



AMT Medical on Track to Hit Next Milestones for Revolutionary Elana® Heart Bypass System

- Company Starting European CE Mark Expansion Trial
- Finalizing Feasibility Trial Discussions With US FDA

EDE, The Netherlands – September 7, 2023 – AMT Medical B.V., a Netherlands-based, clinical-stage medical device company, is on track to hit its next targets. The company is beginning Phase II of the SAFE-CAB Trial to obtain CE (Conformité Européenne) mark of the Elana Heart Bypass System in Europe. Furthermore, final discussions with the U.S. Food & Drug Administration (FDA) have now started to commence the Early Feasibility Trial in the U.S.

AMT Medical created the Elana Bypass System to make coronary artery bypass grafting (CABG) surgery a safer, less invasive procedure that improves patient outcomes. The company is working with experts in major clinics to develop a minimally invasive, closed-chest version of this technique, even enabling robotic heart bypass surgery. AMT Medical is also talking to interested new partners to support the trial program for the Elana Heart Bypass System and make it accessible to millions of patients worldwide.

Previously, the company reported on its first milestone, the positive results of the First-in-Human (FIH) CE mark trial. AMT Medical also succeeded in garnering significant support in the form of a multimillion-euro grant from the European Innovation Council (EIC) Accelerator, and a Dutch Enterprise Agency Innovation Credit.

“Based on the successful results of the FIH trial, the Elana Heart Bypass System has great potential to become a game-changer for severe atherosclerosis patients, offering fewer risks, less recovery time, and more comfort,” says AMT Medical CEO Rutger Tulleken. “Our solution eliminates the need for sutures and stopping the heart, a great advancement for surgeons and patients.”

Promising results were demonstrated in the first phase of the FIH SAFE-CAB trial involving 10 subjects. The Elana Heart Bypass System was shown to be safe and feasible in humans in SAFE-CAB Phase I, with all trial participants free of Major Adverse Cardiovascular Events (MACE) at postoperative day 30. AMT Medical is now ready for another milestone. The trial already started and is currently being expanded to include 75 subjects, with the ultimate goal of achieving European clearance for commercial use. AMT Medical expects to present the first findings at the end of next year.

AMT Medical is also close to finalizing negotiations with the FDA to seek approval for its first feasibility trial in the U.S. “We are partnering with UChicago Medicine and hope to launch this groundbreaking trial in the next two years,” said Tulleken.

The Elana Technology Already Proven in Brain Surgery

The Elana Heart Bypass System is a sutureless procedure, which enables open, beating-heart surgery, as well as minimally invasive surgery. It involves bypassing the blocked vessel using a donor vessel, which is connected behind the blockage using AMT Medical's Heart Clip. The path through the new vessel is then opened by the Elana Heart Laser Catheter, allowing blood to bypass the blockage. Patients with this surgery have a short recovery time, usually 4 to 6 weeks.

The solution is based on a proven similar technique, the Elana Brain Bypass. It was invented more than 30 years ago by Tulleken's father, neurosurgeon Prof. Dr. C.A.F. Tulleken, and introduced in 2005 by Elana B.V., an earlier company founded by Rutger Tulleken and others at AMT Medical. Since then, the Elana Brain Bypass has helped save up to a thousand lives in Europe, the U.S., and Canada, according to the Brain Technology Institute.ⁱ

CABG: Major Cardiac Surgery

Coronary artery disease, a blockage of the arteries that supply blood to the heart, is the most common type of heart disease, and is the number one cause of death worldwide.ⁱⁱ In order to improve blood flow to the heart, coronary artery bypass grafting is performed. Over 95 percent of CABG operations are done in an open-heart setting, sometimes requiring the heart to be temporarily stopped. This is a complex but standardized procedure with associated risks of mortality, important morbidity and a rehabilitation period up to 6 months.ⁱⁱⁱ

About AMT Medical

AMT Medical is a Netherlands-based clinical-stage medical device company with one dream: to make coronary artery bypass grafting (CABG) a safer, less invasive procedure for all eligible patients worldwide. The company is pioneering a new, life-saving technique for CABG, the Elana Heart Bypass System. The Elana Heart Bypass System draws inspiration from the successful Elana Brain Solution, pioneered by Elana B.V. The Heart Bypass is being put into clinical practice by The St. Antonius Hospital in Nieuwegein, the Netherlands, and The University Hospital Charité in Berlin, Germany. AMT Medical operates under the principle "together we are better," fostering collaborations with clinical specialists, advisors, and investors. The company's diverse team, with an extensive history in R&D innovations, quality assurance, regulation, and clinical solutions, is well-equipped to realize its goals.

For more information, please visit www.amt-medical.nl

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ⁱ Brain Technology Institute. (n.d.). <http://www.bt-i.org/from-bench-to-bedside>

ⁱⁱ Thomas, J. (2023, July 20). *Heart Disease: Facts, Statistics, and You*. Healthline. <https://www.healthline.com/health/heart-disease/statistics>

ⁱⁱⁱ *AMT Medical makes open-heart bypass surgeries a thing of the past*. Catalyze. (2023, May 16). <https://www.catalyze-group.com/case/amt-medical-making-open-heart-bypass-surgeries-a-thing-of-the-past/>