

WATCHMAN™

Left Atrial Appendage Closure Device

PROOF OF LEADERSHIP

Uniquely engineered for the LAA¹⁻³ with proven safety and longterm efficacy.⁴⁻⁸



Patients with AF have a 5x increased risk of stroke.⁹

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

Despite its proven efficacy, long-term warfarin therapy is not well-tolerated by some patients and carries a significant risk for bleeding complications.

STOP
THE STROKE
WHERE IT STARTS

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

Life Changing Stroke Risk Treatment Option

WATCHMAN Left Atrial Appendage Closure Device offers patients with non-valvular atrial fibrillation a potentially life-changing stroke risk treatment option which could free them from the burden of long-term warfarin therapy.

Atrial Fibrillation (AF) currently affects more than 6 million Europeans.*

AF projected to increase as population ages.¹³



Prevalence is estimated to at least double in the next 50 years as population ages.*



In non-valvular AF, over 90% of stroke-causing clots that come from the left atrium are formed in the left atrial appendage (LAA).¹⁴



50% of AF-related strokes occur under age 75.¹⁵



<50% of patients eligible for warfarin are NOT being treated (tolerance/compliance).¹⁶

Lifestyle limitations when taking warfarin include high risk of bleeding¹⁷, negative interactions with food and drugs¹⁸, serious side effects that are often difficult to tolerate¹⁹, and required frequent and ongoing monitoring.

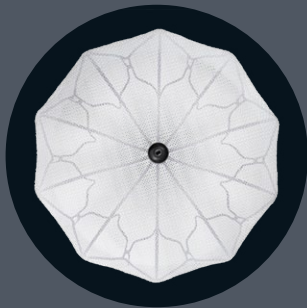
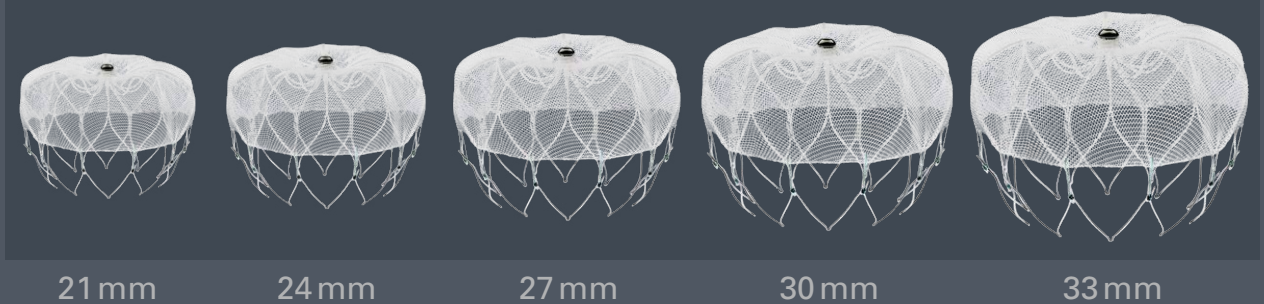


*Guidelines for the management of atrial fibrillation. The task force for the management of atrial fibrillation of the European Society of Cardiology (ESC). Eur Heart J 2010 ; 31 : 2369-2449.

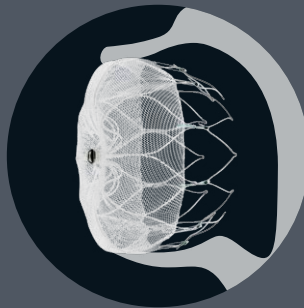
Designed for Implant Success

WATCHMAN is commercially available in more than 55 countries, with over 7,000 implants performed worldwide.

