ABBREVIATED STATEMENT WATCHMAN™ Left Atrial Appendage Closure Device with Delivery System and WATCHMAN Access System

Indications for use

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who: • Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy; • Are deemed by their physicians to be suitable for warfarin; and • Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin. The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

Contraindications

Do not use the WATCHMAN Device if: • Intracardiac thrombus is visualized by echocardiographic imaging. • An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present. • The LAA anatomy will not accommodate a device. See Table 46 in the DFU. • Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present. • There are contraindications to the use of warfarin, aspirin, or clopidogrel. • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

Warnings

• Device selection should be based on accurate LAA measurements obtained using fluoro and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0°, 45°, 90°, 135°). • Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria. • If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE. • The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period. • Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion. • For single use only. Do not reuse, reprocess, or resterilize.

Precautions

• The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. • The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the device. • Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures. • Use caution when introducing the Delivery System to prevent damage to cardiac structures. • To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath. • If using a power injector, the maximum pressure should not exceed 100 psi. • In view of the concerns that were raised by the RE-ALIGN1 study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

Adverse Events

Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism, Airway trauma, Allergic reaction to contrast media/ medications or device materials, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematoma or seroma, Cardiac perforation, Chest pain/ discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the appendage / movement of device from appendage wall, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency/failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions.
There may be other potential adverse events that are unforeseen at this time.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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Sourcing

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16 . Reddy, V et al. TCT 2014.
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Download WATCHMAN Resources at:
www.watchmandownloadcenter.com

Or use your smart phone to scan this code.

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300 Boston Scientific Way
Marlborough, MA 01752-1234
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Patients and Families:
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SH-224903-AA MAR2015

Boston Scientific
Advancing science for life™

Introducing WATCHMAN™ LAAC Device

A first-of-its-kind, proven alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular atrial fibrillation.

watchmandevice.com

Patients with AF have a 5x increased risk of stroke.[1]

AF-related strokes are more frequently fatal and disabling. [2,3] Approximately half of acute stroke victims will die or live with a significant disability, which may result in institutional care.

While warfarin is effective for many patients, long-term warfarin therapy is not well tolerated by some patients, highlighting the need for additional treatment options.

Life Changing Stroke Risk Treatment Option

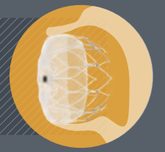
For eligible patients who are seeking an alternative to warfarin, the WATCHMAN™ LAAC Device offers a potentially life-changing stroke risk treatment option which could free them from the challenges of long-term warfarin therapy.

Atrial Fibrillation (AF) currently affects more than 5 million Americans.[4]
AF is projected to increase as population ages.[5]

Patients with AF have a 5x greater risk of stroke.[1]
Strokes in patients with AF are the #1 cause of long-term disability and the #3 leading cause of death.[1]

5x

In non-valvular AF, over 90% of stroke-causing clots that come from the left atrium are formed in the left atrial appendage (LAA).[6]



50% of AF-related strokes occur under age 75.[7]

75 or younger

Approximately 45% of patients with AF who are eligible for warfarin are NOT being treated (tolerance/adherence).[8] Lifestyle limitations when taking warfarin include high risk of bleeding[9], negative interactions with food and drugs[10],serious side effects that are often difficult to tolerate[11], and required frequent and ongoing monitoring.

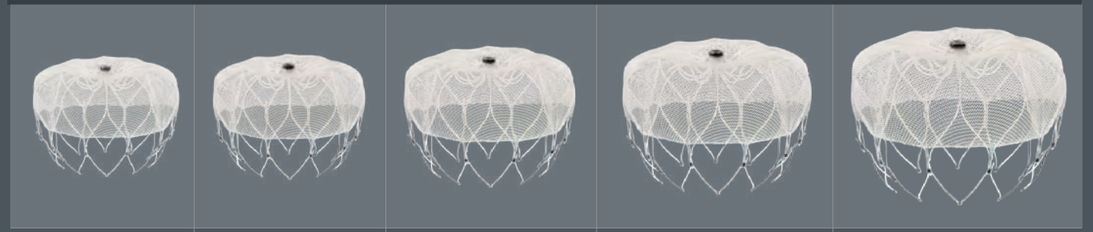
45%

Stroke Risk Reduction

Designed for Implant Success

WATCHMAN™ is delivered via a transfemoral approach and is designed to close the left atrial appendage (LAA) to prevent migration of blood clots, thus reducing the risk of stroke and systemic embolism.

