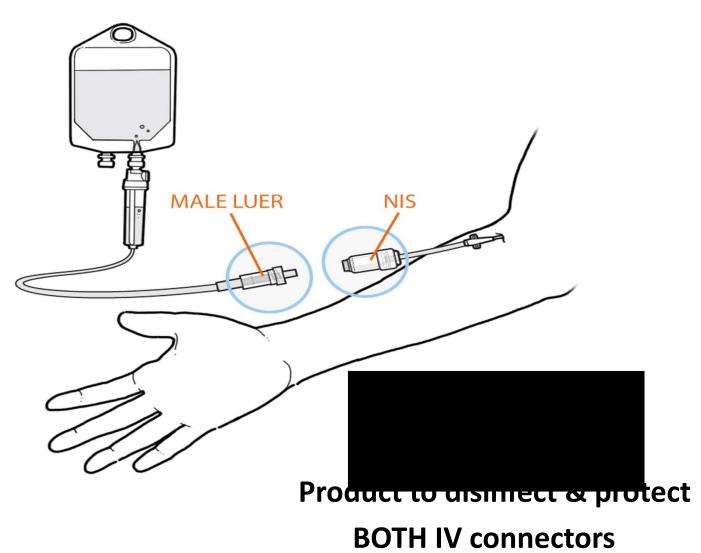
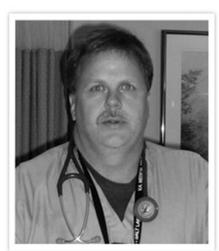
Product Development and Reimbursement

Vicki Farrar, JD Greg Jones, PhD Nic Anderson, MA MBA

Idea!





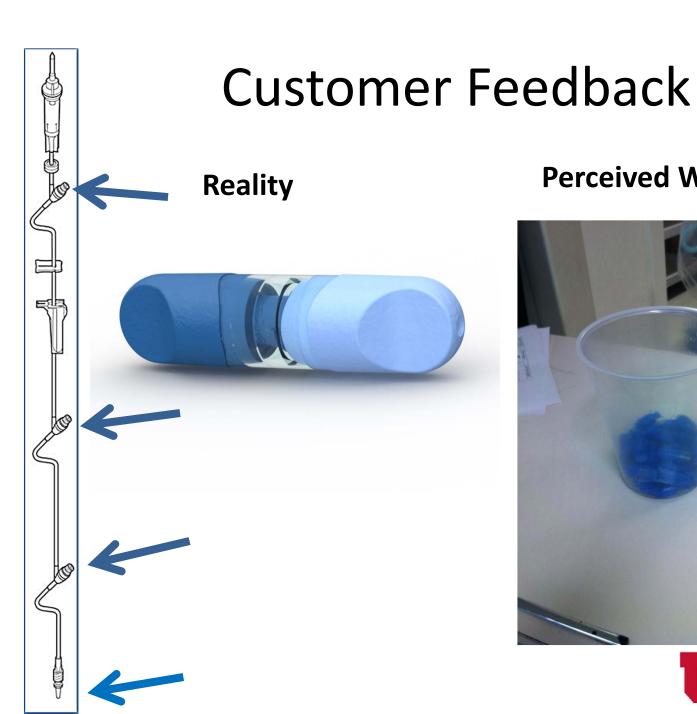




Drawer of Disposable Medical Devices in a Hospital Room







Perceived Waste





The DualCap System™



Use when disconnecting IV tubing from catheter



Use when setting up new IV tubing



Use when only one connector needs capping

- Pouches color-coded for contents
- Completely sterile





Market Research - New Delivery

Early Design

Final Design – IV Pole Strips™





Litigation

 Green cap company sues all competitors for infringement (So. Cal.)



V







 We sue green cap company for infringement of our dark blue cap technology and unfair competition (Utah)



V

Catheter Connections has a Robust Patent Portfolio Critical Asset, Constantly Revised & Monitored



iVeena

Relevant Research, Transformational Therapy

Product Development and Reimbursement

3rd Annual Translational Medicine Symposium February 19, 2013

Greg JonesInterim CEO, *i*Veena

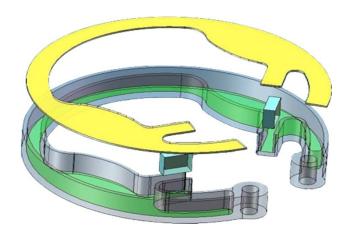
iVeena's Clinical Mission

To make Highly Effective Ophthalmic Therapies combining Proven, Clinically Effective Drugs with Innovative Drug Delivery Technology

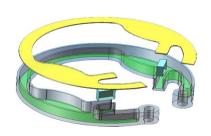
Initial Patient Population Target

Cataract/Macular Degeneration

- •3 million surgeries per year in the U.S.
- •200 million cataract patients worldwide
- Very large cross section with AMD



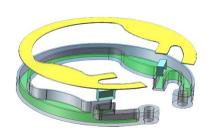
Adjustments



AMD

- Unmet Medical Need
- Return would support costs
- IP Position in the Eye
- Feasibility in Animal
- *FDA Feedback (pre-IND meeting)

Adjustments - Market/Drug



Inflammation and Glaucoma

- Unmet Medical Need
- Return would support costs
- ☑ IP Position in the Eye
- Feasibility in Animal
- FDA Feedback (informal discussion)
- **M**CMC consultant
- *****FDA consultant

Adjustments - Redesign



Inflammation and Glaucoma

- Unmet Medical Need
- Return would support costs
- IP Position in the Eye (FTO opinion)
- Feasibility in Animal
- FDA Feedback (informal discussion)
- **CMC** consultant
- FDA consultant
- Is financing available

Adjustments - Market/Drug



Inflammation

- Unmet Medical Need
- Return would support costs
- ☑ IP Position in the Eye (FTO opinion)
- Feasibility in Animal
- ☑ FDA Feedback (informal discussion)
- **CMC** consultant
- **I**FDA consultant
- ☑ Is financing available

iVeena

Relevant Research, Transformational Therapy

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Payment or Reimbursement

- 1. Technology created by scientist and VC
- 2. Sales representative sales to physician/hospital
- 3. Doctor treats patient with new technology
- 4. Doctor spent someone else's money
- 5. Doctor asks to be reimbursed from patient's insurance company

Principal-Agent Problem

- Physician buys...but doesn't pay
- Insurance company has limited funds

Evidence Based Medicine: Blue Print for a Successful Product Launch

- 1. Technology must have FDA approval
- 2. Evidence must show clinical efficacy
- 3. Technology must improve net health outcomes
- 4. Must be as beneficial as established alternatives
- This is all or nothing
- Notice, there's no mention of money

Watch-outs!

- Get funding specifically for clinical trials
 - RCT, Blinded, Placebo, Sham, Prospective, Multicentered...
- Collect peer-reviewed data from day one
- Publish, publish, publish
- Logic and intuition are poor substitutes for science