term affirm

URL: www.termaffirm.com

Industry: Non-Invasive Prenatal Diagnostics; Medical Devices; Women's Health

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Overview

Term Affirm is a pre-clinical stage startup which aims to prevent preterm birth, specifically the etiology of cervical insufficiency. We provide a complete solution to preterm birth with both an ultrasound-based diagnostic tool and a patient-specific therapeutic device. The diagnostic uses standard ultrasound equipment to 1) take maternal anatomical dimensions, 2) import them into a finite element algorithm, and 3) calculate cervical deformation due to pregnancy loads. The device is a cervical pessary which mechanically supports the cervix throughout pregnancy to prolong gestation. Device personalization is based upon uterine dimensions obtained during the diagnostic ultrasound scan at 18-20 weeks gestation. It is a safe, affordable, and effective way to prevent preterm birth.

Unmet Need - Reducing the Rate of Preterm Birth

Preterm birth is the leading cause of death in children under the age of five, reaching 1 million annually. Each year there are an estimated 182,000 cases of cervical insufficiency in the US and EU. As many as 95% of cervical insufficiency cases are intractable to current therapies.

The average cost of a preterm newborn's first year of life is over ten times that of a normal term baby's ($49,000 vs. $4,500). Furthermore, preterm birth often leads to lifelong health complications such as cerebral palsy, asthma, and numerous learning disabilities, and has an estimated societal cost of $26 billion in the United States each year.

Product - Ultrasound-Based Diagnostic Algorithm

Obstetricians or sonographers will augment the current standard of care in pregnancy ultrasound. In addition to the routine fetal anatomy scan performed at 18 weeks, a maternal anatomy scan will be performed to extract 15 dimensions, which inform the Term Affirm diagnostic algorithm. Computational results can be reported within 30 minutes.

Product - Patient-Specific Cervical Pessary

Using the dimensions obtained during the maternal anatomy scan, a silicone device will be custom-built to each individual patient's anatomy using the latest additive manufacturing techniques. This device is inserted around the cervix during a routine speculum exam, and is kept in place until 37 weeks gestation.

Target Market & Customers

Initially, Term Affirm will target the Maternal Fetal Medicine Units (MFMU) Network's 12 institutions in the United States. With ~220,000 patients per year at these institutions, our target market is $32.9M for the diagnostic, $312M for the device, totaling $345M annually.

The doctors and hospitals in this market are the champion, pregnant patients are the end-user, and we anticipate insurance companies to be the economic buyer.

Business Model

Revenue for the diagnostic will be collected on a per-test basis, with pricing comparable to current obstetric ultrasound scans at $150.

The medical device revenue is value-based at $7,128, where Term Affirm captures 30% of the value created and the insurers and healthcare providers collect the remaining 70%.

Competitors

The current standard of care in cervical insufficiency diagnosis is a sonographic measurement of cervical length, with a length less than 25mm representing a high risk. With an additional 14 dimensions and patient obstetrical collected, the Term Affirm diagnostic will produce more sensitive and specific results.

The cervical pessary has surgical, hormonal, and device competitors. The most direct competitor is the Arabin pessary, which is not custom-fit, and has unproven efficacy results in clinical trials. The Term Affirm pessary reduces tissue contact stresses seen in Arabin pessary use, which delays cervical structure remodeling and softening.

Value Proposition:

- Diagnose, delay, and prevent preterm birth
- Non-surgical
- Minimally invasive
- Lower cost than surgical and hormonal therapies
- Personalized medicine
- Decreased risk
- Delays cervical remodeling and softening

Intellectual Property:

- International (PCT) patent filed March 3, 2017 by Columbia University
- "Devices and Methods for Minimizing Likelihood of Preterm Birth"
- Claims: A method for minimizing a likelihood of preterm birth in a patient, based on the steps of sonographically measuring uterine and cervical dimensions, and designing a customized pessary.

Regulatory:

- Ultrasound scans will follow laboratory developed test (LDT) protocol – does not require FDA approval
- Pessary is Class II device
- FDA De Novo submission

Manufacturing Process:

- 3D printed silicone

Financials:

- $1.2M in NIH R01 grant received February 2017 for feasibility studies of diagnostic
- $65k from private clinic in Utah for diagnostic algorithm refinement
- Additional $7M needed for clinical trials to bring both products to market by 2023

Team

Andrea Westervelt, MS

Founder & Co-Inventor
PhD candidate at Columbia University in Mechanical Engineering; 5 years in biomechanics research and medical device design; PhD thesis topic on finite element modeling of pregnancy

James Croke

Business Development
Previously Enterprise Ireland, responsibility for >30 seed investments with $10M in funding; Diplomas in Strategy & Innovation and Entrepreneurial Studies