-S® showed consistency in Bishop score increases across populations, and was found proven and predictable in TOLAC (trial of labor after cesarean), nulliparous and multiparous patients. In a clinical study of 444 women, the average increase in Bishop score with Dilapan-S was +3.6 (baseline 2.9, ± 1.2). For women with previous cesarean delivery (TOLAC) (n=41), the average Bishop score increase was +3.8. For nulliparous patients (n=289), the average Bishop increase was +3.7, and for multiparous patients (n=114), the average Bishop score increase was +3.5.[4]

In a clinical study of 444 women, **the average increase in Bishop score with Dilapan-S** was +3.6.[4]

Of these 444 women treated with Dilapan-S during induction of labor:

- <1% reported cramping or pain.
- 2.7% experienced bleeding during Dilapan-S insertion or removal.
- No maternal infections (including chorioamnionitis, urinary tract infections, endometritis, and wound infections) were attributed to use of Dilapan-S by the investigating physicians.
- No serious adverse neonatal outcomes have been reported related to use of Dilapan-S.

Mean change in Bishop score



Bishop score increase was similar for TOLAC and other patients.[4]

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Broad application across multiple patient types

Dilapan-S® has demonstrated safety and efficacy in a broad range of patient types and has only one contraindication.[1,3,4]

Nulliparous	TOLAC	Post-date pregnancies (>41 weeks)
Multiparous	Diabetes	Oligohydramnios
Elective induction at term (≥39 weeks)	Obesity	Preeclampsia

Worldwide use

Dilapan-S is available in more than 40 countries. In peer-reviewed studies, Dilapan-S has been proven to effectively ripen the cervix and result in high rates of vaginal delivery.[3,4,11-14]

Care settings

Dilapan-S meets the demands for Labor and Delivery units

With an increase in induction of labor (IoL) deliveries, there is new emphasis on proven, practical induction practices.[5-7,9] The predictability of first-round success and the flexible ripening window of Dilapan-S translate into reliable cervical ripening, giving Labor and Delivery units the flexibility to work around their needs.[1-4,11] A patient can perform daily activities and get restful sleep while her cervix is safely and gently ripening, preparing for labor.[3,11]

Outpatient ripening

The predictability of Dilapan-S means that it can be inserted in a variety of healthcare settings (hospital, outpatient clinic, or HCP office), allowing low-risk patients to return to the comfort of their homes for overnight cervical ripening.[3,4,14] Once Dilapan-S is inserted, no additional fetal monitoring is required. Patients should return to the physician for removal of Dilapan-S at the indicated time. The decision to allow a low-risk patient to return home during the cervical ripening window should be based on a physician's clinical judgment.

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

SUMMARY OF EVIDENCE

Predictable cervical ripening with Dilapan-S®

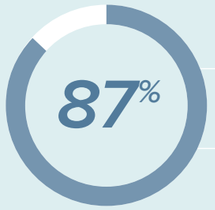
Trusted by expectant mothers and doctors around the world, the patented technology and consistency of Dilapan-S rods enable the predictability of their action.[1,3,4,13]

Dilapan-S provides predictable and reliable first-round cervical ripening success. In 2 clinical studies, the majority of women who used Dilapan-S did not require additional cervical ripening.[3,4]

Reliable first-round success[3,4]

(N=444)
Gupta 2018[4]

- In an international, multicenter (11 study sites, 7 countries) observational study of 444 pregnant women between 37 and 42 weeks with a baseline Bishop score averaging 2.9 (± 1.2), ***Dilapan-S achieved 93% first-round cervical ripening success***. The mean Bishop score increased to 6.5 (± 2.3), an average increase of 3.6 points, with Dilapan-S rods.[4]



(N=208)
Saad 2019[3]

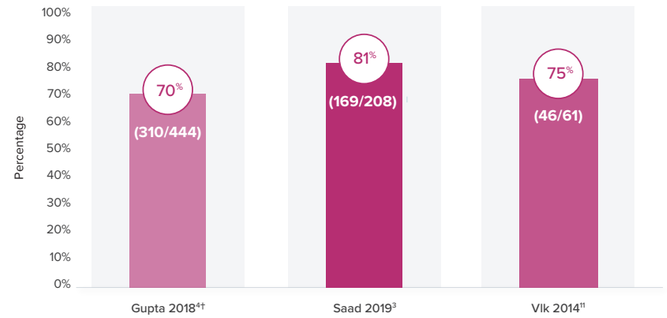
- In a single center, randomized controlled trial of 419 women pregnant 37 weeks or more with an unfavorable cervix, first-round cervical ripening success was achieved in 87% of women with Dilapan-S rods.[3]

