

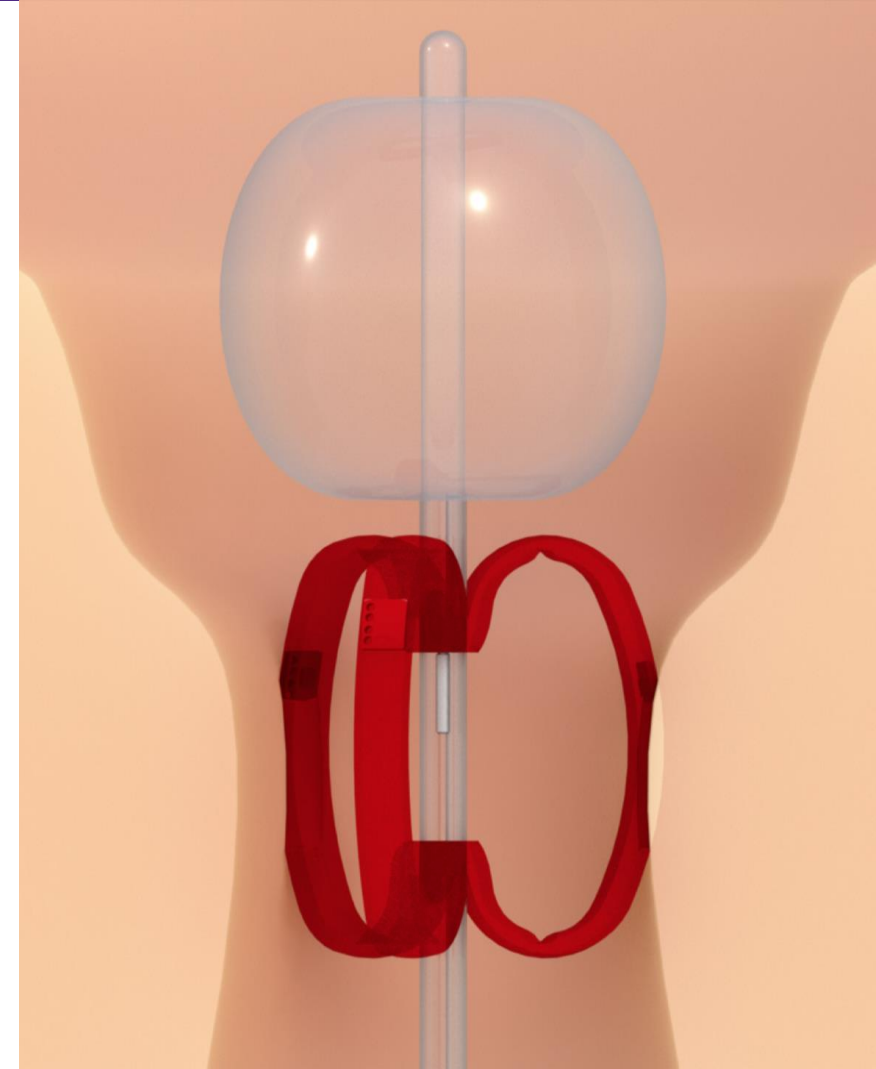
THE BUTTERFLY SYSTEM

**Electronic Cervical Ripening &
Monitoring System for Induction
of Labor**

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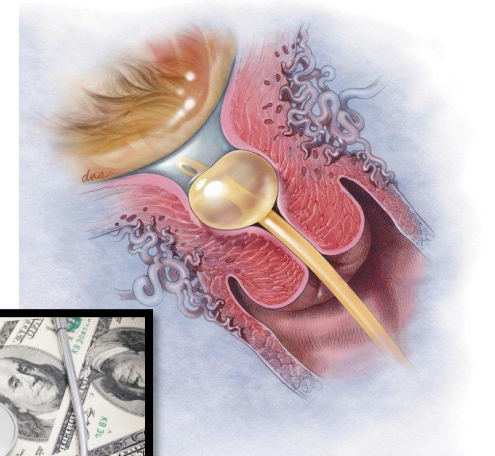


Problem Statement

- 23% of labors in the U.S. are induced
- 2 induction methods: **mechanical** & pharmacological

Current problems:

- Measurements are taken every ~5 hours
- Reaching active labor takes over 6-12 hours
- Every check increases infection rate
- Lack of devices to track progress of cervical ripening in real-time
- Need for early patient hospitalization



Our Solution

BUTTERFLY Monitoring System

- Taps into an existing medical indication (CRIB) adding an expanding monitoring feature
- Real-time monitoring for providers and patients replacing the “Finger Measurement” of dilation
- For in-patient **and** outpatient use
- Reduce the amount of time and resources required for mechanical labor induction

