

Dublin, Ireland, 23 March 2020 - CroíValve announced today the successful first human use of its Duo Tricuspid Coaptation Valve technology for tricuspid repair. The procedure was performed by an experienced Heart Team in St. James University Hospital Dublin, led by Dr. Stephen O'Connor, MD, Interventional Cardiologist and Mr. Michael Tolan, MD, Cardiac Surgeon, assisted by Dr. Andrew Maree, Dr. Charlie McCreery and Dr. Caroline Daly.

The patient had severe tricuspid regurgitation (TR) with reduced heart function and was at risk of a further deterioration in heart function with treatment of the tricuspid valve. Based on this, the patient had been turned down for open surgical repair. Because the unique, atraumatic approach of the Duo device allows for temporary implantation of the device to restore function without any impact to the native anatomy, the Heart Team elected to assess the acute effect of tricuspid valve repair on heart function. The procedure was approved by the Irish regulatory body (HPRA) under their compassionate use program.

"The unique capability of the Duo Coaptation Valve, to restore tricuspid valve function atraumatically, while facilitating straightforward percutaneous removal, enabled us to determine a strategy to treat the patient. Considering this patient has had significant suffering from this disease and had no other options, we are extremely proud the physicians and staff at St James University Hospital found an innovative approach to understanding the right treatment approach for this patient." Mr. Michael Tolan added.



The procedure, delivery and retrieval were completed fully percutaneously, with the device delivered in 5 minutes without complications. TR was reduced from torrential to mild and the mean right atrial pressure reduced from 26 to 13 mmHg, with an increase in systolic BP, while the device was in situ. No significant change in right ventricular function was noted during the 30 minutes that the device was in place. The patient is recovering well from the intervention and permanent transcatheter repair of her valve is planned due to the positive cardiac response to treatment.

"Early use of the CroíValve system indicates it to be an easy to use, safe and effective intervention for patients with severe tricuspid regurgitation" stated Dr. Stephen O'Connor

The Duo Tricuspid Coaptation Valve technology provides a simple and atraumatic approach for addressing severe TR in high risk patients. The device is currently being evaluated in a clinical study in Poland to assess the impact of correction of severe tricuspid regurgitation in patients, prior to surgical intervention. The system is also in development for permanent implantation, with clinical studies planned for early next year.

"We'd like to thank the Heart Team at St. James' Hospital for their commitment to providing care to this patient, who would have otherwise gone untreated. We are excited by these early clinical results and the potential demonstrated in providing a meaningful treatment option for these patients." said Lucy O'Keeffe, CroíValve's CEO. CroíValve spun-out of Trinity College Dublin in early 2019 and is headquartered in Dublin, Ireland.