Wireless Pressure Sensors for Chronic Disease Management

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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
Pressure Monitoring: Applicable to Many Therapeutic Areas

Hydrocephalus  Hypertension  Intraocular Pressure  Obesity

Urology  Gastroenterology  Orthopedics  Cardiovascular
Patient Opportunity (by Cardiovascular Disease)

- Hypertension: 65M
- Heart Failure: 5M (US Clinical Trials)
- Cardiac Surgery: 450k
- Aneurysms: 50k (Commercialized 2005, Technology Introduction)

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

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

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

Shift in resonant frequency

Inductor coil

Pickup coil

Deflection of membrane

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

[Diagrams and images related to blood glucose and 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

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

C. Collins, IEEE Trans. Biomedical Engineering
Research: Fundamental Understanding

Electromagnetic
- Parasitic $\varepsilon_1, \sigma_1$
- Media $\varepsilon_2, \sigma_2$
- L & R $C(P)$

Mechanical Model
- $E, v$
- $\varepsilon_r$
- $t_{m1}, t_{m2}$
- $d_{a1}, d_{a2}$
- $t_g$

Analytical definition

Model Verification
Advances in Fabrication: MEMS
System Design Advantages

- Applicability to Medical Industry
- Wireless
- Hermetic Package
- MEMS Fabrication
- Passive
- Stability
- Reliability No batteries or active circuitry
- Scalability Batch-fabrication Economies of Scale

Sensor
Telemetry
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

<table>
<thead>
<tr>
<th>Bench</th>
<th>Biocompatibility</th>
<th>Animal</th>
<th>Human</th>
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<tr>
<td>• Accuracy</td>
<td>Sensor: Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemocompatibility</td>
<td>4 Animal canine study (mock aneurysm)</td>
<td>16 patient pilot study – Brazil and Argentina</td>
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<td>• Cycle Testing (10 yr)</td>
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<td>• Performance</td>
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<tr>
<td>• Catheter attachment</td>
<td>Delivery Catheter: Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemocompatibility</td>
<td>6 animal canine study – 1 year implant.</td>
<td>84 patient pivotal study – 12 sites, 4 countries, five devices</td>
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<tr>
<td>• Simulated Delivery</td>
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<tr>
<td>• Ship testing</td>
<td>Delivery Catheter: Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Thromboresistance</td>
<td>3 animal porcine study, tissue response, 90 days</td>
<td>4 year follow up</td>
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<td>• Shelf-life testing</td>
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<td>• Sterilization validation</td>
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<tr>
<td>• Electrical safety</td>
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<td>6 animal porcine GLP study, healthy aorta, 1 and 6 month implants, full histo-pathology</td>
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<tr>
<td>• SAR Limit</td>
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<td>• MRI compatibility</td>
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<tr>
<td>• Ultrasound &amp; Defib. Compatibility</td>
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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

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