



4TECH

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4TECH Inc. Reports First U.S. Clinical Implantations of Its TriCinch™ Coil Tricuspid Valve Repair System

GALWAY, Ireland, Nov. 1, 2018 —[4TECH Inc.](#), a leader in the field of transcatheter tricuspid valve repair, initiated its U.S. Early Feasibility Study, following receipt of approval from the U.S. Food and Drug Administration (FDA), with the successful first two implantations of the [TriCinch™](#) Coil System at **Piedmont Heart Hospital**, Atlanta, Georgia, by **Dr. Christopher Meduri**, **Dr. Vivek Rajagopal** and **Dr. Mani Vannan**. The study will evaluate the TriCinch Coil System in 15 patients across seven centers in the U.S.

“We are pleased to be the first center in the U.S. to implant the TriCinch Coil System,” said **Dr. Christopher Meduri**. *“Both procedures went smoothly, and the device was easy to implant. Having a technology like the TriCinch Coil System in our structural heart toolkit allows us to treat a wide range of patients suffering from tricuspid regurgitation, who are at high risk for open heart surgery, in a safe and simple manner.”*

The 4TECH TriCinch Coil System is a simple percutaneous direct annuloplasty device designed to reduce tricuspid regurgitation by means of tricuspid valve (TV) remodeling via a unique nitinol coil anchor that is tensioned by a nitinol stent in the inferior vena cava (IVC).

“This is a major milestone for 4TECH, and I am excited with the progress the team has made,” said **Tom Fleming, 4TECH CEO**. *“The TriCinch Coil System is designed to simply target the underlying pathology of annular dilatation. With this device, we are committed to helping patients who have very limited treatment options.”*

“Through our experience and in collaboration with key physicians, we have built a robust clinical program to evaluate the safety and efficacy of the device,” said **Keith D. Dawkins, MD, 4TECH CMO**. *“I am encouraged by our momentum, and I am confident that we will provide physicians with a novel solution that will benefit patients suffering from TR.”*

The device is being evaluated worldwide with a CE-Trial that has enrollment in both Australia and Europe.

About Tricuspid Regurgitation (TR)

Tricuspid regurgitation is a common condition that is age-related and difficult-to-manage, in which blood “backflows” into the right atrium. Today’s standard of care for TR is medical management. Surgical intervention is high-risk with an in-hospital mortality for isolated TR as high as 37%¹. Patients with TR and related complications result in substantial healthcare spending due to frequent re-hospitalizations. Furthermore, TR leads to chronic renal failure and the need for end-stage dialysis. The combination of these negative outcomes results in a significant unmet need for a minimally invasive solution for TR.

About 4TECH Inc.

4TECH Inc. (www.4TECHtricuspid.com) is incorporated in Delaware, USA, with operations in Galway, Ireland (4TECH Cardio Ltd). 4TECH has developed a proprietary transcatheter solution for the treatment of TR. Because of its unique anchoring and tensioning mechanism, the 4TECH TriCinch™ Coil System for Transcatheter Tricuspid Valve Repair (TTVR) potentially allows a simple and reproducible percutaneous procedure, designed to reduce TR and restore patient quality of life.

Caution: The 4TECH TriCinch™ Coil System for Transcatheter Tricuspid Valve Repair is in the early clinical phase of development and is NOT available for sale in any region of the world.

1. Fender EA, et al. Heart 2017;0:1–9. doi:10.1136/heartjnl-2017-311586