Dilapan-S®

IMPLEMENTING CERVICAL RIPENING WITH DILAPAN-S:

A Comprehensive Toolkit

An interactive resource for developing evidence-based, patient-centered induction practices and improved induction of labor outcomes.

Please see accompanying **Instructions for Use** and **Important Safety Information** on page 22 for more information.

medicem

INTRODUCTION

Welcome. This toolkit is designed to help guide healthcare systems and clinical teams through the process of safely, effectively, and sustainably adopting Dilapan-S for cervical ripening as part of their induction of labor (IOL) programs.

This kit provides practical, evidence-based guidance on protocol development, standardized clinical pathways, and EMR configuration to ensure accurate provider and nursing documentation aligned with appropriate reimbursement. It's structured to support teams from initial planning through go-live, with templates and resources designed to improve workflow efficiency, support patient-centered care, and drive better clinical and economic outcomes.

For simplicity throughout the kit, the term "nurse" refers to nursing directors, managers, educators, perinatal quality nurses, and staff nurses within labor and delivery. The term "provider" includes obstetricians, certified nurse-midwives, family medicine physicians, and other advanced practice obstetric clinicians.

Each section includes a guide to the content and resources specific to that stage of implementation. Throughout, you'll find clickable links and downloadable templates that you can customize for your practice. This toolkit is designed to be used in collaboration with your Dilapan-S Clinical Specialist, and we strongly recommend contacting your Clinical Specialist prior to initiating each step of the implementation process. The Dilapan-S Clinical Team is also available to support your implementation journey with education, consultation, and clinical best practices.

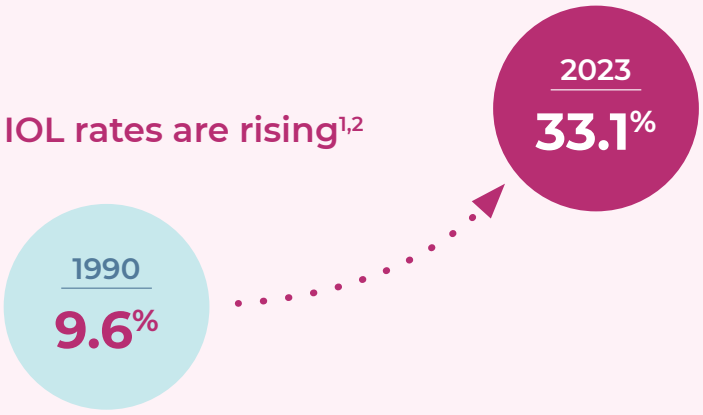
By implementing a structured cervical ripening program that integrates Dilapan-S into existing workflows, hospitals and providers can achieve higher patient satisfaction and align with the principles of value-based care and quality outcomes.

TABLE OF CONTENTS

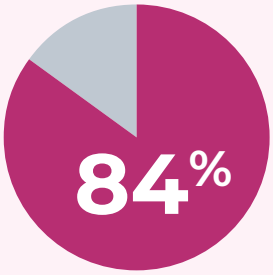
Rising Rates, Rising Need: The Case for Change

Across the U.S., whether elective or medically indicated, induction of labor rates continue to rise. As this trend grows, so does the need for safe, efficient, and patient-centered cervical ripening solutions.

IOL rates are rising[1,2]



Preliminary CDC data indicate this upward trajectory continues, with estimated rates of 33.7% in 2024 and 34.8% in early 2025 (January - May).[3]



84% of women with an indication for IOL **require cervical ripening[4]**

Benefits of a Standardized IOL Approach

Standardizing induction of labor processes supports clinical consistency, enhances patient safety, and drives efficiency across provider and nursing teams. When paired with Dilapan-S, standardization can streamline cervical ripening protocols, minimize variability, and improve outcomes across inpatient and outpatient settings.

