Pr Cervidil®
DINOPROSTONE

INDUCTION CONTROL AT YOUR FINGERTIPS

Get started >

FERRING PHARMACEUTICALS

Pr Cervidil®
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FERRING PHARMACEUTICALS

CERVICAL RIPENING PREPARES THE CERVIX FOR LABOUR

CERVICAL RIPENING
(SOFT, PLIABLE CERVIX)

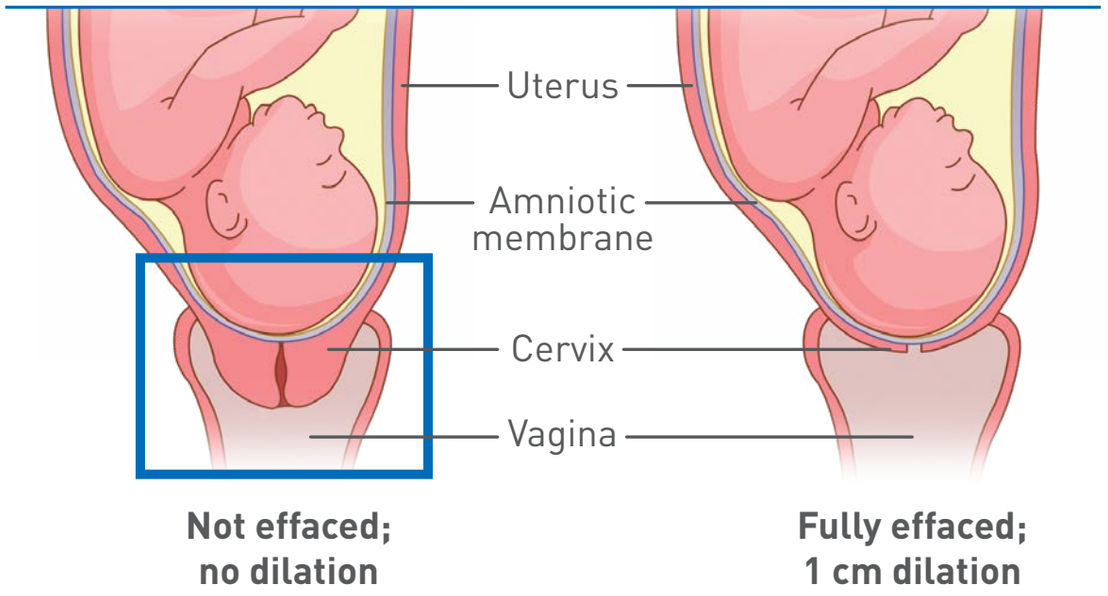
References: 1. National Institute for Health and Clinical Excellence. Induction of Labour Clinical Guideline 2008. 2. Kilpatrick S, *et al.* in Obstetrics: *Normal Delivery and Labour*;2012:303–321.

CERVICAL RIPENING PREPARES THE CERVIX FOR LABOUR

CERVICAL RIPENING (SOFT, PLIABLE CERVIX)

↓

EFFACEMENT/THINNING



Not effaced; no dilation

Fully effaced; 1 cm dilation

References: 1. National Institute for Health and Clinical Excellence. Induction of Labour Clinical Guideline 2008. 2. Kilpatrick S, *et al.* in Obstetrics: *Normal Delivery and Labour*;2012:303–321.

CERVICAL RIPENING PREPARES THE CERVIX FOR LABOUR

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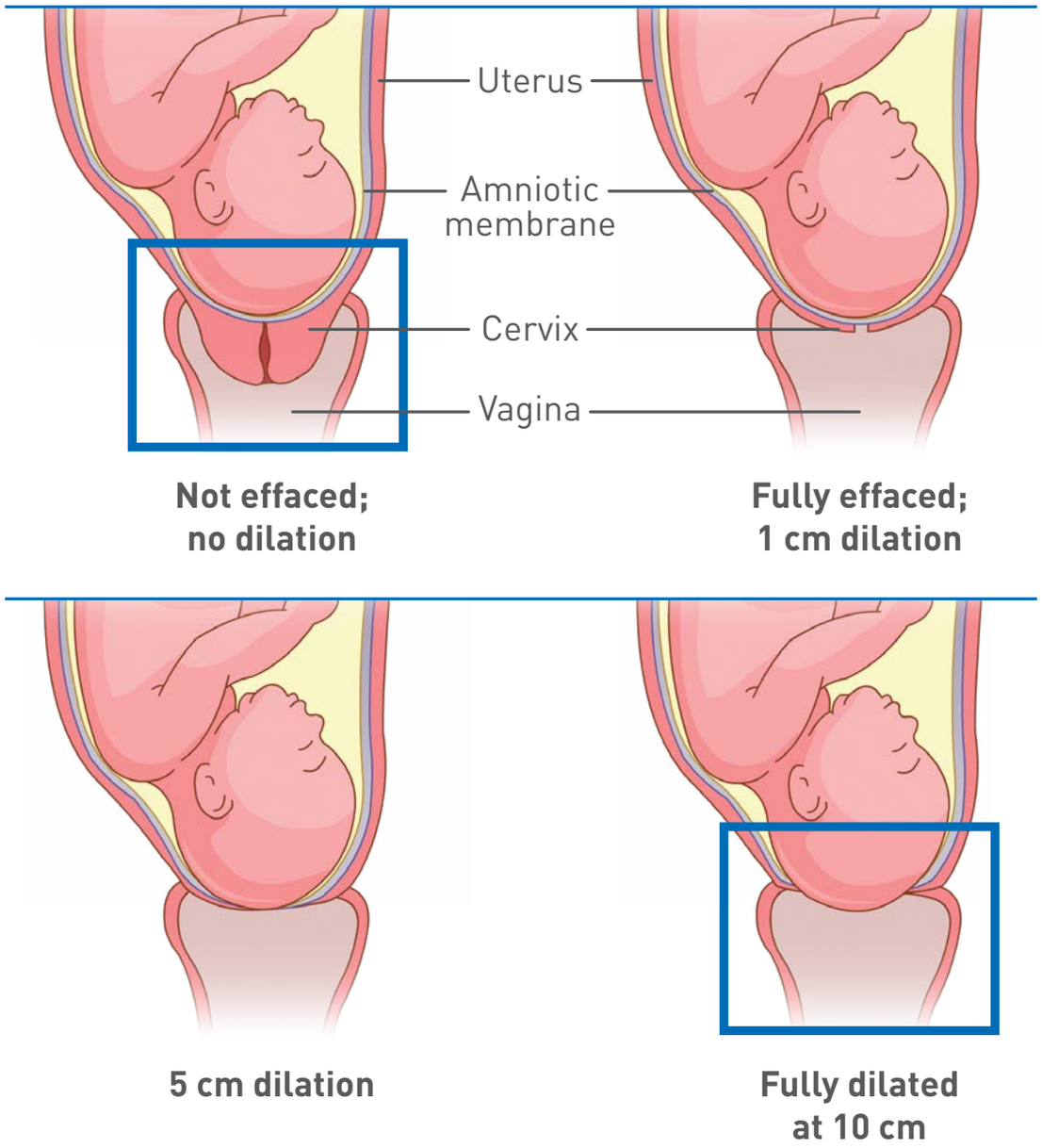
DILATION



References: 1. National Institute for Health and Clinical Excellence. Induction of Labour Clinical Guideline 2008. 2. Kilpatrick S, *et al.* in Obstetrics: *Normal Delivery and Labour*;2012:303–321.

CERVIDIL IS APPROVED FOR CERVICAL RIPENING OVER A 12-HOUR PERIOD[1]

IN CLINICAL TRIALS,
A SINGLE DOSE OF CERVIDIL...

...SUCCESSFULLY RIPENED THE CERVIX IN THE MAJORITY OF WOMEN WITH AN UNFAVOURABLE CERVIX[2,3]

Cervical ripening[4]

The use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery.

Induction of labour[4]

The initiation of contractions in a pregnant woman who is not in labour to help her achieve a vaginal birth within 24 to 48 hours.

Augmentation of labour[5]

The enhancement of contractions in a pregnant woman already in the active phase of labour.

NOTE: Addition of oxytocin in the latent phase is considered an induction, not an augmentation.

References: 1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006. 2. Rayburn WF *et al. Obstet Gynecol* 1992;79:374–379.
3. Witter FR, Mercer BM. J Maternal Fetal Med 1996;5:64–69. 4. SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857. 5. ALARM 2016. *https://www.sogc.org/alarm*.

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ASSESS, COMMUNICATE AND DISCUSS

Induction of labour and your patient

PRE INDUCTION ASSESSMENT [1]

- Review maternal history
- Confirm gestation
- Perform baseline maternal observations (temperature, pulse, respiratory rate and blood pressure)
- Perform abdominal palpation to confirm (presentation, attitude, lie, position and engagement)
- Assess membrane status (ruptured or intact)
- Vaginal examination to assess the cervix
- Assess fetal wellbeing;
  - Fetal heart rate (FHR)
  - Confirm non-stress test (NST) is normal
  - If NST is abnormal, escalate as per local protocol

Discussion follow-up [1]