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

Successful vaginal delivery rates

Dilapan-S® has been proven to predictably ripen the cervix and result in high rates of vaginal delivery. ***Dilapan-S achieved a vaginal delivery rate ranging from 70%-81%.***[3,4,11]

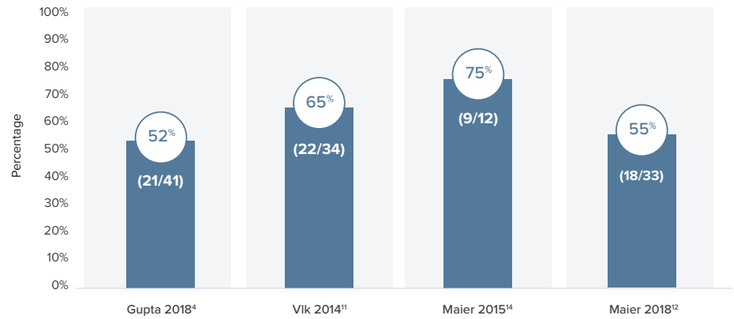
*Overall vaginal delivery rate**



*Includes ventouse/vacuum and/or forceps assisted delivery.
†Includes women with a history of previous cesarean delivery.

Dilapan-S has been studied in Trial of Labor After Cesarean (TOLAC) patients and found to be effective in achieving Vaginal Birth After Cesarean (VBAC). VBAC delivery rates for Dilapan-S ranged from 52% to 75% in 4 clinical studies.[4,11,12,14]

*VBAC delivery rate**

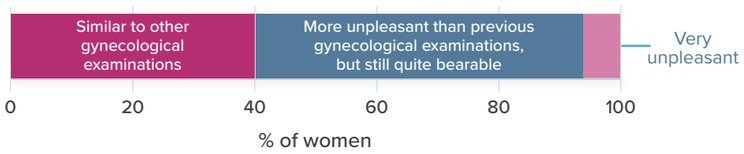


*Includes ventouse/vacuum and/or forceps assisted delivery.
†Includes women with a history of previous cesarean delivery.

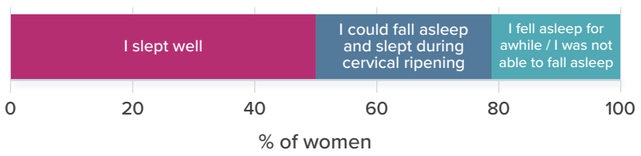
Patient satisfaction

Patients who received Dilapan-S® reported high comfort levels and satisfaction in several domains and when compared with another mechanical ripening device.[3] The sleek design (no introitus protrusion) and gentle method of action of the Dilapan-S rods allow women to partake in daily activities and/or achieve a restful night's sleep.
In a questionnaire completed by 96 women, almost 80% were able to sleep during cervical ripening with Dilapan-S.[3]

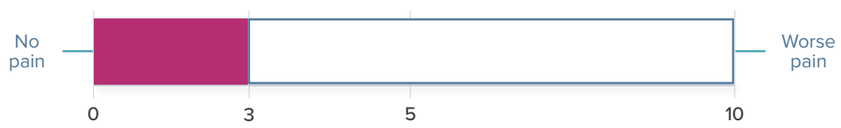
93.7% of women evaluated Dilapan-S insertion as fully acceptable



4 out of 5 women were able to sleep during cervical ripening process with Dilapan-S



Patient assessment of pain (scale of 0-10) on insertion of Dilapan-S



Dilapan-S insertion tenderness resulted in a mean pain score of 3.2 (scale 0–10)

Dilapan-S® preferred over Foley balloon

In a head-to-head trial with 419 pregnant women, patients were more satisfied with Dilapan-S compared with Foley balloon in 3 domains ($P<0.05$)[3]:

- Better sleep ($P=0.01$)
- More relaxing time ($P=0.001$)
- Ability to perform daily activities ($P=0.001$)

The Foley balloon is a widely adopted method of cervical ripening; however, the inflated balloon sits within the cervix and the catheter protrudes from the vaginal opening, so it is taped under tension to the patient's leg.[3]

With Dilapan-S the cervix ripens gently, in a gradual, controlled, and predictable manner – meaning patients can dilate gradually without constant traction or sudden, unpleasant pressure changes on the cervical os. Dilapan-S rods do not require tension.[3]

Patients can perform daily activities as Dilapan-S ripens the cervix

Because patients are able to tolerate Dilapan-S with little to no discomfort, they are free to[3]:

- Move around without uncomfortable tubing
- Shower, use the toilet, and perform other normal daily activities
- Sleep while their cervix ripens gently and gradually

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.

