DILAPAN - S™ Hygroscopic Cervical Dilator

Instructions for Use

NOTE: Read these instructions before using this device

CE 0120

Caution: Keep away form heat. Store at 15°-30°C
DO NOT REUSE or re-sterilize.
STERILE. Product is sterilized by gamma irradiation
Sterile unless the package is damaged or open

Indications for Use

1. Cervical preparation prior to suction termination of pregnancy

PLEASE NOTE:

DILAPAN – S is different from other osmotic cervical dilator with which you may have had experience. This device should be used ONLY by medical practitioners and ONLY after reading the Instructions for Use.

Summary and Explanation of The Device

DILAPAN-S is a hygroscopic cervical dilator that is manufactured from a AQUACRYL a proprietary hydrogel. The dilators are firm hygroscopic rods, similar in shape to natural laminaria tents. DILAPAN – S are capable of increasing in diameter on average from three (3) millimeters to 8.3-10 mm, or four (4) millimeters to 10-12.5 millimeters within 4-6 hours as they absorb moisture from the genital tract[1].

In clinical trials, DILAPAN - S has been shown to dilate the cervix gradually[2,3]. It may not be necessary to use general or local anesthetics during the insertion process, thereby eliminating their associated risks to the patient.

A Marker String is tied securely to the handle of the DILAPAN - S, and is provided to indicate location.

Principle of Action of the Device
The AQUACRYL hydrogel rod absorbs moisture through hygroscopic action and gradually swells in diameter, with sufficient radial force so as to gently dilate the cervical canal.

Contraindications
1. DILAPAN - S is contraindicated in the presence of clinically apparent genital tract infection.
2. DILAPAN - S should not be used in women who are menstruating.

Materials Provided/Product Specifications
- 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
- Each DILAPAN - S is individually wrapped in a single foil pouch and is sterilized by gamma radiation.

The following is a guideline for use:
4mm x 65mm Termination of pregnancy, fetal demise
4mm x 55mm Termination of pregnancy where a shorter length is indicated.
3mm x 55mm When a 4mm diameter DILAPAN - S can not be inserted in early pregnancy, or when removal is to be accomplished in less than four hours

CAUTION: This device is restricted for sale on the order of a physician.

Storage
The DILAPAN - S should be stored in a dry place at the temperature of 15 - 30°C, out of direct sunlight. The device must not be removed from the pouch until use. Refer to the expiration dating on the pouch for stability. Presently, the DILAPAN - S has 36 month expiration dating.

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. The device is sterile unless the pouch is opened or damaged. If the integrity of the pouch has been compromised prior to use, DO NOT USE THE DEVICE.
6. The device should not be allowed to remain in place more than 24 hours.
7. As with all invasive procedures, patients must be kept under physician supervision.
8. Manipulation of the cervix has infrequently been associated with vaso-vagal reaction. Patient must be carefully observed for presence of syncope.
9. Entrapment of the DILAPAN-S in the cervical canal has been observed. Refer to the Instructions for Use, Section III, Potential Problems With DILAPAN - S.
10. Detachment of the handle has been observed. Refer to the Instructions for Use, Section III, Potential Problems with DILAPAN - S.
11. Pulling on the marker string or twisting the device during removal may cause the device to break.
12. In the event of detachment on the handle or device breakage, every attempt should be made to remove all the fragments. Refer to the Instructions for Use, Section III, Potential Problems with DILAPAN-S.
13. The clinical effects of fragments remaining in the genital tract are unknown.
14. DILAPAN-S is a temperature sensitive product and cannot be stored in temperatures in excess of 30 °C for prolonged periods.
15. If the device is in more than one piece, or the handle is detached, DO NOT USE THE DEVICE.

SECTION I - PROCEDURE A

Cervical Preparation Prior to Suction Termination of Pregnancy (or Evacuation of Retained Products Following Missed Abortion)

Informing the Patient
During a surgical termination of pregnancy the cervix is serially dilated, this imparts a degree of trauma to the cervical tissue, and is implicated as a potential cause of second trimester miscarriage in future pregnancy[4]. Cervical preparation with agents such as DILAPAN - S may dramatically reduce this trauma[3].

