



WIRELESS PRESSURE SENSORS FOR CHRONIC DISEASE MANAGEMENT

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Nano@Tech Seminar May 13, 2008

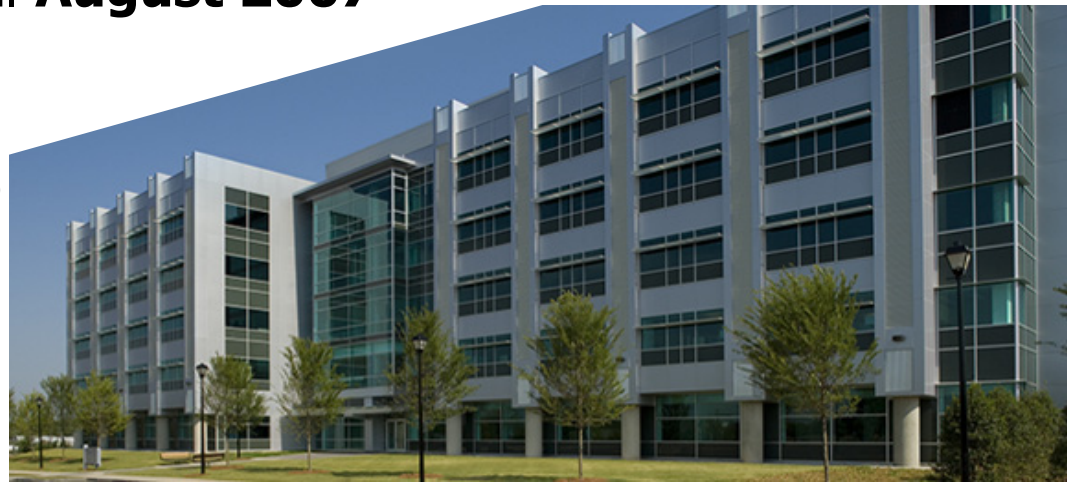
Outline

- Introduce CardioMEMS
- Technology Overview
 - Target Applications
 - Cardiovascular: Heart Failure, Aneurysms
 - Device Concept
 - Implant Procedure
- Introduce Product Development Cycle
 - Research to Product
 - Example: Abdominal Aortic Aneurysms (AAA)
- Conclusion

CardioMEMS, Inc.



- Founded **November 2000**
- Licensed core intellectual Property from Georgia Tech **April 2001**
- Initiated operations in Atlanta **May 2001**
- Graduated ATDC incubator **May 2005**
- First commercial product launched **November 2005**
- Moved to Technology Enterprise Park **July 2007**
- Initiated major U.S. clinical trial **August 2007**
- Raised \$90M in funding
- 120 employees (85 in Georgia)



Founding Fathers

Jay Yadav, M.D.

Co-Founder and Chairman.

Interventional Cardiologist, Piedmont Hospital

Founder and Chairman of AngioGuard, Inc. (sold to J&J in 1998).

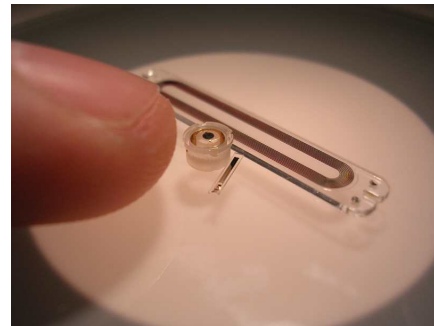
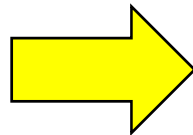
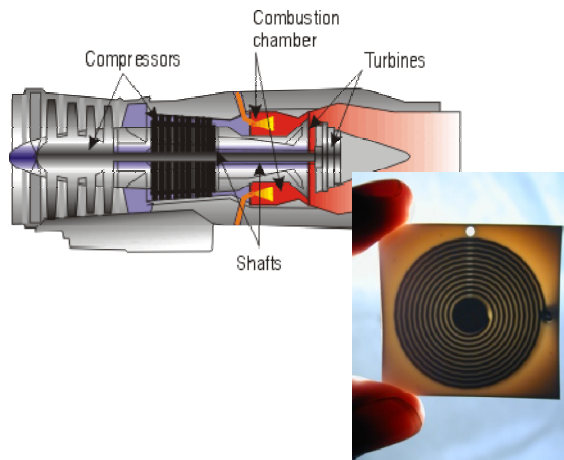
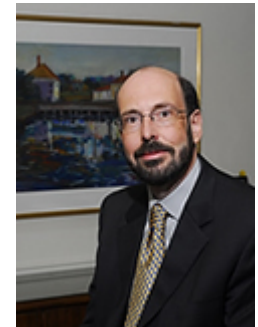


Mark Allen, Ph.D.

Co-Founder and Chief Technology Officer.

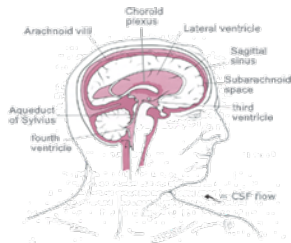
Senior Vice Provost for Research and Innovation; Joseph M. Pettit Professor;
Regents Professor

Co-founder, Redeon (acquired by BioValve in 2001).

