OBSTETRICAL CATHETER
PREVENT THE PRIMARY SECTION

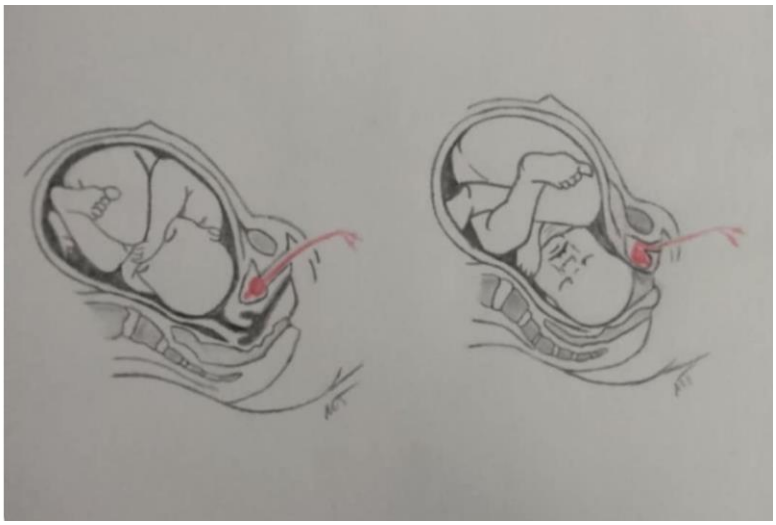
FOR DONORS AND INVESTORS

PURPOSE

We are a diverse group with a common goal to develop a medical device that will reduce the rate of primary cesarean section from failure to progress in labor while preventing injury to sensitive maternal tissues. Currently, sixty percent of primary c-sections are thought to result from failure to progress. The obstetrical catheter should reduce that number by twenty percent. This equates to preventing cesarean sections in approximately 45,000 laboring mothers in the United States and over 2,000,000 Worldwide.

The obstetrical catheter is an improved indwelling urinary catheter of the inflatable type having a unique, low-profile shape by which to retain the catheter within the bladder, so that urine can be removed therefrom while avoiding obstruction to the descending fetal vertex during the process of labor and delivery. This makes the device better suited for obstetrical applications. The retaining device consumes less obstructing volume in the bladder than that which would ordinarily be consumed by a conventional Foley-style balloon, whereby both the frequency and severity of fetal vertex obstruction and its resulting increased time of labor, operative delivery and injury to maternal urologic tissue can be reduced. The obstetrical foley retains the traditional Foley-style balloon distal to the improved low-profile laboring balloon for insufflation in the event a surgical delivery by cesarean section is indicated. The traditional balloon with its larger volume allows easy identification of the bladder during surgical delivery. This unique design allows the added advantage of multiple options and uses in a single catheter without the need of changing catheters.

