WATCHMAN™
Left Atrial Appendage Closure Device

PROOF OF LEADERSHIP
Uniquely engineered for the LAA\textsuperscript{1-3} with proven safety and longterm efficacy.\textsuperscript{4-8}
Patients with AF have a 5x increased risk of stroke.\textsuperscript{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 \textbf{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.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Icon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation (AF) currently affects more than 6 million Europeans.</td>
<td><img src="image" alt="Group" /></td>
</tr>
<tr>
<td>AF projected to increase as population ages.</td>
<td><img src="image" alt="Group" /></td>
</tr>
<tr>
<td>Prevalence is estimated to at least double in the next 50 years as population ages.</td>
<td><img src="image" alt="Group" /></td>
</tr>
<tr>
<td>In non-valvular AF, over 90% of stroke-causing clots that come from the left atrium are formed in the left atrial appendage (LAA).</td>
<td><img src="image" alt="Brain" /></td>
</tr>
<tr>
<td>50% of AF-related strokes occur under age 75.</td>
<td><img src="image" alt="Brain" /></td>
</tr>
<tr>
<td>&lt;50% of patients eligible for warfarin are NOT being treated (tolerance/compliance).</td>
<td><img src="image" alt="Brain" /></td>
</tr>
<tr>
<td>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.</td>
<td><img src="image" alt="Brain" /></td>
</tr>
</tbody>
</table>

**Designed for Implant Success**

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

**Minimally Invasive, Local Solution**

<table>
<thead>
<tr>
<th></th>
<th>Size</th>
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<tbody>
<tr>
<td></td>
<td>21 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33 mm</td>
<td></td>
</tr>
</tbody>
</table>

**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 months\(^7\)

High Success Rate
95% of implants successful\(^20\)

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**

- Deployment Knob
- Y-Adapter Hemostasis Valve
- 2-way Stopcock

**WATCHMAN Delivery Sheath**
- 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

**WATCHMAN Access Sheath**
- Hemostasis Valve
- Sideport
Sheath Options Facilitate Access to the LAA

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

**Double**
- Radiopaque Marker Bands: Help guide precise sheath placement
- Side Holes: Allows multi-directional contrast for LAA visualization
- Measurements:
  - 33 mm
  - 30 mm
  - 27 mm
  - 24 mm

One-Step Deployment: Recaptureable and Repositionable

**Distal Tip**
- Pre-Deployment
- 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
  - \( n = 82, \text{mean CHADS2} = 1.8, \text{mean age} = 69 \)

- **2005** PROTECT AF
  - Endpoints: Safety and Efficacy
  - Comparison: Warfarin
  - \( n = 707 \text{ pts, mean CHADS2} = 2.2, \text{mean age} = 72 \text{ years} \)

- **2008** CAP Registry
  - Endpoints: Collect additional safety and efficacy data to be pooled with PROTECT AF
  - \( n = 566, \text{mean CHADS2} = 2.5, \text{mean age} = 74 \)
- 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  
\( n = 150, \text{mean } CHADS2 = 2.8, \text{mean age} = 72.5 \)

**2010 PREVAIL**  
Endpoints: Safety and Efficacy  
Comparison: Warfarin  
\( n = 407 \text{ pts, mean } CHADS2=2.6 \pm 1.0, \text{mean age} = 74 \)

**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

<table>
<thead>
<tr>
<th>Watchman</th>
<th>Warfarin</th>
</tr>
</thead>
<tbody>
<tr>
<td>40%</td>
<td>2.3</td>
</tr>
<tr>
<td>% Reduction in Primary Efficacy Endpoint</td>
<td></td>
</tr>
<tr>
<td>STATISTICALLY SUPERIOR</td>
<td></td>
</tr>
<tr>
<td>p = 0.96</td>
<td></td>
</tr>
<tr>
<td>60%</td>
<td>1.0</td>
</tr>
<tr>
<td>% Reduction in CV Death</td>
<td></td>
</tr>
<tr>
<td>STATISTICALLY SUPERIOR</td>
<td></td>
</tr>
<tr>
<td>p = 0.0045</td>
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</tr>
<tr>
<td>34%</td>
<td>3.2</td>
</tr>
<tr>
<td>% Reduction in All Cause Death</td>
<td></td>
</tr>
<tr>
<td>STATISTICALLY SUPERIOR</td>
<td></td>
</tr>
<tr>
<td>p = 0.0379</td>
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*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 Endpoint**

**Patients with Events/%**

<table>
<thead>
<tr>
<th>Time/Month</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
<th>30</th>
<th>36</th>
<th>42</th>
<th>48</th>
<th>54</th>
<th>60</th>
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</thead>
<tbody>
<tr>
<td>WATCHMAN</td>
<td>0.30</td>
<td>0.20</td>
<td>0.10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Control</td>
<td>0.30</td>
<td>0.20</td>
<td>0.10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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**No. at Risk**

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>WATCHMAN</th>
<th>463</th>
<th>398</th>
<th>382</th>
<th>370</th>
<th>360</th>
<th>345</th>
<th>337</th>
<th>327</th>
<th>317</th>
<th>285</th>
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</thead>
<tbody>
<tr>
<td>Control</td>
<td>244</td>
<td>230</td>
<td>218</td>
<td>210</td>
<td>200</td>
<td>188</td>
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<td>159</td>
<td>147</td>
<td>121</td>
<td>112</td>
<td>87</td>
</tr>
</tbody>
</table>

**WATCHMAN Group (n = 463)**

**Warfarin Group (n = 244)**

**Posterior Probabilities**

<table>
<thead>
<tr>
<th>Events/Patient-Years</th>
<th>Observed Rate (events per 100 Patient-Years) (95% Crl)</th>
<th>Events/Patient-Years</th>
<th>Observed Rate (events per 100 Patient-Years) (95% Crl)</th>
<th>Rate Ratio (WATCHMAN/Warfarin) (95% Crl)</th>
<th>Non-Inferiority</th>
<th>Superiority</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Efficacy Endpoint</strong></td>
<td>39/1720.2 (2.3 (1.7, 3.2))</td>
<td>34/900.8 (3.8 (2.5, 4.9))</td>
<td>0.60 (0.41, 1.05)</td>
<td>&gt;0.999</td>
<td>0.960</td>
<td></td>
</tr>
</tbody>
</table>

*PROTECT 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.

References
1. Data on file Boston Scientific
2. Schwartz et al., Healing Stages of Intracardiac Devices. JACC vol. 3. 870-7. 2010
10. McGrath ER, Neurology. 2013
18. Warfarin package insert
20. Holmes, DR et al. CIT 2013

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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