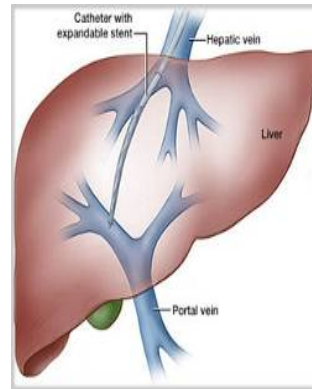


Pressure Monitoring: Applicable to Many Therapeutic Areas

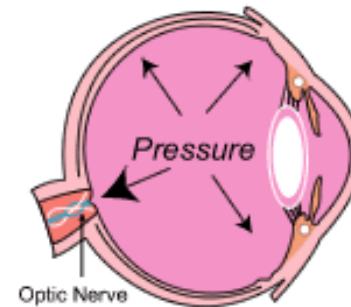
Hydrocephalus



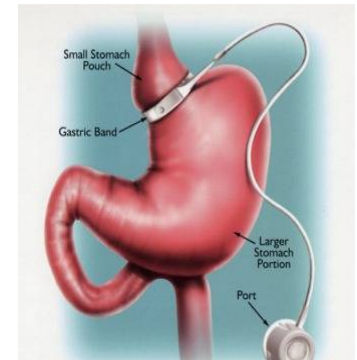
Hypertension



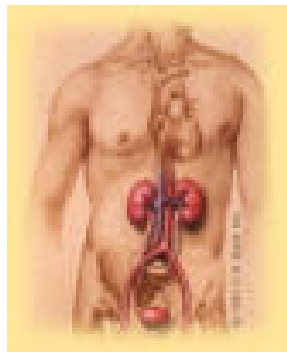
Intraocular Pressure



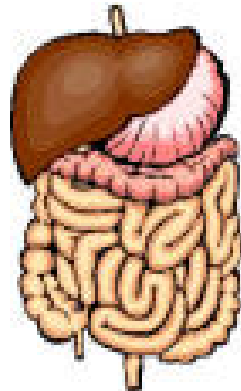
Obesity



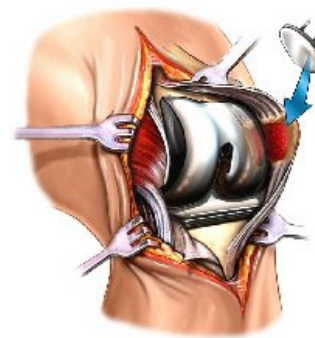
Urology



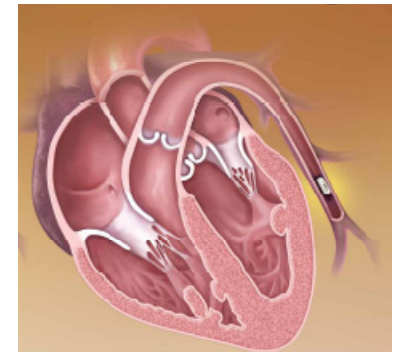
Gastroenterology



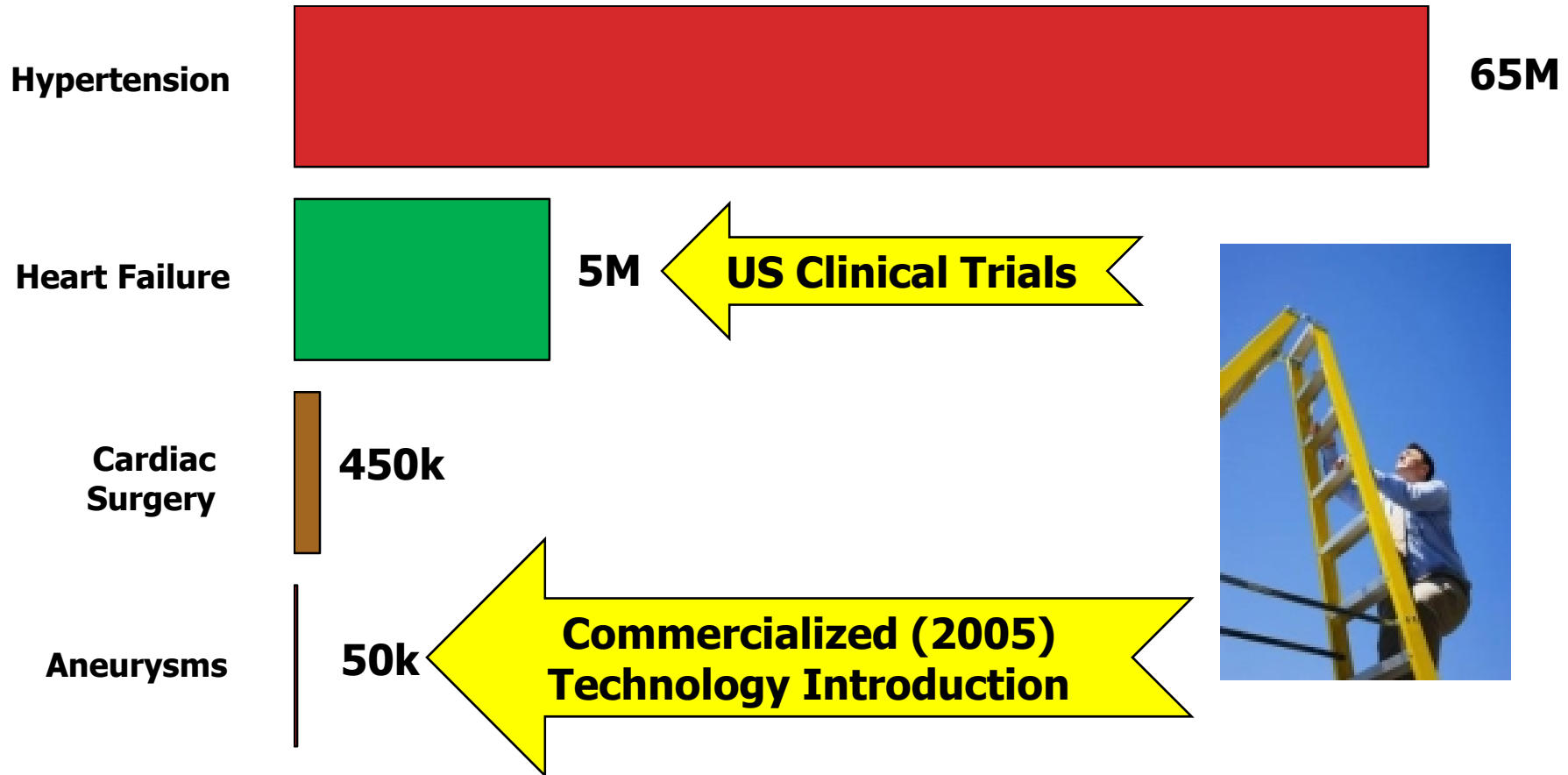
Orthopedics



Cardiovascular



Patient Opportunity (by Cardiovascular Disease)



