



# Dilation Using Electromechanical Obstetrical Dilator

Ellora™ Obstetrical System

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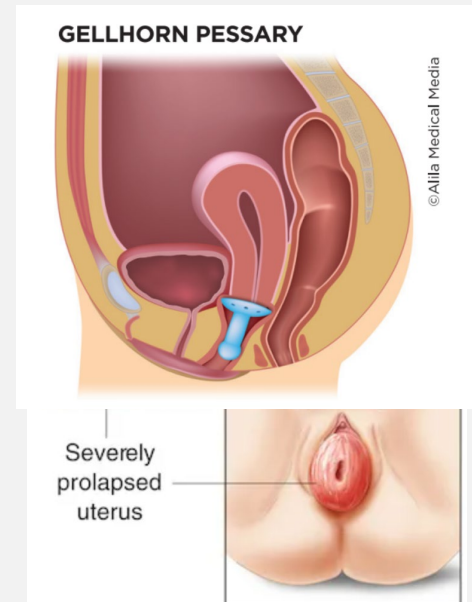
# Pelvic Organ Prolapse (POP): Background

Women who deliver vaginally are  
**5x more likely** to have prolapse<sup>1</sup>

*TODAY...*  
she's excited to  
become a new  
mother but vaginal  
delivery leaves her  
with traumatic pelvic  
floor injury



*...POSTPARTUM*  
she is a  
woman  
facing  
significant  
symptoms  
of pelvic  
prolapse



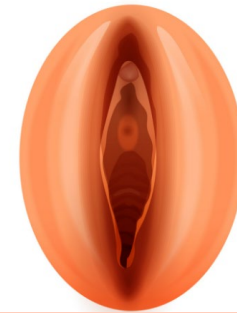
# Pelvic Organ Prolapse (POP) continued:

## Background

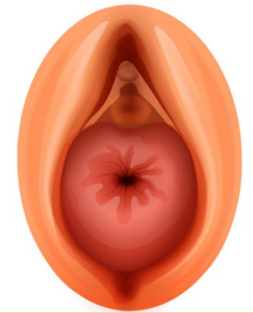
### Definition

- **Clinical:** Anatomical prolapse with descent of at least one of the vaginal walls to or beyond the vaginal hymen with maximal Valsalva effort
- **Symptomatic:** Presence either of bothersome characteristic symptoms, most commonly the sensation of vaginal bulge, or of functional or medical compromise due to prolapse without symptom bother<sup>1</sup>

Normal  
Vaginal Opening

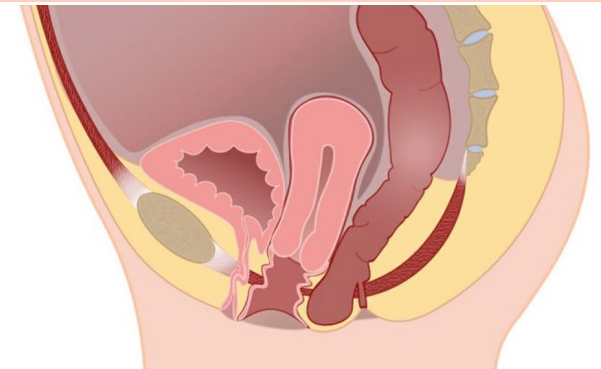


Pelvic Organ  
Prolapse



### Prevalence

- Up to 50% of women at any age have clinical evidence of POP on exam<sup>2</sup>
- 3-6% have symptomatic POP<sup>3</sup>
- Estimated lifetime risk of surgery for POP is 19%<sup>4</sup>



<sup>1</sup>Collins et al. Int Urogynecol J. 2021 Aug;32(8):2011-2019. doi: 10.1007/s00192-021-04875-y.

<sup>2</sup>ACOG, AUGS. Pelvic Organ Prolapse. Female Pelvic Med Reconstr Surg. 2019 Nov/Dec;25(6):397-408. doi: 10.1097/SPV.0000000000000794

<sup>3</sup>Barber, Maher. Int Urogynecol J. 2013 Nov;24(11):1783-90. doi: 10.1007/s00192-013-2169-9.

<sup>4</sup>Smith, Fiona J., et al. "Lifetime Risk of Undergoing Surgery for Pelvic Organ Prolapse." Obstetrics & Gynecology, vol. 116, no. 5, 2010, pp. 1096-1100. doi:10.1097/AOG.0b013e3181f4e2e8.

