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CAISSON INTERVENTIONAL COMPLETES FIRST IN HUMAN IMPLANTS OF ITS TRANSVASCULAR MITRAL VALVE REPLACEMENT

NYU Langone Medical Center Implants First Patients with Groundbreaking New Investigational Device

MAPLE GROVE, MINNESOTA (September 16, 2016) – Caisson Interventional, LLC (“Caisson” or the “Company”) announces the first successful human implants of its fully percutaneous, transvascular mitral valve implant designed as a functional replacement in a diseased, damaged, or malfunctioning mitral valve.

Mathew R. Williams, M.D. and his team from the Heart Valve Center at NYU Langone successfully implanted three patients with the Caisson Transcatheter Mitral Valve System. These are the first patients enrolled in the PRELUDE Study (Percutaneous Mitral Valve Replacement Evaluation Utilizing IDE Early Feasibility Study). The study is designed to provide initial data on the safety and performance of the Caisson TMVR System. The U.S. Food and Drug Administration (FDA) approved the Investigational Device Exemption (IDE) for the PRELUDE study under the Early Feasibility Study program for up to 20 patients in 5 centers.

The Company also reports one patient was successfully implanted in July under the direction of Eric Cohen, M.D. and Gideon Cohen, M.D. at the Schulich Heart Centre at Sunnybrook Health Sciences Centre (Toronto) under the Health Canada Special Access Programme.

The physicians involved stated the patients responded very well to the implant with excellent valve function. They also commented the delivery system performed as designed and facilitated proper placement of the implant with precise control at each step of the procedure.

Dr. Williams, NYU Langone’s chief of Adult Cardiac Surgery, and director of Interventional Cardiology and Structural Heart commented, “NYU Langone is a recognized world leader in cardiac care and we are dedicated to bringing the most advanced minimally-invasive technologies to our patients. We are proud

to be the first medical center in the world to successfully implant three high risk patients with Caisson's cutting-edge new technology to treat their severe symptomatic mitral regurgitation. Thanks to NYU Langone's focus on innovation in the field, and the FDA's dedication to the Early Feasibility Study (EFS) Program, we have the opportunity to be involved with this first-in-class technology at the earliest stage of clinical evaluation."

The Caisson implant consists of two components; an Anchor constructed of a Nitinol frame and a pericardial tissue Valve attached to a Nitinol frame. The implant is fully repositionable and retrievable and only released after the function of the implant is fully assessed. The entire procedure is completed through a single percutaneous femoral venous access utilizing a trans-septal approach to the native mitral valve.

Caisson Interventional CEO C.J. Schweich Jr., M.D. said, "We are thankful to the NYU Langone and Sunnybrook teams for their dedication to outstanding patient care and participation in this groundbreaking clinical experience. These initial implants mark a significant milestone for Caisson's technology in understanding its potential to benefit a significant number of patients with severe mitral regurgitation and limited therapeutic options."

About the company: Caisson Interventional, LLC. is a privately held clinical-stage medical device company located in the Minneapolis area focused on the design, development, and clinical evaluation of a novel percutaneous mitral valve replacement system. The Caisson Mitral Valve Replacement System is approved for investigational use in the United States and therefore limited by Federal (or United States) law to investigational use only.
