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, 52 Proctors in 13 countries in Europe, Middle East and North Africa.

For more information, please go to our dedicated website
https://educare.bostonscientific.eu/s/structural-heart

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WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

PROOF OF LEADERSHIP

Uniquely engineered for the LAA with proven safety and longterm efficacy.

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

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 oral anticoagulation therapy is not well-tolerated by some patients and carries a significant risk for bleeding complications.[2]

STOP THE STROKE WHERE IT STARTS

The WATCHMAN Left Atrial Appendance Device is designed to reduce the risk of stroke in patients with non-valvular 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 oral anticoagulation therapy.

Atrial Fibrillation (AF) currently affects more than 10 million Europeans.[3]
AF projected to increase as population ages.[4]

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

5x

In non-valvular AF, over 90 % of stroke-causing clots from the left atrium originated from the left atrial appendage (LAA).[5]

50 % of AF-related strokes occur under age 75.[6]

< 50%
under 75

The discontinuation rate during the OAC therapy is high (50 % of patients discontinued warfarin and 30 % of patients discontinued NOAC after 2 years).[7] Lifestyle limitations when taking warfarin include high risk of bleeding[8], negative interactions with food and drugs[9], serious side effects that are often difficult to tolerate[10], and required frequent and ongoing monitoring.

Stroke Risk Reduction

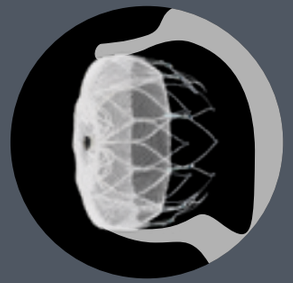
Designed for Implant Success

More than 60.000 patients have already benefited from this one-time therapy for stroke risk reduction with the **WATCHMAN** device.

Minimally Invasive, Local Solution for Stroke Risk Reduction

21 mm | 24 mm | 27 mm | 30 mm | 33 mm

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



Intra-LAA Design
Unique intra-LAA design to close the left atrial appendage without compromising surrounding structures such as mitral valve or upper pulmonary veins.

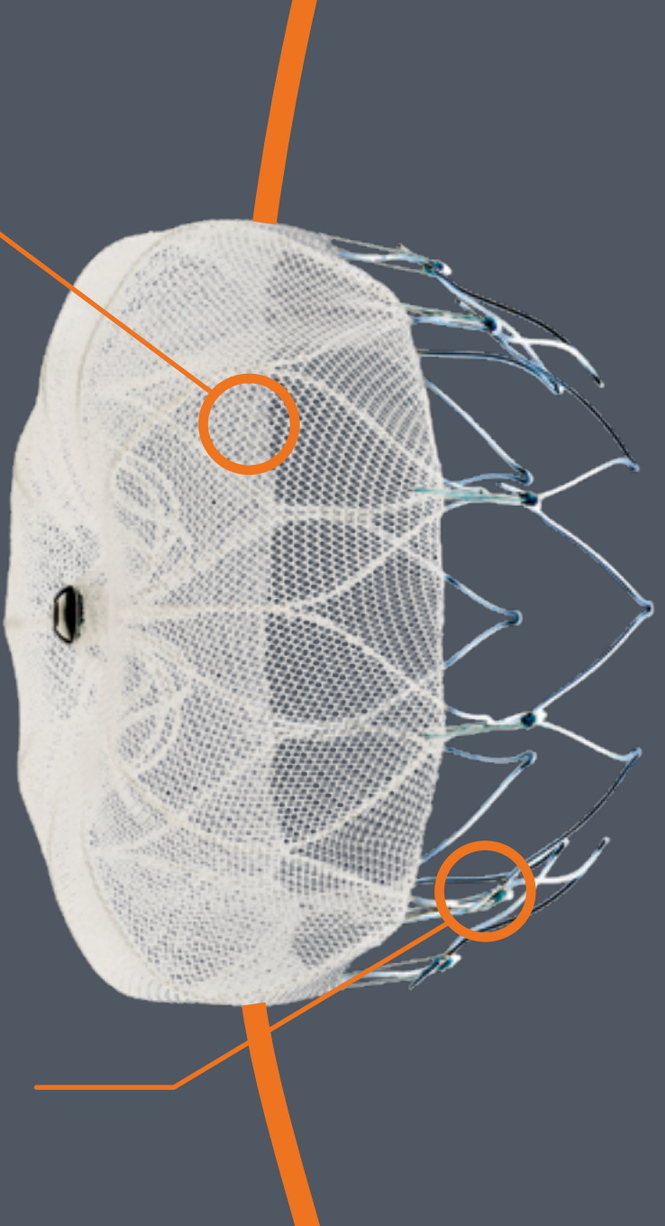
Nitinol Frame
Conforms to the unique anatomy of the LAA to reduce emoblization risk.