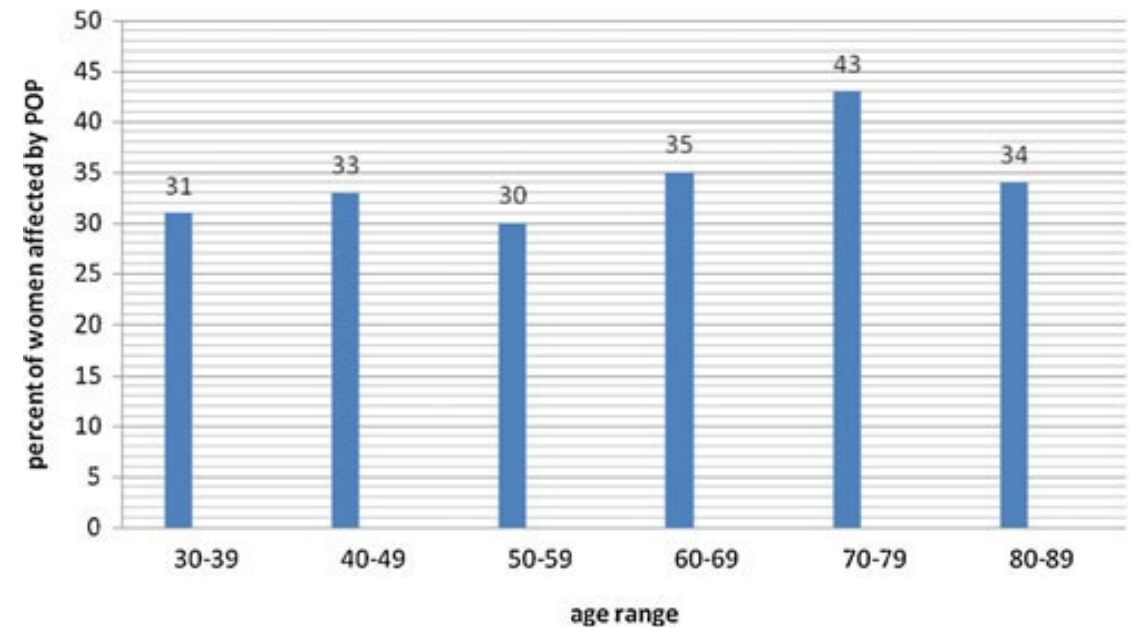
# Pelvic Organ Prolapse (POP):

Affecting women within 5-10 years of vaginal delivery

➤ 14% of women have POP on exam at 5-10 years after vaginal delivery, 4.2% are symptomatic<sup>1</sup>

➤ Younger women affected by pelvic floor disorders are more likely to defer surgery<sup>2</sup>

Age distribution of women with pelvic disorders who have POP



<sup>1</sup>Handa et al. Obstet Gynecol. 2011 Oct;118(4):777-84. doi: 10.1097/AOG.0b013e3182267f2f. Chart

<sup>2</sup>Barber, Maher. Int Urogynecol J. 2013 Nov;24(11):1783-90. doi: 10.1007/s00192-013-2169-9.