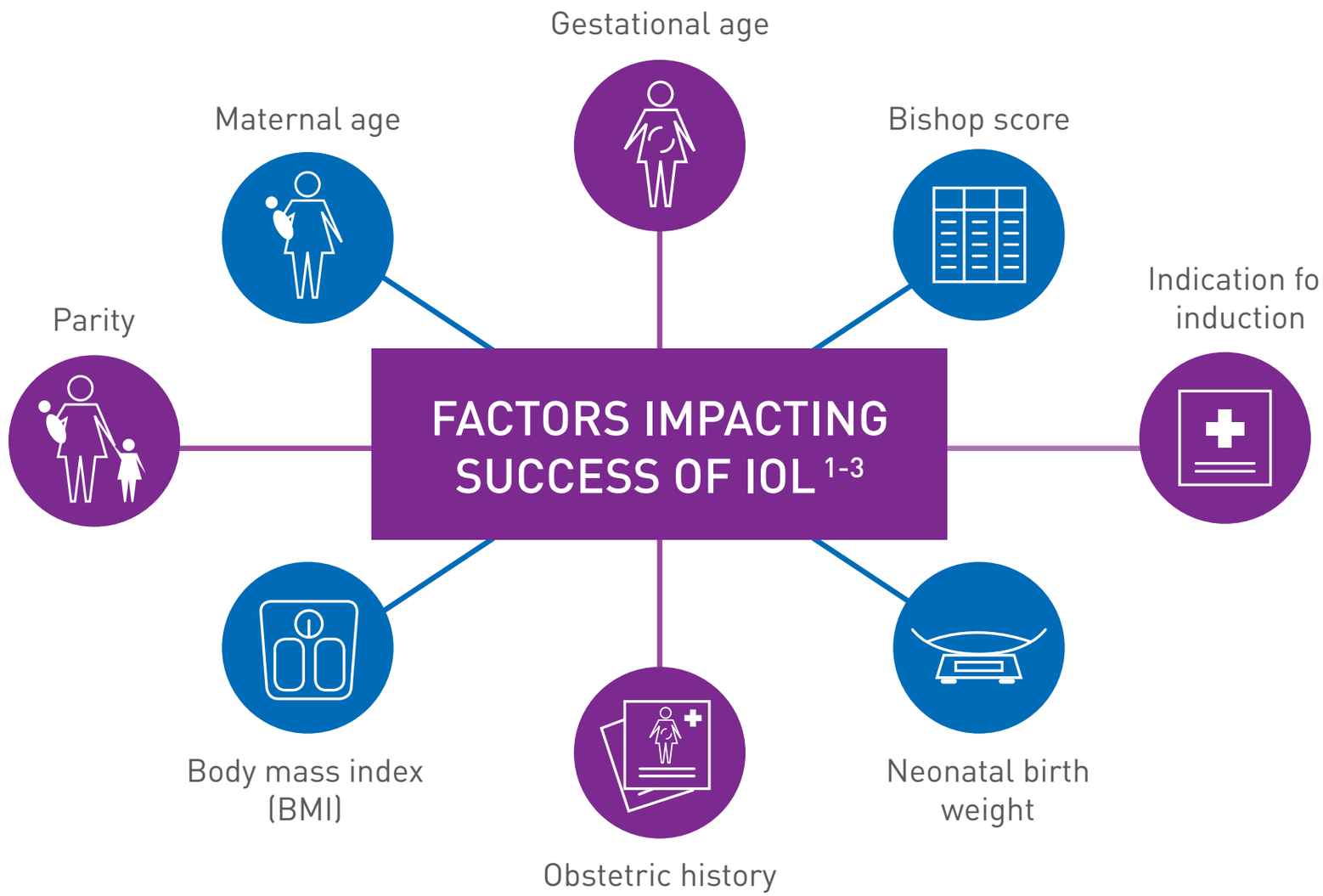
- Allow time for decision-making and asking questions
- Obtain informed consent
- Document the entire discussion

Patient communication [1]

- Maternal and/or fetal benefit and risk
- Proposed methods for cervical ripening and/or induction of labour – their pros and cons
- Individual circumstances determining the choice of method
- Options for pain management

Reference: 1. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR



Understanding the role played by each of the potential predictors of a successful induction of labour (IOL) can aid clinicians in the timing and management of labour[4]

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

GESTATIONAL AGE

• Gestational age is the common term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date.
A normal pregnancy can range from 38 to 42 weeks.

Body mass index (BMI)

Obstetric history

Neonatal birth weight

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

BISHOP SCORE

- In 1964, Bishop published his seminal work on preinduction assessment of cervical status, which eventually became the most widely used scoring system in predicting the likelihood of successful labour induction
- The Bishop pelvic scoring system plays a crucial role in determining the status of the pelvis when labour induction is indicated. If the Bishop score is more than 8, the chances of vaginal delivery after inducing labour is the same as in spontaneous labour.[1-3]

Body mass index (BMI)

Obstetric history

Neonatal birth weight

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

INDICATION FOR INDUCTION

- See Society of Obstetricians and Gynaecologists (SOGC) guidelines

Body mass index (BMI)

Obstetric history

Neonatal birth weight

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

BODY MASS INDEX (BMI)

- BMI serves as an important predictor of success of IOL
- Obesity is associated with increased chances of Caesarean section
- Obstetric history of the patient is yet another important parameter
- Lean = BMI less than 30
- Obese = BMI 30–39.9
- Extremely obese = BMI 40 or higher

Body mass index (BMI)

Obstetric history

Neonatal birth weight

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

Body mass index (BMI)

Neonatal birth weight

Obstetric history

PARITY

- Parity can be another predictor of success of labour induction with an increase in the success rate associated with multiparity
- Parity refers to the number of previous pregnancies of >20 weeks
  - parity: nulliparity, low multiparity, and grand multiparity [1-3]

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

MATERNAL AGE

- The *age* of the mother at the time of delivery
- Advanced maternal age is defined as age 35 years or more at delivery

Body mass index (BMI)

Neonatal birth weight

Obstetric history

References: 1. Battista L *et al. Obstetrics: Normal and Problem Pregnancies* 2007:322–343. 2. Pevzner L *et al. Obstet Gynecol 2009*;114:261–267. 3. Pevzner L *et al. Obstet Gynecol 2009*;114:1315–1321. 4. Gibson KS *et al. Semin Perinatol 2015*;39:475–482.

ASSESS, COMMUNICATE AND DISCUSS

A Bishop score of <6 may be used to determine the need for cervical ripening and for the clinician to estimate the likelihood of a vaginal delivery[1]

MODIFIED BISHOP SCORING SYSTEM (MBS)[1]			
	Score		
	0	1	2
Dilation (cm)	0	1-2	3-4
Effacement (%) Length (cm)	0-30 >3	40-50 1-3	60-70 <1
Consistency	Firm	Medium	Soft
Position	Posterior	Mid	Anterior
Station	SP-3 or above	SP-2	SP-1 or 0

Individual scores for each parameter are combined to give a final score.

Reference: 1. SOGC Induction of Labour Guidelines; *J Obstet Gynaecol Can* 2013;35(9):840–857.

RECOMMENDED INDICATIONS OF INDUCTION OF LABOUR

High Priority

Other Indications

Contraindications to IOL include, but are not limited to the following:

- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities

Reference: SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857.

RECOMMENDED INDICATIONS OF INDUCTION OF LABOUR

High Priority

- Preeclampsia >37 weeks
- Significant maternal disease not responding to treatment
- Significant but stable antepartum haemorrhage
- Chorioamnionitis
- Suspected fetal compromise
- Term pre-labour rupture of membranes with maternal GBS colonization

Other Indications

Contraindications to IOL include, but are not limited to the following:

- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities

Reference: SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857.

RECOMMENDED INDICATIONS OF INDUCTION OF LABOUR

High Priority

Other Indications

- Postdates (>41 + 0 weeks) or post-term (>42 + 0) pregnancy
- Uncomplicated twin pregnancy >38 weeks
- Diabetes mellitus (glucose control may dictate urgency)
- Alloimmune disease at or near term
- Intrauterine growth restriction
- Oligohydramnios
- Gestational hypertension >38 weeks
- Intrauterine fetal death
- Pre Rupture of Membrane (PROM) at or near term, Group B Streptococcus (GBS) negative
- Logistical problems (e.g. history of rapid labour, distance to hospital)
- Intrauterine death in a prior pregnancy

Contraindications to IOL include, but are not limited to the following:

- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities

Reference: SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857.

PROPOSED CONSIDERATIONS FOR PROTOCOL*[1-3]

Procedure

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

*adapted from current hospital protocols.

References: 1. "Induction of Labour: Cervical Ripening. HCS-222-01" Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. "Cervical Ripening and Induction of Labour Guidelines" Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

PROPOSED CONSIDERATIONS FOR PROTOCOL*[1-3]

Procedure	
Once approved, procedure with CERVIDIL requires	• Review maternal history for indication of induction-related complications in pregnancy • Obtain informed consent for medical induction of labour (IOL) • Explain the procedure to the patient • Provide a written order for IOL, stipulating in or outpatient cervical ripening
Prior to inserting CERVIDIL	
All patients should be instructed to inform the RN when one or more of the following occur	
CERVIDIL insertion	

*adapted from current hospital protocols.

References: 1. "Induction of Labour: Cervical Ripening. HCS-222-01" Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. "Cervical Ripening and Induction of Labour Guidelines" Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

PROPOSED CONSIDERATIONS FOR PROTOCOL*[1-3]

Procedure

Once approved, procedure with CERVIDIL requires

- Chart documentation of obstetrical indication
- Absence of contraindications
- Chart-documented ripening of the cervix (Bishop score)
- Consultation with Ob/Gyn in the presence of an “urgent” indication

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

*adapted from current hospital protocols.

References: 1. “Induction of Labour: Cervical Ripening. HCS-222-01” Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. “Cervical Ripening and Induction of Labour Guidelines” Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. “Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22” Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

PROPOSED CONSIDERATIONS FOR PROTOCOL*[1-3]

Procedure

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

- Ensure qualified nursing staff to provide monitoring
- Normal fetal non-stress test (NST) If NST is atypical/abnormal:
  - Perform intrauterine resuscitation
  - Notify HCP/designate
  - Obtain written order to continue IOL
- Baseline maternal vital signs (BP, P, RR, temperature)

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

*adapted from current hospital protocols.

References: 1. "Induction of Labour: Cervical Ripening. HCS-222-01" Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. "Cervical Ripening and Induction of Labour Guidelines" Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

PROPOSED CONSIDERATIONS FOR PROTOCOL*[1-3]

Procedure

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

- Contractions become regular every 5 minutes or closer
- Patient becomes uncomfortable with contractions
- There are signs of bleeding
- Membranes rupture
- Insert falls out or drops lower in the vagina

CERVIDIL insertion

*adapted from current hospital protocols.

References: 1. "Induction of Labour: Cervical Ripening. HCS-222-01" Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. "Cervical Ripening and Induction of Labour Guidelines" Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

PROPOSED CONSIDERATIONS FOR PROTOCOL*[1-3]

Procedure

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

- Keep CERVIDIL in the freezer until used
- Ask patient to empty her bladder
- Position patient supine with wedge under right hip to maintain left uterine displacement for insertion
- Use water or a small amount of water-soluble gel as a lubricant to assist in the insertion of CERVIDIL
  - Ensure that the lubricant does not come into excessive contact with the vaginal insert and does not cover it. This may prevent optimal swelling of the insert
- Insert CERVIDIL digitally, ***placing it transversely in the posterior fornix of the vagina***
- Position the insert string to remain in the vagina with a short length exposed at the introitus, to prevent the insert from accidentally being pulled out
- Inform the physician if signs of uterine hypertonia
- Monitor FHR and contraction continuously with EFM for a minimum of one hour post-insertion; interpret and document tracing per FHS standards
- Maintain patient on bedrest in left lateral or semi-Fowler's position for optimal fetal oxygenation and monitoring. Patient should not be supine
- Instruct patient to remain lying down for 2 hours following insertion of CERVIDIL. They can move around after this time. HCP should determine inpatient vs outpatient use
- To stop the release of prostaglandin, pull the removal cord. Flushing or cleaning the vagina is not necessary

*adapted from current hospital protocols.

