

WATCHMAN IMPLANT DISCUSSION GUIDE

The WATCHMAN Implant may offer an alternative to the lifelong use of blood thinners for people with atrial fibrillation not caused by a heart valve problem.

(also known as non-valvular AFib)

This guide will help you start a conversation with your doctor including the latest WATCHMAN Implant facts, a symptom tracker and a referral form.



”

I had a long talk with my cardiologist who agreed with me that it [WATCHMAN] would provide a better-quality life.

- Sean, WATCHMAN Implanted July 2020



Is the
WATCHMAN
Implant right
for me?

NEXT STEPS

1

Schedule an appointment with your cardiologist to discuss the WATCHMAN Implant and your concerns with your current stroke risk treatment.

2

Connect with a WATCHMAN Education Specialist. They are trained professionals with healthcare experience here to help answer your questions about the WATCHMAN Implant and can connect you with these



Talk to someone who has the WATCHMAN Implant

Patient Ambassadors are a community of people that have received the WATCHMAN Implant. They have volunteered to share their personal experiences.



AFib Education Events

Hear from implanting physicians about treatment options that could help reduce the risk of AFib-related strokes, including blood thinner alternatives such as the WATCHMAN Implant.

1-844-294-3320

Monday - Friday, 8:00 am to 5:00 pm Central time

3

Take the time to fill in any information about yourself and bring this discussion guide into your appointment so you can show your cardiologist your survey results and discuss your eligibility for the WATCHMAN Implant. Give the last two pages to your doctor.

WATCHMAN IMPLANT ELIGIBILITY

In order to be eligible for the WATCHMAN Implant, do you have the following?

- Do you have Atrial fibrillation (AFib) not caused by heart valve problems (*i.e. non-valvular AFib*)?
- Do you have an elevated stroke risk?
- Do you take a blood thinner or have you been prescribed a blood thinner in the past for your non-valvular AFib?
- Would you benefit from an alternative to blood thinners for one or more of the below reasons?
 - Have you had issues with bleeding and/or bruising while on blood thinners?
 - Do you have a medical condition, lifestyle/hobbies or an occupation that puts you at risk for bleeding while on blood thinners?
 - Do you have trouble staying within the recommended blood clotting range? (*a measurement known as INR*)
 - Do you have trouble getting regular blood tests to confirm your INR?
 - Do you occasionally miss a dose of your blood thinners or do not take them as instructed?
 - Do you have an intolerance of warfarin and/or other blood thinners?
 - Do you have a high risk of falling?
 - Do you have a greater risk while on blood thinners due to cognitive impairment conditions?
 - Do you need additional blood thinners? (*such as dual antiplatelet medications due to stents or other conditions*)
 - Do you have an increased bleeding risk not reflected by the HAS-BLED score? (*such as thrombocytopenia, cancer or risk of tumor associated bleeding*)
 - Are there other situations that make you worry about the risks of taking blood-thinners long-term?
 - Do you have a history of serious kidney (renal) failure?

PREPARING FOR THE APPOINTMENT

MY NEXT
APPOINTMENT: / /

To give your cardiologist examples of issues you have experienced while being on blood thinners, keep track of any details below:

Check any of the following that apply to you:

- Bleeding Concerns
- Excessive Bruising
- Falling / Unsteadiness
- Blood Thinner Concerns
- Quality of Life Concerns
- Other Concerns

| | |
|----------------|---------------------|
| Issue: | DATE: / / |
| Details: _____ | |

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| Issue: | DATE: / / |
| Details: _____ | |

AT THE APPOINTMENT

What questions might you have for your cardiologist? Write them down and keep track of how your doctor answers.

Q: _____

A: _____

Q: _____

A: _____

Q: _____

A: _____

If you have any remaining questions about the WATCHMAN Implant after your appointment with your cardiologist, contact a WATCHMAN Education Specialist

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WATCHMAN FACTS

300K+

PEOPLE HAVE LEFT
BLOOD THINNERS BEHIND
WITH THE WATCHMAN IMPLANT

The WATCHMAN Implant has a proven safety record, more than 300,000 procedures have been performed worldwide and over 20 years of U.S. clinical studies.



The WATCHMAN Implant is minimally invasive

The WATCHMAN Implant is a one-time procedure for people with atrial fibrillation not caused by a heart valve problem (also known as non-valvular AFib) who need an alternative to blood thinners. This permanent implant reduces stroke risk and bleeding worry for life.



Clinically-proven long-term outcomes

In a clinical trial, 96% of people were able to stop taking blood thinners just 45 days after the WATCHMAN procedure.¹



The WATCHMAN Implant is affordable

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. It is also covered for eligible Medicare patients who meet certain national coverage criteria.