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Butterfly Technology Features

Measurement accuracy

+/- 0.5 cm

Vertical measurement spatial frequency

3 points along vertical length of cervix spanning 3 cm

Diameter measurement range

1.3 cm - 5 cm

Measurement recording

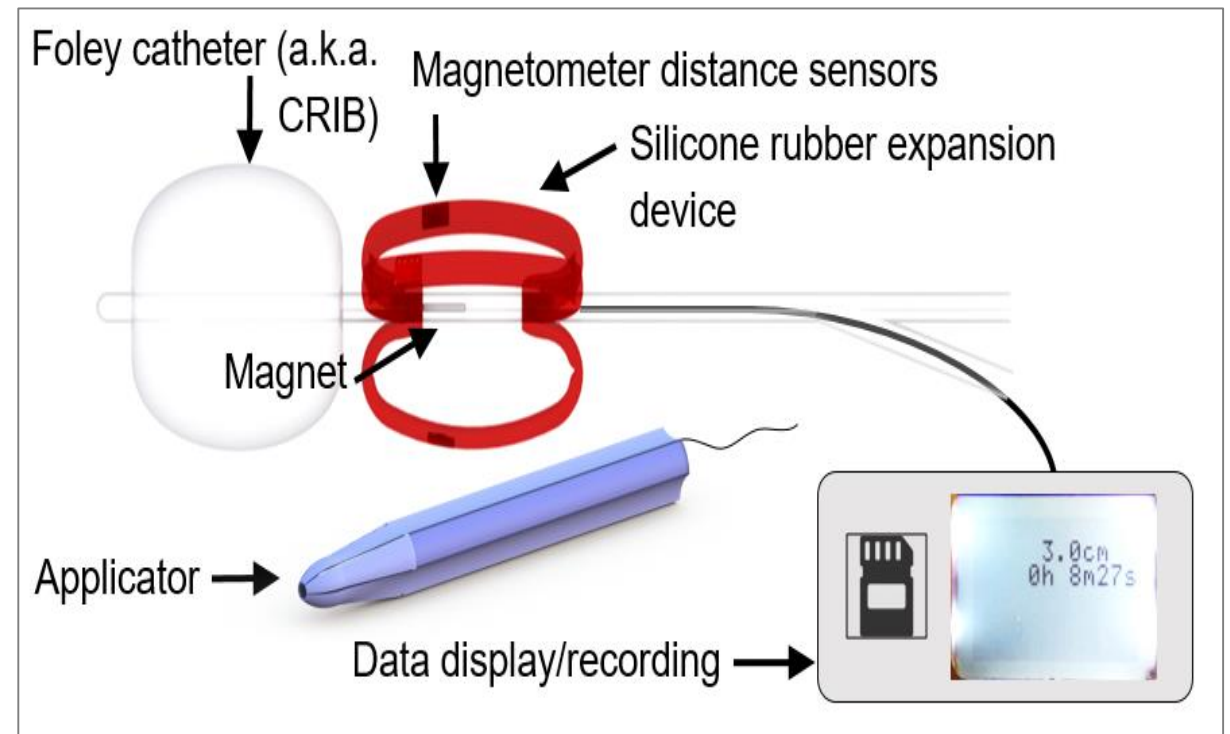
Taken every 2 seconds

Saved to SD card

Displayed on an LCD screen

Safety

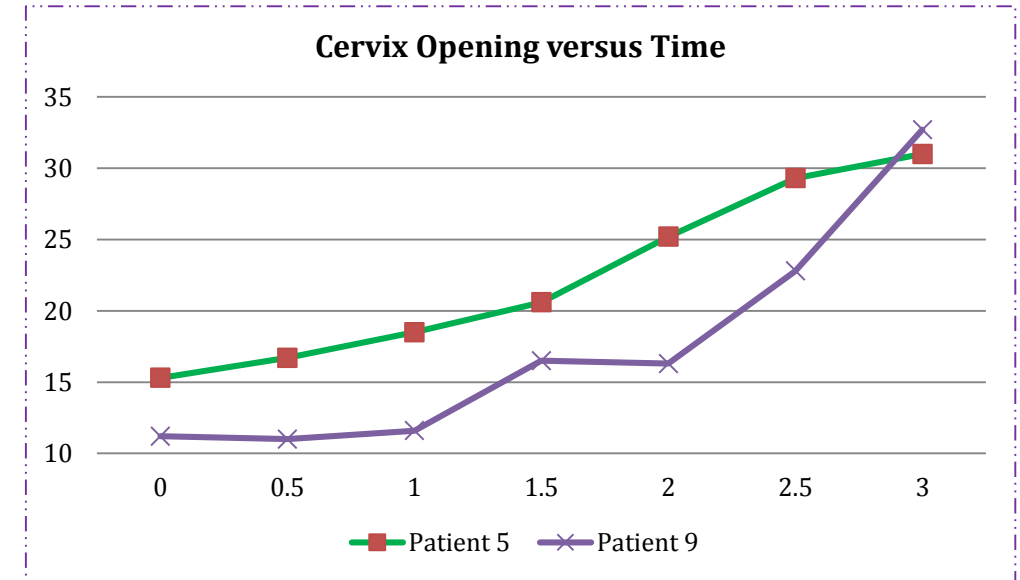
Biocompatible materials



Uniqueness – Preliminary Clinical Data

Key Features:

