

News Release

## FEops AI-enabled solution improves outcomes for heart disease patients

FEops HEARTguide significantly improves efficiency and outcomes of LAAO procedures in the PREDICT-LAA Randomized Clinical Trial

GENT, Belgium, September 17<sup>th</sup> 2022— Data from the PREDICT-LAA trial, presented at the Late-Breaking Innovation session at the TCT 2022 convention in Boston shows that Left Atrial Appendage occlusion (LAAO) procedures planned by means of FEops HEARTguide<sup>TM</sup> result in significantly improved procedural efficiency and outcomes.

The 200 patient PREDICT-LAA prospective, multicenter, randomized controlled trial, led by Dr Ole De Backer (Righshospitalet, Denmark) and Dr Philippe Garot(Institut Cardiovasculaire Paris Sud, France) aimed to assess whether the use of FEops HEARTguide<sup>™</sup> computer simulations based on cardiac CT-imaging can contribute to better preprocedural planning and improved procedural outcomes of percutaneous LAAO procedures with the Abbott Amplatzer<sup>™</sup> Amulet<sup>™</sup> device.

"PREDICT-LAA is the first-ever clinical study proving that Artificial Intelligence (AI)-enabled computational modelling of device-anatomy interaction significantly improves procedural outcomes. We are proud that we have been able to show that the accuracy of device sizing and positioning for LAAO procedures is significantly better when using FEops HEARTguide as compared to standard CT-sizing", said Prof. Dr. Ole De Backer, Principle Investigator of PREDICT-LAA.

In terms of procedural efficiency, the trial results revealed a doubling of successful single device deployment, 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 arm. Procedural outcomes also significantly improved: 40% more complete LAA occlusion with no leak, 60% less retraction of the Amplatzer Amulet disc into the LAA and 80% reduced risk of device-related thrombus.

"These landmark trial results clearly reinforce the value of our pioneering digital twin strategy to alter the course of heart disease," said Matthieu De Beule, cofounder and CEO of FEops. "We are very proud of the results of the PREDICT-LAA trial and I am very grateful for the visionary drive of all study investigators and the excellent support of Abbott as a funder and the entire FEops team for making this happen to advance how physicians access therapy options for patients at risk of stroke due to atrial fibrillation. The trial results support us in our mission to continue to spearhead AI-enabled digital twin solutions that help treating the right heart disease patients with the right technology at the right time."

## About FEops HEARTguide<sup>™</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 is available in the USA for use in LAAo with WATCH-MAN<sup>TM</sup>, WATCHMAN<sup>TM</sup>FLX, Amplatzer Amuletand 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 <u>European Innovation Council (EIC)</u> accelerator programme.

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