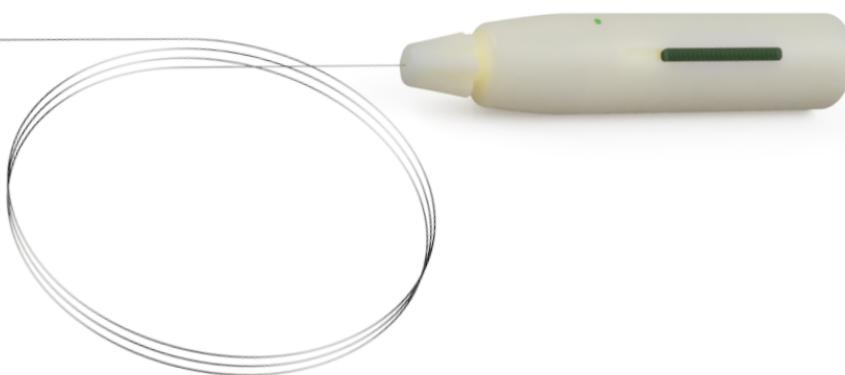




Mount
Sinai



MitralPrint Device



Introduction

Mitral regurgitation (MR) is the most common heart valve disorder in the U.S. with over 4 million individuals affected globally and an incidence of over 250,000 annually. Results of severe MR frequently lead to shortness of breath and fatigue and to potential heart failure and death in absence of treatment. Open heart surgical Mitral valve repair (O-MVR), is the gold-standard option to restore the valve function and patient prognosis. Today minimally-invasive options (transcatheter therapy - tMVR) allow surgeons and interventional cardiologists to perform valvular repairs without opening a patient's chest and represent a safe alternative in a subset of frail patients.

Unmet Need

Approximately 10,000 MitraClip (Abbott) and Pascal (Edwards) procedures are performed per year. This number is increasing thanks to a larger number of eligible patients about 130,000-185,000 patients. Each of these would benefit from the use of MitralPrint, making the total addressable market \$120,000,000 per year in the US alone. Currently, t-MVR are performed under ultrasound guidance (echocardiography) which provides only a precise morphological assessment. Following t-MVR, up to 25% of patients with initial satisfactory repair (based on current diagnostic methodologies) will develop recurrent regurgitation, suggesting an insufficient ability of intraoperative trans-thoracic ultrasound assessment to anticipate mid-and long-term failure following t-MVR. Preliminary work suggests a strong interest in a physical intraoperative assessment to guide t-MVR procedure: the measurement of forces between the two mitral leaflets (i.e. mitral coaptation force - MCF) appears as a promising parameter to help physicians to perform efficient and long-lasting repairs.

Our Solution

The MitralPrint device is an endovascular pressure sensor guidewire designed to quantify MCF in real-time during both open heart and t-MVR. The device can be placed within the beating heart to quantify MCF in real-time during repairs procedure. This innovative solution will serve as a key indicator of surgical efficacy, thereby reducing the occurrence of, repair failures and subsequent need for secondary valve reoperation, and negative long-term outcomes. Substantial prior data supporting this technology has already been acquired during the development and testing of a similar piezoelectric MCF sensor by the study team designed to be deployed by a non-endovascular mechanism. The price of this product will be \$700-\$1,200 (as estimated by the Value Analysis Committee at Mount Sinai Hospital).

Advantages

- **First objective parameter** - no need to rely on subjective trans-thoracic ultrasound assessment.
- **Improved safety and efficacy** - fewer repeat procedures and fewer reoperations

Current Development Status

- Prototypes have been made.
- Proof of concept on human cadaveric heart and on pig has been carried out.
- US Provisional Application has been filed.

Objective - Partnership

- Build an external team.
- Successful licensing of technology to external entity (MSIP).
- Seed funding raise (supported by Sinai BioDesign).