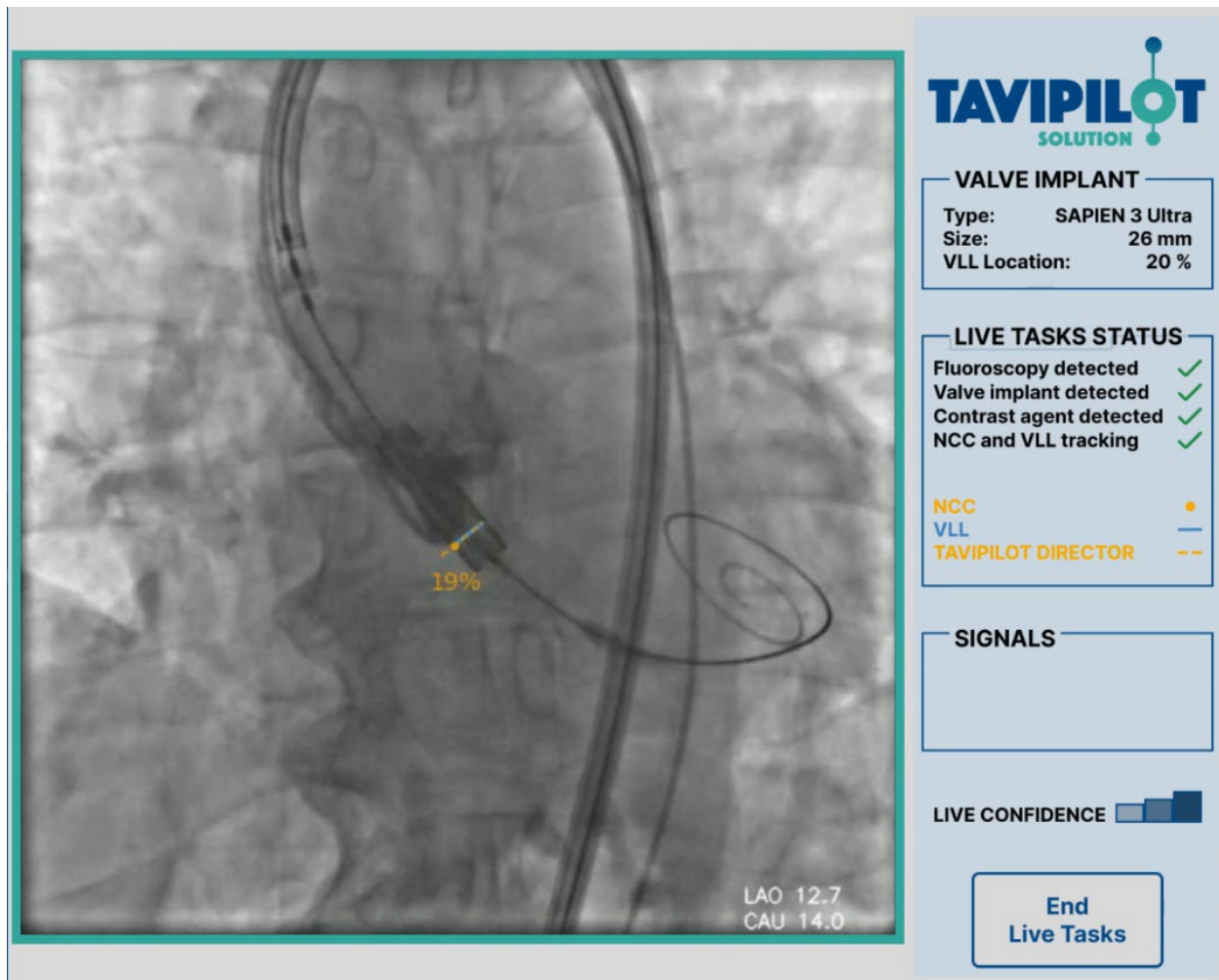


Press Release

Caranx Medical announces FDA submission of TAVIPILOT Soft: the world first AI Software for real-time intra-operative guidance of transcatheter heart valve implantation.

