

**Press Release****Caranx Medical (Carvolix project company) announces first clinical use in patients of the TAVIPILOT Robot at Macquarie University Hospital, Sydney, Australia**

Nice, France, December 16th 2025 – Caranx Medical (“Caranx”), a French medical device company (Carvolix project founded by Truffle Capital) specializing in the development of an autonomous robot (TAVIPILOT Robot) and an AI-driven software (TAVIPILOT Sofware) to democratize access to Transcatheter Aortic Valve Implantation (TAVI), a lifesaving procedure, today announced the first clinical use of the TAVIPILOT Robot was successfully carried out at Macquarie University Hospital in Australia for two patients as part of the ROTAO study (First-in-Human trial).



The study is conducted by Professor Stephen Worthley and his interventional cardiology team at Macquarie University Hospital. Two initial transfemoral TAVI procedures were performed on 16 December 2025 in patients presenting with severe symptomatic aortic stenosis. Both procedures were carried out under local anesthesia using balloon-expandable Edwards Sapien 3 Ultra valves and were completed successfully, without procedural complications.



The TAVIPILOT robotic system was performing reliably throughout these procedures, with no technical incidents reported. The robotic platform provides stable and precisely controlled axial movements during all phases of catheter manipulation and responds accurately to cardiologist commands. Robotic-assisted movements promote accurate valve positioning at the intended implantation site while maintaining full cardiologist control over deployment decisions.

The preliminary clinical study results mark another significant milestone for Caranx (Carvolix project) strategy towards planned FDA submission and clearance of TAVIPILOT Robot in 2026. The AI driven TAVI software (TAVIPILOT Software), the “brain” for the robot was already cleared last July by the FDA for commercial launch in the US.

*“This clinical study of the TAVIPILOT robotic system represents a new major milestone for the Caranx team. The preliminary results of these first cases confirm the potential of robotic assistance in TAVI/TAVR procedures. When it will be combined with the guidance software we have developed and are currently launching for commercial use in the US, this solution will have the potential to substantially simplify and standardize the procedure, supporting safe and predictable valve deployment for cardiology teams”* says Eric Sejor, MD, CMO of Caranx.

The TAVI procedure was introduced app. 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 US and EU, an estimated 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 (Carvolix project) products could potentially dramatically increase the number of patients benefiting from TAVI at more centers.

*“Allowing a broader number of cardiologists and interventional cardiology centers to perform complex procedures, such as TAVI, the Caranx TAVI AI-driven software, FDA cleared for US commercial use, and TAVIPILOT Robot in advanced development are 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 Robot is an easy-to-use, small foot-print and enables precise and accurate heart valve positioning and delivery. TAVIPILOT Robot is expected to be a revolution for the transcatheter replacement of aortic valves, and subsequently of mitral valves, which is currently limited to the most experienced and trained cardiologists. TAVIPILOT Robot is compatible with all main cardiac Imaging Systems and all main TAVI heart valves on the market.

*“This first-in-human use of the TaviPilot robotic platform represents a major milestone for our team and the result of a truly international collaboration. Early clinician feedback is very clear: robotic assistance provides accurate control and accuracy for precise valve positioning. Ultimately, this milestone opens the path toward a new era of structural heart interventions, bringing us closer to autonomous, under cardiologist supervision, valve placement during TAVI procedures.”* says CTO of Caranx Pierre Berthet-Rayne, Ph.D.

*“At Caranx Medical, our vision extends to developing our proprietary TAVIPILOT products, TAVIPILOT Software and Robot and potentially revolutionize other cardiovascular indications, such as mitral and tricuspid valve replacements, reshaping the landscape of interventional medicine”* says CEO of Caranx, Jorgen HANSEN

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#### **About Caranx Medical (Carvolix project)**

Backed by a team of top-tier experts, management team, board of directors, founded and supported by Truffle Capital, a renowned name in European biotech and MedTech investment (founder among others of Abivax), Caranx Medical (CarvOlix project) is a French MedTech company, founded by Philippe Pouletty, MD, CEO of Truffle Capital, co-founded by CMO Eric Sejor, MD, and CTO Pierre Berthet-Rayne, PhD. Caranx has the ambition to become a global leader in AI and robotic assisted transcatheter heart valve implantation.

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