Cleveland Clinic Innovations

Left Atrial Assist Device (LAAD) for treating HFpEF

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PRODUCT
Left Atrial Assist Device (LAAD) – a continuous-flow blood pump

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

VALUE PROPOSITION
- Improved Hemodynamics
- Maintains Aortic Valve Function and Pulsatility

DEVELOPMENT STAGE
- Acute animal study successfully completed (n = 8)
- Chronic animal study showed promise

INTELLECTUAL PROPERTY
- US20210393942A1
- EP3866875

SELECTED PUBLICATIONS

- Journal of cardiac failure 28.5 (2022): 789-798 (In-Vitro and In-Vivo Study)
- The Journal of thoracic and cardiovascular surgery 162.1 (2021): 120-126.
- Heart Failure Reviews 28.2 (2023): 287-296
- The Journal of Heart and Lung Transplantation 40.4 (2021): S176-S177
- The International Journal of Artificial Organs 44.7 (2021): 465-470

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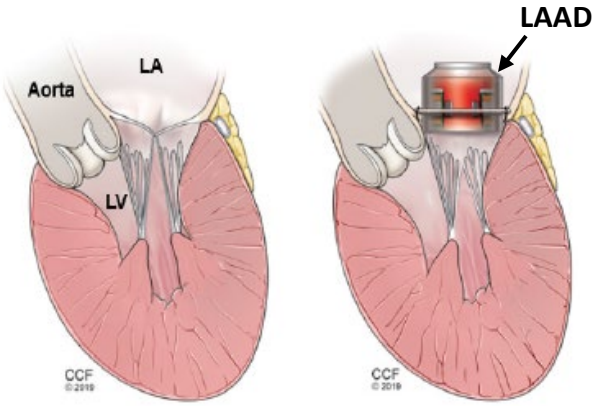
UNMET NEED
Heart failure (HF) is a major public health concern and one of the most common reasons for hospitalization. The majority of HF patients have preserved systolic function, known as HF with preserved ejection fraction (HFpEF). HFpEF is a systemic syndrome that goes far beyond just diastolic dysfunction and is heterogeneous; however, it is typically associated with an increase in left ventricular (LV) diastolic pressures. More specifically, this disease is related to LV stiffness and impaired relaxation. Lack of LV compliance limits the Frank-Starling mechanism which drastically reduces cardiac output, causing hemodynamic morbidity. An increase in LV stiffness often manifests as pulmonary edema, adding complexity to the disease management because of the high left atrial pressure (LAP). Therapies available for patients with this condition are limited and the prognosis is poor. Large randomized clinical trials of therapies improving outcomes in patients with systolic HF (heart failure with reduced ejection fraction, or HFrEF) have mostly failed to demonstrate prognostic benefit in patients with HFpEF. Mechanical circulatory support devices, such as left ventricular assist devices (LVADs) that work for patients with HFrEF do not work well for patients with HFpEF as the LV cavity is small and its volume is insufficient for an LVAD to work effectively. Therefore, no clear treatment guidelines exist for HFpEF, and current options include treating symptoms and the associated comorbidities.

SOLUTION
LAAD is a continuous-flow blood pump that is implanted at the mitral valve position to pump blood from the left atrium to the left ventricle.

Proposed benefits in HFpEF:
- Improved cardiac output
- Reduce LAP by overcoming diastolic pressures to increase filling of the LV
- Allows for physiologic flow which maintains aortic valve function and arterial pulsatility



HFpEF with thick LV wall and small LV volume

HFpEF with LAAD at the mitral position