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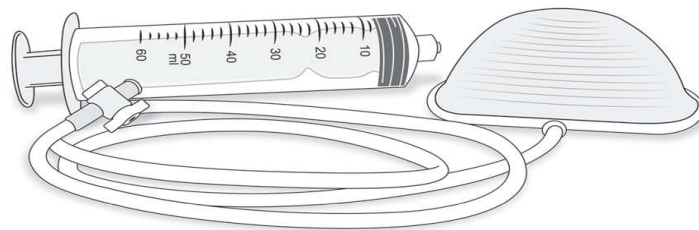
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# Fetal Pillow<sup>®</sup>

**REF** FP-010

## Instructions For Use



# Clinical Studies of Fetal Pillow Use

## Randomized Control Trial of Elevation of Fetal Head With a Fetal Pillow During Cesarean Delivery at Full Cervical Dilation (West Bengal, India) <sup>1</sup>

This publication has been retracted by the journal in accordance with the retraction statement below <https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.14924>

This prospective randomized controlled trial was carried out in two teaching hospitals in India and compared the use of the Fetal Pillow with other methods of delivery in a second stage Cesarean Section (CS). A total of 240 patients who required a CS in second stage of labor were enrolled into the study. Thirteen patients were excluded from the study, due to lack of informed consent (n=4), previous CS (n=2), breech presentation (n=2) and suspected chorioamnionitis (n=5).

### Primary Outcome Measure

Major uterine incision extensions (Grade II and III)

### Secondary Outcome Measures

- Total time taken for CS
- Incision to delivery interval
- Difficulty with delivery of fetal head
- Duration of hospital stay
- Blood loss > 1000 cc
- Need for blood transfusion
- 5 minute APGAR < 3
- NICU stay > 24 hours
- Neonatal sepsis
- Neonatal death

### Inclusion Criteria

- Ability to give informed consent
- CS at full dilation
- CS after failed instrumental delivery

### Exclusion Criteria

- Presence of active genital infection
- Chorioamnionitis
- Breech presentation
- Previous CS
- Pregnancy < 36 weeks
- Inability to give informed consent

### Study Methodology

All patients were informed about the trial when admitted to the labor ward. Patients who were able to give informed consent if requiring a CS at full dilation were included in the study. Participants were randomized 1:1 into two parallel groups, the Fetal Pillow group (FP group) and the non-Fetal Pillow group (NFP group).

CS was carried out using the standard technique and Fetal Pillow was inserted and inflated prior to performing the CS.

### Results

The two groups were similar in terms of their baseline characteristics (Table 1).

Major extensions of uterine incisions were significantly lower in the FP group (Table 2). Incision to delivery interval, total time for CS, need for blood transfusions and length of hospital stay were lower in the FP group. The intra-operative blood loss >1000 cc was more common in the NFP group (Table 2).

**Table 1. Baseline characteristics**

Variable	FP Group n = 120	NFP Group n = 120
<b>Maternal age, y (range)</b>	22.1 ± 2.6 (18-28)	22.8 ± 2.0 (18-33)
<b>Maternal weight, kg</b>	55.6 ± 4.6	54.8 ± 4.9
<b>Parity: n</b>		
0	82 (68.3%)	84 (70.0%)
1	33 (27.5%)	27 (22.5%)
2	5 (4.2%)	7 (5.8%)
3	0	2 (1.7%)
<b>1st Stage of labour, hrs<sup>a</sup></b>	7.8 ± 0.7	7.6 ± 0.6
<b>Augmentation of Labour</b>	79 (65.8%)	80 (66.7%)
<b>2<sup>nd</sup> Stage of Labour hrs<sup>b</sup></b>	1.9 ± 0.3	1.9 ± 0.3
<b>Pregnancy duration, wk</b>	38.9 ± 1.0	39 ± 1.0
<b>Indication for CS</b>		
Failed progress	88 (73.3%)	82 (68.3%)
Failed instrumental	20 (16.7%)	21 (17.5%)
Fetal distress	12 (10.0%)	17 (14.2%)
<b>Station of head</b>		
0	2 (1.7%)	2 (1.7%)
1	46 (38.3%)	50 (41.7%)
2	72 (60.0%)	68 (56.7%)
<b>Position of head</b>		
Occipito Anterior	48 (40.0%)	60 (50.0%)
Occipito Transverse	33 (27.5%)	27 (22.5%)
Occipito Posterior	39 (32.5%)	33 (27.5%)
<b>Birth weight, kg</b>	2.85 ± 0.26	2.87 ± 0.31

<sup>a</sup> Data available for 89 patients in FP group and 92 in NFP group because some were transferred from other hospitals while already in labor.

