

COHEREX MEDICAL, INC.

The Coherex FlatStent™ Radiofrequency System: Device Design and Pre-Clinical Experiences

Brian Whisenant, M.D.

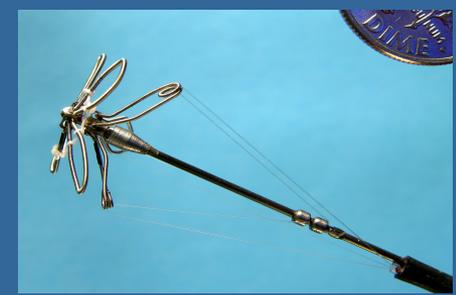
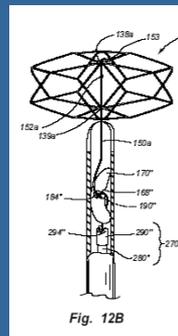
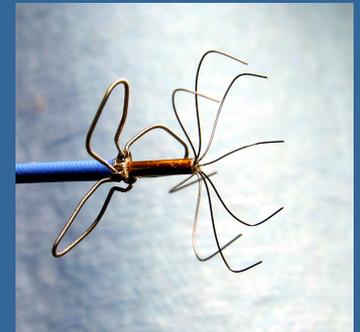
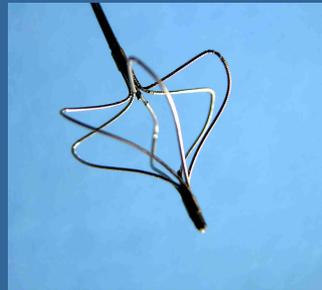
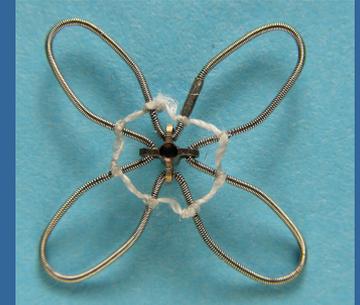
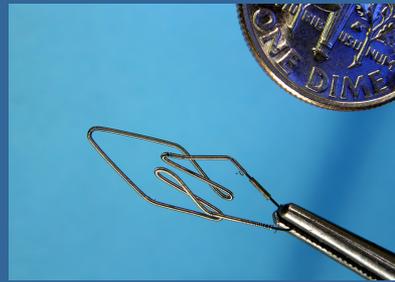


Conflict of Interest Statement

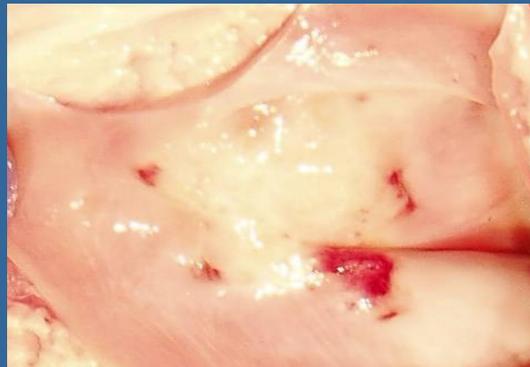
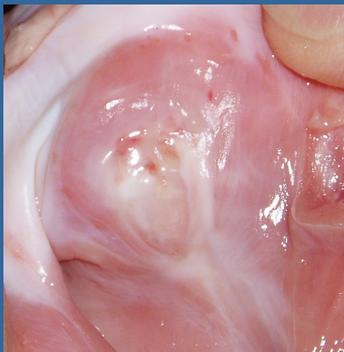
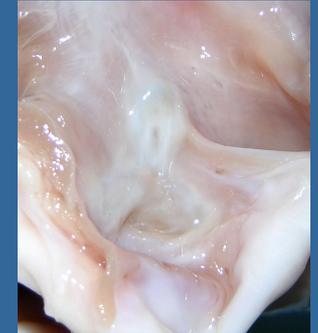
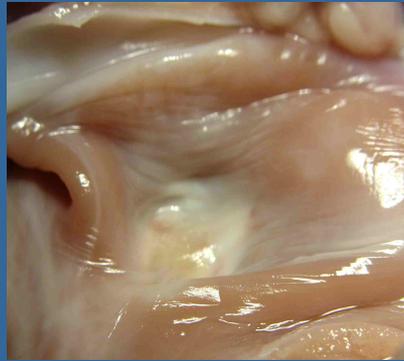
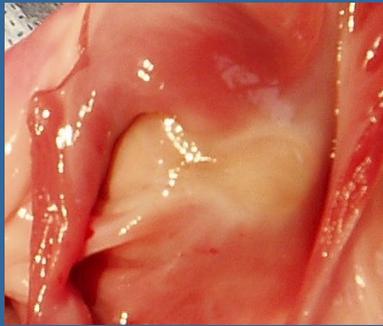
Within the past 12 months, my wife, children, brother, sister, parents, in-laws, college roommates and I have had a financial interest in Coherex Medical.

