Dilapan-S®

Dear Healthcare Professional,

Thank you for considering the use of Dilapan-S® for cervical ripening at your institution. The accompanying Value Analysis Kit provides information on the clinical profile of Dilapan-S to help in making an informed decision about its use.

Dilapan-S has US FDA 510(k) clearance and is registered and available in over 40 countries.[1]

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

In the US, concerns about the overuse of cesarean deliveries are increasing, as rates remain high.[2] A nationwide push to bring these numbers down has lead several societies, such as ACOG, to issue guidelines for the safe prevention of unwarranted cesarean deliveries.[3] Starting in the first quarter of 2021, the Joint Commission will publicly report hospital cesarean delivery rates.[4,5]

In the US, approximately 25% of expectant mothers undergo labor induction.[2] However, obstetricians expect that number to increase.[6,7] Recent evidence from the ARRIVE trial has shown that elective labor in low-risk nulliparous women was associated with lower cesarean delivery rates while not increasing adverse perinatal morbidities.[6] Since many women undergoing labor induction present with unfavorable cervixes, pre-induction cervical ripening is expected to play an important role in achieving a favorable Bishop score (a strong predictor of vaginal delivery).[7] Thus, healthcare providers will want an optimal cervical ripening method, taking into consideration patient characteristics, indications and contraindications of the available methods, safety profile, efficacy/predictability, as well as patient acceptance. Dilapan-S has been shown to meet these needs.[7-14]

Dilapan-S is a hygroscopic cervical dilator made from a proprietary synthetic hydrogel developed specifically for cervical dilation and ripening associated with various gynecological procedures.[8,9]

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.[8,11] 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, or 80%, of rod expansion occurs in 4 to 6 hours, which is the minimum insertion time.[8,9]

Dilapan-S has one contraindication: Dilapan-S is contraindicated in the presence of clinically apparent genital tract infection.

Please see accompanying Instructions for Use.

medicem

Dilapan-S®

References

1. Data on File, Medicem, Inc. 2020.
2. Births: Final data for 2018. *National Vital Statistics Reports.* 2019;68:1-46.
3. Safe prevention of the primary cesarean delivery. Obstetric Care Consensus No. 1. March 2014. Reaffirmed 2016. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2014;123:683-711. Accessed October 16, 2020. https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2014/03/safe-prevention-of-the-primary-cesarean-delivery.
4. Joint Commission makes accreditation and certification performance measure reporting optional and extends timelines. The Joint Commission. Published March 25, 2020. Accessed October 15, 2020. https://www.jointcommission.org/-/media/tjc/documents/measurement/march-2020-performance-measurement-reporting-optional-and-extended-timelines.pdf.
5. Public reporting of high cesarean rates to begin in July 2020. The Joint Commission. Published February 6, 2019. Accessed October 15, 2020. https://www.jointcommission.org/resources/news-and-multimedia/blogs/leading-hospital-improvement/2019/02/public-reporting-of-high-cesarean-rates-to-begin-in-july-2020/.
6. Grobman WA, Rice MM, Reddy UM, et al. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med.* 2018;379:513-23.
7. Saad AF, Villarreal J, Eid J, et al. A randomized controlled trial of Dilapan-S® vs Foley balloon for preinduction cervical ripening (DILAFOL trial). *Am J Obstet Gynecol.* 2019;220(3):275.e1-275.e9.
8. Dilapan-S® Instructions for Use. DSPIenus-Rev018/2020-04.
9. 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.
10. Gupta J, Chodankar R, Baev O, et al. Synthetic osmotic dilators in the induction of labour – An international multicentre observational study. *Eur J Obstet Gynecol Reprod Biol.* 2018; 229:70-75.
11. 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.
12. Maier JT, Metz M, Watermann N, et al. Induction of labor in patients with an unfavorable cervix after a cesarean using an osmotic dilator versus vaginal prostaglandin. *J Perinat Med.* 2018;46(3):299-307.
13. Maier JT, Schalinski E, Gauger U, Hellmeyer L. Cervical ripening with an osmotic dilator (Dilapan-S) in term pregnancies – An observational study. *J Gynecol Neonatal Biol.* 2015;1(3):1- 6.
14. Vlk R, Hruban L, Janků P, et al. Efficacy and safety of the osmotic dilator Dilapan-S® for cervical ripening in women with/without Caesarean section. Poster presented at the 13th World Congress in Fetal Medicine, The Fetal Medicine Foundation. June 29–July 3, 2014. Nice, France.

medicem