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

Sealing (no leaks >5 mm)
observed in 99 % of patients[11]

High Success Rate
98.5% implant success rate[11]

10 Active Fixation Anchors
Designed to engage tissue for stability

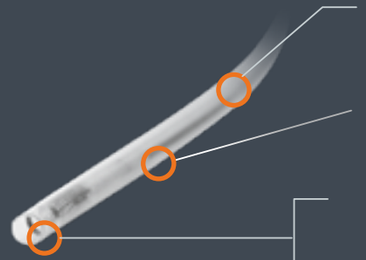


WATCHMAN LAAC Device

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.

WATCHMAN Delivery System



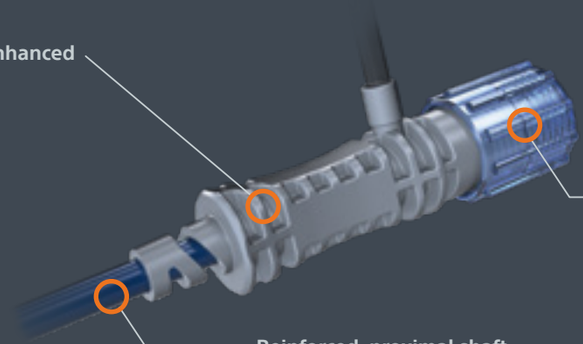
Flexible Core Wire
Provides for natural position post-deployment

Pre-loaded Delivery System
Reduces procedure prep time

Visualization Aid
Radiopaque marker band guides placement

Tri-Cut Tip
Facilitates recapture and maintains sheath integrity

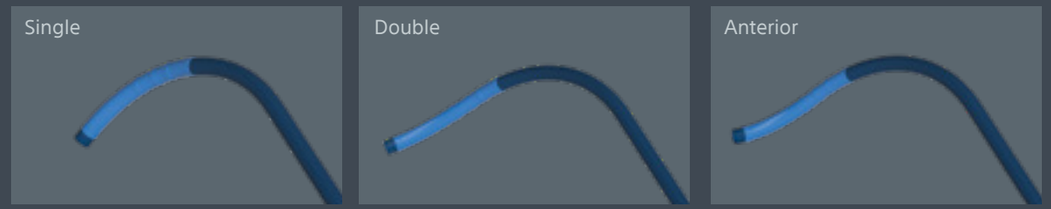
Straight-forward deployment:
Recapturable and repositionable



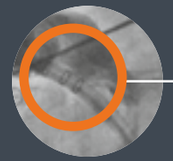
18% Higher proximal kink resistance*

* % compared to the current WATCHMAN™ Access System

WATCHMAN™ TruSeal Access System



12 F inner, 14 F outer diameter



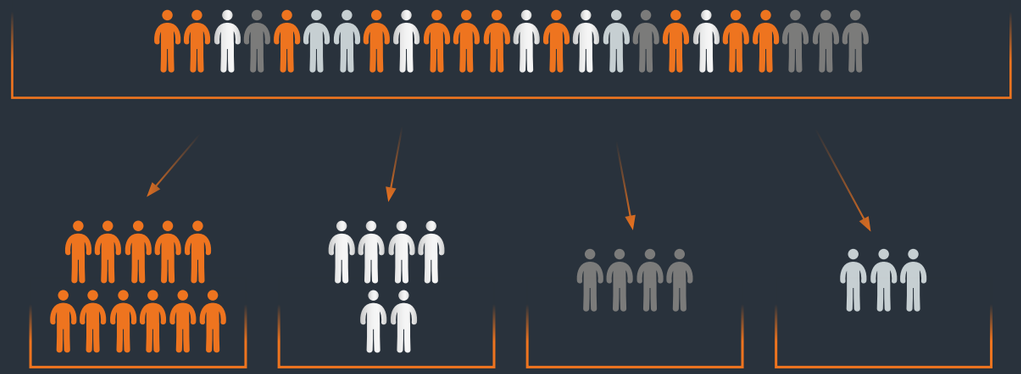
Radiopaque Marker Bands
Help guide precise sheath placement

Soft tip with aspiration holes

Post-Implant Drug Regimens

- Physicians may prescribe an individual post-implant medication considering patient preference, stroke and bleeding risk.
- Treatment options may include a dual antiplatelet therapy (DAPT) or an oral anti-coagulation therapy along with aspirin for at least three months. If the patient receives OAC, switching to DAPT after 45 days could be considered.