References: 1. Declercq E, et al. "Maternal perceptions of the experience of attempted labor induction and medically elective inductions: analysis of survey results from listening to mothers in California". *BMC Pregnancy Childbirth*. 2020 Aug 12;20(1):458. doi: 10.1186/s12884-020-03137-x. **2.** Osterman MJK, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: Final data for 2023. National Vital Statistics Reports; vol 74, no 1. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: https://dx.doi.org/10.15620/cdc/175204. **3.** Centers for Disease Control and Prevention. *Vital Statistics Rapid Release; Births: Provisional Data for 2023*. National Center for Health Statistics; 2024. **4.** Cervical Ripening and Labor Induction and Augmentation, 6th Edition Simpson, Kathleen Rice Nursing for Women's Health, Volume 29, Issue 5, e1 - e49.

Overview of Dilapan-S in Induction of Labor

Dilapan-S is an FDA-cleared synthetic osmotic cervical dilator designed for gentle and predictable cervical ripening in the induction of labor. Its unique hydrogel design gradually absorbs fluid from cervical tissue, leading to gentle, predictable mechanical dilation without pharmacologic stimulation.

Key advantages of Dilapan-S include:

- Predictable and controlled cervical ripening
- Low rate of uterine tachysystole
- High patient satisfaction and comfort
- Suitable for both inpatient and selective outpatient use
- Compatible with patients seeking a non-pharmacologic option

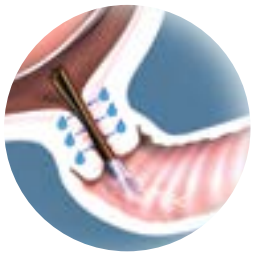
Facilities that use Dilapan-S may reduce costs by[1]

1. Optimal clinical outcomes
2. Overall reduction in cost of care
3. Quality metrics (such as decreased length of stay and patient satisfaction)
4. Enhanced clinical workflows

References: 1. Saunders SJ, Grisamore JL, Wong T, Torrejon Torres R, Saunders R, Einerson B. Moving preinduction cervical ripening to a lower acuity inpatient setting using the synthetic hygroscopic cervical dilator: a cost-consequence analysis for the United States. J Med Econ. 2022;25(1):1185-1198. doi:10.1080/13696998.2022.2136854

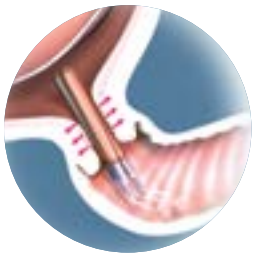
Dilapan-S has multiple modes of action[1,2]

After insertion, Dilapan-S initiates a cascade of biophysical, mechanical and physiological changes in the cervical tissue that continue until rod removal. The cervix gradually and predictably softens and dilates, preparing the mother for the next step in induction of labor.[2,3]



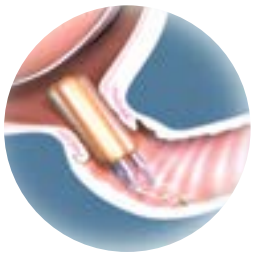
Biophysical

Dilapan-S rods are inserted into the cervical canal, where they absorb moisture from the cervix as it **softens** cervical tissue



Mechanical

The Dilapan-S rods expand, exerting controlled **radial pressure** on the cervical canal, which dilates the cervix



Physiological

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

References: 1. Dilapan-S Instructions for Use. DSPIenus-Rev020/2022-05. **2.** Dilapan-S Issuance of Substantial Equivalence Determination. US Food and Drug Administration. 2015. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143447.pdf. Accessed October 8, 2020. **3.** Drunecký T, Reidingerová M, Plisová M, et al. Experimental comparison of properties of natural and synthetic osmotic dilators. *Arch Gynecol Obstet*. 2015;292(2):349-354.

Expansion Overview and Timing

Dilapan-S at insertion

Dilapan-S at removal

0 Hours | 2 Hours | 4 Hours | 6 Hours | 12-24 Hours

- Each 4mm rod can expand up to 14.6mm in diameter[1,4]
- Typically, 4 to 5 rods are used per procedure[5,6]
- The average time to successful cervical ripening is 12 to 15 hours[1,4,6]
- Maximum insertion time is 24 hours, allowing for a flexible cervical ripening window[4]

References: 1. Dilapan-S Instructions for Use. DSPIenus-Rev020/2022-05. **2.** Gunja MZ, et al. *Commonwealth Fund Issue Briefs*. January 31, 2023. **3.** Grobman WA, et al. *N Engl J Med*. 2018;379(6):513-523. **4.** Wood RL., et al. *JAMA Netw Open*. 2023;6(8):e2328274.