# Pelvic Organ Prolapse:

## Risk Factors<sup>1,2</sup>



### Vaginal Delivery:

- Forceps/vacuum delivery
- Levator ani muscle avulsion



### Age



### Birthweight

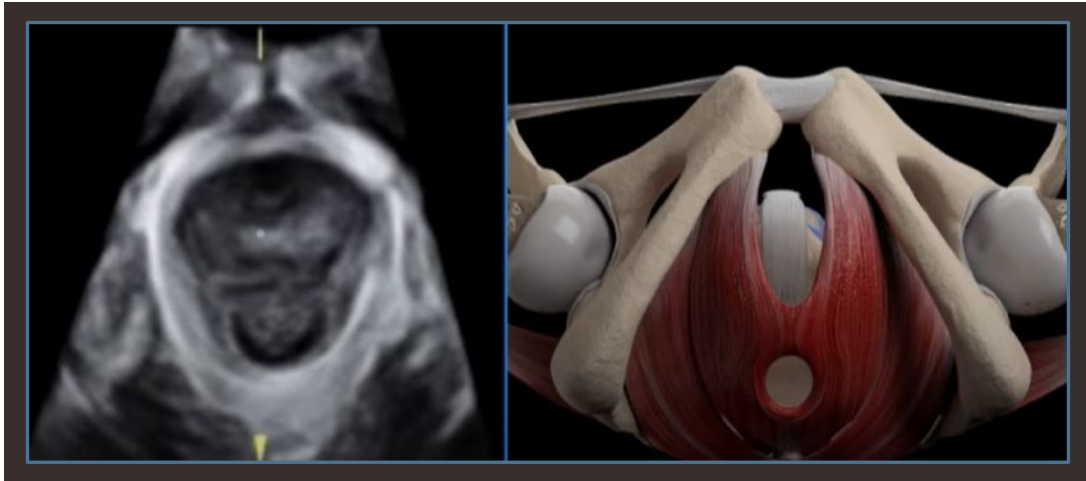


### BMI

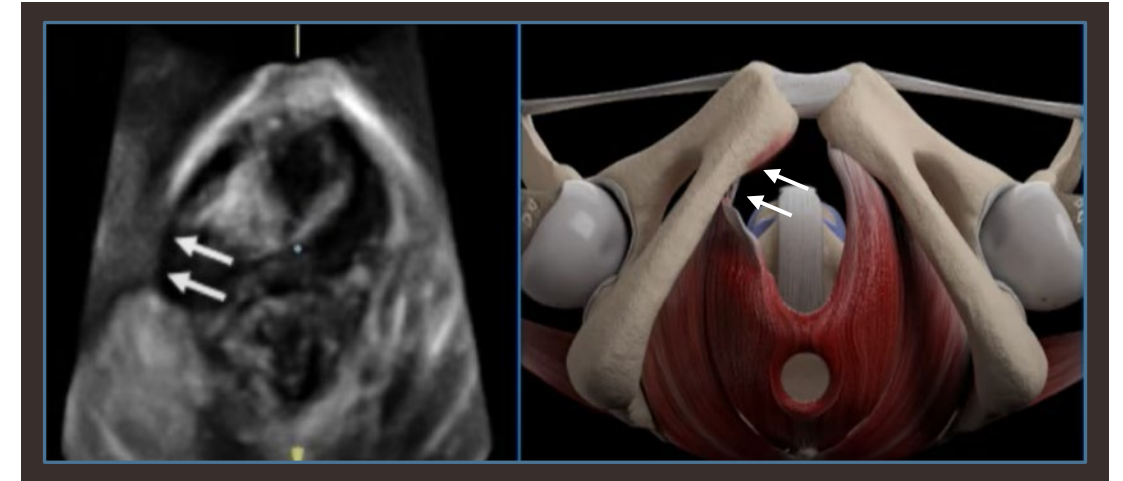
<sup>1</sup>Schulten et al. Am J Obstet Gynecol. 2022 Aug;227(2):192-208. doi: 10.1016/j.ajog.2022.04.046.

<sup>2</sup>Cattani et al. Int Urogynecol J. 2021 Jul;32(7):1623-1631. doi: 10.1007/s00192-021-04724-y.

# Postpartum ultrasounds reveal injuries associated with prolapse



Intact levator ani muscle



Torn levator ani muscle

*Images courtesy of video abstract from Youssef et al. Ultrasound Obstet Gynecol. 2019 Jan;53(1):95-100. doi: 10.1002/uog.19085.*

