

# The WATCHMAN FLX™ Implant: 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 the WATCHMAN Implant, once they learn of it, wonder whether it's right for them.

WATCHMAN sets itself apart from blood thinners by providing the most implanted, FDA-approved device 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 the WATCHMAN FLX Device, a generation ahead.

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

### WATCHMAN Implant Safety

More than 150,000 WATCHMAN Implant procedures have been performed worldwide. With almost 20 years of clinical trial and real-world experience - including 10 clinical trials – The WATCHMAN Implant has a proven safety record.

### WATCHMAN Implant Efficacy

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

Reference: Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.

### WATCHMAN FLX Implant – A Generation Ahead

Science always looks for ways to make effective treatments even better. The WATCHMAN Implant is no exception. The WATCHMAN FLX Implant 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.

# Patient Supporting Messaging

# 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.

- The WATCHMAN™ Implant is a small device 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.

# IMPLANT PROCEDURE

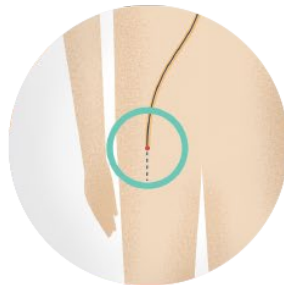


- The WATCHMAN Implant is placed into your heart in a minimally invasive, one-time procedure that is typically done under general anesthesia and takes about an hour. Patients commonly stay in the hospital overnight and leave the next day.

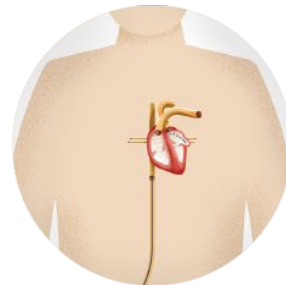


- To implant the WATCHMAN Device, your doctor makes a small cut in your upper leg and inserts a narrow tube. Your doctor then guides the WATCHMAN Implant into the left atrial appendage (LAA) of your heart.
- After the procedure you'll be prescribed blood thinning medication by your doctor until your 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: Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.



1. Cut in upper leg



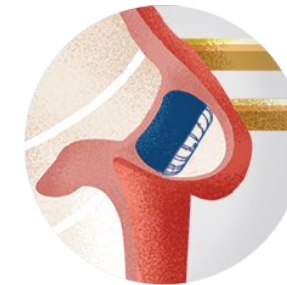
2. Guided to heart



3. Stay overnight



4. Blood thinners for 45 days



5. Tissue grows over WATCHMAN

# WHO THE WATCHMAN™ IMPLANT IS FOR



- The WATCHMAN Implant is the most implanted device 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.

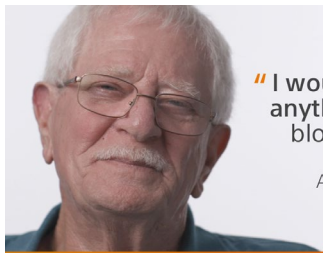
- The WATCHMAN Implant can be an important option for people with a history or risk of serious bleeding on blood thinners.



- If you have AFib not caused by a heart valve problem and need an alternative to blood thinners, The WATCHMAN Implant may be right for you.

- The WATCHMAN Implant is a one-time, permanent implant that never needs to be replaced.

- With the addition of the next generation WATCHMAN FLX Implant, more patients than ever can be treated with this safe, minimally invasive procedure.



**"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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- The WATCHMAN™ Implant is covered for eligible Medicare patients who meet certain national coverage criteria. It's also covered by an increasing number of commercial insurers.



- The WATCHMAN Implant is different from blood thinners not only in how it works, but in how much it costs. While blood thinners must be taken every day for life and represents an ongoing cost, the WATCHMAN Implant is a one-time procedure and one-time cost. This means the WATCHMAN Implant can save you money over time.
- There's no need to settle for the ongoing costs of blood thinners to protect yourself from stroke – the WATCHMAN Implant is a one-time procedure that pays for itself after two years.

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.

- An investment in your health means that you can be there for your family's needs in the future. Put a lifetime of blood thinners and the worries of falls and bleeds behind you with the WATCHMAN Implant.

# Supporting Clinical Data

# CLINICAL DATA

A generation ahead, the WATCHMAN FLX™ Device is built on the most studied and implanted LAAC device in the world. The WATCHMAN FLX Device is designed to **advance procedural performance** and **safety** while **expanding the treatable patient population**.

## Advanced Safety

The low 0.5% event rate\* demonstrates the enhanced safety profile of the WATCHMAN FLX LAAC device

\* Occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention

## Advanced Procedural Performance

The WATCHMAN FLX LAAC device is designed for enhanced LAA closure which was demonstrated with 100% rate of 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

## Expand the Treatable Patient Population

98.8% of patients were successfully treated with the WATCHMAN FLX device (395/400)\*\*\*

\*\*\*Procedure success defined as successful delivery and release of a WATCHMAN FLX device into the LAA

Reference: Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.



# Important Safety Information

# 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.