Daylight®

FETAL HEAD ELEVATOR

Pennvention

February 2016

Daylight Team

Management Team:

- Neil Bansal (President, CEO) – Pursuing MBA from Wharton with concentrations in Health Care Management and Entrepreneurship
  Aaron Fisher (Director, COO) – Pursuing MBA from Wharton with concentrations in Health Care Management
  Christina Wry (Director, Chief Clinical Officer) – Pursuing dual degree MBA from Wharton and MD from Penn Medical
- Liz Golden – (Director, Chief Strategy Officer) – Pursuing dual degree MBA from Wharton and Masters of Engineering from Penn Engineering
- Eric Tepper – Pursuing BA in Health and Societies with a concentration in Health Care Markets and Finance from the Penn College of Arts and Sciences

Select Advisors:

- Dr. Rosemary Leitch: Daylight inventor and OB/GYN at Parkview Health
- Dr. Vincenzo Berghella: Director of Maternal-Fetal Medicine at Jefferson University Hospital
- Bill McLain: Regulatory affairs and quality systems consultant at Keystone Regulatory Service
- Michael Schwartz: Intellectual property attorney at Faegre Baker Daniels
- Robert Town, PhD: Professor at Wharton in medical devices
- Matthew Grennan: Associate Professor at Wharton in health care marketing and entrepreneurship

Executive Summary

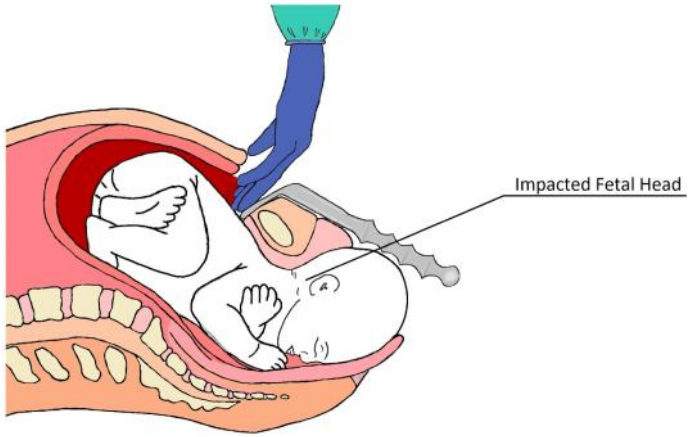
- Daylight OB, LLC is developing a disposable obstetrical instrument, called Daylight, used to reposition a baby for an urgent cesarean delivery
- The device will replace an ineffective and unsafe manual method of repositioning that often requires extending incisions to the uterus and cervix, is associated with longer delivery times, and unnecessarily exposes clinicians to communicable disease transmission
- Daylight is applicable to over 80,000 urgent cesarean procedures annually in the U.S.
- Received a Notification of Allowance from the USPTO regarding patent application 13/904,528 and we are preparing to file additional patents based to strengthen our IP positioning
- Daylight is a Class II 510(k) exempt device with a clear regulatory pathway per FDA guidance
- Developed a medical grade prototype and finalizing designs to begin biocompatibility and bench testing at a contract manufacturing facility

Ineffective Delivery Method for Arrest of Descent

The Problem: Arrest of Descent is the failure of a baby to continue to descend for one hour during labor. This birthing complication requires a physician to call for a cesarean procedure, however, a simple cesarean procedure is not always feasible because the baby has already started to descend and the head cannot be reached through the cesarean incision in the abdomen. The current manual method for repositioning a baby for cesarean deliveries caused by arrest of descent is ineffective and unsafe. The procedure exposes clinicians to communicable disease transmission, is associated with a 6x higher risk of extending the cervix incision and 9x higher risk of a cesarean delivery lasting greater than 90 minutes, as well as incidence of fetal asphyxia and skull fracture

Market Size: Globally, physicians have published research on poor outcomes associated with arrest of descent and difficulties with the current manual repositioning procedure. It is estimated that Daylight is applicable to over 80,000 births annually in the U.S. Including Europe and Canada the market opportunity expands to beyond 200,000 births annually. Given the global nature of this birthing complication, high birth rate countries in Asia, such as India and China, offer significant expansion opportunities.