Proximare 2003 → Coherex 2006

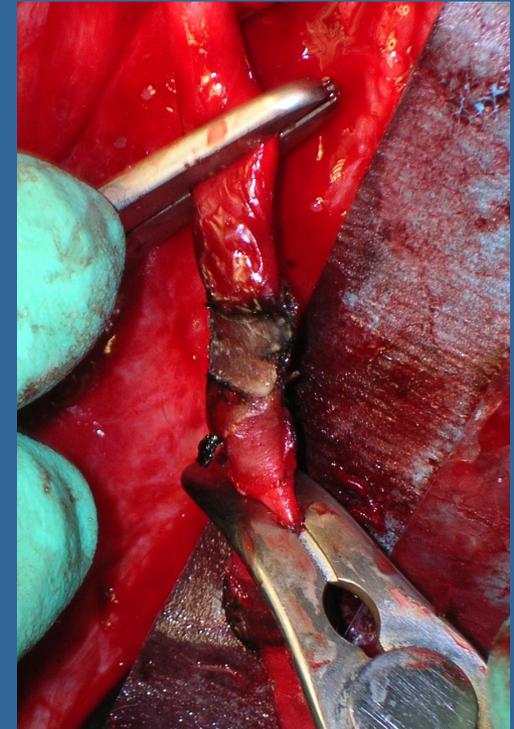
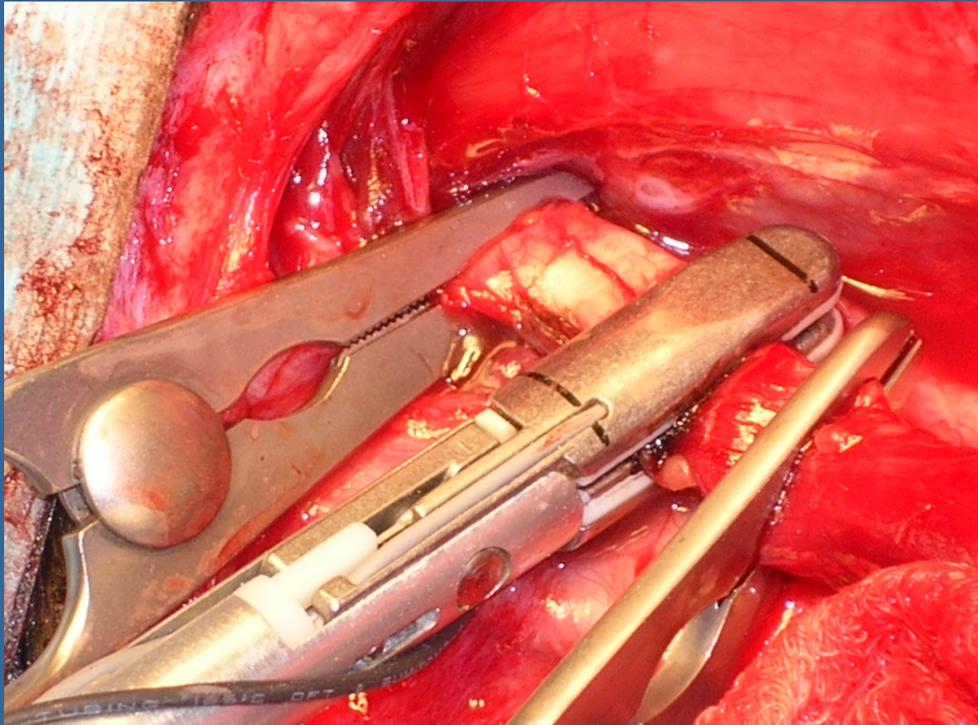
Concepts:
Clips
Polymers
Energy



Numerous successful animal closures with polymers, clips, and RF energy.

