

# WATCHMANFLX™ : *One Time. For a Lifetime.*

Non-valvular AFib patients generally aren't aware of an alternate treatment option to reduce their stroke risk and bleeding risk, which is a top concern for those on blood thinners. We also know that patients who are interested in WATCHMAN, once they learn of it, wonder whether it's right for them. Not surprisingly, the prospect of getting off blood thinners is the most motivating factor behind their intention to talk to their doctors about WATCHMAN.

WATCHMAN sets itself apart from blood thinners by providing the only FDA approved implant alternative of its kind for people who need one. Boston Scientific is dedicated to lasting design innovation to continue to define LAAC therapy and to treat more patients with WATCHMAN FLX.

## **WATCHMAN is a minimally invasive, one-time procedure that reduces stroke risk without the worry that comes with lifelong blood thinners**

### **WATCHMAN Safety**

More than 100,000 WATCHMAN procedures have been performed worldwide. With almost 20 years of clinical trial and real-world experience - including 10 clinical trials - WATCHMAN has a proven safety record.

### **WATCHMAN Efficacy**

In a clinical trial, 96% of people were able to stop taking blood thinners 45 days after getting WATCHMAN FLX.

Reference: PINNACLE FLX 12-month primary safety and efficacy endpoint results, presented at HRS 2020 Science.

### **WATCHMAN Advanced, Heart- Friendly Design**

Science always looks for ways to make effective treatments even better. WATCHMAN is no exception. The WATCHMAN FLX design is an advancement that enables the implant to fit a greater number of patients, giving more people than ever a safe, effective alternative to blood thinners should they need one.

# ATRIAL FIBRILLATION & STROKE RISK



- A person with AFib is 5 times more likely to suffer a stroke than someone with a regular heartbeat.

Reference: National Stroke Association. Making the Afib-Stroke Connection. <https://www.stroke.org/sites/default/files/resources/Afib-Connection%20for%20hcp.pdf>. Published 2012. Accessed September 1, 2016

- In people with AFib not caused by a heart valve problem, more than 90% of stroke-causing clots that come from the heart form in a small space in the upper left chamber (left atrial appendage).

Reference: Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg*. 1996;61:755-759.



- WATCHMAN is a small implant that creates a permanent barrier in the left atrial appendage to keep blood clots from escaping and causing a stroke.
- 40% of people eligible for oral anticoagulants do not take their medication for various reasons and may need a treatment alternative.



Reference: Shah et al. Use of Novel Oral Anticoagulants for Patients with Non-valvular Atrial Fibrillation: Results from the NCDR Pinnacle Registry. *Journal of the American College of Cardiology*. 2014;63.

- More than a third (38%) of those taking oral anticoagulants feel trapped between their fear of having a stroke and their fear of the risks associated with oral anticoagulants.

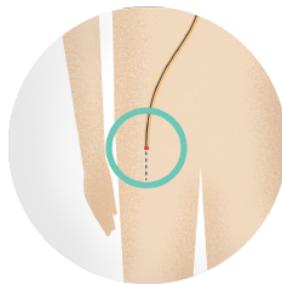
Reference: WatchUsNow.com. The Harris Poll online survey. Boston Scientific. SH-574213-AA. <https://www.watchusnow.com/?page=d75be9d4-ba36-456c-a72d-dc3df07892da>. Accessed March 28, 2019.

# WATCHMAN IMPLANT PROCEDURE

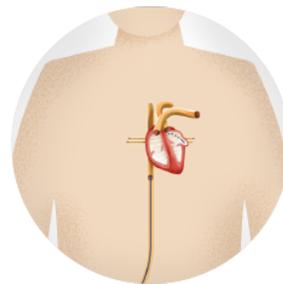


- WATCHMAN is implanted into your heart in a minimally invasive, one-time procedure that is typically done under general anesthesia and takes about an hour. Patients commonly stay in the hospital overnight and leave the next day.
- Getting WATCHMAN is not unlike getting a stent: your doctor makes a small cut in your upper leg, inserts a narrow tube, and guides the implant into the left atrial appendage (LAA) of your heart.
- After the procedure you'll be prescribed blood thinning medication by your doctor until your left atrial appendage is completely closed off, usually within 45 days.
- In a clinical trial, 96% of people were able to stop taking blood thinners 45 days after getting WATCHMAN FLX.

Reference: Doshi S. Primary Outcome Evaluation of a Next Generation LAAC Device: The PINNACLE FLX Trial. Presented at HRS 2020 Science.



1. Cut in upper leg



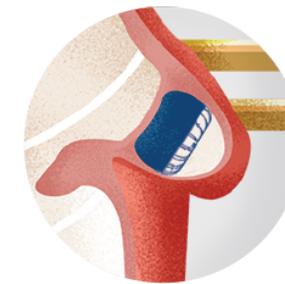
2. Guided to heart



3. Stay overnight



4. Blood thinners  
for 45 days



5. Tissue grows  
over WATCHMAN

# WHO WATCHMAN IS FOR



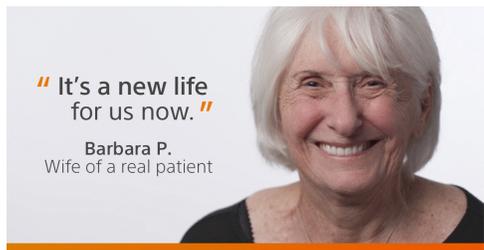
- WATCHMAN and WATCHMAN FLX are the only implants approved by the FDA to safely and effectively reduce the risk of stroke in people with atrial fibrillation not caused by a heart valve problem.
- WATCHMAN can be an important option for people with a history or risk of serious bleeding on blood thinners.



