

## AMPLATZER™ PFO OCCLUDER

### THE LEADING DEVICE, PIONEERING PFO OCCLUSION

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<sup>1</sup>
- 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



## ▶ THE LANDMARK RESPECT TRIAL

### RIGOROUS DESIGN DEMONSTRATING SIGNIFICANT STROKE REDUCTION<sup>1</sup>

- 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

Studied in the landmark RESPECT trial, the AMPLATZER™ PFO Occluder is a double-disc device comprised of Nitinol mesh and polyester fabric.

For more information about the AMPLATZER™ PFO Occluder or the RESPECT clinical trial, contact your Abbott sales representative, or visit [PFOAMPLATZER.com](http://PFOAMPLATZER.com)



#### 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 cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

#### CONTRAINDICATIONS

- Patients with intra-cardiac mass, vegetation, tumor 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 with other source of right-to-left shunts, including an atrial septal defect and/or fenestrated septum.
- Patients with active endocarditis or other untreated infections.

#### WARNINGS

- Patients who are at increased risk for venous thromboembolic events should be managed with thromboembolic risk reduction regimen after the PFO Closure following standard of care.
- Do not use this device if the sterile package is open or damaged.
- Prepare for situations that require percutaneous or surgical removal of this device. This includes availability of a surgeon.
- Embolized devices must be removed as they may disrupt critical cardiac functions. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter or sheath.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- This device should be used only by physicians who are trained in standard transcatheter techniques.
- Transient hemodynamic compromise may be encountered during device placement, which may require fluid replacement or other medications as determined by the physician.
- Do not release the device from the delivery cable if the device does not conform to its original configuration, or if the device position is unstable or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), aorta (AO)). If the device interferes with an adjacent cardiac structure, recapture the device and redeploy. If still unsatisfactory, recapture the device and either replace with a new device or refer the patient for alternative treatment.
- Ensure there is sufficient distance from the PFO to the aortic root or SVC (typically defined as 9 mm or greater as measured).

#### PRECAUTIONS

- The safety and effectiveness of the AMPLATZER™ PFO Occluder has not been established in patients (with):
  - Age less than 18 years or greater than 60 years because enrollment in the pivotal study (the RESPECT trial) was limited to patients 18 to 60 years old
  - A hypercoagulable state including those with a positive test for an anticardiolipin antibody (IgG or IgM), Lupus anticoagulant, beta-2 glycoprotein-1 antibodies, or persistently elevated fasting plasma homocysteine despite medical therapy

1. Saver JL, Carroll JD, Thaler DE, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med* 2017; 377: 1022-32.

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#### Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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- Unable to take antiplatelet therapy
- Atherosclerosis or other arteriopathy of the intracranial and extracranial vessels associated with a  $\geq 50\%$  luminal stenosis
- Acute or recent (within 6 months) myocardial infarction or unstable angina
- Left ventricular aneurysm or akinesis
- Mitral valve stenosis or severe mitral regurgitation irrespective of etiology
- Aortic valve stenosis (mean gradient greater than 40 mmHg) or severe aortic valve regurgitation
- Mitral or aortic valve vegetation or prosthesis
- Aortic arch plaques protruding greater than 4 mm into the aortic lumen
- Left ventricular dilated cardiomyopathy with left ventricular ejection fraction (LVEF) less than 35%
- Chronic, persistent, or paroxysmal atrial fibrillation or atrial flutter
- Uncontrolled hypertension or uncontrolled diabetes mellitus
- Diagnosis of lacunar infarct probably due to intrinsic small vessel as qualifying stroke event
- Arterial dissection as cause of stroke
- Index stroke of poor outcome (modified Rankin score greater than 3)
- Pregnancy at the time of implant
- Multi-organ failure
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to re-sterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- The AMPLATZER™ PFO Occluder device consists of a nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are 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.
- Store 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.