<sup>b</sup> Data available for 90 patients in FP group and 95 in NFP group because some were transferred from other hospitals while already in labor.

There were no differences in characteristics between the two groups.

**Table 2. Maternal outcomes**

Variable	Fetal Pillow Group n = 120	Non-Pillow Group n = 120
<b>Uterine extensions*</b>	12 (10.0%)	43 (35.8%)
<b>Grade of uterine extensions</b>		
I	6 (50.0%)	4 (9.3%)
II	3 (25.0%)	12 (27.9%)
III	3 (25.0%)	27 (62.7%)
Major uterine extensions (Grade 2-3)**	6 (5.0%)	39 (32.5%)
<b>Total Time taken for LSCS, min</b>	32.7 ± 4.3	53.9 ± 10.3
<b>Incision to delivery interval, sec</b>	176.5 ± 14.0	297.2 ± 27.1
<b>Difficulty with delivery of fetal head</b>		
Very difficult	2 (1.7%)	26 (21.7%)
Difficult	5 (4.2%)	21 (17.5%)
Moderate easy	11 (9.2%)	3 (2.5%)
Easy	57 (47.5%)	31 (25.8%)
Very easy	45 (37.5%)	39 (32.5%)
<b>Pre-operation Hgb, g/dL</b>	10.3 ± 0.6	10.3 ± 0.5
<b>Post-operation Hgb, g/dL</b>	9.6 ± 0.5	9.0 ± 0.8
<b>Blood loss &gt; 1000 mL: n [%]</b>	5 (4.2%)	26 (21.7%)
<b>Blood transfusions: n [%]</b>	4 (3.3%)	22 (18.3%)
<b>Hospital stay in days: mean [s.d.]</b>	3.9 ± 0.8	5.0 ± 1.2
<b>Re-laparotomy: n [%]</b>	0	4 (3.3%)

\*RR 0.37 (0.22 to 0.63), \*\*RR 0.23 (0.11 to 0.48)

**Table 3. Neonatal outcomes**

Variable	Fetal Pillow Group n = 120	Non-Pillow Group n = 120
<b>5 minutes APGAR score ≤ 3</b>	1 (0.8%)	8 (6.7%)
<b>Admission to NICU</b>	13 (10.8%)	21 (17.5%)
<b>Duration of NICU stay &gt; 24 hours</b>	3 (23.1%)	12 (57.1%)
<b>Neonatal sepsis</b>	0	4 (3.3%)
<b>Neonatal death</b>	0	3 (2.5%)

## Reanalysis of the Randomized Controlled Trial Data<sup>2</sup>

### Objectives

Randomized Control Trial data was reanalyzed to study the maternal and fetal outcomes in the hand push group from the Non Fetal Pillow group vs. the Fetal Pillow group. The patients in the control group were delivered using three different methods, depending on the preference of the surgeon and difficulty encountered during delivery. These methods were: the normal abdominal delivery method, hand push from below method, and reverse breech extraction method.

### Patient groups

Methods of delivery used in the non-Fetal Pillow arm (n=120)

- 40 women were delivered using the hand push method
- 12 women were delivered using a reverse breech extraction method
- 68 women were delivered using the normal abdominal delivery method

## RCT Reanalysis: Fetal Pillow Group vs Hand Push Method for Maternal outcomes

	Fetal Pillow Group n = 120	Hand Push Method Group n = 40
<b>Extension of uterine incision*</b>		
Yes	10 (8.3%)	23 (57.5%)
No	110 (91.7%)	17 (42.5%)
<b>Mean Incision to Delivery time (sec)</b>	176.5	278.0
<b>Total Time taken for Cesarean Section, (min)</b>	32.7	55.3
<b>Blood loss &gt; 1000 mL</b>	1 (0.8%)	15 (37.5%)
<b>Mean Length of stay in hospital, (days)</b>	3.93	5.30

\*Chi-squared Test p-value  $P < 0.0001$

## Results

Extensions of uterine incisions were significantly less common in the FP group. The observed values for incision to delivery interval, total time for CS, intra-operative blood loss and length of hospital stay were also lower in the FP group when compared with the hand push method of delivery.

## Cephalic Elevation Device for Second-Stage Cesarean Delivery: A Randomized Controlled Trial<sup>3</sup>

This double-blind randomized controlled trial was carried out in a single tertiary care center in the United States. The objective of the study was to evaluate whether this cephalic elevation device reduces time from hysterotomy to delivery and lowers morbidity from cesarean deliveries during the second stage of labor. A total of 60 patients who were to undergo cesarean delivery in the second stage were randomized, 30 to the inflated group and 30 to the not-inflated group. Three hundred and seventy-nine patients were excluded from the study due to cesarean section during first stage of labor, vaginal delivery, or patient or provider preference.

