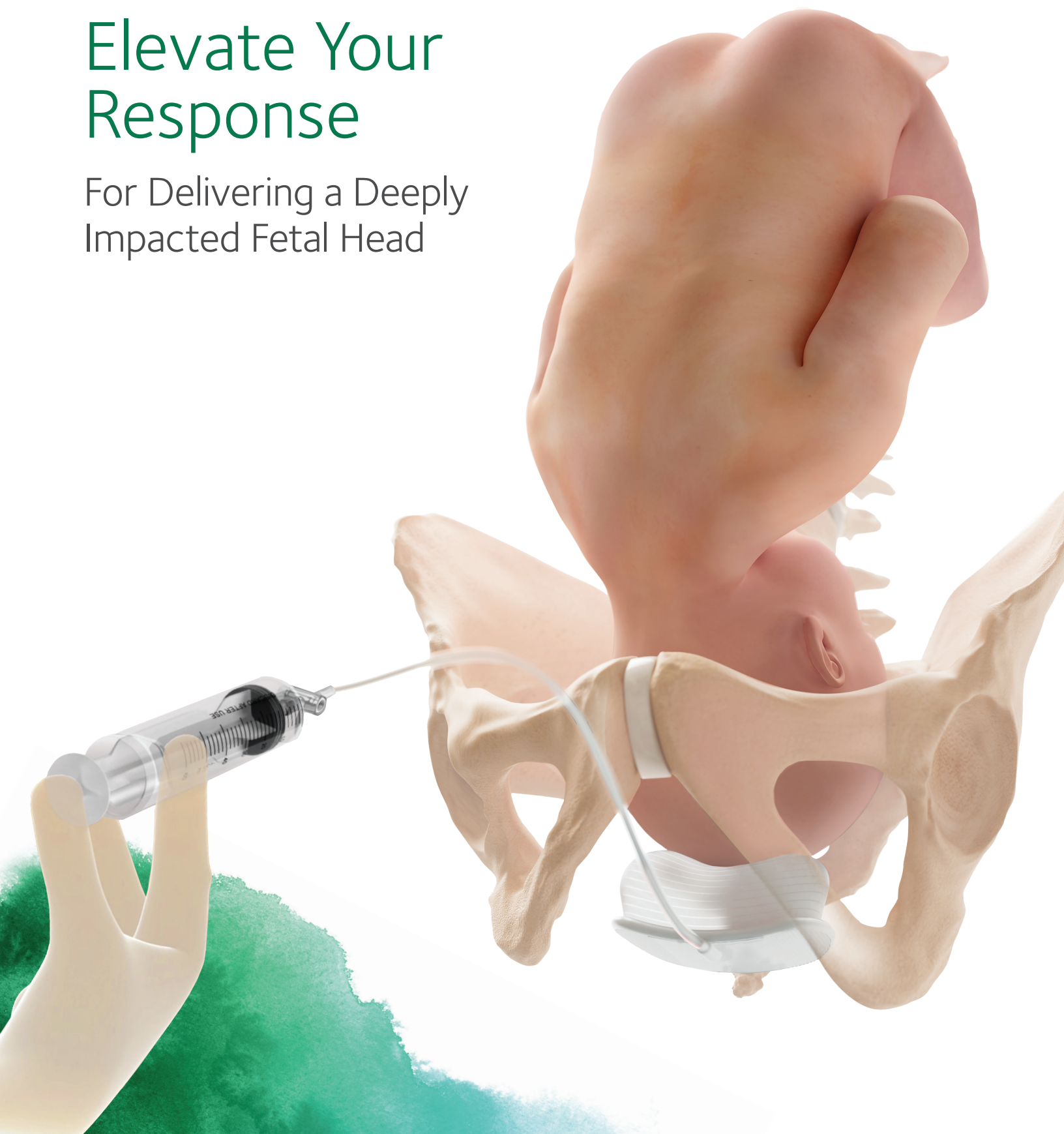


Fetal Pillow® | by  CooperSurgical®

Elevate Your Response

For Delivering a Deeply Impacted Fetal Head



Anticipating Potential Difficulties with Fetal Extraction During Second-Stage Cesarean Delivery

Fortunately, difficult deliveries do not occur every day, but we try to be prepared should they arise.

“A cesarean delivery at full dilatation can be a technically challenging procedure owing to the impacted head: additional measures to dis-impact the fetal head can increase the risk of fetal trauma, including skull and spine fractures, intracranial hemorrhage, and asphyxia, and will inherently increase the risk of maternal complications that can result from lacerations to the genital and urinary tract.”²

Fetal Pillow[®] is a balloon cephalic elevation device for use in cesarean sections performed during the second stage of labor. It was created to elevate the fetal head and facilitate delivery of the fetus in women requiring a C-section at full dilation, or those requiring a C-section after a failed instrumental vaginal delivery.³



Elevates the fetal head and facilitates delivery of the fetus.⁴

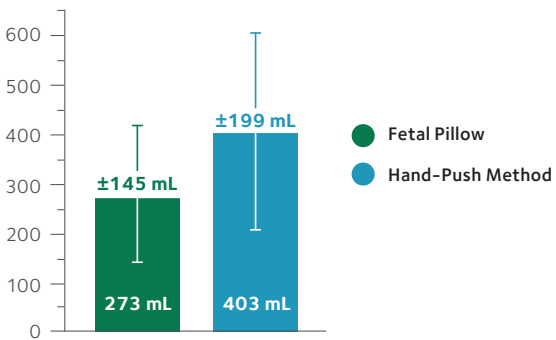
Elevate a Deeply Engaged Fetal Head During Second Stage Cesarean Sections¹