References: 1. "Induction of Labour: Cervical Ripening. HCS-222-01" Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. "Cervical Ripening and Induction of Labour Guidelines" Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

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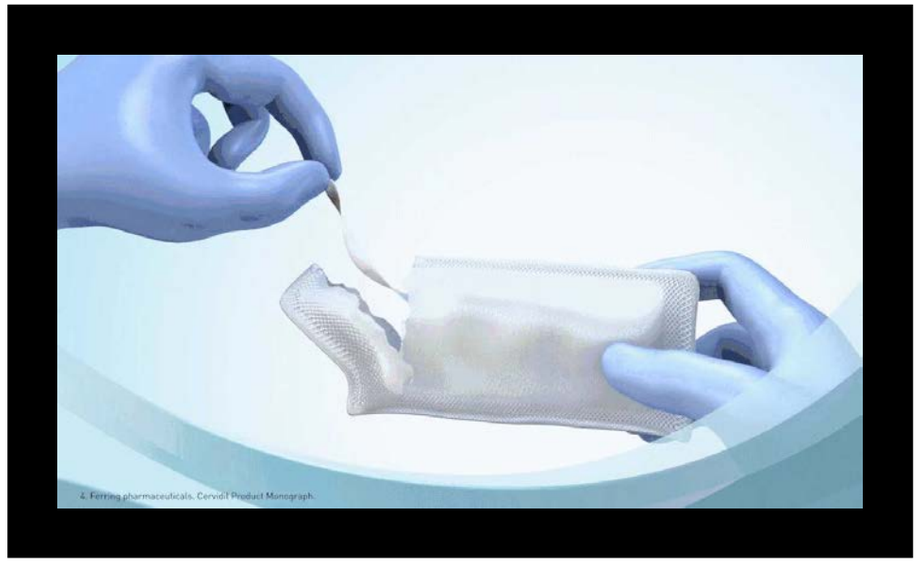

More information

https://drive.google.com/file/d/1xxuEFfwVk4GvXBg08mKd7kt_S22keGoj/view?usp=sharing

*adapted from current hospital protocols.

References: 1. "Induction of Labour: Cervical Ripening. HCS-222-01" Alberta Health Services Guidelines, June 1, 2018, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf. 2. "Cervical Ripening and Induction of Labour Guidelines" Perinatal Services BC, March 2005, http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/CervicalRipeningInductionLabourGuideline.pdf. 3. "Queensland Clinical Guidelines. Supplement: Induction of labour. No. MN17.22-V7-R22" Queensland Health, 2017 https://www.health.qld.gov.au/__data/assets/pdf_file/0021/641424/s-iol.pdf.

METHODS FOR INDUCTION OF LABOUR

CERVIDIL VS OTHER PRODUCTS FOR CERVICAL RIPENING				
	CONTROLLED-RELEASE VAGINAL INSERT[1] (CERVIDIL)			
Dose	10 mg (0.3 mg/hour)			
Format	Controlled-release insert			
Administration	Single insert, 0.3 mg/h controlled release over 12 h, removed using retrieval tape			
Site of administration	Posterior vaginal fornix			
Storage conditions	Frozen, -20° C to -10° C			
Outpatient procedure	Yes			
Vaginal birth after Caesarean (VBAC)	No			
Removable	Yes • Remove upon the onset of active labour • Spontaneous rupture of membranes			
Time to oxytocin	30 min			
Use in PROM patients? According to product monographs	Yes • Listed as warning • Clinical evidence is up to date			

Click to reveal

References: 1. SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857. 2. Prostin E_2 Vaginal Gel Product Monograph. Pfizer Canada Inc., 13 September, 2012. 3. Prepidil Product Monograph. Pfizer Canada Inc., 5 September 2012.

METHODS FOR INDUCTION OF LABOUR

CERVIDIL VS OTHER PRODUCTS FOR CERVICAL RIPENING				
	CONTROLLED-RELEASE VAGINAL INSERT[1] (CERVIDIL)	Intravaginal gel[2]	Intracervical gel[3]	Intracervical Foley catheter
Dose	10 mg (0.3 mg/hour)	1 or 2 mg	0.5 mg /2.5 mL (3 g)	
Format	Controlled-release insert	Pre-filled syringe	Pre-filled syringe	#16 French Foley catheter/urinary catheter with 30 cc balloon
Administration	Single insert, 0.3 mg/h controlled release over 12 h, removed using retrieval tape	Initial dose: 1 mg; Single repeat dose*: 1 or 2 mg *6 h post initial dose.	Single-dose gel 0.5 mg/2.5 mL syringe	Inflation with sterile water or normal saline 30 – 60 mL. Often requires oxytocin administration Equipment required: speculum tray, warm sterile water, 60 mL syringe; 20 mL syringes, cord clamp x1, scissors, condom (if needed), procedural light, assessment bed with stirrups, sterile procedure gloves, lubricant, external fetal monitor (EFM), tape wedge, chlorhexidine 0.05% aqueous solution to disinfect cervix, catheter plug
Site of administration	Posterior vaginal fornix	Posterior vaginal fornix	Cervical canal	Cervical canal
Storage conditions	Frozen, -20° C to -10° C	Refrigeration, 2° C to 8° C	Refrigeration, 4° C	Room temperature
Outpatient procedure	Yes	Yes	Yes	Yes
Vaginal birth after Caesarean (VBAC)	No	No	No	Yes
Removable	Yes • Remove upon the onset of active labour • Spontaneous rupture of membranes	No	No	Yes by HCP ONLY
Time to oxytocin	30 min	6 hours	6 hours	No delay ww Use cautiously with prior uterine scar
Use in PROM patients? According to product monographs	Yes • Listed as warning • Clinical evidence is up to date	Contraindicated in patients with ruptured amniotic membranes or suspected choriamnionitis	Contraindicated in patients with ruptured amniotic membranes or suspected choriamnionitis	Yes

References: 1. SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857. 2. Prostin E_2 Vaginal Gel Product Monograph. Pfizer Canada Inc., 13 September, 2012. 3. Prepidil Product Monograph. Pfizer Canada Inc., 5 September 2012.

Pr Cervidil® DINOPROSTONE

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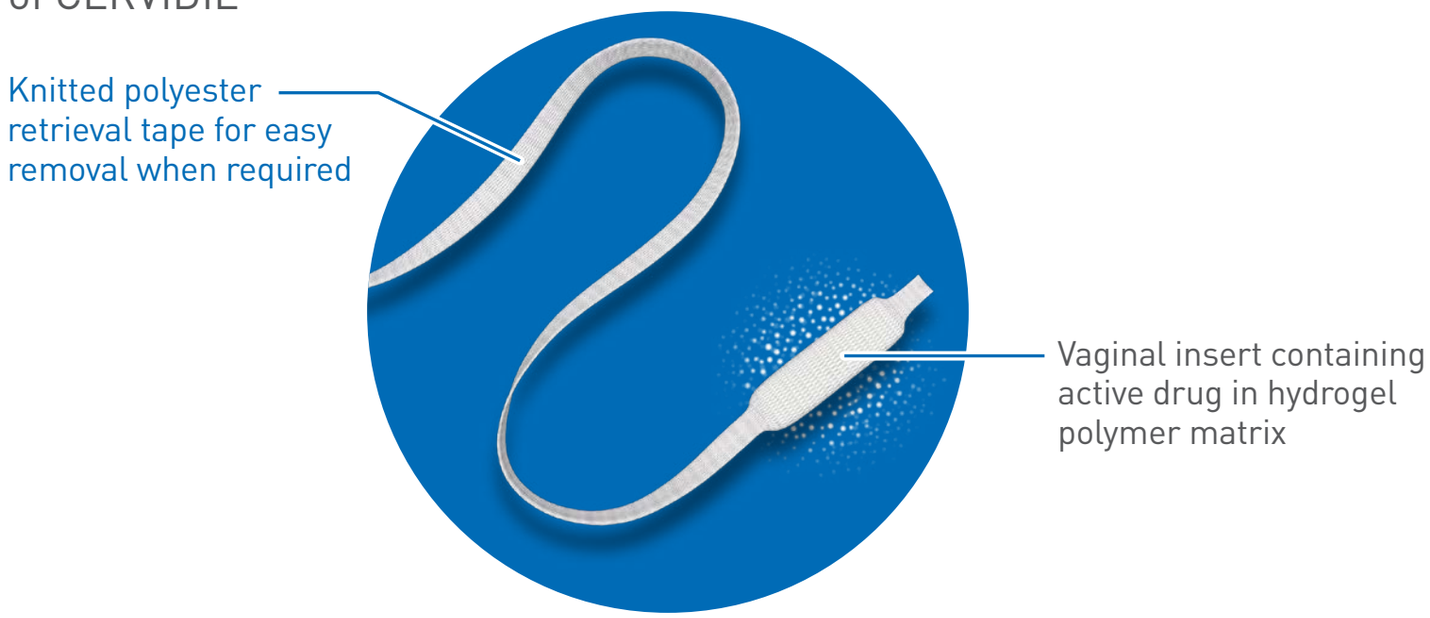
CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS

Simple insertion to start treatment[1]

- A single insert delivers controlled release of the drug at the cervix for up to 12 hours[1]
- Dinoprostone is released continuously at a mean rate of ~0.3 mg/hour over 12 hours[1]
- The long tape retrieval system allows immediate removal if required[1]
- With a half-life of 1–3 minutes, dinoprostone is quickly cleared from the woman's system, upon removal of the insert[1]
- Cases of hyperstimulation reversed within 2–13 minutes after removal of CERVIDIL[2]



Notes:

- In addition to proven efficacy and safety, the delivery system for CERVIDIL offers added control and convenience[1]
- The hydrogel polymer matrix releases the drug in a steady and controlled amount over the administration period[1]
- Unlike other formulations (gels or tablets), the unique retrieval system allows immediate removal if circumstances require it[1]
- Following removal of the CERVIDIL insert (in case of an adverse event), the short half-life of dinoprostone (1–3 minutes) means that the drug is quickly cleared from the woman's system

Reference: 1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006. 2. Rugarn O, *et al. BJOG* 2017;124:796–803.

OUTPATIENT INDUCTION CRITERIA

Careful patient selection[1,2]

Low-risk patients may be discharged and advised to return immediately if[2]

Outpatient IOL is not recommended for:

References: 1. Rath WN. J Perinat Med 2009;37(5):461–7. 2. Alberta Health Services. Induction of Labour: Cervical Ripening; June 1, 2018. Available at: https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf 3. Neale E *et al. JOG* 2002; 22(6): 634-635.

OUTPATIENT INDUCTION CRITERIA

Careful patient selection[1,2]

Low-risk patients may be discharged and advised to return immediately if [2]

- Must be a low risk patient/pregnancy
  - Singleton uneventful pregnancy
  - No fetal or maternal concerns
  - No identified obstetrical risk factors
- Have no contraindication to induction of labour
- Present no logistical issues such as ability of patient to contact the hospital and return quickly should any concerns arise even when she is unable to transport herself
  - Ability to travel to a hospital within 30 minutes
  - Adequate understanding of process and understanding of need to return
- Appropriate indication for induction
- Patients willing to receive outpatient cervical ripening
- Have an EFM tracing classified as normal prior to ripening and following insertion
- Have maternal vital signs within normal limits

Outpatient IOL is not recommended for:

References: 1. Rath WN. J Perinat Med 2009;37(5):461–7. 2. Alberta Health Services. Induction of Labour: Cervical Ripening; June 1, 2018. Available at: https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf 3. Neale E *et al. JOG* 2002; 22(6): 634-635.

