SMT Announces Start of the SAFE-PFO Trial with First Patient Enrolment in Germany

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Congenital Heart Disease (CHD) is one of the most common birth defects, affecting approximately 1% of live births globally and accounting for more than 4.18 million cases in children under five[1]. Despite advances in medical care, CHD continues to be a leading cause of infant and child mortality, highlighting the need for safe and minimally invasive treatment options. Patent foramen ovale (PFO) is also a common heart defect impacting approximately 25% adults globally[2]. A PFO is a small opening that can cause blood clots to travel to the brain and potentially lead to stroke These defects are typically treated using Occluders, which are catheter-based devices designed to close abnormal openings in the heart.

The SAFE-PFO trial has enrolled its first patient at Herz- und Diabeteszentrum NRW (HDZ NRW), marking the formal start of recruitment for a randomized head-to-head evaluation of two widely used patent foramen ovale (PFO) closure technologies. The enrolling site is led by Principal Investigator Dr. med. Werner Scholtz. SAFE-PFO will directly compare the Cocoon and Amplatzer PFO closure devices.

The Cocoon Occluder portfolio from SMT comprises catheter-based devices for the minimally invasive closure of Atrial Septal Defects (ASD), patent ductus arteriosus (PDA), ventricular septal defect (VSD) and Patent Foramen Ovale (PFO), and is designed to support the treatment of congenital

and acquired heart defects.

The study plans to enroll up to 1,260 patients at approximately 60 centres across Europe. Patients will be randomly assigned to receive either the Cocoon PFO Occluder or a device from the Amplatzer PFO Occluder family. Each patient will be monitored for 12 months, and recruitment across the full study is expected to take about two years.

"*This is the first direct head-to-head comparison of the Amplatzer and Cocoon PFO devices, a randomized controlled trial designed to fill an important gap in the clinical evidence for PFO treatment in adults*," stated **Prof. Giuseppe Tarantini, Principal Investigator, SAFE-PFO**. *SAFE-PFO brings together leading centres across Europe to answer an important clinical question*."

Citing the importance of the trial, **Dr. Gabor Toth, Co-Principal Investigator of SAFE-PFO**, said, " *By directly comparing these two PFO closure devices in a large, randomised study, we hope to provide physicians with clear evidence to help guide treatment decisions for their patients*."

"*I welcome the initiation of this important, high-impact trial and look forward to the active participation of several centres across France with experience using both devices for PFO closure*," said **Professor Gilles Montalescot, Co-Principal Investigator of SAFE-PFO in France**.

Commenting on the trial, **Dr. Krishna Sudhir, Chief Medical Officer, SMT,** said, "*Enrolling the first patient is an important milestone for SAFE-PFO. This study will help cardiologists better understand how the Cocoon PFO Occluder*

compares with a widely used PFO closure device. Our aim is to generate clinical evidence to support informed treatment decisions and, ultimately, better care for patients with a PFO."

The Cocoon PFO Occluder features a platinum coating, which effectively mitigates nickel leaching, a common complication associated with traditional nitinol-based Occluders. The study will evaluate its performance against the Amplatzer PFO Occluder family in a randomized controlled setting. No conclusions about comparative safety or effectiveness should be drawn until the study is completed and its results are analysed.

About the SAFE-PFO trial
SAFE-PFO (ClinicalTrials.gov identifier: NCT07380490) is a randomized, multicentre European clinical study comparing the Cocoon PFO Occluder with the Amplatzer PFO Occluder family in adults undergoing transcatheter PFO closure. The first patient was enrolled on 24 July 2026 at HDZ NRW in Germany. Each participant will be followed for 12 months.

About SMT (Sahajanand Medical Technologies)
SMT (Sahajanand Medical Technologies) is a medical devices company with a portfolio of technologically advanced medical devices across vascular and structural heart intervention. SMT offers a portfolio of products focusing on vascular intervention and was the first company in the world to receive CE certification for a DES with a biodegradable polymer. SMT has a global presence with its footprints in more than 72 countries, as on March 31, 2025.

For further details, please visit the website or follow SMT on LinkedIn.

Disclaimer

Sahajanand Medical Technologies Limited is proposing, subject to receipt of requisite approvals, market conditions and other considerations, an initial public offer of its equity shares and has filed a draft red herring prospectus dated July 25, 2025 (“DRHP”) with the Securities and Exchange Board of India (“SEBI”) and the stock exchanges. The DRHP is available on our website at www.smtpl.com as well as on the website of SEBI at www.sebi.gov.in, Motilal Oswal Investment Advisors Limited at www.motilaloswalgroup.com, Avendus Capital Private Limited at www.avendus.com, HSBC Securities and Capital Markets (India) Private Limited at www.business.hsbc.co.in and Nuvama Wealth Management Limited at www.nuvama.com and and the websites of the stock exchange(s) at www.nseindia.com and www.bseindia.com, respectively. Any potential investor should note that investment in equity shares involves a high degree of risk and refer to the Red Herring Prospectus, including the section titled “Risk Factors” of the Red Herring Prospectus when available, for details. Potential investors should not rely on the DRHP for any investment decision.

[1]. pubmed.ncbi.nlm.nih.gov/40454242/

[2]. www.ncbi.nlm.nih.gov/books/NBK493151/