### Primary Outcome Measure

- Time (in seconds) from hysterotomy to delivery of the neonate

### Secondary Outcome Measures

- Uterine hysterotomy extension and type
- Estimated blood loss by the delivering provider
- Change between predelivery and postdelivery hematocrit
- Blood transfusion
- Total operative time (minutes)
- Other potential markers for maternal morbidity (fever, disseminated intravascular coagulation, intensive care unit (ICU) admission, and length of stay)
- Neonatal outcomes including birth weight, 1- and 5-minute Apgar scores, intubation, neonatal intensive care unit (NICU) admission, length of stay, and other fetal trauma

An internally validated survey was also given to obstetricians after delivery to assess ease of delivery and their opinions regarding future use of the device.

### Inclusion Criteria

- Patients 18 years or older
- Full term pregnancy (37 weeks gestation or greater)
- Singleton fetus in cephalic presentation
- Nulliparous patients

### Exclusion Criteria

- Contraindication to vaginal delivery
- Prior cesarean section delivery
- Presence of congenital fetal anomaly
- Non-English speaking patients

### Study Methodology

All patients who met inclusion criteria were approached on the labor floor during the first stage of labor. If a cesarean section was performed in the second stage of labor, patients were randomly allocated to either the cephalic elevation device inflated group or the not-inflated group using a computer-generated randomization scheme. At the time of delivery the cephalic elevation device was inserted vaginally by the obstetrician in all patients enrolled in the study. Once the cephalic elevation device was inserted, the patient's legs were laid flat on the operating table. The delivery provider and other members of the obstetrical team were blinded to whether the device was inflated or not. Group allocation was revealed to the anesthesiologist, who inflated the cephalic elevation device using 180 mL of normal saline (inflated group) or did not inflate the balloon (not-inflated group).

### Results

Data analysis was by intention to treat; the device was unable to be successfully inflated for one person in the inflated group. Women in the inflated group were older but otherwise had similar baseline characteristics compared to the not-inflated group (Table 1). There were also no differences in neonatal birth weight (Table 1).

The primary outcome, the median time from hysterotomy to delivery was significantly shorter in the inflated group (31 vs 54 seconds;  $P < 0.01$ ) (Table 2). There were fewer extensions in the inflated group; but the difference was not statistically significant (20% vs 43%  $P = 0.05$ ) (Table 2).

There was no difference between estimated blood loss or transfusion between the two groups (Table 2). Maternal fever, intensive care unit admission, prolonged length of stay, and readmission were rare events and not different between groups (Table 2).

There were no differences in neonatal outcomes including Apgar scores, neonatal intensive care unit admission, intubation or other fetal morbidities (Table 2). The cephalic elevation device was well received by health care providers.

Table 1. Baseline Characteristics of Women in the Inflated Group Compared with the Not-Inflated Group

Characteristics	Inflated Group	Not-Inflated Group
Age (y)	33.0 (31.0–36.0)	30.5 (26.0–33.0)
BMI at delivery (kg/m <sup>2</sup> )	28.9 (27.0–34.0)	29.7 (26.6–32.5)
Gestational age (wk)	40.0 (39.1–40.6)	40.0 (39.3–40.3)
Maternal hypertension	5 (17)	5 (17)
Maternal diabetes	2 (7)	2 (7)
Other maternal comorbidity	5 (17)	2 (7)
Duration of 2nd stage (min)	232 (164–262)	243 (175–315)
Pitocin use	27 (90)	29 (97)
Epidural use	29 (97)	30 (100)
Attempted operative delivery	1 (3)	1 (3)
Fetal station	2 (1-2)	2 (1-2)
Birth weight (g)	3,503 (3,220–3,805)	3,385 (3,090–3,590)
Primary low-transverse cesarean delivery	28 (93)	28 (93)
Low-vertical cesarean delivery	2 (7)	2 (7)
Failure to progress	27 (90)	23 (77)
Nonreassuring fetal heart rate tracing	5 (17)	9 (30)

Data are median (quartile 1–quartile 3) or n (%).