OUTPATIENT INDUCTION CRITERIA

Careful patient selection[1,2]

Low-risk patients may be discharged and advised to return immediately if [2]

- Contractions are every five (5) minutes or less
- Membranes rupture
- Bright red vaginal bleeding occurs
- The insert falls out
- There are any other concerns

Outpatient IOL is not recommended for:

References: 1. Rath WN. J Perinat Med 2009;37(5):461–7. 2. Alberta Health Services. Induction of Labour: Cervical Ripening; June 1, 2018. Available at: https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf 3. Neale E *et al. JOG* 2002; 22(6): 634-635.

OUTPATIENT INDUCTION CRITERIA

Careful patient selection[1,2]

Low-risk patients may be discharged and advised to return immediately if [2]

Outpatient IOL is not recommended for:

- Abnormal fetal wellbeing
- Fetal conditions that require close fetal monitoring (e.g. Intrauterine growth restriction (IUGR)/ Small-for-gestational-age (SGA)
- Significant maternal medical condition requiring treatment or close maternal monitoring for more than 12 hours
- Type 1 or 2 diabetes mellitus (DM), unstable DM or gestational diabetes mellitus (GDM)
- Uncontrolled hypertension, preeclampsia
- Seizure disorder
- Active venous thromboembolism (VTE)
- Suspected chorioamnionitis
- Previous Caesarean section
- Breech presentation
- Multipara more than 6 births
- Preterm gestation (less than 37 weeks)
- Preterm and term PROM
- Significant vaginal bleeding
- Uterine over-distension i.e. polyhydramnios or oligohydramnios
- Previously scarred uterus
- Patients living greater than 30 minutes from the hospital or with no means of transportation
- Patients without phone access to communicate with the hospital

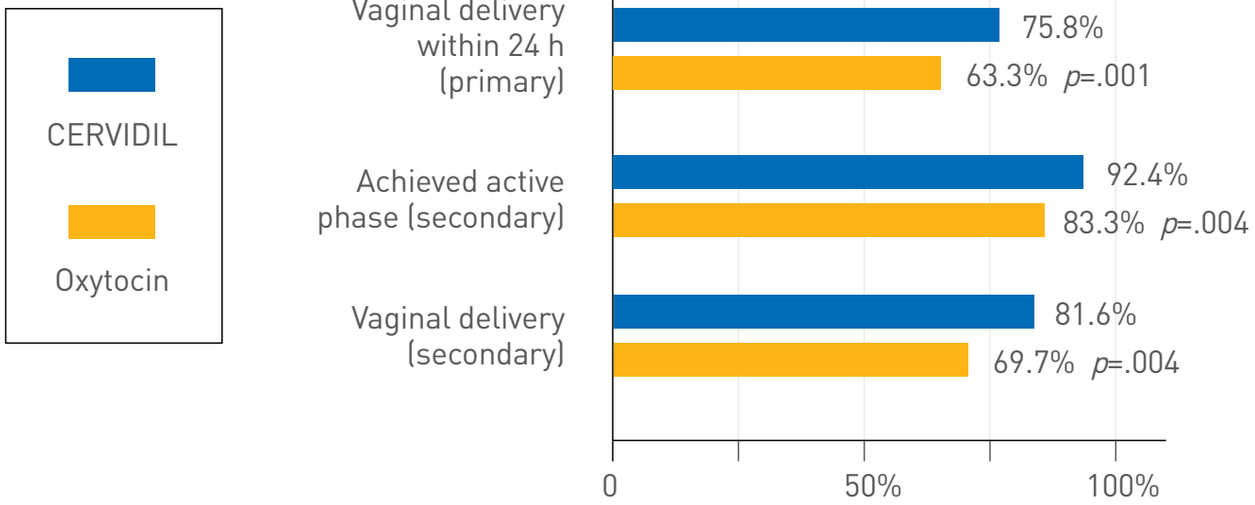
References: 1. Rath WN. J Perinat Med 2009;37(5):461–7. 2. Alberta Health Services. Induction of Labour: Cervical Ripening; June 1, 2018. Available at: https://extranet.ahsnet.ca/teams/policydocuments/1/clp-womens-health-induction-labour-cervical-ripening-hcs-222-01.pdf 3. Neale E *et al. JOG* 2002; 22(6): 634-635.

CERVIDIL AND PREMATURE RUPTURE OF MEMBRANE (PROM)

Safety and use of CERVIDIL in PROM patients[1]

1 IN 5 PATIENTS WERE INDICATED FOR PROM[1]			
	All (n=1179)	Outpatients (n=611)	Inpatients (n=568)
PROM	233 (19.8)	46 (7.5)	187 (32.9)
Postdates	946 (80.2)	565 (92.5)	381 (67.1)

CERVIDIL VS OXYTOCIN IN TERM PROM[2]*



* Women with PROM and a Bishop score ≤5 were randomly assigned to receive either an intravenous oxytocin infusion (n=223) or a dinoprostone insert followed 6 hours later by an intravenous oxytocin infusion (n=227).

References: 1. Cundiff GW *et al. JOGC* 2017:39(5):354-360. 2. Güngördük K *et al. Am J Obstet Gynecol* 2012;206(1):60.e1-8.

CERVIDIL OUTPATIENTS VS INPATIENTS [2*]

Higher level of outpatient satisfaction vs inpatients[1]

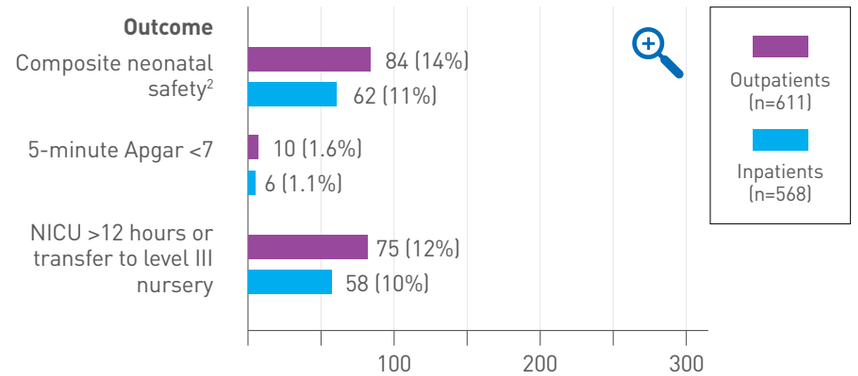
- Outpatients reported a higher level of satisfaction 56% vs 39% inpatients during first 12 hours of induction[1] (p<.008)

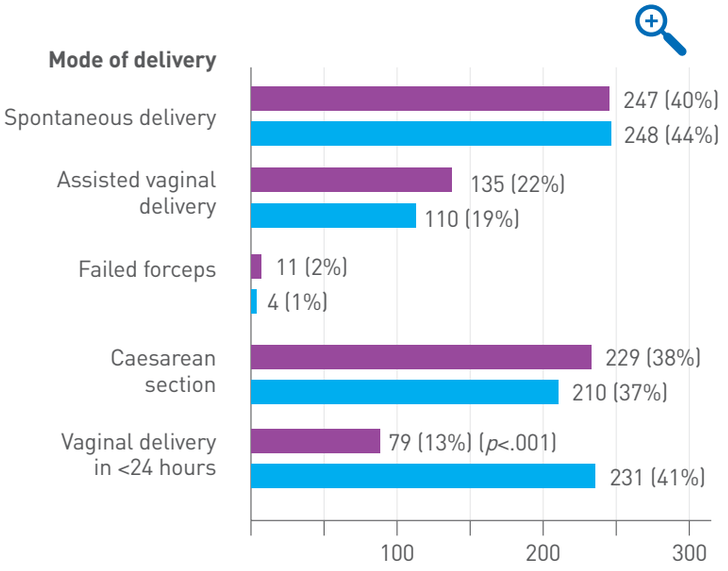
Pain and anxiety levels were similar to inpatients

- In nulliparous women with a Bishop score ≤4, CERVIDIL limits pain compared with vaginal PGE_2 gel[3]
- CERVIDIL was associated with a lower number of vaginal examinations than PGE_2 gel (p=0.012), suggesting that it may reflect a less invasive treatment option that offers greater patient comfort and satisfaction[4]

Outpatient safety

- An outpatient model of labour induction using dinoprostone inserts is feasible and safe[2]
- CERVIDIL use in outpatient induction priming offers similar neonatal safety and efficacy as inpatient induction model and has the potential advantage of enhanced patient control and satisfaction[2]
- Outpatient induction not only allows for a more familiar and less-threatening environment, but it also increases a patient's participation in their labour[2]