- Cervical Ripening + Continuous Monitoring
- Portable
- Wireless Connectivity/Remote monitoring



Y-axis: Cervical dilation (mm)

X-axis: Cervical Ripening (Hours)

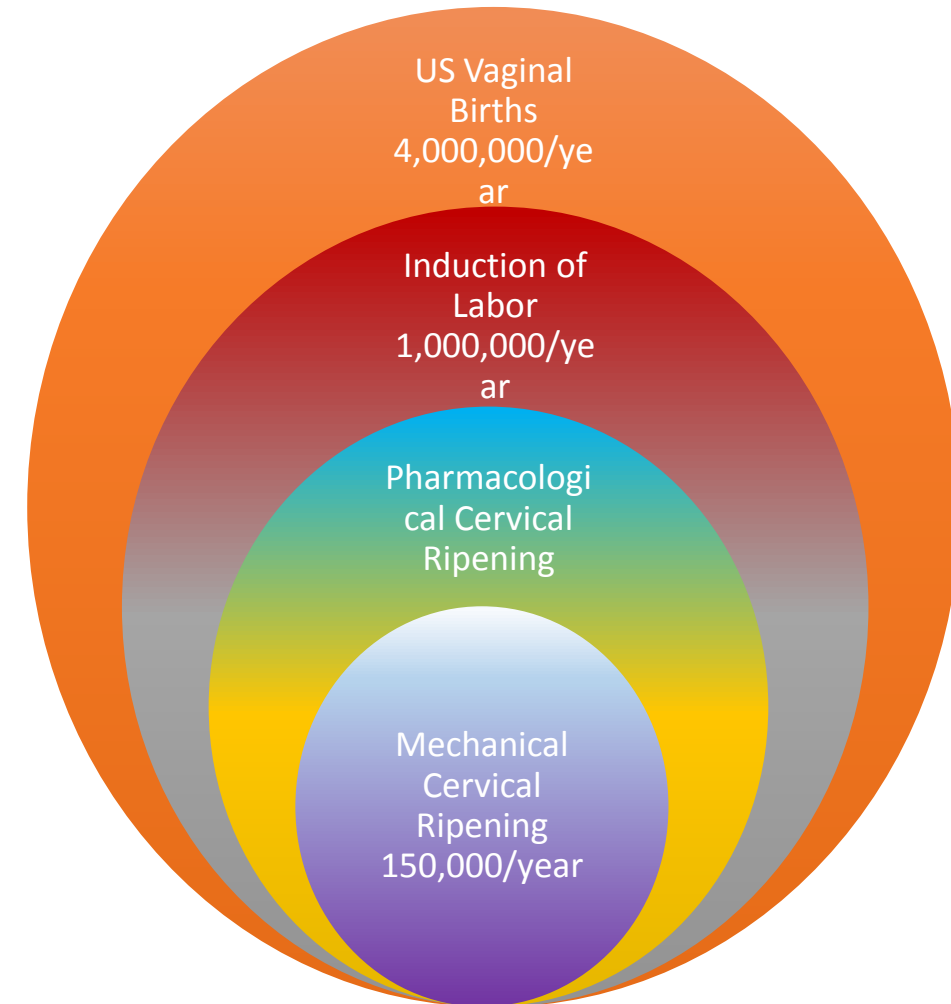
Clinical Need – Market Opportunity

4 million babies are born every year
1 million are born from an induced labor

Approximately 15% of induced labors are through
mechanical induction
150,000 market size every year

Unique design and niche market justifies
an ambitious 1st year market penetration