PROBLEM

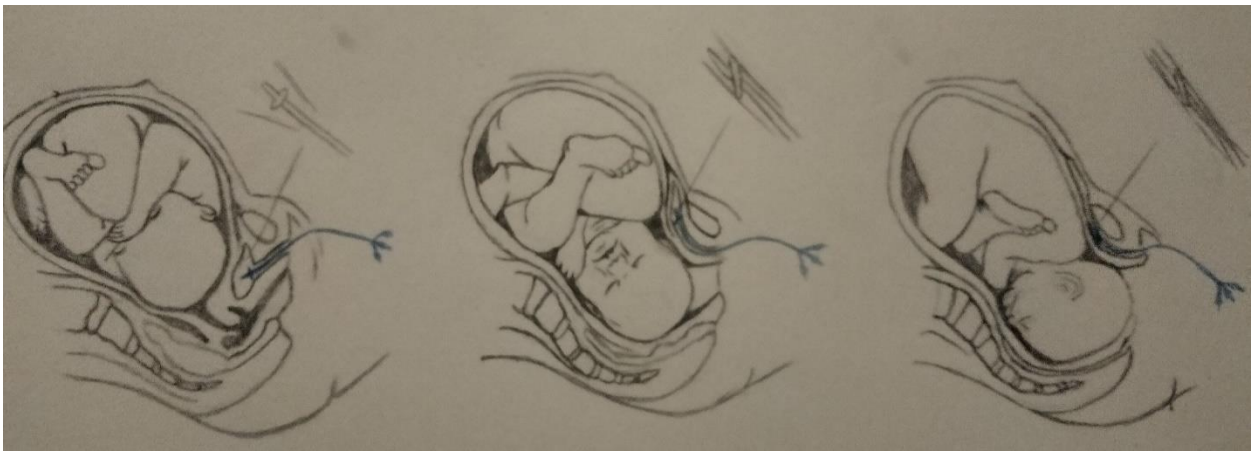


Known to those skilled in the art, a conventional 10cc Foley catheter is inserted into the female urethral opening and through its length into the urinary bladder of a female patient until the proximal end of the catheter contacts the upper wall of the patient's bladder. The Foley catheter balloon is then inflated, while in situ, and the catheter is retracted slowly until the inflated balloon encounters some resistance against the lower bladder wall. The inflated balloon retains the catheter within the bladder so that urine can be removed therefrom and delivered to a bladder bag for disposal.

However, there are several significant problems which may arise as a consequence of using a conventional Foley catheter during the labor process. More particularly, an inflated Foley balloon typically assumes a spherical configuration which consumes a relatively large volume within the patient's bladder and therefore by direct extension impending on the volume of the birth canal. The large volume consumed by the Foley balloon and in its current spherical configuration correspondingly increases the occurrence of direct obstruction of the descending fetal head and the arrest of the labor process and resulting increase in the rate of cesarean section. With prolonged obstruction the occurrence of injury to maternal urethra and bladder may occur resulting in loss of the physiological angle of the urethra, incontinence, and other chronic urinary complaints which may require surgical correction or lead to chronic pain.

An observational study which included over 1,500 patients over a 5-year period compared the inflated traditional foley catheter to that of a deflated foley catheter (The deflated catheter closely approximates/replicates the profile of the current obstetrical catheter device). Patients that had a delay or suspected failure of progress in labor were examined for foley bulb obstruction. Those identified with an obstruction had the catheter deflated and normal labor allow to resume. These observational groups were compared to similar groups with similar placed catheters without inspection (therefore no deflations). The inflated catheter created an obstruction in forty percent of patients that obtained an epidural and foley catheter early in the labor process. The inflated catheter created an obstruction in twenty percent of patients that obtained an epidural and foley further along in the labor process. This is directly related to the station of the presenting part. There were no obstructions with the deflated catheter. The obstetrical catheter closely approximates the deflated catheter in form and volume and therefore is expected to have identical or near identical outcomes as the deflated catheter.