Identifying clinical pathways

Identify your clinical pathways that work best for your facility. This may vary based on different components such as reimbursements, operational capacity, and patient population.

Inpatient Pathways:

May be right for a broad range of patient profiles:[1-6]

- Nulliparous
- Multiparous
- Elective induction at term (≥ 39 weeks)
- Post-dates (>41 weeks)
- Obesity
- Diabetes
- Preeclampsia
- TOLAC
- Poly/oligohydramnios

Outpatient Pathways:

Superior patient satisfaction for low-risk patient populations

- Associated with low unscheduled contact with triage
- Low early return rates
- Supports overall reduction in cost of care and quality metrics such as decreased length of stay

A **Hospital insertion**

- Insert in hospital scheduled OB procedure
- Discharge to home
- Return for IOL

B **Office insertion**

- Insert in office
- Send patient home
- Patient admitted to hospital for IOL

NOTE: **Reimbursement varies by clinical pathway. Reimbursement may be available across all clinical settings; however, multiple considerations apply and should be evaluated accordingly.**

One Contraindication

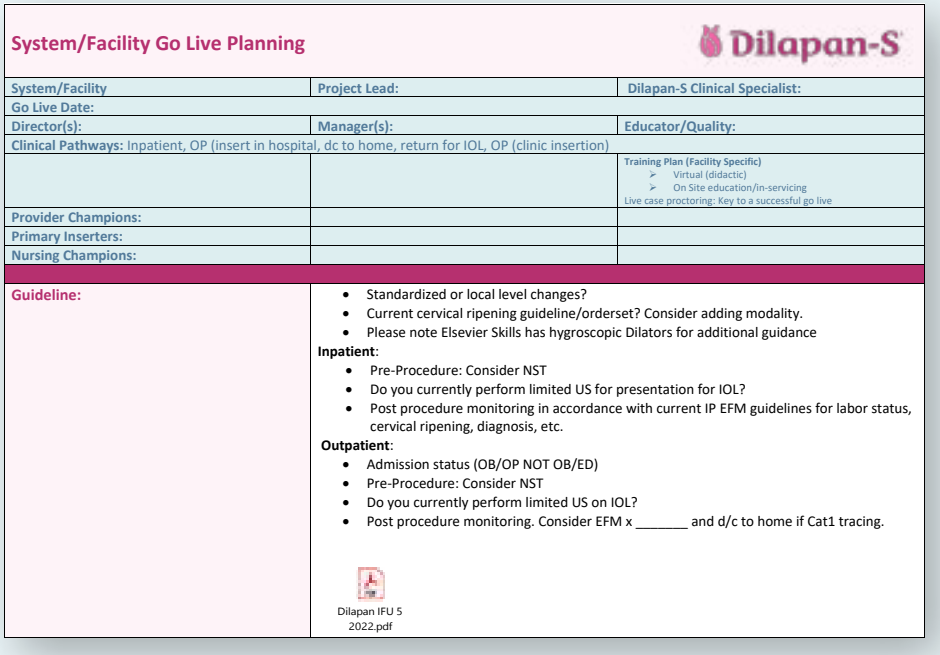
Dilapan-S is contraindicated in the presence of clinically apparent genital tract infection

References: 1. Drunecký, T., et al. "Clinical Experience with Dilapan-S® for Cervical Ripening." *Archives of Gynecology and Obstetrics*, vol. 292, no. 2, 2015, pp. 349–354. **2.** Dilapan-S Instructions for Use. DSPIenus-Rev020/2022-05. **3.** Saad, A.F., et al. "Comparison of Mechanical and Pharmacologic Methods of Labor Induction in Term Pregnancies." *American Journal of Obstetrics and Gynecology*, vol. 220, no. 3, 2019, pp. 275.e1–275.e9. **4.** Maier, J.T., et al. "Clinical Outcomes of Osmotic Dilators in Labor Induction." *Journal of Perinatal Medicine*, vol. 46, no. 3, 2018, pp. 299–307. **5.** Gavara, R., et al. "Comparative Outcomes of Cervical Ripening Methods." *Obstetrics & Gynecology*, vol. 139, no. 6, 2022, pp. 1083–1091. **6.** Gupta, J.K., et al. "Mechanical Methods for Labor Induction: Updated Evidence." *American Journal of Obstetrics & Gynecology MFM*, vol. 4, no. 4, 2022, 100628.

