Why participate in this study?

- Vaginal delivery is associated with **pelvic floor trauma**[1]
- Pelvic floor injury could lead to fecal incontinence and pelvic organ prolapse, two major forms of pelvic floor disorders[2]
- Women who have a vaginal delivery are 5x **more likely** to have **prolapse**[3]

Currently, there are no tools to reduce or prevent pelvic floor damage during vaginal delivery.

The **EASE Study** is evaluating if gradually pre-stretching the birth canal and surrounding pelvic floor muscles using the **Materna Prep device** before vaginal delivery could reduce pelvic injuries and shorten delivery time.

1. Ashton-Miller, 2009 On the Biomechanics of Vaginal Birth and Common Sequelae. Annual Review of Biomedical Engineering, 11, 163-176; **2.** Mant, 1997, May. Epidemiology of genital prolapse: observations from the Oxford Family Planning Association Study. British Journal of Obstetrics and Gynaecology, 104(5), 579-585.; **3.** Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE, Markland AD. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. Obstet Gynecol. 2014 Jan;123(1):141-148.

CL0018 Rev D

You may be eligible if you...

- Are a first-time mother, pregnant with one baby
- Are at least 18-years old
- Are planning for a vaginal birth at this hospital
- Plan to get an epidural

Study participants may receive:

- Monetary compensation for your time completing the follow-up visit(s)
- Reimbursement for your travel expenses
- 3-month diaper subscription ($249 value) after each ultrasound visit.

Interested?

Visit **EASEStudy.org** or scan this QR code for additional information.

Contact a member of our study team.

Name _____

Email _____

Phone _____

Materna MEDICAL

CL0018 Rev D

Are you pregnant with your first child?

You may be eligible to participate in a study evaluating how a new device may prevent pelvic floor injuries and reduce time in labor for first-time moms.

ease

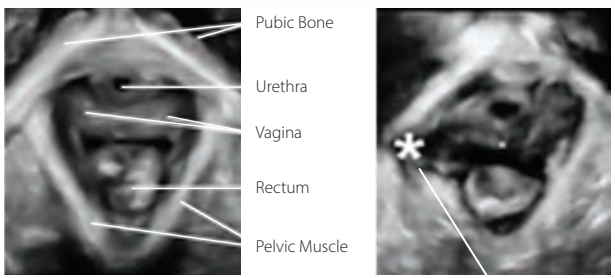
A study on how to protect maternal pelvic health.

Potential benefits that may help first-time moms:

- Shorten delivery time
- Prevent pelvic muscle injuries
- Minimize tearing
- Reduce need for instruments used during deliveries
  (use of vacuum or forceps to deliver your baby)
- Reduce need for C-section
- Improve neonatal outcomes
  (the baby's APGAR scores)
- Reduce maternal recovery time

The Materna Prep device is designed to help pre-stretch the birth canal and surrounding pelvic floor muscles over the course of one hour during labor.

Images below are of the same patient before and after vaginal delivery **without using Materna Prep**



Ultrasound **before** vaginal delivery

Ultrasound showing injury **after** vaginal delivery

What's involved?

Informed Consent

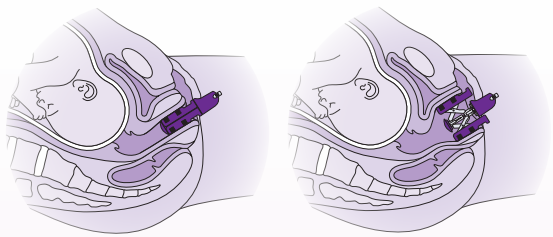
If you are eligible, you will be asked if you are willing to participate in this study. If you agree, you will be asked to sign an Informed Consent Form.

Day of Delivery

After you receive your epidural and a few hours before giving birth, you will be randomized to one of two groups:

1. *Participants who receive the device (device group), or*
2. *Participants who deliver without use of the device (control group).*

If you are assigned to the device group, Materna Prep will be inserted into your vagina and will gradually expand over about an hour. Before the baby arrives, the device will be removed. If you are assigned to the control group, you will deliver without using Materna Prep



Materna Prep inserted

Materna Prep inserted and expanded

Participants in both groups will continue in the study for approximately twelve months after delivery.

Six Weeks After Delivery

Data will be collected for the study when you return for your routine 6-week postpartum visit.

Three Months After Delivery

You will return for a study visit with a unique ultrasound to check on your pelvic floor muscles.

One Year After Delivery

You will return for your final study visit with a unique ultrasound to check on your pelvic floor muscles.

What else should I know?

You may not be able to participate in this study if:

You are delivering more than one baby (e.g., twins, triplets, etc.), if this will not be your first time giving birth, or if your doctor does not feel you are a good study candidate. Additionally, if you will not be available to return for the 3 and 12 month study visit and ultrasound, you will not be eligible to participate.

What are the risks?

As with any device inserted into the vagina, there is the risk of infection and damage vaginal/perineal tissues and surrounding muscles. The Materna Prep device is an investigational medical device, so there may be risks that are unknown at this time. The Materna Prep device has been categorized as a non-significant risk device.

Will using the device hurt?

The device is placed after you have had your epidural, and your clinician will adjust your pain medication as needed. The device also may be removed quickly if necessary.

CAUTION: Investigational Device. Limited by United States Law to investigational use.