The device is inserted under direct vision, approximately three to four hours prior to surgery and will require a speculum examination. This procedure is not unduly uncomfortable; some period type cramping may be experienced. ONCE THE DILAPAN - S HAS BEEN INSERTED, IT SHOULD BE ASSUMED THAT THE TERMINATION IS INEVITABLE. All patient consent forms and legal documents should be completed PRIOR TO insertion of the DILAPAN - S.

Insertion Instructions
1. Insert a bivalve speculum and cleanse the vagina and cervix with an antiseptic solution.
2. Remove the DILAPAN - S from its foil pouch packaging using sterile technique. The product is packaged in a single foil pouch.
3. Correct insertion will ensure that best results occur. Refer to Diagrams I and II.
   a) A tenaculum to grasp the cervix may be necessary for stabilization of the cervix and to straighten the cervical canal.
   b) Moisten the DILAPAN - S with sterile water or saline to lubricate the surface prior to insertion.
   c) Grasp the DILAPAN - S at the handle (see Diagrams). Gradually and without undue force, insert the DILAPAN - S until it traverses the external and internal os (see Diagram II).
   d) DO NOT INSERT THE DILAPAN - S PAST THE HANDLE. The border of the handle should rest at the external os (see Diagram II)
   e} If inserting multiple DILAPAN - S, repeat steps B through D for each DILAPAN - S used.
4. Do not leave the device in place more than 24 hours.

Follow-up Instruction to Patient
The patient should be instructed to report any excessive bleeding, pain, temperature elevation and that it is necessary to return for removal of the DILAPAN-S at the indicated time.

PROTOCOL: TERMINATION OF PREGNANCY /FETAL DEMISE

Gestational Age	# of DILAPAN-S	DILAPAN - S specification	Time in Situ
Up to 12 weeks	1	3mm x 55mm	< 4 hours
Up to 16 weeks	1	4mmx65mm or 4mmx55mm	4 hours

When more than one DILAPAN - S has been inserted, the removal process has the potential for increased resistance.

SECTION II

Clinical/Mechanical Test Results
Clinical research using DILAPAN - S has shown that it is safe and effective when used in accordance with these instructions. Anesthesia is generally not needed for insertion. Post insertion cramping may occasionally require an oral analgesia. The amount of dilation achieved depends on the amount of time in situ. The following is provided as a guide.

# DILAPAN - S (4mm)	Time in Situ (hours)	Expected Dilation (in mm +/- 0.5)*
1	2	7.8-10.0
1	4	10.0-11.2

Less dilation will be achieved using the 3mm DILAPAN-S.

# DILAPAN-S (3mm)	Time in situ (hours)	Expected Dilation (in mm +/- 0.5)*
1	2	7.2 - 8.3
1	4	8.4 - 9.5

SECTION III

Potential Problems with DILAPAN - S

1. Infection
There have been sporadic reports of infection occurring after insertion of laminaria tents, but the consensus is that this is rare. It is likely that uterine infection occurring would be due to pathogens lower down in the genital tract being inoculated higher up at the time of insertion. If such an infection were to occur following insertion of DILAPAN - S, then the device should be removed and sent for culture. Appropriate management of the patient should be instigated AS A MATTER OF URGENCY.

2. Inadequate Dilation at the Internal Os
Mechanical test data has demonstrated that the DILAPAN - S will change in length by approximately -27.48% to +18.23% when during hydration, the greatest length reduction occurring from 2-6 hours, after which gradual elongation occurs. Inadequate dilation at the internal os is less likely to happen if the longer, 65mm device, is used in preference to the shorter, 55mm device. The 55mm device is suitable in circumstances where the cervix is clinically determined to be decreased in length.

3. Entrapment of The DILAPAN - S
Entrapment of any osmotic dilator will occur when the resistance to dilation is greater than the outward radial force produced by the particular device. True entrapment is quite rare, especially in later gestation. True entrapment has been associated with cervical stenosis, scarring, or spasm about the internal os. Under such rare occurrence, the dilator will more neither in nor out of the cervical canal.