Note: Cardiovascular patients, USA only

Heart Failure Market

- Definition
 - Progressive disorder in which damage to the heart causes weakening of the cardiovascular system
 - Manifests by fluid congestion or inadequate blood flow to tissues
- Prevalence
 - Afflicts > 5 million Americans with Chronic Heart Failure¹
 - 14 percent of Medicare beneficiaries have congestive heart failure²
- Impact¹
 - Annual hospitalization expense - \$6 Billion
 - 47% of newly diagnosed HF patients are rehospitalized
 - HF is the most common cause of hospitalization in the US
 - Estimated 2007 expense of managing these patients - \$33 billion
 - Heart failure is the most common reason for hospitalization among Medicare patients³

1 American Heart Association. 2001 Heart and Stroke Statistics Update. 2000: American Heart Association.

2 Senior Journal. Aug. 2, 2005 Medicare Testing Program to Help Diabetes, Heart Failure Patients Have Better Lives

3 Centers for Disease Control and Prevention. The Burden of Heart Disease and Stroke in the United States: State and National Data, 1999. Atlanta: Centers for Disease Control and Prevention, 2004.

CardioMEMS Products



- EndoSure™ AAA Wireless Pressure Sensor (FDA cleared for marketing October 2005)
- CardioMEMS Heart Failure Pressure Measurement System (currently undergoing clinical evaluation)
- CardioMEMS Hypertension System (currently in development)



CardioMEMS Technology

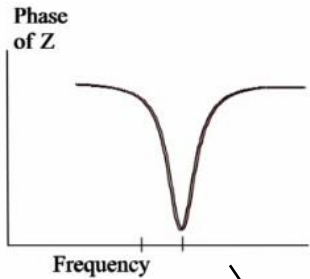
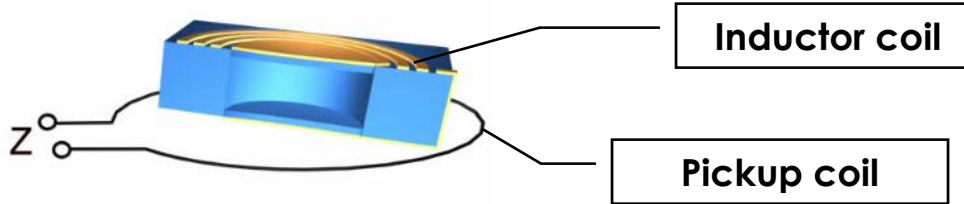


- **CardioMEMS is focused on the development of miniature sensors and wireless communication technology**
- **CardioMEMS' sensors:**
 - Have no batteries
 - Are designed for permanent implant in the human body
 - Can be implanted using minimally invasive techniques
 - Are capable of transmitting cardiac output, blood pressure and heart rate data
 - Use radiofrequency (RF) energy to transmit data to proprietary external electronics
 - Are designed to improve the management of chronic cardiovascular diseases such as heart failure, aneurysms and hypertension.



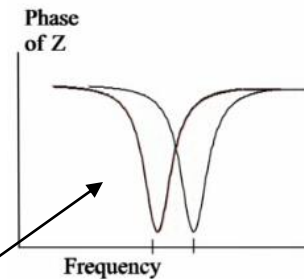
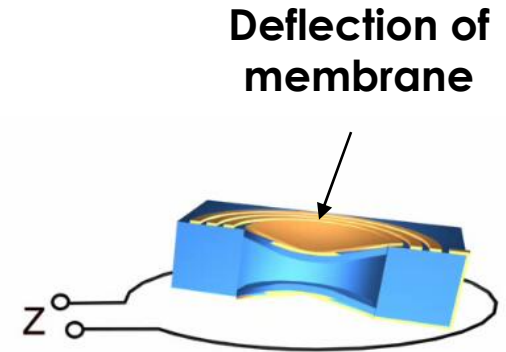
Sensor Concept

$$f = \frac{1}{2\pi\sqrt{L C(P)}}$$



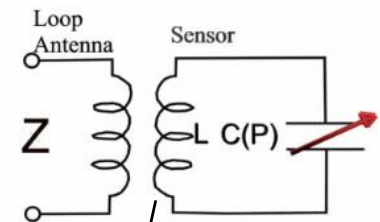
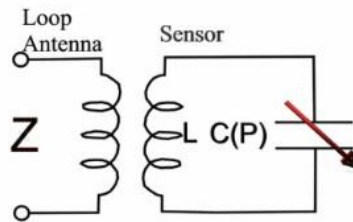
Graph of frequency vs. phase. Minimum represents resonant frequency of sensor.

$$f = \frac{1}{2\pi\sqrt{L C(P)}}$$



Shift in resonant frequency

Equivalent electronic circuits

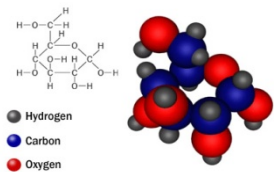


Pressure is Critical to Chronic Disease Management

In the same way that...

Blood Glucose

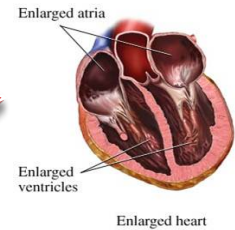
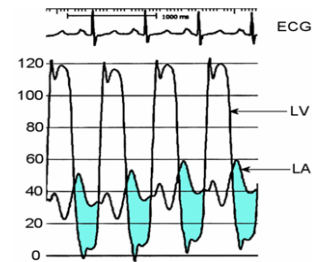
Diabetes



We know that...