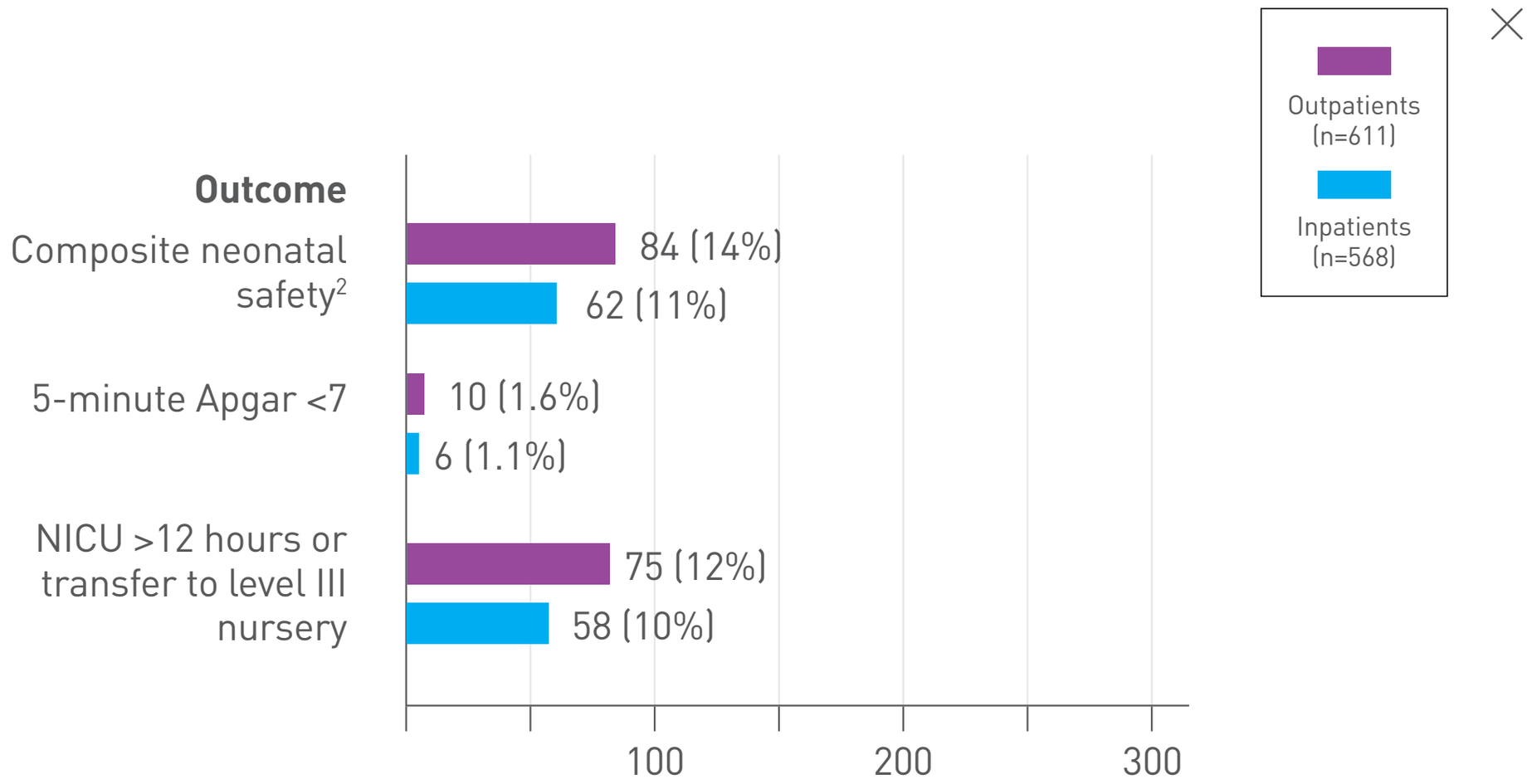


- No differences in neonatal measures or mode of delivery were seen in CERVIDIL outpatients[2]
- **Outpatient induction with CERVIDIL can be a reasonable option for low-risk women[1]**

* Unadjusted analysis by location of delivery vs inpatient.

References: 1. Biem SR *et al. J Obstet Gynaecol Can* 2003:25(1):23-31. 2. Cundiff GW *et al. J Obstet Gynaecol Can* 2017:39(5):354-360. 3. Zanconato G, *et al. J Matern Fetal Neonatal Med* 2011;24:728–731. 4. Kalkat RK, *et al. J Obstet Gynaecol* 2008;28:695–699.

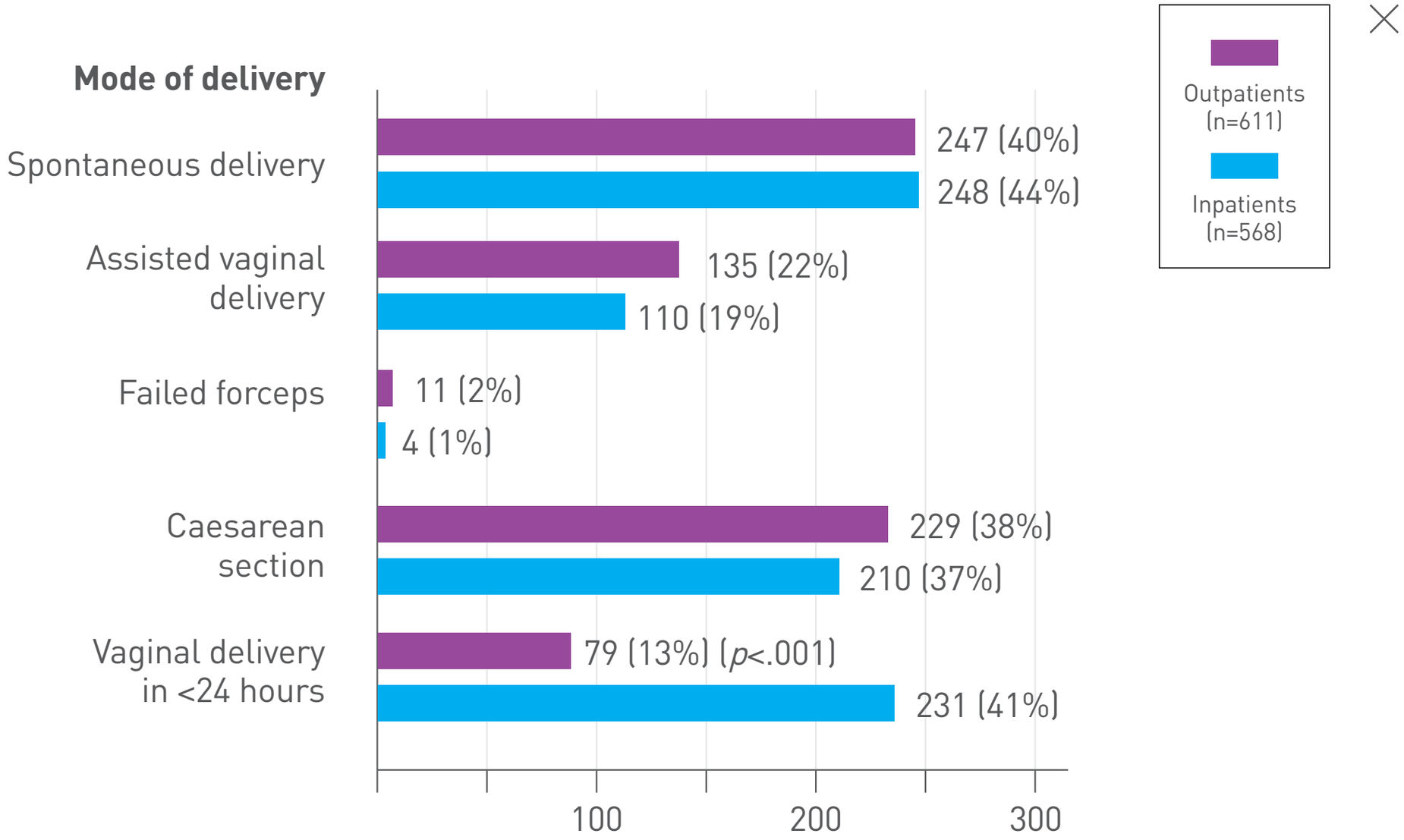
CERVIDIL OUTPATIENTS VS INPATIENTS [2*]



* Unadjusted analysis by location of delivery vs inpatient.

References: 1. Biem SR *et al. J Obstet Gynaecol Can* 2003:25(1):23-31. 2. Cundiff GW *et al. J Obstet Gynaecol Can* 2017:39(5):354-360. 3. Zanconato G, *et al. J Matern Fetal Neonatal Med* 2011;24:728–731. 4. Kalkat RK, *et al. J Obstet Gynaecol* 2008;28:695–699.

CERVIDIL OUTPATIENTS VS INPATIENTS [2*]



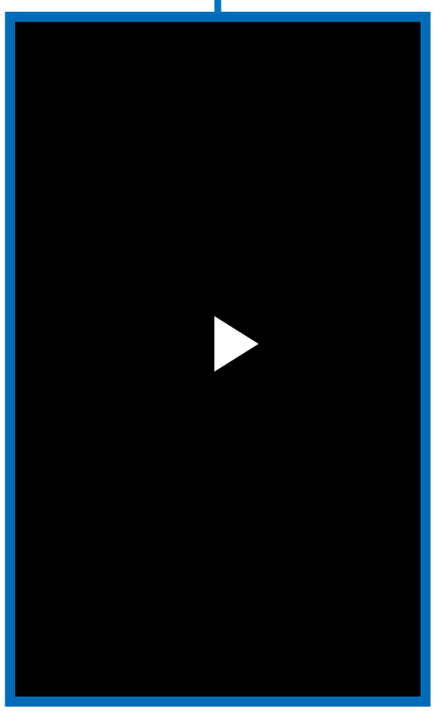
* Unadjusted analysis by location of delivery vs inpatient.

References: 1. Biem SR *et al. J Obstet Gynaecol Can* 2003:25(1):23-31. 2. Cundiff GW *et al. J Obstet Gynaecol Can* 2017:39(5):354-360. 3. Zanconato G, *et al. J Matern Fetal Neonatal Med* 2011;24:728–731. 4. Kalkat RK, *et al. J Obstet Gynaecol* 2008;28:695–699.

CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS[1]

Simple insertion in the posterior fornix to start treatment

Click Arrows to Reveal



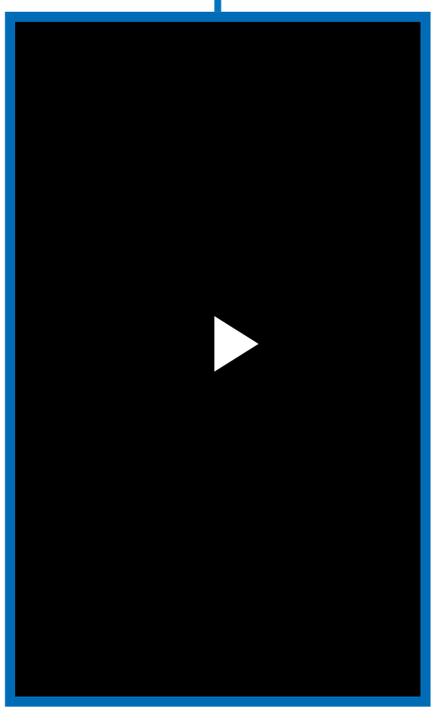
https://drive.google.com/file/d/1xxuEFfwVk4GvXBg08mKd7kt_S22keGoj/view?usp=sharing

Reference: 1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006.

CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS[1]

Simple insertion in the posterior fornix to start treatment

Single insert delivers controlled release of the drug at the cervix for up to 12 hours



https://drive.google.com/file/d/1xxuEFfwVk4GvXBg08mKd7kt_S22keGoj/view?usp=sharing

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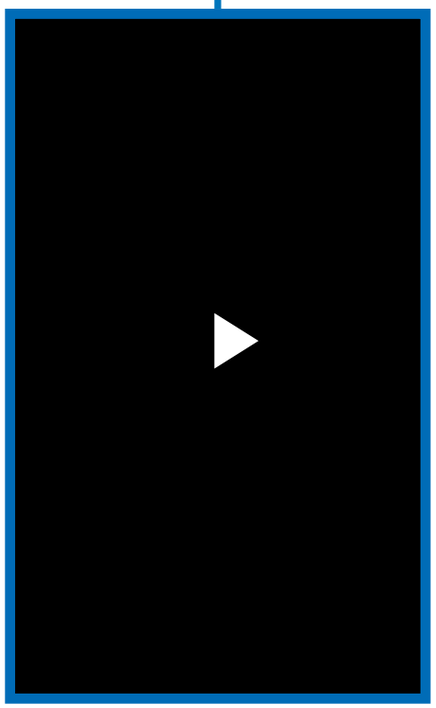

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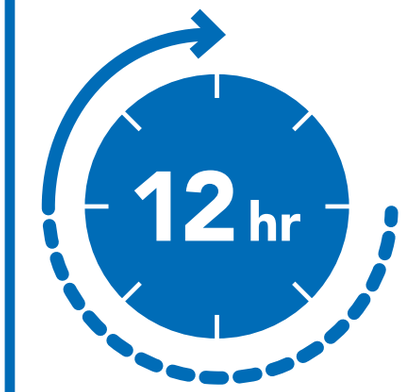


Long tape retrieval system allows immediate removal if required

https://drive.google.com/file/d/1xxuEFfwVk4GvXBg08mKd7kt_S22keGoj/view?usp=sharing

Reference: 1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006.

Pr Cervidil® DINOPROSTONE

TABLE OF CONTENTS

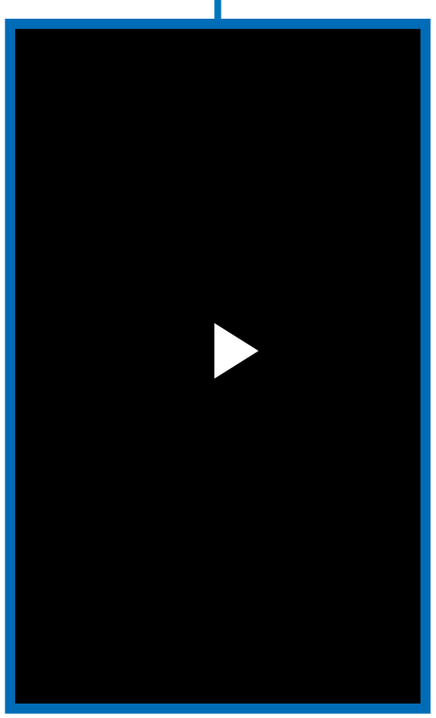
CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS[1]

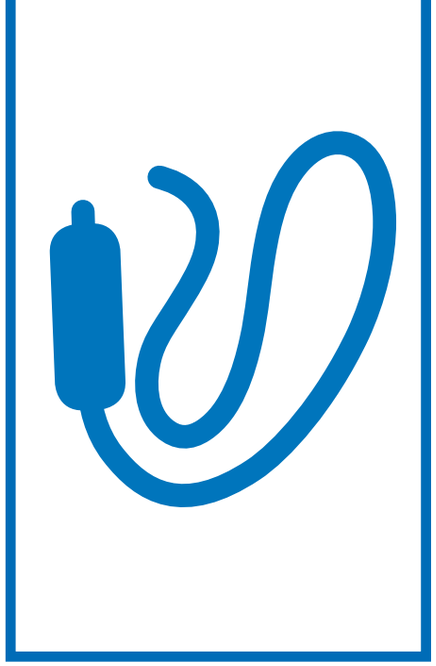
Simple insertion in the posterior fornix to start treatment

Single insert delivers controlled release of the drug at the cervix for up to 12 hours

Long tape retrieval system allows immediate removal if required

Half-life of 1-3 minutes means quick clearance of the drug from the woman's system





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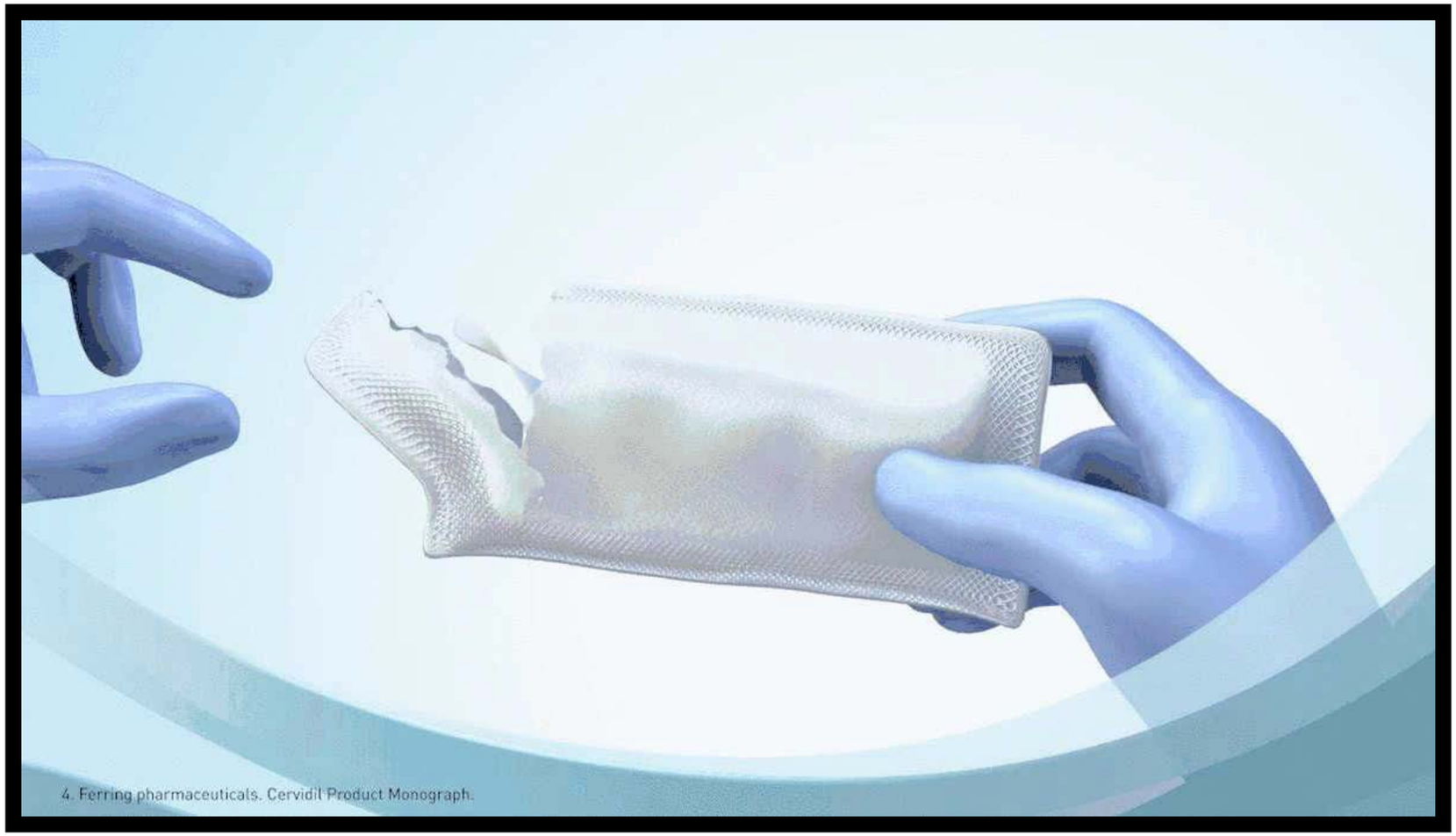


https://drive.google.com/file/d/1xxuEFfwVk4GvXBg08mKd7kt_S22keGoj/view?usp=sharing

Reference: 1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006.

IOL REDUCES CAESAREAN SECTION RATES

Compared with expectant management, IOL was associated with a lower Caesarean section rate.[1]

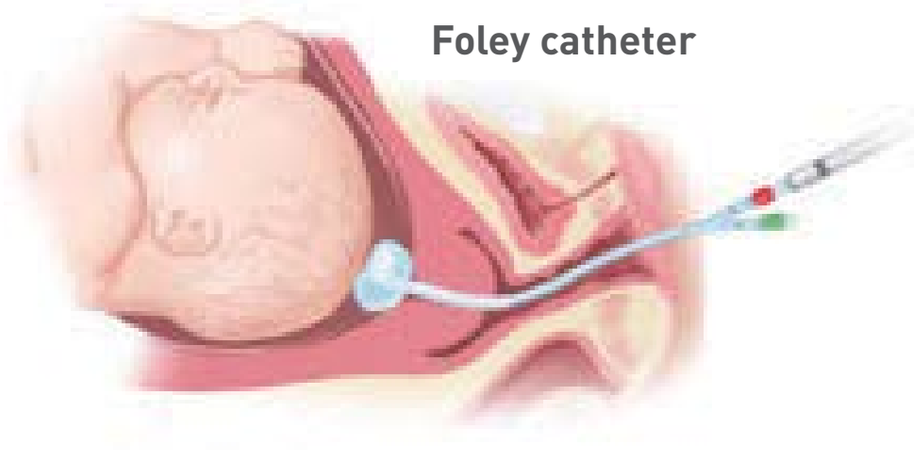
Study/subgroup	Induction n/N	Expectant n/N	Risk ratio M-H, Fixed (95% CI)	Weight	Risk ratio M-H, Fixed (95% CI)
37–39 weeks Subtotal (95% CI)	481	235		2.6%	0.58 (0.30–1.11)
39–40 weeks Subtotal (95% CI)	415	395		2.4%	0.74 (0.38–1.41)
41 weeks Subtotal (95% CI)	501	497		13.6%	0.74 (0.58–0.96)
>41 weeks Subtotal (95% CI)	3004	2990		78.9%	0.91 (0.82–1.00)
Total (95% CI)	**4515**	**4234**		**100.0%**	**0.89 (0.81–0.97)**

(RR 0.89, 95% CI 0.81–0.97; *p*=0.0067).[1]

Reference: 1. Gülmezoglu AM, *et al. Cochrane Database Syst Rev* 2012;CD004945.

