# VANDERBILT VUNIVERSITY

CTTC Center for Technology Transfer & Commercialization

# Novel Cryo-tipped Catheter Combining Cryo-anchoring and RF Ablation for Treating Mitral Valve Disease

### Summary

Heart valve disease is the 3rd most prevalent source of cardiovascular disease, leading to approximately 20,000 deaths per year in the U.S. alone. Moreover, there are an estimated 41,000 mitral valve procedures performed in the U.S. each year.

The only effective, long-term treatment for mitral valve disease is open-chest valve replacement surgery, which is highly undesirable for elderly patients. Thus, there is a pressing need to develop novel percutaneous strategies for treatment that will reduce the number of open-chest surgeries. David Merryman and colleagues have developed a new, combined catheter that uses cryo temperatures to adhere to moving mitral valve leaflets and radiofrequency ablation to alter the compliance of the leaflet tissue to prevent prolapse and regurgitation.

## Description

The cryo-tipped catheter has the following advantages over current designs:

- 1. Cryo-ablation is generally less destructive and results in minimal thrombus formation and disruption of the endothelial layer.
- 2. Cryo-ablation has also been shown to maintain extracellular collagen matrix, without collagen denaturation or contracture related to thermal effects.
- B: Cryo only C: Cryo + RF А RF Сгуо leaflet <-20°C 108°C 1 cm 1.0 n 1400 () 1.0 5 0.8 D E (kPa) 1200 1000 0.6 0.4 Strength tissue area > 65°C 800 tissue area < 0°C 0.4 U.2 III U.2 600 400 Anchor 200 5 25 0 10 15 20 30 0 Time (s) Cryo Cryo + RF
- Cryo-anchoring at temperatures as low as
  -30°C is an excellent choice for attachment of a catheter to a moving MV leaflet without causing undesired side-effects.

### **Stage in Development:**

A desk-top prototype has been made, and tested on a MV leaflet (Fig. A) (similar to approaching the leaflet trans-septally from the atrium), anchored with a cryo-temperature of under -20°C and RF ablated. The procedure has been imaged using a thermal imager. The results demonstrate that the cryo anchoring has no effect on the RF ablation temperature (Fig. C and D) and is able to maintain anchoring strength that is robust enough to maintain adherence simultaneous with the RF ablation procedure (Fig. E).

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