

Early Patient Cases with Mitra-Spacer™ System presented at PCR London Valves 2015

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English ▾

BERLIN and BOSTON, Sept. 21, 2015 /PRNewswire/ -- Cardiosolutions, Inc., a development stage company possessing a novel, atraumatic, volume adjustable, mitral valve therapeutic device, unveiled its first-in-human experience with the Mitra-Spacer™ System. The technological achievement was presented at PCR London Valves in Berlin, Germany. The proprietary Mitra-Spacer System is intended to treat or bridge heart failure patients whose operative mortality risk for undergoing conventional open-heart surgery is deemed too high.

Cardiosolutions' pioneering technology involves the use of a tethered atraumatic inflatable and volume adjustable balloon placed between the anterior and posterior mitral valve leaflets via a trans-apical approach on the beating heart. The Mitra-Spacer System does not focus on the repair of various anatomical changes of the mitral valve but acts to fill the gap between the native leaflets, thus reducing the mitral regurgitation.

The implant procedures were performed by Olaf Wendler MD, PhD, FRCS, Professor of Cardiac Surgery, King's College Hospital London, in selected patients on compassionate grounds. "A unique design feature of this promising technology is the ability to modify the fill volume of the Mitra-Spacer System post-procedure. This allows adjusting the mitral regurgitation therapy to the capacity of the left heart function and to eliminate residual mitral regurgitation in the long term course after implant", said Professor Olaf Wendler.

Thomas Piemonte, MD FACC, FSCAI, Chief Medical Officer, Cardiosolutions, Inc. commented: "This challenging early clinical stage in very sick patients demonstrates the implant feasibility of the Mitra-Spacer System as well as the immediate performance of the device in reducing mitral regurgitation".

"The first implants of the Mitra-Spacer System are an important step toward our goal of introducing a transformational therapy for the treatment of mitral regurgitation to provide patients with an alternative, less invasive treatment option", said Steven Tallarida, Chairman, Cardiosolutions, Inc.

About Mitral Regurgitation

Today two to three percent of the world's population suffers from mitral regurgitation and approximately 2.3 million patients in the US and Europe suffer from severe mitral regurgitation. Every year approximately 500,000 new patients are diagnosed with this disease, of which over 80% are untreated. A substantial group of patients have no option because they are too sick to survive the surgery and many others delay treatment because they have only moderate symptoms.

About Cardiosolutions

Cardiosolutions, Inc. (www.cardiosolutionsinc.com) is developing a less invasive alternative to open heart surgical repair of the mitral valve. The Cardiosolutions Mitra-Spacer System is designed to provide a therapeutic substitute to this complicated open heart valve repair procedure. Cardiosolutions was incubated and spun out of Primo Medical Group, Inc. (Stoughton MA.) partnering with BioVentures Investors (www.bioventuresinvestors.com), a leading Medtech venture firm and Sorin Group (www.sorin.com), a global medical device company and a leader in the treatment of cardiovascular diseases.

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