

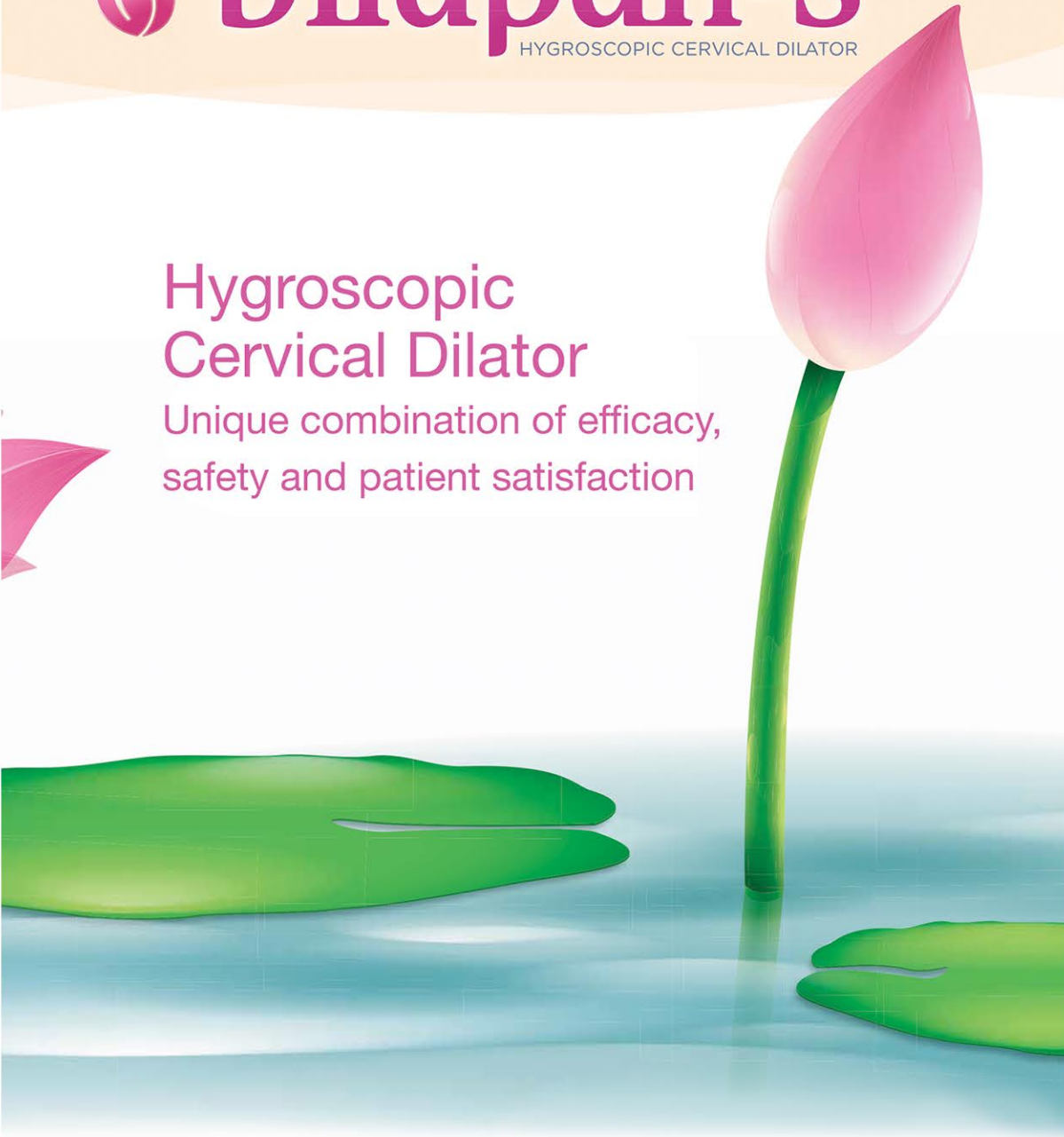


# Dilapan-S<sup>®</sup>

HYGROSCOPIC CERVICAL DILATOR

## Hygroscopic Cervical Dilator

Unique combination of efficacy,  
safety and patient satisfaction



## Your Exclusive Canadian Distributor



Unit 7 - 11771 Horseshoe Way, Richmond, BC CANADA V7A 4V4 Toll Free: 1-855-246-2442

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**Dilapan-S®** is an osmotic hygroscopic dilator produced from a patented Aquacryl hydrogel that guarantees consistency of action. It is a rigid gel rod that increases in volume by absorbing fluids so gradually dilating the cervix. After 4 to 6 hours, the 3 mm rod will have expanded to 8.3–10 mm and the 4 mm rod up to 10–12,5 mm. Simultaneously, Dilapan-S® initiates endogenous prostaglandin release causing collagen degradation which softens the cervix.

