

FEops' AI-enabled solution changes TAVI pre-procedural decision in one third of patients, associated with favorable clinical outcomes

GENT, Belgium, November 29th, 2022— Data from the PRECISE-TAVI study, presented at the PCR Valves 2022 convention in London shows that Transcatheter Aortic Valve Implantation (TAVI) procedures planned by means of FEops HEARTguide™ result in an important change of pre-procedural decision making by the heart team, associated with favorable clinical outcomes.

This prospective multicenter observational study, led by Prof Nicolas Van Mieghem (Erasmus Medical Center, The Netherlands), included patients with complex aortic anatomy defined as bicuspid aortic valve, small annulus or severely calcified aortic valve, treated with the Medtronic Evolut pro (+) device. This trial aimed to assess whether the use of FEops HEARTguide™ computer simulations based on cardiac CT-imaging can contribute to a change of the heart team's TAVI planning decision compared to their traditional CT planning decision and if this is associated with favorable clinical outcomes.

The trial results revealed a 35% change of pre-procedural decision from the heart team, associated with favorable clinical outcomes. New pacemaker implantation rate and paravalvular leak (more than trace) in PRECISE-TAVI are 13% and 28% respectively, which is lower to what has been reported in scientific publications on patients with complex anatomy.

Prof. Dr. Nicolas Van Mieghem, Principal Investigator of PRECISE-TAVI added following: “FEops HEARTguide informs physicians with accuracy which patients are at risk for new pacemakers or paravalvular leaks. Procedure simulations complement contemporary precision medicine”

Christian Vincent, Sr Director Therapy Development at FEops concluded: “Although TAVI is a well introduced and safe procedure, patients with complex aortic anatomies may pose specific challenges and are still today associated with higher paravalvular leakage and new pacemaker implantation. With the results of the PRECISE-TAVI, we are very proud to have a strong impact on the heart team decision, contributing to favorable clinical outcome, also for these type of patients”

About FEops HEARTguide™

FEops HEARTguide™ cloud-based procedure planning environment uses digital twin technology to provide clinicians and medical device manufacturers with first-ever insights into the interaction between transcatheter structural heart devices and specific patient anatomy – pre-operatively. FEops HEARTguide is available in the USA for use in LAAo with WATCHMAN™, WATCHMAN™FLX, Amplatzer Amulet and in EU, UK, Canada and Australia, FEops HEARTguide is available for use in TAVI and LAAo. FEops HEARTguide has to date been used worldwide for over 6000 patients in over 300 hospitals in over 25 countries. Such insights have the power to improve clinical outcomes in real-world hospital settings, as well as to accelerate research and development of novel device-based solutions.

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About FEops

Privately held FEops, headquartered in Gent, Belgium, is a digital health scale-up altering the course of heart disease by providing physicians with unique digital tools to treat the right patients with the right technology at the right time. FEops is supported by Valiance Advisors, Capricorn partners, PMV and the EIC fund.

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