SOLUTION

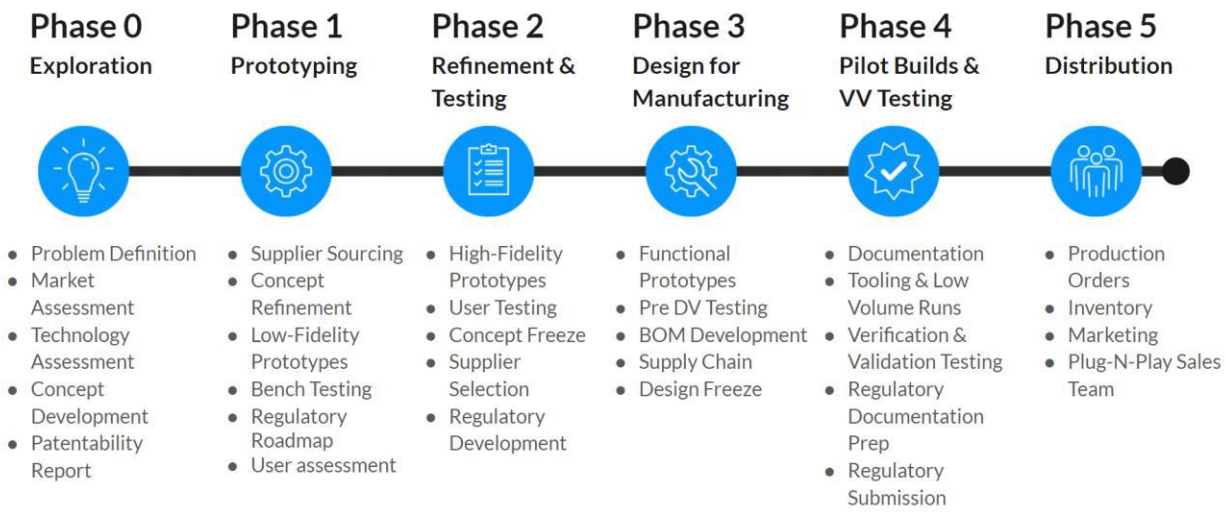


This obstetrical catheter relates to an improved urinary catheter having a unique low profile by which to retain the catheter within the bladder so that urine can be removed therefrom during the labor and delivery process without obstruction of the fetal vertex and resulting iatrogenic obstruction of labor and injury to maternal urethral and bladder tissue. Briefly, an improved urinary catheter is disclosed by which to overcome the shortcomings of the traditional foley catheter. To restate, the catheter includes a low volume, low profile means by which to retain the catheter within the bladder so that urine may be removed therefrom without obstruction of the descending fetal vertex during the labor process. More particularly, the retaining means of the improved catheter has less obstruction volume and presence in the bladder than that which would ordinarily be consumed and obstructed by a conventional spherically shaped foley balloon. Accordingly, both the frequency and severity of fetal vertex obstruction and maternal tissue injury by the application of excessive obstructive volume, such as that generated when a foley type balloon is inflated within the bladder, can be reduced. Thus, by eliminating the obstruction within the bladder, the patient will be less likely to incur an obstructed or arrested labor from iatrogenic cause and the subsequent increase in operative delivery and future urologic complications.

OVERVIEW

The following overviews the required steps to investigate and develop an innovative obstetrical catheter system for childbirth that reduces the size and shape of the balloon to prevent obstructing the baby, which would prevent the progression of the baby through the birth canal. The overall goal is to create a product that disrupts the marketplace by making a system that provides key advantages to the clinician and patient and then accelerating development to go to market as fast as possible. The process will begin with Phase 0, where we will investigate typical systems on the market, confirm the feature set, research technology, and define critical requirements. Next, we will conceptualize a range of approaches utilizing a selection of off-the-shelf components to test geometries, diameters, durometers, and unique features. Then, we will down-select and refine the most advantageous directions and create additional prototypes. Then, in phase I, we will down-select the most appealing concept, refine and add more features and details to the system and create a higher-fidelity and more comprehensive prototype that will be used to showcase the product. Finally, we will develop the product's commercialization roadmap, regulatory pathway, IP patentability, commercial opportunity, and value and create a presentation pitch deck. Subsequently, we will continue development through the remaining phases to bring the product to market. Completion of phases 0 thru 1 will place the project in a competitive position for large scale investment interest with an estimated doubling of project value. Completion of phases 2 thru 5 will place the project in position for investment and acquisition of market leaders with an estimated project value of 25 million.

Development Process



Phase 0: Exploration

Goals: Investigate current technology and features, identify pain points, research technology, and define critical requirements. Conceptualize solutions for the components of the system and create low-fidelity prototypes using off-the-shelf components. Refine the best ideas and include more details and aspects of the system and create higher-fidelity prototypes.

Deliverables:

- Problem Definition & User Requirements
- Competitor Research
- Procedure Steps
- Technology Research & Sourcing
- Concept Development
- Low-fidelity sub-system Prototypes
- Additional Concept Development
- Refined Low-Fidelity sub-system Prototypes
- Simple vascular bench model evaluation
- User Research

Phase I: Prototyping

Goals: Select the most appealing concepts and refine the design, adding more detail and features. Sourcing of additional components, materials and refining the details. Create a higher fidelity prototype that will be used to showcase the product. Gather volume cost-of-goods ballparks and feedback.

Deliverables:

- Concept Down selection
- Concept Refinement
- CAD Database Development
- Additional Component & Material Sourcing
- High-Fidelity Prototypes
- Simple Bench model Testing
- Database Refinement
- User Assessment

DEVELOPMENT COST AND TIMELINE

Phase 0 thru 5: Description

Overall Phase Ballpark Timelines and Estimates Included

Phase	Description	Speed	Cost	Other Companies speed	Other Companies cost
Phase 0	Exploration	2 months	$17K	3-5 months	$65K-$100k
Phase 1	Prototyping	2 months	$17K	5-6 months	$185K-$250K
Phase 2	Refinement & Testing	2-4 months	$80K-$120K	5-6 months	$280K-$300K
Phase 3	Final Refinement & Manufacturing Freeze	4-5 month	$160K-$275K	6-7 months	$295K-$400K
Phase 4	First Article & DV Testing	3-4 months	$195K-$275K	5-6 months	$250K-$350K
Phase 5	510k & Production	2-3 months	$175K-$275K	2-3 months	$150K-$200K
Total	**15-20 months**	**$643K-$978K**		**26-33 months**	**$1.2m-$1.6m**

