A LANDMARK DEVICE. AND A TURNING POINT FOR PFO CLOSURE.

AMPLATZER™ PFO OCCLUDER
FIRST TO MARKET, STILL FIRST WORLDWIDE

As the device that created the category, AMPLATZER™ PFO occluder has sustained leadership over decades of use by pursuing clinical evidence—even beyond an initial study end date—to become the first device supported by positive PFO trial results1. Today, we continue to innovate around advancing patient safety and reducing risk for patients around the world.

A LANDMARK DEVICE. AND A TURNING POINT FOR PFO CLOSURE.

• Industry-leading device, designed for ease of use and effective closure
• Backed by the largest trial with the most extensive patient follow-up
• Demonstrated excellent safety and efficacy

WHY IS AMPLATZER PFO OCCLUDER RELIED UPON BY THOUSANDS OF PHYSICIANS AROUND THE WORLD?

WE RAISE THE BAR: THE LANDMARK RESPECT TRIAL1

• Most extensive patient follow-up, >2X more than other PFO trials
• Only trial to include patients on anticoagulation therapy, a real-world cross-section of patients

WE DEMONSTRATE EXCELLENCE

• ZERO device erosions, thrombus, or embolization events in SIX** published trials with 990 patients1-6
• 94.2% effective closure rates at 6 months1

INDICATIONS AND USAGE: The AMPLATZER™ PFO Occluder is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. See important safety information referenced within.

GLOBALLY OVER 100K IMPLANTS

WE SET THE STANDARD

• Pioneered treatment with a PFO-specific device
• Over 100,000 devices implanted globally

5,810 PATIENT YEARS OF DATA

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990 PATIENTS IMPLANTED WITH DEVICE IN RCTS*

WE DEMONSTRATE EXCELLENCE

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* RCTs=Randomized Clinical Trials
** Patients in device group of each trial implanted with AMPLATZER PFO occluder device: RESPECT = 465, PREMIUM = 119, PC = 191, CLOSE = 121, DEFENSE = 53, PRIMA = 41. RCTs=Randomized Clinical Trials

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OFTEN IMITATED, NEVER MATCHED
Industry-leading device. Developed specifically for the treatment of PFO closure.

DESIGN ADVANTAGES THAT MAKE THE DIFFERENCE

**DURABLE NITINOL WIRE MESH WITH POLYESTER FABRIC THREAD**
Excellent visibility under flouro

**INTAGLIO™ WIRE TREATMENT**
Designed to reduce nickel leaching

**ASYMMETRIC DOUBLE DISC DESIGN**
Minimizes material in the Left Atrium

**ONE STEP AHEAD: MINIMIZING COMPLEXITY IN CLOSURE**

**UNIQUE SELF-EXPANDING DISCS**
Linked by a short-connecting waist, the discs align to the PFO without an additional “locking” step.

**LOW PROFILE DELIVERY**
8 F & 9 F introducer sheaths for multiple sizes (18, 25, 35 mm) enables treatment of patients with smaller vasculature.

**FULLY RECAPTURABLE AND REPOSITIONABLE DESIGN**
Allows confirmation of device placement prior to final release of the device.

94% CLOSURE RATE* at 6 months in RESPECT trial

94%

*On the most commonly used sizes (25mm and 35mm devices)

†Effective Closure

See important safety information referenced within.
THE TURNING POINT FOR PFO CLOSURE

Three trials published concurrently in the NEJM provide conclusive evidence of the superiority of PFO closure versus medical management in reducing risk of recurrent stroke.

<table>
<thead>
<tr>
<th>Devices Used</th>
<th>RESPECT¹</th>
<th>REDUCE²</th>
<th>CLOSE³</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMPLATZER™ PFO Occluder</td>
<td>100%</td>
<td>39% GORE® HELEX, 61% GORE Cardioform</td>
<td>51% AMPLATZER PFO Occluder; 49% other approved PFO devices</td>
</tr>
</tbody>
</table>

| Patients | 980 | 664 | 473 |
| Follow-Up-Patient Years | 5,810 (median 5.9 yrs) | 2,232 (median 3.2 yrs) | NR* (mean 5.4 yrs) |

| Anticoagulant Allowed in Control Group? | Yes | No | No |

| Relative Risk Reduction | 62% (Recurrent ischemic stroke of unknown mechanism) | 77% (Recurrent ischemic stroke) | 97% (Recurrent ischemic stroke) |

| Effective Closure | 94.2% Freedom from >9 bubbles (Evaluated after 6 months) | 94.5% Freedom from >25 bubbles (Evaluated after 12 months) | NR* |

PUBLISHED DATA HIGHLIGHTS EXCELLENT SAFETY

LOW RISK OF DEVICE-RELATED EVENTS

<table>
<thead>
<tr>
<th>Event</th>
<th>RESPECT¹</th>
<th>REDUCE²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Embolization/Dislocation</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Aortic Erosion/Dissection</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Device Thrombus</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

LOW RISK OF ATRIAL FIBRILLATION (AF)

<table>
<thead>
<tr>
<th>Rate (per 100 pt yrs)</th>
<th>RESPECT¹</th>
<th>REDUCE²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious AF**/Flutter</td>
<td>0.22</td>
<td>0.65</td>
</tr>
<tr>
<td>Any AF/Flutter</td>
<td>0.76</td>
<td>1.90</td>
</tr>
</tbody>
</table>

CLOSE Trial data not included due to device- and procedure-related events reported in combination.

CLOSE Trial data not included as follow-up patient-years was not reported.

¹Not reported
See important safety information referenced within.
INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

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Patients with intracardiac mass, vegetation, or thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the PFO is gained. Patients whose vasculature, through which access to the PFO is gained, is inadequate to accommodate the appropriate sheath size. Patients with anatomy in which the AMPLATZER™ PFO device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins. Patients allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted. STORES IN A DRY PLACE. Pregnancy - Minimize radiation exposure to the fetus and the mother. Nursing mothers - There has been no quantitative assessment for the presence of leachables in breast milk. ADVISORY EVENTS Potential adverse events that may occur during or after a procedure using this device may include, but are not limited to: Air embolus; Allergic drug reaction; Allergic dye reaction; Allergic metallic reaction: Nitinol (nickel, titanium), platinum/sidium, stainless steel (chromium, iron, manganese, molybdenum, nickel); Anesthesia reactions; Anemia; Arthritis; Bacterial endocarditis; Bleeding; Blood platelet dysfunction; Cardiac perforation; Cardiac tamponade; Cardiac thrombus; Chest pain; Device embolization; Device erosion; Deep vein thrombosis; Death; Endocarditis; Esophagus injury; Fever; Headache/migraine; Hypersensitivity/hypotension; Myocardial infarction; Pacemaker placement secondary to PFO device closure; Palpitations; Percutaneous lesion; Percutaneous tamponade; Pericarditis; Peripheral embolism; Pleural effusion; Pulmonary embolism; Reintervention for residual shunt/device removal; Sepsis; Stroke; Transient ischemic attack; Thrombus; Valvular regurgitation; Vascular access site injury; Vessel perforation.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuls.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott Structural Heart

3200 Lakeside Dr, Santa Clara, CA 95054 USA, Tel 1.800.227.9902

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