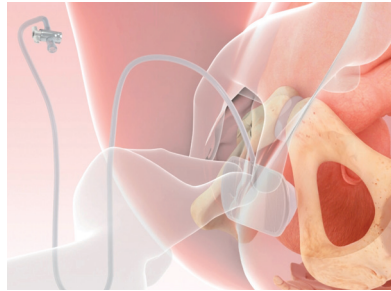


Key Steps Guide¹



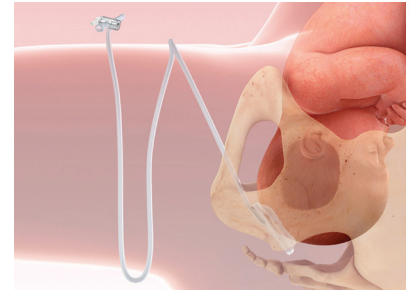
1. BEFORE INSERTING

- 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 Fetal Pillow between fingers and thumb as shown and fold to squeeze the dome (balloon) between the base plate.
- 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.



2. INSERTION

- Insert the device using a sterile lubricating cream or gel. The process is similar to inserting a soft vacuum (ventouse) 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 will not inflate or function effectively if placed incorrectly.



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 (ventouse) cup for an occiput posterior position.

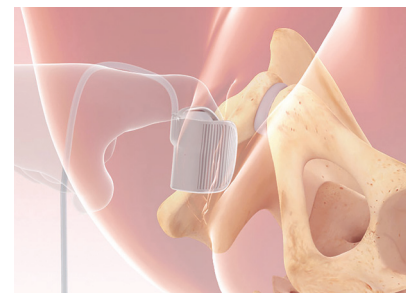


4. INFLATION

- Patient's legs must be placed flat before inflation is carried out using sterile saline with the 60 cc syringe provided.
- If the 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 luer valve after filling to stop the fluid from leaking.
- Inflation volume should not exceed 180 cc.

5. CESAREAN SECTION

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



6. DEVICE REMOVAL

- After delivery of the baby, the two-way luer valve is opened to release the fluid.
- The device is removed by the assistant at the end of 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 luer valve fails, the tube can be cut to release the fluid for removal.

¹ Fetal Pillow – Instructions for Use
www.fetalpillow.com/instructions-for-use

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



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