# Levator Ani Muscle (LAM) Avulsion:

## Ultrasound Diagnostic Technique<sup>1</sup>



Translabial/transperineal 4D ultrasound



Volume imaging data acquired at rest, Valsalva, and pelvic muscle contraction



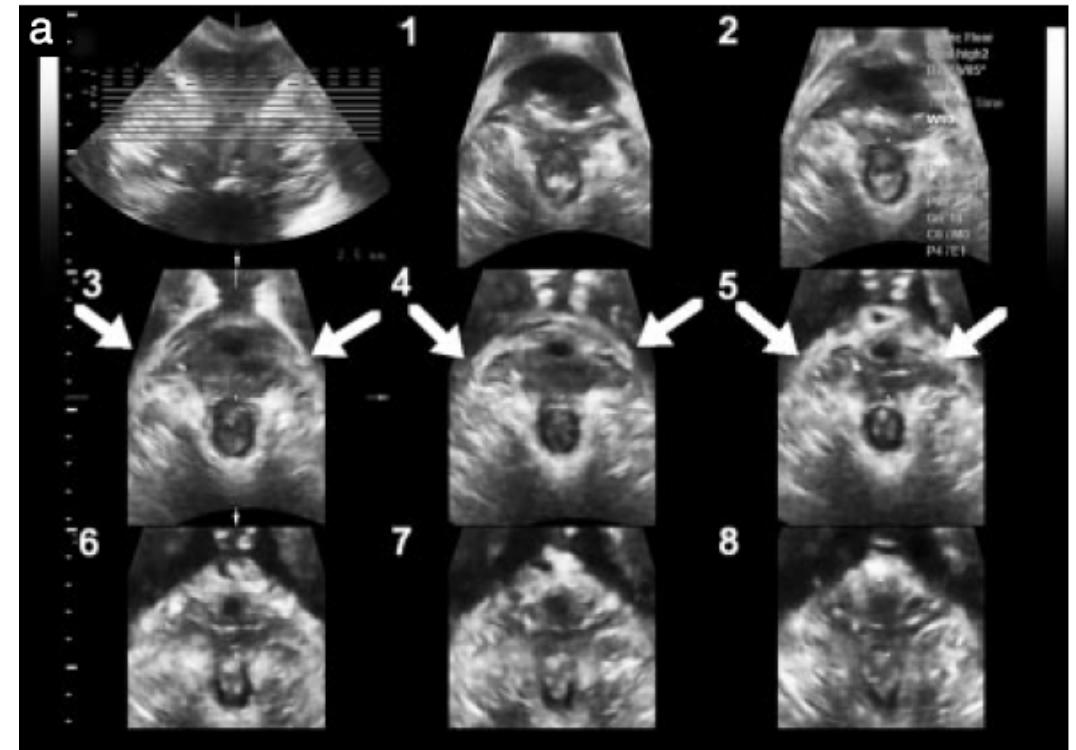
Avulsion diagnosed as discontinuity between the LAM and the pubic bone.



Full avulsion diagnosed if abnormal insertion observed in the 3 central slices



Method Internationally standardized and endorsed by AIUM, IUGA, ACR, AUGS, AUA, and SRU<sup>2</sup>



<sup>1</sup>Dietz et al. Ultrasound Obstet Gynecol. 2022 Nov;60(5):693-697. doi: 10.1002/uog.26034.

<sup>2</sup>AIUM/IUGA, ACR, AUGS, AUA, SRU. Int Urogynecol J. 2019 Sep;30(9):1389-1400. doi: 10.1007/s00192-019-03954-5



# LAM Avulsion: Association with POP<sup>1</sup>



Incidence of avulsions after first vaginal delivery—10-30%



Longitudinal data (median 11yrs)

- LAM avulsion “strongly associated” with the development of POP (OR 2.7; 95% CI 1.3-5.7) and symptomatic POP (OR 3.0; 95% CI 1.2-7.3)

## UROGYNECOLOGY

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### ORIGINAL ARTICLE

#### Pelvic Floor Disorders After Obstetric Avulsion of the Levator Ani Muscle

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Alvaro Muñoz, PhD,§ and Hans Peter Dietz, MD, PhD§

**Objectives:** With vaginal childbirth, 10% to 30% of women sustain levator ani muscle avulsion. The objective of this study was to estimate the cumulative incidence of prolapse and other pelvic floor disorders (PFDs), comparing vaginally parous women with and without levator avulsion.

**Methods:** Parous women enrolled in a longitudinal study were assessed annually for PFDs with the Pelvic Organ Prolapse Quantification Examination (for prolapse) and the Epidemiology of Prolapse and Incontinence Questionnaire (for stress incontinence, overactive bladder, and anal incontinence). Three-dimensional transperineal ultrasound was used to identify levator avulsion. Women with and without levator avulsion after vaginal delivery were compared for the cumulative incidence of PFDs. Further analysis also stratified by forceps delivery.

