By appropriately closing PFOs associated with cryptogenic stroke with the AMPLATZER™ PFO Occluder, physicians can significantly reduce the risk of stroke recurrence.

- Backed by the largest trial with the most extensive patient follow-up
- Demonstrated excellent safety and efficacy
- Industry-leading design for ease of use and effective closure
- A legacy of excellence across the AMPLATZER™ Occlusion Portfolio
- With over 1 million devices successfully implanted worldwide

For more information about the AMPLATZER™ PFO Occluder or the RESPECT clinical trial, contact your Abbott sales representative, or visit PFOLANDMARKRESPECT.com

RIGOROUS DESIGN DEMONSTRATING SIGNIFICANT STROKE REDUCTION

- MOST EXTENSIVE patient follow-up (13+ years of data)
- LARGEST trial, with broad inclusion criteria (including patients on anticoagulation therapy)
- EXCELLENT safety profile
- SIGNIFICANTLY reduced risk of recurrent ischemic stroke

**THE LARGEST TRIAL, WITH BROAD INCLUSION CRITERIA**

The trial enrolled 980 patients with a PFO who had previously suffered a cryptogenic ischemic stroke. Patients on anticoagulation therapy were not excluded from the trial.

**LOW RISK OF SERIOUS ATRIAL FIBRILLATION (AF)**

There was no statistical difference in serious AF events between the closure and medical therapy groups (0.48 vs. 0.34 per 100 patient-years, P = 0.36).

**THE LANDMARK PFO TRIAL**

Total Patients Enrolled
The landmark trial included more patients than any other PFO trial conducted.

1:1 Randomization
Patients were randomly assigned to receive either the AMPLATZER® PFO Occluder or medical therapy.

Anticoagulation Therapy
Trial participants included approximately 20% of patients on anticoagulation therapy (a patient population thought to have a higher risk of venous thromboembolism).

**EXCELLENT PROCEDURAL RESULTS**

The device demonstrated significant technical and procedural success, and achieved excellent effective closure.

**99.1%**
Technical Success
Designed for optimized ease of use, the device showed highly successful delivery and release.

**96.1%**
Procedural Success
An excellent rate of successful implantation without in-hospital SAEs was demonstrated.

**94.2%**
Effective Closure
(≤9 Bubbles at 6 months)
Effective closure was achieved according to highly stringent criteria (2x more stringent than the criteria utilized in other PFO device trials).

**DEMONSTRATING INVALUABLE PATIENT BENEFITS**

**AN EXCELLENT SAFETY PROFILE**

Low rates of Serious Adverse Events (SAEs) were reported, including any SAE (0.064 per pt-yr rate), device related SAE (0.004 per pt-yr rate) and death (0.002 per pt-yr rate). Additionally, the trial showed no device embolization, no aortic erosion/dissection, no thrombus formation and low risk of atrial fibrillation, consistent with medical therapy.

**SIGNIFICANTLY REDUCED RISK OF RECURRENT STROKE**

The RESPECT trial demonstrated a clear benefit of closure with AMPLATZER® PFO Occluder for reducing the risk of recurrent stroke and helping patients live healthy through significant stroke reduction.

**Device Embolization**
Aortic Erosion/Dissection
Device Thrombus

**LOW RISK OF SERIOUS ATRIAL FIBRILLATION (AF)**

There was no statistical difference in serious AF events between the closure and medical therapy groups (0.48 vs. 0.34 per 100 patient-years, P = 0.36).

The AMPLATZER® PFO Occluder also demonstrated a 62% RELATIVE RISK REDUCTION for recurrent ischemic stroke of unknown mechanism.