

## **News Release**

# FEODS HEARTguide Proven to Significantly Enhance Efficiency and Outcomes of LAA Closure Procedures.

GENT, Belgium, February 24<sup>th</sup> 2023— Today, FEops announced the publication of the PREDICT-LAA study in JACC: Cardiovascular Interventions, showing that Left Atrial Appendage Closure (LAAC) procedures planned by means of FEops HEARTguide<sup>TM</sup> resulted in significant improvement of procedural efficiency and outcomes.

Prof. Dr. Ole De Backer (Copenhagen, Denmark), Principal Investigator of this study, commented "PREDICT-LAA is the first prospective trial showing that the accuracy of the selection of the LAAC device size and implant position is significantly better when using FEops HEARTguide<sup>TM</sup> as compared to standard CT-sizing".

PREDICT-LAA is a prospective, multicenter, randomized clinical trial (ClinicalTrials.gov NCT04180605) in which 200 patients were 1:1 randomized to standard planning vs. cardiac computed tomography (CT)-simulation-based planning of LAAC with the Amplatzer Amulet<sup>TM</sup> LAA occluder (Abbott, USA).

In terms of procedural efficiency, the PREDICT-LAA trial revealed a 15% reduction of the total number of LAAC devices used, a 50% reduction of the number of device repositionings, a 25% reduction of the use of radiation and contrast medium, a 20% reduction of procedural time and procedural success without major complications in 100% of cases in the FEops HEARTguide<sup>TM</sup> arm.

Procedural outcomes also significantly improved: 40% more complete LAA occlusion with no LAA patency, 60% less retraction of the Amplatzer Amulet disc into the LAA and 80% reduced risk of device-related thrombus.

"We are very proud to add this milestone to the other key accomplishments from 2022" said Matthieu De Beule PhD, co-founder and CEO of FEops. "In 2022, we obtained FDA clearance for FEops HEARTguide<sup>TM</sup> LAAO workflow, we became a global digital health player with more than 6000 patients analysed in over 300 hospitals in 27 countries and we have now, as the first company ever, randomized controlled clinical trial data evidencing the value of digital twin technology in the cardiovascular space. This is putting us in pole position to commercialise globally and extend our game-changing predictive digital twin offering to other applications with our upcoming Series C round."

## **About PREDICT-LAA Trial**

JACC, Cardiovascular Interventions: "Impact of Computational Modeling on Transcatheter Left Atrial Appendage Closure Efficiency and Outcomes".(<u>Link to JACC Cardio Intv. Feb 22, 2023. Epublished DOI: 10.1016/j.jcin.2023.01.008</u>)

# About FEops HEARTguide<sup>TM</sup>

**FEops HEARTguide<sup>TM</sup>** 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 − preoperatively. FEops HEARTguide<sup>TM</sup> is available in the USA for use in LAAo with Amplatzer Amulet<sup>TM</sup>, Watchman<sup>TM</sup>, Watchman<sup>TM</sup>FLX and in EU, UK, Canada and Australia, FEops HEARTguide<sup>TM</sup> is available for use in TAVI and LAAo. FEops HEARTguide<sup>TM</sup> has to date been used worldwide for over 6000 patients in over 300 hospitals in over 27 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 European Innovation Council (EIC).

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