



Micro Interventional Devices, Inc.

Taking Aim at Structural Heart Disease

Micro Interventional Devices, Inc.[™] Successfully Treats First-in-Human Patient with Percutaneous MIA[™], Minimally Invasive Annuloplasty Technology

Clinical Enrollment in STTAR (The Study of Transcatheter Tricuspid Annular Repair) Continues in Europe

Newtown, PA – October 12, 2018 – [Micro Interventional Devices, Inc.[™]](#) (MID) announced today the world's first percutaneous implantation of its MIA[™], Minimally Invasive Annuloplasty, technology for tricuspid and mitral repair. This marks the first patient enrolled in the transcatheter arm of the STTAR (Study of Transcatheter Tricuspid Annular Repair) trial being conducted in Europe.

The procedure was performed by a team lead by Professor Audrius Aidietis, MD, Chief of Cardiology and Angiology and Professor Kestutis Rucinskas, MD, Chief of Cardiac Surgery at the Vilnius University Hospital Santariskiu Clinic. Proctoring the case were renowned experts, Mathew Williams, MD, Director of the Heart Valve Program, and Alan Vainrib, MD, Cardiologist and Echocardiography Specialist, both from NYU Langone Health. A successful outcome was achieved with the 12F MIA delivery catheter and PolyCor[™] anchors to reduce tricuspid annular dimensions and tricuspid regurgitation (TR) in this patient.

The first ever percutaneous bicuspidization was performed on a 61-year-old female suffering from severe torrential tricuspid regurgitation. Utilizing MIA's proprietary technology, the physicians were able to reduce the dilated tricuspid annulus by 29%, from 20.9cm² to 14.9cm². Additionally, MIA achieved a 36% reduction in effective regurgitant orifice area (EROA), from 2.5cm² to 1.6cm², a quantitative measure of tricuspid regurgitation. No complications or adverse events were reported or experienced. The image-guided procedure relied on fluoroscopy and 3D echocardiography to place the PolyCor anchors accurately on the tricuspid annulus. MIA's unique PolyCor anchoring technology enables the percutaneous bicuspidization of the tricuspid valve, replicating an open surgical bicuspidization procedure.

"The percutaneous MIA system has the potential to be a safe and effective intervention for patients with moderate to severe tricuspid regurgitation," stated Prof. Audrius Aidieitis, MD.

"I expect the reduction in tricuspid regurgitation and annular area achieved during this procedure to improve the patient's symptoms resulting in favorable right ventricular remodeling," Prof. Kestutis Rucinskas, MD added. "We look



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forward to continuing to enroll patients in STTAR to assess the safety and performance of this new therapy.”

This is the first of 40 patients to be enrolled in the percutaneous arm of the STTAR multicenter clinical trial. The STTAR study has two arms, a surgical and percutaneous arm. As of this October, MID now has one year follow up data on three patients in the surgical arm, which confirms that the reduction in tricuspid regurgitation and tricuspid annular dimensions observed acutely are maintained at one year. The team anticipates enrollment in the percutaneous arm will move quickly given the short learning curve associated with the technology.

“The one year follow up data generated from the surgical arm of STTAR and the first clinical percutaneous use of MIA are major milestones for MID,” stated Michael Whitman, President and CEO. “The 12F delivery system is simple to use and MIA’s low mass implant will preserve physiological function and all future options for intervention. This differentiates MIA from other technologies being developed for tricuspid applications. There are over 1.1 million patients suffering from tricuspid regurgitation in the US alone. MID’s focus is on this large patient population, with the intent of improving their quality of life.”

About Micro Interventional Devices, Inc. (MID):

MID is the world leader in percutaneous transcatheter compliant fixation technology addressing unmet needs in structural heart disease.

MIA utilizes proprietary, compliant PolyCor™ anchors, the world’s first low mass polymeric implant designed to comply with normal physiological valvular function. The MIA implant is engineered to plicate and comply with cardiac tissue once deployed.

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