

# Medical Device Development and Entrepreneurship

Presented by:

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# Introduction

- Overview
- Medical Device Development
- Device Startups
- Consulting



# Medical Device Applications

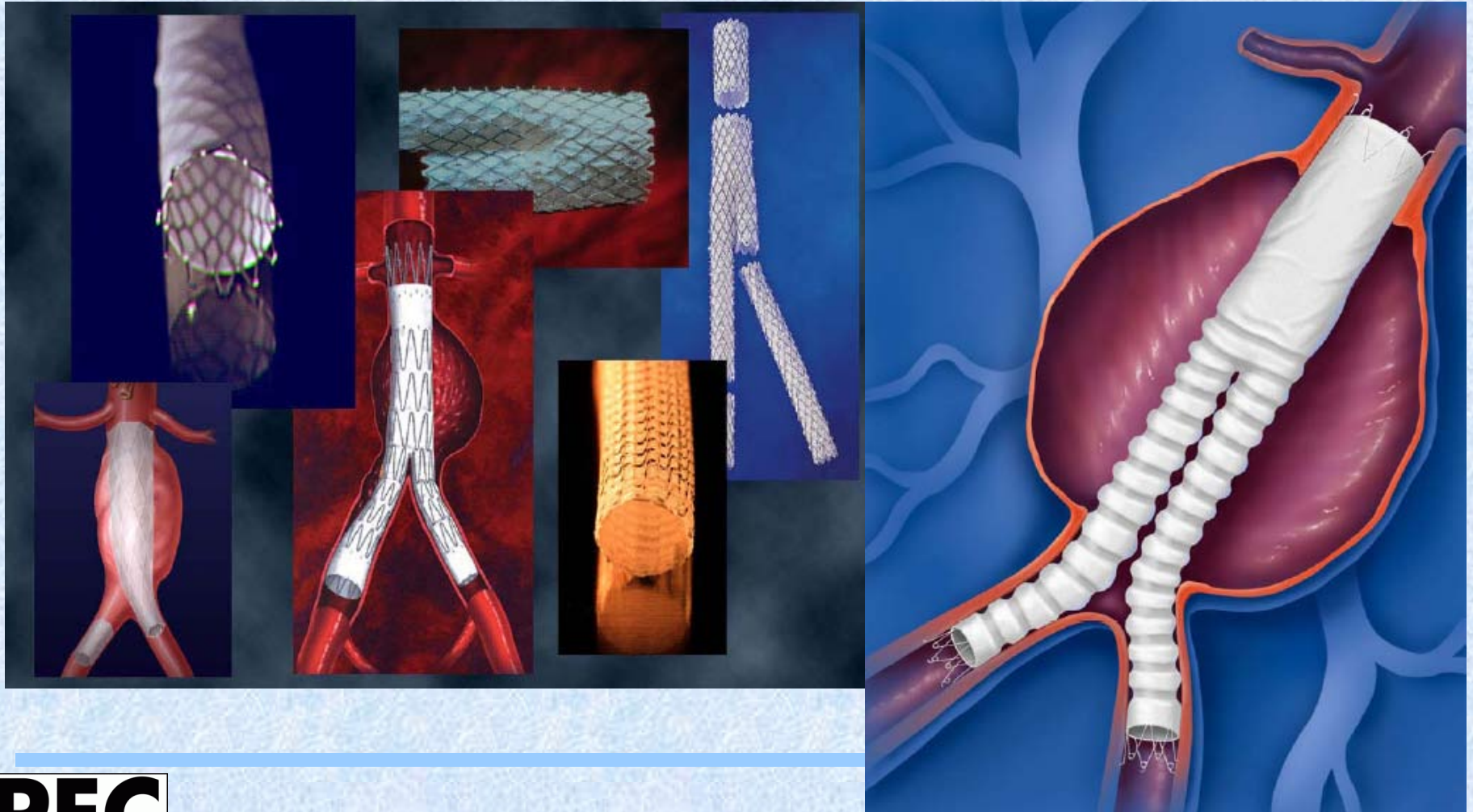


# Some Device Fields...

- Cardiovascular
- Orthopaedic
- Sleep disturbances
- Vascular closure
- Cosmetic
- Etc.

