

FOR IMMEDIATE RELEASE

Cardiawave granted 3 new patents extending its intellectual property protection for its technology in the United States

Levallois-Perret, France, February 13, 2023 – Cardiawave SA, a deeptech medical device manufacturer that has developed Valvosoft[®], an innovative non-invasive medical device to treat aortic stenosis, the most prevalent heart valve disease in adults, announces the issuance of 3 new patents in the United States.

These patents protect Valvosoft[®]'s ultrasound imaging and therapy device and its medical applications and strengthen Cardiawave's U.S. patent portfolio for its innovative non-invasive treatment of heart valve diseases and other cardiovascular applications.

The first U.S. Patent protects Cardiawave's ultrasound imaging and therapy device, and more specifically the system that allows an optimal imaging for safety and performance purposes by keeping the ultrasound imaging probe stationary and in direct with the patient's chest while the ultrasound therapeutical transducer treats different target zones.



Figure 1 - Cardiawave's medical device Valvosoft[®]

The second U.S. Patent protects the technology and the means to detect and monitor with ultrasound imaging the cavitation bubbles which create the therapeutic effect generated by the emission of focused ultrasound.

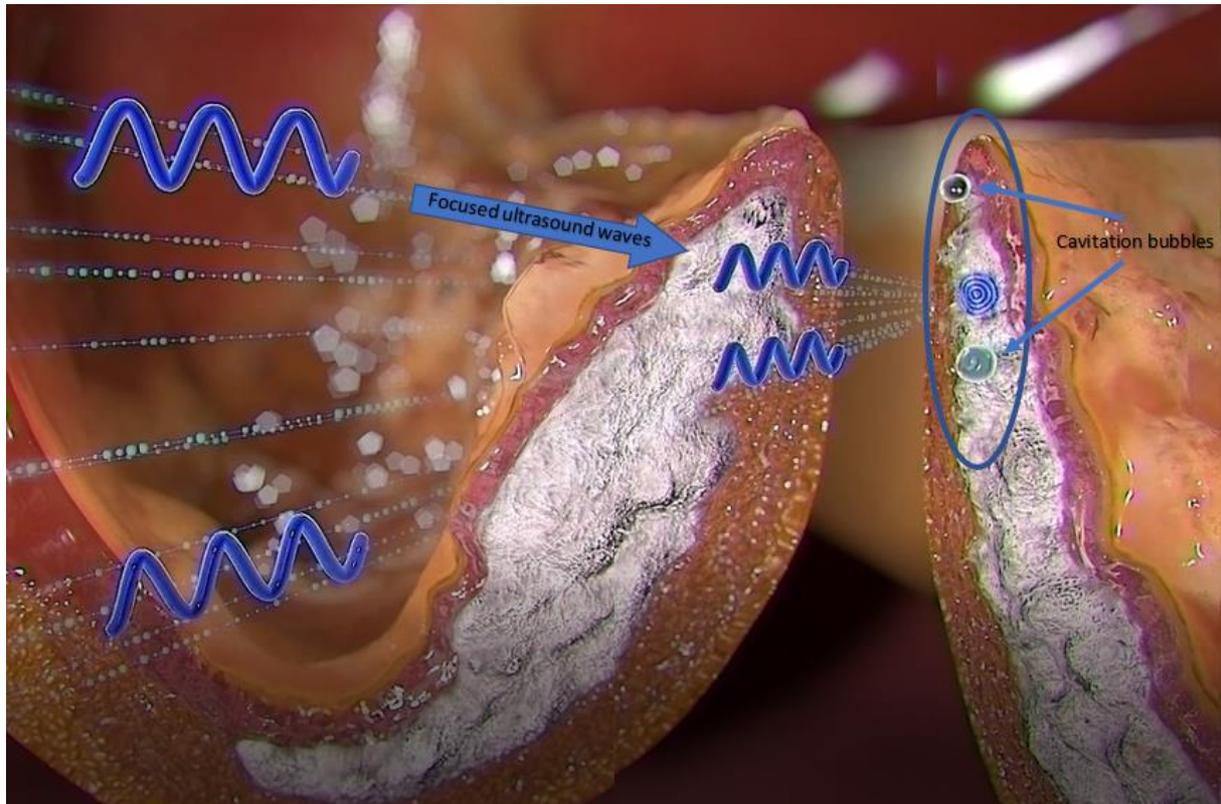


Figure 2 - Cavitation bubbles generated by focused ultrasonic waves

The third U.S. Patent protects the entire apparatus for treating deep vein thrombosis with focused ultrasounds.

