FineHeart
A Healthier Life With Every Beat

Press Release

Severe Heart Failure Treatment

FineHeart breaks new ground with successful removal of the ICOMS FLOWMAKER® in a 90-day in-vivo trial

Towards a new standard for device indication: Implantation for temporary or permanent use

- ***Easy removal with a beating heart without damage to the myocardium 30 days after implantation***
- ***Normal heart functioning 60 days after explantation***
- ***Completely sealed operation with dedicated implant fixation system***
- ***Quick recovery and short hospital stay***
- ***Autonomy and free from complications or infection, or structural damage to the heart and vital organs***

Bordeaux, France (May 4, 2021) – FineHeart S.A a preclinical medical device company that has developed the ICOMS FLOWMAKER®, an Implantable Cardiac Output Management System designed to address the unmet need of patients suffering from severe heart failure, today announced the successful, simple, and breakthrough implantation and removal of its device in a 90-day in-vivo trial.

This study confirms the ICOMS FLOWMAKER's ability to support cardiac function without any heart alteration after being implanted for 30 days. The device's unique fixation system allows for easy removal performed on a beating heart, unchanged blood flow, and without trauma to the myocardium. The locking ring of the fixation system is intended to remain in place upon explantation, sidestepping additional cutting or grafts to the heart. Once the device was removed, a fully sealed occluder was introduced, and after 60 days, no structural, histological, or embolic tissue damage occured. This pioneering technique highlights FineHeart's technology's ability to adapt and support shorter surgical cardiac procedures for ventricular assist devices.

"After demonstrating the ease of implantation of the ICOMS FLOWMAKER®, we are very proud to show the ease of removal of the device 30 days after implantation, with post-op recovery in less than 48 hours, and more than 60 days totally free of cardiac assistance, without any structural damage to the heart," said **Arnaud Mascarell, CEO and co-Founder of FineHeart**. "*This operation to remove a cardiac assistance device with a beating heart is a world first. These results underpin the confidence of the medical community in our approach to treat patients suffering from severe heart failure. They will be able to avoid lengthy hospitalization that is often fraught with major complications. This achievement, allows for the use of the ICOMS FLOWMAKER® either as temporary or permanent treatment depending on the severity of the pathology, paves the way for the First implantation in Human."*

"The ability to implant with minimally invasive surgery and subsequently explant the ICOMS FLOWMAKER® paves the way for progress in facilitating hemodynamic ventricular unloading and consequent myocardial recovery. Once clinically proven, this can be a potentially disruptive step forward in the treatment of advanced heart failure," **said Harvard Medical School Professor Mandeep R. Mehra, MD, the William Harvey Distinguished Chair in Cardiovascular Medicine at Brigham and Women's Hospital, Boston, and FineHeart scientific advisory board member.**

About the ICOMS FLOWMAKER®

The ICOMS FLOWMAKER® is the first fully intraventricular, wireless flow accelerator that provides physiological support synchronized with the heart's natural contractions. It respects the natural blood flow and does not require aortic bypass surgery. It is the first miniaturized device - barely 10 cm in size - that is adjustable to patients' needs, like a pacemaker to treat patients with varying degrees of severity. It has no external driveline as it is recharged via a wireless transcutaneous energy transfer system (TET). The device is implanted using a minimally invasive beating-heart procedure, commonly performed by cardiac surgeons, and lasts on average 90 minutes.

FineHeart demonstrates that the protocol for implanting and removing the ICOMS FLOWMAKER® resolves the severe complications associated with implantation of left ventricle assist device (LVAD) surgery, which deteriorates the fragile cardiovascular condition of the patients treated. Today, within two years of the implantation of a classic LVAD, 80% of patients develop a severe complication that makes them dependent on their assistance device.

About Heart Failure

Heart failure (HF) is the second leading cause of death in the United States and Europe and has become a global pandemic affecting 26 million people worldwide, with a steadily rising incidence (over one million new cases in G8 countries). This degenerative disease is associated with a reduced quality of life, frequent, costly hospitalizations, and early mortality. Cases of severe HF require a device to improve the pumping capacity of the left ventricle. Despite the pressing need, current LVADs are bulky, which causes significant myocardial damage. They are associated with a risk of infection, bleeding, and thrombosis, which is why they are almost exclusively implanted in very severe patients with short life expectancy. In the event of a sudden attack (cardiogenic shock), it is often necessary to wait before deciding whether to implant an LVAD and force physicians to resort to temporary circulatory assist solutions. These less invasive aids are limited in time (30 days maximum) and require the patient is bedridden a large part of the time. The prospect of a single device, such as the ICOMS FLOWMAKER®, that is capable of providing both temporary support (with no time limit and preserving the patient's mobility) and permanent support if the patient does not recover sufficiently from the shock, constitutes a paradigm shift in the way severe Heart Failure patients will be treated.

About FineHeart - www.fineheart.fr

FineHeart is a French medical device company headquartered in Bordeaux. Its patented ICOMS innovation holds the potential to treat 200,000 severe heart failure patients annually, with FineHeart initially targeting the 50,000 patients who are eligible for hemodynamic support but today are not treated by current LVADs; a $5B unmet market need.

FineHeart was founded in 2010 by a team of internationally renowned cardiac surgeons and cardiologists, led by Stephane Garrigue, MD, PhD, CSO, Philippe Ritter, MD, MS, co-inventor of cardiac resynchronization therapy (CRT), and FineHeart CEO, Arnaud Mascarell. The company benefits today from 17 patent families.

FineHeart is supported by major U.S. venture capital firms specializing in the cardiovascular space, prime French investors, the European Union, and Region Nouvelle Aquitaine and Region Centre. It has been recognized by FierceMedTech as one of its "Fierce 15," designating it as one of the most promising private MedTech companies in the industry.

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