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Medtronic adds innovative Penditure™ Left Atrial Appendage Exclusion System to Cardiac Surgery portfolio

The PendiTureTM Left Atrial Appendage (LAA) Exclusion System is
for the exclusion of the LAA in patients undergoing a concomitant cardiac surgery procedure.

Medtronic plc, a global leader in healthcare technology, today announced the launch of its Penditure™ Left Atrial Appendage (LAA) Exclusion System in the United States. The Penditure LAA Exclusion System is an innovative, implantable clip that comes pre-loaded on a single-use delivery system for use in left atrial appendage management (LAAM) during concomitant cardiac surgery procedures. The Penditure clip is curved to better match the atrial anatomy[1] and was designed without fabric for atraumatic closure and reduced inflammation.[2] The Penditure device is the only LAA clip that can be recaptured, repositioned, and redeployed after deployment during a procedure, putting greater control in the hands of surgeons.[3]

Medtronic completed the acquisition of the Penditure device technology from Syntheon LLC in August 2023. The acquisition expands the company's Cardiac Surgery product portfolio to include left atrial appendage management. The first cases were performed by Drs. Gorav Ailawadi and Basel Ramlawi at the University of Michigan Frankel Cardiovascular Center and Lankenau Heart Institute, part of Main Line Health, respectively.

"This launch brings innovation to the space, offering a solution that is low profile and can provide more control and visibility than ever before. And while we hope we don't need to use it often, the Penditure clip is recapturable and redeployable should we ever want to reposition an already deployed clip, which is a nice safety feature," said Gorav Ailawadi, M.D., Director, Frankel Cardiovascular Center, Helen F. and Marvin M. Kirsh Professor of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan.

"The Penditure device was effective at completely excluding the LAA at its base [4], achieving an excellent result surgically and on echo imaging. Given successful initial experience, surgeons can place the device safely and reliably while having the added benefit of repositionability if needed for optimal placement," said Dr. Basel Ramlawi, System Chief, Cardiothoracic Surgery & Co-Director, Lankenau Heart Institute at Main Line Health, Philadelphia, Pennsylvania.

The American College of Cardiology (ACC) [5], American Heart Association (AHA) [6], and Society of Thoracic Surgeons (STS) guidelines[7] recommend that patients undergoing a concomitant cardiac surgery procedure and have pre-operative (pre-op) AF should have their LAA closed. This is because patients with atrial fibrillation (AF) experience a five times greater risk of stroke[8], and most stroke-causing clots originate in the LAA.[9] Closing the LAA may prevent these blood clots from entering the bloodstream.

Medtronic will begin enrollment in the exClusion of the Left atrlal appendage with PendITure™ (CLIP-IT) Post-Market Study, in early calendar year 2024. The study will aim to further evaluate

the performance and clinical outcomes of the Penditure™ LAA Exclusion System in subjects undergoing concomitant cardiac surgery. CLIP-IT will be a multi-center, single-arm, nonrandomized, interventional, post-market study enrolling approximately 150 patients at 25 US sites.

"The strategic addition of the Penditure Left Atrial Appendage Exclusion System demonstrates our commitment to investing in cardiac surgeons and their growing needs for managing patients with more complex cardiac disease. The Penditure device reinforces our commitment to innovation and provides an important, new, differentiated LAA management option for cardiac surgeons in the care of their patients," said Karim Bandali, PhD, president of the Cardiac Surgery business within the Cardiovascular Portfolio at Medtronic.

The Penditure LAA Exclusion System received a 510k clearance in August 2023 and is commercially available in the US on a limited basis at this time.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] Product Specification Matrix PRS-00001 and Curvature report (EGS-00006)

[2] Syntheon's LAA Tissue testing. Reference EGS-00007 / GLP Animal Study TR-0023

[3] Syntheon Product Specification Matrix (PRS-00001-R05) and IFU ((DRW-00081-002)

[4] Syntheon Product Specification Matrix (PRS-00001-R05)

[5] Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: A report of the american college of cardiology/american heart association joint committee on clinical practice guidelines. *Circulation*. 2021;143(5). doi:10.1161/cir.0000000000000923

[6] January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the american college of cardiology/american heart association task force on clinical practice guidelines and the heart rhythm society in collaboration with the Society of Thoracic Surgeons. *Circulation*. 2019;140(2). doi:10.1161/cir.0000000000000665

[7] Badhwar V, Rankin JS, Damiano RJ, et al. The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation. *Ann Thorac Surg*. January 2017;103(1):329-341

[8] Win NT, Teo SP. Atrial fibrillation in older patients-reducing stroke risk is not only about anticoagulation. *J Geriatr Cardiol*. 2016;13(10):880-882. doi:10.11909/j.issn.1671-5411.2016.10.004

[9] Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg*. 1996;61(2):755-759. doi:10.1016/0003-4975(95)00887-X