- If you have AFib not caused by a heart valve problem and need an alternative to blood thinners, WATCHMAN may be right for you.
- WATCHMAN is a one-time, permanent implant that never needs to be replaced.
- With the addition of WATCHMAN FLX, WATCHMAN can treat even more patients.



**"I would have done anything to get off blood thinners."**  
Mike P.  
A real patient



**"It's a new life for us now."**  
Barbara P.  
Wife of a real patient



**"For me, the WATCHMAN was a lifesaver."**  
Cliff D.  
A real patient



**"WATCHMAN took away my fear of having a stroke due to a blood clot."**  
Susan B.  
A real patient



**"Because of WATCHMAN I can cut my own grass at 81 years old."**  
Liliane W.  
A real patient

# COST & COVERAGE

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- WATCHMAN is covered for eligible Medicare patients who meet certain national coverage criteria. It's also covered by an increasing number of commercial insurers.
- WATCHMAN is different from blood thinners not only in how it works, but in how much it costs. While warfarin must be taken every day for life and represents an ongoing cost, WATCHMAN is a one-time procedure and one-time cost. This means WATCHMAN can save you money over time.
- WATCHMAN has been shown to be less expensive than warfarin two years after implant and half the cost five years after implant.



Reference: Armstrong S, Amorosi SL, Patel P, et al. An Analysis of patient out-of-pocket spending for stroke prevention in non-valvular atrial fibrillation. J Am Coll Cardiol. 2014;63(12\_S):A349.

# CLINICAL DATA

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WATCHMAN FLX was studied in the PINNACLE FLX US IDE Clinical Trial. The study was designed to establish the procedural safety and closure efficacy of next generation LAAC device, WATCHMAN FLX.

- Primary Safety Endpoint – low 0.5% adverse event rate.
- Primary Efficacy Endpoint - 100% effective LAA closure at 12 months (LAA closure at 12 months is defined as any peri-device flow with jet size  $\leq 5$ mm per core laboratory-assessed TEE)
- 96.2% of patients discontinued DOAC at 45-day follow-up
- 98.8% patients were successfully implanted (Implant success defined as successful delivery and release of a WATCHMAN FLX device into the LAA)

## Study Design

- 400 patient, 29 US site, single arm, non-randomized trial evaluating WATCHMAN FLX for non-inferiority to safety and efficacy performance goals based on the WATCHMAN™ device.
- Follow-up: 45 days (+TEE), 6 months, 12 months (+TEE), 18 months, and 24 months
- Patient Characteristics: Average CHA2DS2-VASc of  $4.2 \pm 1.5$ , Average HAS-BLED of  $2.0 \pm 1.0$
- Post Implant Drug Regimen: NOAC/ASA for 45 days, Clopidogrel/ASA to 6 months, ASA post 6 months
- **Primary Safety Endpoint:** All-cause death, ischemic stroke, systemic embolism, or device- or procedure-related adverse events requiring surgery or major endovascular intervention within 7 days following the procedure or by hospital discharge, whichever is later.
- **Primary Efficacy Endpoint:** The rate of effective LAA closure defined as any peri-device flow  $\leq 5$ mm demonstrated by TEE at 12 months
- **Secondary Efficacy Endpoint:** The occurrence of ischemic stroke or systemic embolism at 24 months from the time of enrollment
- Inclusion/exclusion criteria is consistent with WATCHMAN clinical study inclusion/exclusion criteria. Patients must be eligible for short-term NOAC vs warfarin in previous clinical studies.

Reference: Doshi S. Primary Outcome Evaluation of a Next Generation LAAC Device: The PINNACLE FLX Trial. Presented at HRS 2020 Science

# IMPORTANT SAFETY INFORMATION

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The WATCHMAN and WATCHMAN FLX Devices are permanent implants designed to close the left atrial appendage in the heart in an effort to reduce the risk of stroke.

With all medical procedures there are risks associated with the implant procedure and the use of the device. The risks include but are not limited to accidental heart puncture, air embolism, allergic reaction, anemia, anesthesia risks, arrhythmias, AV (Arteriovenous) fistula, bleeding or throat pain from the TEE (Trans Esophageal Echo) probe, blood clot or air bubbles in the lungs or other organs, bruising at the catheter insertion site, clot formation on the device, cranial bleed, excessive bleeding, gastrointestinal bleeding, groin puncture bleed, hypotension, infection/pneumonia, pneumothorax, pulmonary edema, pulmonary vein obstruction, renal failure, stroke, thrombosis and transient ischemic attack. In rare cases death can occur.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the device.