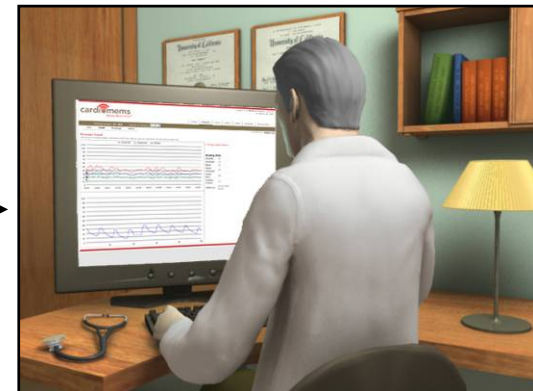
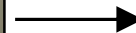
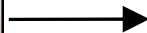
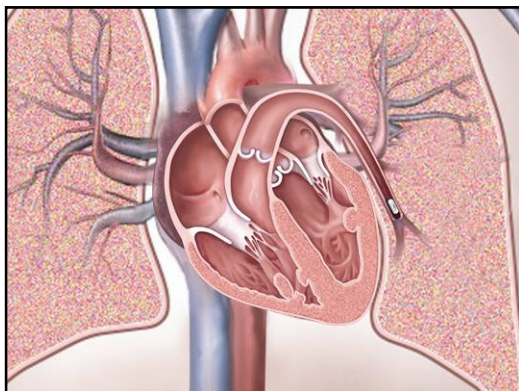
Intracardiac Pressure

Heart Failure



CardioMEMS Overview

- **Real-time monitoring of vital information holds the promise of:**
 - reducing hospitalizations,
 - improving a patient's quality of life
 - delivering more efficient and cost effective health care



Heat Failure Implant Procedure

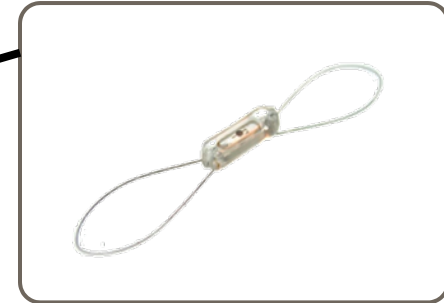
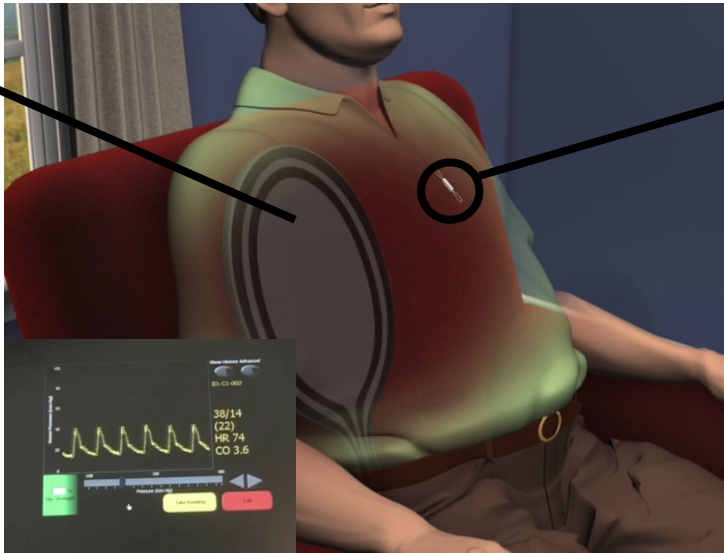