Minimally Invasive, Local Solution



WATCHMAN is engineered to conform to the unique anatomy of the LAA to reduce embolization risk, as well as minimize the surface area facing the left atrium to reduce the risk of post-implant thrombus formation.

Intra-LAA Design
Unique intra-LAA design to avoid contact with the left atrial wall

160 Micron Membrane
Polyethylene terephthalate (PET) cap designed to block emboli and promote healing

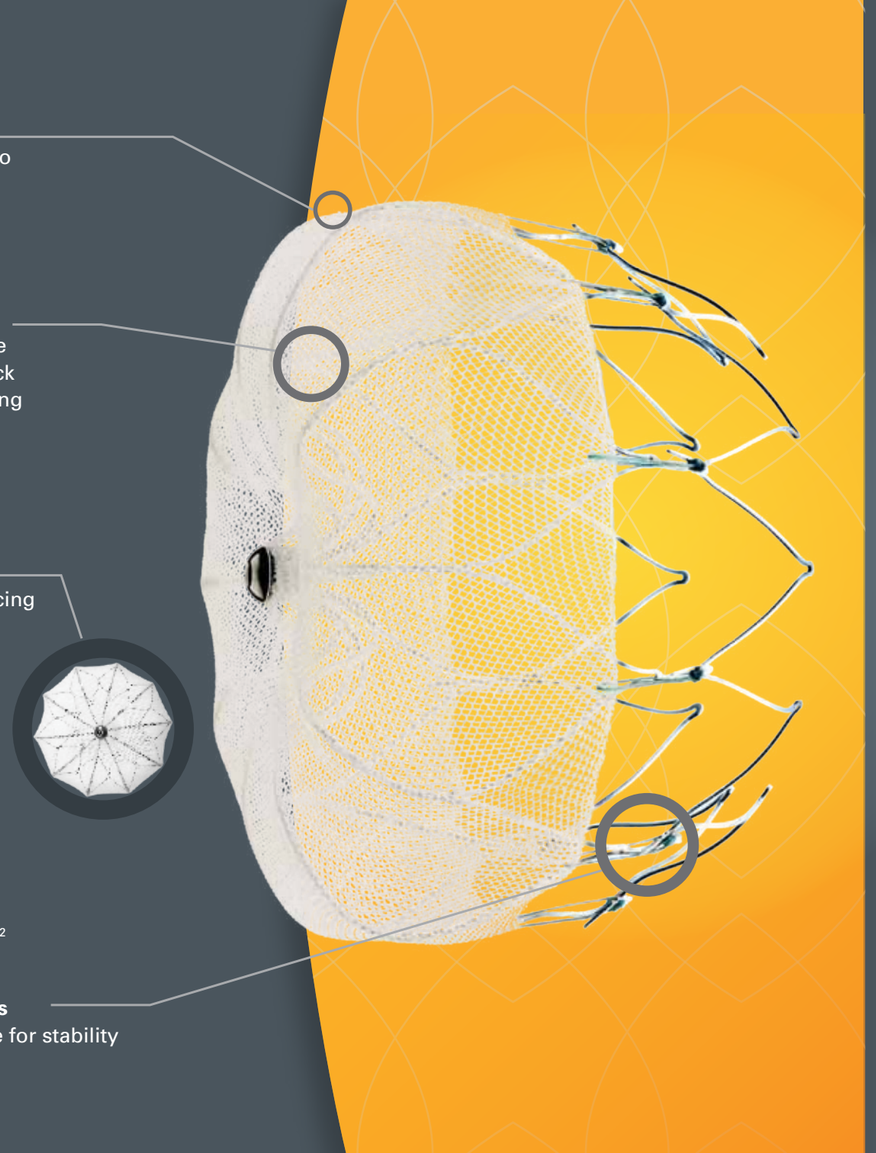
Warfarin Cessation
>92% after 45 days[12]