Implementation Overview

The pages that follow will provide a **step-by-step roadmap for successful Dilapan-S implementation**, including guidance for what to compile for your organization, plus downloadable checklists and templates you can customize.

Utilize this planning template as you work through the planning steps below with your team to complete your foundational build, communication, and follow-up on actionable items.



System/Facility Go Live Planning

System/Facility	**Project Lead:**	**Dilapan-S Clinical Specialist:**
Go Live Date:		
Director(s):	**Manager(s):**	**Educator/Quality:**
Clinical Pathways: Inpatient, OP (insert in hospital, dc to home, return for IOL, OP (clinic insertion)		
		Training Plan (Facility Specific) ➢ Virtual (didactic) ➢ On Site education/in-servicing Live case proctoring: Key to a successful go live
Provider Champions:		
Primary Inserters:		
Nursing Champions:		
Guideline:	• Standardized or local level changes? • Current cervical ripening guideline/orderset? Consider adding modality. • Please note Elsevier Skills has hygroscopic Dilators for additional guidance **Inpatient**: • Pre-Procedure: Consider NST • Do you currently perform limited US for presentation for IOL? • Post procedure monitoring in accordance with current IP EFM guidelines for labor status, cervical ripening, diagnosis, etc. **Outpatient**: • Admission status (OB/OP NOT OB/ED) • Pre-Procedure: Consider NST • Do you currently perform limited US on IOL? • Post procedure monitoring. Consider EFM x _____ and d/c to home if Cat1 tracing. Dilapan IFU 5 2022.pdf	

Download

Identification of Key Stakeholders

Create provider and nursing champions for utilization and to support insertion:

- OB/Gyns
- Hospitalists/Laborists
- CNMs
- PAs
- NPs
- Nurse Leadership

Helpful information to provide to VAC

- 25 rods/box
- $2,000 per box (Non-GPO pricing)
- Patients treated: 5-8 patients per box
- For IOL sizes include 4x55 and 4x65, consult with a clinical specialist to confirm sizing and quantity for your facility.
- Portfolio management available through Lumere, Symplr/Greenlight

DISTRIBUTOR:
HPSRx Enterprises
(800)850-1657 (phone)
(800)361-6984 (fax)
customerservice@hpsrx.com

Identification of Key Stakeholders

Manage VAC Approval or New Product Approval

Leverage these frequently utilized resources to support you through your VAC approval or your new product acquisition.

Clinical Resources

Instructions For Use

Download

FDA Clearance Letter

Download

Core Visual Aid

Download

HOMECARE trial summary
Avritscher EBC et al, 2023

Full Study →

Balloon catheter vs Dilapan-S
Wood RL et al, 2025

Full Study →

DILAFOL trial
Saad AF et al, 2019

Full Study →

HEOR Resources

HOMECARE Economic Evaluation

Download

Ordering guide (Non-GPO price)

Download

Check your GPO affiliation for updated contract pricing

Reimbursement Guide

Download

Inpatient Cervidil® and Foley vs outpatient ripening with Dilapan-S
Saunders SJ et al, 2021

Full Study →

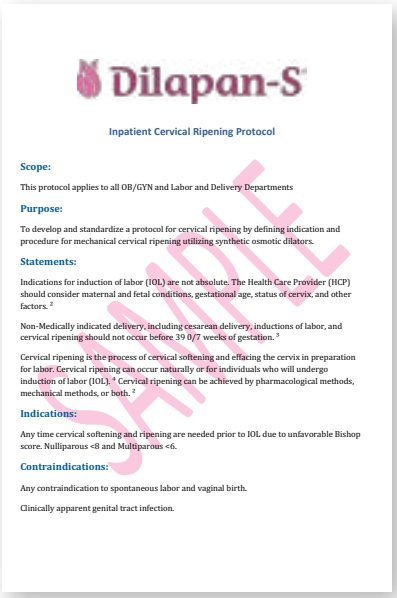
Inpatient prostaglandins vs inpatient Dilapan-S
Saunders SJ et al, 2022

Full Study →

Before moving forward, contact your Dilapan-S Clinical Specialist to review VAC approval and confirm ordering and account setup requirements.