DEVELOPMENT TEAM

VitaTek, the combined company of I-Tek Medical Technologies and Vita Group, has been selected to partner with on this project. They are excited to develop and manufacture a product solution that meets our needs and bring their vertically integrated accelerated services to make the product a success. VitaTek possesses two very capable combined groups located in the heart of Minnesota's medical alley, St. Paul, MN. Vita Group is a medical device incubator that works with various companies and inventors to bring ideas from napkin sketch to manufacturing, commercialization, and sales in the field. They have worked on over 36 products and have over eight products on the market, or that will be next year. I-Tek Medical is an ISO 13485 certified and FDA-registered contract design, development, and manufacturing company and has offered an extensive range of medical device manufacturing services for over 20 years, from early concept prototyping, tooling, injection molding, clean room assembly to sterile barrier packaging and sterilization coordination, as well as project and supply chain management. I-Tek Medical has designed, developed, and manufactured over 150 medical devices, and the employees are trained in all areas of medical device development and manufacturing. They manufacture Class I to Class III devices. The unique combined company allows them to offer an unmatched vertically integrated solution to achieve high-speed, low-cost medical product development. They also have in-house EO sterilization capabilities, enabling them to complete sterilization faster and batch process smaller quantities as needed, all in their facility. Additionally, I-Tek's molding shop offers a broad range of services, including part design, review for moldability, mold flow analysis, 3D modeling, custom mold building, mold transfer, mold modification, and mold repair. The manufacturing facility includes Class 7 (10,000) and Class 5 (100) Cleanroom manufacturing environments and cost-efficient white room manufacturing areas. As a result, VitaTek is the best and most cost-effective solution to medical device development and manufacturing to decrease development time and increase our speed to market.

The device and patent holder, **Douglas Wood, MD**, in conjunction with VitaTek and its key leaders: **Jason Scherer, CEO**, **Adam Johnson**, President of Quality and Regulatory, **Richard Thompson**, President of R&D & Engineering, **Frankie Mead**, VP of Business Development, and **Matt Newman**, President of Sales, along with many others plan to take this device from phase 0 to placing the device into hospitals and in use by over 98 million women worldwide. Below is bios on the key players involved in project development.

Jason Scherer
VitaTek CEO

Founder of Vita Group as a Medical Device Incubator
Built 40+ person Plug & Play Sales team resulting in over multi-millions in sales over the last 4 years
2 Successful Medical Device Exits: NeuWave to Johnson and Johnson (JNJ) $350 million; and Auris to JNJ $5.75 billion
Nearly 20 years of experience in medical device sales across 15 States
4 x President's Club Award Winner within a variety of medical device products and sales categories for 2 of the largest med dev companies in the world
Hired, trained, and mentored teams of top reps across the country
Notable Achievements:
BA Gustavus Adolphus College
Inventor on 10+ US patents
Launching 20+ medical devices presently with others in process
Started Vita Group from scratch. Grown the company to over $40m in revenue.

Adam Johnson
President of Quality and Regulatory VitaTek

ControlPrior to joining VitaTek, Adam was Vice President of Regulatory, Quality, and R&D for pharmaceutical manufacturer Apex International.
Adam also spent 10 years at Smiths Medical (now ICU Medical) in increasing roles ending as Director of Regulatory Affairs and Quality Systems.
During his tenure at Smiths Medical, he lead regulatory and quality systems teams globally focusing on European MDR, FDA 510K submission, Medical Device Single Audit Program geographies (US FDA, Health Canada, Japan MHLW-PMDA, TGA Australia, ANVISA Brazil), and over 100 additional geographies.
Adam offers over 20 years of managerial experience within the medical device, pharmaceutical, in-vitro diagnostics, and Research and Development space managing multiple size teams as well as project/program management.
Notable Achievements:
20+ Years of Regulator & Quality Experience
Gustavus Adolphus College with degrees in Chemistry, Biochemistry and Molecular Biology.
Attended graduate school with studies in Biochemistry, Biophysics, and Molecular Biology.