Dilapan-S® is sterilized by irradiation. It is manufactured in an ISO 9001 Certified facility and is fully CE Certified under the Medical Device Directive (EN46002).

**Approved by Health Canada for sale in Canada (licence no. 71899) and available exclusively from MEDISAFE DISTRIBUTION INC.**



#### Indications for use:

- cervical ripening prior to the induction of labour
- cervical dilation prior to instrumentation of the uterine cavity, eg. termination of pregnancy, ERPC, fetal demise, etc.

#### Contra-Indications:

- clinically evident genital infection
- menstruation

#### Recommendation for use:

Type	Indication
4 mm x 55 mm	Cervical ripening prior to the induction of labour
4 mm x 65 mm	Cervical preparation prior to the termination of pregnancy
3 mm x 55 mm	When Dilapan-S® 4 mm can not be inserted in early pregnancy, or when removal is to be accomplished in less than 4 hours

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

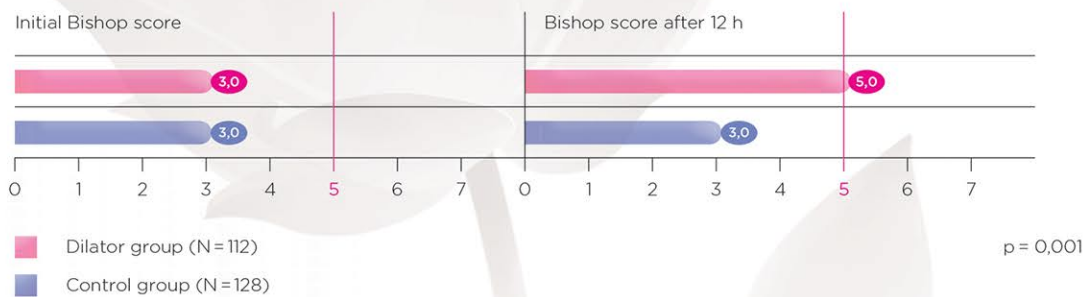
## Gentle and predictable preinduction of labour

*“Successful labour induction is clearly related to the state of the cervix. Women with an unfavorable cervix who have not experienced cervical ripening phase before labor present the greatest challenge with regard to labor induction”<sup>3</sup>*

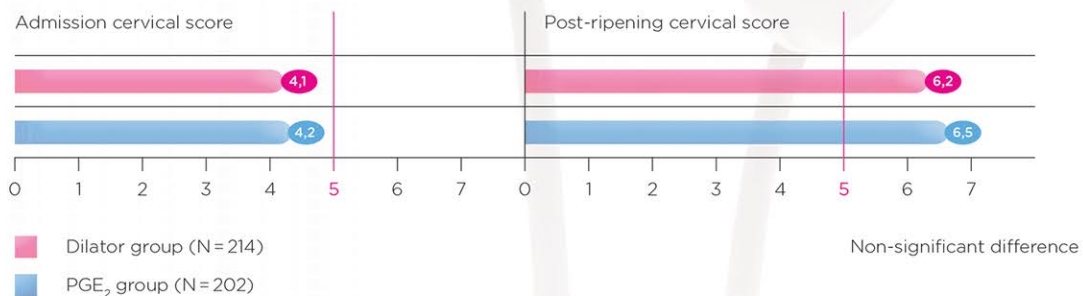
*“Labour should only be induced if the Bishop Score is 5 or higher – this indicates sufficient cervical ripening”<sup>2</sup>*

Hygroscopic dilators (like Dilapan-S<sup>®</sup>) significantly enhance cervical ripening and increase the Bishop Score enabling smoother labour induction<sup>4,5</sup>

### Comparison with control group<sup>4</sup>



### Comparison with PGE<sub>2</sub><sup>5</sup>



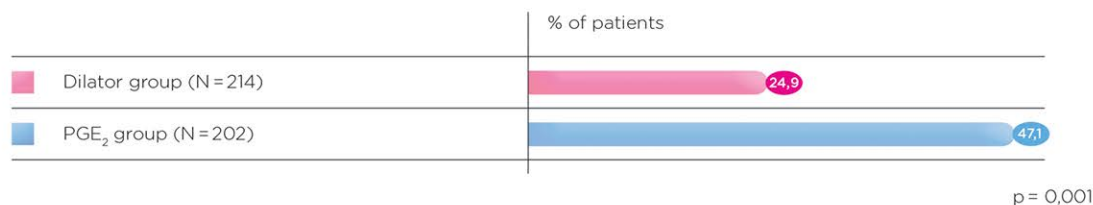
## Gentle and predictable preinduction of labour