**Results:** At the time of assessment, 453 participants were 6 to 17 years from first delivery (median, 11 years). Levator avulsion was identified in 15% (66/453) and was more common among those who had undergone forceps-assisted delivery ( $P < 0.001$ ). Levator avulsion was strongly associated with prolapse beyond the hymen (odds ratio, 2.7; 95% confidence interval, 1.3-5.7) and with symptoms of prolapse (odds ratio, 3.0; 95% confidence interval, 1.2-7.3). These associations persisted after controlling for forceps-assisted delivery. In contrast, the odds of stress incontinence, overactive bladder, and anal incontinence were marginally (but not significantly) increased among women with levator avulsion in this cohort.

**Conclusions:** Obstetric levator avulsion is strongly associated with pelvic organ prolapse. The relationship between levator avulsion and other PFDs may not be significant.

**Key Words:** forceps-assisted vaginal delivery, obstetric levator ani avulsion, pelvic organ prolapse

(Female Pelvic Med Reconstr Surg 2019;25: 3-7)

Over the past decade, imaging studies have demonstrated obstetric levator ani avulsion after 10% to 30% of vaginal deliveries.<sup>1-3</sup> The risk of levator avulsion is further increased by forceps-assisted birth.<sup>2,4,5</sup> In studies comparing women with prolapse and controls, levator avulsion is significantly associated with prolapse.<sup>6,7</sup> Together, these observations suggest that levator avulsion may be an important risk factor for pelvic organ prolapse among parous women.

However, several questions are unanswered. First, what is the incidence of prolapse after levator avulsion (and how does this compare with the incidence among vaginally parous women without levator avulsion)? Second, given that forceps-assisted birth is a risk factor for levator avulsion,<sup>2,4,5</sup> and given that forceps-assisted birth is also a risk factor for prolapse,<sup>8</sup> can some of the association between

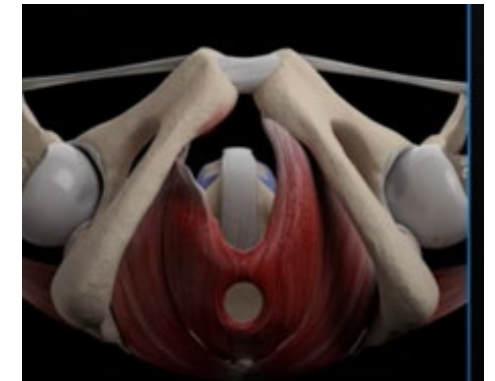
levator avulsion and prolapse be attributed to a confounding effect of forceps birth? Finally, is levator avulsion significantly associated with other pelvic floor disorders (PFDs), such as stress urinary incontinence, overactive bladder, and anal incontinence? This study was designed to address these questions in a cohort of vaginally parous women.

#### MATERIALS AND METHODS

Recruitment and data collection methods for this study have been previously described.<sup>9</sup> Data were derived from a supplemental study of the Mothers' Outcomes After Delivery (MOAD) study, a longitudinal cohort study of parous women.<sup>10,11</sup> Participants for the MOAD study were community volunteers, recruited 5 to 10 years after delivery of their first child and followed annually.<sup>11</sup> Administrative data were used to identify eligible women; their hospital charts were reviewed to verify eligibility and to confirm delivery type. Each participant provided written informed consent. Institutional review board approval was obtained for this research.

Participants for this supplemental study<sup>9</sup> were recruited from the MOAD cohort at an annual study visit between May 2015 and April 2017. During that interval, all participants with at least 1 vaginal birth were invited to join this substudy. Thus, sample size for this supplementary study was fixed by the size of the eligible population. Although the entire cohort included women who have delivered by cesarean, this supplemental study focused on women who had experienced at least 1 vaginal birth. As previously reported,<sup>11</sup> all participants in this substudy underwent 3-dimensional transperineal ultrasound. Ultrasound acquisition and interpretation were based on published protocols.<sup>12,13</sup> Imaging was performed by 1 of 3 experienced sonographers. Masked to the participants' obstetric history and symptoms, Acquisition was performed with a GE Voluson s6 system with a RA2-6-RS convex transducer (General Electric Healthcare, Chicago, IL). The ultrasound transducer, covered with a sheath, was applied to the perineum in the midsagittal plane. Three-dimensional ultrasound volumes were captured as cine loops at rest and with pelvic floor muscle contraction. Volumes were stored for later analysis.

