Cleveland Clinic Innovations

PRODUCT
Extracardiac Atrial Assist Device (AADx)

INDICATION
Heart failure, Heart failure with preserved ejection fraction, HFpEF, minimally invasive cardiac surgery,

VALUE PROPOSITION
- Minimally Invasive
- Eliminates need for CPB
- Improved Hemodynamics
- Maintains native heart function

DEVELOPMENT STAGE
- In vitro performance successfully tested
- Acute animal study successfully completed (n = 4) [Using PediPump]

INTELLECTUAL PROPERTY
Patent pending

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Extracardiac Atrial Assist Device (AADx) for treating HFpEF

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UNMET NEED

Heart failure (HF) is one of the leading reasons for hospitalization. HF is a primary contributor to global cardiovascular mortality, affecting approximately 64 million people. More than 40% of HF patients have preserved systolic function, known as HF with preserved ejection fraction (HFpEF), and the prevalence of this condition is increasing compared with HF with reduced ejection fraction (HFrEF). HFpEF is a heterogeneous systemic syndrome that goes far beyond diastolic HF, but it typically has elevated left atrial pressure (LAP) due to increased left ventricular (LV) stiffness and impaired relaxation. Loss of LV compliance limits the Frank-Starling mechanism, which reduces cardiac output. Increased LV stiffness often manifests as pulmonary edema due to high LAP, which further complicates disease management. Patients experience limitations in exercise capacity and abnormal elevation in pulmonary artery pressures with exertion. Unlike HFrEF, there are limited treatment options for HFpEF. LV assist devices (LVADs) that are effective for patients with HFrEF do not work effectively for patients with HFpEF due to small LV cavity. Heart transplantation is an option, but the number of donor hearts is very limited (~5,000/year worldwide) and the age and multiple comorbidities associated with HFpEF typically disqualifies patients from heart transplants. Therefore, there is a critical need for a new therapy for this patient population.

SOLUTION

AADx is a miniature mechanical circulatory support device intended for extracardiac application. The device consists of the motor section, and at least two endings such as inflow and outflow cannulas, intended for blood pull and ejection into the cardiac chambers. The device is designed to be delivered through a small surgical incision, working port or endoscopic port, and is implanted in the left or right atrium (inflow) and into LV or right ventricle (RV) (outflow), outside the heart. In that position the device will be capable of pumping blood from the left atrium or right atrium to the LV or RV, reduce the LAP or right atrial pressure, and increase LV or RV filling volume.

Proposed benefits in HFpEF:
- Reduced LAP
- Extracardiac implantation eliminates need for Cardiopulmonary Bypass
- Improved cardiac output
- Maintains function of Mitral and Aortic Valves and native Pulsatility