

# Disclosures

- Royalty: Cook, Teleflex
- Consultant: Cook, Teleflex, MedComp, Adrenas, B Braun, BD Bard, Lutonix, WL Gore
- National PI, Lutonix AV Trial
- Co-PI, Lutonix AV postmarket study

# Innovations in IR- Systems of Percutaneous Thrombectomy

# Bringing a Device to Market



# Top 10 Tips for Success with Your Invention

1. Do the research needed to support the concept
2. Do not rest on your laurels-never stop improving
3. Design your clinical trial/choose investigators well
4. Have friends in high places/get lucky
5. Work closely with partner's engineers
6. Have a champion for your idea
7. Find an appropriate industry partner/license
8. Get a working prototype
9. Protect your intellectual property
10. Identify a real need

# Basic Problem

- Developing dialysis declotting
- Infusion lysis prolonged, high bleeding rates
- Looking for a faster, better way
- Recognized problem of adherent clot

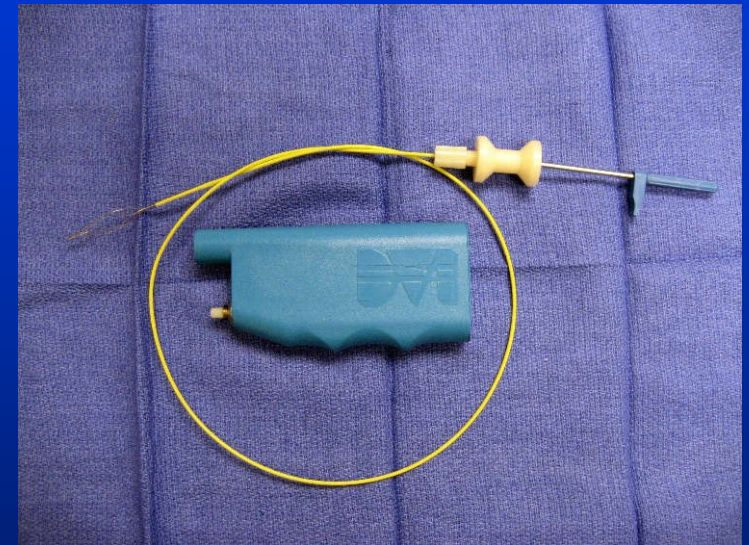
# Key Concept: Protect Your Idea

- Report of invention filed immediately



# Key Concept: (Functioning) Prototype

- Small device lab at Johns Hopkins
- Crude prototype
- In vitro testing of particle size
- Small clinical pilot project reported S(CV)IR 1992 with good results



# Finding a Partner

- Big (private) company #1-concerned about patentability
- Big (public) company #2-"no future for rotational mechanical thrombectomy devices"

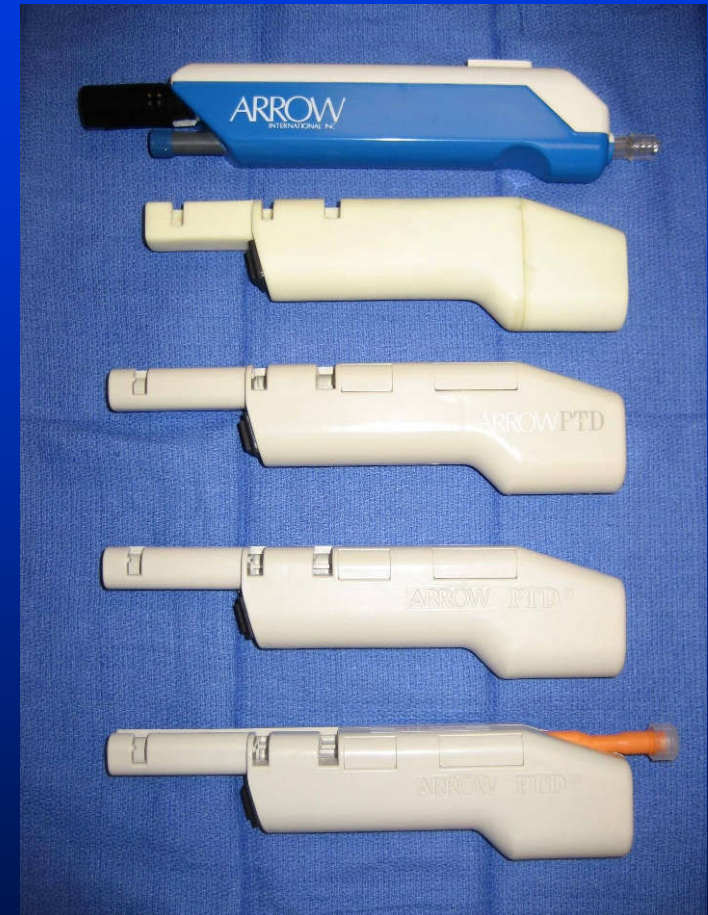


# Key Concept: Champion

- Independent contractor working with Arrow saw design
- Personally discussed with Arrow CEO
- Presented device at Arrow HQ
- Arrow licensed PTD