The ultrasound volumes were analyzed off-line using GE 4Drive (General Electric Healthcare, Chicago, IL). The 2 examiners reviewing the ultrasound volumes (VLH and HED) were masked to obstetric history, to the physical examination, and to any symptoms. Validated methods were used to identify levator avulsions.<sup>13</sup> Specifically, tomographic ultrasound images were prepared from contraction volumes at 2.5-mm slice intervals, from 5 mm below to 12.5 mm above the plane of minimal hiatal dimension. The diagnosis

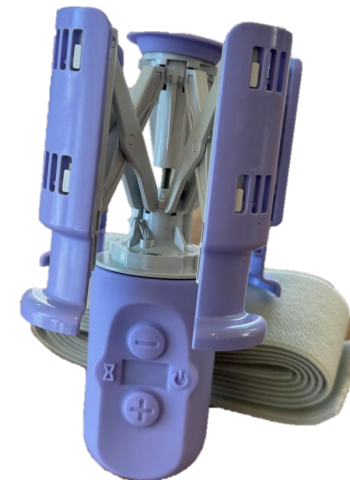
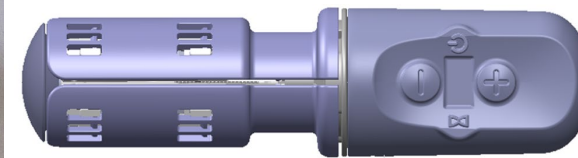


<sup>1</sup>Handa et al. Female Pelvic Med Reconstr Surg. 2019 Jan/Feb;25(1):3-7. doi: 10.1097/SPV.0000000000000644.



# Ellora™ Obstetrical System

- The primary component is an incremental, electromechanical obstetrical dilator, provided with an optional retention set
- The Ellora™ obstetrical dilator is inserted into the vagina to slowly stretch the pelvic floor muscles in preparation for vaginal delivery
- The Ellora™ retention set supports the dilator and maintains placement in the vagina during procedure
- The Ellora™ Obstetrical System is intended to be used by first time moms during labor to reduce the likelihood of injury to the LAM
- Avulsions of the LAM have been correlated to subsequent POP



# Peer-reviewed, published results

Published Clinical Outcomes (n=214)	Control group (no intervention)	Device group (Ellora™)	Reduction
Full Levator Ani muscle avulsion*	10.9% (7/64)	0.0% (0/46)	100%
Duration of 2nd Stage of Labor (Min in Delivery Suite)	104.7 (n=85)	92.7 (n=68)	11%
Postpartum hemorrhage (vaginal deliveries)	5.90% (5/85)	2.90% (2/68)	51%
Cesarean Section due to arrest of descent in Stage 2	6.93% (7/101)	3.66% (3/82)	47%
Brachial plexus injury	2.4% (2/85)	0.0% (0/68)	100%
Neonates with AE	18.8% (16/85)	11.8% (8/68)	37%
# Neonates with any SAE	4.7% (4/85)	1.5% (1/68)	68%
# Neonates with L&D Related SAE	3.5% (3/85)	0.0% (0/68)	100%

*\*LAM full avulsion reduction is statistically significant (p=0.05 with Fisher's Exact), analysis based on participants who received full treatment and returned for ultrasound. Secondary endpoints are not powered and did not have pre-defined statistical hypotheses.*

# Phase 2 Outcomes

## Published Results<sup>1</sup>

- Pelvic Floor Disability Index (PFDI-20)
  - Assesses presence of symptoms associated with pelvic floor disorders (urinary, fecal, sexual, pain)
  - Higher score means greater distress
- Pelvic Floor Impact Questionnaire (PFIQ-7)
  - Assesses impact of POP symptoms on activities, relationships or feelings
  - Higher score means greater impact
- Data reported below based on Phase 2 vaginal deliveries

