DILAPAN-S® Hygroscopic Cervical Dilator

Instructions for Use

GENERAL INFORMATION

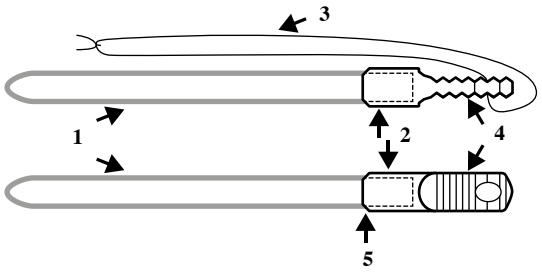
Content

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. Product samples for evaluation are provided in a box of 10 dilators. The following dimensions are available: 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
	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)