'First-in-Man' Clinical Study Of Permaseal Initiated

/PRNewswire/ -- Micro Interventional Devices, Inc.™ [1] (MID), an emerging cardiovascular medical device company, announced today that the first patient has been treated using its self-sealing, cardiac access and closure technology, Permaseal™ [2]. The patient is the first to be enrolled in the company's STASIS clinical trial that has commenced in Europe.

Designed as a non-randomized, multi-center, CE-Mark study, STASIS (Sutureless Transapical Access and Closure Study) will evaluate the safety and performance of Permaseal for left ventricular transapical access and closure. The study will be conducted at five sites within the European Union (EU) and will enroll 40 patients scheduled for a transapical transcatheter aortic valve replacement procedure utilizing Edward's Sapien XT. MID expects top-line data from the trial to be available by Q1 2013.

Professor Lange commented, "This marks the initiation of the first human safety and performance study for the Permaseal device. The need for a safe, reliable and easy-to-use access and closure device for structural heart repair procedures, specifically during TA TAVI, is well known. I am honored to play a lead role in the development of this potential solution to transapical access site complications."

Permaseal is the first transapical access device to enable true self-sealing, sutureless cardiac access and closure. The technology combines soft tissue anchors and advanced biocompatible elastomers that form a "web" around the myocardial access site. The device is applied to the myocardium prior to the procedure and provides hemostatic access to the left ventricle during minimally invasive cardiac procedures.

Once the procedure is completed and the cannula and guide wire are extracted, the Permaseal webbing constricts around the opening in the heart, providing instantaneous closure while allowing for flexibility to accommodate a beating heart. Permaseal is designed for a range of structural heart repair procedures including transcatheter aortic valve implantation (TAVI) and mitral valve repair.

"Deploying Permaseal for the first time in human patients is an exciting milestone for our company," stated Michael Whitman, President and CEO of MID. "We look forward to completing STASIS and collecting the data from our first clinical study as an important step in our effort to commercialize the technology and provide a safer, less-invasive access and closure platform to patients undergoing cardiac surgery."

Wilson Szeto, M.D., University of Pennsylvania, will include Permaseal in his

presentation titled "LV Apical Closure Devices" during the "Innovative Surgical Techniques and Technologies" session of the Transcatheter Cardiovascular Therapeutics (TCT) Conference in Miami, FL this week. Dr. Szeto's presentation will take place October 24, 2012 at 9:20 a.m. EDT in the Junior Ballroom D of the Miami Beach Convention Center.

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