



Carvolix submits 510(k) for TAVIPILOT Robot, advancing toward US commercial launch of Its Integrated TAVIPILOT Platform.

- 510(k) submission filed with the FDA for the TAVIPILOT Robot — a key regulatory submission ahead of the planned US launch of the integrated TAVIPILOT platform in 2027.
- Submission supported by the completed ROTA01 First-in-Human study, in which the TAVIPILOT Robot performed successfully in 10 of 10 procedures. Initiation of the SAIRO study evaluating TAVIPILOT Robot and software in combination, with 7 patients treated successfully to date.
- TAVI market expected to expand in the US following the recent Centers for Medicare and Medicaid Services coverage update. TAVIPILOT platform well positioned to support procedure expansion with safe and standardized robotic valve positioning.

Aix-en-Provence, September 22, 2026 – 17:45 CET – Carvolix (formerly Affluent Medical) (ISIN: FR0013333077 – Ticker: CVX), a French medical devices company at the commercial stage, specializing in the development of AI-driven mini-robots and biomimetic implants, announces the filing of a 510(k) submission with the U.S. Food and Drug Administration (FDA) for the TAVIPILOT Robot, the robotic component of its integrated TAVIPILOT platform to augment transcatheter aortic valve replacement (TAVI) procedures.

This is a key regulatory submission required before Carvolix can bring the integrated TAVIPILOT platform to the US market.

Continued progress toward commercialization of the integrated TAVIPILOT platform

The TAVIPILOT platform brings together:

- the TAVIPILOT Software, a real-time intra-procedural AI guidance software, which received FDA 510(k) clearance in July 2025 and is already in commercial use in the United States, and
- the TAVIPILOT Robot, which provides catheter stability and millimetric precision control under the operator's supervision.

Subject to FDA clearance, Carvolix confirms its objective of launching the integrated TAVIPILOT platform in the United States in early 2027. This step also brings Carvolix closer to drawing the second tranche of €10 million under the €30 million structured debt facility [secured](#) with Claret Capital, which is conditional on FDA clearance of the TAVIPILOT Robot.

*"With this new regulatory step, we are executing against our clinical and commercial roadmaps, each one bringing us closer to the same goal: to democratize access to complex cardiovascular procedures," said **Sébastien Ladet, CEO of Carvolix.** He continued: "Our AI-driven robotic platform is not a single-feature product. Precision positioning is the first commercial feature we deliver, but the same software and robotic architecture is designed to host additional intra-procedural capabilities. Building a platform, not a single product, is how we scale value delivery to each cath-lab we will equip."*

Potential US market growth with supportive coverage update

The US regulatory and reimbursement environment is evolving in favor of wider access to TAVI procedures. On September 10, 2026, the Centers for Medicare & Medicaid Services (CMS) published its final national coverage determination for transcatheter aortic valve replacement, easing requirements for patients with symptomatic severe aortic stenosis: hospital procedural volume thresholds are removed, and coverage with evidence development no longer applies to this population. The updated determination also allows procedures to be performed by a single operator where previously two operators were required.

In addition, coverage is extended to patients with asymptomatic severe aortic stenosis under evidence development.

More centers are expected to become eligible to offer TAVI as a result, with a need to scale up. Against a backdrop in which only 17% of eligible patients are treated each year, Carvolix believes this reinforces the need for technologies such as TAVIPILOT that make procedures more precise, reproducible while shortening the learning curve for interventional teams.

An FDA submission supported by the completed ROTAO1 study

The filing follows the completion of the ROTAO1 First-in-Human study, which evaluated the robotic building block of the TAVIPILOT platform in 10 patients undergoing TAVI procedures.

ROTAO1 was a prospective First-in-Human study assessing the feasibility, safety and technical reliability of the AI-driven TAVIPILOT Robot, without the software, during transfemoral TAVI procedures.

It was conducted by Professor Stephen Worthley, MD, PhD, interventional cardiologist, and his team at Macquarie University Hospital, Sydney, Australia. Ten consecutive patients with symptomatic severe aortic stenosis (mean age 82.9 years; median EuroSCORE II 3.45) were treated with balloon-expandable valves.

