

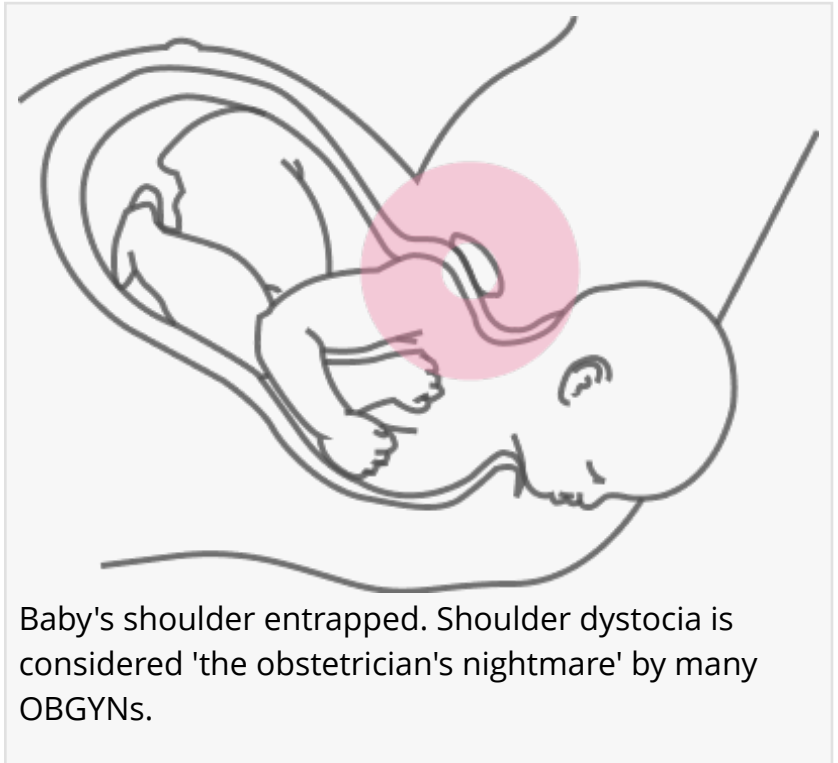
FetalEase Initiates IDE Pivotal Clinical Study and Appoints Anne Geary Schmults as Vice President Marketing and Sales

Company announces initiation of IDE pivotal clinical study for the Yaari Extractor with enrollment underway at initial US clinical site.

HAIFA, NONE, ISRAEL, January 16, 2024

/EINPresswire.com/ -- [FetalEase](#)

announces the initiation of its IDE pivotal clinical study for the Yaari Extractor. Enrollment is already underway at its initial US clinical site with additional US sites to join the study over the coming months. The Yaari Extractor is a medical device intended for the treatment of shoulder dystocia, a serious complication during labor and delivery. There are currently no medical devices available to treat this condition. The IDE pivotal clinical study will evaluate safety and effectiveness of the Yaari Extractor device for its intended use. The data generated from this study will be used to support a marketing application to the FDA.



Baby's shoulder entrapped. Shoulder dystocia is considered 'the obstetrician's nightmare' by many OBGYNs.

In parallel, the company has announced the appointment of Anne Geary Schmults as its Vice President of Marketing and Sales. In this role, Anne will be responsible for the preparation and implementation of the Yaari Extractor's release to market.

Anne has served in various senior commercial roles in the medical device industry including in the high-risk obstetrics market. Previously, Anne was the Director of Business Development at Alydia Health, a company that commercialized the Jada device for the treatment of postpartum hemorrhage, which was acquired by Organon. Additionally, Anne served as a Business Development Consultant at Safe Obstetric Systems, a company that commercialized the Fetal Pillow, acquired by Cooper Surgical. Anne held sales leadership positions at Stryker, Kyphon (acquired by Medtronic), Spine Tech (acquired by Sulzer Medica), and Johnson and Johnson. She currently serves on the Board of Directors of the New England Medical Innovation Center Foundation.



Anne brings to our company a successful track record in launching innovative devices for obstetric emergencies and we are thrilled that she will be leading this process for the Yaari Extractor."

*Aaron Feldman, FetalEase
CEO*

"With our IDE pivotal clinical study in progress, we are now looking ahead and preparing for bringing our Yaari Extractor to US OBGYNs once market clearance is secured. Anne brings to our company a successful track record in launching innovative devices for obstetric emergencies and we are thrilled that she will be leading this process for the Yaari Extractor", stated Aaron Feldman, FetalEase's CEO.

"I am excited to be joining the FetalEase team at this important time in the company's development. It is an honor to work with the well-respected FetalEase team and

team of clinician advisors to address the maternal and fetal morbidities and mortalities in two percent of births due to shoulder dystocia", noted Schmults.

About Shoulder Dystocia:

Shoulder dystocia is a rare but feared obstetric emergency in which the baby's head has been born but one of the shoulders becomes stuck behind the mother's pubic bone, delaying the birth of the baby's body. The dystocia must be dealt with within 5-7 minutes to prevent serious injury or death to the baby and is currently managed by a series of manual maneuvers which are intended to release the baby's shoulder. Shoulder dystocia and the use of manual maneuvers can result in maternal injury as well as injury, permanent disability, and death to the baby, with the most common injury being brachial plexus injury (BPI).

About the Yaari Extractor:

The Yaari Extractor is a mechanical device that is intended to resolve shoulder dystocia by removing the impacted anterior fetal shoulder from behind the maternal pubic bone and moving it to a position where it can be delivered, without applying traction to the fetal head or brachial plexus. The device, invented by Dr. Abraham Yaari, an OB/GYN with over 20 years of experience delivering babies in the U.S. and Israel, has been successfully used in initial clinical cases as part of a First-in-Woman study at the Suyog Women's Hospital in Mumbai.

About FetalEase:

FetalEase Ltd. is a privately held Israeli start-up company founded in 2016 to develop the Yaari Extractor and to commercialize it worldwide.

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