The Problem

- Over 400,000 patients in the US receive hemodialysis for end-stage renal disease and 100,000 new patients start hemodialysis yearly
- Hemodialysis costs an average of $89,000 per patient annually in the US; a total annual cost of $42 billion (significant portion is maturation and catheter issues)
- AV fistulas are the preferred method of vascular access for hemodialysis
- 70% of fistulas thrombose or require corrective procedures to maintain or restore blood flow within 1 year of initial surgery
- 65% of radiocephalic fistulas (RCFs) created are not used for hemodialysis

The Solution

- The **Fist Assist® device**
  - Novel
  - Non-invasive
  - Patient Compliant
  - Easy to apply and monitor
  - Wearable intermittent pneumatic compression device
- The Fist Assist® device helps ensure fistula dilation and maturation in a low cost setting
- Patent No.: US 8231558 B2
- IP protected through July 2032

“Changing the Standard of Care in Vein Dilation”
The Data

- **Study Location:** MS Ramaiah Medical College in Bangalore, India
- **2015 Feasibility Study:**
  - All participants were currently undergoing hemodialysis with a catheter; planned dialysis with fistula
  - 7 test subjects and 5 controls enrolled in IRB approved study
  - Device worn for 3 hours, 3 times per week
  - No patients experienced adverse effects, thrombosis or device failure
  - Continued enlargement of vein detected in 5 of 7 subjects at 3 months
- **2016 Efficacy Study:**
  - 30 test subjects and 16 sham controls
  - Device worn 6 hours daily
  - At 1 month, mean increases in vein size for the treatment group outperform that of the control group at proximal distances of 5 cm and 10 cm
  - Significant increase in vein size 5 cm proximal to the anastomosis (p=0.026)
  - 1 month data pending publication in the Journal of Vascular Access
  - Initial analyses indicate that vein dilation is higher for RCF versus brachiocephalic fistula at 5 cm, 10 cm, and 15 cm proximal to the fistula for the treatment group
  - 3 month data pending
- **Conclusions**
  - For Patients: Fist Assist® is a simple, easy to use and affordable device that can help to safely dilate veins after fistula creation
  - For Physicians: Fist Assist® ensures excellent fistula dilation, resulting in fewer complications
  - For Partners: Fist Assist® offers an opportunity to join and lead AVF cost saving and quality initiatives

"Playoff or Payoff" Opportunity Bracket

Contact Us

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