

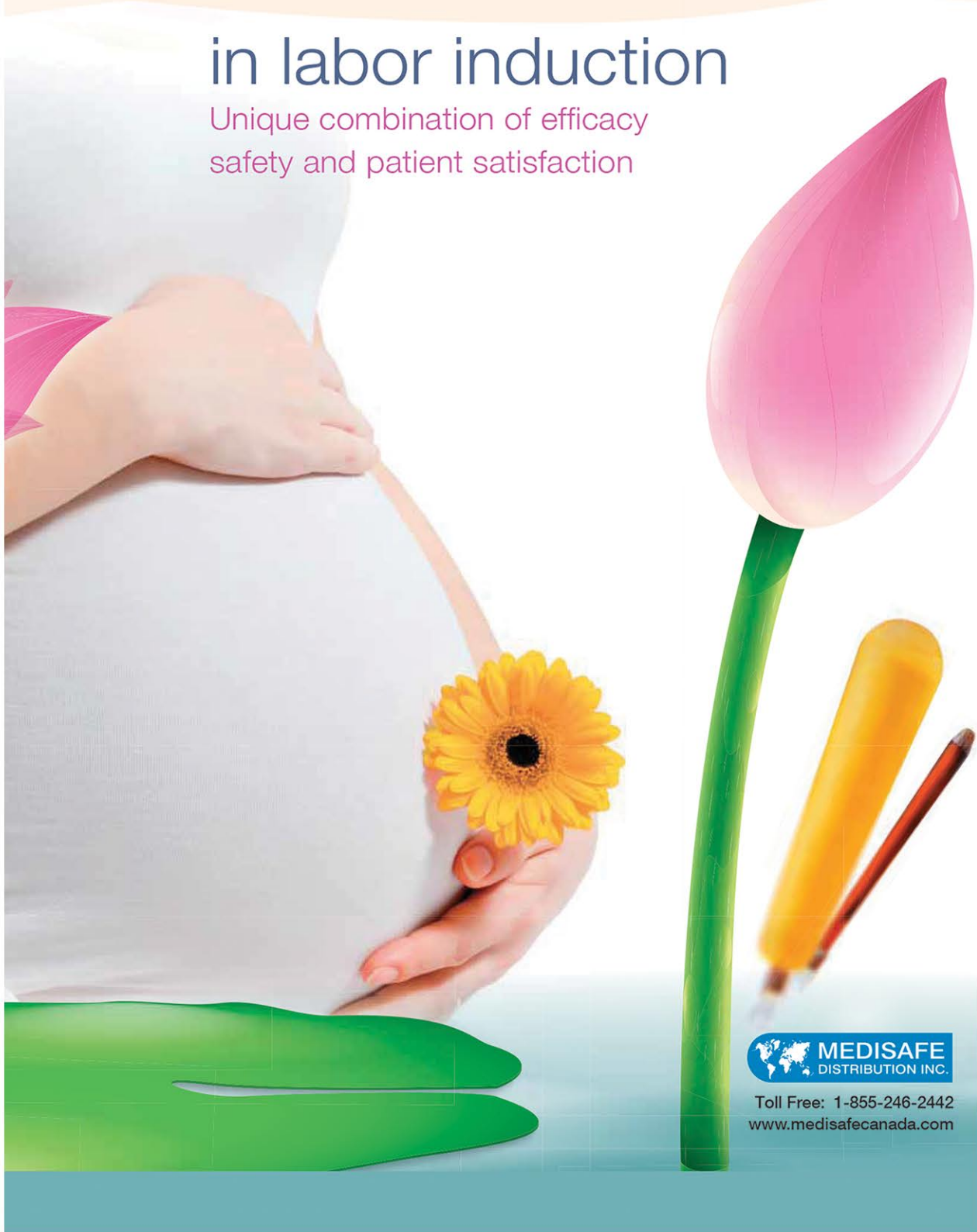


# Dilapan-S<sup>®</sup>

HYGROSCOPIC CERVICAL DILATOR

## in labor induction

Unique combination of efficacy  
safety and patient satisfaction



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## Multiple mode of action <sup>1</sup> mimics physiological processes of the labor

- Mechanical: Controlled pressure on the cervical wall dilates the cervix
- Biophysical: Partial reversible osmotic dehydration softens the tissue
- Physiological: Promotion of endogenous prostaglandins release causing collagen degradation and tissue restructuring

Dilapan-S<sup>®</sup> doesn't contain any pharmacologically active substance, which could be released during its use.

## Efficacy and safety confirmed by

- **International observational e-registry on the use of Dilapan-S<sup>®</sup> osmotic dilator for cervical ripening prior to labor induction (ongoing)** <sup>2,3</sup>
  - 11 study sites from 7 countries participate in the project to collect induction of labor clinical data
  - Data from 6 centers / 214 patients included in the 1st interim analysis in Q4/2015
- **Prospective clinical study comparing Dilapan-S<sup>®</sup> with PGE2 gel and Estradiol gel** <sup>4</sup>
  - 247 patients randomized, 82 treated by Dilapan-S<sup>®</sup>
- **Prospective, observational, multicentre data collection on the use of osmotic dilator Dilapan-S<sup>®</sup> in labor pre-induction in females with/without Caesarean section in medical history** <sup>5-8</sup>
  - 6 study sites collected data from 96 patients, incl. women with previous Caesarean section
- **Prospective observational study evaluating Dilapan-S<sup>®</sup> efficacy and safety** <sup>9</sup>
  - 92 patients
- **Retrospective study evaluating efficacy and safety of Dilapan-S<sup>®</sup> in labor pre-induction** <sup>10,11</sup>
  - 68 patients, incl. women with previous Caesarean section

## General recommendation for the treatment regimen:

Cervical ripening	Labor induction (promotion of uterine contraction)
3 - 4 pieces of Dilapan-S <sup>®</sup> 4 x 55 mm for 12 -15 hours*	ARM** + uterotonic***

\* Number of pieces can differ depends on initial Bishop score.