System Development for Management of Chronic Diseases

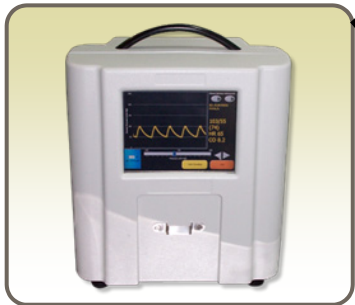
cardiomems™



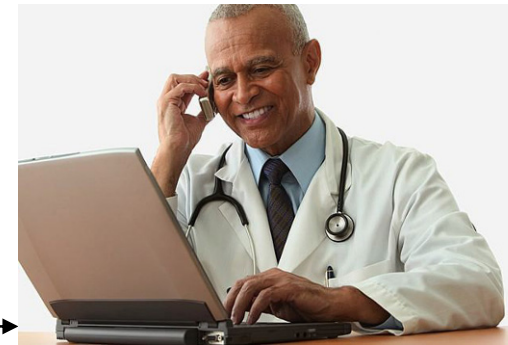
RF Antenna



Sensor Implant



**Electronic
Communication**



**Remote
Physician
Monitoring**

Overview: Research to Product



Passive Wireless: Not a New Concept

Implantable Sensor for physiological Parameter Measurement

April, 1967

76

IEEE TRANSACTIONS ON BIO-MEDICAL ENGINEERING, APRIL 1967

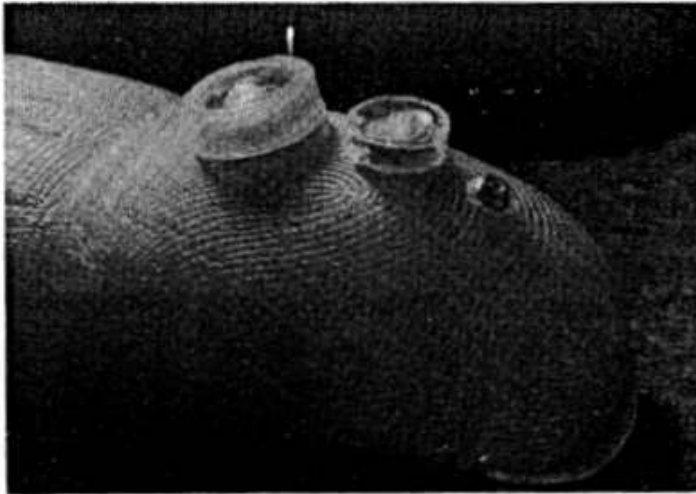
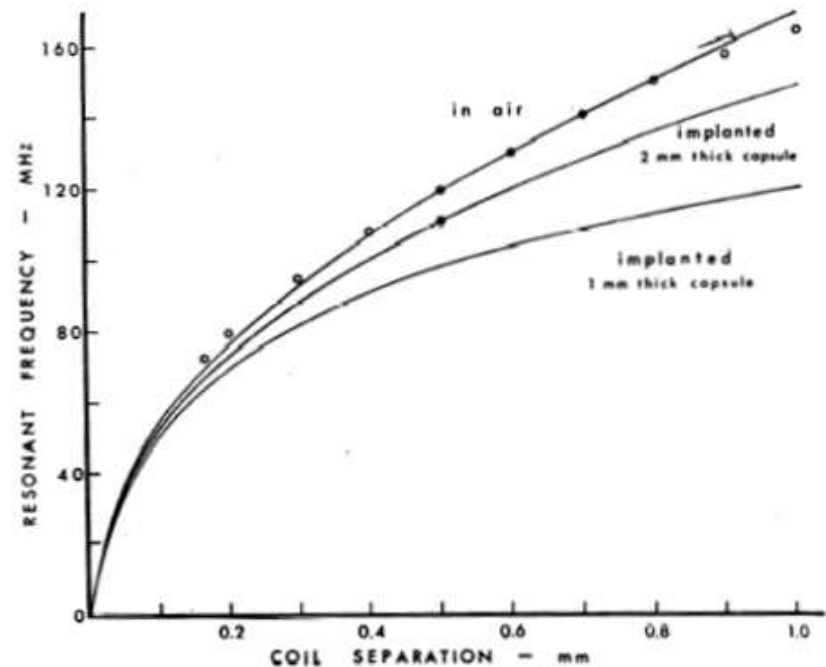


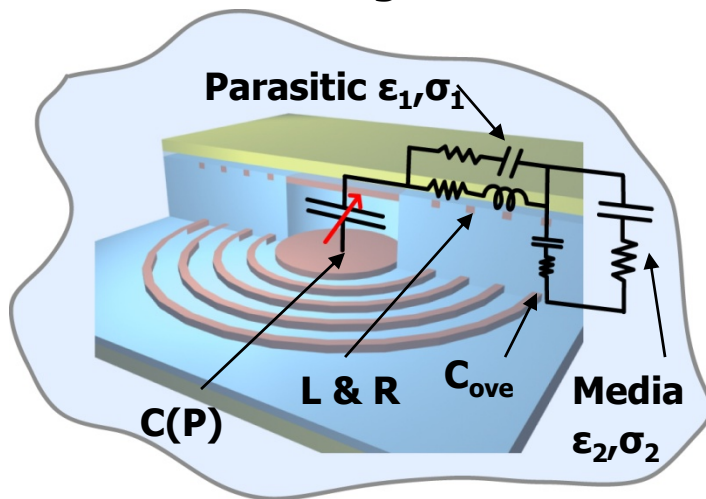
Fig. 3. Bubble tonometers 6, 4, and 2 mm in diameter. The smallest tonometer displayed here was detected when implanted in the anterior chamber of the eye, but requires further development. The larger models are used when pressures are desired from progressively deeper structures.



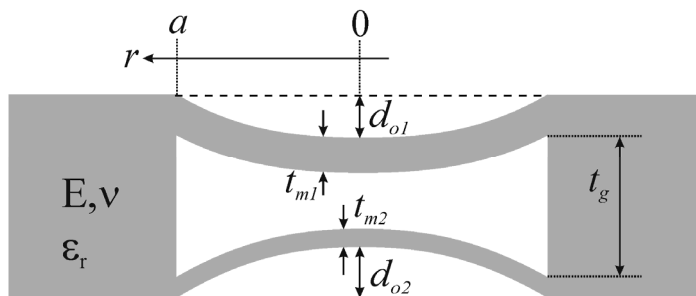
C. Collins, IEEE Trans. Biomedical Engineering

Research: Fundamental Understanding

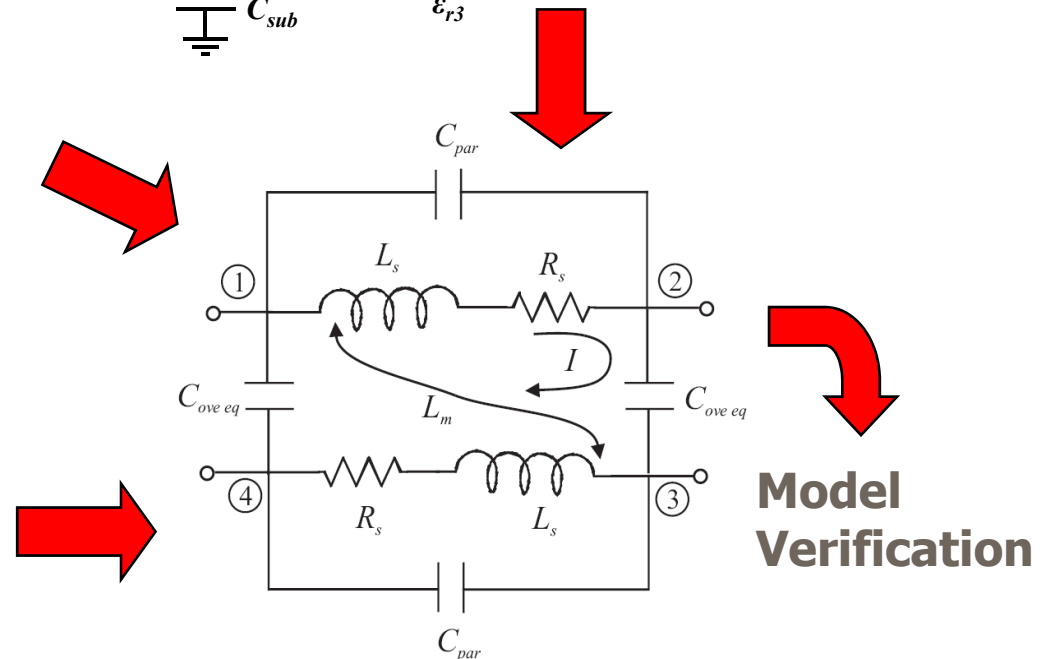
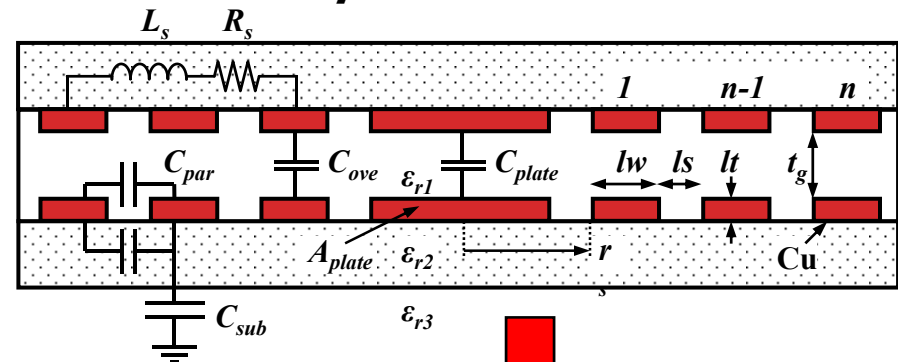
Electromagnetic



