

A nonpharmaceutical option
for preinduction dilation.



Cervical Ripening Balloon

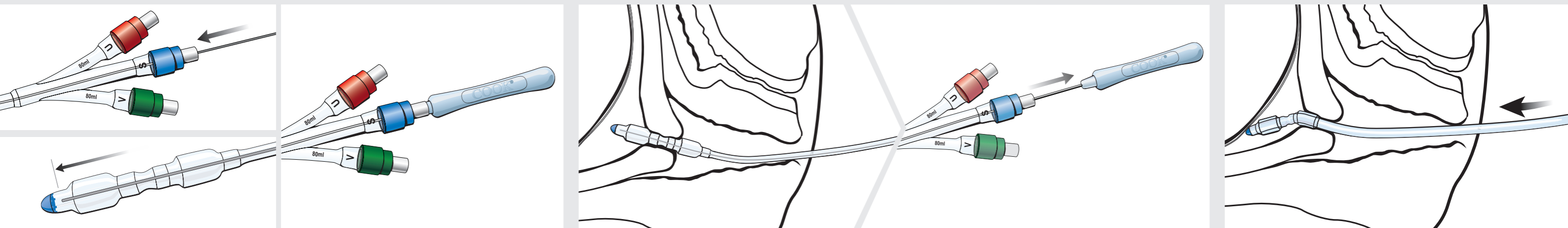
WITH STYLET

The Cook Cervical Ripening Balloon is a silicone double-balloon catheter with a malleable stylet. It is a nonpharmaceutical option for dilating the cervical canal prior to labour induction at term when the cervix is unfavourable for induction.

The Cervical Ripening Balloon with Stylet

- Is an option for nonpharmaceutical dilation.
- Is associated with reduced rates of tachysystole,¹ excessive uterine activity²; fetal acidaemia,³ and the need for neonatal intensive care unit admissions² in comparison to prostaglandin E₂.
- Is associated with increased rates of vaginal delivery within 24 hours^{1,3} and more unassisted vaginal births.³
- Has been shown to improve Bishop scores in nulliparous women⁵ and multiparous women⁴ in comparison to Foley balloon catheters.
- Ceases its mechanical action when the device is removed.
- Does not require traction.
- Creates steady pressure on the internal and external os throughout the dilation process.
- Has a stylet that is completely contained within the catheter.

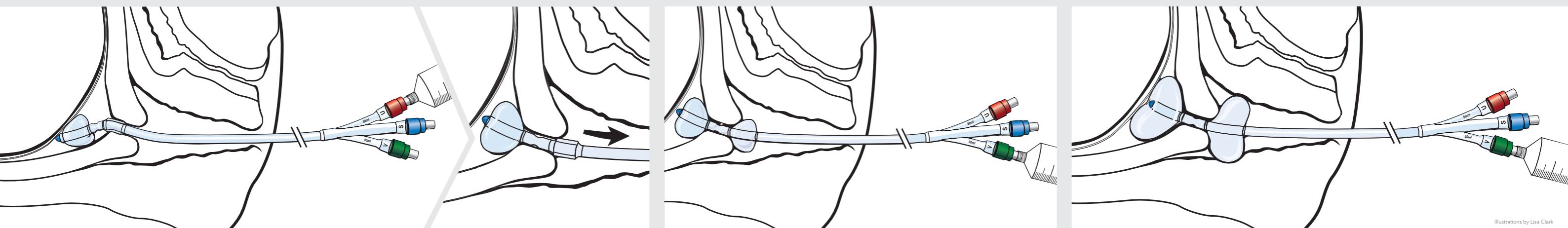
Technique for cervical dilation



1 Seat the stylet handle firmly into the blue port labelled "S".

2 Use the Cervical Ripening Balloon with stylet to traverse the cervix. **Note:** Once the cervix has been traversed and the uterine balloon is above the level of the internal uterine opening (internal os), remove the stylet before further advancing the catheter.