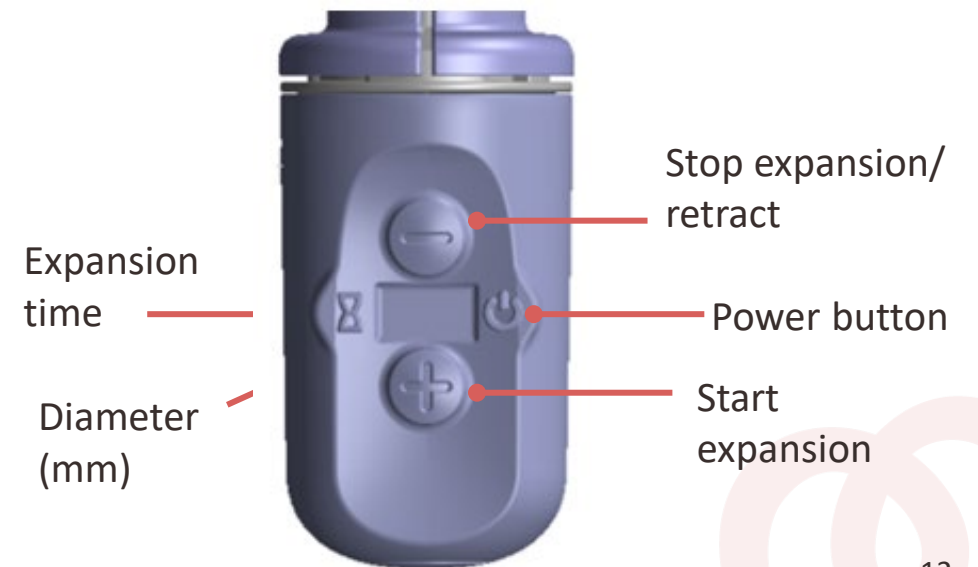
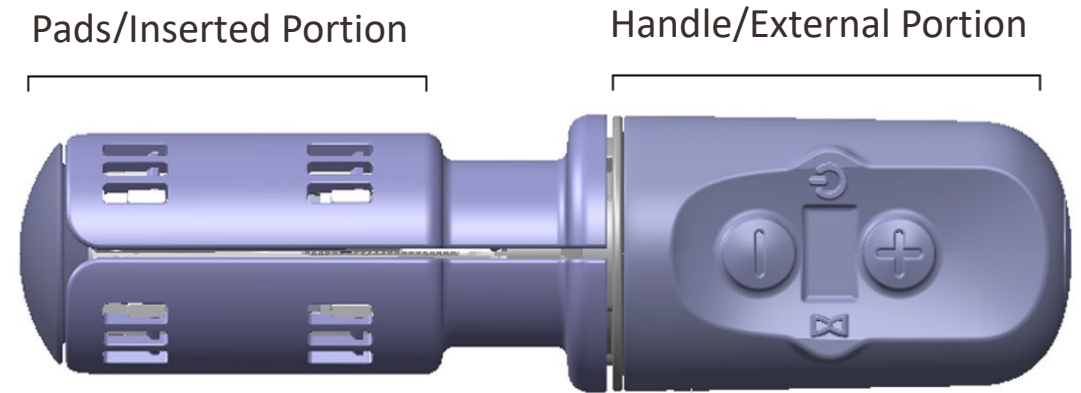
Category	Device <sup>2</sup>	Standard of Care	Delta
Subjects	54	66	-
PFDI-20	30.88	37.23	17.1% improvement
PFIQ-7	12.43	20.56	39.5% improvement

<sup>1</sup>Data on file at Materna; manuscript submitted for publication.

<sup>2</sup>Includes patients who received both partial and full device treatment