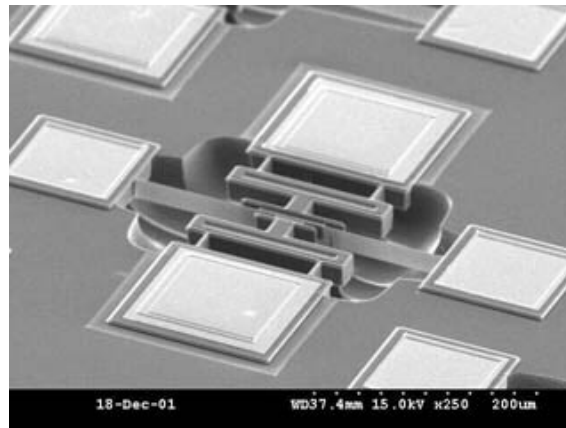
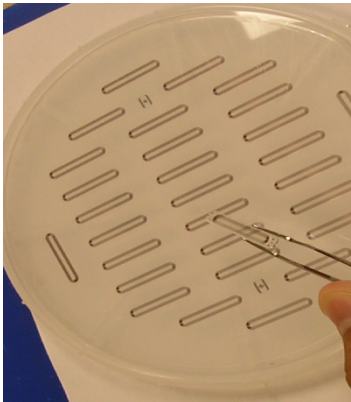
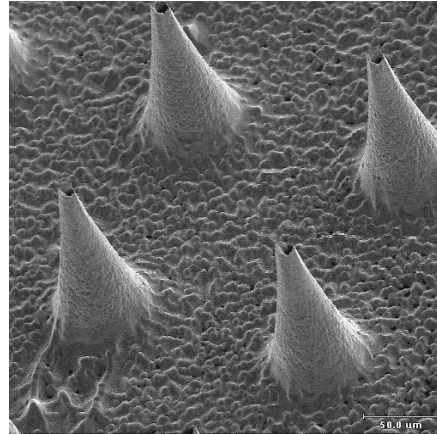
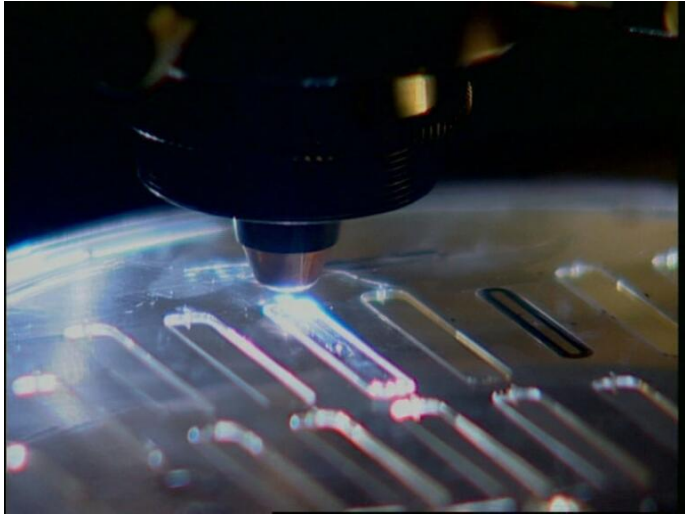
Mechanical Model



