

DILAPAN-S®

Instructions for Use

GENERAL INFORMATION

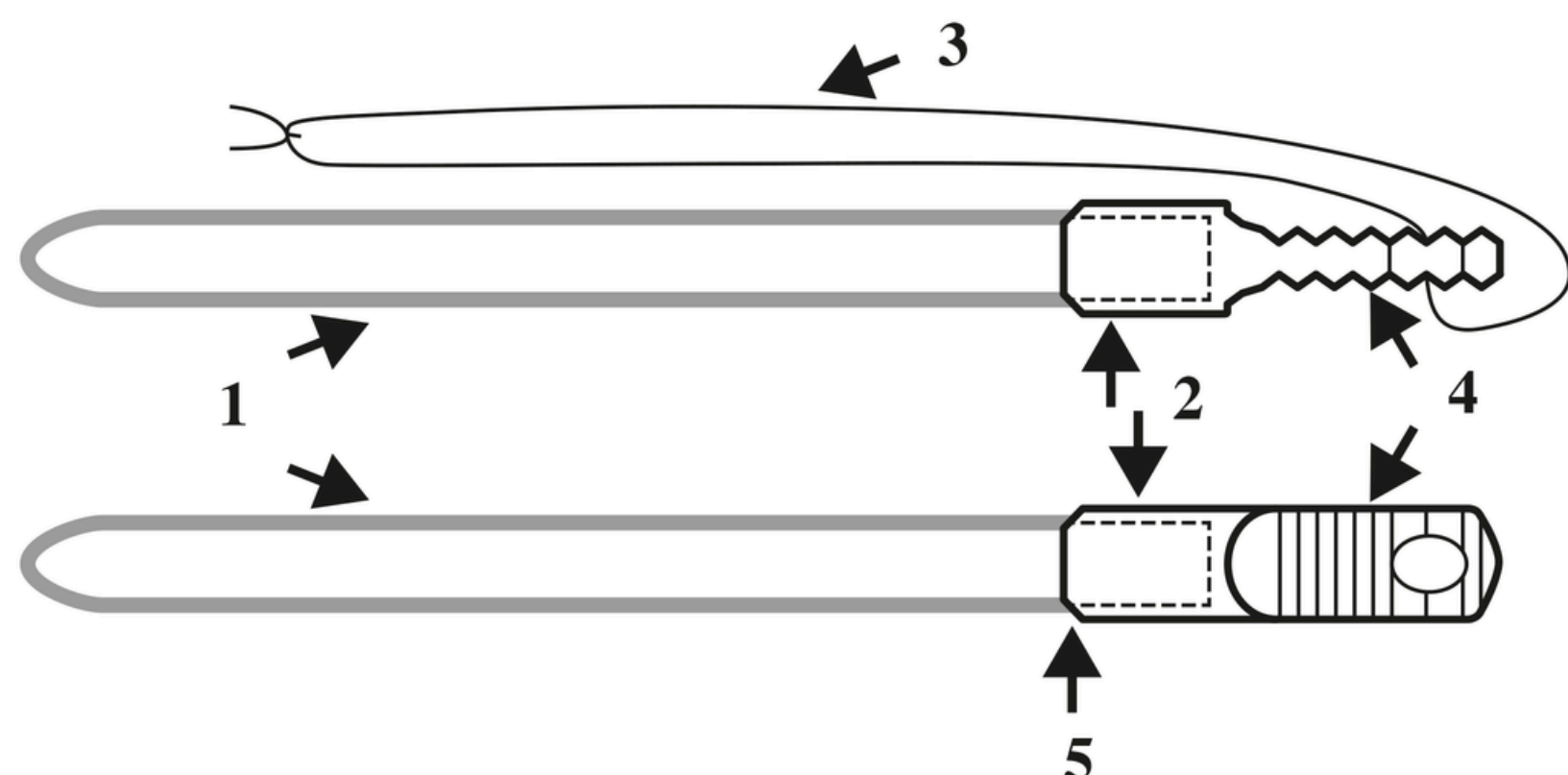
Content

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

The DILAPAN-S® is available in boxes of 10 or 25 dilators and in the following dimensions: 4 × 65 mm, 4 × 55 mm, 3 × 55 mm.

Device description and performance

Hygroscopic 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 hydrogel AQUACRYL. The dilator increases in diameter as it absorbs moisture from the genital tract. The marker string is tied securely to the handle of the DILAPAN-S® to indicate its location.



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

Handling, transport, storage and waste management

Do not expose to temperatures lower than +4 °C and higher than +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 intended for use wherever cervical softening and dilation are desired, such as cervical ripening prior to labour induction, cervical preparation prior to termination of pregnancy or other instrumentation inside the uterine cavity.

Patient target group

The DILAPAN-S® is targeted for women indicated to labour 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.

Clinical benefits

The DILAPAN-S® provides clinically meaningful benefits by enabling safe and effective cervical softening and dilation. These outcomes are essential for procedures such as cervical ripening prior to labour induction, cervical preparation before termination of pregnancy, or other intrauterine interventions. Within these indications, the device contributes to enhanced patient management and procedural outcomes, in line with its intended purpose.

