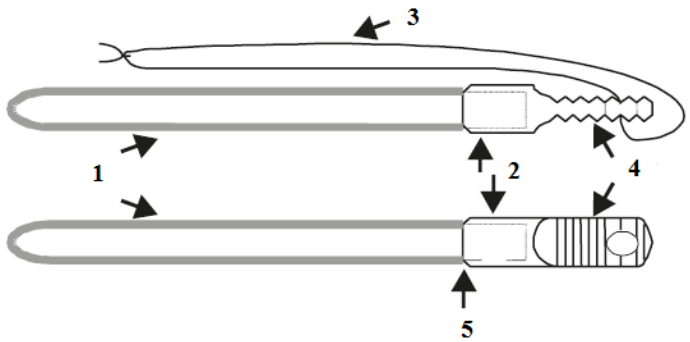
For informative purpose only!
Please always follow the country-specific revision of instructions for use supplied with your device.

Excerption of Instructions for Use

DILAPAN-S®

Device description
Hygroscopic cervical dilator manufactured from an anisotropic xerogel of AQUACRYL. The dilator increases in diameter as it absorbs moisture from the genital tract. A marker string is tied securely to the handle of the DILAPAN-S to indicate its location. Supplied sterile, in peel-open packages. Single use only.

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



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

Indications for use
DILAPAN-S is for use wherever cervical softening and dilation are desired, such as cervical ripening prior to labor induction, cervical preparation prior to termination of pregnancy or other instrumentation of the uterine cavity, etc.

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

Warnings
DILAPAN-S may fragment if removed using an incorrect technique. This may result in pieces of the device being retained in the uterus. Do not attempt to remove the DILAPAN-S by pulling the marker string. The device should be removed holding the handle only. Do not grasp the knob/collar with forceps to remove the device, as this may cause the device to break. Do not twist handle when attempting to remove the device.

Sterile unless package opened or damaged.
Single use only, do not reuse.
Disposable – discard after use.

The device is for use by healthcare professionals only.

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

2. Clinical trials have not demonstrated any infections related to DILAPAN-S. However, in the presence of known pathogens, contamination of the device during insertion is possible.
3. This is a single-use device and should not be re-sterilized or re-used.
4. 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.
5. Sterile unless package is opened or damaged. Do not use if package is broken.
6. The device should not be left in place for more than 24 hours.
7. Pulling on the marker string or twisting the device during its removal may cause the device to break.
8. In case of breakage, every attempt must be made to remove all fragments from the uterus. All fragments that are 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.
9. Any cervical manipulation may cause a vaso-vagal reaction. Patients should be monitored for evidence of any unusual pallor, nausea, vertigo or weakness. By remaining recumbent for 3 to 10 minutes these symptoms usually disappear.
10. DILAPAN-S is for use by healthcare professionals trained in obstetrics and gynecology.
11. The patient should be instructed to report any excessive bleeding, pain, or increase in temperature.
12. The patient should be instructed that it is necessary to return for removal of the DILAPAN-S at the indicated time.
13. Under no circumstances should the patient attempt to remove DILAPAN-S herself.
14. The patient should be instructed to avoid bathing, douching and to refrain from sexual intercourse while DILAPAN-S is in place.
15. All instructions must be carefully read prior to using DILAPAN-S.
16. When the dilator has been inserted 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 Dilapan-S on the fetus has not been clinically investigated.

Potential risks

Risks associated with use of the DILAPAN-S may include, but are not limited to:

- Device entrapment and/or 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

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 package using sterile technique.
3. Moisten the DILAPAN-S with sterile water or saline 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 traverses the internal and external os.
5. Use an appropriate technique to view the cervix and straighten the cervical canal for easier insertion of the DILAPAN-S, if necessary.
6. Do not insert the DILAPAN-S past the handle. The border of the knob/collar should rest at the external os.
7. 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. When using several dilators, repeat steps 2 to 4.
8. Insert a gauze pad 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. Do not try to remove the DILAPAN-S using the string. Do not twist the DILAPAN-S during removal. Do not grasp the knob/collar with forceps.

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.

In very rare cases a "tight cervix" has been known to cause ballooning 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.

NOTE: the DILAPAN-S is not radiopaque.

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

	Expected Dilation (in mm)	
Time in situ (hours)	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

Product information
Report product failures or complaints relating to DILAPAN-S to the manufacturer.

Please report all serious adverse events, potential and actual product errors, and product quality problems associated with the use of the DILAPAN-S directly to the distributor or manufacturer.

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.

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