Evidence-Based Guidelines for Induction of Labor

Establishing standardized, evidence-based guidelines is critical for successful integration of Dilapan-S into induction of labor protocols. Clinical pathways should be developed for both inpatient and outpatient settings, clearly defining patient selection, procedure workflow, and follow-up care. This toolkit includes example policy templates that can be customized for your institution.


Dilapan-S

Inpatient Cervical Ripening Protocol

Scope:

This protocol applies to all OB/GYN and Labor and Delivery Departments

Purpose:

To develop and standardize a protocol for cervical ripening by defining indication and procedure for mechanical cervical ripening utilizing synthetic osmotic dilators.

Statements:

Indications for induction of labor (IOL) are not absolute. The Health Care Provider (HCP) should consider maternal and fetal conditions, gestational age, status of cervix, and other factors. [2]

Non-Medically indicated delivery, including cesarean delivery, inductions of labor, and cervical ripening should not occur before 39 0/7 weeks of gestation. [3]

Cervical ripening is the process of cervical softening and effacing the cervix in preparation for labor. Cervical ripening can occur naturally or for individuals who will undergo induction of labor (IOL). [4] Cervical ripening can be achieved by pharmacological methods, mechanical methods, or both. [2]

Indications:

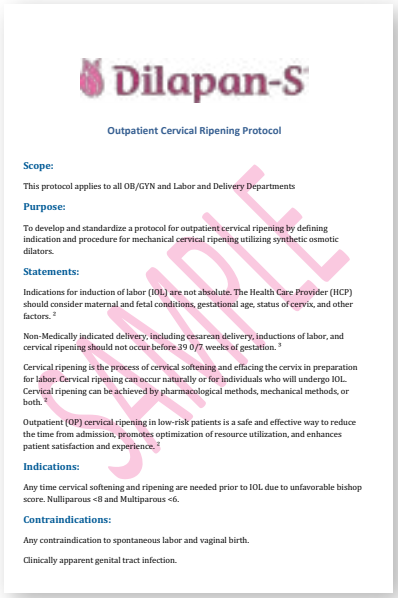
Any time cervical softening and ripening are needed prior to IOL due to unfavorable Bishop score. Nulliparous <8 and Multiparous <6.

Contraindications:

Any contraindication to spontaneous labor and vaginal birth.

Clinically apparent genital tract infection.

SAMPLE


Dilapan-S

Outpatient Cervical Ripening Protocol

Scope:

This protocol applies to all OB/GYN and Labor and Delivery Departments

Purpose:

To develop and standardize a protocol for outpatient cervical ripening by defining indication and procedure for mechanical cervical ripening utilizing synthetic osmotic dilators.

Statements:

Indications for induction of labor (IOL) are not absolute. The Health Care Provider (HCP) should consider maternal and fetal conditions, gestational age, status of cervix, and other factors. [2]

Non-Medically indicated delivery, including cesarean delivery, inductions of labor, and cervical ripening should not occur before 39 0/7 weeks of gestation. [3]

Cervical ripening is the process of cervical softening and effacing the cervix in preparation for labor. Cervical ripening can occur naturally or for individuals who will undergo IOL. Cervical ripening can be achieved by pharmacological methods, mechanical methods, or both. [2]

Outpatient (OP) cervical ripening in low-risk patients is a safe and effective way to reduce the time from admission, promotes optimization of resource utilization, and enhances patient satisfaction and experience. [5]

Indications:

Any time cervical softening and ripening are needed prior to IOL due to unfavorable bishop score. Nulliparous <8 and Multiparous <6.

Contraindications:

Any contraindication to spontaneous labor and vaginal birth.

Clinically apparent genital tract infection.