Contraindications

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

WARNINGS

The DILAPAN-S® is a single-use medical device. 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 / reprocessing¹⁾ 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.

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 if removed using an incorrect technique. This 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 use if the dilating part is broken or the handle is separated or broken.

Do not re-use, single use only.

Do not re-sterilize this device by any method.

Do not expose to temperatures lower than +4 °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®.

The device should be used **soon** after opening.

PRECAUTIONS

Consider making a note on number of inserted and removed dilators to avoid issues on potentially missing devices.

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 pre-existing conditions impacting cervix dilatability possibly causing "tight cervix".

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, or increase in temperature. The patient should be instructed to avoid bathing, vaginal douching and to refrain from sexual intercourse while the DILAPAN-S® is in place.

If out-patient cervical ripening is considered/planned, thorough clinical and safety assessment should be made by the healthcare professional, to maintain patient's (mother and fetus) well-being.

Detailed instructions should be provided to patients sent to out-patient setting during ripening period. 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 attempt to remove the DILAPAN-S® herself.

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

If the dilator has been inserted for cervical dilation during a procedure for termination of pregnancy, the procedure of termination of pregnancy should always be completed. In the event that the procedure of termination of pregnancy is not completed under these circumstances, the subsequent effect of dilation by the DILAPAN-S® 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 effort must be made to remove all fragments within the 24 hours interval from insertion. All fragments that are removed should be checked to ensure complete evacuation. If in doubt, a hysteroscopy or ultrasound/MRI 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. Patients 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.

Residual risks and complications

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

- Vaso-vagal reaction
- Allergic reaction
- Patient discomfort
- Bleeding during and/or after insertion
- Rupture of membranes
- Spontaneous onset of labour
- Traumatic injury
- Cervical laceration
- Infection
- Device entrapment
- Fragmentation
- Detachment of the handle
- Device migration / displacement (e.g. device expulsion, device retraction into the uterus)
- Dumbeling

Additional diagnostic or therapeutic intervention may be required as a consequence of the procedure.

For informative purpose only! Please always follow the country-specific revision of instructions for use supplied with your device.

USE

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

Instructions for insertion

- 1.If necessary, use an appropriate technique to view the cervix and straighten the cervical canal for easier insertion of the DILAPAN-S®. Prepare the vagina and cervix with an antiseptic solution.
- 2.Remove the DILAPAN-S® from the pouch using sterile technique. Continue with the next steps of the insertion procedure without undue delay.
- 3.Moisten the DILAPAN-S® with sterile water, saline or water-based lubricant to lubricate the surface prior to insertion.
- 4.Insert the DILAPAN-S® into the cervical canal gradually and without undue force. It is important that the DILAPAN-S® passes the internal os. Do not touch the dilating part with a sharp instrument.
- 5.Do not insert the DILAPAN-S® past the handle (see the figure above – 5. Point of maximal insertion). The border of the collar should rest at the external os.
- 6.More than one DILAPAN-S® may be inserted into the cervical canal as deemed appropriate by the healthcare professional following clinical judgement of the risk/benefit ratio.
- 7.When using several dilators, repeat steps 2 to 5. 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 healthcare professional and indications.
- 8.Consider inserting a gauze pad moistened with sterile water or saline to help keep the DILAPAN-S® in place, if needed.

Removal instructions

- 1.Remove vaginal packing first, if used during the insertion procedure.
- 2.Carefully remove the DILAPAN-S® by grasping the handle or pulling the string. Do not twist²⁾ the DILAPAN-S® during removal. Do not grasp the collar²⁾ with forceps. Do not grasp the marker string³⁾ and/or swollen parts⁴⁾ of the dilator with a sharp instrument.

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.

⁴⁾ Do not grasp the swollen parts of the dilator with a sharp instrument (incl. forceps), as this may cause the device to break.

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 handle of the DILAPAN-S® 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 a “tight cervix” has been known to cause “dumbeling” of the inserted DILAPAN-S® above and/or below the internal cervical os, making it difficult to remove. 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 outside cervical canal, it may be located using ultrasound or MRI.

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 and MRI 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 any of its 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.

Mechanical

The amount of dilation achieved depends on the amount of time in situ. The following table is provided as a guide, based on data obtained in in vitro experiment.

Time in vitro (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 any serious incident that has occurred in relation to the DILAPAN-S®, to the manufacturer and your competent authority.

Please report any potential and actual product deficiencies, and product quality insufficiencies associated with the use of the DILAPAN-S® directly to your distributor and to the manufacturer.



Manufacturer:
MEDICEM Technology s.r.o.
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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.



TABLE OF USED SYMBOLS

	Keep in a dry place
	Keep away from sunlight
	Temperature limits to which the product can be safely exposed
	Sterile, Sterilized using irradiation
	Do not re-use
	Degrees Celsius
	Caution, Consult accompanying documents
	Do not resterilize
	Do not use if package is damaged
	Consult instructions for use
	Millimeters
	Batch number
	Expiration date
	Date of manufacture
	Manufacturer
	Quantity
	Piece(s)
	Medical device
	Unique device identifier
	Single sterile barrier system

For informative purpose only! Please always follow the country-specific revision of instructions for use supplied with your device.