At 1% penetration: goal 1st year sales = 1,500 units sold



Business Model

Reduced time = Improved Efficiency = **Increased Revenue**

	Current System		BUTTERFLY Monitoring System *
<u>Time</u>			
• Cervical Ripening	9 ± 3 hours	↓	2 - 9 hours
• Induction of Labor	10-36 hours		10-36 hours
<u>Cost</u>			
• Healthcare Providers	\$\$\$	↓	\$ TBD
• Hospitals, Insurers, Patients	\$\$\$	↓	\$ (~\$48)
<u>Induction Fee Bundles @NU:</u>			
US\$256 mechanical / pharmacological	US\$1,220 induction /augmentation <24 hrs		US\$1,646 fetal monitoring & nursing

Intellectual Property

Two US provisional application and one PCT Utility application are filed

<u>Internal No.</u>	<u>Country of Filing</u>	<u>Status</u>	<u>Type</u>	<u>Application Serial Number</u>	<u>Application Date</u>
<u>2015-113-01</u>	United States	Expired / Converted	Provisional	62/256,547	Nov 17, 2015
<u>2015-113-02</u>	(PCT App)	Filed	PCT	PCT/US2016/062441	Nov 17, 2016
<u>2015-113-03</u>	United States	Filed	Provisional	62/518,993	Jun 13, 2017

Competition

	<u>Maasal cervical dilator</u>	<u>Cervical dilation measurement instrument</u>	<u>Cervical dilation measuring device</u>	<u>Cervix dilation and labor progression monitor</u>	<u>Transvaginal Sonography</u>	BUTTERFLY System
Safety During Induction of Labor	-	-	-	+	+	+
Portability	-	-	-	-	-	+
Dilation/Ripening	+	-	-	-	-	+

Team



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Obstetrical Anesthesiologist
Assistant Professor
Northwestern University



Robert McCarthy, PharmD
Research Professor
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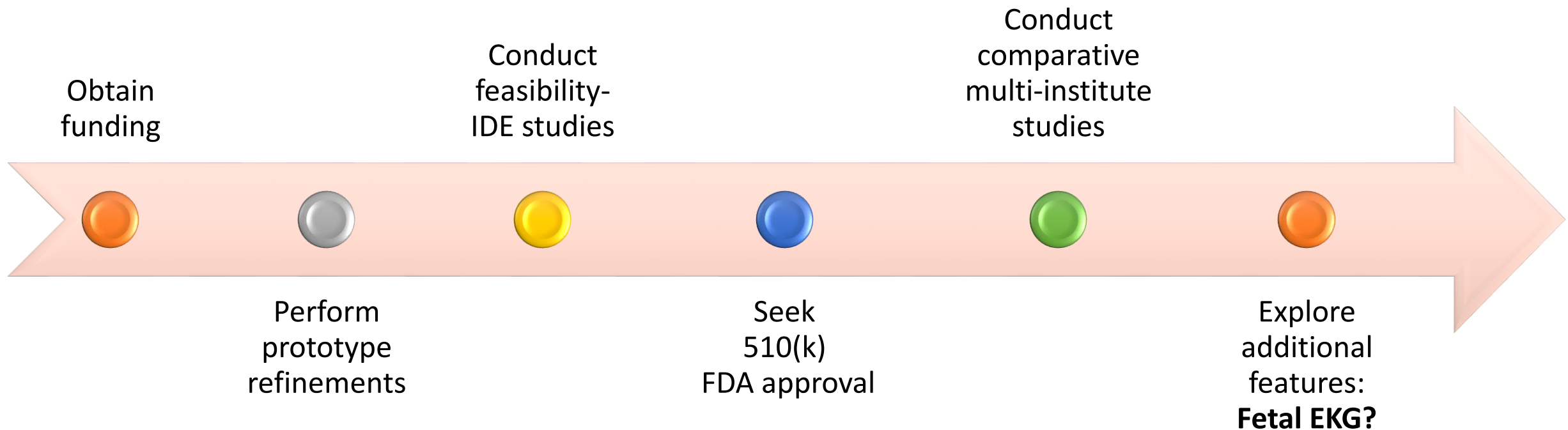


Alan Peaceman, MD
Professor of Obstetrics
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Next Steps



The Summary

- ✓ Untapped problem in women's health
- ✓ **Enhanced experience during induction at labor & delivery (reduce hospital stays)**
- ✓ Real-time monitoring of cervical dilation during cervical ripening
- ✓ **Accurate and sensitive information of progress; eliminating manual process**
- ✓ The BUTTERFLY system will change the clinical paradigm of labor induction