SAMPLE

Inpatient Protocol

Download

Outpatient Protocol

Download

Reminder: Schedule an initial planning meeting with your Dilapan-S Clinical Specialist to collaboratively review your facility-specific guidelines and determine the best clinical pathway for your facility.

EMR Guidance

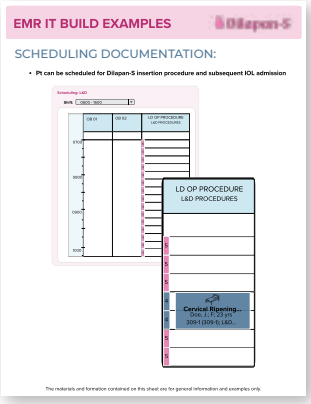
Development of EMR is essential to capture provider/nursing documentation and support appropriate billing and coding.

Key EMR Build Elements:

Nursing Documentation: Record insertion details (timeout, rod and gauze count, insertion time, date, lot number, and expiration date). Record removal details (date, time, rod and gauze count, provider name). Document delivery summary, after visit summary (AVS)/ discharge documentation (for OP) and patient education/discharge teaching.

Provider documentation: Smart/dot phrases for insertion and removal procedures (e.g., indication, number of rods inserted, lot number, time/date)

Correctly capture procedure code: CPT 59200 and charge capture (insertion of cervical dilator)



Review your EMR Community Library for existing IT build examples, or use the sample template provided here as a reference to support your analytics and IT teams in developing your EMR build.

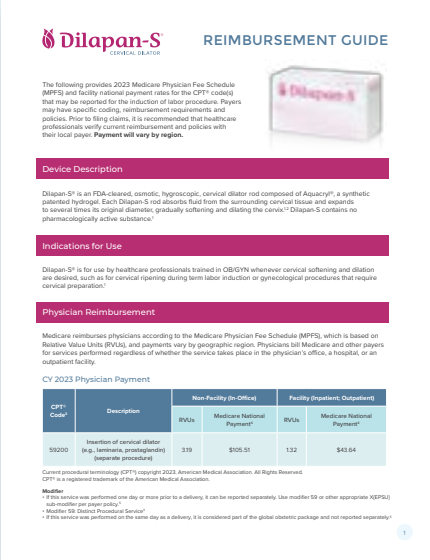
Download

Before advancing your EMR build, connect with your Dilapan-S Clinical Specialist to review build elements and ensure alignment with clinical workflows and documentation needs.

Reimbursement

Understanding and optimizing reimbursement for cervical ripening procedures is an important aspect of implementing a sustainable Dilapan-S program.

You are responsible for appropriate selection of procedures/services/treatment CPT codes. Medicem's reimbursement team can provide additional guidance on coding and billing best practices to help ensure compliant and optimized reimbursement.


Dilapan-S® CERVICAL DILATOR REIMBURSEMENT GUIDE

The following provides 2023 Medicare Physician Fee Schedule (MPFS) and facility national payment rates for the CPT® code(s) that may be reported for the induction of labor procedure. Payers may have specific coding, reimbursement requirements and policies. Prior to filing claims, it is recommended that healthcare professionals verify current reimbursement and policies with their local payer. **Payment will vary by region.**

Device Description

Dilapan-S® is an FDA-cleared, osmotic, hygroscopic, cervical dilator rod composed of Aquacryl®, a synthetic patented hydrogel. Each Dilapan-S rod absorbs fluid from the surrounding cervical tissue and expands to several times its original diameter, gradually softening and dilating the cervix.[1,2] Dilapan-S contains no pharmacologically active substance.[1]

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.[1]

Physician Reimbursement

Medicare reimburses physicians according to the Medicare Physician Fee Schedule (MPFS), which is based on Relative Value Units (RVUs), and payments vary by geographic region. Physicians bill Medicare and other payers for services performed regardless of whether the service takes place in the physician's office, a hospital, or an outpatient facility.

CY 2023 Physician Payment

CPT® Code[3]	Description	Non-Facility (In-Office)		Facility (Inpatient; Outpatient)	
		RVUs	Medicare National Payment[4]	RVUs	Medicare National Payment[4]
59200	Insertion of cervical dilator (eg., laminaria, prostaglandin) (separate procedure)	3.19	$105.51	1.32	$43.64

Current procedural terminology (CPT®) copyright 2023. American Medical Association. All Rights Reserved. CPT® is a registered trademark of the American Medical Association.

