



Device and Method for Transseptal Puncture

Summary

Atrial fibrillation (AF) and mitral valve (MV) disease are two of the most common cardiac conditions. AF affects between 2.7 and 6.1 million American adults each year. MV disease is the most common heart valve lesion, impacting 1.7% of U.S. adults (9.3% of people ≥ 75 years old). Both AF and MV disease are frequently treated using catheter-based (percutaneous) technology that requires access to the left side of the heart using a transseptal puncture (TSP). TSP technology is a fertile target for innovation because TSP can be time-consuming, is imprecise in locating proper puncture location, is difficult to learn, and is associated with significant complications.

Key Investigator

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Field

Cardiology

Technology

Atrial fibrillation
Mitral valve
Catheter
Transseptal puncture

Advantages

Improved safety and targeting of fossa ovalis in transseptal puncture

Status

Available for licensing

Patent Status

PCT/US2018/023800

UMB Docket Reference

JG-2017-030

External Reference

American College of Cardiology/American Heart Association Task Force Report Circulation 2014, 130(23):e199-267

American Heart Association Circulation. 2017. 135(10):e146-603

ClinicoEconomics and Outcomes Research. 8:613-627

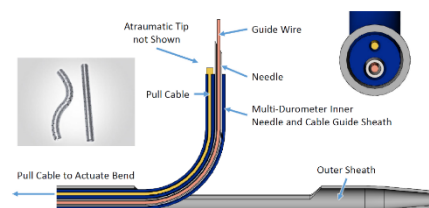
University of Maryland, Baltimore researchers have developed a novel (TSP) device and procedure that allows the surgeon to access structures on the left side of the heart from the right side of the heart. The device differs from those currently available as it provides a method for the surgeon to tune the stiffness of the device. This allows the device to remain flexible as it enters the vasculature and stiffen so that it can provide a stable platform for penetration of the fossa ovalis.

Market

The lifetime risk of AF development in men > 40 years old is 26%, with AF contributing to $> 99,000$ deaths/year. An AF diagnosis adds \$8,700/year to the individual cost of treatment with an estimated impact on healthcare in the U.S. of \$26 billion/year. MV disease is the most common heart valve lesion, impacting 1.7% of U.S. adults (9.3% of people ≥ 75 years old), with an estimated cost per hospitalization of \$51,415. Symptomatic MV disease increases annual health care expenditures by \$7.6 billion in the U.S., with an overall total incremental expenditure for valvular heart disease of \$23.4 billion.

Technology

The fundamental design features of the invention are: 1) a stiffening element within the catheter that becomes a rigid platform from which to puncture the fossa ovalis (FO), 2) an element that can be advanced to the FO from the stiffened catheter from which the puncture needle is extended and, 3) a blunt tip at the end of the element that protects the FO from inadvertent puncture.



Technology Status

A prototype cannula and needle assembly has been created and tested in a porcine heart *in vitro*. Twenty computed tomography (CT) scans from pre-operative cardiac surgery patients were analyzed using the Osirix™ imaging platform in order to optimize preliminary device design parameters based on normal human anatomical measurements.