YOUR PATIENTS HAVE DIFFERENT NEEDS



at least 3 months DAPT

at least 3 months (N)OAC

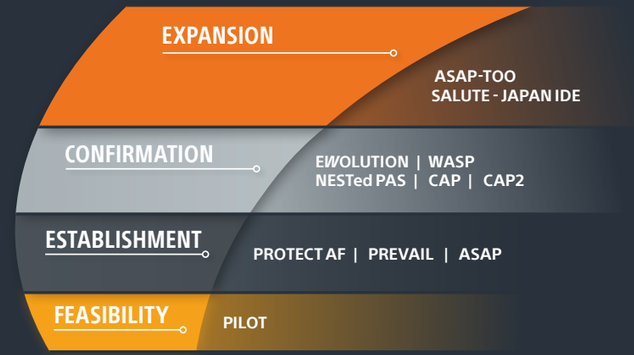
45 days NOAC, then DAPT 3 months post-implant

45 days VKA, then DAPT 3 months post-implant

ASA is recommended for at least 12 months post-implant.

Leadership in Clinical Evidence

- The **WATCHMAN** clinical evidence consists of over 5,800 patients studied in 2 randomised trials (with 5 years of follow-up of PROTECT AF and PREVAIL) and multiple prospective registries.
- Proven safe and effective alternative to long-term warfarin therapy for primary efficacy.[13]



STUDIED IN MORE THAN
5,800 PATIENTS AND
10,000 PATIENT YEARS
OF FOLLOW-UP

Clinical Leadership: Safety and Efficacy Data

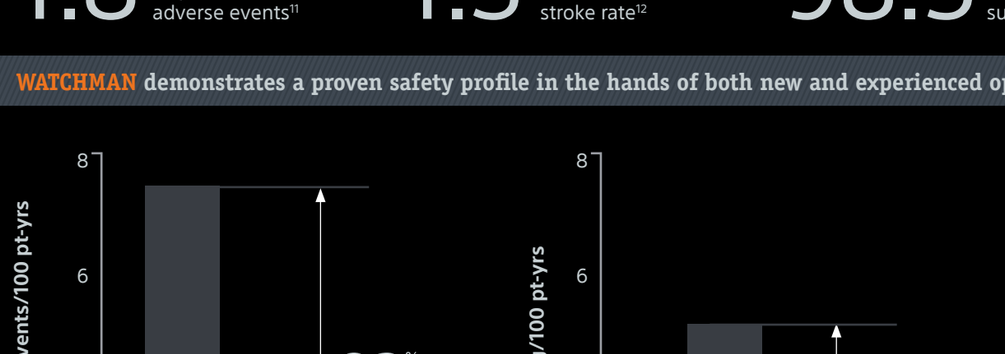
EVOLUTION – Outcomes in real-life utilization – 2 year Follow Up[12]

1.8% Major cardiac adverse events[11]

1.3% Annual ischemic stroke rate[12]

98.5% Implant success[11]

WATCHMAN demonstrates a proven safety profile in the hands of both new and experienced operators



* Effectiveness in stroke reduction vs. estimated in the absence of therapy for comparable CHA_2DS_2- VASc scores based on Friberg et al. EHJ 2012.
** Effectiveness in bleeding reduction vs. estimated under VKA therapy for comparable HAS-BLED scores based on Lip et al. JACC 2011.

5-Year Patient Level Meta-Analysis of PROTECT AF and PREVAIL[13]

WATCHMAN Group N = 732
Warfarin Group N = 382

52%
Reduction in non-procedural, major bleedings **STATISTICALLY SIGNIFICANT** p= 0.0003

41%
Reduction in CV Death
STATISTICALLY SIGNIFICANT
p= 0.03

55%
Reduction in Disabling/Fatal Stroke
STATISTICALLY SIGNIFICANT
p= 0.03

WATCHMAN is proven safe and effective alternative to long-term warfarin therapy.[13]

Endpoint	Reduction	Hazard Ratio (95% CI)	P-Value	Statistical Significance
Primary Efficacy	**18%**	0.82 (0.58 – 1.17)	0.27	No statistical difference
All Cause Stroke	**4%**	0.96 (0.60 – 1.54)	0.87	No statistical significant difference
Disabling / Fatal Stroke*	**55%**	0.45 (0.21 – 0.94)	0.03	Statistically significant
Ischemic Stroke	**N/A**	1.71 (0.94 – 3.11)	0.08	No statistical significant difference
Hemorrhagic Stroke	**80%**	0.20 (0.07 – 0.56)	0.0022	Statistically significant
Non-procedure related major bleeding	**52%**	0.48 (0.32 – 0.71)	0.0003	Statistically significant
Mortality				
All-Cause	**27%**	0.73 (0.54 – 0.98)	0.04	Statistically significant
CV/Unexplained	**41%**	0.59 (0.37 – 0.94)	0.03	Statistically significant