Hygroscopic dilators produce minimal uterine activity during the ripening process<sup>5,7</sup>

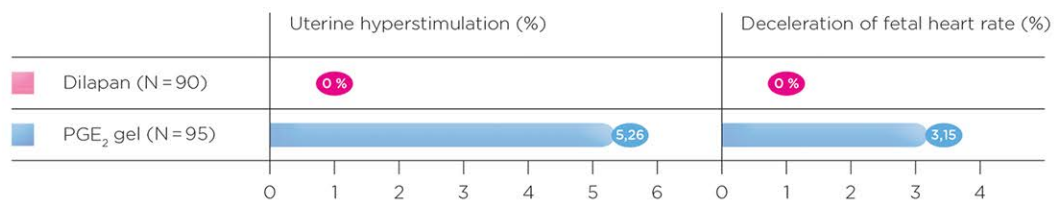
*“Onset of regular uterine activity as a result of preinduction is negative and unwanted side effect”<sup>1</sup>*

*“The principal role of the agents used for cervical ripening is to soften an unripe cervix independent of uterine activity”<sup>3</sup>*

### Uterine contraction during ripening phase<sup>5</sup>



### Uterine hyperstimulation and abnormal fetal heart rate changes<sup>10</sup>



### Key benefits of Dilapan-S<sup>®</sup> in preinduction of labour:

- significant increase in cervical ripening and Bishop Score<sup>4,5</sup>
- minimal risk of uterine hyperstimulation and impact on the fetal heart rate<sup>5,6</sup>
- no pharmacological side effect
- very high patient acceptability
- accentuates the physiological processes of labour
- easy application<sup>3</sup>

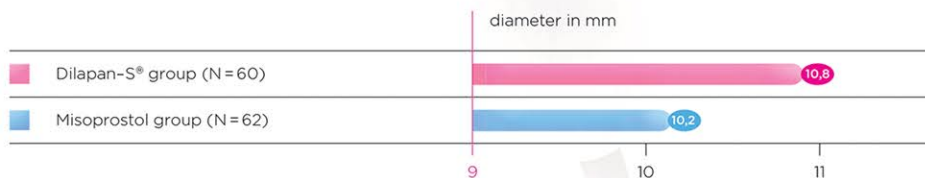
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# Gentle and predictable cervical preparation prior to the termination of pregnancy

## Fast acting synthetic osmotic cervical dilator

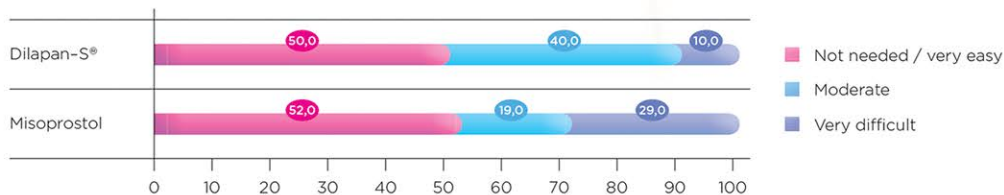
Developed to enable same-day D&E procedure in late first and second trimester<sup>8,11</sup>

### Cervical dilation over the course of the 3–4 hours period<sup>11</sup>



Treatment with Dilapan-S® demonstrated statistically improved dilation over misoprostol, when analysis was controlled for the inequity of cesarean deliveries between the two arms (P=0.049), and when the five participants misclassified according to strata were removed in a per-protocol analysis (P=0.047) respectively.<sup>11</sup>

### The ease of further mechanical dilation (% of patients)<sup>11</sup>



### Dilapan-S® key benefits:

- in comparison with misoprostol, Dilapan-S® offers higher efficacy and better predictability helping to avoid challenging situations<sup>8,11</sup>
- efficacy enables same-day D&E procedure in late 1<sup>st</sup> and 2<sup>nd</sup> trimester<sup>8,11</sup>
- gradual atraumatic dilation
  - significantly reduces the risk of cervical injury and suture repair<sup>8</sup>
  - preserves full functionality of the cervix for future pregnancy
- no pharmacological side effects
- minimising risk of uncontrolled abortions, eg. during the night
- evaluated by SFP Guidelines as the best product in its class of osmotic cervical dilators<sup>8</sup>

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

Similar mode of action, huge difference in clinical outcomes



- Dilapan-S expands radially more rapidly, consistently, and to a greater degree than laminaria. Therefore, fewer Dilapan-S can be inserted for shorter periods of time.
- Dilapan-S is uniform in shape and manufactured to specification, thus improving predictability of the procedure.

