

### Press release

Electroducer announces major medical advance in treatment of heart valve disease; raises €3 million to market its device in Europe and US – commencing in 2022

Grenoble, France, June 30, 2021 — Electroducer, the designer and developer of the innovative medical device Electroducer Sleeve® which treats heart valve disease, today announces that it has raised €3 million (\$3.65M) from private investors and French public stakeholders. The funds will be used for marketing its new technology, which has been proven to be safe and effective in a pilot study involving 60 patients in France.

Prior to their official release, the results of the clinical trial were presented on May 18, 2021, at <u>EuroPCR</u>, an international interventional cardiology conference - attended by nearly 10,000 doctors. The study was a world first; it represents a quantum leap forward within this field of medicine.

#### Major clinical requirement

Valvuloplasty is a procedure in which a damaged heart valve is replaced with a synthetic one through endovascular surgery. Electroducer's new medical device makes valvuloplasty easier and safer.

The technique, which was invented in the early 2000s by Professor Alain Cribier, requires a temporary pacemaker, which is inserted directly into the patient's heart. This is a key step, as it requires doctors to 'pause' the heart and ensure that the replacement valve is positioned correctly. However, in 2-5% of cases there are some risks and major complications involved for patients, which can include death.

#### One-of-a-kind technology, based on a proven medical technique

The Electroducer Sleeve® is a device with no equivalent anywhere in the world. It is based on a medical technique called Direct Wire Pacing (DWP®), which was invented by the company's founder, Benjamin Faurie, and used for the first time ever in 2011. It removes the traumatic and painful step where a pacemaker would be temporarily placed into the patient's heart, replacing this with stimulation sent via the "guidewire", an instrument used to move the valve into position. In simple terms, a low intensity electric current is generated along the guidewire, safely stimulating the heart during the procedure, with no risk of complications for the patient. The technique is now regularly employed by French doctors when replacing heart valves.

#### Proven clinical benefits

The 'EASY TAVI' study, published in the prestigious Journal of the American College of Cardiology (JACC) in 2019, proved that this technique works better than the conventional approach<sup>1</sup>. Direct Wire Pacing significantly reduced per- and post-operational trauma for patients, and reduces the length of the procedure. For the doctor, the technique means a simpler procedure and better working conditions, with less exposure to X-rays, which are known to cause serious injuries such as cancer. Lastly, using this device also saves hospitals money; a reduction of roughly 12% per procedure —as some devices are no longer needed and the reduced risk of complications means this can be an outpatient procedure. The technique also proved beneficial during the COVID-19 pandemic<sup>2</sup> by

<sup>&</sup>lt;sup>1</sup> Benjamin Faurie, Géraud Souteyrand, Patrick Staat, Matthieu Godin, Christophe Caussin, Eric Van Belle, Lionel Mangin, Pierre Meyer, Nicolas Dumonteil, Mohamed Abdellaoul, Jacques Monségu, Isabelle Durand-Zaleski, Thierry Lefèvre and for the EASY TAVI Investigators. Left Ventricular Rapid Pacing Via the Valve Delivery Guidewire in Transcatheter Aortic Valve Replacement, Journal of American College of Cardiology (JACC), Volume 12, Issue 24 (2449-2459), December 2019. https://www.jacc.org/doi/full/10.1016/j.jcin.2019.09.029

<sup>&</sup>lt;sup>2</sup> Oualid Zouaghi, MD, Jérôme Wintzer-Wehekind, MD, Yves Lienhart, MD, Mohamed Abdellaoui, MD, Benjamin Faurie, MD. Ambulatory TAVR: early feasibility experience during the COVID-19 pandemic, Canadian Journal of Cardiology (CJC Open), August 2020. https://www.cjcopen.ca/article/S2589-790X(20)30126-8/fulltext



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limiting the amount of time patients were in hospital, increasing the number of patients being treated and freeing up medical and paramedical resources.

#### Ready-to-use device, offering safe and effective treatment

However, Direct Wire Pacing has some technical limitations that hinder widespread adoption. The purpose of the Electroducer Sleeve® is to simplify, enhance and expand the use of this revolutionary technique using a turnkey method with proven clinical benefits.

The results of the pilot study, which involved 60 patients in three French centers, showed that the use of this device is both safe and effective. In particular, it increases patient tolerance, with no pain caused during stimulation. It also makes the technique used by the doctor more easily repeatable.

Benjamin Faurie, chairman, chief executive officer, and founder of Electroducer, said: "I'm proud to see the technique that I established ten years ago is now widespread in France and is continuing to be developed through a new medical device that is 100% safe and effective for the patient. Initial reports are very promising and indicate a shallow learning curve, as the solution is universal and needs no other special equipment. We're very much looking forward to receiving marketing authorization, which will allow the technique to be rolled out worldwide and save a lot of lives."

#### Potential market of nearly 1.5 million procedures per year worldwide

The Electroducer Sleeve is expected to come onto the market in the US and Europe during 2022, following FDA authorization in the US and CE marking in Europe.

Initially, the Electroducer Sleeve device will be used for aortic valve replacement procedures and for more complex coronary procedures treating the narrowing of the arteries that supply the heart. Subsequently, the technology will also be applied to procedures involving the mitral and tricuspid heart valves.

By 2025 the Electroducer Sleeve could be used in nearly 1.5 million procedures per year worldwide. The company has set itself a target of supplying 8% of this market by then; around 120,000 procedures per year.

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#### **ABOUT ELECTRODUCER**

Founded in 2018 by Dr. Benjamin Faurie, Electroducer is designing and developing a world-first medical device, Electroducer Sleeve®, specifically to treat heart malfunctions that lead to valve replacement or percutaneous coronary intervention (treatment of the arteries that supply the heart).

The device is based on a medical technique known as Direct Wire Pacing (DWP®), also developed by the business' founder and used for the first time in 2011 to treat the aortic valve. The Electroducer Sleeve® limits the risk of complications during Transcatheter Aortic Valve Implantation (TAVI) by dispensing with the implantation of a temporary pacemaker in the right ventricle of the heart. Instead, the instrument that delivers the valve, the guidewire, is used to stimulate the heart muscle directly. This key step is critical to the success of the procedure. Without the use of this technique, 2 to 5% of patients undergoing the procedure experience potentially fatal complications associated with the implantation of a temporary pacemaker. For the hospital, meanwhile, it represents a real cost saving of around 12%, compared with the conventional approach.

However, Direct Wire Pacing has some technical limitations that hinder widespread adoption. The goal of the Electroducer Sleeve® is to increase the number of people with access to this revolutionary



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technique. The device helps limit per- and post-operative trauma for the patient by significantly reducing the invasive nature of the procedure and the time required to complete it. For the physician, the technique is simplified.

It is expected that this turnkey device, covered by seven international patents, will be marketed in Europe and the US during 2022. Initially, the Electroducer Sleeve® will be used for both TAVI and more complex coronary procedures (700,000 per year worldwide). The technology will subsequently also be used in procedures involving the mitral and tricuspid valves of the heart, nearly 1.5 million procedures per year by 2025.

Electroducer is based in Grenoble, France, and is supported financially by public sector financing bodies (French public investment bank Bpifrance and the Auvergne-Rhône-Alpes regional authority) and private investors.

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