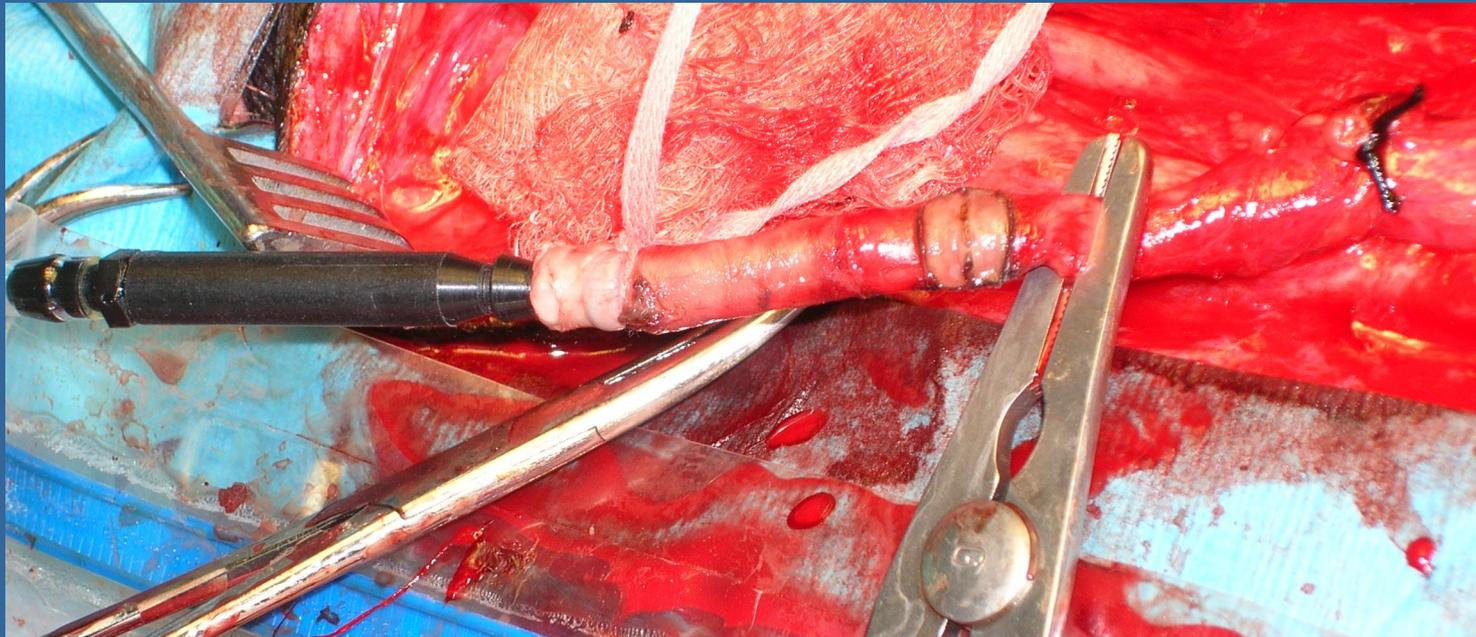


Is the mechanism of RF induced PFO closure acute tissue welding or delayed healing?



Calf carotid artery isolated and heated with escalating temperatures of 50 - 90 C, and pressure of 5 - 50 PSI.