Cardiawave intends to bring its innovative medical device to the American market to treat Aortic Stenosis which remains an immense unmet medical need in spite of the development of TAVR. A large number of patients diagnosed with severe Aortic Stenosis in their 80's are not treated in the USA: about 78% aged 70-79 and 84% aged 80-89 which represent approximately 200,000 patients in their 80's untreated (2022 TCT presentation, 2021 figures). Patients affected with severe symptomatic AS who do not undergo treatment have limited lifespans and cost Medicare as much as \$1.3 billion each year due to rehospitalization, prolonged stays, admissions to skilled nursing facilities, and use of hospice care (Clark *et al.* 2012).

Cardiawave is currently carrying out a pivotal clinical study in Europe, in order to obtain the CE marking and launch the commercialization of its device.

"We are thrilled to receive these new patents for our innovative solution to treat non-invasively aortic stenosis and other cardiovascular diseases," said Benjamin BERTRAND, CEO of Cardiawave. "Our IP portfolio is a key asset for our future development. We will continue to build high barriers to entry to protect our market from competition. Our team has worked tirelessly to bring this innovative technology to life, and we are proud to bring it soon to the market to help patients who suffer from this life-threatening condition."

About VALVOSOFT®

Valvosoft® is a non-invasive ultrasound therapy medical device for the treatment of calcific aortic stenosis developed by Cardiawave. It is currently undergoing clinical investigations for safety and efficacy. It has not yet received CE Marking or marketing authorization and its use is limited to clinical investigations.

Cardiawave has developed its new breakthrough technology following the work of the prestigious French academic laboratories Institut Langevin (INSERM/CNRS/ESPCI) and Physics for Medicine Paris (INSERM/CNRS/ESPCI/PSL). This non-invasive treatment of aortic stenosis combines therapeutic ultrasound, robotics, and ultrasound imaging. All software and most hardware components have been developed in-house thanks to the unique know-how of Cardiawave and its academic partners. This device uses a new and unique ultrasound technology with a remote repair procedure on the aortic valve. Ultrasound softens the tissue, restores leaflet mobility, and enables a wider opening of the valve.

About CALCIFIC AORTIC STENOSIS

Calcific aortic stenosis is a degenerative and potentially life-threatening condition, caused by calcium buildup which prevents the aortic valve from fully opening. Aortic Stenosis evolves over time leading to heart failure and increases the risk of sudden death during its final stage (severe & symptomatic stenosis). Aortic stenosis has become a public health issue as the pathology affects between 2 and 12% of subjects over 65 years old. With age, the aortic valve calcifies, becomes more rigid and narrow, and no longer opens properly leading to poor blood circulation.

Aortic Stenosis (AS) can be mild, moderate, and severe. 2 million people are estimated to suffer from severe AS in Europe and in the USA, of whom 500,000 benefit from Transcatheter Aortic Valve Replacement (TAVI) or open-heart surgery. 1.5 million patients remain untreated and face a low life expectancy of 2 to 5 years. Around 3 million further patients suffer from moderate AS for whom there is no early treatment.

About CARDIAWAVE

Cardiawave has developed a non-invasive ultrasound therapy medical device for the treatment of valvular heart diseases, and in particular, Aortic Stenosis, the most prevalent heart valve disease in adults and one of the most common causes of cardiovascular mortality worldwide. Based near Paris, Cardiawave is a member of the national research consortium RHU Stop-AS, and has EN ISO 13485:2016 certification since 2019. Cardiawave employs 30 people and has secured over €22M in funding since its creation in 2014. Learn more: www.cardiawave.com

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