Medtronic

ExClusion of the Left atrIal appendage with PendITure (CLIP-IT) post-market study

Designed to collect post-market clinical evidence on the performance and clinical outcomes of the Penditure™ left atrial appendage exclusion system in patients undergoing concomitant cardiac surgery

Study design, population, and objectives

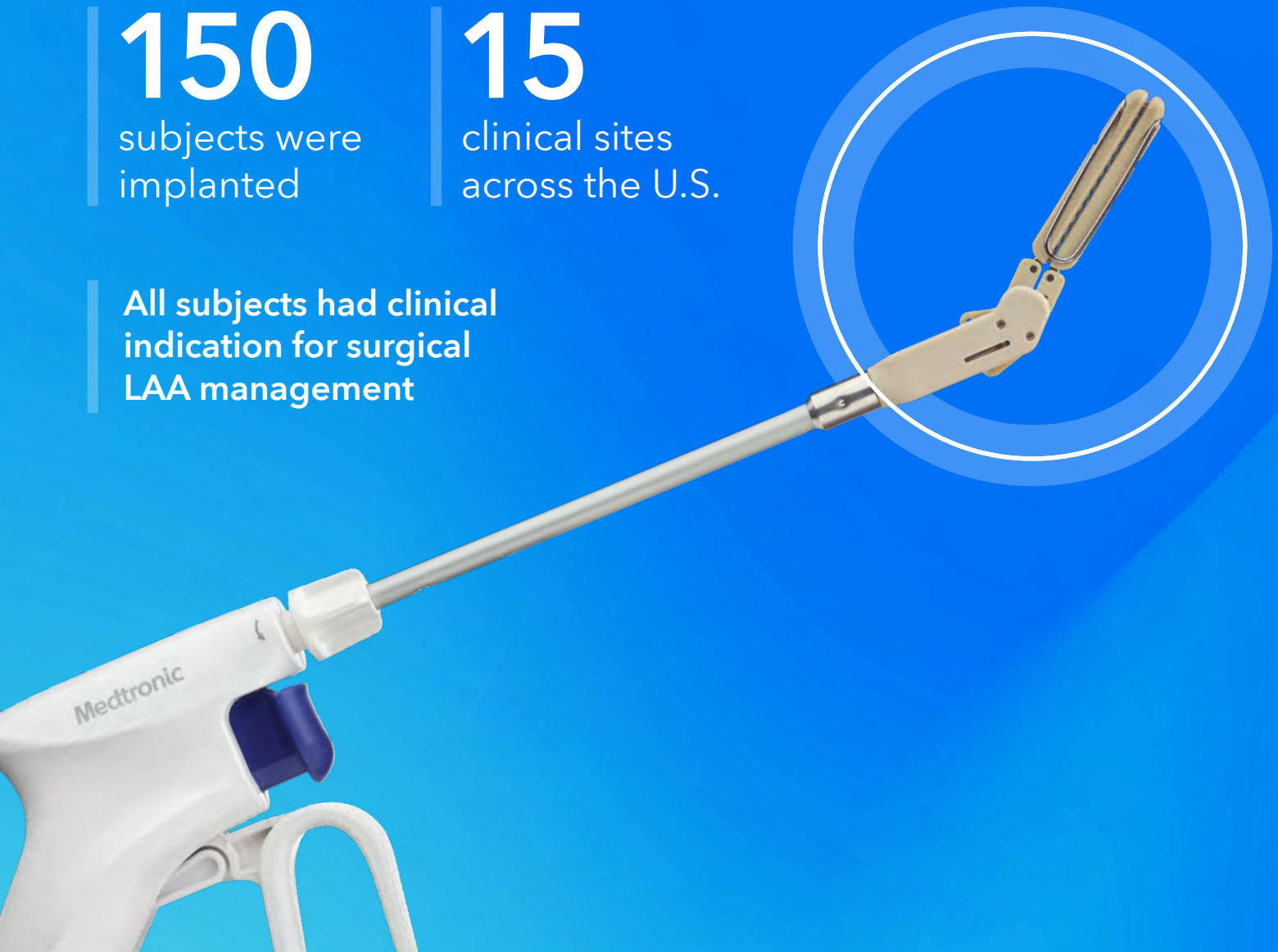
The study endpoints will further analyze the safety and efficacy of the Penditure™ device when used for surgical left atrial appendage (LAA) management under direct visualization.

The CLIP-IT study was a prospective, multicenter, single-arm, nonrandomized, interventional post-market study generating data on performance and clinical outcomes of the Penditure™ LAA exclusion system following its commercial introduction in the United States.

150
subjects were implanted

15
clinical sites across the U.S.

