DILAPAN - S™ Hygroscopic Cervical Dilator

Instructions for Use

Device description
Synthetic hydrogel cervical dilator manufactured from an anisotropic xerogel of AQUACRYL. The dilator is capable of increasing in diameter as they absorb moisture from the genital tract. A Marker String is tied securely to the handle of the DILAPAN-S, and is provided to indicate location. Supplied sterile, in peel-open packages. Intended for one-time use.

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

Indications for Use
Dilapan-S is to be used whenever 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
- Difficult embryo transfer

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

Warnings

Dilapan-S may fragment during removal using incorrect technique. Fragmentation may result in pieces of the device being retained in the uterus. DO NOT attempt to remove the Dilapan-S by the marker string. The device should be removed BY THE HANDLE only. DO NOT TWIST HANDLE DURING REMOVAL.

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

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

Precautions
1. Clinical trials have not demonstrated any allergic reactions to the device. However, an allergic reaction could result from hypersensitivity to the components.
2. Clinical trials have not demonstrated any infections related to the 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 if the package is unopened or undamaged. Do not use if package is broken.
6. The device should not be left in place more than 24 hours.
7. Pulling on the marker string or twisting the device during removal may cause the device to break.
8. In case of breakage, every attempt must be made to remove all fragments from uterus. All fragment removed should be checked to ensure complete evacuation of the cavity. If in doubt, hysteroscopy or ultrasound scan should be performed. The clinical effects of retained in genital tract fragments are unknown.
9. Any cervical manipulation may cause a vaso-vagal reaction. Patient should be watched for evidence of unusual pallor, nausea, vertigo or weakness. By remaining recumbent for 3 to 10 minutes these symptoms usually disappear.
10. Dilapan-S is to be used by a healthcare professional who has been trained thoroughly in operative obstetrics and gynecology.
11. The patient should be instructed to report any excessive bleeding, pain, temperature elevation.
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 patient try to remove Dilapan-S herself
14. Patient should be instructed to avoid bathing, douching and refrain from intercourse while Dilapan-S is in place.
15. All instructions to be carefully read prior to the use of Dilapan-S.
16. When dilator has been inserted during procedure for termination of pregnancy, the procedure should be completed. Effect of termination the procedure 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 in the cervical canal gradually and without undue force. It is important that the DILAPAN-S traverses the internal and external os.
5. Use appropriate technique to visualize the cervix and to 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 in the cervical canal as determined to be appropriate by the physician. When using several dilators, repeat steps 2 to 4.
8. Insert a gauze pad to help maintain the DILAPAN-S in place, if needed.

Removal instructions

1. Vaginal packing is first removed, if used during 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.

Occasionally, it may be necessary to use forceps to grasp the Dilapan-S by 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.

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 permit 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.

Mechanical Test Results

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

	Expected Dilation (in mm)	
Time in situ (hours)	DILAPAN-S (3mm)	DILAPAN - S (4mm)
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 dissatisfactions with Dilapan-S to manufacturer

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

Manufacturer:
MEDICEM Technology, s.r.o.
Karlovarska trida 20, Kamenne Zehrovice, -273 01, Czech Republic
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http://www.medicem.com.

Distributor and US Agent:
HPSRx Enterprises, Inc.
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Distributor:
MPM Medical Supply
265 Willow Brook Road, Unit 10
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CE 0120

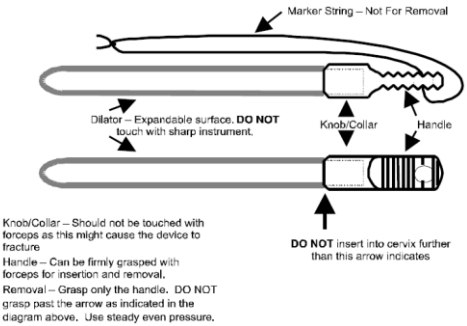

Table of used symbols

	Keep in a dry place
	Keep away from sun
+15°C +30°C	Store at 15°-30°C
STERILE R	Sterile, Sterilized using irradiation
	Do not reuse
°C	Degrees of Celsius
	Caution, consult accompanying documents
STERILIZE	Do not repeat the sterilization
	Sterile unless package is damaged or open
	Consult instructions for use
mm	milimeter