To see how the WATCHMAN Implant works, please visit watchman.com/video

References:

1. PINNACLE FLX 12-month primary safety and efficacy endpoint results, Doshi, SK. presented at HRS 2020 Science.
2. 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.

Important Safety Information

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.

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

Boston Scientific

WATCHMAN Referral Form

PATIENT NAME _____ DOB _____

PHONE NUMBER _____ EMAIL _____

DRUG REGIMEN _____ CHA₂DS₂-VASc _____ HAS-BLED _____

YES NO

Patient has Non-Valvular Atrial Fibrillation (NVAF)

Patient has an increased risk for stroke and is recommended for oral anticoagulation (OAC)

CHA₂DS₂-VASc of ≥ 2 (or CHA₂DS₂-VASc of ≥ 3 for Medicare patients). See table on back page.

Patient is suitable to short-term oral anticoagulation therapy but deemed unable to take long-term OAC

Patient has an appropriate rationale to seek a non-pharmacologic alternative to OACs. Specific factors may include one or more of the following:

- History of bleeding or increased bleeding risk (See HAS-BLED table on back page.)
- History or risk of falls
- Documented poor compliance with OAC therapy
- Inability or difficulty maintaining therapeutic range
- Increased bleeding risk not reflected by the HAS-BLED score (e.g., thrombocytopenia, cancer, or risk of tumor associated bleeding in case of systemic anticoagulation)
- Occupation/lifestyle that puts patient at an increased bleeding risk
- Severe renal failure
- Avoidance of triple therapy after PCI or TAVR
- Other situations for which OAC is inappropriate
- Drug or medication regimen not compatible with oral anticoagulant therapy

REFERRING DR. _____

PHONE NUMBER _____ EMAIL _____

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT



CHA₂DS₂-VASc Score (Stroke Risk)^a

| | Condition | Points |
|----------------|---------------------------------------|--------|
| C | Congestive heart failure | 1 |
| H | Hypertension (SBP > 160) | 1 |
| A | Age ≥ 75 years | 2 |
| D | Diabetes mellitus | 1 |
| S ₂ | Prior stroke, TIA, or thromboembolism | 2 |
| V | Vascular disease (PAD, MI) | 1 |
| A | Age 65-74 years | 1 |
| Sc | Sex category (Female) | 1 |
| Total Points | | |

| Score | Yearly Stroke Risk (%) | | |
|-------|------------------------|---------------------------|----------------------------|
| | No Warfarin | With Aspirin ^b | With Warfarin ^b |
| 0 | 0 | 0 | 0 |
| 1 | 1.3 | 1.0 | 0.5 |
| 2 | 2.2 | 1.8 | 0.8 |
| 3 | 3.2 | 2.6 | 1.1 |
| 4 | 4.0 | 3.2 | 1.4 |
| 5 | 6.7 | 5.4 | 2.3 |
| 6 | 9.8 | 7.8 | 3.4 |

HAS-BLED Score (Bleeding Risk with OACs)^c

| | Condition | Points |
|--------------|---|--------|
| H | Hypertension | 1 |
| A | Abnormal renal/liver function (1 pt each) | 1 or 2 |
| S | Stroke | 1 |
| B | Bleeding history or disposition | 1 |
| L | Labile INR | 1 |
| E | Elderly (e.g. age > 65 years) | 1 |
| D | Current drugs (medication) or alcohol use (1 pt each) | 1 or 2 |
| Total Points | | |

| Score | Yearly Major Bleeding Risk (%) [*] |
|-------|---|
| 0 | 1.13 |
| 1 | 1.02 |
| 2 | 1.88 |
| 3 | 3.74 |
| 4 | 8.70 |
| 5+ | 12.5 |

References

- a. CHA₂DS₂-VASc: *Chest*. 2010;137(2):263-272.
- b. Warfarin Stroke Reduction: *Ann Intern Med*. 2007;146:857-867.
- c. HAS-BLED: *Chest*. 2010;138(5):1093-1100.

*Major Bleed = ICH or bleeding resulting in a hospitalization, a hemoglobin drop > 2 g/dL, or a blood transfusion.
NOTE: A high HAS-BLED score is ≥3.

Formal Shared Decision Making

The patient must have a formal shared decision making interaction with an independent, non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAf prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record. THIS IS NOT A FORMAL SHARED DECISION MAKING DOCUMENT AND CANNOT BE USED FOR RECORDING THE SHARED DECISION MAKING INTERACTION.