CERVIDIL VS FOLEY CATHETER FOR LABOUR INDUCTION

Study	Details	Key conclusions
Controlled-release dinoprostone insert versus Foley catheter for labor induction: A meta-analysis.[1]	Six randomised controlled trials comparing women who received CERVIDIL (n=731) with Foley catheter balloon (n=722).	• **Time from induction to delivery significantly shorter in CERVIDIL group compared with Foley catheter group** **(mean difference=5.73 hours; 95% CI: 1.26–10.20; *p*=0.01)** • No significant differences in vaginal delivery within 24 hours between CERVIDIL group compared with Foley catheter group (RR: 0.75; 95% CI: 0.43–1.30; *p*=0.31) • No significant differences for Caesarean section between CERVIDIL group compared with Foley catheter group (RR: 0.94; 95% CI: 0.80–1.12; *p*=0.50) • CERVIDIL was associated with increased rate of excessive uterine contraction compared with Foley catheter (RR: 0.07; 95% CI: 0.03–0.19; *p*<0.01) • **CERVIDIL was associated with less oxytocin use compared with Foley catheter** **(RR: 1.86; 95% CI: 1.25–2.77; *p*<0.01)**

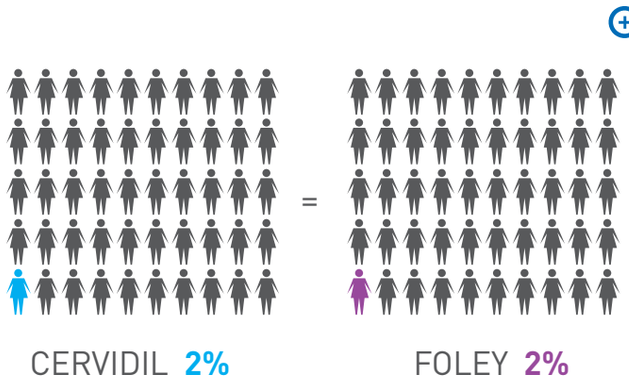


Reference: 1. Wang H, *et al. J Matern Fetal Neonatal Med* 2016;29:2382–2388.

CERVIDIL VS FOLEY CATHETER

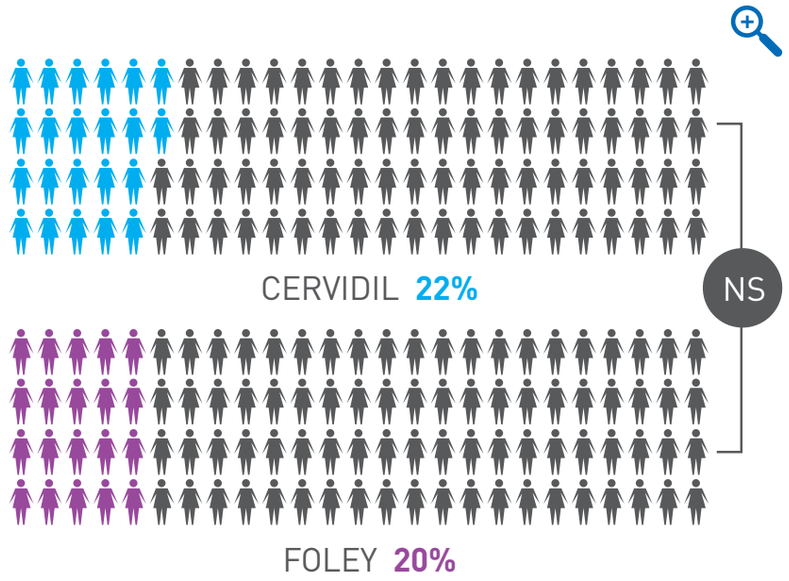
CERVIDIL has comparable Caesarean section rates to Foley catheter[1]*

Tachysystole Rates



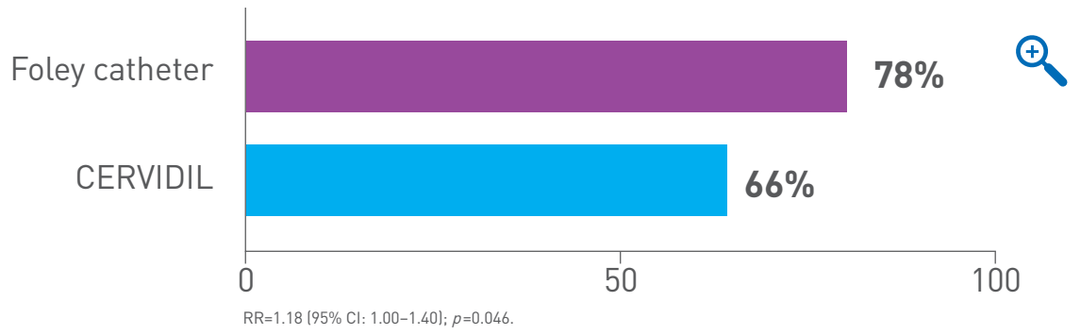
*RR=1.11 (95% CI: 0.16–7.76); p=1.00.

Caesarean Section Rates



*RR=0.90 (95% CI: 0.54–1.50); p=0.68.

Rate of Oxytocin Augmentation vs Foley catheter[1]



RR=1.18 (95% CI: 1.00–1.40); p=0.046.

Reference: 1. Jozwiak M, *et al. Eur J Obstet Gynecol Reprod Biol* 2013;170:137–145.

CERVIDIL VS FOLEY CATHETER

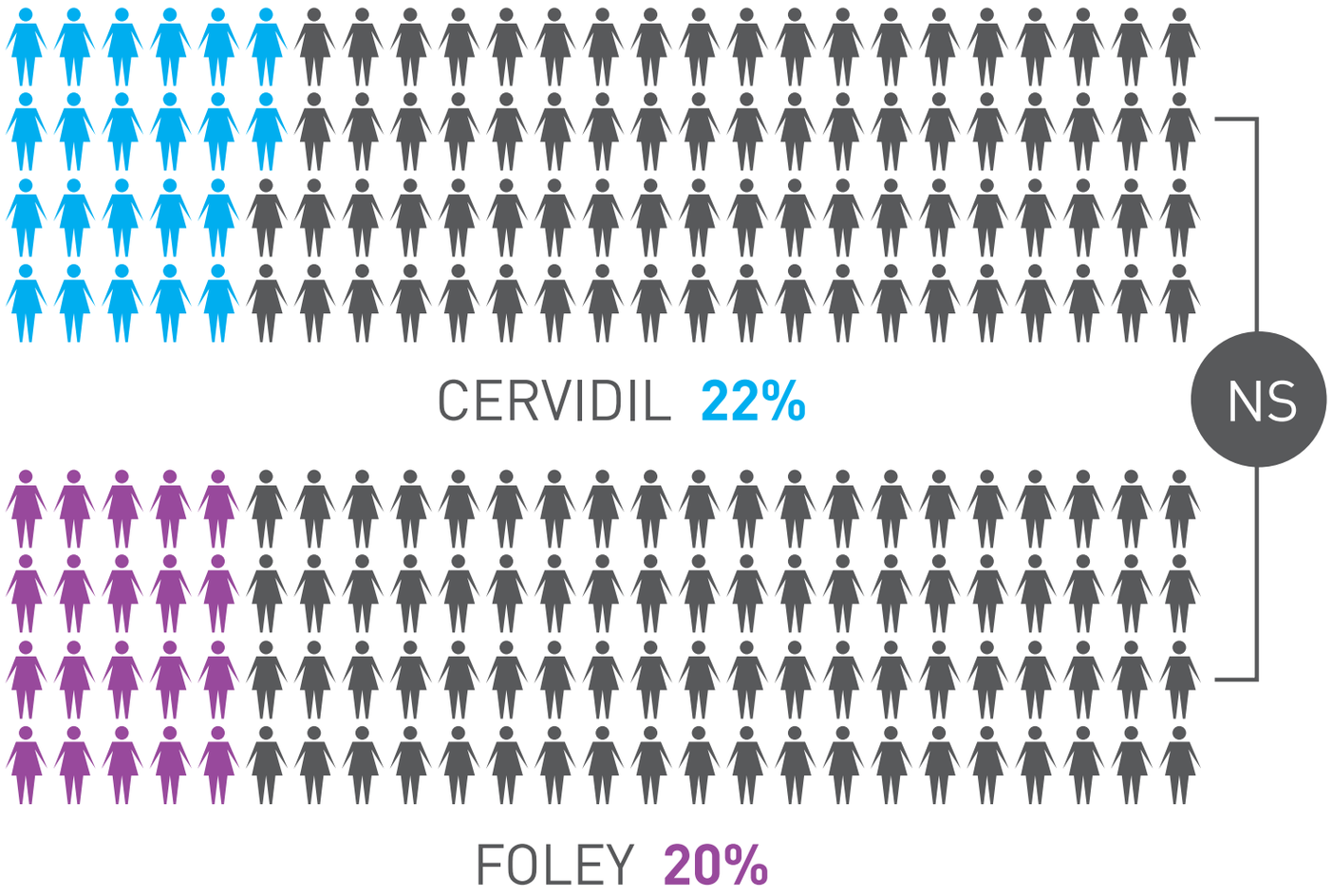
Tachysystole Rates

CERVIDIL **2%** = FOLEY **2%**

*RR=1.11 (95% CI: 0.16–7.76); *p*=1.00.

CERVIDIL VS FOLEY CATHETER

Caesarean Section Rates



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CERVIDIL VS FOLEY CATHETER

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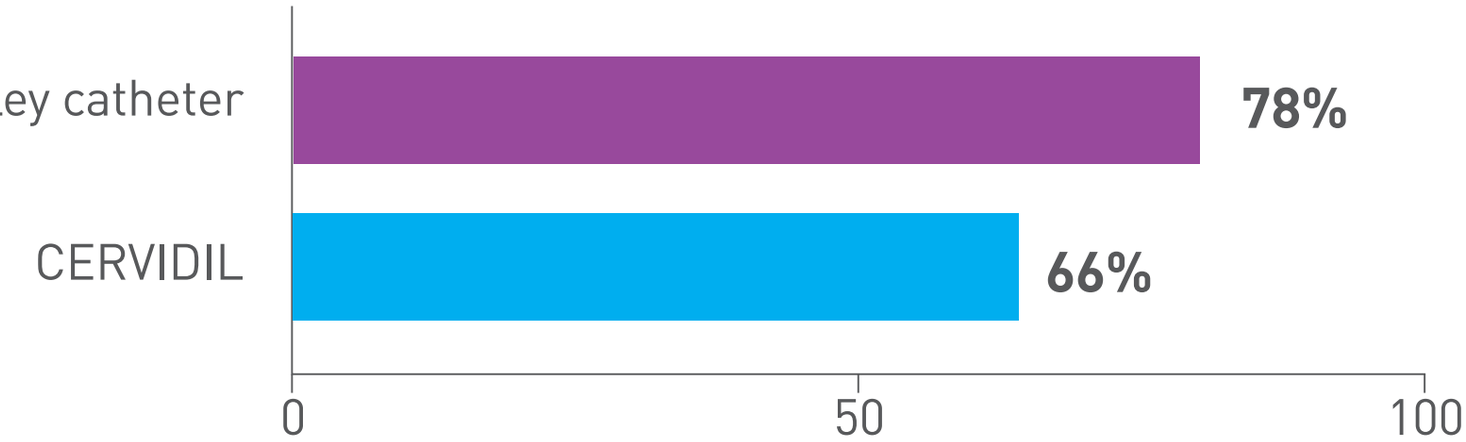


RR=1.18 (95% CI: 1.00–1.40); *p*=0.046.

Reference: 1. Jozwiak M, *et al. Eur J Obstet Gynecol Reprod Biol* 2013;170:137–145.

