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

REFERENCES

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.\(^2\)

**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.\(^1\)**

- **50% of AF-related strokes occur under age 75.\(^5\)**

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

The discontinuation rate during the OAC therapy is high (50% of patients discontinued warfarin and 30% of patients discontinued NOAC after 2 years).\(^6\)** Lifestyle limitations when taking warfarin include high risk of bleeding, negative interactions with food and drugs, serious side effects that are often difficult to tolerate, and required frequent and ongoing monitoring.
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

- **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 embolization risk.
- **10 Active Fixation Anchors**: Designed to engage tissue for stability.

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

**Sealing (no leaks >5mm)**
Observed in 99% of patients.

**High Success Rate**
98.5% implant success rate.

**Sealing (no leaks >5mm)** observed in 99% of patients.

**10 Active Fixation Anchors**
Designed to engage tissue for stability.
**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.

**Pre-loaded Delivery System**

- **Deployment Knob**
- **Y-Adapter Hemostasis Valve**
- **2-way Stop-cock**

**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

**Ergonomic design for enhanced ability to navigate**

**Dual-Start Thread Technology**
Rotation to fully open and close

**Reinforced, proximal shaft for greater torque control**

**18” Higher proximal kink resistance**

**Soft tip with aspiration holes**

**WATCHMAN™ TruSeal Access System**

- **Single**
- **Double**
- **Anterior**

**12 F inner, 14 F outer diameter**

**Radiopaque Marker Bands**
Help guide precise sheath placement

**33 mm 27 mm 21 mm**

**30 mm 24 mm**
### 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.\(^{13}\)

### 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.
Clinical Leadership: Safety and Efficacy Data

**EWOLUTION – Outcomes in real-life utilization – 2 year Follow Up**

- **1.8 %** Major cardiac adverse events
- **1.3 %** Annual ischemic stroke rate
- **98.5 %** Implant success

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

**WATCHMAN** is proven safe and effective alternative to long-term warfarin therapy.

### 5-Year Patient Level Meta-Analysis of PROTECT AF and PREVAIL

**WATCHMAN** Group N = 732

Warfarin Group N = 382

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Reduction</th>
<th>Hazard Ratio (95% CI)</th>
<th>P-Value</th>
<th>Statistical Significance</th>
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<td>Primary Efficacy</td>
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**Reduction in non-procedural, major bleedings** STATISTICALLY SIGNIFICANT *p* = 0.0003

**Reduction in CV Death** STATISTICALLY SIGNIFICANT *p* = 0.03

**Reduction in Disabling/Fatal Stroke** STATISTICALLY SIGNIFICANT *p* = 0.03

**Statistical significance**

- **Reduction in CV Death**
- **Reduction in Disabling/Fatal Stroke**
- **Statistically significant**

### Endpoint Reduction Hazard Ratio (95% CI) P-Value

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*Effectiveness in stroke reduction vs. estimated in the absence of therapy for comparable CHA2DS2-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.”