

News Release

Clinical utility of FEops AI-enabled predictive pre-planning for LAAO demonstrated in US

Data showing FEops HEARTguide significantly improves efficiency of LAAO procedures presented at the 2024 AF symposium

GENT, Belgium, February 2nd 2024— Data from the first US comprehensive single center experience at St Bernard's Medical Center and Arrhythmia Research Group, presented at a Late-Breaking session at the AF Symposium 2024 in Boston, shows that Left Atrial Appendage Occlusion (LAAO) procedures planned by means of FEops HEARTguideTM result in significantly improved procedural efficiency.

The 178 patient US single center evaluation, led by Dr Devi Nair (St Bernard's, Jonesboro, US) aimed to assess the safety, efficiency and accuracy of FEops HEARTguideTM predictive pre-planning based on cardiac CT-imaging for both the Boston Scientific Watchman FLXTM and the Abbott AmplatzerTM AmuletTM device.

"This is the first-ever comprehensive clinical evaluation in the US proving that Artificial Intelligence (AI)-enabled predictive pre-planning significantly improves LAAO procedural efficiency for both the Watchman FLX and the Amulet device. Our results confirm that the accuracy of device sizing and positioning for LAAO procedures is significantly better when using FEops HEARTguide as compared to standard CT-based planning.Our real-world evidence reinforces the excellent results from the landmark PREDICT-LAA trial [1]", said Dr. Devi Nair. In terms of procedural efficiency, the evaluation results revealed that in 97% cases a single LAAO device was successfully implanted with a single transseptal puncture. The average procedure time was 21 min compared to 55 min in the control group, the average fluoroscopy time was 4 min compared to 17 min and average contrast used during the procedure was 20 ml compared to 80 ml.

"This real world evidence clearly reinforces the value of our pioneering digital twin strategy to alter the course of heart disease," said Matthieu De Beule, co-founder and CEO of FEops. "We are extremely proud of the results of this comprehensive evaluation and I am very grateful for the visionary drive of Dr Devi Nair and the entire FEops team for making this happen. Together we continue to advance how

physicians access therapy options for patients at risk of stroke due to atrial fibrillation. The results support us in our mission to continue to spearhead AI-enabled predictive solutions that help treating the right heart disease patients with the right technology at the right time."

 [1] De Backer O, Iriart X, Kefer J, et al. Impact of Computational Modeling on Transcatheter Left Atrial Appendage Closure Efficiency and Outcomes. J Am Coll Cardiol Intv. 2023 Mar, 16 (6) 655–666.

About FEops HEARTguideTM

FEOPS HEARTguideTM cloud-based predictive 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 – preoperatively. FEOps HEARTguide is available in the USA for use in LAAo with WATCH-MANTM, WATCHMANTMFLX, 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 8000 patients in over 300 hospitals in over 30 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 <u>European Innovation Council (EIC)</u>.

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