Table 2. Maternal and Neonatal Outcomes for the Inflated Group Compared with the Not-Inflated Group

Outcome	Inflated Group	Not-Inflated Group	Average Difference Between Groups*	P value
Hysterotomy-to-delivery time (sec)	31 (24-37)	54 (41-72)	-38.2 (-56.1 to -20.3)	< 0.01
Total operating time (min)	56 (50-62)	59 (52-70)	-8.7 (-18.5 to 1.2)	0.14
Uterine extension	6 (20)	13 (43)	-0.23 (-0.46 to -0.01)	0.05
Uterine extension type 1 (easy to suture)	5 (17)	2 (7)	n/a	0.02
Uterine extension type 2 (increased operative time and blood loss)	1 (3)	7 (23)	n/a	n/a
Uterine extension type 3 (into the cervix, vagina, or bladder)	0 (0)	4 (13)	n/a	n/a
Maternal blood loss (mL)	800 (700-900)	900 (750-1,050)	-191.7 (-370.3 to -13.0)	0.09
Change in hematocrit	-8.0 (5.7-9.5)	-8.6 (5.4-10.9)	-0.6 (-2.3 to 1.0)	0.53
Change in hematocrit excluding people who received transfusion	8.0 (5.7-9.5)	8.2 (5.2-10.2)	-0.1 (-1.7 to 1.5)	0.88
Maternal blood transfusion	0 (0)	3 (10)	-0.1 (-0.21 to 0.01)	0.24
Maternal length of stay (d)	4 (4-4)	4 (4-4)	-0.1 (-0.2 to 0.1)	0.43
Maternal fever	6 (20)	5 (17)	0.10 (-0.16 to 2.3)	1.0
Prolonged maternal catheterization (more than 4 d)	0 (0)	0 (0)	n/a	1.0
Maternal ICU admission	0 (0)	0 (0)	n/a	1.0
DIC	0 (0)	1 (3)	-0.03 (-0.1 to 0.03)	1.0
Maternal readmission	0 (0)	1 (3)	-0.03 (-0.1 to 0.03)	1.0
1-min Apgar score	8 (8-8)	8 (8-8)	0.0 (-1.1 to 1.0)	0.92
5-min Apgar score	9 (9-9)	9 (9-9)	-0.1 (-0.5 to 0.3)	0.84
Neonatal need for intubation	1 (3)	2 (7)	0.1 (-0.14 to 0.1)	1.0
NICU length of stay (d)	0 (0-0)	0 (0-0)	-1.1 (-2.9 to 0.8)	0.91
Other fetal trauma	0 (0)	2 (7)	-0.1 (-0.16 to 0.02)	0.49

Data are median (quartile 1-quartile 3) or n (%).  
\* Calculated as risk difference with 95% CI for categorical variables and mean with 95% CI for continuous variables.

### Comparison of Outcomes at Full-Dilation Cesarean Section With and Without the Use of a Fetal Pillow Device<sup>4</sup>

This retrospective cohort analysis was completed for all cesarean deliveries completed at full dilation at a single institution in Australia. The objective of the study was to identify whether use of the Fetal Pillow device resulted in a reduction in intraoperative complications.

The researchers reviewed a total of 245 records that met the inclusion criteria. Seventy-one records were excluded from the study for breech presentation, not fully dilated, or incomplete patient record. A total of 174 patient records were identified, 114 with Fetal Pillow and 60 without.

#### Primary Outcome Measure

- Maternal operative complications (uterine incision extension, breech extraction, use of vertical incision, bladder/ureter/bowel injury)

#### Secondary Outcome Measures

- Uterorelaxant use
- Estimated blood loss
- Requirement for blood transfusion
- Return to operating room
- Duration of hospital stay

#### Secondary Neonatal Outcome Measures

- Neonatal weight
- APGAR at 5 minutes
- Umbilical artery pH
- Admission to special care nursery
- Neonatal death

#### Inclusion Criteria

- All records with a cesarean delivery at full dilation

#### Exclusion Criteria

- Incomplete health records
- Fetal Pillow use at full dilation for breech presentation
- Fetal Pillow use less at less than full dilation

#### Study Methodology

All patients who had a cesarean delivery at full dilation or who had the use of a Fetal Pillow were reviewed for this study. All records that met inclusion and exclusion criteria standards were included in the study.

## Results

All cesarean deliveries were completed through a Pfannenstiel incision with a Joel Cohen technique after the incision. There was no statistically significant difference between the Fetal Pillow and non-Fetal Pillow groups for any of the baseline patient or intrapartum variables (Table 1). There was however a decreased likelihood of needing to use the "hand push" technique when the Fetal Pillow was used (10.00% vs 0.88%;  $P = 0.007$ ). There was no statistically significant difference in operative complications between the Fetal Pillow and non-Fetal Pillow groups (Table 2).

There were no statistically significant differences in neonatal outcomes between the Fetal Pillow and non-Fetal Pillow groups except for umbilical arterial pH between the Fetal Pillow and non-Fetal Pillow groups which was statistically significant (7.25 vs 7.19;  $P < 0.01$ ) (Table 2).

