Indications 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.

Please see Instructions for Use on pages 20-21.
INTRODUCTION

A fresh look at Induction of Labor (IoL)

Changing attitudes aim to lower C-section rates

In the US, concerns about the overuse of cesarean deliveries (C-sections) are increasing. In 2018, there were 3.79 million births in the US, with almost one-third of these occurring via C-section.5 Entities such as the World Health Organization and the US Department of Health and Human Services are aiming to lower the rate of C-sections to 10-15%.5,6

Rates of IoL expected to increase

Historically, induction of labor (IoL) represents a small portion of all deliveries in the US.8 However, this number is expected to increase due to changing attitudes which aim to lower C-section rates.3,9 Additionally, data from the ARRIVE* trial published in 2018 showed that low-risk, nulliparous women who were induced at 39 weeks had a lower risk of C-section, furthering the case for IoL.9

Ideal cervical ripening agent: versatile and predictable

Response to these changing attitudes suggests new emphasis on practical induction practices as both hospitals and healthcare providers look for ways to reduce C-section rates. As a vaginal delivery is more likely in a woman with a favorable cervix, approximately 70% of IoLs will require cervical dilation and ripening.4 Pharmacologic or mechanical cervical ripening agents can assist in a successful vaginal delivery by softening and opening the cervix.6

Dilapan-S® as your standard of care cervical ripening agent

Dilapan-S is an FDA-cleared mechanical cervical dilator designed for predictable and gentle cervical ripening prior to induction of labor.14 Dilapan-S contains no pharmacologic agents, and only has one contraindication, clinically apparent genital tract infection.12,13 As such, it can be readily administered as your standard of care cervical ripening device that offers flexibility in patient application and pre-labor induction settings.14

Indications 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.

Dilapan-S® benefits

MULTIPLE MODES OF ACTION
- Patented design produces biophysical, mechanical, physiological changes to gradually ripen the cervix10

PREDICTABLE
- First round cervical ripening in up to 93% of patients9
- Vaginal delivery rates as high as 81%3

HIGH IN PATIENT COMFORT
- Allows for better sleep11
- Patients can shower, walk, use the toilet, and perform other daily activities3

ACCEPTED WORLDWIDE
- Available in over 40 countries13

BROAD UTILITY ACROSS PATIENT TYPES
- Predictable in nulliparous, multiparous, elective induction at term (≥39 weeks), post-date pregnancies (>41 weeks), obesity, diabetes, preeclampsia, TOLAC, and oligohydramnios1,42

DESIGNED WITH SAFETY IN MIND
- No pharmacologically active substances12,20
- No uterine tachysystole23
- Non-serious adverse events14
- In a clinical trial of 444 women treated with Dilapan-S during induction of labor6:
  - <1% reported cramping or pain
  - 2.7% experienced bleeding during Dilapan-S insertion or removal
  - No maternal infections (including chorioamnionitis, urinary tract infections, endometritis, and wound infections) were attributed to use of Dilapan-S by the investigating physicians
  - No serious adverse neonatal outcomes were attributed to use of Dilapan-S
  - No observed device malfunctions, such as retraction, retention, or fragmentation with Dilapan-S use13

FLEXIBLE
- Results achieved overnight10
- 80% of rod swelling occurs within 4-6 hours13

CONVENIENT CARE SETTING
- Flexible cervical ripening window can be beneficial to L & D units13,4
- No additional fetal monitoring required
**Handling, transport, storage and waste management**

Store Dilapan-S® between +15°C and +30°C. Keep away from direct sunlight and humidity. No refrigeration needed. Do not freeze.

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.

**Equipment recommended for insertion and removal**

- Two sponge forceps
- Bivalve vaginal speculum
- Sterile water or saline
- Sterile gauze pads
- Source of light
- Antiseptic solution
- Gloves
- Dilapan-S rods (typically 3-5)

**Patient positioning**

The patient may remain on a bed or exam table with her legs folded upward. Special stirrups or lithotomy position is not necessary.

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**Using Dilapan-S®**

**Product description**

Dilapan-S is a hygroscopic rod made of a patented Aquacryl® hydrogel. Dilapan-S does not contain latex. The thin (3 or 4 mm) rod is inserted into the cervical canal, where it absorbs fluid from the cervical tissue, and can expand up to ~15 mm in diameter (for the 4 mm rod) over a 12-24 hour period. Typically, 3 to 5 rods are inserted in a single procedure, with the rods inserted one at a time.

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.

**FIGURE 1. SCHEMATIC DIAGRAM OF DILAPAN-S**

**How Dilapan-S is supplied**

Each Dilapan-S rod (Figure 1) is a sterile cervical dilator packed in a printed composite primary peel-open pouch. Dilapan-S is available in boxes of 25 dilators and in the following dimensions:

- 4 mm x 65 mm
  (25 ea/px)
- 4 mm x 55 mm
  (25 ea/px)
- 3 mm x 55 mm
  (25 ea/px)
INSTRUCTIONS FOR INSERTION

Dilapan-S® rods are smooth and firm to allow ease of insertion. Typically, 3-5 Dilapan-S rods are used.

