Mitral Leaflet Modification

Project Description

TMVR

Transcatheter Mitral Valve Replacement (TMVR) is a minimally invasive surgical procedure that is used to replace the failing mitral valve within the heart. An artificial heart valve is guided from a catheter port into the heart and is installed to replace the mitral valve. The installation of the mitral valve may cause blood flow restriction in some patients, resulting in an obstruction of the Left Ventricular Outflow Tract (LVOT). This obstruction reduces the total amount of blood exiting the patient's heart, resulting in decreased blood flow and increased blood pressure. There are some processes in use to solve LVOT obstructions, but there are many patients who are ineligible due to the geometry of their mitral valve leaflets

Goal

The goal of the project is to design a prototype that will capture the anterior mitral leaflet for it to be cut to a shape that will allow the replacement valve to be installed without causing an LVOT obstruction. Modification of the leaflets would allow for an increase in the number of eligible candidates for TMVR.

Company Information

AMX Technologies, INC

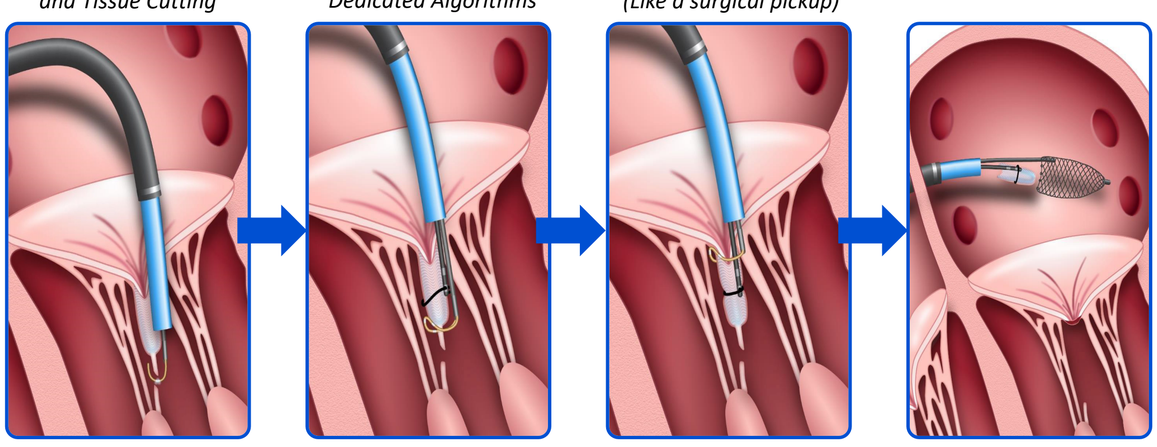
- Founded in 2019 by Dr. Paul Sorajja and structural heart experts
- Minneapolis, MN-based
- Three areas of intellectual property
  - TEER Management
  - Septal Crossing
  - Leaflet Modification (SYR Capstone)

Electro-surgical Innovation	Propriety RF technology enables safe and reliable **tissue incision in blood pool.**
Catheter Technology	Catheter and accessories to enable percutaneous **targeting of any heart chamber.**
Clinical Expertise	**Cardiovascular interventions and imaging** expertise to tackle critical unmet needs.

Transcatheter Edge-to-Edge Repair (TEER) Removal

TEER devices are placed on the mitral valve to clip the valve leaflets together and reduce leakage (regurgitation) without open-heart surgery. However, for TMVR, where the whole valve is replaced, these clips can block or distort the valve opening, so they often need to be removed to safely fit the new valve.

Surrounding Chord and Tissue Cutting → *Tissue Cutting with Dedicated Algorithms* → *Device Snaring (Like a surgical pickup)* → *Placement in Basket*



Design Input Requirements

Ensure Safety and Efficacy

Design inputs translate clinical needs into quantitative engineering specifications per FDA 21 CFR 820.30. These requirements establish measurable targets with defined tolerances and verification methods, ensuring the device performs safely and effectively for its intended use.

