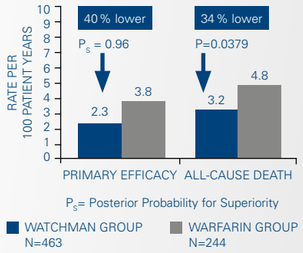
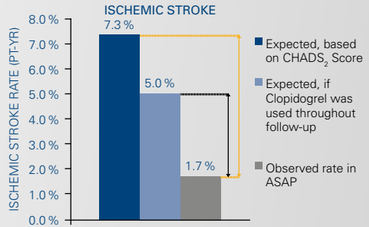
WATCHMAN™ DEVICE: A CLINICALLY PROVEN THERAPY

WATCHMAN is the only LAA closure device with more than 2,000 patients enrolled in clinical trials and about 6000 patient-years follow up.

STROKE RISK & ALL-CAUSE MORTALITY REDUCTION

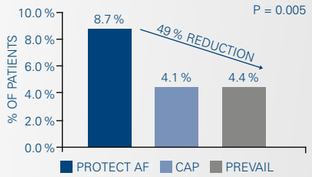




PROTECT AF 4 year study[7] demonstrated a statistically superior 40% relative risk reduction of stroke, systemic embolism and cardiovascular death; and a statistically superior 34% relative risk reduction in all-cause mortality.

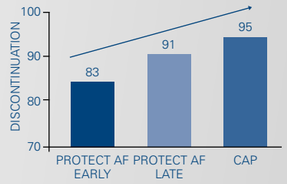
ASAP study[8] showed that WATCHMAN™ device reduces risk of stroke by 77% in patients contraindicated for oral anticoagulants.

SAFETY



PREVAIL study[9] confirmed the safety of the procedure with WATCHMAN™ LAA closure device, with additional reduction in vascular complications from previous WATCHMAN studies.

NO LONG-TERM OAC ADMINISTRATION



87% (PROTECT AF study) to 95% (CAP REGISTRY study) of patient were able to stop warfarin at 45 days.[10,11]

INDICATION

The WATCHMAN™ LAA closure technology is intended to prevent thrombus embolization from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation who are eligible for anticoagulation therapy or who have contraindication to anti-coagulation therapy.

STOP THE STROKE WHERE IT STARTS

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1 Go AS et al. JAMA 2001; 285:2370-2375.
2 Holmes DR et al. Seminars in Neurology 2010;30:528-536.
3 Blackshear JL Odell JA. Annals of Thoracic Surgery, 1996; 61:755-759.
4 Margaret C. Fang et al., Circ Cardiovasc Qual Outcomes. 2010 November 1; 3(6):624–631 Warfarin Discontinuation after Starting Warfarin for Atrial Fibrillation.
5 Sudlow et al. Lancet. 1998; 352:1167-1171; Willems et al. J Interv Card Electrophysiol. 2004; 10:9-16.
6 when compared to warfarin. Holmes D et al. PROTECT AF – Quality of Life Assessment in the Randomised PROTECT AF Trial of Patients at Risk for Stroke with Non-Valvular Atrial Fibrillation. Poster presented at ACC 2012.
7 Reddy, VY et al. JAMA. 2014; 312(19):1988-1998.
8 Reddy, et al. JACC; Left Atrial Appendage Closure with the WATCHMAN device in patients with a contraindication for oral anticoagulation; The ASAP Study 2013.
9 Holmes DR et al. Randomized Trial of LAA Occlusion. JACC. Vol. 64: 1-12, 2014.
10 Holmes D et al. Lancet 2009;374:534-42.
11 Reddy VR et al. Circulation 2011;123:417-424.

The WATCHMAN™ LAA Closure Device is designed to reduce the risk of stroke in patients with Atrial Fibrillation by preventing thrombus embolization from the left atrial appendage.

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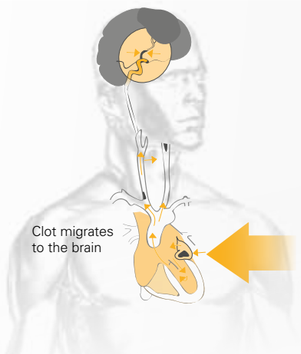
WATCHMAN™

Left Atrial Appendage Closure Device

REDUCING STROKE RISK
IN PATIENTS WITH ATRIAL FIBRILLATION

PATIENTS WITH ATRIAL FIBRILLATION ARE AT INCREASED RISK OF STROKE



Atrial fibrillation increases five times the risk of stroke[1]

Strokes in patient with atrial fibrillation are the:

#1 cause of long-term disability[2]
#3 highest cause of mortality[2]

Irregular heartbeats, during atrial fibrillation, can cause the blood to pool in the left atrial appendage. This may result in the development of blood clots which can be pumped out of the heart to the brain.

91% of strokes in patients with atrial fibrillation are caused by blood clots from the left atrial appendage[3]

TREATMENT OPTIONS:

Anticoagulant therapy is generally used to avoid the formation of thrombus; the most commonly prescribed treatment is warfarin.

Medication such as warfarin can lead to lifestyle limitations like:

- Negative interactions with food and drugs
- Serious side effects often difficult to tolerate
- Frequent and ongoing monitoring required

Oral anticoagulants' limitations include:

- Risk of bleeding
- High risk of discontinuation (26.3% within one year after warfarin)[4]
- 25% of patients indicated for oral anticoagulants are contraindicated[5]

REDUCING RISK OF STROKE WITH WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE DEVICE

LEFT ATRIAL APPENDAGE CLOSURE IS AN ALTERNATIVE TO MEDICATION

Local therapy with WATCHMAN™ is an option to reduce the risk of stroke in patients with non-valvular atrial fibrillation. It is designed to avoid the embolization of thrombi that may form in the left atrial appendage (LAA).

WATCHMAN™ LAA closure device is a self-expanding nitinol frame covered by a permeable fabric (PET).

It is available in 5 different sizes (from 21 to 33 mm diameter).

Device in position within the LAA resulting in closure

The WATCHMAN™ device is designed to reduce the risk of stroke by closing off the left atrial appendage, which is known to be the main source of blood clots in patients with atrial fibrillation.

Benefits of LAA Closure:

- Stroke risk reduction
- Long term anticoagulation therapy cessation
- Better quality of life[6]

WATCHMAN™ DEVICE IMPLANT PROCEDURE

The WATCHMAN™ device is implanted via a trans-septal approach by using the catheter-based delivery system, which is capable of recapturing the device, if necessary. The procedure is usually done under general anesthesia and lasts about 60 minutes.

During the procedure, a transoesophagial echography (TOE) is done.
It will help to:

- Identify presence of thrombus in the LAA
- Obtain LAA measurements to determine the proper implant size
- Well position the catheter in the left appendage

WHAT HAPPENS AFTER THE PROCEDURE?

As the procedure is minimally invasive patient recovery takes about 24 hours.

After the device has been implanted, patient should receive warfarin (or other OACs) for 45 days, to facilitate device endothelialisation.

A follow-up TOE will be performed at 45 days. At this stage, physician may decide to discontinue warfarin therapy and prescribe clopidogrel (75mg) and aspirin (81-325mg) until completion of the 6 months visit, from which point aspirin alone should be continued.

Physicians may prescribe clopidogrel and aspirin daily dose for up to six months to the patients contraindicated to anticoagulation therapy. These patients should remain on aspirin indefinitely.