Problem Statement:

Statement of Need:

The purpose of this project is to create an endovascular tissue removal device that operates with the most minimal invasive procedure possible in the aortic root to remove valve leaflet tissue, both healthy and severely calcified, to prepare for the introduction of a prosthesis. Many previous devices and procedures such as stents and angioplasty simply leave the valve leaflets intact and pressed against the aortic wall, causing distortion of the prosthesis, paravalvular leakage, or regurgitation.

Endovascular procedures reduce the risk of severe complications of the surgeries that these procedures would be replacing, especially in patients with advanced age or co-morbidities. This product would be greatly useful due to the fact that aortic stenosis is the most common valvular heart disease in the western world.

Introduction and Overview

The device is designed to perform an endovascular procedure which will cut out or macerate calcified or diseased tissue in order to prepare the site for a valve replacement prosthesis. While held in place on the other side of the aorta, this device will cut the leaflets using a rotating cutting blade. This cutting blade would be attached to a thin wire that would be driven by an motor external to the body. The floating debris would then be suctioned into an attached catheter via a funneling filter which would still allow blood to flow past. The massicated debris will then either to be removed from the body immediately or stored within the device until the procedure was complete. The entire device needs to fit inside the catheter (7.83 mm) and then would need to be expandable to between two and three times the size once it has reached its destination inside the aorta. At the same time, the device needs to be able to be recollapsed before exiting the body. The device may include some or all of the
following: motorized cutting blade, soft shaft, filter, vacuum tube, tissue holder, external motor and controller.

**Realistic Constraints**

Size of this device is a huge issue. Since the Aorta and arterial tissues range in size in millimeters to centimeters in diameter, and designed to be in a standard 24F catheter, the size of the device is limited. The drive shaft must be incredibly flexible and mobile as it needs to be snaked through the patient’s circulatory system in order to reach the procedure site in the aorta. In addition to being flexible, it needs to at the same time be strong and deliver enough force to cut through calcified tissue. Since the area that needs attention in the aorta is larger than the rest of arteries it will pass through upon entering and exiting the body, the cutting portion of the device needs to be entirely collapsable. Another issue that arises with the procedure is the cutting blades cannot come into harmful contact with aortic walls, which could potentially cause damage or possibly rupture. The device is hoped to be patented within the near future, and manufacturable due to its potential impact for aortic stenosis.

**Questions**

- Holder on one side, cutter/macerator on other?
- Motor intended to be internal, or outside with “controller unit”?
- What is our budget?
- What exactly are we filtering? Is this catching the particles? Is this filtering out the particles to be suctioned out?
- Exact size restraints?
- Is the vacuum necessary?
- Forces that are necessary to cut through the calcified valve leaflets and forces within the aortic valve.
Material to use for the cutting blade/filter?

Material to use for the flexible driveshaft?

Other Data

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