User Needs → Design Inputs (Requirements) → Design Outputs (Specifications) → Verification Testing → Validation (Clinical)

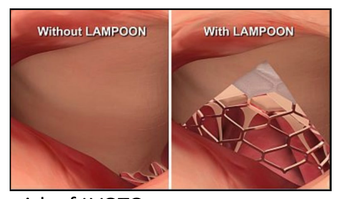
Key Requirements

Category	Requirements	Target	Rationale
Leaflet Stabilization	The device should stabilize the motion of the AML to enable cutting	0-15 Hz ± 2 Hz	Suppresses motion across cardiac cycle frequency and harmonics to enable precise RF cutting
Clamping Force	The device can securely hold onto AML	2 N ± 1 N	Balances effective leaflet immobilization while preventing tissue damage
Hemodynamic Stability	Critical intervention phase (clamp and cut) duration	≤ 3 min ± 2 min	Limits hemodynamic disruption while allowing adequate time for precise leaflet modification and debris capture.
Device Compatibility	The device shall interface with the AMX Clip Removal System	Pass/Fail	Integrates with existing delivery system to streamline procedure and reduce additional components.
AML Modification (Resection approach)	The system is capable of removing sections of the anterior mitral leaflet.	125 mm^2 ± 25 mm^2	Provides sufficient neo-LVOT expansion to prevent obstruction; derived from LAMPOON clinical outcomes

Existing Process

LAMPOON

Laceration of the Anterior Mitral Leaflet to Prevent Outflow Obstruction is the most prominent leaflet management procedure as it directly targets the root cause of LVOT Obstruction. This technique requires two catheters, one equipped with an electrified guide wire and the other with a snare to catch the wire inside the valve. Using this connection, surgeons are able to precisely split the leaflet.



Alcohol Septal Ablation

Alcohol Septal Ablation (ASA) is a much less common procedure for treating LVOTO but still shows promise. In this technique, a catheter fitted with a balloon is used to release Ethanol into the septal artery, this damages surrounding cells by causing a localized heart attack (myocardial infarction). The damaged tissue is then replaced by much thinner scar tissue, reducing the risk of LVOTO.

Clinical Problems/Needs

Clinical Need

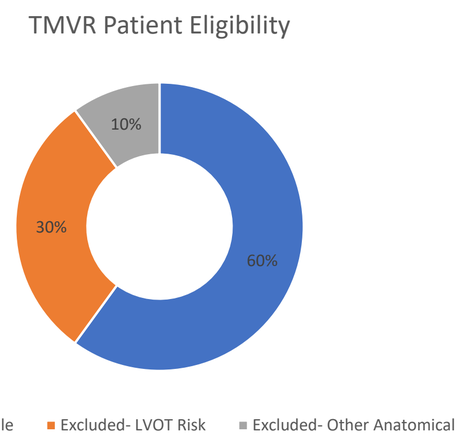
Patients with Mitral Regurgitation who are considered high-risk for open-heart surgery face limited treatment options. TMVR offers a minimally invasive alternative by deploying an artificial valve within the native mitral annulus via transcatheter. However, many of the patients who could otherwise benefit from TMVR are deemed ineligible to receive the treatment due to anatomical constraints, especially unfavorable leaflet geometry that may lead to Left Ventricular Outflow Tract Obstruction (LVOTO). This has created a critical gap in care for these excluded patients.

Clinical Population

Due to the nature of the procedure (Transcatheter Mitral Valve Replacement), the vast majority of patients suffering from heart problems that demand a TMVR typically range in age from 60 to 80 years.