# AAA Devices

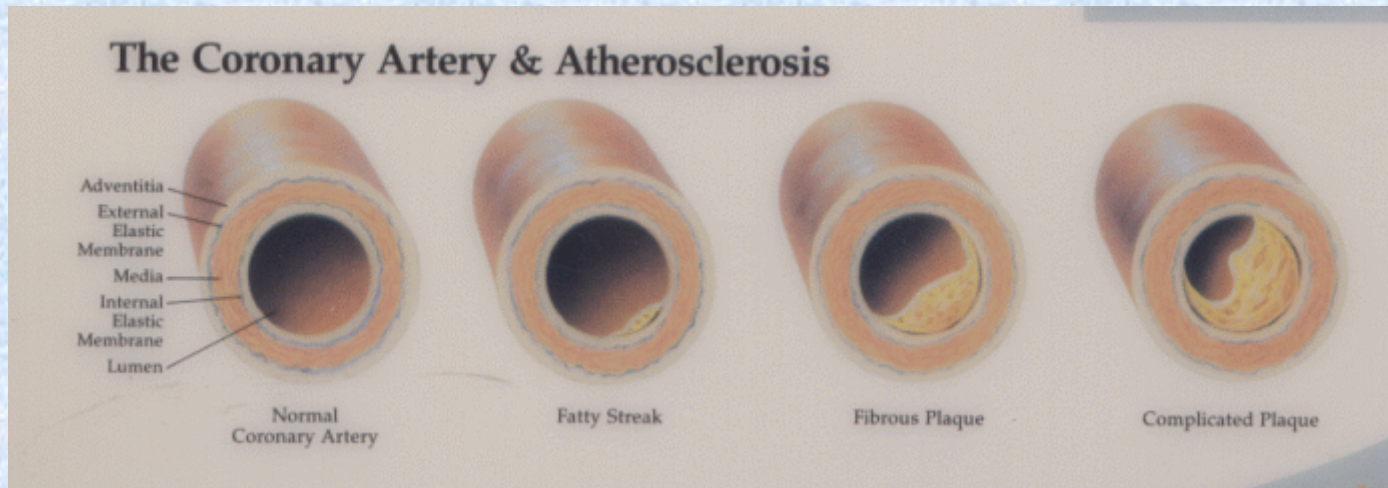
## Abdominal Aortic Aneurysm



# AAA Device



# Coronary Artery Disease



- Stents are used as scaffolds to hold open the artery

# Finite Element Analysis (FEA)

- Design
- Life prediction
- FDA requirements
- Can shorten the design cycle

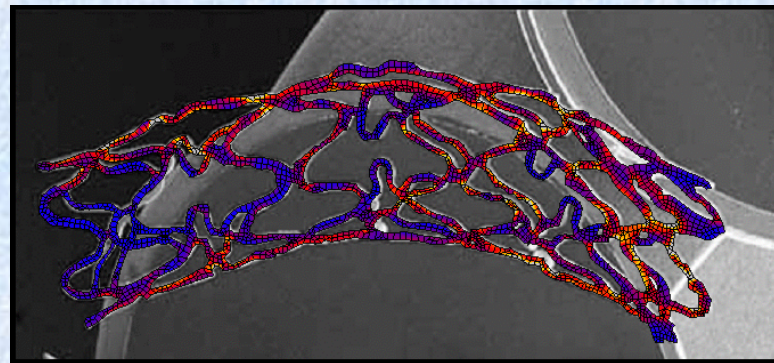
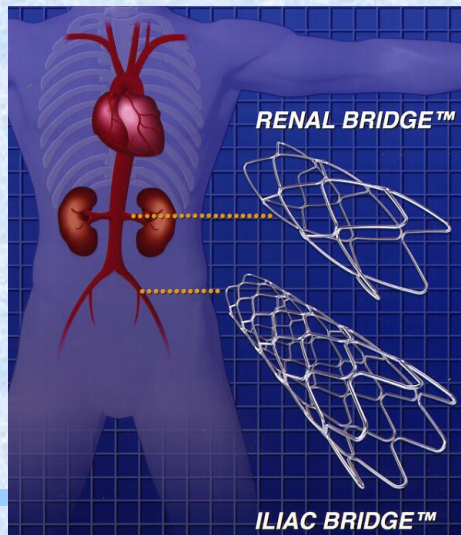


