

Transcatheter Tricuspid Valve Replcaement

The TriSol patented device concept and unique design was created out of deep understanding and knowledge of the unmet need and current products' limitations and weaknesses.

The Need

Tricuspid Regurgitation (TR) occurs when the tricuspid valve fails to close properly, causing blood to flow backward into the right atrium. Many cases of TR are accompanied by the Dysfunction of the Right Ventricle (RV). In the US alone, there are about 1.6 million patients suffering from TR. TR is currently treated by surgery. Due to the high risk related to the surgical procedure (in-hospital mortality post-cardiac surgery for isolated TR is about 10%), most of the patients cannot be treated. As such, there is a significant unmet clinical need for a transcatheter solution to TR.

The Product

The TriSol device is a transcatheter Tricuspid valve replacement, which is delivered during a catheterization procedure. The TriSol valve is constructed out of nitinol frame **with specially designed sail-like leaflet**. Its unique design provides a comprehensive solution to the anatomical and functional challenges which arise when treating TR by a replacement valve.

At a Glance

IP: Granted patent: "Device for placement in the tricuspid annulus" Priority date Nov. 2011

National phase application: "Prosthetic valve and deployment system"

Priority date: Dec. 2014

Funding: July 2016 - raised \$820K from Alon MedTech Ventures Incubator and Dr. Carlos Ruiz.

Status: Pre-clinical

The Advantages

- TriSol is a **Replacement valve rather than repair device** (replacement valves are standard of care for transcatheter agric valve replacement)
- TriSol valve addresses RV Dysfunction as well as TR
- TriSol valve anchors very well to the challenging Tricuspid annulus
- Does not damage conductive tissue

TriSol Valve unique advantages were proven in animal trails and advanced simulator.

The Market

There are 1.6 million patients suffering from moderate to severe TR in the US. The price of commercial transcatheter valves, is between \$20K to 30K. As such the total addressable market in the US alone ranges between \$32-48 billion.

The Competition

Currently there are a few transcatheter devices in development stage, which intent to address moderate to severe TR. NaviGate develops a replacement valve. Navigate performed their first compassionate human implants and raised \$17M. Other companies, such as: Edwards Life Sciences, Valtech Cardio, 4tech and Mitralign develop valve repair solutions.

The Team

Ron Davidson – CEO: B. Sc. And MBA. 20 years of experience in managing and accelerating companies in the healthcare field. Led companies from early stage to successful acquisitions by multinational companies.

Eli Ben-Hamou – VP R&D: M. Sc. in Mechanical Engineering. 10 years of experience in the medical device industry. R&D Project Engineer in Ventor (acquired by Medtronic) and Medtronic.

Tal Gollan – Founder & CTO: B. Sc. in Biomedical Engineering. 10 years of experience in the medical device industry. Project engineer of Ventor technology (Aortic Valve) in Medtronic.

Igor Kovalsky: M. Sc. in Mechanical Engineering. 10 years of experience in transcatheter valve development. R&D principal product engineer in PVT, Ventor, Medtronic and Tendyne

Dr. Mordehay Vaturi – Founder & Medical Director: Senior Cardiologist at the Echocardiography Unit and Valve Clinic, the department of Cardiology, Rabin Medical Center, Petah-Pikva, Israel.

Prof. Giora Weisz – Medical Advisor: Director of Coronary Care, Montefiore Einstein Center for Heart and Vascular Care. Associate Professor at Columbia University, NY & Hebrew University, Israel.