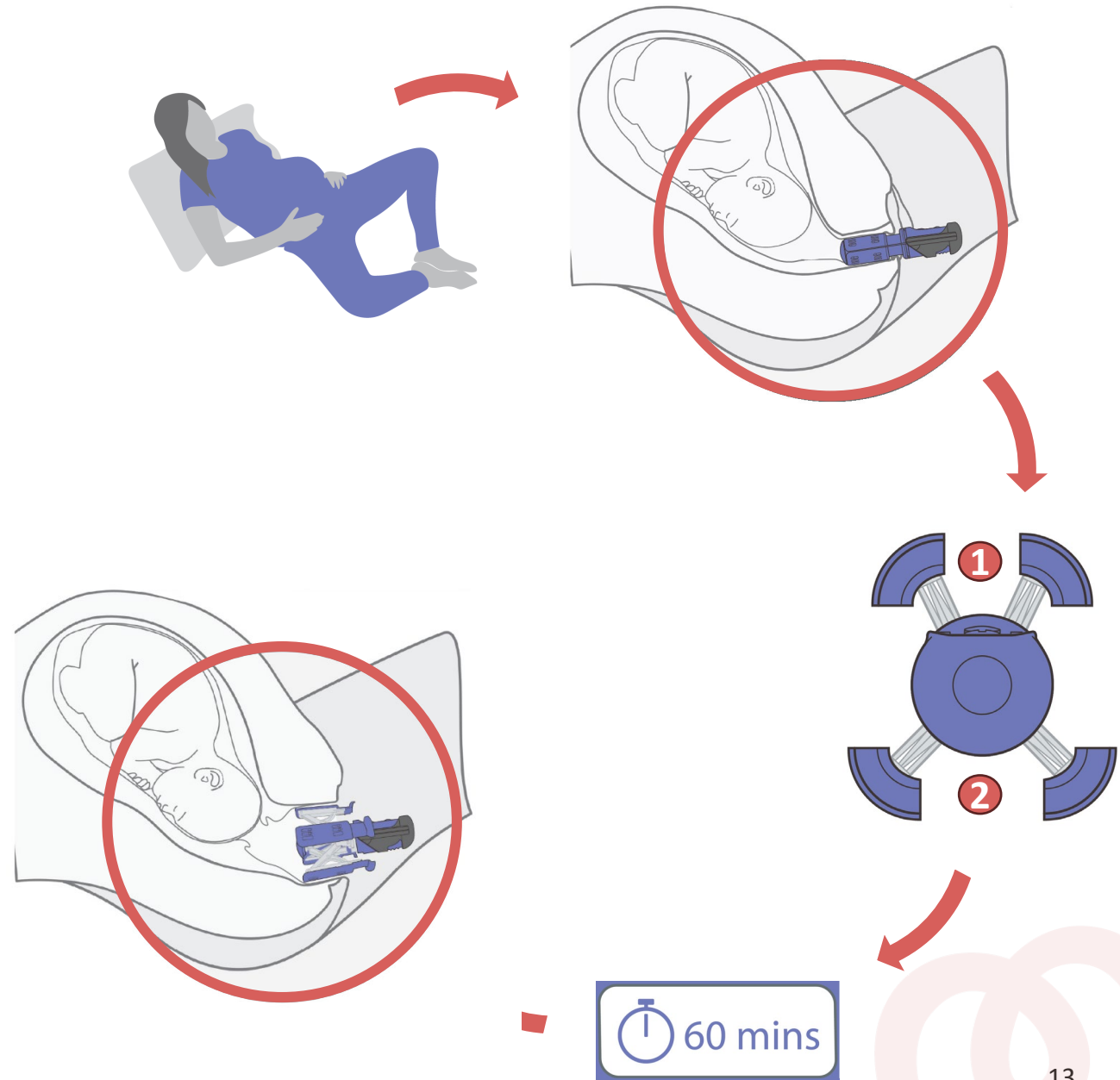
# Use Summary

- The Ellora™ obstetrical dilator is inserted during the first phase of labor in the active stage when the cervix is dilated 6cm or more, and contractions are consistent.
- Inserted by a trained healthcare professional licensed to deliver babies
- The Ellora™ obstetrical dilator slowly stretches vaginal canal and surrounding pelvic floor muscles to 8 cm in diameter to prepare for delivery and is removed before the 2<sup>nd</sup> phase of labor.
- The Ellora™ obstetrical dilator is single use and disposable.
- The handle display is used to start and stop expansion and indicates diameter throughout expansion.
- Safety features include
  - “Baby Bumper” notification senses forces on the distal end which could indicate fetal descent
  - Expansion force monitoring which will slow expansion if necessary to ensure stretching occurs at a safe rate



# Procedural Steps

- Position patient for insertion
- Insert device into birth canal so that pads are completely internal, the recessed portion sits at the vaginal introitus
- Initiate expansion
- Dilator will initially expand to 55mm
- Route urinary catheter between top arms (1)
- Route any ancillary devices (IUPC, FSE, etc.) between bottom arms (2)
- Expansion will continue for approximately 1 hour until device reaches 80mm.
- Remove Ellora™ Obstetrical System prior to phase 2 of labor



# Ellora™ Obstetrical System Documentation

- Documentation of the Ellora™ Obstetrical System would likely be found in the Labor and Delivery notes
- Alternate terms used to identify and describe the Ellora™ Obstetrical System
  - Ellora™
  - Ellora™ Obstetrical System
  - Ellora™ Obstetrical Dilator
  - Ellora™ Dilator
  - Ellora™ Retention Set
  - Retention straps
  - Retention adaptor



# Summary Slide