# FEA & Testing

- Finite element analysis (FEA) and physical testing are complementary
- A comprehensive program needs to include both components
- With judicious experimental validation, FEA can be used to reduce the amount of physical testing that is needed and shorten the design cycle

# The Challenge for Medical Device Development

- Reduce development time
- Increase confidence of success
- Avoid surprises and delays



# Prototype Development

- **Physical prototype**

- Cost and lead time is often a limitation
- Essential for animal testing and determining needed characteristics
- Want to reduce the number of design iterations that are prototyped



- **Virtual prototype**

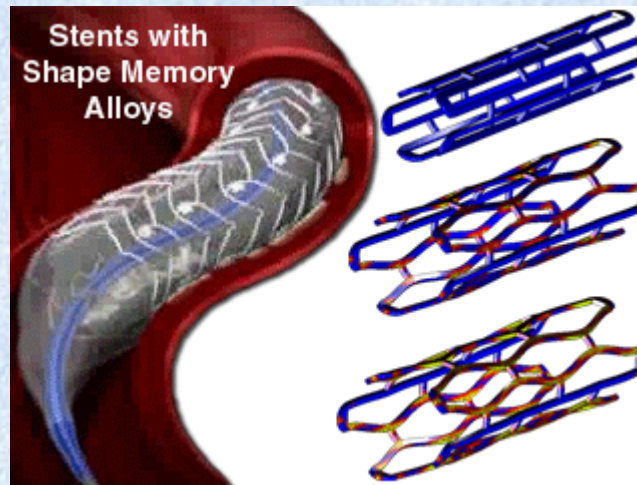
- Assess more design options
- Compare alternatives



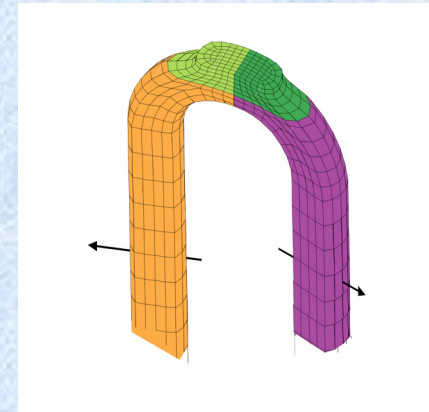
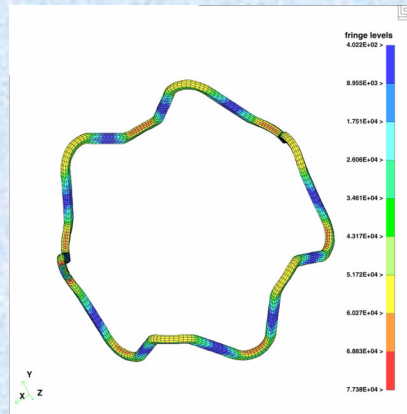
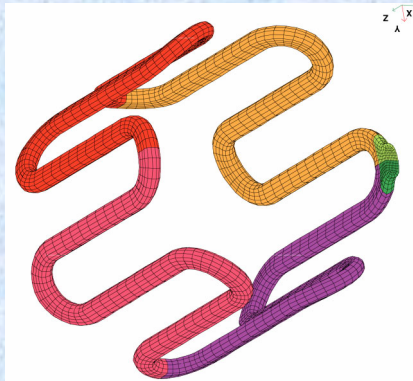
# Testing Is Essential for:

- Detailed characterization of the material; Getting data needed for the analysis
- Fatigue testing taking into account surface finish, processing steps
- Validation

# Nitinol Stent FEA

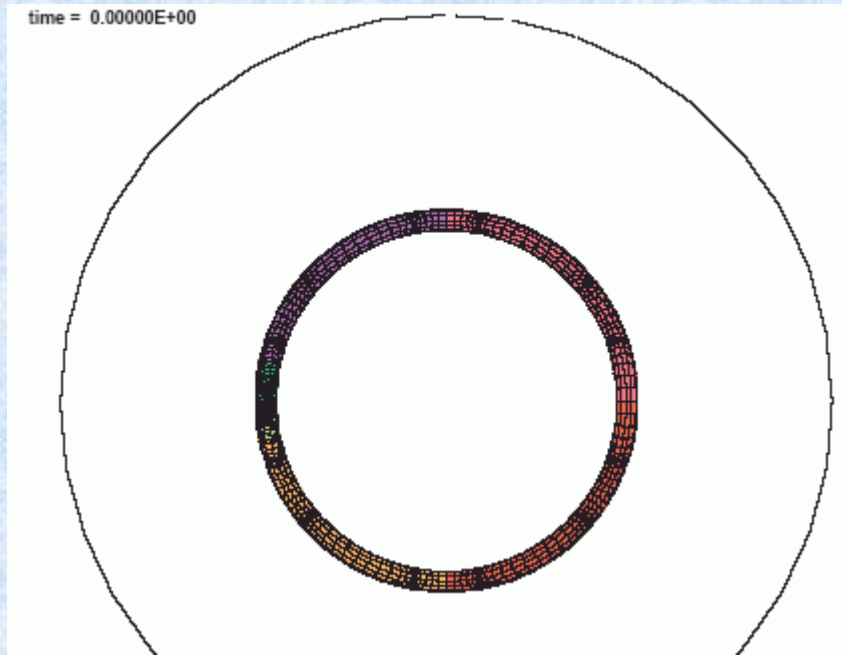


# Stent FEA

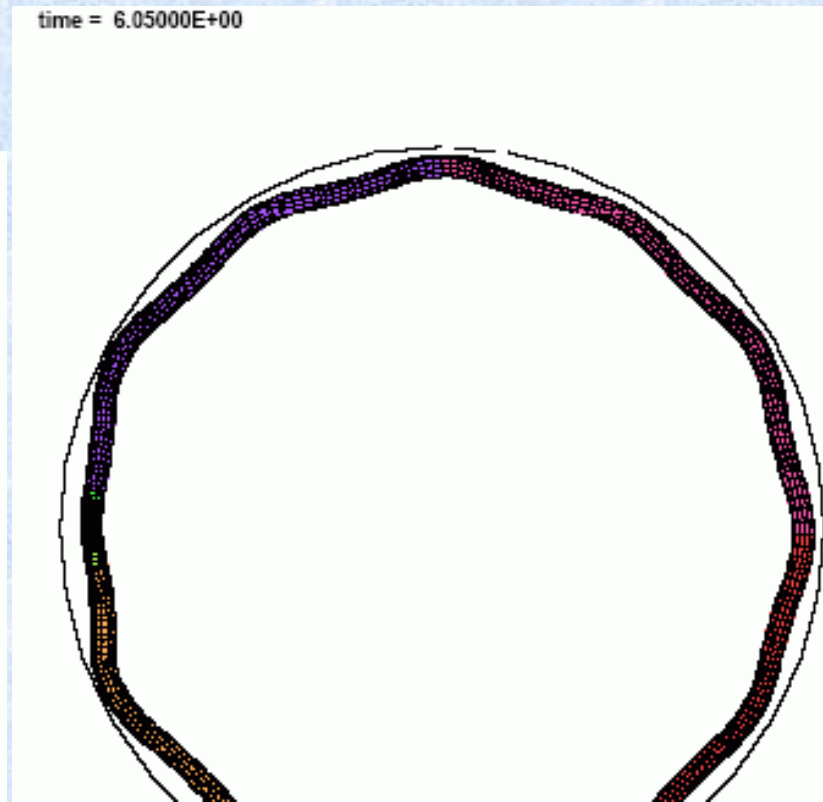


# Stent FEA

- Rolldown



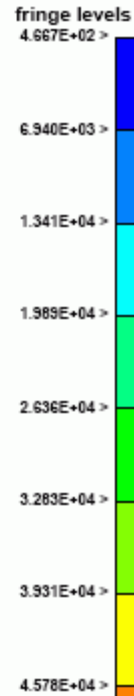
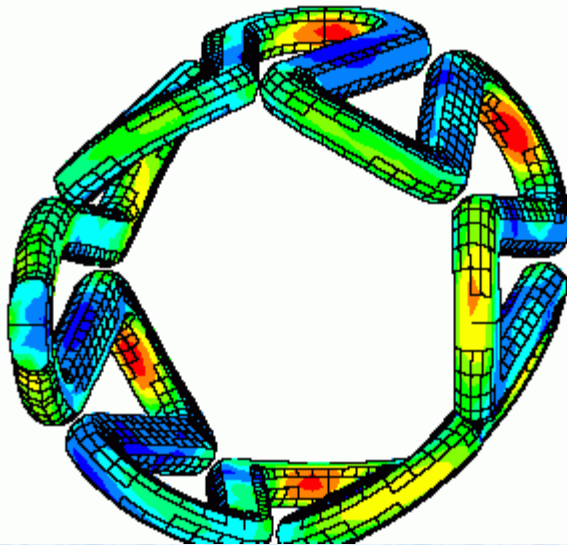