Favorable safety profile

No pharmacologically active substances

Dilapan-S® works with the body, without medications.

No uterine tachysystole

In 2 large studies representing a total of 640 women (including VBAC patients) using Dilapan-S, there were no cases of uterine tachysystole related to Dilapan-S use during cervical ripening.[2,11]

Non-serious adverse events

In a clinical trial of 444 women treated with Dilapan-S during induction of labor[4]:

- <1% reported cramping or pain
- 2.7% experienced bleeding during Dilapan-S insertion or removal
- No maternal infections (including chorioamnionitis, urinary tract infections, endometritis, and wound infections) were attributed to use of Dilapan-S by the investigating physicians
- No serious adverse neonatal outcomes were attributed to use of Dilapan-S
- No observed device malfunctions, such as retraction, retention, or fragmentation with Dilapan-S use[13]

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).

IMPORTANT SAFETY INFORMATION

Indication 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 on pages 20-21 or click here.

You are encouraged to report adverse events related to Dilapan-S by calling 1 (888) 257-9676. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit http://www.fda.gov/MedWatch or call 1-800-FDA-1088.

DILAPAN-S® Hygroscopic Cervical Dilator

Instructions for Use

GENERAL INFORMATION

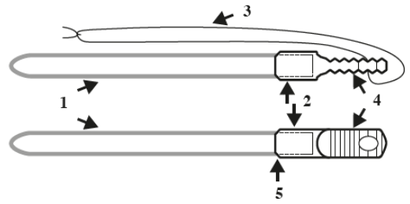
Content

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: 4×65 mm, 4×55 mm, 3×55 mm.

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®.

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
30° 15°	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)

CONTACT AND ORDERING INFORMATION

Dilapan-S® is the non-pharmacologic, versatile choice for cervical ripening in a broad range of patients[1,2,4]

HPS RX ENTERPRISES

PRODUCT INFO

3 mm x 55 mm	Item #: 23170310010T UOM: 25 ea/bx
4 mm x 55 mm	Item #: 23170312410T UOM: 25 ea/bx
4 mm x 65 mm	Item #: 23170314810T UOM: 25 ea/bx

ORDERING

Online Portal Registration:
https://www.hpsrx.com

Customer Service: 800-850-1657
Fax: 800-361-6984
Email: customerservice@hpsrx.com

For more information, please visit us at www.DilapanS.com
Please see accompanying Instructions for Use on pages 20-21.

REFERENCES: 1. Dilapan-S® Instructions for Use. DSPlenus-Rev019/2021-04. **2.** Dilapan-S® Issuance of Substantial Equivalence Determination. US Food and Drug Administration. 2015. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143447.pdf. Accessed October 8, 2020. **3.** 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. **4.** Gupta J, Chodankar R, Baev O, et al. Synthetic osmotic dilators in the induction of labour. An international multicenter observational study. *Eur J Obstet Gynecol Reprod Biol*. 2018;229:70-75. **5.** Martin JA, Hamilton BE, Osterman MJK, Driscoll AK. Births: Final Data for 2018. *Natl Vital Stat Rep*. 2019;68(13):1-47. **6.** American College of Obstetricians and Gynecologists; Society for Maternal-Fetal Medicine. Obstetric care consensus no. 1: safe prevention of the primary cesarean delivery. *Obstet Gynecol*. 2014;123(3):693-711. doi:10.1097/01.AOG.0000444441.04111.1d. **7.** World Health Organization. WHO Statement on Cesarean Section Rates. https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/cs-statement/en/. Accessed May 17, 2020. **8.** Market Research for IoL Landscape & Dilapan-S® Positioning. Final Report. Healogix. October 15, 2019. **9.** Grobman WA, Rice MM, Reddy UM, et al. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med*. 2018;379:513-23. **10.** Drunecký T, Reidingerová M, Plisová M, et al. Experimental comparison of properties of natural and synthetic osmotic dilators. *Arch Gynecol Obstet*. 2015;292(2):349-354. **11.** 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. **12.** 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;(3):299-307. **13.** Data on File, Medicem, Inc. 2020. **14.** 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.

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