



## **TRiCares Announces Successful Implantation of Minimally Invasive Topaz Tricuspid Heart Valve Replacement System in Patient with a Pacemaker**

**Paris, France and Munich, Germany, December 21, 2023** – TRiCares SAS (“TRiCares”), a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, today is pleased to announce the successful implantation of its Topaz transfemoral tricuspid heart valve replacement system (“Topaz”) in a patient with a pacemaker at the University Medical Center of Mainz, Germany.

Tricuspid regurgitation (TR) is a common 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 most patients with TR. Topaz is an innovative, minimally invasive device designed specifically to help patients suffering from severe TR, without the need for open heart surgery.

The Topaz device was implanted in a 74-year-old female patient with a pacemaker lead passing through the tricuspid annulus, classed as having New York Heart Association (NYHA) class III heart failure and presenting with torrential TR. The procedure took less than 30 minutes, and the valve was implanted at the precise location required, with regurgitation reduced to trace with no transvalvular leakage. Importantly, the performance of the pacemaker was not affected by the valve. Two months later the patient came back for a follow-up visit which confirmed the excellent results of the Topaz implantation.

The successful implantation took place at the University Medical Center of Mainz in Germany, led by Prof. Ralph Stephan von Bardeleben and Hendrik Treede. Tobias Ruf was responsible for echo guidance, supported by Pascal Lim. The procedure was recorded as a live case for European Association for Cardio-Thoracic Surgery (EACTS) and was presented at a medical congress in early October.

To date, a total of 24 Topaz implantations have been performed across Europe and Canada.

**Prof. Dr Ralph Stephan von Bardeleben, Head of the Center of Structural Heart Disease Interventions and the Heart Valve Center in Mainz, Germany, commented:** “I am proud to have been involved in another successful patient implant of the Topaz tricuspid valve replacement system, particularly given the severity of the patient’s disease and presence of a pacemaker. This innovative solution has the potential to provide a much-needed solution to this patient group which lacks effective long-term treatment options.”

**Prof. Dr Hendrik Treede, Director Department of Cardiac and Vascular Surgery of University Hospital Mainz, commented:** “I was impressed at how easily the Topaz valve could be implanted and how well the prosthesis adapts to the anatomical conditions. The implantation in our clinic has shown that also patients with a pacemaker benefit from it.”

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**Helmut Straubinger, Chief Executive Officer of TRiCares, commented:** “The excellent result of the first implantation in a patient with a pacemaker motivates us to drive the successful use of our Topaz prosthesis in many more pacemaker patients suffering from severe tricuspid regurgitation.”

### **About TRiCares**

TRiCares is a dedicated medical device company located in Paris, France and Munich, Germany having the vision of bringing to the market a transfemoral tricuspid valve replacement system (TTVR). This system aims at helping patients suffering from severe tricuspid regurgitation (TR) without the need for open-heart surgery. With a unique dual stent design, the company was able to produce two valve sizes that both fit into the same catheter system. This catheter system is inserted via the femoral vein and transports the prosthesis into the right half of the heart, where it is finally released to replace the diseased tricuspid valve. This user-friendly implantation technique also allows the treatment of severely ill patients. The company is currently conducting a clinical trial in several European countries.

The experienced team of TRiCares is supported by the leading European life science venture capital firms: 415 Capital, Andera Partners, Bayern Kapital, BioMed Partners, Credit Mutuel Innovation, GoCapital, Karista, and Wellington Partners.

### **About Tricuspid Regurgitation (TR)**

The tricuspid valve is the heart valve that regulates the blood flow between the right atrial and ventricular chamber. TR occurs when the tricuspid valve fails to close properly, causing blood to flow backwards into the right atrium. TR 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. Interventional cardiologists and cardiac surgeons have long waited for a transcatheter based solution. The progress in developing minimally invasive treatment options for heart valves as well as the experience gained in numerous research projects has strongly increased the awareness of the importance of this disease.

### **About the Medical Need**

Heart valve diseases are among the most serious cardiac complications affecting more than 100 million patients worldwide. For TR patients, very few solutions exist to replace or repair the diseased heart valve due to anatomic, functional, and technological challenges. The main treatment focus for TR patients lies on repairing the malfunctioning tricuspid valve by so-called edge to edge devices. However, this technique is not suitable for all patients and in most cases, the leakage cannot be eliminated. Consequently, open-heart surgeries to repair the insufficient valve and medical treatments still represent the standard treatment option. Due to excessive risk of the procedures (10–35 % surgical mortality), most TR patients are considered ineligible for curative surgeries and are only maintained on symptomatic pharmacologic treatment with poor prognosis (2.2 years median survival). Therefore, physicians are urgently seeking minimally invasive, low-risk solutions to improve clinical outcomes in TR patients.