\*\* Artificial rupture of membranes can be proceeded if beneficial and in line with local clinical protocol.

\*\*\* Dilapan-S<sup>®</sup> ripens the cervix independently on uterine contractions. After the cervical ripening, uterotonic such as oxytocin is recommended to promote adequate uterine contractions, if cervical ripening does not develop into spontaneous vaginal birth.

## Dilapan-S®

## High therapeutic potential

### Efficacy

- Significant Bishop score increase 2–11 and vaginal delivery rate up to 80% <sup>2,3,4</sup>
- Spontaneous vaginal delivery with no pharmacological intervention up to 20% <sup>2,3,5–8,11</sup>
- Suitable for VBAC <sup>2,3,6,10</sup>

### Safety <sup>2–11</sup>

- No hyperstimulation or fetal pathology during cervical ripening
- No infectious complications related to the use of Dilapan-S®
- No limitation related to mother's gestational age and/or comorbidities



### Patients' satisfaction

- Low rate of uterine contractions during cervical ripening <sup>2,3,5–8,10,11</sup>
- Up to 90 % of women can relax or sleep during cervical ripening <sup>5–8</sup>
- Minimising of vaginal examination during cervical ripening

### Cost-effectiveness

- Potential prevention of C. sections in high-risk groups of patients <sup>2,3,5–8,10,11</sup>
- Out-patient regimen (home cervical ripening) for low-risk groups of patients <sup>2,3,4</sup>
- Saving time of health care professionals thanks to one-time application and no need of continuous CTG monitoring<sup>12</sup>

## Unique combination of efficacy, safety and patient satisfaction

- For clinicians helps to minimize safety risks while maintaining high efficiency <sup>2–11</sup>
- For mothers ensures gentle and predictable cervical ripening and promotes natural vaginal delivery <sup>2–11</sup>
- For health care providers offers reduction of overall healthcare cost <sup>2,3,4</sup>

 **Dilapan-S®**  
Gentle. Predictable.



# Dilapan-S<sup>®</sup>

HYGROSCOPIC CERVICAL DILATOR

- Fast acting hygroscopic cervical dilator made of patented AQUACRYL hydrogel specifically developed for obstetrics and gynaecology.<sup>1</sup>
- Approved in more than 40 countries worldwide<sup>#</sup> for labor induction, including USA (510(k), Class II) and EU (CE mark, Class IIa).
- Manufactured at an ISO 13485 certified facility. Sterilized by gamma irradiation.

#### Sources/References:

1. Drunecy T et al.: Experimental comparison of properties of natural and synthetic osmotic dilators. Arch Gynecol Obstet. *Published online: 25 January 2015* 2. Gupta JK et al. Mechanical methods of cervical ripening. *Oral presentation at All India Congress of Obstetrics & Gynaecology 2016, Agra, India 13-17 January 2016* 3. Mehta P et al. Use of the mechanical cervical ripening method, osmotic dilator Dilapan-S<sup>®</sup>, prior to induction of labor. *Oral presentation at All India Congress of Obstetrics & Gynaecology 2016, Agra, India 13-17 January 2016* 4. Roztocil A et al.: A comparison of three preinduction cervical priming methods: Prostaglandins E2 gel, Dilapan-S<sup>®</sup> rods and Estradiol gel. *CZ Gynecol. 63, 1998, 6, 1, str. 3-9* 5. Hruban L et al: Use of the osmotic dilator Dilapan-S<sup>®</sup> for cervical ripening prior to induction of labor in females with/without caesarean section in medical history. *Oral presentation, 23<sup>rd</sup> European Congress of Obstetrics and Gynaecology, May 2014, Glasgow, UK* 6. Hruban L et al: Effectiveness and safety of the osmotic dilator Dilapan-S<sup>®</sup> for cervical ripening in females with/without C. section in medical history. *Poster presentation, XXIV. European Congress of Perinatal Medicine, June 10-14, Florence, Italy* 7. Zahumensky J et al: The impact of the number of pieces of osmotic dilator Dilapan-S<sup>®</sup> used for cervical ripening on the course and outcome of labor. *Poster presentation, 13<sup>rd</sup> World Congress in Fetal Medicine, June-July 2014, Nice, France* 8. Vlk R et al: Efficacy and safety of the osmotic dilator Dilapan-S<sup>®</sup> for cervical ripening in women with/without C. section. *Poster presentation, 13<sup>rd</sup> World Congress in Fetal Medicine, June-July 2014, Nice, France* 9. Šimetka O et al. Effect of hygroscopic dilator (Dilapan-S<sup>®</sup>) on cervical ripening prior to induction of labor. *Poster presentation, XXIV. European Congress of Perinatal Medicine, June 10-14, Florence, Italy* 10. Hruban L et al.: Evaluation of efficacy and safety of Dilapan-S<sup>®</sup> for cervical ripening in labor preinduction. *Oral presentation, XI. World congress of Perinatal Medicine, June 2013, Moscow, Russia* 11. Hruban L et al: What is the position of mechanical preinduction cervical ripening in modern obstetrics? *Oral poster presentation, RCOG World Congress, June 2013, Liverpool, UK* 12. Data on file 13. Dilapan-S<sup>®</sup> Instruction for use

<sup>#</sup>The date of January 2016 it is 44 countries. Worldwide registrations including premarket notifications, no objection letters and other types of governmental approvals and EEA, incl. Switzerland and Turkey.



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