## Expansion



# Stent FEA

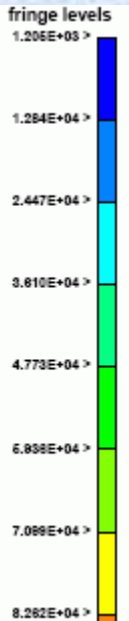
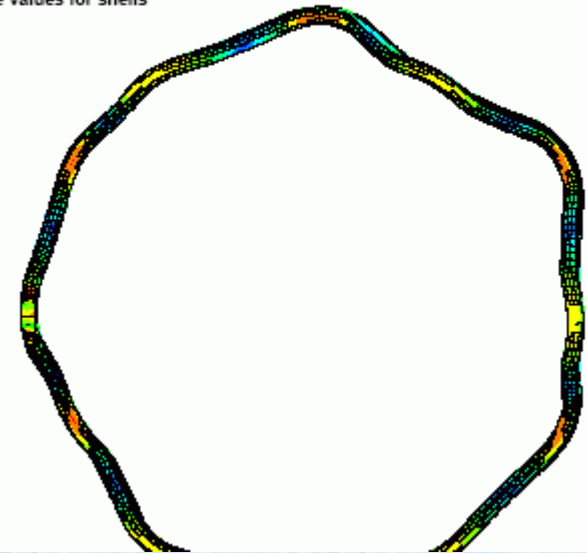
- **Roll-down**

time = 4.10000E+00  
fringes of eff. stress (v-m)  
min= 4.667E+02 in element 3802  
max= 5.873E+04 in element 6747  
ref. surface values for shells



## Expansion

time = 6.05000E+00  
fringes of eff. stress (v-m)  
min= 1.205E+03 in element 13087  
max= 1.059E+05 in element 14091  
ref. surface values for shells