# Preclinical Development

- Allows fulfillment of academic mission for University inventor
- Company refines device
- Addressed all potential issues long before going to FDA



1992-1996

Top 10 tips

# Next Hurdle: FDA

- 2 ongoing device trials, randomized to surgery per FDA, very slow enrollment
- Key role of Anne Roberts at FDA
- First trial randomized to pulse-spray, much faster enrollment



# Clinical Trial

- Pick good partners:
  - Good track record in clinical trial performance (ie, few deviations, good audits, etc)
  - Interest and expertise
  - Adequate volume
- Completed enrollment <1 year

# Approval!

- Already 4 papers published or in press-key for sales force in era of evidence based medicine
- Do not stop there!!!
  - Continued refinement, research, publication
  - Led to approval for treatment of arterial plug, only device so approved
  - Led to approval for fistulae



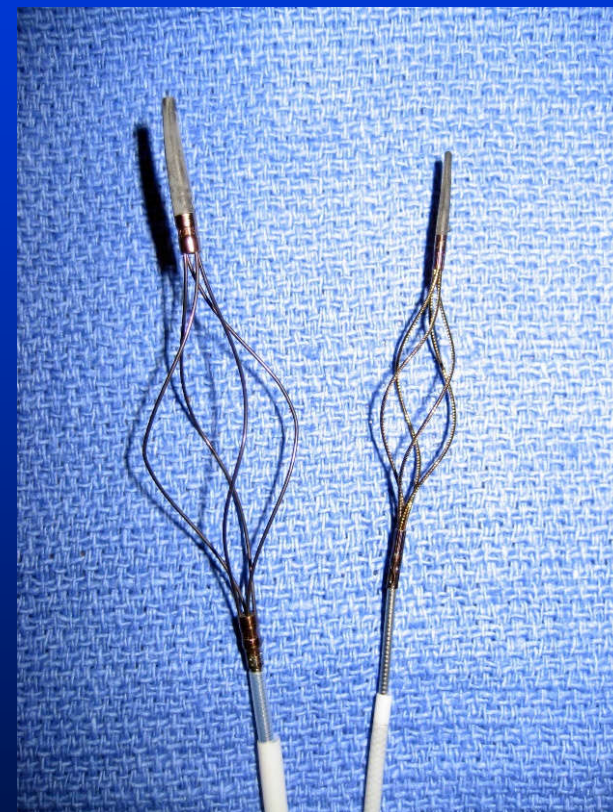
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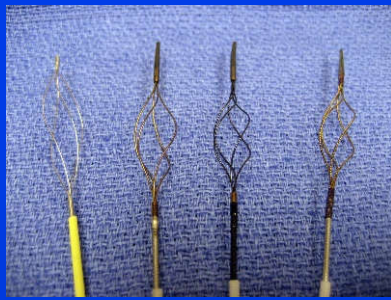
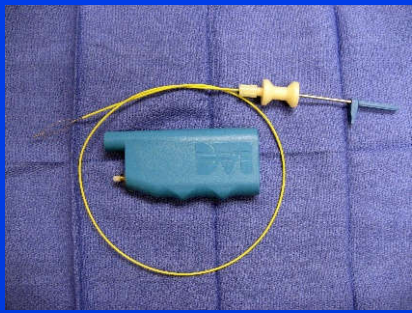
Top 10 tips



# The Research Track Record

- 5 papers from our group for dialysis
- 3 papers from our group for DVT
  - Clinical trial for DVT
- 2 from other groups for PE
- 5 from other groups for dialysis
- 2 from other groups for DVT
- Multiple dialysis related case reports
- Several for other apps: arterial, biliary, abscess





# Summary

- Protect your idea
  - Ensure process is moving forward
- Prototype it if possible
- Research and publish
- A champion helps
- Find a good partner
- Continue to explore new avenues

“What a long, strange trip it’s been”-Jerry Garcia



# Different in 2018?

- IP more crowded
  - Always room for more
- Regulatory pathway tighter
  - A good idea will fly
- Pace of change faster
  - Works both ways
- Good idea, perseverance, partnership will be successful in combination
  - Alone none will be