1. Insert a vaginal bivalve speculum and prepare the vagina and cervix with an antiseptic solution.
   Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus (see Instructions for Use—Insertion).

2. Moisten the Dilapan-S rods with sterile water or saline to lubricate the surface.

3. Place Dilapan-S rods by using forceps to grasp the handle of the Dilapan-S rod. Insert the rods one at a time through the external cervical os, so that the border of the collar rests at the external os.
   Record the number of rods placed.
   Insert a gauze pad moistened with sterile water or saline to help keep the rod(s) in place, if needed.

INSTRUCTIONS FOR REMOVAL

Dilapan-S® should not be left in place more than 24 hours.

1. Remove any gauze in vaginal canal placed during insertion procedure, if used.

2. Remove Dilapan-S rods by grasping the handle or carefully pulling the marker string (occasionally it may be necessary to use forceps).
   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.

3. Ensure all inserted rods are removed.

For additional information, please see the Insertion and Removal Guide.
Multiple modes of action

After insertion, Dilapan-S® initiates a cascade of biophysical, mechanical, and physiological changes in the cervical tissue that continue until rod removal.2,10

**BIOPHYSICAL**

- The biophysical mode of action occurs when the Dilapan-S rods are inserted into the cervical canal, where they absorb moisture from the cervix.

**MECHANICAL**

- As the Dilapan-S rods expand, they exert controlled radial pressure on the cervical canal, which dilates the cervix.

**PHYSIOLOGICAL**

- Stretching of the cervical tissue promotes the release of local endogenous prostaglandins. These local prostaglandins initiate collagen degradation and cervical softening and ripening.

Dilapan-S works with a woman’s body

Dilapan-S rods work by absorbing fluid from the adjacent cervical tissue. These rods then uniformly expand in diameter and gradually dilate the cervical canal by exerting radial pressure. This mechanical stretch leads to the release of endogenous prostaglandins, which initiates collagen degradation and cervical softening and ripening.

Through these 3 modes, the cervix gradually and predictably softens and dilates, preparing the patient for the next step in induction of labor.2,10

Flexible cervical ripening window

After insertion, the Dilapan-S® rod expands to several times its original diameter. The amount of dilation achieved depends on the amount of time in situ, but the majority, up to 80%, of rod expansion occurs in 4 to 6 hours, which is the minimum insertion time. Dilapan-S rods should not be left in place for more than 24 hours.1,2,4 The following is provided as a guide.

<table>
<thead>
<tr>
<th>Time in situ (hours)</th>
<th>Expected Dilation (in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One DILAPAN-S (3 mm)</td>
</tr>
<tr>
<td>2</td>
<td>7.2–8.3</td>
</tr>
<tr>
<td>4</td>
<td>8.4–9.5</td>
</tr>
<tr>
<td>6</td>
<td>9.0–10.0</td>
</tr>
<tr>
<td>24</td>
<td>9.6–11.3</td>
</tr>
</tbody>
</table>

Clinical studies have shown that the average time for successful cervical ripening was between 12-15 hours, allowing for flexibility in labor & delivery units.1,2,4

Flexible cervical ripening window

**AVERAGE TIME**

- to successful cervical ripening
- 12-15 hours

**MAXIMUM**

- insertion time
- 24 hours

80% of rod expansion occurs within 4-6 hours
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).

Bishop score increases in multiple populations

Clinical studies with Dilapan-S® showed consistency in Bishop score increases across populations, and was found proven and predictable in TOLAC (trial of labor after cesarean), nulliparous and multiparous patients. In a clinical study of 444 women, the average increase in Bishop score with Dilapan-S was +3.6 (baseline 2.9, ± 1.2). For women with previous cesarean delivery (TOLAC) (n=41), the average Bishop score increase was +3.8. For nulliparous patients (n=289), the average Bishop increase was +3.7, and for multiparous patients (n=114), the average Bishop score increase was +3.5.4

In a clinical study of 444 women, the average increase in Bishop score with Dilapan-S was +3.6.4 Of these 444 women treated with Dilapan-S during induction of labor:

- <1% reported cramping or pain.
- 2.7% experienced bleeding during Dilapan-S insertion or removal.
- No maternal infections (including chorioamnionitis, urinary tract infections, endometritis, and wound infections) were attributed to use of Dilapan-S by the investigating physicians.
- No serious adverse neonatal outcomes have been reported related to use of Dilapan-S.