“The system performed successfully in every case, which is very encouraging in a first-in-human trial. It gave us stable, consistent catheter control and supported precise valve positioning, while every clinical decision stayed with the operator. These are preliminary results, but they justify continuing the clinical development of robotically assisted TAVI, as only a fraction of patients who could benefit from this procedure are treated today”, said Professor Stephen Worthley, MD, PhD, Principal Investigator of ROTAO1, Macquarie University Hospital, Sydney.

Robotic-assisted navigation and valve positioning were successfully performed in all 10 procedures. The TAVIPILOT Robot functioned successfully in 100% of procedures, with no failure to connect the delivery system or the single-use cassette, no navigation failure, and no unexpected robot behaviour. No serious adverse event was considered related to the TAVIPILOT Robot. All 10 patients completed their 1-month follow-up, with no death and no study withdrawal, and clinician satisfaction was consistently high throughout the study, with a mean satisfaction score of 8.0/10.

Investigators consistently agreed or strongly agreed that the robot provided enhanced stabilization of the catheter and consistent movements, responded accurately to commands, and facilitated precise valve positioning.

A growing body of clinical evidence

Carvolix is continuing the clinical development of the platform through the SAIRO study, which evaluates the combined use of the TAVIPILOT Robot and the TAVIPILOT Software in open-loop, AI-guided use during TAVI procedures. The software provides the operator with real-time analysis of anatomical landmarks and valve position, while the robot enables precise, controlled movements under clinical supervision.

Interim analysis of the first 7 of 20 planned patients, all successfully treated at Macquarie University Hospital (n=1) and St Vincent's Hospital Sydney (n=6), showed high clinician satisfaction with the software and the integrated robot-guided workflow. No record of robot or software device deficiencies was reported. These preliminary findings support the continued clinical evaluation of the integrated TAVIPILOT platform.

Together with the post-market data [already reported](#) for the TAVIPILOT Software, ROTAO1 and SAIRO progressively build the evidence base for each component of the platform and for their combined use in the cath-lab. Carvolix expects to complete the SAIRO cohort and to initiate a clinical cohort evaluating the TAVIPILOT platform in supervised autonomy¹ by the end of 2026.

About the TAVIPILOT Robot

The TAVIPILOT Robot is a robotic platform designed to assist with the navigation and positioning of transcatheter heart valves. The system allows the operator to precisely control catheter movements while retaining full control

¹ in which the system performs the positioning sequence under the direct supervision of the operator, who retains control of every clinical decision.

over clinical decisions and valve deployment. The TAVIPILOT Robot is a device under clinical development and is not authorized for commercial use.

About the TAVIPILOT Software

TAVIPILOT Software is an AI-powered real-time intra-procedural guidance software for percutaneous aortic valve implantation (TAVI). It provides automatic real-time detection of anatomical landmarks as well as continuous depth assessment during valve deployment. TAVIPILOT Software received FDA 510(k) clearance (K243884, July 2025) and commercial deployment in the United States began in H2 2025. A CE marking dossier was submitted in August 2026.



About Carvolix

Carvolix is a French medical technology company at the commercial and clinical stages, founded by Truffle Capital (also founder of the leading European biotechnology company), with the ambition of becoming a global leader in the treatment of structural heart diseases and strokes, the leading causes of mortality and disability worldwide. According to the Truffle 10 MedTech Index, Carvolix ranks first in Europe and fifth worldwide. Carvolix develops novel AI- and imaging-powered mini-robots that make complex procedures accessible to interventional cardiologists, as well as biomimetic heart valves.

For more information: www.carvolix.eu

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Forward-looking statements

This press release contains forward-looking statements regarding Carvolix's clinical development, regulatory pathway, commercial plans and market estimates. These statements are based on current expectations and assumptions and involve known and unknown risks and uncertainties — including, but not limited to, those related to clinical trial results, sample sizes, follow-up data, regulatory approvals and market conditions — that could cause actual results to differ materially. The clinical results described concern a limited number of patients and remain subject to longer-term follow-up and publication following peer review. Forward-looking statements speak only as of the date of this press release, and Carvolix undertakes no obligation to update them, except as required by law.

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