Designed to be Simple and Safe*

The Cervical Ripening Balloon is a non-pharmaceutical solution for preinduction dilation.[1]

Cervical Ripening Balloon | by CooperSurgical®

Designed to Support Cervical Induction[1]

Intended to dilate the cervix and may improve labor outcomes.[1,2,3,4] Healthcare providers can feel confident the device will facilitate induction in their patients.[1]

Improved safety demonstrated by a **lower likelihood of causing uterine hyperstimulation.**[2*]

Has shown significantly **reduced rates of fetal acidemia.**[5†]

Constant pressure on both the internal and external os **facilitates the process of gradual dilation**.[1]

Mobility Matters

The Cervical Ripening Balloon **allows your patients to remain mobile.** No traction is required, which may cause additional discomfort.[1]

May Improve Your Labor Outcomes[2,6]

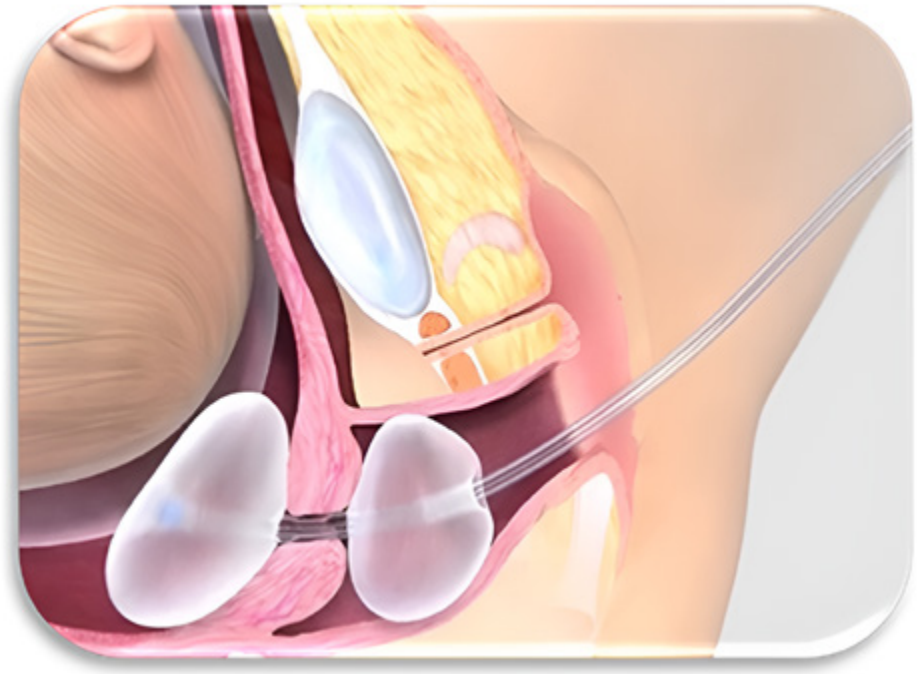
- Cervical Ripening Balloon (CRBS) has been reported to achieve a favorable cervix in as little as 8.6 hours[7‡]
- Designed to hold a maximum of 80 mL of sterile saline in each balloon to achieve a maximum dilation of ≥ 5.0 cm.[1,8]
- Has been shown to significantly **increase rates of vaginal delivery** within 24 hours.[2,5†]
- The Cervical Ripening Balloon with Stylet has been shown to significantly improve Bishop scores in multiparous women compared to 40 mL Foley balloon catheters.[3§]
- Has been shown to significantly improve Bishop scores in nulliparous women compared to 30 mL Foley balloon catheters.[6Ω]
- CRBS has been reported to outpace competitors across almost all metrics for ease of use, favorable outcomes within a reasonable time frame, and outcome predictability.[7††]

Non-pharmacological[1]

No traction required[1]

Double-balloon advantage[1]

Stylet for improved insertion[1]