- Pressure added to sealed vessel
- All segments opened at < 2 PSI



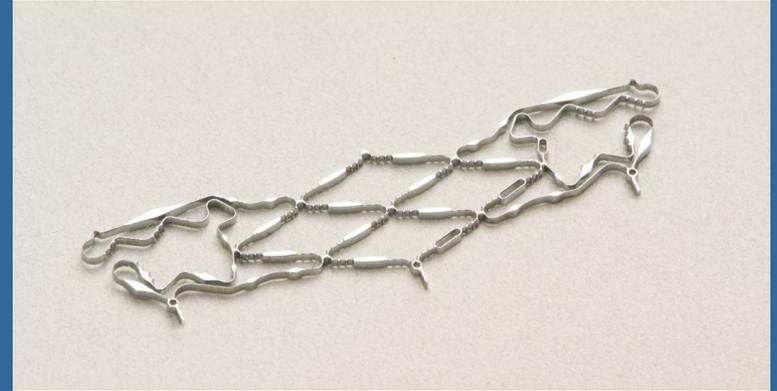
Internal RF Conclusions

- PFOs cannot be welded closed with the temperature and pressure tolerated by the interatrial septum.
- Mechanism of RF induced PFO closure is delayed healing.
- Stand alone RF may not achieve adequate closure.

**Coherex Decision:
Pair RF energy with implant**

Coherex FS™

- Laser cut nitinol
- Distal and proximal “moose horns” anchor against the PFO/atrial wall in the left and right atria.
- Stent body laterally stretches PFO.
- Platform for tissue growth enhancing technologies, ie. RF energy, drugs, ingrowth materials.



Coherex FSTM

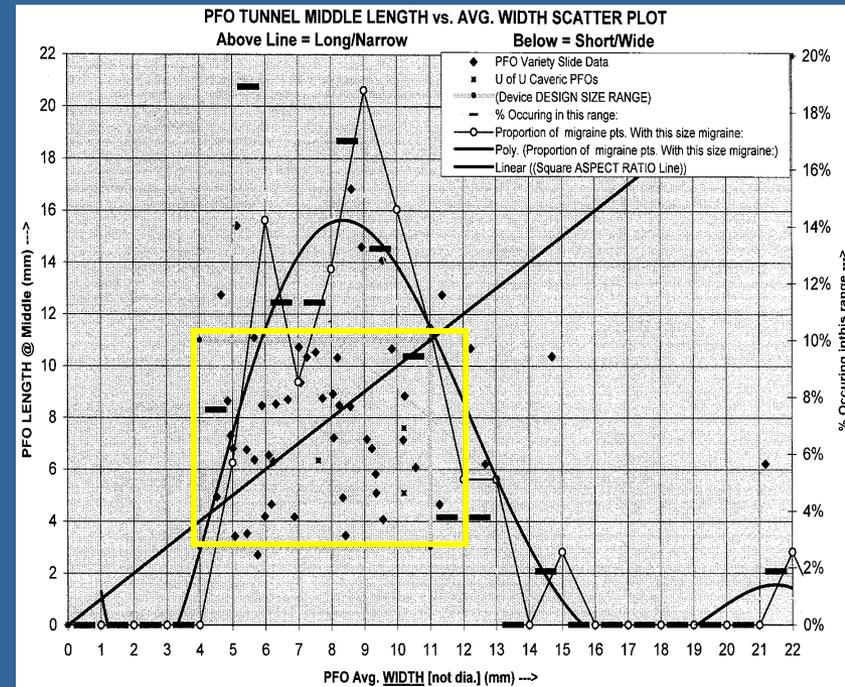
Instructions for Use



Coherex FS™ Design & Function



- Workhorse stent accommodates tunnel widths 4-12 mm and tunnel lengths 2-11 mm
- Central stent accommodates variable PFO widths.
- “Moose horns” accommodate both various PFO widths and tunnel lengths.



Coherex FSTM

Design & Function

- Fully recaptured by advancing the delivery catheter over the deployed stent
- Familiar push/pull functionality



Coherex FS™ Closure Assurance

3 Mechanisms

- 1) Lateral stretch of PFO
- 2) Foreign body reaction
 - LA opening
 - Tunnel
 - RA opening
- 3) Dispersed RF energy
 - enhanced cellular response
 - may capture fenestrations



