EASE Clinical Study Phase 3 Underway!

Materna Medical is currently recruiting potential participants for Phase 3 of the EASE clinical study of the investigational Materna Prep Device.

- *Phase 1 of the EASE study enrolled over 100 participants between 2020-2021 and evaluated an earlier version of the Materna Prep Device.*
- *Phase 2 of the EASE study, which included the current version of the device, enrolled over 200 participants between 2021-2022.*
- *Phase 3 began in 2023 and will enroll over 300 subjects.*

The EASE study is primarily designed to determine if use of the Materna Prep Device can reduce the risk of pelvic floor muscle injury that can occur with vaginal childbirth and that is associated with subsequent pelvic organ prolapse.

Results from Phase 2 of the study comparing the incidence of pelvic floor injury in the group of study participants who received the Materna Prep Device (Device Group) to the group who received standard of care without the use of the Materna Prep Device (Control Group) are now available.

The pelvic floor muscle injury rate was 83% lower in the Materna Prep Device group than in the group that did not receive the Materna Prep Device.

	Rate of significant pelvic floor muscle injury	Phase 2 Participants total = 120*
Prep Device Used	**1.8%**	**n = 56**
Prep Device Not Used	**10.9%**	**n = 64**

**Number of study participants who delivered vaginally and returned for 3-month ultrasound*

The most common Materna Prep device-related adverse events were vaginal abrasion, bruising, and bleeding. In almost all cases, these adverse events were reported and characterized as minor.

It is important to note that the Materna Prep Device is an investigational device, and the FDA has not yet reviewed the Phase 2 results from the EASE study. The data represents only a potential benefit of study participation in Phase 3, and no claims of safety or effectiveness can be made at this time.

Please review the informed consent form for a full discussion of potential risks and benefits.

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