Douglas Wood, MD
Product Developer and Patent Holder

Private Solo Practitioner in Obstetrics and Gynecology 24+ years
OBHG-Laborist/Hospitalist
VeloSource Laborist/Hospitalist
Managed and delivered 9,500+ pregnancies to date
US Army Deployment to Saudi Arabia
William Boman School of Law, Little Rock, Arkansas
Obstetrics and Gynecology State University of New York Upstate Medical University at Syracuse, New York
Obstetrics and Gynecology Internship, Kansas University School of Medicine-Wichita, Kansas
Transitional Internship, University of Arkansas for Medical Sciences, Little Rock, Arkansas
Medical School, University of Arkansas for Medical Sciences Little Rock, Arkansas
Undergraduate: University of Arkansas at Little Rock, Arkansas
Premedical Studies and Bachelor of Science-Accounting, 1988
Hendrix College, Conway, Arkansas
Sylvan Hills High School, Sherwood, Arkansas

ACADEMIC APPOINTMENTS:
OB/GYN Clinical Faculty- Family Practice Residency Program
Baptist Health- UAMS Medical Education Program
North Little Rock, Arkansas
OB/GYN Clinical Faculty- Third year medical student rotations
New York Institute of Technology, College of Osteopathic Medicine at Arkansas State University, Jonesboro, Arkansas
Preceptor Faculty- Nurse Practitioner Program
University of Central Arkansas, Conway, Arkansas
Preceptor Faculty- Physician Assistant Program, Harding University Searcy, Arkansas

AWARDS/MILITARY SERVICE:
Arkansas Army National Guard- LTC
Army Deployment Saudia Arabi and Kuwait 2023
NYIT Outstanding Preceptor Award 2021
Wyeth Pharmaceutical Resident Research Award 1999

CERTIFICATION:
Board Certification ABOPCS (OB/GYN)-Current 2024
Board Eligible ABOG until Dec-2029
Advance Trauma Life Support
Basic Life Support-
Advance Cardiac Life Support-
Neonatal Resuscitation Program-Current 2023

PROFESSIONAL SOCIETIES:
American College of Obstetricians and Gynecologists
Arkansas Medical Society
Aircraft Owners & Pilots Association, AOPA
Experimental Aircraft Association

Richard Thompson
President of R&D & Engineering VitaTek

Key Experience:
23-year user-centered, product development experience for all types of clients from startups to fortune 500 companies
Developed over 20 products in the Electrosurgical, Electrophysiology, structured heart, and capitol equipment categories.
Seasoned leader of multidisciplinary teams running medical, industrial, and consumer development programs
Notable Achievements:
BS Industrial Design, Univ. of Cincinnati
BA in Economics, St. Olaf College
Notable products: Olympus PKS HALO, Orbio os3, Enovate Envoy cart, Abbott Flexability Ablation Catheter, Medtronic RF Enhancr II, Olympus Thunderbeat Gen 2,
Guest Lecturer, University of MN
20+ US patents granted

Frankie Mead
VP of Business Development

Frankie brings an impressive 25 years of experience in the medical device industry, with a strong focus on sales leadership and capital equipment expertise. In his previous role as Director of Sales at Sientra, Frankie skillfully managed teams of up to 11 sales representatives, driving sales strategy and execution across a portfolio of breast implants, tissue expanders, fat transfer, and acellular dermal matrix products. His unwavering commitment to exceeding sales targets, nurturing key accounts, and fostering long-lasting relationships with surgeons and hospitals has been instrumental in fueling growth and expansion.
Beyond his sales accomplishments, Frankie has made valuable contributions to product innovation and improvement, offering market insights, collaborating with cross-functional teams, and participating in product development and launch initiatives. His dedication to advancing the field of plastic surgery and improving patient outcomes aligns seamlessly with VitaTek's mission to provide safe, effective, and differentiated solutions.
Frankie's wealth of experience includes 15 years as a Regional Sales Manager at Mentor Worldwide, where he gained extensive knowledge and skills in selling and marketing medical devices such as breast implants, facial aesthetics, body contouring, and operating room equipment. Frankie also served as General Manager for Mentor's practice building arm, Mentor Solutions, whereby he and his team consulted with surgeons to optimize their practices and maximize revenue through the science of patient acquisition and process optimization. He also spent several months in Australia to turn around a failing Mentor franchise, rebuilt the sales team and infrastructure, and left the recovered business in the capable hands of the new incoming General Manager. His diverse background and driven, collaborative, customer-oriented approach make him an invaluable addition to the VitaTek team.