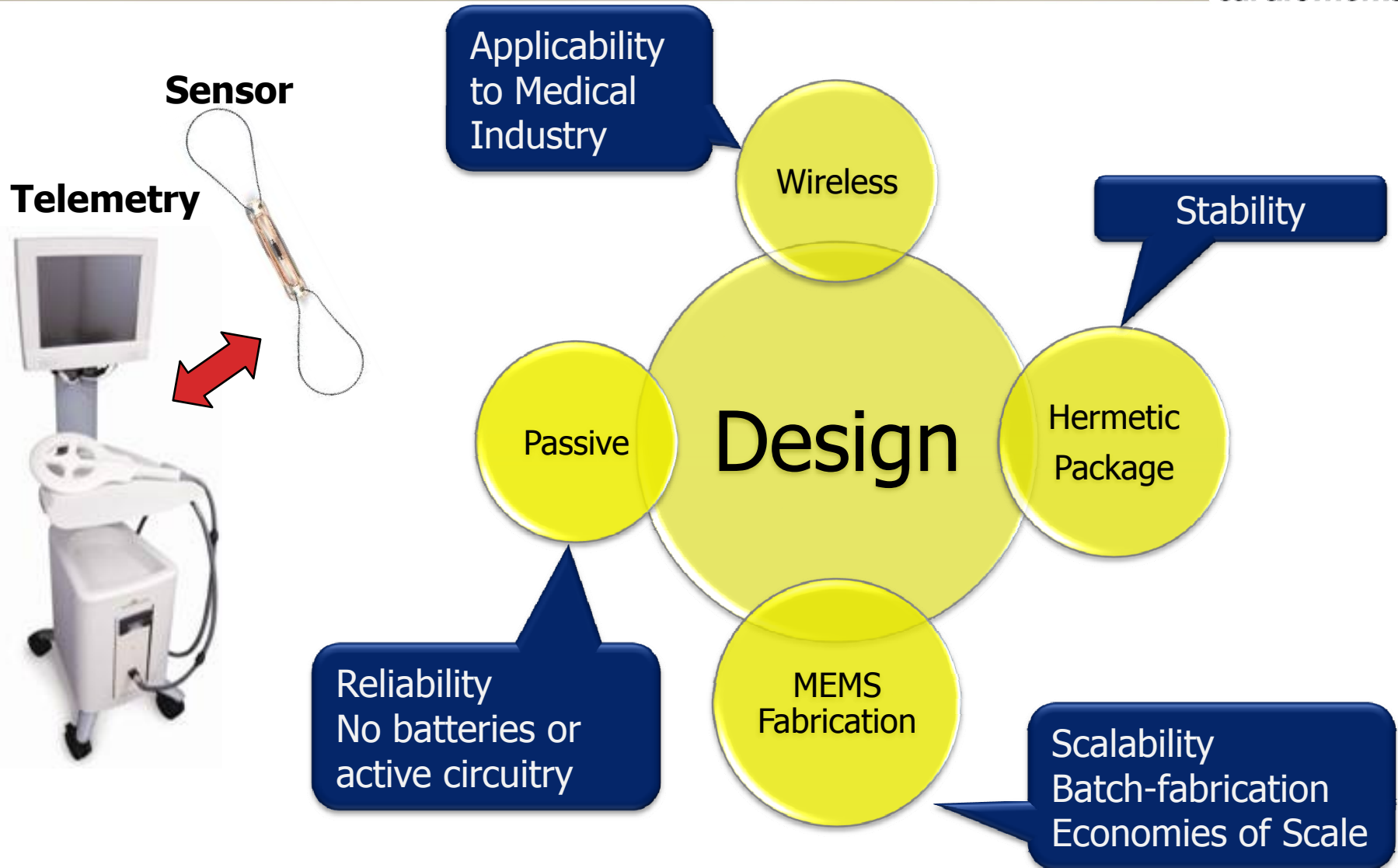
Analytical definition



Advances in Fabrication: MEMS



System Design Advantages



Development: Research to Product

- **Concept Inception**

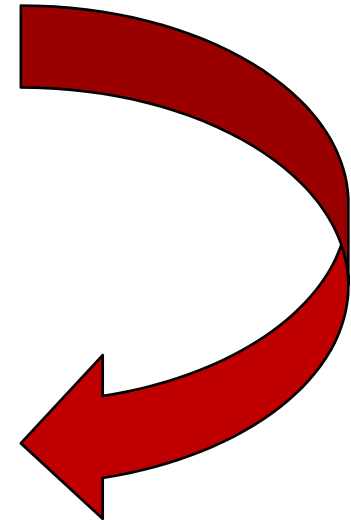
- In literature since the late 1950's and early 1960's
- Limited by sensor fabrication technology and electronic telemetry capabilities

- **Scientific Research**

- Research at Georgia Tech for > 10 years
 - 2 Ph.D. graduates
 - Intellectual Property (Patent)
- Proof of concept

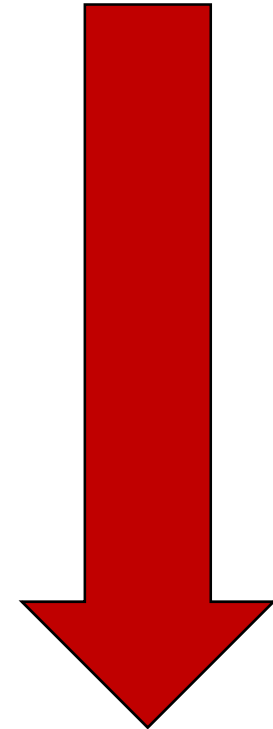
- **Initial Product Development**

- Define **System** Requirements
- System Design (sensor, catheter, & electronics)
- Sensor Design (challenges: material subset)
- Sensor **Reliability & Stability**



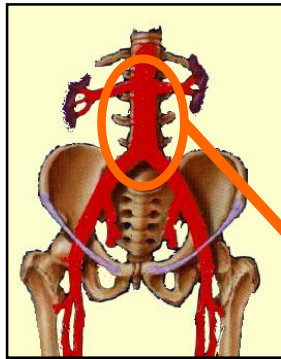
Development: Research to Product

- Product Development
 - Bench testing (performance)
 - **Process Development for Manufacturability**
 - Animal Implants (demonstration system)
- Product **Safety**
 - Biocompatibility
 - MRI & Defibrillator compatibility
 - SAR Testing
 - Animal implants (safety & monitoring)
 - Outside US (OUS) Human Trials
- Clinical Trials & **FDA Approval**
 - Patient follow-up

