V-SLING, A LEFT VENTRICULAR TRANSCATHETER REPAIR DEVICE FOR HFREF

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Background:

Despite recent advances in guideline-directed medical therapy, heart failure with reduced ejection fraction (HFrEF) continues to be a leading cause of hospitalizations and mortality. Cardiac Success has developed the V-sling device to improve outcomes for patients with HFrEF. The V-sling is a transcatheter ventricular repair device that has been designed as a lesser invasive approach to achieve papillary muscle approximation, a successful surgical procedure for patients with heart failure.

HFrEF is characterized by ventricular dilation, papillary muscle dislocation, and low ejection fraction. 80% of the HFrEF patients do not have significant mitral valve regurgitation and are therefore not suitable for mitral valve repair or replacement. Five-year mortality for this population is ~35%. There are currently no approved devices to directly treat the failing left ventricle.

The V-sling is a transcatheter band that passes around the bases of the papillary muscles and approximates the papillary muscles, thereby directly reducing LV size, improving ventricular function and correcting the geometry of the mitral valve apparatus.

The concept of the papillary muscle sling has been used successfully by a number of surgeons for many years, typically concomitant with CABG and annuloplasty procedures in patients with ischemic heart disease and severe mitral regurgitation. The published results have been encouraging (Nappi, 2016) (Mihos, Abstract 15036: Papillary Muscle Sling and Mitral Valve Repair for Secondary Mitral Regurgitation: The SLING Study, 2016b) (Hvass, The papillary muscle sling for ischemic mitral regurgitation, 2010) (Mihos, 2018). However, the procedure has to date been limited to on-pump open heart surgery (Hvass, 2003) (Lamelas, 2013). As such, although successful, surgical morbidity and mortality have been considerable.

Our Solution:

The V-sling enables implantation of a papillary muscle sling via a transcatheter procedure, which will make the procedure easier, safer, and more accessible than surgery. The V-sling system includes both the adjustable sling implant and the transcatheter delivery system which allows the positioning of the implant around the papillary muscles, its adjustment, and deployment under transesophageal echocardiographic guidance.

Technology Advantages:

- Leverages existing clinical effectiveness of the surgical papillary muscle sling procedure
- Treats LV dilatation directly by repositioning the papillary muscles
- Adjustable implant size for optimized papillary muscle repositioning using real time TEE
- Safe anchorless implant without penetration of the myocardium

- Implant does not block future interventions
- Applicable to patients with HFrEF with and without mitral regurgitation

Methods:

Testing of the Cardiac Success transcatheter papillary muscle repositioning device was performed in a variety of ways:

1) Fatigue testing was performed by "implanting" the implant on a fatigue test jig and applying cyclic tension to mimic the tension of diastolic filling in a heart failure patient.
2) Tissue compatibility and ingrowth testing was performed by surgical implantation of the implant into sheep heart and assessment at 30, 60, and 90 days.
3) Transcatheter implantation feasibility was tested by implantation in a transfemoral procedure in a living animal model and human cadavers.

Results:

1) 6 implants were tested on the fatigue testing jig for over 30 Million cycles with no failures.
2) Complete tissue encapsulation of the implant occurred by 30 days after implantation. Histological analysis showed no sign of clinically significant pathology.
3) Transcatheter implantation was successfully demonstrated in both a living animal model and human cadavers.

Conclusions:

The Cardiac Success transcatheter papillary muscle repositioning device has demonstrated technical and pre-clinical feasibility and is scheduled for First In Human in Q2 2022. The device has the potential to treat heart failure patients with reduced ejection fraction and functional mitral regurgitation grade ≤ 2+.