Coherex FS™ Safety

Total stent weight <0.25 mg

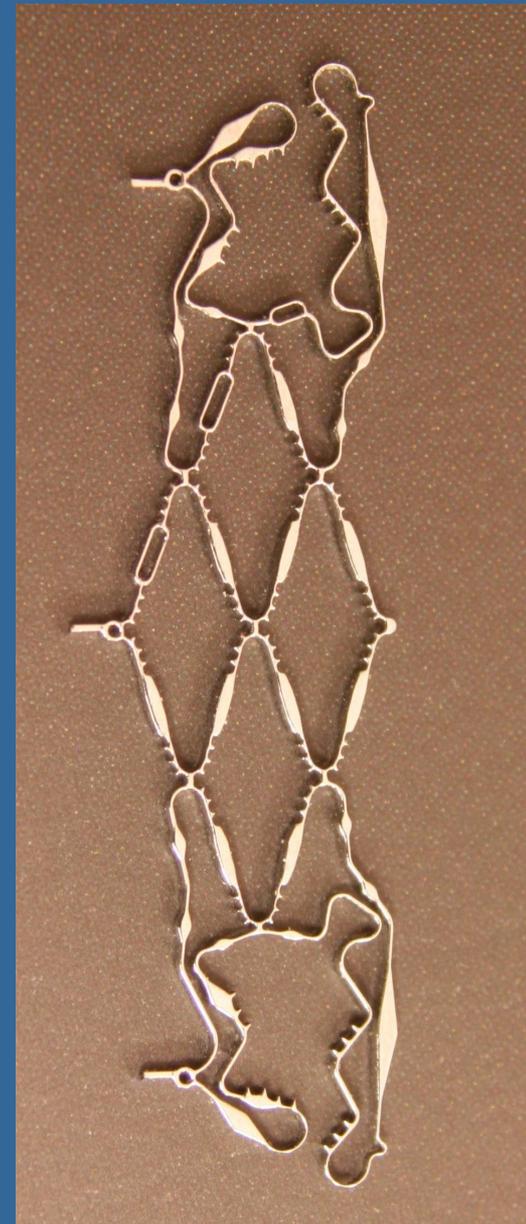
- BMS like endothelialization

Multiple anchoring mechanisms

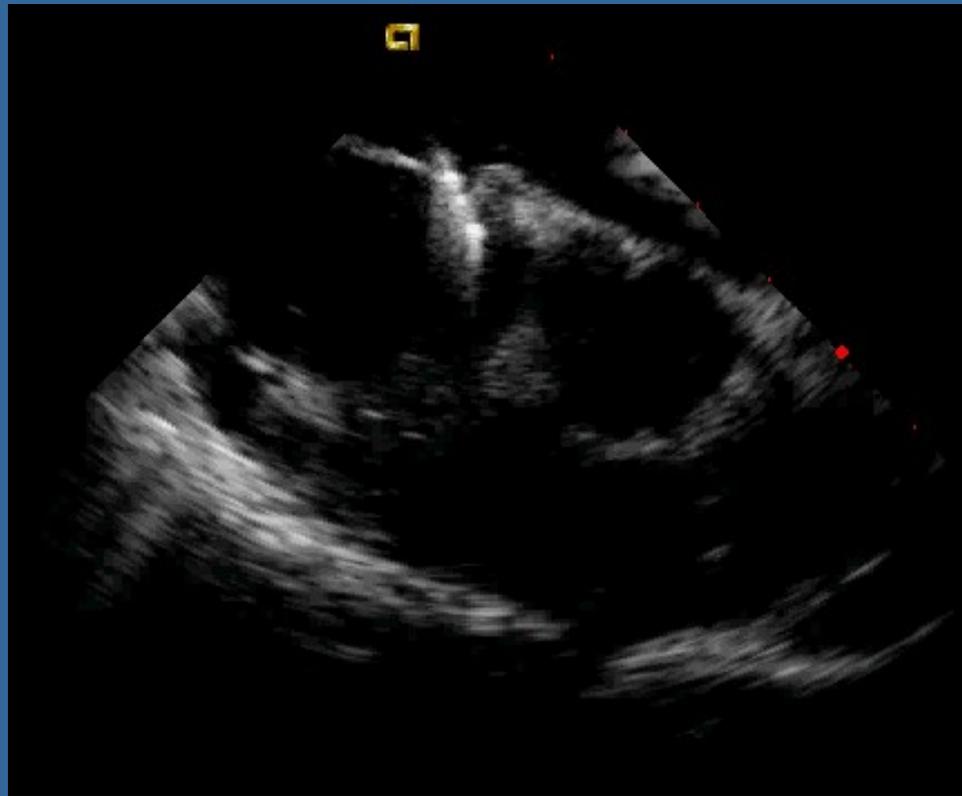
- moose horns
- pincer joint
- microtines

