

Fact Sheet:

The WATCHMAN™ Left Atrial Appendage (LAA) Closure Device

About WATCHMAN™

- The WATCHMAN™ Left Atrial Appendage (LAA) Closure Device is a proven, safe and effective solution in reducing the risk of stroke in non-valvular atrial fibrillation (AF) patients.
- WATCHMAN is the most studied LAA closure device worldwide with over 3,400 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, safety and patient benefits have been demonstrated under large multi-centre, prospective, randomised clinical trials. (Continue reading for more information about the clinical evidence).
- 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 anaesthesia 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.

ⁱ Also referred to as TOE.
SH-354411-AB MAR2017

- 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 therapy or other equivalent oral anticoagulant (OAC). Patients who are not eligible for OACs will be prescribed dual antiplatelet therapy after the procedure. 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.^{1,2,3} 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

As said above, WATCHMAN is the most studied LAA closure device worldwide. The clinical evidence includes two randomised trials, PROTECT AF^{4,5} and PREVAIL,⁶ as well as in four registries, ASA Plavix (ASAP), CAP I, CAP II and EWOLUTION.

- It demonstrated comparable stroke risk reduction, and statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death compared to warfarin over long-term follow-up in the PROTECT AF Study.⁷
- Efficacy has been demonstrated in patients contraindicated for oral anticoagulants in the ASAP prospective registry with a 77 percent reduction in the risk of stroke⁸
- EWOLUTION included more than 1,000 patients and is the largest European registry with WATCHMAN real-world data.⁹ The registry showed a 2.8 percent peri-procedural risk rate, the lowest peri-procedural risk rate reported in all WATCHMAN trials.¹⁰

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, around 20,000 people have been treated worldwide.

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: www.bostonscientific.eu

Media Contacts

Sharron Tansey
Market Access, Health
Economics & Government Affairs
+44 7770 834 947
TanseyS@bsci.com

Chiara Ennas
Media Relations and Corporate
Communications Europe
44 7766 086882
ennasc@bsci.com

References

- ¹ The ACTIVE Steering Committee on behalf of the ACTIVE Investigators *Am Heart J.* 2006 Jun;151(6):1187-93.
- ² Gage BF et al. *Circulation.* 2004;110:2287-2292.
- ³ Gage BF et al. *JAMA.* 2001 Jun 13;285(22):2864-70.
- ⁴ Reddy VY et al. Safety of percutaneous left atrial appendage closure: results from the Watchman Left Atrial Appendage System for Embolic Protection in Patients with AF (PROTECT AF) clinical trial and the Continued Access Registry, *Circulation* 2011;123(4):417-24.
- ⁵ 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.
- ⁶ Holmes DR et al. Randomized Trial of LAA Occlusion. *JACC.* Vol. 64: 1-12, 2014
- ⁷ Reddy VY, Sievert H, Halperin J, et al; for the PROTECT AF Steering Committee and Investigators. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial. *JAMA.* 2014;312(19):1988-1998.
- ⁸ Reddy V et al. LAA Closure Using the Watchman Device in Patients with Contraindications to Warfarin: Preliminary Results from the "ASA Plavix Registry" (ASAP). *HRS Congress 2012*, PO06-63.
- ⁹ 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.
- ¹⁰ Boersma L. V.A. et al., Implant Success and Safety of Left Atrial Appendage Closure with the WATCHMAN device: periprocedural outcomes from the EWOLUTION Registry . *Eur Heart J.* 2016;37(31):2465-74.