Cleveland Clinic Innovations

Modular Transcatheter Valve Replacement Docking System

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PRODUCT
A transcatheter tricuspid valve replacement multi-component modular system.

INDICATION
Cardiology, minimally invasive surgery, transcatheter procedure, valve replacement, tricuspid regurgitation.

VALUE PROPOSITION
- Novel implantable prosthetic valve device to fit the large size or shape of the target site (e.g., annular dilatation).
- Solution for patients with severe tricuspid valve regurgitation with a very dilated annulus and vena cava system.

DEVELOPMENT STAGE
- Prototype developed
- Human study using prototype

INTELLECTUAL PROPERTY
US: 10,335,272 B2
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PARTNERING OPPORTUNITY
Development and commercialization partnership

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UNMET NEED
Repair or replacement of the tricuspid valve is not performed as often as required due to the high risk of complications. The mortality rate of a tricuspid valve replacement procedure is around 10% and has a reoperation rate ranging from 19% to 50%. Symptoms of tricuspid regurgitation can be quite severe, and this condition has a mortality rate larger than 44% at 5 years. A better way to repair or replace the tricuspid valve in patients with severe tricuspid valve regurgitation is needed to lower mortality and reoperation rates, making treatment more accessible and effective.

SOLUTION
We have developed a prototype of a percutaneous device to facilitate transcatheter valve replacement in a less-than-ideal environment (inferior vena cava for heterotopic tricuspid valve replacement or dilated aortic root). It is constructed as a multi-component modular system that allows for the delivery of the stented docking system onto the intended target location to create a neo-landing zone for a second piece transcatheter device. The docking system device components include a widest diameter component made up of mostly bare stents, a cloth covered diaphragm component intended to interrupt blood flow across the dilated area of the seal, and another stented section of smaller caliber attached to the diaphragm. This smaller stented section is the docking area for either the sutured aortic valve or a separately delivered transcatheter valve. The prototype device has been placed in 6 patients with a high degree of technical success.