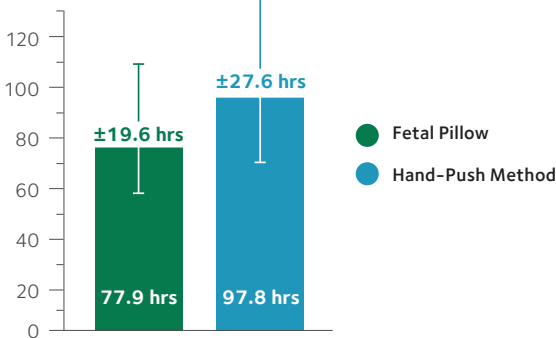
Reducing Maternal Complications

- Data from a small study showed Fetal Pillow may lower uterine extensions in a full dilation cesarean section.^{1†}
- May reduce mean operative blood loss (in a full dilation cesarean section).^{2‡}
- Use of Fetal Pillow during cesarean delivery at full dilation may be associated with a reduction in hospital stay.^{2§}

Estimated Blood Loss^{2‡}



Duration of Postpartum Hospital Stay^{2§}



[†]Inflated (n = 6), Not-Inflated (n=13), numerically significant (P = 0.05).
[‡]Fetal Pillow (n= 91), Hand-Push (n= 69); (P=0.026).
[§]Fetal Pillow (n= 91), Hand-Push (n= 69); (P= 0.002).



Reducing Fetal Complications

- Use of Fetal Pillow has been shown to reduce time to delivery after hysterotomy by 23 seconds.^{1Ω}
- In a study, the use of Fetal Pillow resulted in a higher mean cord arterial pH of 7.24 vs 7.19 with hand-push method.^{2††}

Reduced Time to Delivery after Hysterotomy^{1Ω}



^ΩInflated (n=30), Not-Inflated (n=30); median 31 (24–37) vs 54 (41–72) seconds respectively (P<0.01).
^{††}Fetal Pillow (n=91), Hand-Push (n=69); (P=0.003).



Easy to Use

- 97% of physicians who used Fetal Pillow would recommend it to their colleagues, and would use the device again.^{1**}
- 100% of physicians found ease of delivery with Fetal Pillow.^{1§§}
- Fetal Pillow is inserted during patient preparation and inflated with 180 cc of saline to elevate the fetal head.⁴



100%
of physicians found ease of delivery with Fetal Pillow.^{1§§}

^{**}29 out of 30 physicians agreed when comparing Inflated vs Not-Inflated (P=0.03).
^{§§}30 out of 30 physicians agreed when comparing Inflated vs Not-Inflated (P<0.01).



Surgical preparation for cesarean birth should include anticipating potential difficulties with fetal extraction, taking steps to prevent these difficulties from occurring, and having a plan for managing them if they do occur. This involves mobilization of the proper resources, both personnel and equipment, prior to initiation of the procedure.⁵



Use of Fetal Pillow may reduce duration of postpartum hospital stay[§]

[§]Fetal Pillow (n= 91), Hand-Push (n= 69); mean 77.9 ± 19.6 hours vs 97.8 ± 27.6 hours respectively (P= 0.002).



Data from a small study showed Fetal Pillow may lower uterine extensions in a full dilation cesarean section[†]

[†]Inflated (n = 6), Not-Inflated (n=13), numerically significant (P = 0.05).



Fetal Pillow may reduce mean operative blood loss (in a full dilation cesarean section)[‡]

[‡]Fetal Pillow (n= 91), Hand-Push (n= 69); mean 273±145 mL vs 403±199 mL respectively (P=0.026).

Ordering Information

NUMBER	DESCRIPTION
FP-O10	Fetal Pillow (6/Box)

IMPORTANT SAFETY INFORMATION

Fetal Pillow is indicated to elevate the fetal head and facilitate delivery of the fetus in women >37 weeks gestation undergoing cesarean section at full dilation (with or without an instrumental delivery). The Fetal Pillow is contraindicated in the presence of an active genital infection. The safety and effectiveness of Fetal Pillow has not been established in the following: previous cesarean section, <37 weeks gestation, non-vertex presentation, intrauterine fetal death, pregnancy induced hypertension, intrauterine growth retardation, diabetes, major congenital abnormalities, chorioamnionitis, and multiple gestations. For detailed benefit and risk information, please consult Instructions for Use. www.fetalpillow.com/instructions-for-use

References:

1. Lassey S.C., MD, Little S.E., et al. Cephalic Elevation Device for Second-Stage Cesarean Delivery. *Obstetrics and Gynecology*. 2020;00(00): 1-6
2. Safa H., Beckmann M. Comparison of maternal and neonatal outcomes from full-dilatation Cesarean deliveries using the Fetal Pillow or hand-push method. *Int J Gynecol Obstet* (2016), <http://dx.doi.org/10.1016/j.ijgo.2016.06.013>
3. FDA Approval Letter - July 27, 2017.
4. Fetal Pillow – Instructions for Use.
5. Greenberg J., MD, Lassey S., MD. Cesarean birth: Management of the deeply impacted head and the floating head. *UpToDate* 2023; (41)1-15

800.243.2974 | 203.601.5200
www.coopersurgical.com