### Products' characteristics

	Laminaria	DILAPAN-S
Material	Natural Made of sea-grown plant	Synthetic Made of patented hydrogel Aquacryl
Diameter	2-10mm	3 and 4mm
Length	60-85mm	55 and 65 mm
Time to minimal effect	6 hrs	2 hrs
Time to maximum effect	12-24 hrs	4-6hrs*
Maximum dilation achieved	Approx. 3 times dehydrated diameter	Approx. 4 times dehydrated diameter
Sterilization	Ethylen oxide	Irradiation
Predictability and consistency of action	Low. Its properties, shape and dimensions are inconsistent since it is a natural product	High, thanks to pre-defined synthetic material
Risk of allergic reactions	Higher. Natural material. Residues of sterilizing agent can be present.	Lower / inert synthetic material
Risk of infections	Higher. More difficult to sterilize. Natural product can transfer spores.	Lower because of synthetic material

\* Dilation reached with laminaria in 24 hours can be reached with DILAPAN-S in 4-6 hours

### Required cervical dilation (according to the stage of pregnancy)

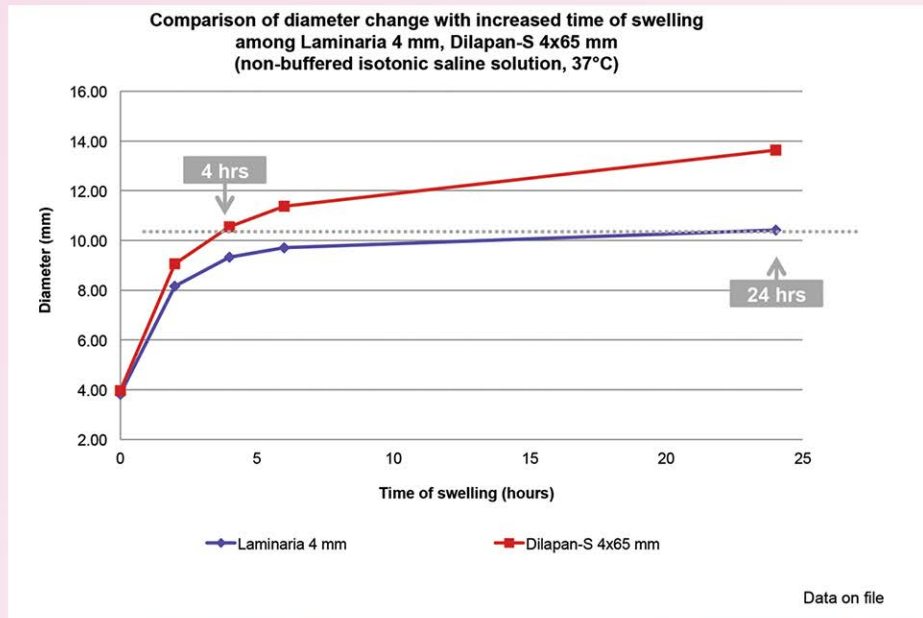
	< 8. week	10. week	14. week	> 18. week
Cervical dilation	6-8 mm	10 mm	13-15 mm	20-24 mm
Number of dilators (type)	1 (3 mm)	1 (4 mm)	2 (4 mm)	4 (4 mm)
Time in situ	2 hours	4 hours	6-10 hours	Overnight



# Dilapan-S<sup>®</sup>

HYGROSCOPIC CERVICAL DILATOR

Significant difference in speed and maximum dilation that can be reached

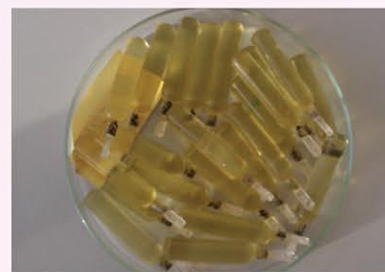


Significant difference in predictability and consistency of action

Swollen rods are illustrative of difference in predictability and consistency of action between synthetic hydrogel AQUACRYL (DILAPAN-S) and natural material (laminaria)



Laminaria



Dilapan-S



# Dilapan-S<sup>®</sup>

HYGROSCOPIC CERVICAL DILATOR

## Gentle and predictable cervical ripening prior to the labour induction

- **significant increase in cervical ripening**
- **high predictability due to material and mode of action**
- **minimal risk of uterine hyperstimulation and impact on the fetal heart rate**
- **no pharmacological side effects**
- **effective and safe even in women with C.section\* in medical history**
- **accentuates the physiological processes**
- **very high patient acceptability**

*\*C.section = Caesarean section*



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