Modifier
- If this service was performed one day or more prior to a delivery, it can be reported separately. Use modifier 59 or other appropriate X{EPSU} sub-modifier per payer policy.[3]
- Modifier 59: Distinct Procedural Service[3]
- If this service was performed on the same day as a delivery, it is considered part of the global obstetric package and not reported separately.[4]

1

DOWNLOAD

Key reimbursement considerations:

- Use Procedure Code: **CPT 59200**
- Payer coverage and reimbursement rates may vary by institution and region
- Review payer-specific policies prior to implementation

Economics Video For Healthcare Administrators

Watch Video →

Reminder: Request support from your Dilapan-S Clinical Specialist to ensure proper reimbursement requirements and billing and coding.

Scheduling

Typical scheduling scenarios include:

1 Morning insertion
patient returns in the evening for induction

2 Midday insertion
patient returns around midnight for induction

3 Afternoon/evening insertion
patient returns the next morning (approximately 12 hours post-insertion)

Flexible Cervical Ripening Window

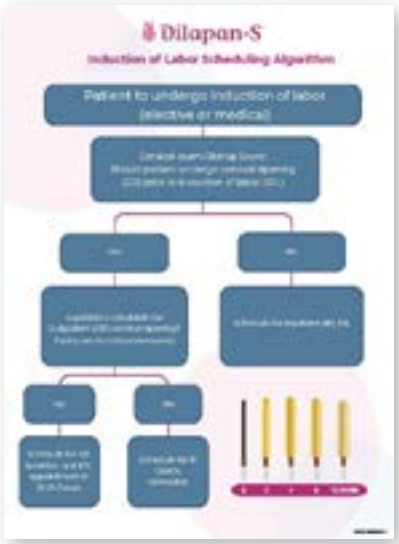
80% EXPANSION within 4 to 6 hours of rod insertion[1]

MAXIMUM insertion time of 24 hours[1]

Use this timeline as a consideration when scheduling to ensure proper dwell time for rod expansion.

References: 1. Dilapan-S Instructions for Use. DSPIenus-Rev020/2022-05.

Scheduling



Induction of Labor Scheduling Algorithm

A visual guide to determine if a patient is a candidate for in-patient or outpatient and next steps

DOWNLOAD

Pre-Procedure Prep Form

Print out this simple but informative one-page summary for patients prior to their procedures. It can help answer many common questions. Space also available to write down appointment and induction times.

DOWNLOAD

Reminder: **Prior to distributing these materials, review them with your Dilapan-S Clinical Specialist to ensure proper scheduling and workflow. Facilitate clinical specialist outreach to the clinic setting to support education, patient selection, and scheduling to allow effective implementation.**

Instrumentation

Successful Dilapan-S insertion requires proper equipment setup and readily available supplies.

Recommended instruments and supplies include:

- Sterile gloves and sterile field setup
- Two (2) sponge forceps
- Bivalve vaginal speculum
- Antiseptic solution of choice (e.g., povidone-iodine swabs)
- Dilapan-S rods (typically 4x65 mm for IOL; 4x55 mm may be used per provider discretion)

Facilities should confirm supplies and instrumentation readiness before go-live. Visual aids and reference posters can be displayed to reinforce proper setup and equipment/supply.

Before go-live, confirm equipment and supply readiness with your Dilapan-S Clinical Specialist to ensure proper instrumentation is available on the unit.

End-User Education

Comprehensive education is essential to ensure successful implementation and sustained adoption of Dilapan-S. This has proven valuable to implementation of a successful program.

Education should focus on:

1. **Clinical Understanding** – Product overview, patient selection, clinical pathways for use, and insertion training
2. **Virtual and On-site Education/In-Servicing** – Simulation-based instruction
3. **Live case proctoring** – Facilitates provider and nursing confidence

The Dilapan-S Clinical Team can support educational rollout through a structured program that includes didactic sessions, virtual learning modules, and onsite proctoring. Ongoing education and in-services should be regularly scheduled.