Proximal Face
Minimizes surface area facing the left atrium to reduce post-implant thrombus formation

Nitinol Frame
Conforms to the unique anatomy of the LAA to reduce embolization risk

High Success Rate
95% implant success rate[12]

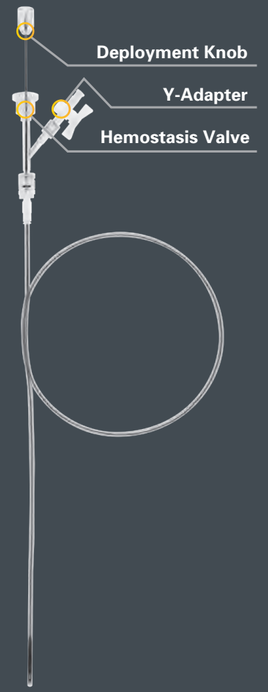
10 Active Fixation Anchors
Designed to engage tissue for stability



WATCHMAN LAAC Device

Pre-loaded Delivery System

Dual Catheter Delivery: One Access Sheath Fits All Device Sizes



WATCHMAN Delivery Catheter

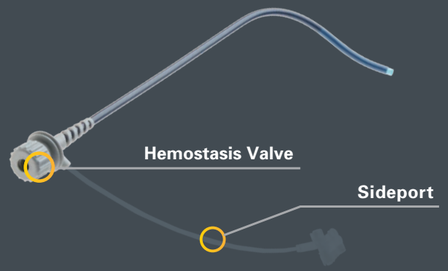
Pre-loaded Delivery System
Reduces procedure prep time

Flexible Core Wire
Provides for natural position post-deployment

Visualization Aid
Radiopaque marker band guides placement

Tri-Cut Tip
Facilitates recapture and maintains sheath integrity

WATCHMAN Access Sheath



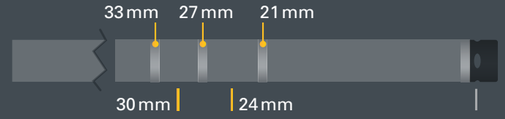
WATCHMAN™ is approved in more than 70 countries, with over 10,000 implants performed worldwide.

Sheath Options Facilitate Access to the LAA

Single Curve | Double Curve | Anterior Curve

12F inner, 14F outer diameter; 75 cm working length

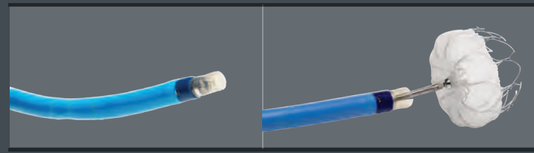
Radiopaque Marker Bands
Help guide precise sheath placement



Side Holes
Allows multi-directional contrast for LAA visualization

One-Step Deployment: Recaptureable and Repositionable

Distal Tip Pre-Deployment | Distal Tip Full Deployment



Designed to be repositioned if neccessary

History of Clinical Leadership

WATCHMAN™ is the most studied LAAC device, and the only one proven with long-term data from randomized trials. The robust **WATCHMAN** clinical program consists of numerous studies, more than 2400 patients and nearly 6000 patient-years of follow-up.

Robust Clinical Trial Program

2002 PILOT
Endpoints: Feasibility and Safety
Comparison: Non-randomized
n = 82, mean CHA_2DS_2-VASc = 1.8, mean age = 69

2005 PROTECT AF
Endpoints: Safety and Efficacy
Comparison: Warfarin
n = 707 pts, mean CHA_2DS_2-VASc = 3.4, mean age = 72

2008 CAP Registry
Endpoints: Collect additional safety and efficacy data to be pooled with PROTECT AF
n = 566, mean CHA_2DS_2-VASc = 3.9, mean age = 74

2009 ASAP*
Endpoints: Efficacy
Comparison: $CHADS_2$ score expected stroke rate
n = 150, mean CHA_2DS_2-VASc = 2.8, mean age = 72.5

2010 PREVAIL
Endpoints: Safety and Efficacy
Comparison: Warfarin
n = 407 pts, mean CHA_2DS_2-VASc = 3.8, mean age = 74

2012 CAP2 Registry
Endpoints: Collect additional safety and efficacy data
n = 579, mean CHA_2DS_2-VASc = 4.5, mean age = 75