If difficulty is encountered when trying to remove DILAPAN - S, the following maneuvers may be attempted. If the patient is not under general anesthesia, it is important to keep her informed of what is happening, as time will be required to remove the entrapped DILAPAN - S. A paracervical block may relax the cervix and allow for removal.

a) Allowing time to elapse (5 minutes) before re-attempting removal has anecdotally been found to be of benefit, the reason being unclear.
b) Grasp the handle of the DILAPAN - S with sponge forceps and draw with constant force along the axis of the cervical canal. Gradually increase the force, monitoring patient discomfort. An assistant should be monitoring the pulse in case of vaginal stimulation.
c) Occasionally a gentle axial rotating action may be necessary, but should be used with caution as breakage of the device may result.
d) If alignment of the cervix is such that it is not possible to draw in the axis of the cervical canal, e.g. posterior os that has not aligned on insertion of the speculum, then digital removal should be attempted.
   Remove the speculum and perform a vaginal examination. Grasp the handle of the device between the index and middle finger and draw in the longitudinal axis.
e) Leave the DILAPAN - S in situ overnight. The longer time may allow for softening of the cervix with subsequent easier removal.

If a longer time in situ does not allow for removal, operative removal will need to be performed under cervical block, regional or if desired general anesthesia. Under such circumstances:

1. The DILAPAN-S should be broken up with toothed clamps until a residual nubbin is left at the internal os.
2. The nubbin can then be advanced with care into the uterine cavity using a Hegar dilator. Care must be taken not to perforate the fundus by the advancing nubbin.
3. A standard serial dilation is then performed, with equal care, and the nubbin retrieved either by hysteroscopic technique or with polyp forceps.
4. If the cervix is severely stenosed and serial dilation not possible, multiple DILAPAN-S should be inserted and time allowed for adequate dilation before re-attempting the procedure. NEVER INTRODUCE DILATORS AROUND AN ENTRAPPED DILAPAN - S. The risks include creation of a false passage and uterine perforation.

EVERY ATTEMPT MUST BE MADE TO REMOVE ALL FRAGMENTS FROM THE 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 effect of retained fragments is unknown.

4. Breakage of the Device or Detachment of the Handle

Breakage has not been associated with DILAPAN - S. If breakage or detachment of the handle does occur, every attempt should be made to gently, but firmly grasp the proximal end of the gel and draw with constant force along the axis of the cervical canal. If this is not possible, the DILAPAN-S should be broken up with toothed clamps until a residual nubbin is left at the internal os. The nubbin can then be advanced with care into the uterine cavity using a Hegar dilator. Care must be taken not to perforate the fundus by the advancing nubbin. A standard serial dilation is then performed, with equal care, and the nubbin retrieved either by hysteroscopic technique or with polyp forceps.

5. Retraction into the Uterus

Upward displacement of the DILAPAN - S either partially or entirely the uterine cavity is a potential problem. If this should occur, the following action should be taken.

a) If the marker string is visible, careful, gentle, steady traction should be used to extract the DILAPAN - S.

b) If the device cannot be removed in this fashion, or grasped by the handle with a dressing forceps, it may be necessary to push the device entirely into the uterus. In this instance, one should proceed as outlined above with respect to removing a nubbin or broken fragment of the DILAPAN - S left within the uterine cavity. See #3 above, Entrapment of the DILAPAN - S. A 14 or 16mm suction curette should be used for removal of the DILAPAN - S or its fragments.

To reduce the possibility of this complication, DO NOT INSERT THE DILAPAN - S PAST THE HANDLE. The border of the handle should rest at the external os (see Diagram II).

NOTE: Before looking for the device within the uterus, the patient should be carefully questioned to ascertain whether or not the device might have been expelled and dropped form the vagina. Careful ultrasonic examination has been used to locate missing DILAPAN - S.

Follow -up Instruction to Patient

The patient should be instructed to report any excessive bleeding, pain, temperature elevation and that it is necessary to return for removal of the DILAPAN - S at the indicated time.