Nice, France, 6 January 2025 – Caranx Medical (“Caranx”), a French medical device company specializing in the development of an autonomous robot to democratize access to Transcatheter Aortic Valve Implantation (TAVI), a lifesaving procedure, today announced FDA submission of the world first AI Software for real-time intra-operative guidance of transcatheter heart valve implantation.



The FDA submission marks a significant milestone of Caranx strategy towards planned market introduction of TAVIPILOT Soft by end of 2025.

“The team at Caranx has achieved an important milestone in the submission to the Food and Drug Administration, FDA. This extremely promising step paves the way to early commercialization of the TAVIPILOT Soft by end 2025. I am very excited about the real-time guidance of TAVI/TAVR, a key to accurate and precise positioning of the heart valve as well as the promotion of potentially more predictable and controlled valve deployment” says CEO of Caranx Jorgen Hansen

“Allowing a broader number of cardiologists and interventional cardiology centers to perform complex procedures, such as TAVI, the Caranx AI-driven software and autonomous robot is at the heart of our mission of entrepreneurs and business builders to save lives and revolutionize medicine” says Philippe Pouletty, MD, cofounder of Caranx and CEO of Truffle Capital

“This first release of our Tavipilot software marks an important step toward AI-augmented procedures. Our software is designed to be user-friendly, ensuring that cardiologists and surgeons can integrate it seamlessly into their usual practice. TAVIPILOT Soft allows clinicians to position a prosthetic valve more easily and with high precision, ensuring that more patients can benefit from the highest quality of care.” says Caranx co-founder and CTO Pierre Berthet-Rayne

“TAVIPILOT soft is a breakthrough for TAVI procedures, providing millimeter precision using augmented reality. Clinicians use precise preoperative images (CT-scan) for the planning of TAVI. But during the procedure, they rely only on fluoroscopy, which shows the anatomy indirectly (requiring contrast injection) and transiently. Accurately positioning the valve requires long training and experience. Our TAVIPILOT Soft identifies key heart anatomical features for precise valve placement and is expected to transform TAVI procedures for patients and clinicians” says Caranx co-founder and CMO Eric Sejour.

The TAVI procedure was introduced app. 20 years ago, and still critical challenges and long learning curves are faced by cardiologists during these procedures in a precise and accurate delivery of the heart valve. While 300.000 TAVI procedures are performed annually in the USA and EU, 1.700.000 patients are in need of a TAVI procedure. According to Frost and Sullivan, the current TAVI market is \$8Bn growing double digits annually. Caranx products could broadly increase the number of patients benefiting from TAVI.

TAVIPILOT Soft is a simple, easy-to-use, AI-driven intra-operative software which tracks real-time anatomical and instrument landmarks. It enables precise and accurate heart valve positioning and delivery. TAVIPILOT Soft is expected to be a revolution for the transcatheter replacement of aortic valves, which is restricted because it is reserved for the most experienced cardiologists. TAVIPILOT Soft is compatible with all cardiac Imaging Systems and will be compatible with all TAVI heart valves on the market.

“At Caranx Medical, our vision extends to developing our Artificial Intelligence Platform, currently containing more than 5000 of annotated multimodality images of CT, Fluoroscopy, Echo, data, etc. used to feed our AI algorithms and to revolutionize other cardiovascular indications, such as mitral and tricuspid valve replacements reshaping the landscape of interventional medicine” says CEO of Caranx, Jorgen HANSEN

About Caranx Medical

Backed by a team of top-tier experts, management team and supported by Truffle Capital, a renowned name in European biotech and MedTech investment, Caranx Medical is a French MedTech company, founded by Philippe Pouletty, MD, CEO of Truffle Capital, CMO Eric Sejour, MD, and CTO Pierre Berthet-Rayne. Caranx has the ambition to become a global leader in AI and robotic assisted transcatheter heart valve implantation.

Subject to bringing TAVI PILOT Robotic solution with autonomous control to First in Human in 2025, Caranx ambition is to gradually commercialize its products and is poised for rapid growth.