The logistic regression models did not produce statistically significant results with the Fetal Pillow variable as the predictor for any categorical outcome reviewed. When holding age, BMI, fetal station, and method of induction of labor constant, a linear regression model shows the use of the Fetal Pillow resulted in a statistically significant reduction in hospital stay of 9.4 hours (95% CI -17.8 to -0.99;  $P = 0.029$ ).

Table 1. Demographic Baseline Data Between the Fetal Pillow and Non-Fetal Pillow Groups<sup>a</sup>

Demographic Data	Fetal Pillow	Non-Fetal Pillow	P value
Age (years)	28.04 ± 5.33	26.60 ± 5.75	0.10 <sup>b</sup>
Parity	0.41 ± 1.12	0.47 ± 0.96	0.35 <sup>c</sup>
BMI (kg/m <sup>2</sup> )	28.91 ± 7.76	28.61 ± 6.58	0.89 <sup>c</sup>
Fetal station	n/a	n/a	0.54 <sup>d</sup>
Fetal station -2	2 (0.88)	1 (3.70)	n/a
Fetal station -1	20 (17.70)	5 (9.26)	n/a
Fetal station 0	33 (29.20)	17 (31.48)	n/a
Fetal station 1	49 (43.36)	25 (46.30)	n/a
Fetal station 2	9 (7.96)	5 (9.26)	n/a
Fetal station 3	1 (0.88)	0 (0.00)	n/a
Neonatal weight (g)	3658 ± 456	3632 ± 492	0.97 <sup>c</sup>
Induction of labor	n/a	n/a	0.26 <sup>b</sup>
Induced labor	57 (50.00)	24 (40.00)	n/a
Spontaneous labor	57 (50.00)	36 (60.00)	n/a
Fetal position	n/a	n/a	0.52 <sup>b</sup>
OA	31 (28.70)	11 (20.00)	n/a
OP	30 (27.78)	19 (34.55)	n/a
BROW	2 (3.64)	2 (1.85)	n/a
Smoker – yes	14 (12.28)	9 (15.00)	0.61 <sup>d</sup>
Diabetic status – yes	15 (13.16)	10 (16.67)	0.53 <sup>d</sup>
Epidural	n/a	n/a	0.19 <sup>d</sup>
Epidural – yes	70 (61.95)	31 (51.67)	n/a
Anesthetic	n/a	n/a	0.788 <sup>b</sup>
Neuraxial blockade	104 (91.23)	54 (90.00)	n/a
General anesthetic	10 (8.77)	6 (10.00)	n/a
VBAC	n/a	n/a	0.11 <sup>d</sup>
VBAC – yes	7 (6.19)	8 (13.33)	n/a
Hand push – yes	1 (0.88)	6 (10.00)	0.007 <sup>e</sup>
Instrumental - yes	43 (37.72)	27 (45.00)	0.35 <sup>d</sup>

<sup>a</sup>Values are given as number (%) or mean ± standard deviation, <sup>b</sup>t-test, <sup>c</sup>Wilcoxon/Mann-Whitney test, <sup>d</sup>χ<sup>2</sup> test, <sup>e</sup>Fisher exact test

Table 2. Maternal and Neonatal Outcomes Between the Fetal Pillow and Non-Fetal Pillow Groups

Outcome	Fetal Pillow	Non-Fetal Pillow	Coefficient/ OR (95% CI)*	P value*
Maternal patients with operative complications	19 (16.67)	15 (26.00)	OR 0.56 (0.26-1.22)	0.146
Incision extension (towards angles or cervix)	13	11	n/a	n/a
Cystotomy	2	2	n/a	n/a
Addition of vertical component to hysterotomy	3	2	n/a	n/a
Breech extraction	1	0	n/a	n/a
Maternal length of hospital stay (hours)	66.75 ± 24.27	72.56 ± 28.21	-7.5 (-15.65 to 0.64)	0.71
Estimated blood loss (mL)	730 ± 400	726 ± 374	1.76 (-123.75 to 127.27)	0.98
Estimated blood loss >1 L	15 (13.16)	7 (11.67)	OR 1.15 (0.44-3.00)	0.77
5 min APGAR score	8.65 ± 1.08	8.63 ± 1.02	0.27 (-0.31 to 0.36)	0.87
5 min APGAR <7	105 (92.92)	56 (93.33)	OR 1.07 (0.31-3.70)	0.91
NICU stay	37 (33.04)	24 (40.00)	OR 0.76 (0.39-1.47)	0.41
NICU duration of stay (h)	1 ± 2.1	1.5 ± 2.3	-0.42 (-1.11 to 0.26)	0.24
Umbilical cord arterial pH	7.25 ± 0.08	7.19 ± 0.10	0.06 (0.03-0.09)	0.0001
Requirement for maternal transfusion	1 (0.88)	3 (5.17)	OR 0.22 (0.03-1.64)	0.14
Use of uterorelaxant	9 (7.89)	7 (11.67)	OR 0.68 (0.25-1.86)	0.45
Requirement for return to operating room	2 (1.75)	2 (3.33)	OR 0.48 (0.05-4.19)	0.51
Use of peritoneal drain	7 (6.14)	5 (8.33)	OR 0.61 (0.18-2.11)	0.44
Maternal readmission to hospital	8 (7.02)	5 (8.33)	OR 0.79 (0.25-2.54)	0.70
Maternal urinary retention	1 (0.88)	2 (3.33)	OR 0.22 (0.16-3.14)	0.27

