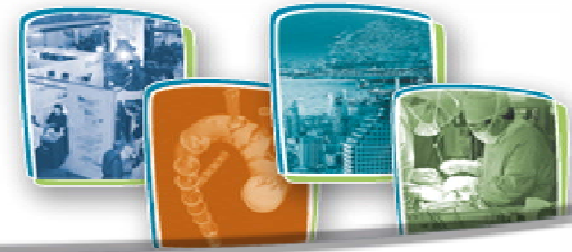


ICI Meeting
2008

**Innovations
in Cardiovascular
Interventions**



December 7-9, 2008 | Tel-Aviv, Israel



***Cutting Time to Market
Keys to Speed***



Douglas Wilkins, USA

Presentation Goals

- *Discuss the Keys to Expediting Product Development.*
- *Bring Forth Common Engineering Mistakes in Initial Product Cycles.*
- *Illustrate Pathways to Achieve Product Goals in Shorter Cycles.*



Product Development Steps-Early Stages

- *Protect your idea.*
- *Market Evaluation*
- *Concept Evaluation*
- *Prototype Evaluation*
- *Funding the Idea*
- ***Product/Specification Development***
- ***InVivo/Invitro Product Evaluation***
- ***Product/Sterility Validations***
- *Regulatory Filing*



Engineering Timeline Bottlenecks

- *1. Material Selection*
 - *- Biocompatibility*
 - *- Sterility and Processing Effects*
- *2. Sterility Selection*
 - *- Irradiation vs. ETO*
 - *- Validation Timelines*
- *3. DV/Packaging Testing*
 - *- Lead Time to Manufacture and Test*
 - *- Shelf Life Testing*



Keys to Speed – Material Selection

- Obtain Previous Approval Information or Bio Data from Suppliers.
- Visit Websites during selection, www.matweb.com, www.loctite.com, www.zeus.com.
- Stay away from plasticized materials, causes additional Biocomp. Testing and Time.
- Follow the ISO10993-1 Framework for Testing.
- Do not Re-Invent, use your supplier resources.



Keys to Speed – Sterility Selection

- *Request Data from Sterility Suppliers*
- *Choose a Sterility Source with Testing Resources and Expedite Capability.*
- *Ensure your design matches your Sterility Method (i.e open channels for ETO)*
- *For Time – When in doubt – Design for irradiation.*
- *Access the OEM Supplier network of data (i.e., TACTX, Creganna, Advanced Polymers, Clearstream).*



Keys to Speed – DV/Packaging Tests

- *Set Tolerances/Specifications to meet the clinical and product safety needs. DO NOT OVERTOLERANCE.*
- *Do the upfront work to make the design manufacturable.*
- *Run one or two small Pre-DV Lots to ensure success. Failure is unforgiveable.*
- *Combine Test Units to minimize quantity and time. Run subassemblies when possible.*
- *Use Packaging Materials that have support data.*



Keys to Speed – Common Mistakes

- **1. Design for Perfection vs. Design for Functionality.**
 - - **Overdesign/Over Tolerance**
 - - **Continual Design Iteration.**
- **2. Material Selection Incorrect**
- **3. Failure of Initial DV Testing.**
- **4. Lone-Wolf Approach- Work w/Partners**
- **5. Stay Local when Possible.**



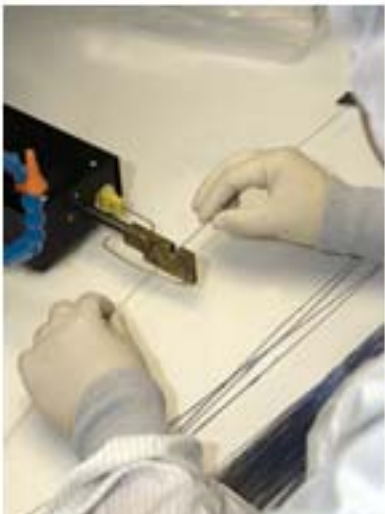
- New Site:
- **TACPRO, Israel**
- **4 Gefen Street**
- **Zur Moshe, Israel 42810**

- In addition to:
- Tactx Medical California
- 1353 Dell Avenue
- Campbell, CA. 95008

- Tactx Medical Minnesota
- 13845 Industrial Park Blvd.
- Plymouth, MN. 55441

- AVALON, Inc. (Tactx Medical)
- 29 Woodlands Industrial Park E1
- #04-1314 North tech Lobby 3
- Singapore





FROM IDEA TO REALITY