ESC*
Expanded guidelines and indication

2013 Real World Registries in Europe and Asia*
Endpoints: Additional information in a real-world setting

** The ASAP, ESC expanded guidelines and indication and Real World Registries in Europe and Asia studied the patient population not in scope of the FDA approved indications for use.*

The robust **WATCHMAN** clinical program collectively provides strong evidence that **WATCHMAN** therapy can be implanted safely[13], enables patients to discontinue warfarin[14] and reduces AF stroke risk comparably to warfarin.[15]

95%
Implant Success in the hands of both new and experienced operators[12]

92%
of patients successfully implanted with WATCHMAN discontinued warfarin at 45 days with >99% off warfarin at 1 year[12]

WATCHMAN Therapy: Proven Stroke Risk Reduction Alternative

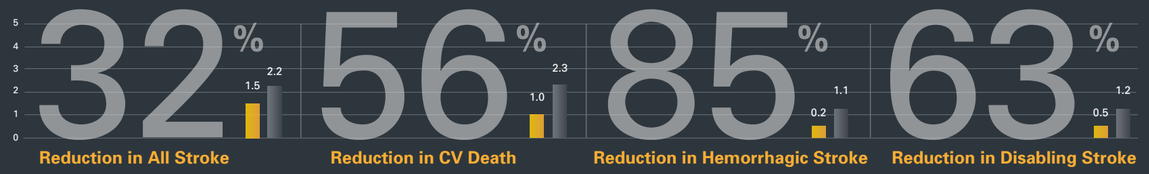
The **WATCHMAN™** LAAC Device demonstrated comparable stroke risk reduction, and statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death compared to warfarin over long-term follow-up.

PROTECT AF 5-Year Primary Efficacy Results[16]

	Event Rate (per 100 Pt-Yrs)		Rate Ratio	Posterior Probabilities	
	WATCHMAN	Warfarin	(95% CrI)	Non-Inferiority	Superiority
Primary Efficacy	2.2	3.7	0.61 (0.42, 1.07)	>99.9%	95.4%
Stroke (all)	1.5	2.2	0.68 (0.42, 1.37)	99.9%	83%
Systemic Embolism	0.2	0.0	N/A	--	--
Death (CV/unexplained)	1.0	2.3	0.44 (0.26, 0.90)	>99.9%	98.9%

For Bayesian analysis, a posterior probability of 97.5% represents non-inferiority; ≥95% represents superiority.

PROTECT AF Study Results[16, 17]

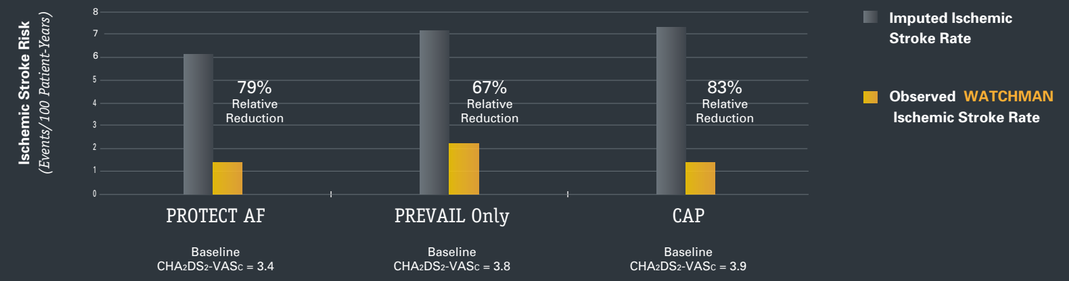


WATCHMAN Group N = 463, Warfarin Group N = 244

WATCHMAN | Warfarin

Relative risk reductions in all stroke, hemorrhagic stroke, cardiovascular death as reported in PROTECT AF 5 year results, relative risk reduction in disabling stroke as reported in 4 year results. Disabling or fatal strokes were those with a Modified Rankin Score of 3-6 after the stroke.

WATCHMAN Reduces Ischemic Stroke Over No Therapy[18]



Imputation based on published rate with adjustment for score (3.0).