Values are given as number (%) or mean ± standard deviation.  
\* P value, coefficient/OR (95 CI) calculated from adjusted model.

### Comparison of Maternal and Neonatal Outcomes from Full-dilatation Cesarean Deliveries using the Fetal Pillow or Hand-Push Method (Brisbane study).<sup>5</sup>

#### Objectives

To compare maternal and neonatal outcomes a of full-dilatation cesarean deliveries at term using the Fetal Pillow or Hand-Push method.

#### Methods

A retrospective cohort study included data from all women who underwent full dilatation cesarean deliveries at term that involved the use of a Fetal Pillow or the hand-push method at Mater Mothers' Hospital, Brisbane, Australia between May 1, 2013 and March 31, 2015. Materna (estimated blood loss, need for blood transfusion, uterine angle extension, and duration of stay in hospital following delivery) and neonatal outcomes (5-minute Apgar score below 7, cord arterial pH, admission to neonatal intensive care unit, and need for endotracheal intubation) were compared between the treatment methods.

#### Inclusion criteria

- Singleton pregnancies
- Cesarean section at full dilatation
- Pregnancy >37 weeks

#### Exclusion criteria

- Multiple pregnancies
- Intrauterine fetal death
- Major congenital abnormalities

#### Results

Of 361 cesarean deliveries performed at full dilatation during the study period, clinicians documented the use of a Fetal Pillow in 91 deliveries and use of the hand-push method in 69. Lower mean intra-operative blood loss ( $P = 0.026$ ), a shorter duration of postpartum hospital admission ( $P = 0.002$ ), and higher mean cord arterial pH ( $P = 0.003$ ) were observed in the Fetal Pillow group (Table 2).

Table 1. Patient characteristics\*

Baseline characteristics	Fetal Pillow method (n = 91)	Hand Push Method (n = 69)
Maternal age, y	29.94 ± 4.5	31.0 ± 4.9
Duration of pregnancy at delivery, wk	39.7 ± 1.1	39.8 ± 1.1
Nulliparous	75 (82)	45 (65)
BMI	24.7 ± 6.1	24.0 ± 4.5
Previous failed instrumental delivery	6 (7)	3 (4)
Category 1 cesarean section	45 (49)	36 (52)

\* Values are given as mean ± SD or number (%)

Table 2. Maternal and neonatal outcomes\*

Outcome	Fetal Pillow method (n = 91)	Hand Push Method (n = 69)
5-min Apgar score <7	3 (3) 7-10	4 (6) 6-10
Neonatal required intubation	0	2 (3)
Neonatal ICU admission	14 (15)	17 (25)
Cord arterial pH	7.24 ± 0.06	7.19 ± 0.09
Estimated blood loss, mL	273 ± 145	403 ± 199
Blood transfusion required	3 (3)	2 (3)
Uterine angle extension	18 (20)	24 (35)
Duration of hospital stay, hours	77.9 ± 19.6	97.8 ± 27.6

\*Values are given as number (%) range, number (%), mean ± SD.

## Retrospective audit of Fetal Pillow use in 75 patients in a UK hospital (Wishaw Hospital).<sup>2</sup>

The existing dataset was reanalyzed to see the effect of high BMI, fetal weight and epidural use on the outcomes

### Inclusion criteria

All patients having cesarean section at full dilation or after a failed instrumental delivery where Fetal Pillow was used.

### Maternal outcomes studied

- Mean incision to delivery time.
- Extension of uterine incision.
- Blood loss > 1000 mL.
- Need for blood transfusion.
- Length of post-operative hospital stay.

### Results

There was no difference observed in the outcomes studied from Fetal Pillow use in this analysis when maternal BMI, Fetal weight and use of epidural in labor were taken into account.

