

Fact Sheet: The Watchman[™] Left Atrial Appendage (LAA) Closure Device

About Watchman[™]

- The Watchman[™] Left Atrial Appendage (LAA) Closure Device is a proven device alternative to warfarin for reducing the risk of stroke in patients with non-valvular atrial fibrillation (AF). This has been shown in three studies PROTECT AF^{1,2}, PREVAIL³ and ASA Plavix (ASAP).⁴ Data from the latter showed a 77 percent reduction of ischemic stroke risk in patients with AF, who have been implanted with the device and are contraindicated to warfarin.⁵
- It is designed to be permanently implanted at or slightly distal to the ostium (opening) of the LAA to close it off, avoiding the formation of thrombi (blood clots), which might exit the LAA and dislodge into circulation, potentially causing a stroke.
- The Watchman (LAA) Closure Device consists of the implantable device and the tools for implantation.
- The implantable device consists of a self-expanding nickel titanium (nitinol) frame structure with fixation anchors and a PET fabric that covers the atrial facing surface of the device, which is designed to prevent clots from forming in the LAA.
- The device is preloaded within a delivery catheter and is available in five different sizes (21, 24, 27, 30 and 33 mm) to accommodate the unique anatomy of each patient's LAA and allow appropriate sizing within the ostium.

The Watchman device implant procedure

• The Watchman implant procedure can be performed under local or general anesthesia in a catheterisation laboratory setting. The procedure is conducted by a team of physicians, which includes structural heart interventional cardiologists/electrophysiologists and physicians with special expertise in echocardiographic imaging.

The device is implanted via a trans-septal approach by using the catheter-based delivery system, which is capable of recapturing the device, if necessary.

- To measure the LAA and determine which size of the Watchman device needs to be implanted, a transesophageal echocardiogram (TEE)ⁱ is performed upfront to better visualise the structure of the heart.
- After the inter-atrial septum is crossed the Watchman Access Sheath and Dilator are advanced over a guide wire into the left atrium. The Watchman Delivery System is prepped, inserted into the access sheath, and slowly advanced under fluoroscopic guidance. The Watchman device is then deployed into the LAA.
- The device release criteria are confirmed via fluoroscopy and a TEE prior to releasing the device. The entire procedure usually lasts about an hour and the patient typically needs to stay in the hospital for 24 hours afterwards.
- After the procedure, warfarin therapy for a minimum of 45 days (International Normalised Ratio/INR 2.0 to 3.0) is required in all patients receiving a Watchman device who are eligible for warfarin

ⁱ Also referred to as TOE. SH-354411-AA NOV2015

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therapy or other equivalent oral anticoagulant (OAC). At 45 days after the implantation, a TEE is performed for further assessment of the device.

Patient eligibility

The Watchman LAA Closure Device is indicated as a treatment alternative to patients with AF, either indicated or contraindicated to anticoagulation therapy, thus extending the benefits of the therapy to a wider population and especially to those at higher risk than others.^{6,7,8} The LAA closure procedure aims at reducing the risk of ischemic stroke and systemic thromboembolism by closing off the LAA permanently and thereby avoiding the migration of emboli to the brain or the body.

Existing clinical evidence

Watchman is the most studied LAA closure device with over 2,400 patients enrolled in prospective studies and nearly 6,000 patient years of follow-up. In addition, it is the only LAA closure device with long-term clinical data whose efficacy and safety have been demonstrated under large multi-centre, prospective, randomised clinical trials.

For additional information about the clinical evidence supporting the Watchman Device, please refer to the "Clinical study factsheet".

Market availability

In March 2011, Boston Scientific announced the completed acquisition of Atritech Inc., the company which originally developed Watchman. The device received the CE Mark in 2005 and was commercialised outside the United States in 2009. In the US, the Watchman device Received FDA approval in March 2015. Today, Watchman is registered in 75 countries worldwide, including most European countries and more than 10,000 patients have been treated with the Watchman device. Boston Scientific is dedicated to training physicians in even more countries on the safe and effective use of the device to make this therapy option available to a larger patient base.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, please visit: <u>www.bostonscientific.eu</u>

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^{2011;123(4):417-24.} ² Reddy VY et al. Long term results of PROTECT AF: The mortality effects of left atrial appendage closure versus warfarin for stroke prophylaxis In AF, *HRS* 2013; Abstract LBA01-03.

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⁴ Reddy VY, Left Atrial Appendage Closure with the Watchman Device in Patients with a Contraindication for Oral Anticoagulation: ASA Plavix Feasibility Study with Watchman Left Atrial Appendage Closure Technology (ASAP Study), JACC (2013), doi: 10.1016/j.jacc.2013.03.035. ⁵ Reddy V et al. 144

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⁷ Gage BF et al. Circulation. 2004;110:2287-2292.

⁸ Gage BF et al. *JAMA*. 2001 Jun 13;285(22):2864-70.