Minimally Invasive, Local Solution



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



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



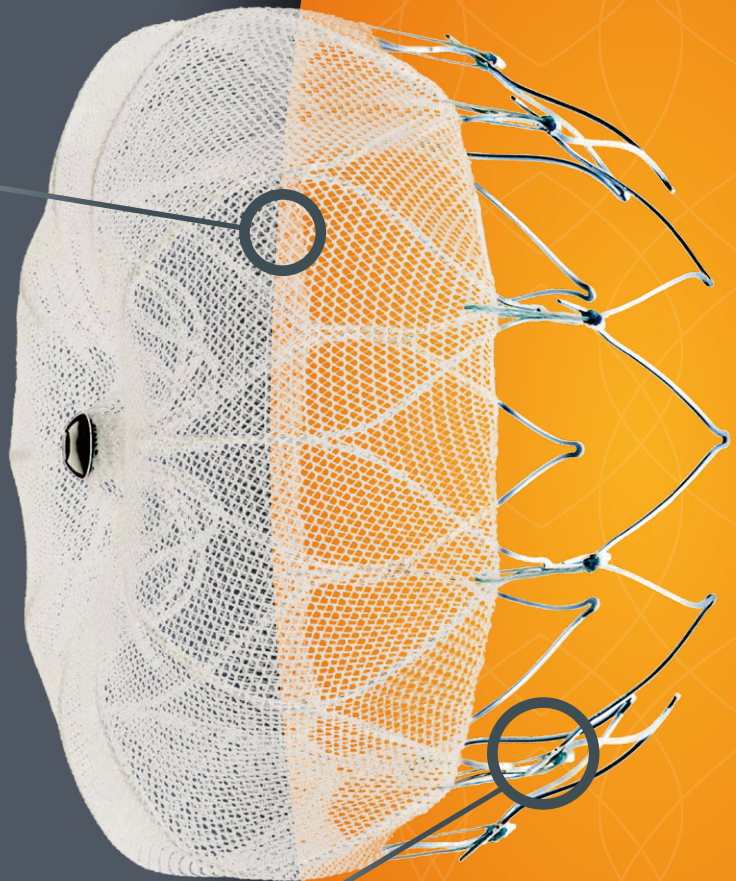
Nitinol Frame
Conforms to the unique anatomy of the LAA to reduce embolization risk

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

Warfarin Cessation
99% at 12 months⁷

High Success Rate
95% of implants successful²⁰

10 Active Fixation Anchors
Designed to engage tissue for stability



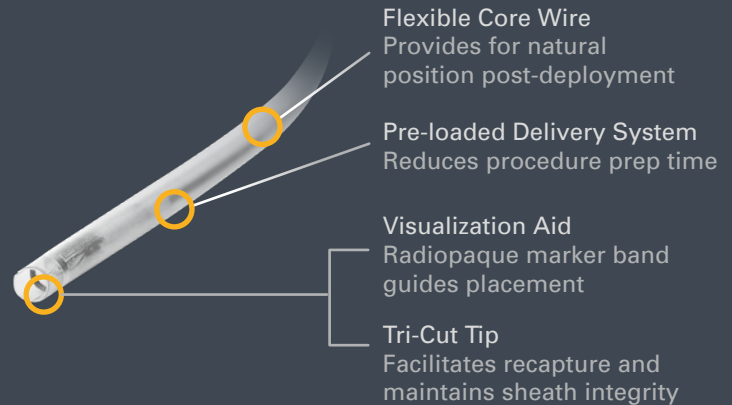
Pre-loaded Delivery System

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.

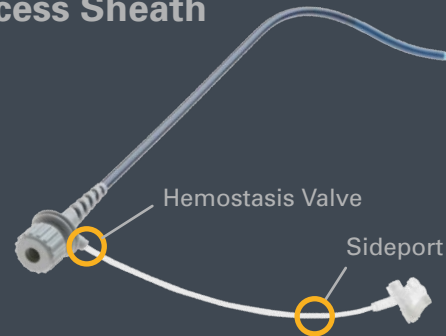
Dual Catheter Delivery: One Access Sheath Fits All Device Sizes



WATCHMAN Delivery Sheath



WATCHMAN Access Sheath

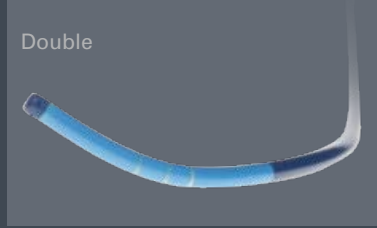


Sheath Options Facilitate Access to the LAA

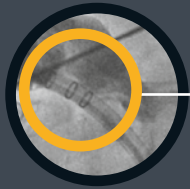
Single



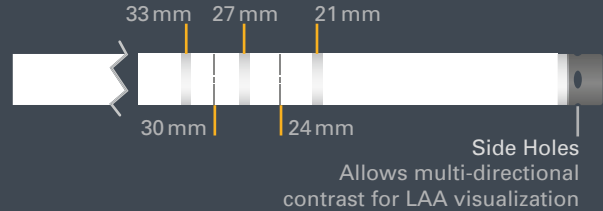
Double



12F inner, 14F outer diameter



Radiopaque Marker Bands
Help guide precise sheath placement



One-Step Deployment: Recaptureable and Repositionable

Distal Tip
Pre-Deployment



Distal Tip
Full Deployment



Designed to be
repositioned if necessary

History of Clinical Leadership

WATCHMAN with its unique intra-LAA design, is a proven safe, effective and statistically superior* alternative to long-term warfarin therapy for stroke risk reduction in non-valvular AF patients.⁴⁻⁸