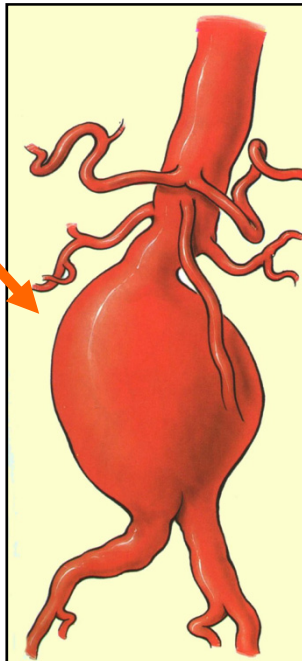


System Development for AAA's

Problem: AAA

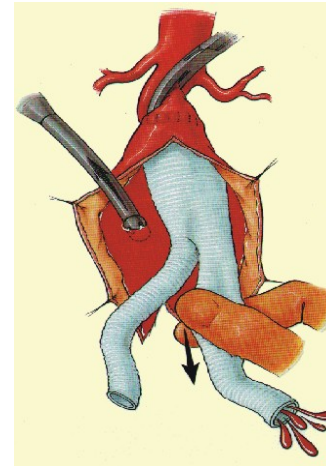


Normal
Abdominal
Aorta



Diseased

Treatment



Patient Monitoring



Product Development Matrix

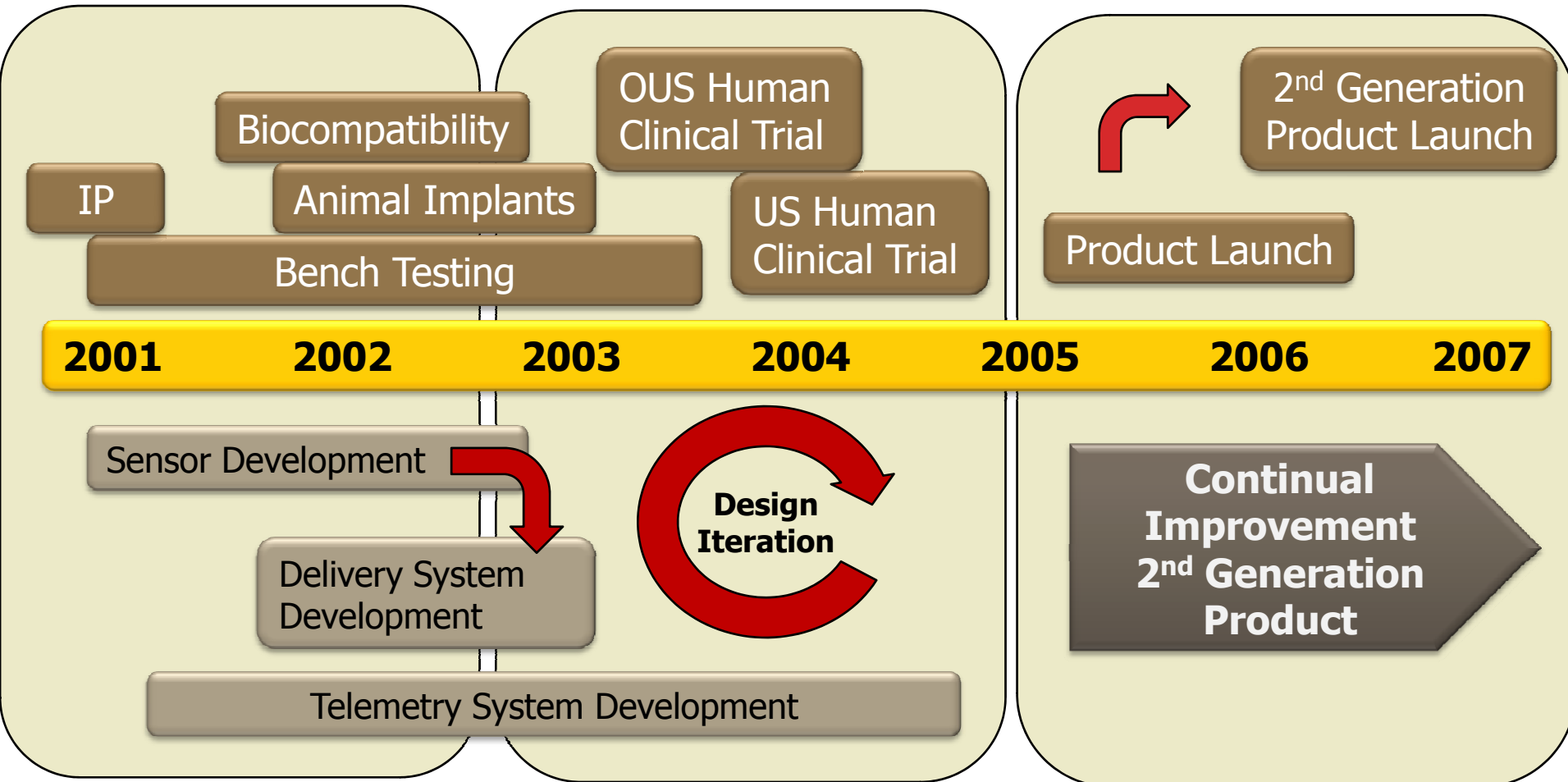
Bench	Biocompatibility	Animal	Human
<ul style="list-style-type: none"> •Accuracy •Cycle Testing (10 yr) •Performance 	Sensor: Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemocompatibility	4 Animal canine study (mock aneurysm)	16 patient pilot study – Brazil and Argentina
<ul style="list-style-type: none"> •Catheter attachment •Simulated Delivery 	Delivery Catheter: Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemocompatibility	6 animal canine study – 1 year implant.	84 patient pivotal study – 12 sites, 4 countries, five devices
<ul style="list-style-type: none"> •Ship testing •Shelf-life testing •Sterilization validation 	Delivery Catheter: Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Thromboresistance	3 animal porcine study, tissue response, 90 days	4 year follow up
<ul style="list-style-type: none"> •Electrical safety •SAR Limit •MRI compatibility •Ultrasound & Defib. Compatibility 	-----	6 animal porcine GLP study, healthy aorta, 1 and 6 month implants, full histo-pathology	-----

AAA Product Development Timeline

Initial Technology Dev.

Product Dev.

FDA Approval Commercial Sales



Product Development Summary

- Initial research
 - Concept inception
 - Research (GT)
- New technology development.
 - Introduce technology to the market place
 - Develop passive wireless infrastructure for medical field
- Product development
 - Design optimization
 - Process development
 - Design for manufacturability
 - Reliability
 - Process control
 - Documentation (FDA and ISO regulations)
 - Validations
- Product Safety and Performance In Vivo – FDA Approval
- Commercialization

Conclusion

- Presented CardioMEMS Overview
- Presented Technology & Motivation
- Introduced Development from Research to Product for Abdominal Aortic Aneurysms

**Thanks to Dr. David Gottfried the MiRC
Nano@Tech Group**