Table 1. Maternal BMI & distribution of maternal outcomes in women treated with the Fetal Pillow

	Maternal BMI ≥ 30 n = 38	Maternal BMI < 30 n = 37
Mean incision to delivery time (mins)	4.63	5.43
Extension of uterine incision		
Yes	13 (34.2%)	11 (29.7%)
No	25 (65.8%)	26 (70.3%)
Blood loss >1000 mL	4 (10.5%)	5 (13.5%)
Blood transfusion		
Yes	1 (2.6%)	1 (2.7%)
No	37 (97.4%)	36 (97.3%)
Mean length of stay in hospital (days)	3.18	3.02

**Table 2. Fetal weight and distribution of maternal outcomes in women treated with the Fetal Pillow**

	Fetal weight ≥ 3500g n = 53	Fetal weight < 3500g n = 22
Mean incision to delivery time (mins)	5,11	4,81
Extension of uterine incision		
Yes	17 (32,1%)	7 (31,8%)
No	36 (67,9%)	15 (68,2%)
Blood loss > 1000 mL	8 (15,1%)	1 (4,5%)
Blood transfusion		
Yes	2 (3,8%)	0
Mean length of stay in hospital (days)	3,15	3,00

**Table 3. Epidural use and Distribution of maternal outcomes in women treated with Fetal Pillow**

	Epidural used n = 54	No Epidural used n = 21
Mean incision to delivery time (mins)	5,22	4,52
Extension of uterine incision		
Yes	14 (25,9%)	10 (47,6%)
No	40 (74,1%)	11 (52,4%)
Blood loss > 1000 mL	5 (9,3%)	4 (19,0%)
Blood transfusion		
Yes	0	2 (9,5%)
Mean length of stay in hospital (days)	3,11	3,10

## References

- <sup>1</sup> Seal SL, Dey A, Barman SC, Kamilya G, Mukherji J, Onwude JL. Randomized control trial of elevation of fetal head with a fetal pillow during caesarean delivery at full cervical dilation. *Int J Gynaecol Obstet.* 2016; 133(2): 178-82  
Note: This publication has been retracted by the journal in accordance with the retraction statement below (<https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.14924>)
- <sup>2</sup> United States Food and Drug Administration. De Novo Classification Request For Fetal Pillow. De Novo Summary (DEN150053), 2015;1-14.
- <sup>3</sup> Lassey SC, Little SE, Saadeh M, Patton N, Farber MK, Bateman BT, Robinson JN. Cephalic Elevation Device for Second-Stage Cesarean Delivery: A Randomized Controlled Trial. *Obstet Gynecol.* 2020;135(4):879-884.
- <sup>4</sup> Hanley I, Sivanesan K, Veerasingham M, Vasudevan J. Comparison of outcomes at full-dilatation cesarean section with and without the use of a fetal pillow device. *Int J Gynaecol Obstet.* 2020;150(2):228–233.
- <sup>5</sup> 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 Gynaecol Obstet.* 2016;135(3):281-284.

## **Indications for use**

Fetal Pillow® System is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a cesarean section at full dilation or those requiring a cesarean section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use in gestational age  $\geq$  37 weeks

## **Caution**

Federal (U.S.A.) Law restricts the use of this device by or on order of a physician.

## **Contraindications**

Fetal Pillow should not be used in the presence of an active genital infection, as it could increase the risk of ascending infection.

## **Precautions**

1. Make sure that the package is intact before use
2. DO NOT use air to inflate the device
3. Inflate the device with 60 cc saline solution prior to use to check the integrity of the device
4. Maximum inflation should not be more than 180 cc
5. The device may fail to elevate the fetal head if the dome/balloon surface of the device is not in contact with the fetal head when inserted.

## **Warnings**

The safety and effectiveness of Fetal Pillow has not been established in the following:

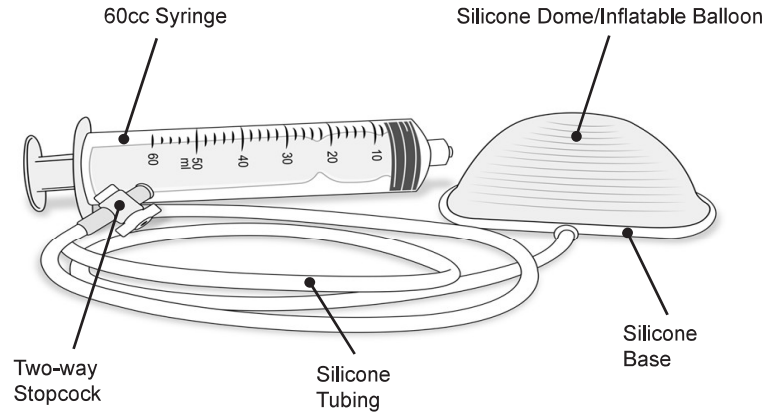
1. In women who have had a previous cesarean section
2. In women with a pregnancy less than 37 weeks
3. Non vertex presentation
4. Pregnancy with intrauterine fetal demise
5. Pregnancy induced hypertension
6. Intrauterine growth restriction
7. Diabetes in pregnancy
8. Major congenital abnormalities
9. Presence of chorioamnionitis
10. Multiple gestations

## **Please read all information carefully**

Failure to properly follow instructions may result in improper functioning of the device.