Robust Clinical Trial Program

2002 Pilot

Endpoints: Feasibility and Safety

Comparison: non-randomized

n= 82, mean CHADS2 = 1.8, mean age = 69

2005 PROTECT AF

Endpoints: Safety and Efficacy

Comparison: Warfarin

n = 707 pts, mean CHADS2 = 2.2, mean age = 72 years

2008 CAP Registry

Endpoints: Collect additional safety and efficacy data to be pooled with PROTECT AF

n=566, mean CHADS2 =2.5, mean age = 74

- Largest body of clinical evidence, with over 2000 patients studied and 2 completed randomized trials
- With over 4 years of follow-up, **WATCHMAN** continues to provide long-term stroke risk reduction without the need for long-term oral anti-coagulation therapy
- Proven safe, effective and statistically superior* alternative to long-term warfarin therapy for primary efficacy

● **2009** ASAP

Endpoints: Efficacy

Comparison: CHADS2 score

expected stroke rate

n=150, mean CHADS2 = 2.8, mean age = 72.5

● **2010** PREVAIL

Endpoints: Safety and Efficacy

Comparison: Warfarin

*n = 407 pts, mean CHADS2=2.6 ± 1.0,
mean age = 74*

● **2013** Real World
Registries in Europe
and Asia

Endpoints: Additional
information in a
real-world setting

Clinical Leadership: Safety, Efficacy and Mortality Data

Proven implant safety profile demonstrating a 95% implant success in the hands of both new and experienced operators, as well as a declining procedural complications rate to less than 5% in later trials.⁹

91%
PROTECT AF⁴
Implant Success
p = 0.01

94%
CAP⁶
Implant Success
p = 0.01

95%
PREVAIL⁷
Implant Success
p = 0.01

WATCHMAN is a proven safe, effective and statistically superior* alternative to long-term warfarin therapy.⁸

WATCHMAN Group N = 463, Warfarin Group N = 244

WATCHMAN Warfarin



%
Reduction in
Primary Efficacy Endpoint
STATISTICALLY SUPERIOR
p = 0.96



%
Reduction in
CV Death
STATISTICALLY SUPERIOR
p = 0.0045



%
Reduction in
All Cause Death
STATISTICALLY SUPERIOR
p = 0.0379

*PROTECT AF 4 Year results for the composite primary efficacy endpoint of stroke, CV unexplained death and systemic embolization

PROTECT AF 4-Year Primary Efficacy Endpoint⁸

WATCHMAN Warfarin



WATCHMAN Group (n = 463)		Warfarin Group (n = 244)		Posterior Probabilities		
Events/ Patient-Years	Observed Rate (events per 100 Patient-Years) (95% CrI)	Events/ Patient-Years	Observed Rate (events per 100 Patient-Years) (95% CrI)	Rate Ratio (WATCHMAN/ Warfarin) (95% CrI)	Non-Inferiority	Superiority
Primary Efficacy Endpoint	Primary Efficacy Endpoint	Primary Efficacy Endpoint	Primary Efficacy Endpoint	Primary Efficacy Endpoint	Primary Efficacy Endpoint	Primary Efficacy Endpoint
39/1720.2	2.3(1.7, 3.2)	34/900.8	3.8(2.5, 4.9)	0.60(0.41, 1.05)	>0.999	0.960

⁸PROTECT AF 4 Year results for the composite primary efficacy endpoint of stroke, CV unexplained death and systemic embolization

Training Excellence

Boston Scientific has developed a strong training curriculum to provide Health Care Professionals with world-class education for safe and effective device implantation. 15 Professional Training Centers in 7 countries 36 Proctors in 10 countries in Europe, Middle East and North Africa. For more information, please go to our dedicated website www.instituteforadvancingscience.com.

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ADVANCING SCIENCE

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PROTECT AF: Primary safety endpoint: major bleeding, pericardial effusion and device embolization.
Primary efficacy endpoint: stroke, cardiovascular death, and systemic embolism.

* Composite of vascular complications includes cardiac perforation, pericardial effusion with tamponade, ischemic stroke, device embolization, and includes observed PE not necessitating intervention, AV fistula, major bleeding requiring transfusion, pseudoaneurysm, hematoma and groin bleeding.

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Advancing science for life™

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