Press release

Cardiawave Announces First Routine Treatments Performed with Valvosoft® Following CE Mark Approval and Accelerates Its Deployment

- *After demonstrating its safety and performance in more than 100 patients during clinical development, Valvosoft®, the first non-invasive ultrasound technology designed to treat severe symptomatic aortic stenosis, is now being used in routine clinical practice across several European centers.*
- *This innovation makes it possible to repair the valve rather than replace it in patients who cannot immediately undergo a valve replacement procedure.*

Levallois-Perret, France, June 15, 2026 – Cardiawave, a French medtech pioneer in non-invasive ultrasound therapies for the treatment of aortic stenosis, has reached a major milestone. Following the CE marking[1] of Valvosoft® at the end of 2025, the Company today announces the first patients treated in routine clinical practice in Europe with Valvosoft®, marking the beginning of the deployment of this innovation across France, the Netherlands, and Germany.

A Breakthrough Innovation: Repairing the Valve Rather Than Replacing It

Valvosoft® is the first non-invasive medical device developed for the treatment of severe symptomatic aortic stenosis. The technology is intended for patients for whom immediate valve replacement (TAVR or SAVR) is not recommended, or who decline surgical intervention.

"*The rollout of Valvosoft® following CE mark approval represents a major milestone for Cardiawave and for patients suffering from severe symptomatic aortic stenosis. We can now offer a non-invasive treatment option to patients for whom immediate valve replacement is either not feasible or not desired. This achievement also marks Cardiawave's transition into a new phase of growth, driven by the deployment of Valvosoft® across several European countries and our ambition to become a leading player in the non-invasive treatment of aortic stenosis,"* said **Carine Schorochoff, Chief Executive Officer of Cardiawave.**

Aortic stenosis is a degenerative disease caused by the progressive calcification of the aortic valve leaflets, leading to valve stiffening and reduced oxygenated blood flow to the body's organs.

[1] https://cardiawave.com/valvosoft-the-first-non-invasive-treatment-for-severe-symptomatic-aortic-stenosis-ssas-from-cardiawave-receives-ce-marking/

The consequences include chest pain, shortness of breath, heart failure, and an increased risk of sudden cardiac death. The condition affects approximately 2% of people over the age of 65 and 12.4% of those over 75[2][3][4]. Without treatment, life expectancy drops to 2.3 years in patients with severe symptomatic aortic stenosis, with a significant risk of sudden death[5].

Valvosoft® offers a unique approach worldwide: restoring the mobility of the native valve without surgery or implantation. The technology uses high-intensity ultrasound pulses to fragment calcifications on the valve leaflets while preserving surrounding tissues. The result is a sustained improvement in valve opening and hemodynamic performance, without the need for general anesthesia.

Twelve-month results from the **Valvosoft® First-in-Human (FIM) Study** and **the Valvosoft® Pivotal Study**, presented at **EuroPCR 2025**[6] (100 patients treated across 12 European centers), confirmed both the safety of the technology and its effectiveness in improving cardiac function and patients' quality of life.

"*Severe symptomatic aortic stenosis remains a life-threatening condition with a poor prognosis if left untreated. Valvosoft® introduces a unique approach: restoring the mobility of the native valve without surgery or implantation. Clinical study results obtained in 100 patients confirm the feasibility, efficacy, and safety of this non-invasive therapy for patients who previously had no therapeutic option available*," said **Professor Emmanuel Messas, Interventional Cardiologist at HEGP (AP-HP) and Clinical Investigator of the study.**

Deployment in Europe and Global Expansion Prospects

CE mark approval paves the way for large-scale deployment of Valvosoft®. Since May 2026, several Valvosoft® systems have been placed into clinical use, with a progressive rollout across multiple hospital centers in France and throughout Europe. Distribution agreements are currently under discussion across Europe, the United Kingdom, the Middle East, and India.

Cardiawave is initially targeting approximately 300,000 patients in Europe and the United States who are either ineligible for immediate aortic valve replacement (AVR) or unwilling to undergo such procedures.

In the longer term, the technology could benefit several million patients suffering from moderate forms of the disease. The global addressable market for aortic stenosis exceeds €10 billion.

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[2] Durko AP, et al. Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections. European Heart Journal. July 01, 2018; 39(28):2635-2642. (DOI:10.1093/eurheartj/ehy107)
[3] Lindman B, et al. Calcific Aortic Stenosis. Nature Reviews Disease Primers 2, Article number: 16006. March 03, 2016. (DOI: 10.1038/nrdp.2016.6)
[4] Osnabrugge R., et al. Aortic Stenosis in the Elderly: Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study. Journal of American College of Cardiology, Volume 62, Issue 11, Pages 1013-1014. September 2013. (DOI: 10.1016/j.jacc.2013.05.015)
[5] Malaisrie S, et al. Transcatheter Aortic Valve Implantation Decreases the Rate of Unoperated Aortic Stenosis. European Journal of Cardio-thoracic Surgery, Volume 40, Issue 1, Pages 43-48. July 2011. (DOI:10.1016/j.ejcts.2010.11.301)
[6] https://cardiawave.com/wp-content/uploads/2025/05/Cardiawave-Announces-Positive-12-Month-Results-May-22nd-2025.pdf

Building on its European success, the Company is preparing its entry into the U.S. market through the submission of an Investigational Device Exemption (IDE) application.

At the same time, Cardiawave is strengthening its manufacturing capabilities in collaboration with French industrial partners to meet growing demand.

To support these ambitions, Cardiawave has launched a financing round that will accelerate Valvosoft® production, support ongoing clinical studies in Europe and the United States, and advance the development of additional therapeutic applications.

For more information :
https://vimeo.com/1172170018/f7bf449742?share=copy&fl=sv&fe=ci

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About Cardiawave

Founded in 2014 by Mickaël Tanter, Mathieu Pernot, Emmanuel Messas, Mathias Fink, and Benjamin Bertrand, Cardiawave develops innovative non-invasive ultrasound therapies for cardiovascular diseases. Valvosoft® is a CE-marked medical device in the European Union and currently remains an investigational device outside Europe, intended solely for clinical research purposes. The device is based on Cardiawave's proprietary Non-Invasive Ultrasound Therapy (NIUT) technology, developed in collaboration with leading academic institutions, including the Langevin Institute, Inserm Physics for Medicine, and HEGP. The Company has built a strong intellectual property portfolio comprising 10 patent families.