

DILAPAN-S® PRODUCT INFORMATION

How Supplied

Dilapan-S is available in boxes of 25 rods

Rods come in the following dimensions:

- **4 mm x 65 mm:** 25 ea/bx
- **4 mm x 55 mm:** 25 ea/bx
- **3 mm x 55 mm:** 25 ea/bx



Storage and Handling



Store between +15°C and +30°C.

No refrigeration needed



Keep away from direct sunlight and high humidity.



Do not freeze.

Distributor



Online Portal Registration Form:

<https://www.hpsrx.com>

Customer Service: 800-850-1657

Fax: 800-361-6984

Email: customerservice@hpsrx.com

TO LEARN MORE ABOUT **DILAPAN-S**

- Visit www.DilapanS.com
- **Medical inquiries**, email: usmedical@medicem.com
- Contact your **Dilapan-S Sales Representative**

Please see additional Important Safety Information on the following page and full [Instructions for Use](#).

IMPORTANT SAFETY INFORMATION

Indication for Use:

Dilapan-S® is for use by healthcare professionals trained in OB/GYN whenever cervical softening and dilation are desired, such as for cervical ripening during term labor induction or gynecological procedures that require cervical preparation.

Contraindication:

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

Warnings & Precautions:

- Dilapan-S® is intended for single use only. **Do not** reuse, resterilize, reprocess, or use if primary packaging has been opened or damaged. Discard after use.
- Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus (see [Instructions for Use—Insertion](#)). The device should not be left in place more than 24 hours. **Instruct patients to:** Report any excessive bleeding, pain, or temperature elevation, and to avoid bathing, douching, and intercourse. Patients should return to the physician for removal of Dilapan-S® at the indicated time and should be instructed not to attempt self-removal under any circumstances.
- Potential Complications/Risks: Twisting of device during removal may cause the device to break (see [Instructions for Use—Removal](#)). Complications may include: device entrapment and/or fragmentation, expulsion, or retraction; patient discomfort or bleeding; spontaneous rupture of membranes; spontaneous onset of labor; cervical laceration.
- Storage & Handling: Store between +15°C and +30°C and keep away from direct sunlight and high humidity.

Please click [here](#) to download the Instructions for Use.

You are encouraged to report adverse events related to Dilapan-S by calling 1 (888) 257-9676.

If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly.

Visit <http://www.fda.gov/MedWatch> or call 1-800-FDA-1088.