See step 8: Go Live Materials for educational support (simulation tools, in-service flyers, etc).

Reminder: **Contact your designated Clinical Specialist to coordinate all end-user training for both nursing and providers, in conjunction with the scheduled go-live and onsite support.**

Go-Live Materials

The go-live phase marks the official launch of your Dilapan-S cervical ripening program. Preparation, communication, and collaboration are key to ensuring a smooth transition from planning to integration.

Prior to go-live, notify your Dilapan-S Clinical Specialist to finalize go-live details and develop your educational planning and rollout.

During the go-live period, the Clinical Specialist team can provide onsite or virtual support, including proctoring of early cases and assistance with workflow troubleshooting. Post-launch, maintain open communication with the Clinical Specialist team for ongoing guidance.

Go Live Materials include*:

- Dilapan-S Insertion and Removal Guide
- Patient Education Brochure
- Badge buddies
- Patient care card
- Inservice flyer
- Patient Safety bracelets

*These will be delivered by your Clinical Specialist and are also available in your Go-Live Template here

Contact us to connect to your designated Dilapan-S Clinical Specialist here or 857-488-0441

Implementation Support & FAQs

Following go-live, ongoing monitoring and support help sustain success and identify opportunities for optimization. This section provides guidance on post-implementation follow-up, performance tracking, and access to expert support.

Recommended implementation follow-up activities include:

Monitoring key data metrics such as cervical ripening success, induction-to-delivery windows, length of admission, and patient satisfaction.

Your Clinical Specialist can provide:

- A data collection sheet for additional data metrics based on your initial objectives
- Information on the healthcare economic impact (clinical, quality) of value-based initiatives

Gathering feedback from providers, nurses, and patients.

- Encourage patients to fill out patient satisfaction survey through their bracelet

On-going clinical education/in-servicing for nursing and providers

Retrospective reimbursement review

Facilities are encouraged to connect with the Dilapan-S Clinical Team for continued education, data review, and practice optimization support.

For additional resources and support:

- Visit the Dilapan-S Clinical Resource Library at https://www.dilapans.com/
- Contact a Dilapan-S Clinical Specialist or account representative at usinfo@medicem.com or 857-488-0441
- FAQs can be found at https://www.dilapans.com/pdf/resources-dilapan-s_faq.pdf
- Executive summaries and published literature on pages 11

Advancing Value-Based Care

Implementing a standardized cervical ripening program with Dilapan-S is more than a procedural enhancement. It represents a meaningful shift toward value-based, patient-centered obstetric care. By integrating an evidence-based, non-pharmacologic option into the induction of labor process, healthcare systems can improve outcomes while optimizing efficiency and cost-effectiveness.

Value-based benefits include[1]:

Enhanced clinical outcomes

Predictable, gentle cervical ripening with reduced incidence of uterine tachysystole

Improved patient experience

A more comfortable, low-intervention option that supports patient choice and satisfaction.

Operational efficiency

Reduced length of stay and improved unit throughput.

Cost management/Resource optimization

Streamlined workflows and optimized resource utilization

Each component of this toolkit, from VAC approval to EMR integration, **has been designed to support sustainable**, system-level improvement.

Facilities that invest in structured planning and continuous education can **expect measurable gains in quality, safety, and patient experience**.

References: 1. Saunders SJ, Grisamore JL, Wong T, Torrejon Torres R, Saunders R, Einerson B. Moving preinduction cervical ripening to a lower acuity inpatient setting using the synthetic hygroscopic cervical dilator: a cost-consequence analysis for the United States. J Med Econ. 2022;25(1):1185-1198. doi:10.1080/13696998.2022.2136854

IMPORTANT SAFETY INFORMATION

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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.

If you have any questions about Dilapan-S, be sure to discuss them with your healthcare provider. You are encouraged to report adverse events related to Dilapan-S by emailing USRegulatory@medicem.com.

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Dilapan-S®

The Dilapan-S Clinical and Commercial Teams are committed to partnering with institutions on this journey. Together, we can advance the standard of induction care, delivering outcomes that reflect the best of modern obstetrics: **safe, efficient, and centered on every patient's birth experience**.

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