## Device Description

Fetal Pillow is a sterile single use device consisting of a base plate and a dome (inflatable balloon) made of silicone. A 100 cm long tubing is attached to this for inflation. The tubing has a two-way stopcock at the distal end for inflation and deflation. A sterile 60 cc syringe is provided with the device for inflation using sterile saline solution. The dome inflates only in upward direction when placed correctly.



## Instructions for Use

### Step 1:

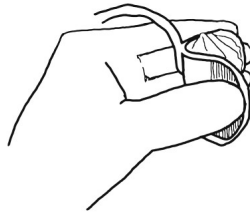
#### Before Inserting

Insertion and inflation of the device should be carried out just before performing the cesarean section.

Inflate the device with 60 cc saline prior to use to check the integrity of the device. Empty the device using the syringe provided before insertion.

Hold the base plate of the Fetal Pillow between fingers and thumb as shown and fold to squeeze the Dome (balloon) between the baseplate.

The tube attachment should be at the superior end during insertion as shown. If the tube attachment is facing downwards the tube is likely to block due to twisting, making it difficult or impossible to inflate the device.



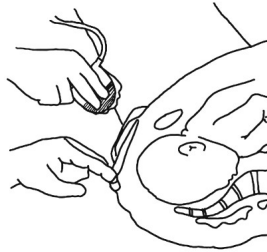
## Step 2:

### Insertion

Insert the device using a sterile lubricating cream or gel. The process is similar to inserting a soft vacuum cup.

Make sure that the dome/balloon surface of the device is in contact with the fetal head and the base plate in contact with the pelvic floor.

The device may not inflate or function effectively if placed incorrectly.



## Step 3:

### Device Position

Once inserted the device should be pushed posteriorly until it is touching the coccyx.

The position is similar to the insertion of a vacuum cup for an occiput posterior position.



## Step 4:

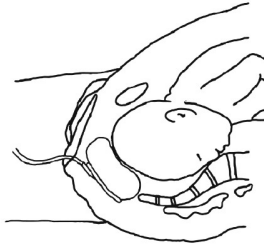
### **Inflation**

Patient's legs must be placed flat before inflation is carried out using sterile saline with the 60 cc syringe provided.

If legs are not placed flat before inflating, the device can be expelled or could move during inflation and fail to produce the desired elevation.

A total of 180 cc of saline is required to produce the desired elevation (3 syringes of fluid). Close the two-way stopcock after filling to stop the fluid from leaking.

Inflation volume should not exceed 180 cc.



## Step 5:

### **Cesarean Section**

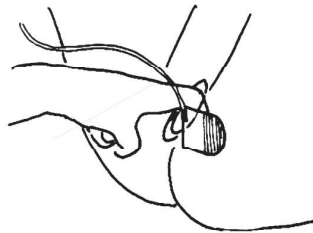
Once the inflation is complete, the cesarean section is performed using the standard technique.

## Step 6:

### **Device Removal**

After delivery of the baby, the two-way stopcock is opened to release the fluid.

The device is removed by the assistant at the end of the procedure by pulling on the tubing or hooking a finger on the plate and pulling the device out of the vagina. If the two-way stopcock fails, the tube can be cut to release the fluid for removal.




















## Device Disposal

This device must be handled and disposed of as healthcare medical waste in accordance with hospital procedures and applicable regulations. Any device that has been contaminated with potentially infectious substances of human origin (such as bodily fluids) must be handled according to hospital protocol for infectious medical waste.

## Glossary of Symbols

Source: ISO 15223-1 and ISO 7000

	Packaging unit
	Medical Device
	Catalogue number
	Batch code
	Do not re-use
	Do not re-sterilize
	Use-by date
	Consult instructions for use or consult electronic instructions for use
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)
	Date of manufacture
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Temperature limit
	Manufacturer
	Sterilized using ethylene oxide
	Single sterile barrier system
<b>Rx Only</b>	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

US PATENT NUMBERS US 9,055,073 B2, US 8,556,913 B2  
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