



Principal Investigator

Ibaraki University **Toru Masuzawa**

Adopted Theme

Development and Commercialization of an Implantable Right Ventricular Assist Device System

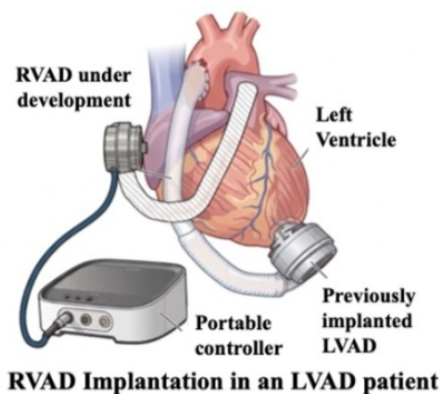
Subject of Research

Development and Commercialization of an Implantable Right Ventricular Assist Device System

GTIE VC Collective

Keio Innovation Initiative, Inc.

Overview



Heart failure is the leading cause of death worldwide, affecting approximately 60 million patients. The number of heart transplants is limited to about 6,000-7,000, and implantable left ventricular assist devices (LVADs) are the most practical therapy for severe heart failure. However, 10-20% of LVAD patients develop life-threatening right heart failure due to the lack of innovative treatment options.

There is a strong need for an ultra-compact right ventricular assist device (RVAD) that can be implanted simultaneously with an LVAD to provide long-term support for patients with right heart failure. This project aims to commercialize a next-generation implantable RVAD system based on our original fully magnetically levitated double-stator motor technology. Its ultra-compact design overcomes anatomical space constraints while providing excellent hemocompatibility and a high level of safety of the blood pump, helping patients with LVADs and right heart failure return to their daily lives and society.

Business Models (when applying)

We will establish an OEM manufacturing partnership with a medical device manufacturer to generate robust preclinical and clinical proof-of-concept data. By enhancing its value as a unique therapeutic solution for refractory right heart failure, we will pursue an M&A exit strategy with a medical device manufacturer seeking to expand its LVAD product portfolio.

Activity Planning (when applying)

We will conduct an engineering evaluation of the nonclinical blood pump already developed and design and manufacture a clinical pump to advance it to clinical trials. We will perform a quantitative evaluation using a mechanical biventricular failure circulatory simulator and complete preparations to proceed to long-term animal studies for nonclinical evaluation.

We will design and manufacture a portable controller equipped with measurement and control algorithms for a ventricular assist device. By integrating the controller with the clinical pump, we will establish a right ventricular assist device (RVAD) system ready for nonclinical testing.

We will consult with the Pharmaceuticals and Medical Devices Agency (PMDA) and the U.S. Food and Drug Administration (FDA) on regulatory matters to agree on nonclinical testing requirements in Japan and the U.S. In parallel, we will refine the business plan to incorporate the post-incorporation nonclinical and clinical testing plans, establish a team capable of executing the business plan, select prospective CXO candidates, and establish the management structure. We will launch the startup company after securing strong investment commitments from domestic and international investment institutions.