



Frequently Asked Questions

1. Can Dilapan-S be inserted without a speculum?

o According to IFU, a bivalve speculum is used.

2. What is the incidence of infection related to Dilapan-S?

- o Medicem makes no claims for incidence of infection related to Dilapan-S.
- o In recently published meta-analysis of Individual Patient Data, coming from four large randomized trials, the incidence of both maternal and neonatal infections was similar in Dilapan-S group and group of comparators. (Saad AF et al. Dilapan-S vs standard methods for cervical ripening in term pregnancies: an individual patient data meta-analysis. Am J Obstet Gynecol MFM 2025;7:101583.)
 - In these studies, however, infection is not deemed to be attributed to the use of Dilapan-S

3. Can Dilapan-S be used concurrently with other uterine stimulants (pitocin or misoprostol)?

o According to IFU, using Dilapan-S does not impose any specific limitations on standard medication (incl. uterotonic agents) administered alongside Dilapan-S.

4. How many dilators are used for sufficient cervical preparation for Induction of Labor?

The number of dilators varies based on the indication, cervical condition, and desired outcome. For instance, 4–5 dilators are often used for labor induction with successful cervical ripening in approximately 80% of induced women, The maximum number is not defined in the product's Instructions for Use; always take into account the clinical judgement of the risk/benefit ratio and mode of action.

5. Can insertion of Dilapan-S cause rupture of membranes?

While theoretically possible, clinical evidence doesn't link Dilapan-S insertion to rupture of membranes (ROM).





6. Can Dilapan-S be used in patients with premature rupture of membranes (PROM)?

DILAPAN-S is not contraindicated in PROM cases. There is anecdotal clinical evidence proposing its use is effective and safe.

In case of PROM requiring cervical ripening, follow institutional guidelines.

Rupture of membranes can occur spontaneously during the cervical ripening process and usually suggests the onset of labor. Follow institutional guidelines for further management while assessing risk vs benefit to both patient and fetus.

7. Can Dilapan-S be used in patients with previous Caesarean section?

Dilapan-S is not contraindicated in cases of previous Caesarean section. Several clinical trials evaluated using Dilapan-S for VBAC/TOLAC, concluding that Dilapan-S can be an effective and safe option for these patients.

8. What are the contraindications of Dilapan-S?

- o The only listed contraindication is the presence of a clinically apparent genital tract infection.
- o IFU states that any infection of the genital tract of any etiology is a contraindication, but the infection must be clinically apparent such as seen with e.g. yeast infections and bacterial vaginosis (BV).
- o GBS positivity itself is not a contraindication for DS insertion. Your decision must be made based on your local clinical guidance or SOP for GBS positivity in IOL.

9. Are there any gestational age limitations for Dilapan-S?

There are no specific gestational age limitations; use depends on clinical judgement.

If you need further clarification on these questions, please contact our Medical Affairs Team at: <u>USMedical@Medicem.com</u>