All subjects had clinical indication for surgical LAA management



Study results

The CLIP-IT post-market study further evaluates the Penditure™ LAA exclusion system, the only recapturable surgical LAA clip, allowing surgeons to reopen, reposition, and redeploy the device for optimal placement.[1]

100%

Rate of successful exclusion of the LAA from the heart defined as the absence of residual communication between the left atrium (LA) and the LAA[2]

100%

Successful recapture and redeployment of the clip when the recapture feature was used[2]

0%

Composite rate of device- related serious adverse cardiac events at 30 days post-procedure[2]

100%

Successful acute electrical isolation in evaluated subset (n = 25)[2]

1. Medtronic Data on file. IFU (M050807C001B).
2. Ailawadi G, Moront MG, Cavalcante JL, et al. Safety and efficacy of an innovative system for exclusion of the left atrial appendage: primary results. Paper presented at: 62nd Society of Thoracic Surgeons Annual Meeting; January 29–February 1, 2026; New Orleans, LA.

Penditure™ LAA Exclusion System

Indications: The Penditure LAA Exclusion System is indicated for the exclusion of the left atrial appendage of the heart, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the physician can see the heart directly, with or without assistance from a camera, endoscope, and so forth, or any other appropriate viewing technologies.

Contraindications:
- Do not use this device if the patient has a known allergy to nitinol (nickel titanium alloy).
- Do not use this device as a contraceptive tubal occlusion device.

Potential Adverse Effects: Possible complications related to the use of Penditure™ LAA exclusion system in combination with open heart surgery are: bleeding, tissue damage, thromboembolism, and pericardial effusion. For a complete listing of all indications, contraindications, precautions, and warnings, please refer to the Instructions for Use, which accompany each product.

Warnings: Read all warnings, precautions, and instructions for use carefully before use. Failure to read and follow all instructions or failure to observe all stated warnings could cause serious injury to the patient.

- Before removing the device from the packaging, inspect the packaging and device for damage. Do not use the device if the use-by date has passed or if the device or package is damaged. Using an expired or damaged device could result in infection.
- The contents are supplied sterile using a gamma irradiation process. Do not use if the sterile barrier is damaged. If damage is observed, call a customer service representative.
- The device is single use only. Do not reuse, repurpose, or re-sterilize the device, as this could increase the risk of contamination of the device and cause the transmission of infectious diseases between patients and users. Contamination of the device may lead to illness, injury, or death.
- Do not actuate (open and close) the implant more than 5 times before final deployment. Doing so may result in displacement or incomplete exclusion of the LAA.
- Clip size should be determined by using the Penditure selection guide and referencing the Penditure selection guide instructions for use. Failure to correctly size or deploy the clip may result in improper exclusion of the LAA, displacement of the clip, or damage to adjacent patient anatomy.
- Before placing the clip onto the LAA, the physician should assess the suitability of the tissue for established closure techniques (surgical suturing, stapling, and so forth). Implanting the Penditure LAA Clip on tissue that is not suitable may cause tissue trauma or tearing.
- Do not use on a LAA less than 29 mm or greater than 50 mm when tissue is uncompressed. Doing so may result in incomplete exclusion or damage to adjacent anatomy.
- Failure to use the delivery system to reposition or remove the clip after deployment may result in tissue damage or tearing.
- Improper clip placement that allows blood flow into the LAA may result in incomplete exclusion or electrical isolation.
- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- Dispose of the product and packaging in accordance with administrative, hospital, and local government policies.

Precautions:
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Use of this product should be performed only by physicians with adequate training and familiarity with cardiac surgical procedures. Read all instructions carefully. Failure to properly follow these instructions may result in improper function of the device.
- Do not use a device that has been dropped or appears to be damaged. Instead, discard and replace such a device with a new device.
- Careful consideration of prior treatments (radiation therapy, for example) performed on the patient before surgery may result in changes to the tissue that may impact LAA exclusion. Physician judgement should be used to assess the suitability of the tissue before placement.
- Do not attempt to twist or manually manipulate the components on the distal end of the shaft. This may result in damage to the device. Excessive bending or kinking of the shaft may affect device performance.
- Bend the device by grasping only the shaft with fingers and thumbs. Do not grasp the distal end while bending as this could damage the device. Excessive bending or kinking of the shaft may adversely affect device performance.
- Do not attempt to twist the clip, as this may cause impaired function.
- Do not modify the Penditure LAA exclusion system. Medtronic makes no claim or representation regarding performance of this product if any modifications have been made to the device or clip.
- Evacuate thrombus from the LAA prior to clip application as required with other conventional LAA surgical techniques. Evaluation for the presence of thrombus should be performed at the physician's discretion and using standard of care.
- To avoid suboptimal clip placement, position and deploy the clip only with adequate visualization of the LAA and adjacent anatomy.
- Minimize manipulation of the LAA and clip after clip deployment.
- It is recommended that the clip be deployed in a dry surgical field.
- Do not attempt to rotate the shaft without pushing the knob out of the locked position. Rotating the knob while in the locked position may damage the device.
- Only actuate the release trigger when the clip is properly positioned on the LAA. Pulling the release trigger allows for the release of the clip from the delivery system.
- Do not use the clip in temperatures below 68 °F. Application of the clip in temperatures below 68 °F may affect device performance.

Only physicians who are trained in standard cardiac surgical procedures can use this device.

For more information, contact your local Medtronic cardiac surgery representative. U.S. Customer Service: 1-800-328-1357.

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