Cleveland Clinic Innovations

Stent-Shunt Device to treat Pulmonary Hypertension and Heart Failure

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PRODUCT

Trans-Catheter Right Pulmonary Artery/Azygous Vein Stent-Shunt Device to treat Pulmonary Hypertension and Heart Failure

INDICATION

Cardiovascular, Heart Failure, Pulmonary Hypertension, Trans-catheter, Stent-shunt

VALUE PROPOSITION

- Option for patients with unmanaged left heart diseases
- Left-to-right shunt did not meet desired outcomes
- Designed to improve symptoms & decrease cardiovascular events

DEVELOPMENT STAGE

Prototype developed & deployment across membranes tested.

INTELLECTUAL PROPERTY

PCT Application filed

CONTACT INFORMATION

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UNMET NEED

Pulmonary hypertension (PH) due to left-sided heart disease, classified by the World Health Organization into group 2 pulmonary hypertension, is the most common cause of pulmonary hypertension and is associated with impaired exercise capacity and reduced survival. In these patients, lung congestion and pressure increase are due to elevated left atrial pressure and failure of the heart to keep up with blood returning from the lungs. These patients have a mean pulmonary arterial pressure greater than 20 mm Hg and pulmonary capillary wedge pressure greater than 15 mm Hg. Current treatments for PH are unsatisfactory. There are no FDA approved devices to treat Group 2 PH, as standard of care is volume management or treatment of the left-sided heart disease.

SOLUTION

This invention relates to a transcatheter shunt from the pulmonary artery (PA) to the Azygous vein (AV) to reduce the volume and pressure in the PA, consequently decreasing patient clinical symptoms of pulmonary hypertension and heart failure. These two vascular structures (PA and AV) are anatomically in contact which facilitates the access for the stent-shunt placement. PA-AV shunting provides a right-to-right shunt method (i.e., does not introduce right-to-left embolic risk). The AV provides an upstream vessel to decompress the pulmonary system, while still allowing normal return of blood flow to the heart. The proposed stent design includes an extension graft and separate bare stent frame to fixate the shunt exit further from the heart / PA.