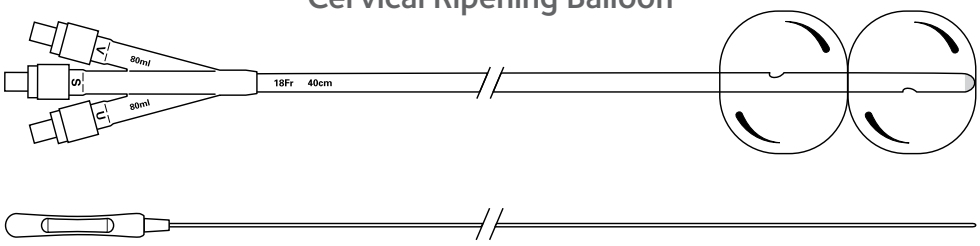
Footnotes:

* Improved safety demonstrated by a lower likelihood of causing uterine hyperstimulation compared to pharmacologic interventions (Compared to PGE2) prospective controlled trial, non-randomized. n=473.
† (Compared to PGE2) matched retrospective cohort study. n=854.
‡ Based on CooperSurgical Market Research (n=250).
§ Randomized controlled trial. n=180.
Ω Randomized controlled trial. n=98.
†† Based on CooperSurgical Market Research (n=250; $p < 0.05$).

References:

1. Cook Cervical Ripening Balloon with Stylet Instructions for Use. Bloomington, IN: Cook Medical; 2021.
2. Wang L, Wang G, Cao W, et al. Comparison of the Cook vaginal cervical ripening balloon with prostaglandin E2 insert for induction of labor in late pregnancy. Arch Gynecol Obstet. 2020;302(3):579-584.
3. 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.
4. Lajusticia H, Martínez-Domínguez SJ, Pérez-Roncero GR, Chedraui P, Pérez-López FR. Single versus double-balloon catheters for the induction of labor of singleton pregnancies: a meta-analysis of randomized and quasi-randomized controlled trials. Arch Gynecol Obstet. 2018;297(5):1089-1100.
5. Brown J, Beckman M. Induction of labour using balloon catheter and prostaglandin gel. Aust N Z J Obstet Gynaecol. 2017;57(1):68-73.
6. 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.
7. L&D Claims Research Report. Inspire Survey April 2024.
8. R&D Report Non-Clinical Bench Testing Study Report: Inflation, Dimensional, and Volume Recovery Testing of the Cook Inc. Cervical Ripening Balloon 2209043-04-R 2022.

Cervical Ripening Balloon



Stylet

Ordering Information

NUMBER	REFERENCE PART #	DESCRIPTION	Fr	LENGTH	BALLOON VOLUME
G48149	J-CRB-184000	Cervical Ripening Balloon	18	40 cm	80 mL per balloon
G19891	J-CRBS-184000	Cervical Ripening Balloon w/ Stylet	18	40 cm	80 mL per balloon

Talk to your CooperSurgical representative or visit us online to learn more.

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IMPORTANT SAFETY INFORMATION

The Cervical Ripening Balloon with Stylet is a single use device, indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

CONTRAINDICATIONS: Patients planning to undergo exogenous prostaglandin administration; placenta previa, vasa previa or placenta percreta; transverse fetal orientation; prolapsed umbilical cord; prior hysterotomy, myomectomy or any other full-thickness uterine incision; pelvic structural abnormality; genital herpes infection; invasive cervical cancer; abnormal fetal heart rate; breech; maternal heart disease; multiple gestational pregnancy; polyhydramnios; presenting part above pelvic inlet; severe maternal hypertension; any contraindication to labor induction; ruptured membranes.

WARNINGS: Concomitant use of the Cervical Ripening Balloon with exogenous prostaglandins may increase the risk of adverse events associated with prostaglandin administration. The stylet should only be used to traverse the tip of the catheter through the cervix and be removed as soon as the uterine balloon is above the level of the internal os prior to full insertion of catheter. Aggressive insertion may result in injury to baby. Should not be left indwelling for longer than 12 hours. Always inflate with sterile saline; do not overinflate the balloon or use air, carbon dioxide, or any other gas. If spontaneous rupture of membranes occurs with the device in place, it is recommended both balloons be deflated and device to be removed due to risk of device becoming entangled in the umbilical cord which would necessitate an emergent cesarean delivery.

Consult the IFU prior to use of the Cervical Ripening Balloon, for detailed instructions and potential risks. https://coopersurgical.com/crbs-ifu

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