

Treatment of Severe Heart Failure – AI

FineHeart: "ICOMS FLOWMAKER® Algorithms Patented in the U.S."

First Fully Implantable Electro-Physiological Cardiac Assistance Device

Bordeaux, France – March 3, 2022 – FineHeart S.A, a preclinical medical device company that has developed the ICOMS FLOWMAKER®, a fully Implantable Cardiac Output Management System designed to address the unmet need of patients suffering from severe heart failure, today announced the grant by the USPTO (United States Patent and Trademark Office) in the United States, of their new patent **US 11 097093**.

The patent named "**Method for managing a heart pump**" covers various therapeutic modes of **the ICOMS FLOWMAKER®**, **the world's first and only fully implantable electro-physiological cardiac assistance device for the treatment of severe heart failure**.

Besides being totally adaptable, the mini intracardiac pump developed by FineHeart is the only circulatory assistance device capable of synchronizing with the opening of the aortic valve to increase the native cardiac function with every heartbeat. The algorithms used in the ICOMS FLOWMAKER® represent the real intelligence of the device. Much like the algorithms used in pacemakers, they allow to recognize the patient's effort, identify arrhythmias and to adjust the level of assistance provided in real time.

This key patent adds to FineHeart's strong international portfolio of more than 72 patents in 18 various fields of expertise spanning from the design, the control, to the surgical implantation of the ICOMS FLOWMAKER®.

Designed by renowned electrophysiologists, the ICOMS FLOWMAKER® offers great autonomy to patients with severe heart failure. It requires little energy: **its 70 g battery is recharged through the skin via a wireless transcutaneous energy transfer system (TET), avoiding any risk of infection**.

For Dr Stéphane Garrigue, CSO Cardiologist and co-Designer of the ICOMS Flowmaker: *"The ICOMS FLOWMAKER® started as a vision and resulted in the development of a totally disruptive approach to the treatment of severe heart failure. It is the first smart mini cardiac device that is programmable by the doctor, regardless of the characteristics of the sick heart and the heart rhythm. It preserves and assists the normal function of the heart to optimize the therapeutic effect and help its progression, in a personalised way for each implanted patient. This is the first device ever to produce blood flow in strict accordance with cardiac physiology. This enables the heart to increase its chances of spontaneous recovery, and for the patient to avoid vital dependence on cardiac assistance, a major downside of all current cardiac assistance devices. Thanks to its unprecedented functionality, the ICOMS FLOWMAKER® brings hope for doctors and thousands of patients suffering from severe heart failure, whose only current therapeutic solution is a transplant."*

For Arnaud Mascarell, CEO and co-Founder of Fineheart: *"Even if the technologies developed over the last few decades allow patients to recover their vital functions and regain a certain degree of autonomy, there remain limitations and constraints which prevent them from leading a normal life. With the ICOMS FLOWMAKER®, our ambition is to enable patients with severe heart failure to return to a normal life.*

Severe heart failure is the second leading cause of death worldwide after cancer. It is a degenerative disease that progresses to a severe form and results in the inability of the heart to pump normally. Each year 200,000 patients cannot be appropriately treated due to a lack of therapeutic solutions.

With its unique features, the ICOMS FLOWMAKER® represents an effective therapeutic alternative for all these patients.

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, which, on average lasts 90 minutes.

About FineHeart

FineHeart is a medical device company that is developing its innovative ground-breaking product, ICOMS FLOWMAKER®, with the potential to treat 200,000 patients with severe heart failure each year. First-In-Human trials are expected in 2023. FineHeart will initially target the 50,000 most severe patients who are eligible for cardiac assistance. Initial estimates value this market segment to be worth over US\$5 billion.

Founded in 2010, FineHeart is based in Bordeaux employing close to 50 employees. It is led by a team of internationally renowned cardiac surgeons and electro-physiologists: Dr. Stéphane Garrigue, PhD, CSO co-inventor of ICOMS FLOWMAKER®; Dr. Philippe Ritter, MS, co-inventor of cardiac resynchronization (CRT); and Arnaud Mascarell, FineHeart's CEO. The company holds a portfolio of 72 patents in 18 families.

FineHeart is supported by a wide pool of public and private industrial and independent investors: Lauak Group, Doliam, Med-INNOV, FineHeart Founders' Holding representing domestic and international private investors, mainly from the cardiology sector, and the European investment fund Verve Ventures as well as historical shareholders Irdi, Aquti, Galia, Broadview Ventures, and M Capital. FineHeart also benefits from the financial support of the European Union, Bpifrance, the New Aquitaine Region and the Centre Region.

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