CERVIDIL VS INTRACERVICAL PGE_2 GEL

FURTHER RECENT DATA		
Study	**Details**	**Key conclusions**
PGE_2 GEL compared to dinoprostone vaginal insert for cervical ripening and induction of labor.[1]	• Retrospective, single-centre study of women who required induction of labour with an unfavourable cervix, Bishop score ≤6 • Women underwent induction with administration of either intracervical gel (n=100) or vaginal insert (CERVIDIL; n=200)	• Comparable efficacy: 73% of women in the CERVIDIL group delivered within 24 hours, compared with 52% in the gel group (p=0.09) • **Greater percentage of women in the CERVIDIL group (86%) delivered after single application compared with the gel group (68%)** • No significant difference in Caesarean section rate between the two groups: CERVIDIL (13.5%) and gel (10.0%) • 3 neonates with Apgar <6 at 1 minute in the gel group compared with one in the CERVIDIL group (p=NS) • Hyperstimulation with abnormal fetal heart rate occurred in 11 cases (5.5%), all of them in the CERVIDIL group, requiring device removal in all cases and administration of tocolysis in 3% of cases
Efficiency of dinoprostone insert for cervical ripening and induction of labor in women of full-term pregnancy compared with PGE_2 Gel: A meta-analysis.[2]	• Meta-analysis of 15 randomised controlled trials involving 1779 women undergoing cervical ripening and induction of labour with CERVIDIL (n=845) or intravaginal gel (n=857), who had a Bishop score of <7 • The primary outcomes were the rates of vaginal delivery and Caesarean section	• No significant difference between CERVIDIL and gel in rates of vaginal delivery (OR: 1.12; p=0.34) or artificial-assisted vaginal delivery (OR: 0.96; 95% CI: 0.59–1.56; p=0.87) • No significant difference between CERVIDIL and gel in the Caesarean section rate (OR: 0.89; 95% CI: 0.71–1.12; p=0.34) • **CERVIDIL significantly reduced time to vaginal delivery compared with gel (OR: 2.35; 95% CI: 1.34–4.13; p=0.003)** • **The rates of hospital stay more than 4 days were 0.41 with CERVIDIL (n=123) vs 0.46 with gel (n=123)** • **The rate of postpartum haemorrhage was 0.13 for CERVIDIL versus 0.23 for gel**

References: 1. Duarte-Maldonado P, *et al. J Perinatal Med* 2015;43:P-0339. 2. Zeng, X *et al. Drug Discov Ther* 2015;9;165-172.

CERVIDIL VERSUS VAGINAL PGE_2 GEL[1]

CERVIDIL **72%** spontaneous vaginal delivery

Vaginal PGE_2 GEL **54%** spontaneous vaginal delivery

*Difference: 18%; 95% CI: 2–34%; p=0.03.

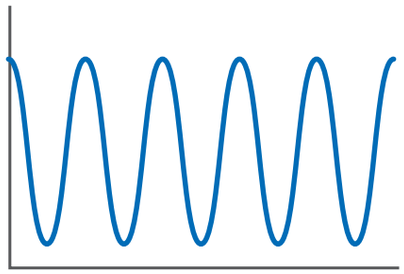
PRIMARY OUTCOMES BASED ON THE INDUCTION METHOD[2]			
	CERVIDIL (N=26)	PGE_2 GEL (N=26)	*P* VALUE
Women initiating labour after vaginal prostaglandin	17 (65.4%)	19 (73.1%)	0.764
Oxytocin in dilating phase	11 (42.3%)	16 (61.5%)	0.267
Infusion time, minutes (mean ± SD)	143.6 ± 98.0	157.5 ± 103.8	0.726
Caesarean section deliveries	9 (34.6%)	10 (38.5%)	0.990

References: 1. Triglia MT, *et al. Acta Obstet Gynecol Scand* 2010;89:651–657. 2. Zanconato G, *et al. J Matern Fetal Neonatal Med* 2011;24:728–731.

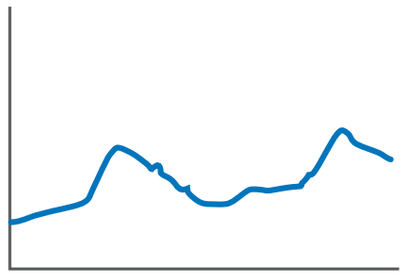
CERVIDIL DEMONSTRATES A RAPID RESOLUTION OF TACHYSYSTOLE FOLLOWING RETRIEVAL[1]

REVERSAL 2-13 MINUTES

TACHYSYSTOLE



RESOLUTION



PRIMARY REASON FOR RETRIEVAL IN WOMEN RECEIVING CERVIDIL FOR IOL	n/N (%)	MEDIAN TIME TO RESOLUTION (MINUTES)
Intrapartum adverse events (AEs), any	27/680 (4.0)	47
Uterine tachysystole† with FHR involvement‡	8/680 (1.2)	8.5
Category II/III FHR pattern AE‡	13/680 (1.9)	87
Uterine tachysystole† or uterine hypertonus	2/680 (0.3)	Not reported
Meconium in amniotic fluid	2/680 (0.3)	Not reported
Other AEs	3/680 (0.4)	Not reported

The SOGC Guidelines state that the controlled-release preparation (CERVIDIL) allows for removal in case of uterine tachysystole with FHR changes and requires a 30-minute delay before the initiation of oxytocin upon its removal[3]

† Uterine tachysystole was defined as uterine activity >5 contractions in a 10-minute window, averaged over 3 consecutive 10-minute periods (i.e. ≥18 contractions in 30 minutes, with each 10-minute period having at least 6 contractions). The contractions must have been of adequate intensity and duration, i.e. moderate intensity and duration ≥45 seconds, in order for the uterine activity to be characterized as tachysystole.

‡ FHR involvement was defined as late decelerations, bradycardia or prolonged decelerations.

References: 1. Edwards RK *et al. Obstet Gynecol* 2014;123:1280–1287. 2. Rugarn O *et al. BJOG* 2017;124:796–803. 3. SOGC Induction of Labour Guidelines. *J Obstet Gynaecol Can* 2013;35(9):840–857.

DEFINING UTERINE TACHYSYSTOLE (HYPERSTIMULATION)

DEFINITIONS OF UTERINE ACTIVITY IN LABOUR [1]	
Term	**Definition**
Frequency	Number of uterine contractions in a 10-minute period
Duration	Interval (seconds) between contraction beginning to end, measured from the uterine tone baseline, usually with external abdominal tocography
Intensity	Strength of the peak of uterine contractions minus the resting tone measured: a) Objectively through the use of intrauterine pressure transducer catheter (IUPC). This may range from 25 to 50 mm Hg in the first stage of labor and may rise to >80 mm Hg in the second stage. Contractions can be defined as mild (<50mm Hg), moderate or strong (>50 mm Hg) b) Subjectively through palpation of the uterus through the maternal abdomen and described as mild, moderate or strong
Relaxation time	Time (seconds) between the end of one contraction and the onset of the next contraction summed over a 10-minute period
Montevideo units	Peak Intensity of each contraction calculated in millimetres of mercury (mm Hg) minus resting uterine tone, summed over a 10-minute period
Uterine tachysystole	Greater than 5 contractions in 10 minutes, averaged over 30 minutes: a) Without fetal heart rate changes, previously termed hypertonus b) With fetal heart rate changes, previously termed uterine hyperstimulation

FACTORS ASSOCIATED WITH AN INCREASED RISK OF UTERINE TACHYSYSTOLE [2]		
Factor	**Characteristics associated with tachysystole**	
Patient	- Younger maternal age - Nulliparity	- Chronic hypertension - Smoking/alcohol/drug history
Pregnancy/Delivery	- Preeclampsia - Oligohydramnios - Induction of labour (not effective)	- Use of oxytocin - Use of misoprostol - Longer time in labor - Epidural

References: 1. Hobson *et al. J Pernatal Med* 2018;47(2):1-7. 2. Pierce *et al. Am J Perinatol Rep* 2018;8:e307–e314.

CERVIDIL IS EASILY ADMINISTERED[1]

Insertion of CERVIDIL involves a series of simple steps, which do not require a syringe, a vaginal speculum or stirrups

1. Remove CERVIDIL from freezer and open the aluminum foil at the tear provided

2. Pull out the CERVIDIL vaginal delivery system using the retrieval tape

3. Position CERVIDIL insert securely between the middle and index fingers

4. Introduce CERVIDIL high up into the vagina assisted by a small amount of aqueous gel

5. Position CERVIDIL behind the **posterior vaginal fornix transversely** to ensure it remains in situ

https://drive.google.com/file/d/1xxuEFfwVk4GvXBg08mKd7kt_S22keGoj/view?usp=sharing

Proper administration is critical to avoid potential risk and should be performed by trained personnel

Reference: 1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006.

CERVIDIL® SAFETY INFORMATION

Indication and clinical use:

CERVIDIL (dinoprostone) is indicated for: Initiation and/or continuation of cervical ripening in patients at or near term in whom there is a medical or obstetrical indication for the induction of labour.
CERVIDIL is not recommended in the geriatric and pediatric populations.

Contraindications:

- All contraindications to labour induction
- Relative contraindications specific to CERVIDIL
- Hypersensitivity to prostaglandins
- Patients in whom there is clinical suspicion or definite evidence of fetal distress where delivery is not imminent
- Patients in whom oxytocic drugs are contraindicated or when prolonged contraction of the uterus may be detrimental to fetal safety or uterine integrity (previous caesarean section or major uterine surgery)
- Multipara with 6 or more previous term pregnancies
- Patients with a history of difficult labour and/or traumatic delivery
- Patients with overdistension of uterus (multiple pregnancy, polyhydramnios)
- Patients with a history of epilepsy whose seizures are poorly controlled
  - History of previous uterine hypertonicity, glaucoma, or childhood asthma
  - Caution in patients at risk for developing disseminated intravascular coagulation
  - Caution in patients with severe renal disease and/or severe hepatic disease accompanied by metabolic aberrations
- Simultaneously with other oxytocics
- Current pelvic inflammatory disease, unless adequate prior treatment has been instituted

Most serious warnings and precautions:

For Hospital Use Only: CERVIDIL should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.

Other relevant warnings and precautions:

- Removal prior to oxytocin administration
- Removal if uterine tachysystole is encountered or if labour commences; prior to amniotomy; if there is fetal distress; if there is evidence of maternal or fetal adverse reactions
- Monitoring: After insertion, the patient should remain supine and monitored for 2 hours for any evidence of uterine tachysystole, change in fetal heart rate or maternal blood pressure or heart rate

For more information:

Please consult product monograph https://www.ferring.ca/en/products/reproductive-health/obstetrics-and-gynecology-products/#obstetrics-and-gynecology-products-expanded-2 for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece.
The Product Monograph is also available by calling 1-866-384-1314.

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