#### ADVERSE 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 metal reaction: Nitinol (nickel, titanium), platinum/iridium, stainless steel (chromium, iron, manganese, molybdenum, nickel); Anesthesia reactions; Apnea; Arrhythmia; Bacterial endocarditis; Bleeding; Brachial plexus injury; Cardiac perforation; Cardiac tamponade; Cardiac thrombus; Chest pain; Device embolization; Device erosion; Deep vein thrombosis; Death; Endocarditis; Esophagus injury; Fever; Headache/migraine; Hypertension/hypotension; Myocardial infarction; Pacemaker placement secondary to PFO device closure; Palpitations; Pericardial effusion; Pericardial 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.

THE RESULTS OF THE LANDMARK RESPECT TRIAL WERE PUBLISHED IN THE SEPTEMBER 14, 2017 ISSUE OF THE NEW ENGLAND JOURNAL OF MEDICINE.



### THE MOST EXTENSIVE PATIENT FOLLOW-UP

The RESPECT trial enrolled patients at 69 centers across the U.S. and Canada, collecting a total of 5,810 patient-years of data.



More Patient-Years

The most extensive patient follow-up of any PFO closure trial ever conducted.



Longer Median Follow-up

Patients in the RESPECT trial were followed significantly longer (nearly 2x more follow-up time) than patients in any other PFO trial.



# THE LANDMARK PFO TRIAL

## 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.

# 980

### 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.

# 20%

### 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

(n≤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.

# 0%

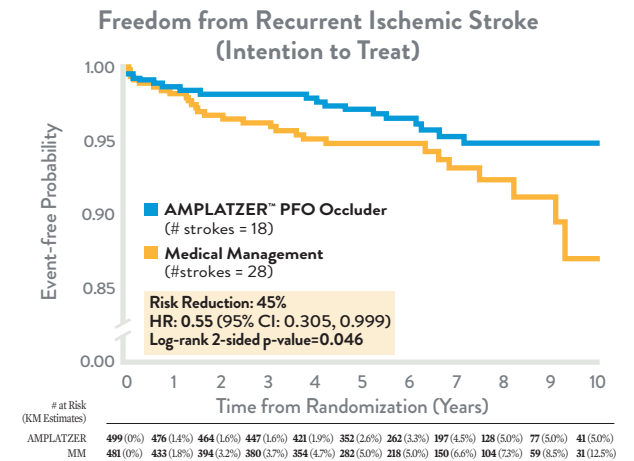
## DEVICE EMBOLIZATION AORTIC EROSION/DISSECTION DEVICE THROMBUS

## LOW RISK OF SERIOUS ATRIAL FIBRILLATION (AF)

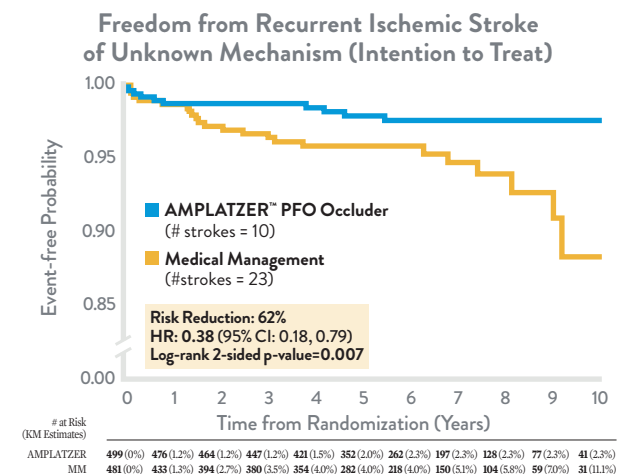
There was no statistical difference in serious AF events between the closure and medical therapy groups (0.48 vs. 0.34 per 100 patient-years, P = 0.36).

## 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.



The RESPECT trial showed there was a **45% RELATIVE RISK REDUCTION** for any recurrent ischemic stroke over nearly six years of follow-up with the use of the AMPLATZER™ PFO Occluder.



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