# Creative Strategies in Medical Devices

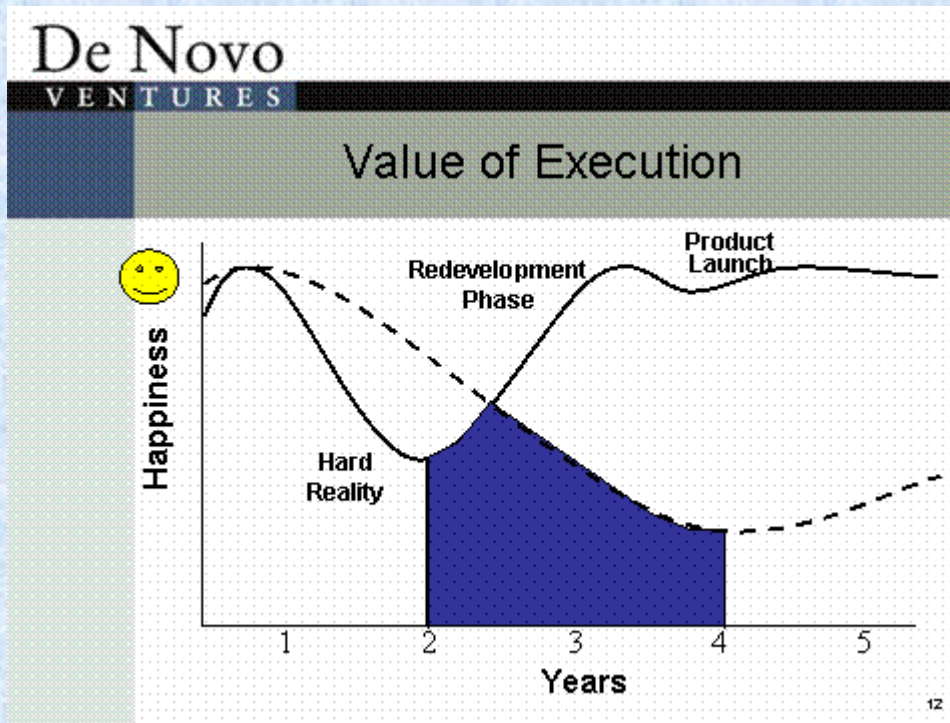
## 510(K) vs PMA?

- 510(K)
  - Concept of equivalence
  - May 28, 1976 Medical Devices Amendments to the FDA
  - Pro's
    - Speed
    - Lower risk
  - Con's
    - Low barriers to entry
    - 510(K) with clinical trials
- PMA – Pre Market Approval
  - Clinical trials for safety and efficacy of device
  - Pro's – barriers to entry
  - Con's – time, expense and risk

# Medical Device Development

- **Needs Assessment**
- **Research**
- **Intellectual property**
- **Biomedical ethics**
- **Brainstorming**
- **Assessing Clinical and Market Potential**
- **Developing patent strategies**
- **Prototyping**

# Value of Execution



- Ref: Rich Ferrari

# Consulting Implications

- Reduced fees for equity?
  - Incentive
  - Upside potential
- Need some assessment of the company
  - Capitalization
  - Burn rate

# Resources

## Startups & Business

- SVEBP [www.siliconvalleypace.com](http://www.siliconvalleypace.com)
- Stanford BUS16 [continuingstudies.stanford.edu](http://continuingstudies.stanford.edu)
- TVC [www.techventures.org](http://www.techventures.org)
- TEN [www.tensv.org](http://www.tensv.org)
- Girvan Institute [www.girvan.org](http://www.girvan.org)

# Resources (cont)

## Medical Device

- Stanford Biodesign [innovation.stanford.edu](http://innovation.stanford.edu)
- BioDesign Network [mdn.stanford.edu](http://mdn.stanford.edu)
- NanoBioConvergence [www.nanobioconvergence.org](http://www.nanobioconvergence.org)
- DeviceLink [www.deviceblink.com/mddi](http://www.deviceblink.com/mddi)
- TCT [www.tctmd.com](http://www.tctmd.com)
- Vulnerable Plaque [www.vp.org](http://www.vp.org)
- Vascular News [www.CXvascular.com](http://www.CXvascular.com)

# Summary

- Many opportunities in medical devices
  - Entrepreneurs
  - Consultants
- Increasingly multi-disciplinary
- Technology can be applied to advantage