# CERVIGAUGE

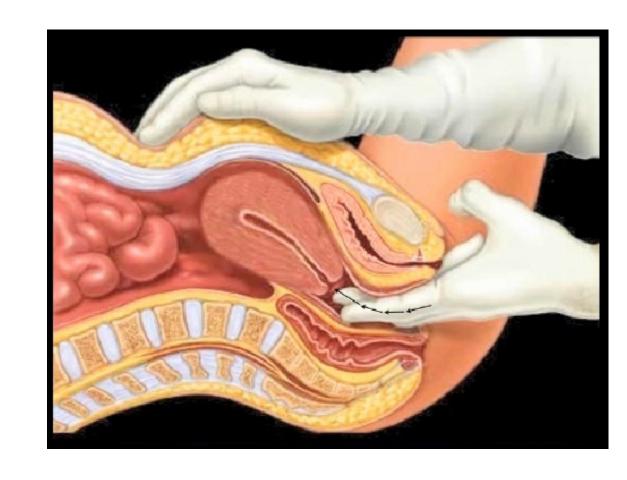
### The Problem

### Intrauterine Infection

The greatest contributor to intrauterine infection is the digital exam used to assess a woman's cervical dilation during labor.

This exam pushes bacteria from the vaginal canal into the uterus, infecting the tissues of the amniotic sac.

### Doctors Cause Intrauterine Infection



Intrauterine infection causes morbidity and mortality in laboring women and neonates

Neonatal Pneumonia
Neonatal Sepsis
Neonatal Brain Injury
Cerebral Palsy
Death

Intrauterine infection costs the health care system hundreds of millions of dollars a year in avoidable costs

#### **Cost of Damages**

7000 cases of Neonatal Infection x \$3900 = \$27.3 M1700 cases of Neonatal Sepsis x \$187,000 = \$317.9 M430 deaths x \$250,000 = \$107.5 MTotal annual savings possible = \$452.7 Million dollars

## The Solution

**CERVIGAUGE** replaces manual exams during labor, decreasing intrauterine infection



### The Business

### Reducing Intrauterine Infection

75% decrease = \$339.5 Million Saved

### Saving Provider Time

(4,130,665 - 38,568) American births/year x 6 exams/birth

x 3 mins/exam

1,227,629 Provider hours saved

x \$98.31/Provider hour

\$120,688,200 Saved

### Manufacturing Costs

CERVIGAUGE	Initial Cost	Cost after Scaling
Component		
Tube Housing Clip	\$0.70	\$0.45
Adhesive Pads (2)	\$1.00	\$0.60
Tubing	\$2.50	\$1.90
Placement Stylet	\$0.55	\$0.40
Luer-lock Syringes	\$0.16	\$0.16
Water Vial	\$0.40	\$0.40
Batch Testing	\$1.50	\$1.50
Total	\$7.81	\$6.01

### Regulatory Pathway

**CERVIGAUGE** qualifies as a Class I Obstetric-gynecologic specialized manual instrument (section 884.4530) eliminating the requirement for pre-market approval clinical trials.

### Market Segmentation

<b>Practice Setting</b>	%
Hospital Employee	24%
Single Specialty Group	22%
Solo Practice	18%
Multispecialty Group	11%
Academic/Research Economy	10%
Partner, Private Practice	9%
Private Practice Employee	5%
Independent Contractor	2%
Outpatient Clinic	0%