Arrest of Descent

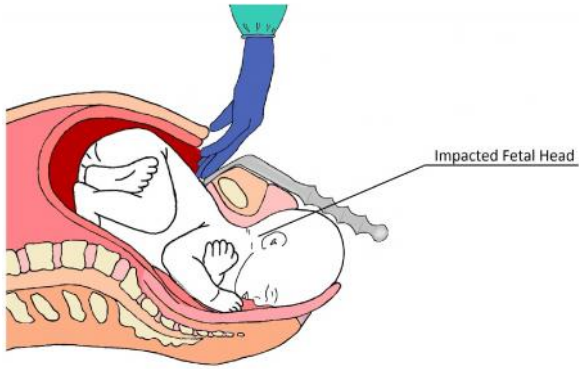


Current Repositioning Method

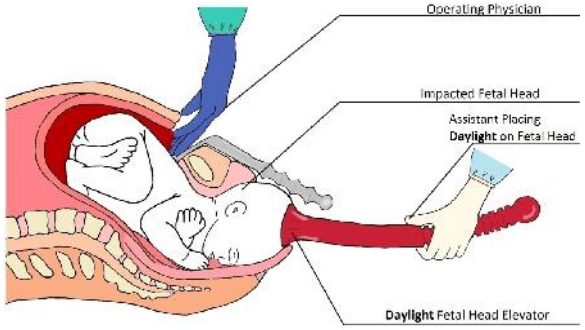
Daylight is a safer, faster, and easier repositioning method

The device eliminates the need to extend the cervix extension and reduces delivery times by allowing clinicians to utilize leverage, while maintaining tactile control, to more easily and effectively reposition the baby for delivery

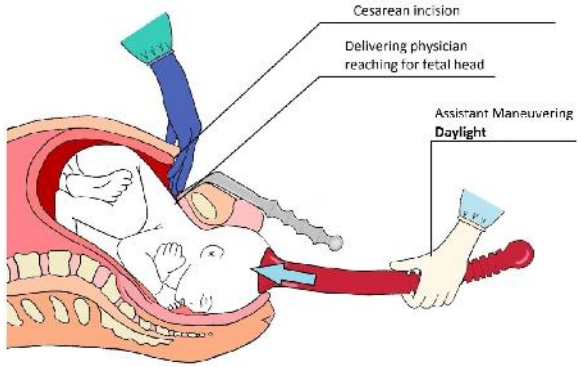
Fetal head must be elevated



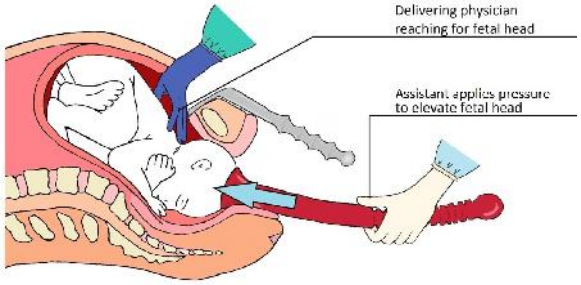
Daylight is applied



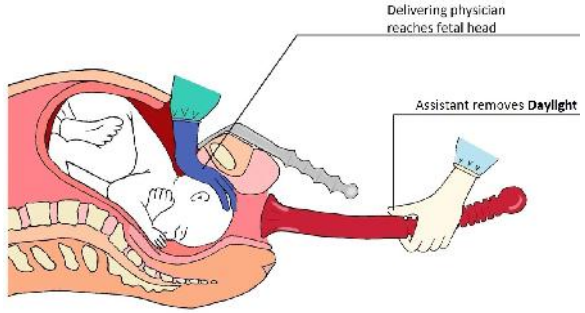
Assistant applies controlled force



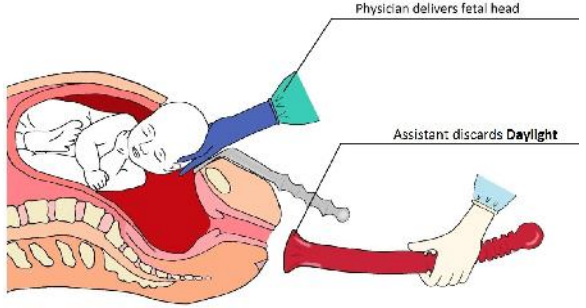
Surgeon reaches fetal head



Daylight is Removed



Cesarean progresses as normal



Daylight Key Achievements and Upcoming Milestones

Key Achievements

Key Achievements to date have cost $50,000

- Developed initial medical grade prototype
- Received notification of allowance for initial patent application from USPTO
- Obtained Class II 510(k) exempt classification guidance from FDA via 513(g) filling
- Conducted over 40 physician interviews and reviewed available research to validate market size and need
- Formed development company Daylight OB, LLC
- Recruited management team and significant team of advisors
- Developed pricing strategy
- Conducting RFP process with manufacturers
- Received two rounds of funding from the Wharton Innovation Fund
- Progressed into Wharton Business Plan Competition Semi Finals

Upcoming Milestones

Milestones are budgeted to cost $150,000

<u>February - March 2016 ($10,000)</u>

- Select injection molding manufacturer
- Finalize material selection for handle and cushion
- Determine sterilization process
- Finalize daylight designs
- Select Daylight packaging

<u>April – May 2016 ($120,000)</u>

- Create mold for injection molding manufacturing
- Complete axial loading and other strength and bench testing
- Complete biocompatibility testing
- Outline IRB process
- New patent applications
- Formation Scientific advisory board

<u>June – July 2016 ($20,000)</u>

- Select one to two site for marketing study
- Register with FDA