3 Advance the Cervical Ripening Balloon through the cervix until both balloons have entered the cervical canal.

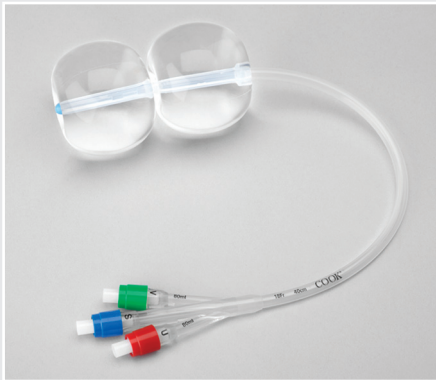


4 Inflate the uterine balloon with 40 mL of saline. Once the uterine balloon is inflated, pull the device back until the balloon abuts the internal cervical os.

5 The vaginal balloon is now visible outside the external cervical os and should be inflated with 20 mL of saline.

6 Once the balloons are situated on each side of the cervix and the device has been fixed in place, add more fluid to each balloon in turn, until each balloon contains a maximum of 80 mL of fluid. Time the balloon placement so that the balloon is in place no longer than 12 hours before active labour is induced.

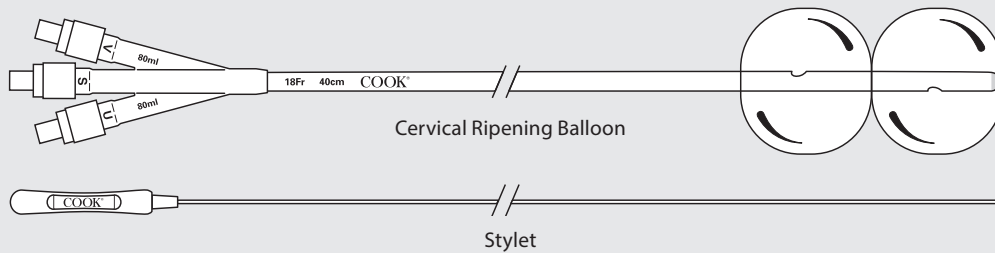
Refer to the Instructions for Use for complete information on product usage and a complete list of precautions, warnings, and contraindications.



Cervical Ripening Balloon

WITH STYLET

The Cook Cervical Ripening Balloon is a silicone double-balloon catheter with a malleable stylet. It is intended for mechanical dilation of the cervical canal prior to labour induction at term when the cervix is unfavourable for induction.



Order Number	Reference Part Number	Fr	Length cm	Balloon Volume mL
G19891	J-CRBS-184000	18	40	80

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Delivery for details.

Refer to the Instructions for Use (IFU) for complete product information and full prescribing information including indications, contraindications, warnings, precautions, and potential adverse events. Please see product risk information in the IFU at cookmedical.eu.



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References

1. Cromi A, Ghezzi F, Uccella S, et al. A randomized trial of preinduction cervical ripening: dinoprostone vaginal insert versus double-balloon catheter. *Am J Obstet Gynecol.* 2012;207(2):125.e1-e7. doi:10.1016/j.ajog.2012.05.020.
2. Du YM, Zhu LY, Cui LN, et al. Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials. *BJOG.* 2017;124(6):891-899.
3. Brown J, Beckman M. Induction of labour using balloon catheter and prostaglandin gel. *Aust N Z J Obstet Gynaecol.* 2017;57(1):68-73.
4. Solt I, Frank Wolf M, Ben-Haroush S, et al. Foley catheter versus cervical double balloon for labor induction: a prospective randomized study. *J Matern Fetal Neonatal Med.* 2021;34(7):1034-1041.
5. Hoppe KK, Schiff MA, Peterson SE, et al. 30 mL single- versus 80 mL double-balloon catheter for pre-induction cervical ripening: a randomized controlled trial. *J Matern Fetal Neonatal Med.* 2016;29(12):1919-1925. doi:10.3109/14767058.2015.1067297.

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