Mean change in Bishop score

Dilapan-S® has demonstrated safety and efficacy in a broad range of patient types and has only one contraindication.3,4

<table>
<thead>
<tr>
<th>Nulliparous</th>
<th>TOLAC</th>
<th>Post-date pregnancies (&gt;41 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiparous</td>
<td>Diabetes</td>
<td>Oligohydramnios</td>
</tr>
</tbody>
</table>

Worldwide use

Dilapan-S is available in more than 40 countries. In peer-reviewed studies, Dilapan-S has been proven to effectively ripen the cervix and result in high rates of vaginal delivery.3,4,11-14

Care settings

Dilapan-S meets the demands for Labor and Delivery units

With an increase in induction of labor (IoL) deliveries, there is new emphasis on proven, practical induction practices.5-7 The predictability of first-round success and the flexible ripening window of Dilapan-S translate into reliable cervical ripening, giving Labor and Delivery units the flexibility to work around their needs.1-4 A patient can perform daily activities and get restful sleep while her cervix is safely and gently ripening, preparing for labor.3,8

Outpatient ripening

The predictability of Dilapan-S means that it can be inserted in a variety of healthcare settings (hospital, outpatient clinic, or HCP office), allowing low-risk patients to return to the comfort of their homes for overnight cervical ripening.4,14 Once Dilapan-S is inserted, no additional fetal monitoring is required. Patients should return to the physician for removal of Dilapan-S at the indicated time. The decision to allow a low-risk patient to return home during the cervical ripening window should be based on a physician’s clinical judgment.

Contraindication: Dilapan-S is contraindicated in the presence of clinically apparent genital tract infection.
Dilapan-S® has been proven to predictably ripen the cervix and result in high rates of vaginal delivery. **Dilapan-S achieved a vaginal delivery rate ranging from 70%-81%**.3,4

### Predictable cervical ripening with Dilapan-S®

Trusted by expectant mothers and doctors around the world, the patented technology and consistency of Dilapan-S rods enable the predictability of their action.\(^1\,^3\,^4\)

Dilapan-S provides predictable and reliable first-round cervical ripening success. In 2 clinical studies, the majority of women who used Dilapan-S did not require additional cervical ripening.\(^3\,^4\)

#### Reliable first-round success\(^3\,^4\)

- In an international, multicenter (11 study sites, 7 countries) observational study of 444 pregnant women between 37 and 42 weeks with a baseline Bishop score averaging 2.9 (± 1.2), **Dilapan-S achieved 93% first-round cervical ripening success**. The mean Bishop score increased to 6.5 (± 2.3), an average increase of 3.6 points, with Dilapan-S rods.\(^4\)

- In a single center, randomized controlled trial of 419 women pregnant 37 weeks or more with an unfavorable cervix, first-round cervical ripening success was achieved in 87% of women with Dilapan-S rods.\(^3\)

#### 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.

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### Successful vaginal delivery rates

Dilapan-S® has been studied in Trial of Labor After Cesarean (TOLAC) patients and found to be effective in achieving Vaginal Birth After Cesarean (VBAC). VBAC delivery rates for Dilapan-S ranged from 52% to 75% in 4 clinical studies.\(^4\,^11\,^12\,^14\)

#### Overall vaginal delivery rate\(^*\)

- Gupta 2018\(^4\): 70% (310/444)
- Saad 2019\(^3\): 81% (369/458)
- Vlk 2014\(^11\): 75% (46/61)

\(^*\)Includes vacuum/forceps delivery.

#### VBAC delivery rate\(^\dagger\)

- Gupta 2018\(^4\): 52% (22/42)
- Vlk 2014\(^11\): 65% (59/91)
- Maier 2015\(^14\): 72% (8/12)
- Maier 2018\(^12\): 55% (6/11)

\(^\dagger\)Includes vacuum/forceps delivery.
**Patient satisfaction**

Patients who received Dilapan-S® reported high comfort levels and satisfaction in several domains and when compared with another mechanical ripening device. The sleek design (no introitus protrusion) and gentle method of action of the Dilapan-S rods allow women to partake in daily activities and/or achieve a restful night’s sleep. In a questionnaire completed by 96 women, almost 80% were able to sleep during cervical ripening with Dilapan-S.

**Dilapan-S® preferred over Foley balloon**

In a head-to-head trial with 419 pregnant women, patients were more satisfied with Dilapan-S compared with Foley balloon in 3 domains (P<0.05):

- Better sleep (P=0.01)
- More relaxing time (P=0.001)
- Ability to perform daily activities (P=0.001)

The Foley balloon is a widely adopted method of cervical ripening; however, the inflated balloon sits within the cervix and the catheter protrudes from the vaginal opening, so it is taped under tension to the patient’s leg.

With Dilapan-S the cervix ripens gently, in a gradual, controlled, and predictable manner – meaning patients can dilate gradually without constant traction or sudden, unpleasant pressure changes on the cervical os. Dilapan-S rods do not require tension.