Compliant design

Energy/temperature are well
within published margins of safety



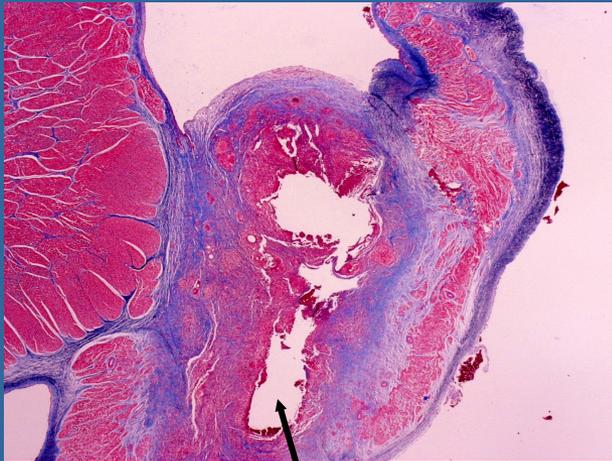
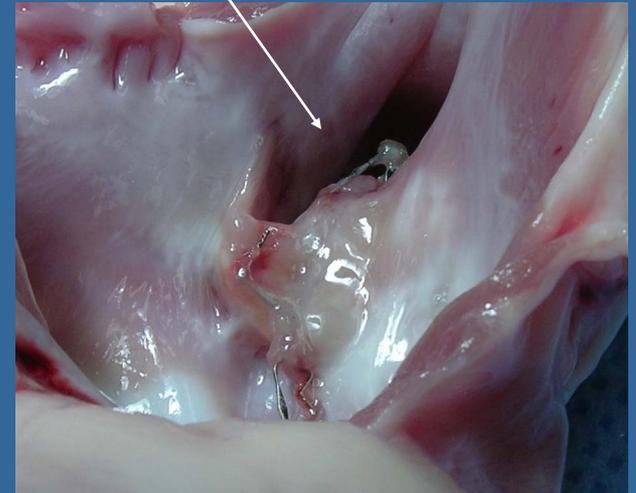
Siemens AcuNav Intracardiac Imaging



13 Day Survival Pigs

- Solid closure
- Appropriate auto-orientation
- Fibrotic capsule surrounding central inflammation
- No evidence of necrosis

Pulmonary vein



Cavity from extracted stent

Medical Advisory Board

- Peter Casterella, M.D.
- Bill Gray, M.D.
- David Holmes, M.D.
- Marty Leon, M.D.
- Jack Sweeney, M.D.
- Jon Tobis, M.D.
- Brian Whisenant, M.D.

The Coherex Team

Rich Linder, President and CEO

Trent Loveless, VP and CFO

Clark Davis, Chief Scientific Officer

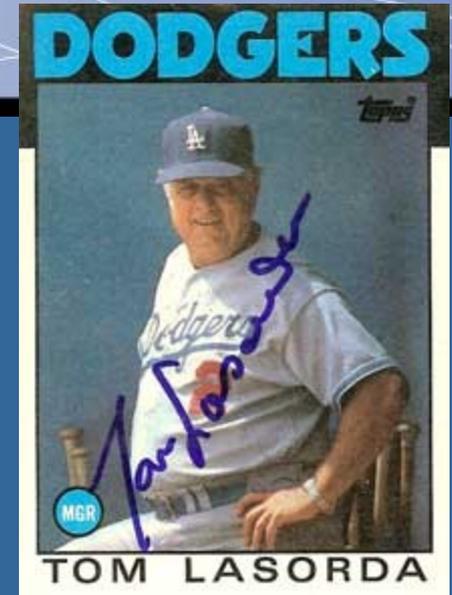
Phil Carter, VP Marketing

Daryl Edmiston, VP Research and Development

Gary Snow, VP Quality

Scott Miles, Director Research and Development

DeWayne Fox, Director of Manufacturing



"I Love these guys!"