

TRiCares Announces Successful First in Human Implantation of Minimally Invasive Topaz Tricuspid Heart Valve Replacement System in Germany

Paris, France and Munich, Germany, April 25, 2022 – TRiCares SAS (“TRiCares”) a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, today is pleased to announce the successful first in human implantation of its Topaz transfemoral tricuspid heart valve replacement system (“Topaz”) in Germany.

Heart valve diseases are among the most serious cardiac conditions, affecting more than 12.7 million patients in Europe and many more worldwide. In the last decade minimally invasive catheter-based solutions have been developed for other heart valve diseases, but none have been designed specifically for the tricuspid valve.

Tricuspid regurgitation is a frequent and serious disease for which open heart surgery and symptomatic pharmacologic treatment are the current standard treatment options. Owing to high mortality risk, access to open heart surgery is severely restricted and is not considered an option for more than 99 % of patients with tricuspid regurgitation. The prognosis for patients without surgical repair is poor, with 2.2 years median survival. As such, there is an urgent need for minimally invasive, lower risk solutions to improve outcomes for patients with no other viable treatment options.

Topaz is an innovative device designed specifically to help patients suffering from severe tricuspid regurgitation without the need for open heart surgery. The Topaz device is the result of a French and German collaboration and is implanted in a minimally invasive procedure through the patient’s femoral vein. It is designed specifically to fit the tricuspid valve anatomy and thus supports ease of positioning and functionality.

Today’s announcement marks the successful first in human implantation of Topaz in a patient in Germany, which was done as a compassionate use treatment.

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The procedure in Germany was performed for a 76-year-old woman with heart failure due to massive tricuspid regurgitation that recurred despite a previous suture annuloplasty of the tricuspid valve in 2014. The patient has a history of multiple cardiac surgeries like mitral valve replacement and bypass surgery, and has numerous risk factors that made a surgical treatment too hazardous. The successful implantation of the Topaz tricuspid heart valve replacement system took place at University Hospital Mainz in Germany, on 8 April 2022, and was performed by Prof. Ralph Stephan von Bardeleben. Prof. Hendrik Treede, cardiac surgeon at University Hospital Mainz, and Prof. Ulrich Schäfer, interventional cardiologist of the military hospital in Koblenz, Germany proctored the procedure. After an implantation time of 25 minutes the Topaz prosthesis anchored safely in the significantly enlarged ventricle and achieved complete correction of the tricuspid regurgitation. The patient recovered quickly from the intervention and was discharged from hospital after eight days.

In total nine implantations of the Topaz tricuspid heart valve replacement system have been performed to date across Europe.

Building upon the success of these procedures, TRiCares is preparing a clinical study in the coming months to confirm the value of its Topaz tricuspid heart valve replacement system for these types of patients, who until now have had no satisfactory treatment option.

Prof. Dr. Ralph Stephan von Bardeleben, Head of Heart Valve Center Mainz at University Hospital Mainz, commented, "I am delighted to have conducted the first implantation of the Topaz tricuspid valve replacement system in Germany. This patient, like the vast majority of patients with tricuspid regurgitation, had no other viable treatment options. It is tremendous to have successfully treated her using the innovative Topaz system, which provided perfect seating and valve functionality, and I hope this will be available in future for all patients in need."

Prof. Dr. Treede, Director of the Department of Cardiac and Vascular Surgery at the University Medical Centre in Mainz, who proctored all Topaz procedures that were performed until now, commented, "I am very pleased to have attended all of the implantations of the Topaz tricuspid heart valve replacement system, which represents a significant improvement in the treatment of patients with tricuspid regurgitation."

Helmut Straubinger, CEO of TRiCares, commented, "I am very glad to announce the first successful implantation of our Topaz tricuspid heart valve replacement system in Germany. I am proud of our team for developing an innovative treatment possibility for severely ill patients suffering from tricuspid regurgitation with no other treatment options. This successful implantation together with the results of further eight

compassionate use cases give us confidence in our development and in taking the next steps.”

About TRiCares

Founded in 2013, TRiCares is a medical device startup company headquartered in Paris, France, with its operating location in Munich, Germany. The team’s vision is to bring to the market a transfemoral tricuspid valve replacement system to help patients suffering from severe tricuspid regurgitation without the need for open heart surgery. The company is supported by leading European life science venture capital firms: Andera Partners, BioMedPartners, Credit Mutuel Innovation, GoCapital, Karista and Wellington Partners.



About Tricuspid Regurgitation (TR)

The tricuspid valve is the heart valve that regulates the blood between the right atrial and ventricular chamber. Tricuspid regurgitation occurs when the tricuspid valve fails to close properly, causing blood to flow backwards into the right atrium. Tricuspid regurgitation is a frequent problem and a severe disease that was neglected for many years, leading to a large number of untreated patients without an effective treatment option. Cardiac surgeons and interventional cardiologists have long waited for a transcatheter based solution to help patients suffering from severe TR.

About the Medical Need

Heart valve diseases are among the most serious cardiac complications affecting more than 12.7 million patients in Europe. In the last decade, innovative minimally invasive catheter-based solutions have been developed for the treatment of aortic and mitral heart valve disease, creating a fast-growing transcatheter heart valve replacement market. However, for patients with tricuspid heart valve disease (tricuspid regurgitation), no such solutions exist due to anatomic, functional and technological challenges specific to this so-called “forgotten valve”. Consequently, open-heart surgeries to repair the insufficient valve and medical treatments currently represent the standard treatment options. Due to excessive risk of the procedures (10–35 % surgical mortality), more than 99 % of TR patients are considered ineligible for the curative surgeries and are only maintained on symptomatic pharmacologic treatment with poor prognosis (2.2 years median survival). Therefore, cardiac surgeons are urgently seeking minimally-invasive, low-risk solutions to improve clinical outcomes in TR patients with no other viable treatment option.