Matt Newman
President of Sales

Key Experience:
Matt has 19 years of sales experience, predominantly in the medical device space, with innovative technology and surgical robotics companies.
He has been a member of the initial commercial sales teams at a variety of early stage startups, including Hansen Medical, Inc. (Acquired by Auris Surgical Robotics in 2016), Echosens North America, Inc., and most recently at Auris Health, Inc.
Notable Achievements:
Matt has a bachelor’s degree in Communication Studies from Ohio University.
In 2019, Auris was acquired by Johnson & Johnson for $5.75 billion, one of the largest pre-IPO medical device company acquisitions to date.

OPPORTUNITY/PARTICIPATION

As mentioned earlier, we are a diverse group of donors and investors with a common goal to develop a medical device that will reduce the rate of primary cesarean section for failure to progress in labor and prevent injury to sensitive maternal tissues. The are two ways to get involved, as either a donor or investor. In either role, donor and/or investor there is a place and a need for your participation.

Donors include a vast background of individuals and groups who are concerned about the high rate of primary cesarean sections being performed not only in the United States but Worldwide. They are all too aware, that preventing the primary cesarean section will have a positive impact on decreasing the associated increase in recovery, morbidity and mortality that comes with having a cesarean section, including the increasing number of cesarean hysterectomies from the increased number of placenta-accrete syndromes that are occurring from having multiple cesarean sections. These individuals and groups realize the need for reducing the primary cesarean section rate. This maybe providers within the obstetrical field with vested interest such as physicians, midwives, doulas, and L&D nurses. Women and their family members who maybe expecting or planning to become pregnant. Women and family members who have experienced childbirth and have gone through the concerns and worries of laboring and the possibilities of cesarean section or those who have had a cesarean section. In fact, anyone can be a donor and any amount small or large makes a difference. Read more about donor opportunities and benefits on the web page at https://www.ob-medical.org/ or the donor campaign site at https://donorbox.org/preventing-the-primary-section-2.

Investors also come from a diverse group. They may share the same compassion and interest as donors and maybe compelled to invest. Investors may simply be people or other entities that see an opportunity to commit capital with the expectation of not only receiving financial returns but making a difference in women's health. The project has an estimated current value of $5MM (5MM shares at $1 per share). This value is based on information provided by experts in the medical development industry after assessment of the patented device and its current value as a potential breakthrough technology device in women's health. The project is offering $1mm or twenty percent as equity shares in the project. Currently, shares are being offered at $1 per share through phases 0-1. On completion of phase 0 and 1, the device will have completed concept refinement and have a high-fidelity prototype developed. The product's commercialization roadmap, regulatory pathway, IP patentability, and commercial opportunity will be defined. Completion of phases 0 thru 1 will place the project in a competitive position for large scale investment interest with an estimated doubling of project value. On completion of phase 1, any remaining shares of the 1mm initially offered will be offered at $2 per share.

Also, on completion of phase 1, an accurate cost of goods sold can be determined and a competitive percent mark-up determined. Additionally, sales and revenue estimates can be determined. The device is expected to be considered as break thru technology, meaning it is the only product in its niche. This will provide a competitive and pricing advantage. Completion of phases 2 thru 5 will place the project in position for investment and acquisition by market leaders with an estimated project value of $25 million- or 5-times original value. Individuals or groups interested in becoming investors, please send your investment request to dwoodmd@yahoo.com.

INVESTMENT TABLE

PHASE COMPLETED:	**INITIAL**	**Phase 0-1**	**Phase 2-5**
Total Shares	$5,000,000	$5,000,000	$5,000,000
VALUE	$5,000,000	$10,000,000	$25,000,000
Available Investment	**Shares Offered***	**Shares Offered***	
Price Per Share	$1	$2	$5
Percent Available	20.00%	20.00%	20.00%
Available Shares	1,000,000	1,000,000	1,000,000
Value of Shares:	**$1,000,000**	**$2,000,000**	**$5,000,000**

* Shares offered while available until phase 3 completed.

CONCLUSION

We look forward to working with our donors and investors to develop the obstetrical catheter and bring breakthrough technology into women's health. With your support, we will make a significant improvement in obstetrical care and reduce the primary cesarean rate not only in the United States but Worldwide. We are confident that we can meet the challenges ahead, and stand ready to partner with you in delivering the next breakthrough in obstetrical care.

If you have questions on this proposal, feel free to contact Douglas at your convenience by email at dwoodmd@yahoo.com or by phone at (501) 247-8519. We will be in touch with you next week to arrange a follow-up conversation on the proposal.

Thank you for your consideration,

Douglas Wood, MD
Product Developer