Bibliography

1. DILAPAN-S Mechanical Test Data on file with the manufacturer
2. Robinson G.: A Comparative Study of DILAPAN - S and Laminaria for Preparation of The Cervix Prior to Suction Termination of Pregnancy Dept.Clin.Lab.Sci.Univ.Hosp., Nottingham U.K.,1997
3. Roztocil A., Pilka L., Jelinek J., Koudelka M., Miklica J.: A Comparison of Three Preinduction Cervical Priming Methods: Prostaglandin E2 Gel, DILAPAN - S and Estradiol Gel, Ces.Gynek. 63:3-9,1998
4. Edstrom K.G.B.: Early Complications and Late Sequelae of Induced Abortion: A review of the Literature. Bulletin of the World Health Organization: 52: 123-219
5. Hulka J.F.& Higgins G.: Trauma to the Internal Os During Dilation for Diagnostic Curettage, Am. J. Obstet. Gynec.,82:193-196,1961
6. Olsen C.E., Nielson H.B. &Ostergaard E.: Complication to Therapeutic Abortions, Int. J.Gynec.Obstet.8: 823-827,1970

Product Information

All reports of product failures or dissatisfactions with Dilapan-S are to be reported to J.C.E.C. Company, Inc. at PO Box 316, KendallPark, New Jersey 08824, USA; or by phone, 908-420-3759; or facsimile, 888-606-4420; or email, info-jcec@dilapan.com. Additionally, all reports of product failure or dissatisfaction with Dilapan-S are to be reported to manufacturer (see below).

Report all serious adverse events, potential and actual product quality problems associated with the use of Dilapan-S to the FDA. Information about how to report to FDA under the MedWatch Program is located at the following web page: http://www.fda.gov/medwatch/index.html

Manufacturer:

DILAPAN-S is produced by MEDICEM Technology, s.r.o.
Production plant: Karlovarska 20, Kamenne Zehrovice, CZ-273 01, tel./fax: +420 312 658 186, e-mail: technology@medicem.com, http://www.medicem.com.cz

DISTRIBUTOR:

Diagram I – INSERTION & REMOVAL

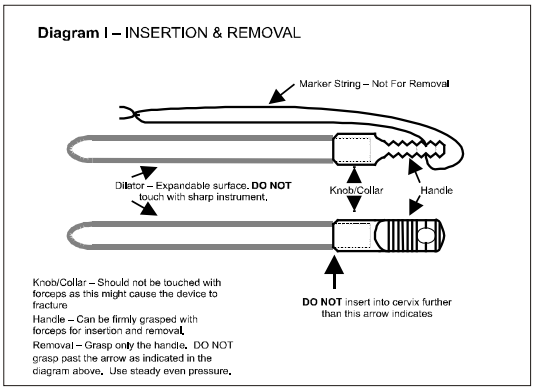

Diagram II - CORRECT INSERTION

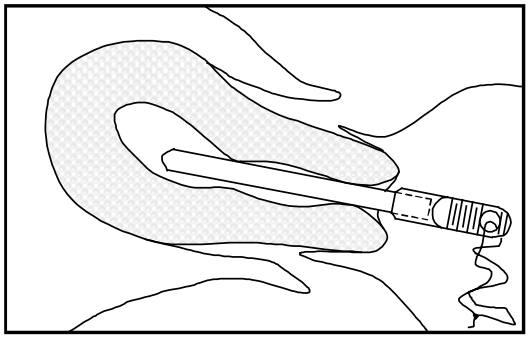

Diagram III – INCORRECT REMOVAL

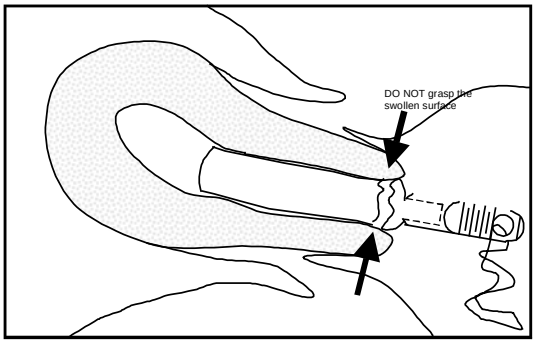

Diagram IV – CORRECT REMOVAL TECHNIQUE