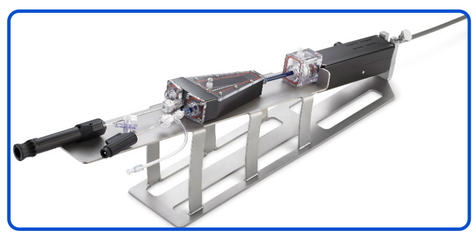
Clinical Outcome

We have been given an opportunity to work with AMX on this upcoming design of their own, aiming to create a device preventing LVOT obstruction; the expectation is to expand the treatable patient population by 30-40%

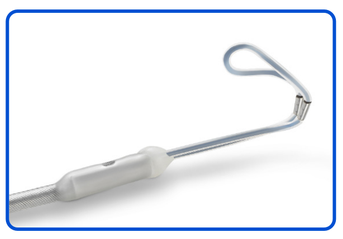


Proposed Design

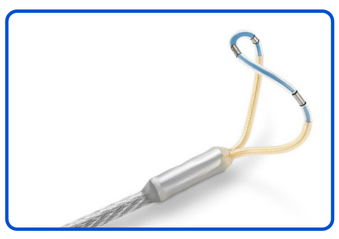
Use existing AMX products for navigation to the mitral valve and RF modification of the leaflet



Steerable and Removal Catheter

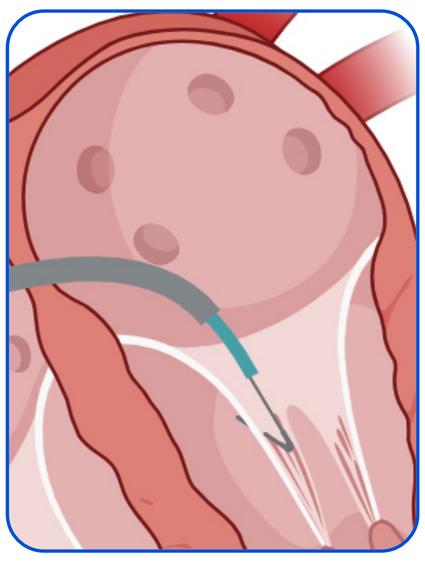


Leaflet Laceration Device

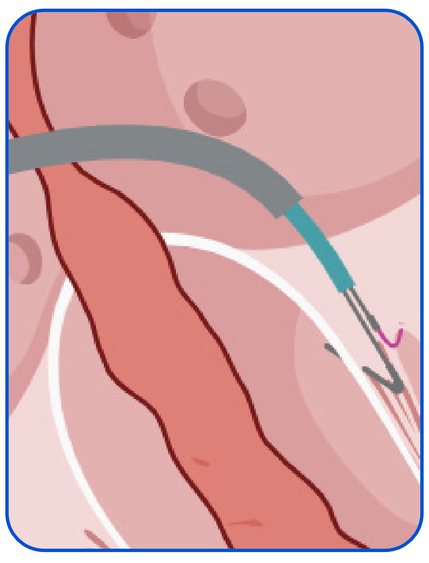


Leaflet Resection Device

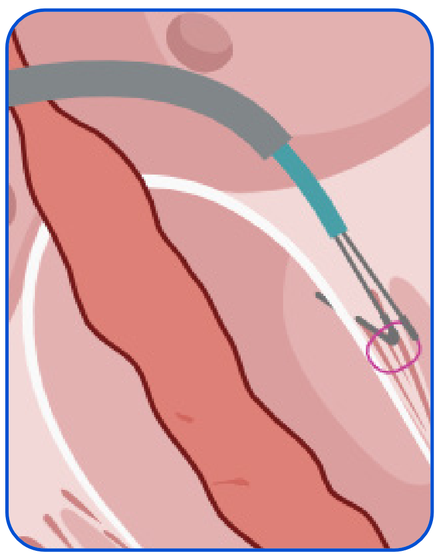
Create a device to immobilize the anterior mitral leaflet (AML) during cutting operations



Clamp captures and stabilizes AML for procedure



Laceration Approach: Targeted leaflet modification via slit creation



Resection Approach: large leaflet removal via wedge removal

Semester Deliverables

Analyze LVOT Obstruction in TMVR → Define Design Input Requirements → Develop Concept Design → Perform dFMEA → Contruct 3D Model

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