

## Fetal Pillow™ Cephalic Elevation Device

# FDA Grants Additional 510(k) Clearance After Comprehensive Review

### Here's What You Need to Know to Advocate for Use

The FDA has reviewed the complete body of clinical evidence supporting the use of Fetal Pillow, a cephalic elevation device designed for use in cesarean sections performed during the second stage of labor ( $\geq 37$  weeks)<sup>1</sup> and granted an updated 510(k) clearance in August 2025.<sup>2</sup>

It remains the **only FDA cleared device** specifically designed to elevate the fetal head during second-stage cesarean. This milestone reinforces confidence in Fetal Pillow as a reliable solution for challenging deliveries.



As of 2025, there are **2,500+** birthing hospitals globally using the device, including large systems across the U.S.<sup>3</sup>



**220K+** units sold worldwide as of 2025<sup>3</sup>

## Why Was Fetal Pillow Created?

Fetal Pillow was developed to address a challenging scenario in obstetrics: cesarean delivery during the second stage of labor when you anticipate a deeply impacted fetal head in the maternal pelvis.<sup>1</sup>

High risk, second stage cesarean section often results in increased maternal and neonatal morbidity and mortality including:

- Uterine incision extensions<sup>4,5</sup>
- Increased maternal blood loss<sup>5</sup>
- Prolonged operative time<sup>4</sup>
- Risk of fetal injury<sup>4,5</sup>



The device was invented by Dr. Rajiv Varma after witnessing a tragic case where a baby sustained fatal skull fractures during a difficult second-stage cesarean. Fetal Pillow was developed to provide a controlled method to elevate the fetal head.<sup>6</sup>



[obgaccess.com/case-study/fetal-pillow](https://obgaccess.com/case-study/fetal-pillow)



[youtube.com/watch?v=TzfevNN4cy8](https://youtube.com/watch?v=TzfevNN4cy8)



## What Is Fetal Pillow?

Fetal Pillow is a cephalic elevation device designed for use in cesarean sections performed during the second stage of labor ( $\geq 37$  weeks).<sup>1</sup> It is:

- Inserted vaginally during cesarean section preparation prior to incision<sup>1</sup>
- Inflated with saline (180 mL) to elevate the fetal head<sup>1</sup>
- Used to facilitate delivery of the fetus in cases of full dilation or failed instrumental vaginal delivery<sup>1</sup>

# Available Clinical Data

Additionally, there has been evidence of other clinical benefits including:

## Reducing Maternal Complications:

- Data from a small Randomized Controlled Trial showed that Fetal Pillow™ may lower uterine extensions in a full dilation cesarean section<sup>7,†</sup>

### A retrospective study of 160 patients demonstrated:

- Fetal Pillow may reduce mean operative blood loss (in a full dilation cesarean section)<sup>8,‡</sup>
- Use of Fetal Pillow during cesarean delivery at full dilation may be associated with a reduction in hospital stay<sup>8,§</sup>

## Reducing Fetal Complications:

- Use of Fetal Pillow in a small Randomized Controlled Trial has been shown to reduce time to delivery after hysterotomy by 23 seconds<sup>7,Ω</sup>
- In the same retrospective study, the use of Fetal Pillow resulted in a higher mean cord arterial pH of 7.24 vs. 7.19 with hand-push method<sup>8,§</sup>



There are **more than 40 additional peer-reviewed publications** evaluating the **safety and efficacy of Fetal Pillow**, and many of these studies have **demonstrated statistically significant benefits** when compared to standard techniques.



If you have further questions about the clinical data or would like a deeper understanding of the evidence, **please contact your sales representative who will connect you with CooperSurgical Medical Affairs.**

# Resources for Clinicians

## Hands-On Training

- In-servicing with our L&D 3-in-1 simulation trainer with your sales representative

## Clinical Evidence Review

- Contact your sales representative to connect you with CooperSurgical Medical Affairs

## Peer-to-Peer Learning

- Engage with experienced colleagues through Professional Education peer-to-peer programs to share best practices and real-world insights
- Contact your sales representative to connect you with CooperSurgical Professional Education
- Webinars for Fetal Pillow are available on the CooperSurgical website at [coopersurgical.com/webinar/fetal-pillow-for-full-dilation-cesarean-section](https://coopersurgical.com/webinar/fetal-pillow-for-full-dilation-cesarean-section)



## FOOTNOTES

- † Inflated (n = 6), Not-Inflated (n=13), numerically significant (P = 0.05).  
Ω Inflated (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.  
‡ Fetal Pillow (n= 91), Hand-push (n= 69); mean 273 ± 145 mL vs 403±199 mL respectively (P=0.026).  
§ Fetal Pillow (n= 91), Hand-push (n= 69); mean 77.9 ± 19.6 hours vs 97.8 ± 27.6 hours respectively (P = 0.002).

## REFERENCES

1. Fetal Pillow – Instructions for Use
2. Fetal Pillow Approval Letter– August 29, 2025
3. Sales Data on file
4. Van der Krogt L, Suff N, Story L, Shennana A. Management of impacted fetal head at caesarean section – Current practice and future development. *Eur J of Obstet and Gyn and Repr Bio.* (2025) 307:170–174.
5. Wyn Jones N, Mitchell EJ, Wakefield N, et al. Impacted fetal head during second stage Caesarean birth: A prospective observational study. *Eur J Obstet Gynecol Reprod Biol.* 2022;272:77–81.
6. SOS website/YouTube [https://youtu.be/TzfevNN4cy8?si=p1KlaWrKeii\\_h1\\_J](https://youtu.be/TzfevNN4cy8?si=p1KlaWrKeii_h1_J)
7. 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
8. 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>

## 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 as not been established in the following: previous cesarean section, <37 weeks gestation, non-vertex presentation, Intrauterine Fetal Demise, Pregnancy induced hypertension, Intrauterine Growth Restriction, 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](http://www.fetalpillow.com/instructions-for-use)