**Patients can perform daily activities as Dilapan-S ripens the cervix**

Because patients are able to tolerate Dilapan-S with little to no discomfort, they are free to:

- Move around without uncomfortable tubing
- Shower, use the toilet, and perform other normal daily activities
- Sleep while their cervix ripens gently and gradually

**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.
Favorable safety profile

No pharmacologically active substances
Dilapan-S® works with the body, without medications.

No uterine tachysystole
In 2 large studies representing a total of 640 women (including VBAC patients) using Dilapan-S, there were no cases of uterine tachysystole related to Dilapan-S use during cervical ripening.2,11

Non-serious adverse events
In a clinical trial of 444 women treated with Dilapan-S during induction of labor4:
• <1% reported cramping or pain
• 2.7% experienced bleeding during Dilapan-S insertion or removal
• No maternal infections (including chorioamnionitis, urinary tract infections, endometritis, and wound infections) were attributed to use of Dilapan-S by the investigating physicians
• No serious adverse neonatal outcomes were attributed to use of Dilapan-S
• No observed device malfunctions, such as retraction, retention, or fragmentation with Dilapan-S use13

SUMMARY OF EVIDENCE

IMPORTANT SAFETY INFORMATION

Indications 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 see Instructions for Use on pages 20 and 21.
Visit DilapanS.com.
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 plastic dilator handle, and a marker string (see the figure below). The dilator 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.

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 dilator 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.

Indications
1. Placement and removal of intrauterine devices
2. Uterine curettage
3. Suction aspiration cannula

Risks associated with the procedure
• 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 visual technique to identify the cause of these difficulties before removing the dilator
• The patient should be instructed to avoid bathing, douching and refrain from sexual intercourse until the cervix is stabilized by placing an axillary tampon through the anterior lip of the cervix.

Expected Dilation (in mm)

<table>
<thead>
<tr>
<th>Time in situ (hours)</th>
<th>Expected Dilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 – 3.5</td>
</tr>
<tr>
<td>2</td>
<td>5 – 6.5</td>
</tr>
<tr>
<td>3</td>
<td>6 – 7.5</td>
</tr>
<tr>
<td>4</td>
<td>7 – 8.5</td>
</tr>
<tr>
<td>5</td>
<td>8 – 9.5</td>
</tr>
</tbody>
</table>

Withdrawal of the device
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 the DILAPAN-S® during removal. Do not grasp the collar with forceps. Do not grasp the marker string with a sharp-edged instrument.
3. Grasp the collar with forceps to remove the device. As the device is being removed, do not cause the device to break. As the dilator has been manufactured from an anisotropic xerogel of AQUACRYL, it is possible that the dilator will break during removal. 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 on the fetus has not been clinically investigated.
4. The dilator 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 on the fetus has not been clinically investigated.

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 extraction
• Device retraction into the uterine cavity
• Patient discomfort or bleeding during and/or after insertion

Furthermore, 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.

CONTACTS AND VIGILANCE
Please report incidents of death or serious injury to your distributor (USRegulatory@medicem.com) or to the manufacturer (technology@medicem.com) in relation to the DILAPAN-S®.

Internal Importer, Distributor and US Agent: Medicem Inc.
125 High St., Suite 174
Boston, MA 02120
Tel.: +1 617 534 2396
e-mail: USA@medicem.com

Manufacturer: Medicem Technologies a.s.
Karlovandska trida 20, Kamenice Zdrojova
273 01, Czech Republic
Tel.: +420 317 070 375

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.

TABLE OF USED SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ON</td>
<td>Sterile, Standardized using sterilization</td>
</tr>
<tr>
<td>°C</td>
<td>Degrees of Celsius</td>
</tr>
</tbody>
</table>

Consult instructions for use

LOT

Batch number

Expiration date

Date of manufacture

Manufacturer

Quantity

pc / pcs

PediaQ

PDA approved text_DSFilmsa-Rev18/2020-04

FDA approved text_DSFilmsa-Rev01/2020-04
Dilapan-S® is the non-pharmacologic, versatile choice for cervical ripening in a broad range of patients.1,2,4

**PRODUCT INFO**

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<tr>
<th>Size</th>
<th>Item #:</th>
<th>UOM:</th>
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<td>25 ea/bx</td>
</tr>
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</table>

**ORDERING**

- **Online Portal Registration:**
  [https://www.hpsrx.com](https://www.hpsrx.com)

- **Contact Customer Service for Order Form**

Customer Service: 800-850-1657
Fax: 800-361-6984
Email: customerservice@hpsrx.com

For more information, please visit us at [www.DilapanS.com](http://www.DilapanS.com).

Please see accompanying Instructions for Use on pages 20-21.

**REFERENCES:**