



TRiCares Announces First Topaz Implantations in US Early Feasibility Study

Paris, France and Munich, Germany, January 09, 2025 – TRiCares SAS (“TRiCares”), a company pioneering a minimally-invasive tricuspid valve that flexes with every heartbeat, announces that the first patients have been successfully implanted with Topaz, its transcatheter tricuspid heart valve replacement (TTVR) system, in an Early Feasibility Study (EFS) in the US.

The TRICURE EFS ([NCT06506942](https://clinicaltrials.gov/ct2/show/study/NCT06506942)), a prospective, multi-center, single arm study approved under an FDA IDE, will assess the safety and performance of TRiCares’ Topaz TTVR system in adult patients with severe tricuspid regurgitation (TR) who are identified with increased operative risk. The study is taking place in up to 8 sites across the US and Canada, aiming to enroll 15 patients.

The first two implantations in the TRICURE EFS were carried out by the experienced teams at Piedmont Heart Institute in Atlanta, GA and the Medical University of South Carolina (MUSC) in Charleston, SC.

Ahmed Elmouelhi, President & CEO of TRiCares, said: “Starting the EFS study in the US alongside the ongoing European pivotal study for CE marking is testament to the hard work of the TRiCares team and the excellent support from leading medical centers. We are positively progressing our ambition for Topaz to become the valve of choice for the millions of patients suffering from tricuspid regurgitation.”

Dr. Susheel Kumar Kodali, Director of the Structural Heart and Valve Center at Columbia University/New York Presbyterian Hospital & Principal Investigator of the TRICURE EFS study stated: “I am pleased to oversee this important TTVR study. In the months ahead, I’ll work with the study participants and organizers to investigate how Topaz might improve long term outcomes for TR patients. Physicians are certainly in need of new solutions that address adverse events and simplify the implantation procedure.”

Dr. Pradeep Yadav, Director of Structural Interventions at the Marcus Heart and Vascular Center, Piedmont Heart Institute commented: “Our first implant of the Topaz valve was successful with the patient’s TR eliminated and the patient discharged in good condition shortly thereafter. The simple Topaz procedure was completed in less than an hour and it was less demanding of our imaging specialists than other TR therapies.” Dr. Yadav performed the procedure with **Dr Vinod Thourani, Marcus Chief of Cardiovascular Surgery, Piedmont Heart Institute.**

Dr. Nick Amoroso, Structural Heart & Valve Clinic and Associate Professor of Medicine, MUSC added: “The implantation of the Topaz valve took place as pre-planned, and we are pleased to see the patient recovering well. Given the unique advantages of TOPAZ that made treatment possible for this patient, we are encouraged by the valve’s performance.” The procedure was performed alongside **Dr. Nicolas Pope, Cardiac Surgery, MUSC.**

TRiCares is also making progress in Europe, with growing patient enrollment in its [TRICURE EU Pivotal study](#), with the first implantation completed in September 2024 at the Algemeen Stedelijk Ziekenhuis hospital, in Aalst, Belgium.

About TRiCares

TRiCares is a privately held company developing Topaz, a minimally invasive tricuspid valve replacement system for the elimination of tricuspid regurgitation (TR). Topaz’s unique dual stent design is easy to implant and uses established transfemoral and transjugular delivery methods, avoiding the need for high-risk open-heart surgery. Topaz is designed to fit a wide range of anatomies and replaces the diseased tricuspid valve. Once in place, it flexes with every heartbeat. A European Pivotal Study and a US/Canadian Early Feasibility Study are underway, with progress being made towards FDA approval and CE marking. TRiCares has focused on TR since its inception and its ambition is for Topaz to become the valve of choice for the millions of TR patients worldwide, overcoming the limitations of current treatment approaches.



TRiCares is a global business, with offices in France, Germany, the US and Brazil, and is supported by a strategic partner and leading life science venture capital firms: 415 Capital, Andera Partners, Bayern Kapital, BioMed Partners, Credit Mutuel Innovation, GoCapital, Karista, and Wellington Partners.

About Topaz

The Topaz Transcatheter Tricuspid Valve Replacement (TTVR) System is designed to eliminate tricuspid regurgitation through a minimally invasive approach. This system consists of the Topaz Heart Valve Prosthesis and a catheter-based implantation system. It is developed exclusively for use in the tricuspid position and to provide a system for physicians that is safe and easy to implant. The unique two-stent valve prosthesis is inserted primarily via the femoral vein and transports the prosthesis into the right side of the heart, where it is finally released to replace the diseased tricuspid valve.

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