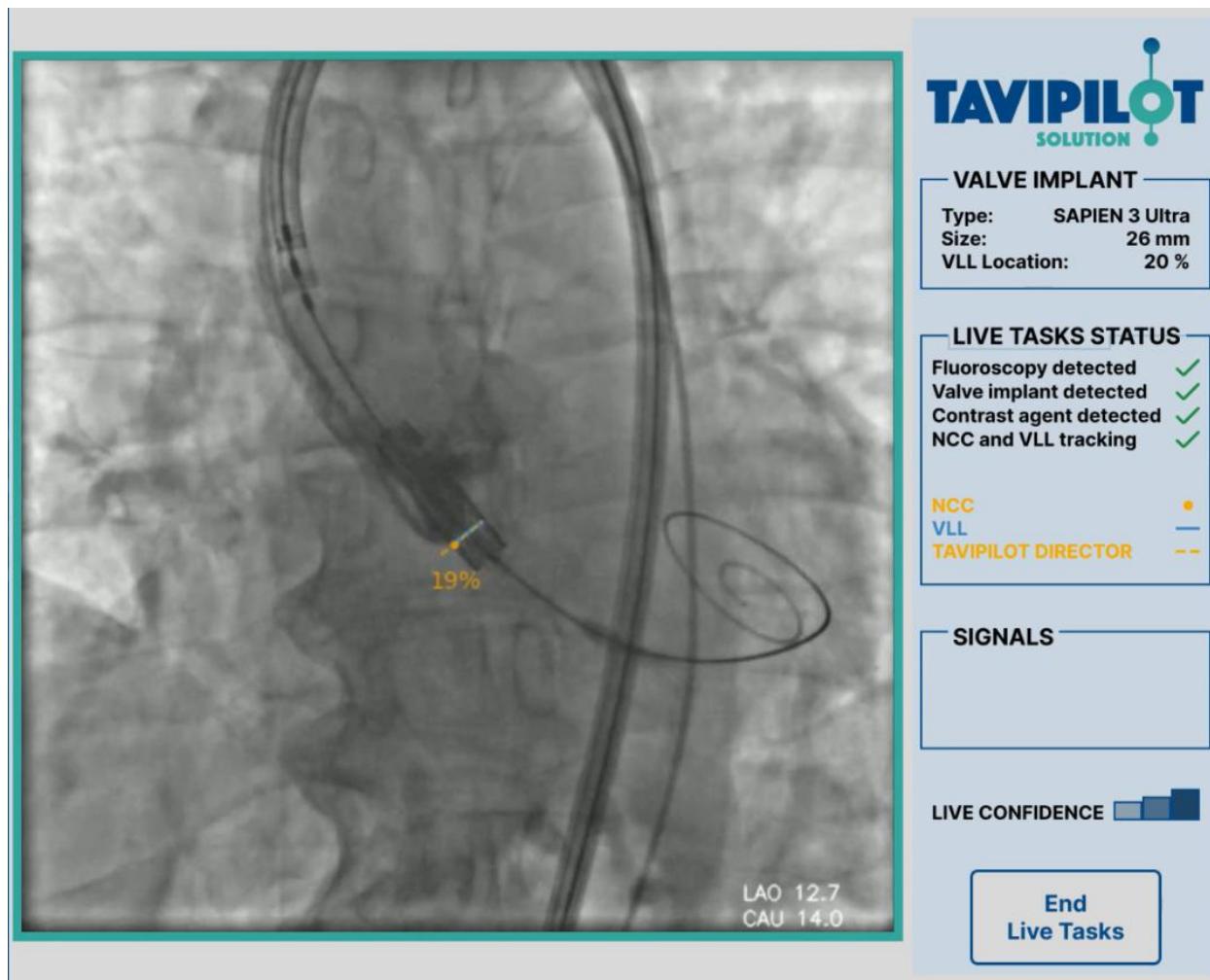


Press Release

Caranx Medical announces first clinical use of the TAVIPILOT Soft, cleared by FDA for commercial in July: the world first AI Software for real-time intra-operative guidance of transcatheter heart valve implantation.

Nice, France, November 17th 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 the first clinical use of the TAVIPILOT Soft was successfully carried out in France, at Clinique Pasteur (Toulouse) with Dr. Didier Tchetche and his team, between October 20 and 22, 2025, as part of the SAITO-1A study (First-in-Human trial).





This study included 10 patients with severe aortic stenosis, all treated via the transfemoral approach during a transcatheter aortic valve implantation (TAVI) procedure using an Edwards Sapien 3 valve.

The TAVIPILOT Soft performed without any technical issues in 100% of the procedures, enabling autonomous identification of anatomical landmarks and accurate assessment of implantation depth during the TAVI procedure. Comparative measurements between the TAVI Soft predicted valve positioning and the final implanted position selected by the investigator demonstrated an excellent accuracy of the software in all cases. No intra-procedural complications were reported, and investigator satisfaction was very high. These results confirm the feasibility, safety, and technical robustness of TAVIPILOT Soft during its use in TAVI procedures.

The FIH study results mark a significant milestone of Caranx strategy towards planned market introduction of TAVIPILOT Soft expected by end of 2025 in the United States.

“Our First Clinical use of the TAVIPILOT Soft is a major achievement for the Caranx team. This study confirms the potential of real-time guidance in TAVI/TAVR procedures to enhance precision and improve patient outcomes. We are excited to now move forward with early commercialization expected by end 2025 and to provide interventional teams with a solution that can support safer and more predictable valve deployment.” says CMO of Caranx, Eric Sejor, MD.

The TAVI procedure was introduced approximately 20 years ago, and still critical challenges and long learning curves are faced by cardiologists during these procedures for a precise and accurate transcatheter delivery of heart valves. 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, current TAVI product sales are \$8Bn growing double digits annually. Caranx products could broadly increase the number of patients benefiting from TAVI.

“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, founder of Caranx and CEO of Truffle Capital

TAVIPILOT Soft is an 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 main TAVI heart valves on the market.

“This successful first trial demonstrates how work that begins as academic research can evolve into real-world impact on everyday medical procedures. It is a true team achievement with potentially life-saving consequences. Our software now can guide clinicians in real time during TAVI procedures, much like a GPS system assists drivers, potentially improving precision and safety. TaviPilot software has demonstrated impressive robustness to patient cardiac motion, large breathing motion, and even C-arm/table motion.” says CTO of Caranx, Pierre Berthet-Rayne.

“At Caranx Medical, our vision extends to developing our proprietary Artificial Intelligence Platform, currently containing more than 5000 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 Dr. Philippe Pouletty, M.D., CEO and co-founder of Truffle Capital, CMO Eric Sejor, M.D., and CTO Pierre Berthet-Rayne. Caranx has the ambition to become a global leader in AI and robotic assisted transcatheter heart valve implantation.

Caranx’s ambition is to gradually commercialize its products and is poised for rapid growth.

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