AMPLATZER™ PFO OCCLUDER

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

Abbott

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 results[1]. 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[1]

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.

See important safety information referenced within.

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

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

WE RAISE THE BAR: THE LANDMARK RESPECT TRIAL[1]

- 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

990 PATIENTS IMPLANTED WITH DEVICE IN RCTS*

WE DEMONSTRATE EXCELLENCE

- **ZERO** device erosions, thrombus, or embolization events in **SIX**** published trials with **990** patients[1-6]
- **94.2% effective** closure rates at 6 months[1]

* 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

OFTEN IMITATED, NEVER MATCHED

Industry-leading device. Developed specifically for the treatment of PFO closure.

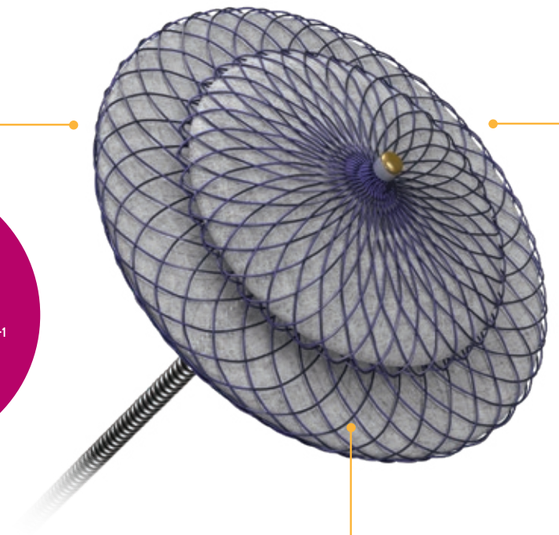
DESIGN ADVANTAGES THAT MAKE THE DIFFERENCE

DURABLE NITINOL WIRE MESH WITH POLYESTER FABRIC THREAD

Excellent visibility under flouro

ASYMMETRIC DOUBLE DISC DESIGN

Minimizes material in the Left Atrium*

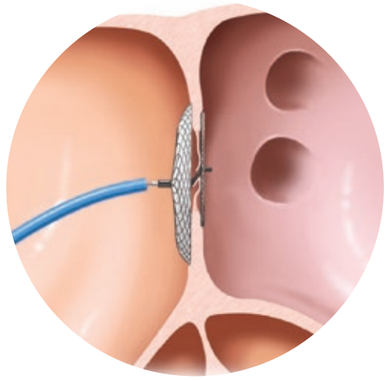


94%
CLOSURE RATE†[1]
at 6 months in RESPECT trial[1]

INTAGLIO™ WIRE TREATMENT

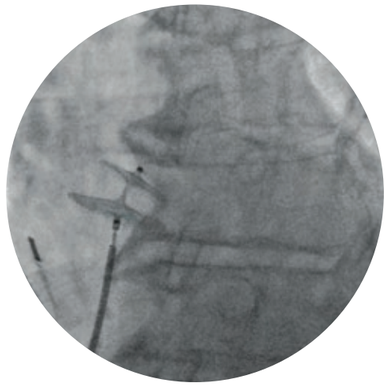
Designed to reduce nickel leaching[7]

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.

*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.

	RESPECT[1]	REDUCE[8]	CLOSE[4]
Devices Used	100% AMPLATZER™ PFO Occluder	39% GORE† HELEX, 61% GORE Cardioform	51% AMPLATZER PFO Occluder; 49% other approved PFO devices
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*

*Not reported
See important safety information referenced within.

PUBLISHED DATA HIGHLIGHTS EXCELLENT SAFETY

LOW RISK OF DEVICE-RELATED EVENTS

	RESPECT[1]	REDUCE[8]
Device Embolization/ Dislocation	**0**	**2**
Aortic Erosion/ Dissection	**0**	**1**
Device Thrombus	**0**	**2**

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

LOW RISK OF ATRIAL FIBRILLATION (AF)

RATE (PER 100 PT YRS)	RESPECT[1]	REDUCE[8]*
Serious AF/ Flutter**	**0.22**	**0.65**
Any AF/ Flutter	**0.76**	**1.90**

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

*Rates calculated based on data in final publication.
**In RESPECT, serious AF was adjudicated by an independent board of physicians. In REDUCE, it was determined by the local investigator.

AMPLATZER™ PFO OCCLUDER

Device Specifications

SIZING AND DEVICE SELECTION

AMPLATZER™ PFO Occluder

Model/Reorder Number	Right Atrial Disc Diameter [A]	Left Atrial Disc Diameter [B]	Minimum Recommend Sheath Size
9-PFO-018	18 mm	18 mm	8 F; 45° curve
9-PFO-025	25 mm	18 mm	8 F; 45° curve
9-PFO-035	35 mm	25 mm	9 F; 45° curve

DELIVERY SYSTEM

AMPLATZER™ TorqVue® 45° Delivery System

Model/Reorder Number	Sheath Size	Tip Angle	Sheath Inner Diameter	Sheath Outer Diameter	Usable Length
9-ITV08F45/80	8 F	45°	2.69 mm/0.11 inch	3.45 mm/0.14 inch	80 cm
9-ITV09F45/80	9 F	45°	3.00 mm/0.12 inch	3.81 mm/0.15 inch	80 cm

ANCILLARY PRODUCTS

AMPLATZER™ Guidewire

Model/Reorder Number	Diameter	Body	Tip Description	Usable Length
9-GW-002	0.035 inch	Super Stiff	1.5 mm, Modified J-tip	260 cm

AMPLATZER™ TorqVue® Exchange Systems
Ordering Information – Contents: 1 each delivery sheath, dilator, exchange wire, hemostasis valve, loader, and plastic vise

Model/Reorder Number	Sheath Size	Tip Angle	Sheath Inner Diameter	Sheath Outer Diameter	Usable Length
9-EITV09F45/80	9 F	45°	3.00 mm/0.12 inch	3.81 mm/0.15 inch	80 cm
9-EITV12F45/80	12 F	45°	3.99 mm/0.16 inch	4.80 mm/0.19 inch	80 cm

REFERENCES

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. **2.** Tobis J, Charles A, Silbertson D, et al. Prospective, randomized investigation to evaluate incidence of headache reduction in subjects with frequent migraine and PFO using the AMPLATZER PFO occluder to medical management. *J Am Coll Cardiol* 2017; 70:2766-74. **3.** Meier B, Kalesan B, Mattle HP, et al. Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N Engl J Med* 2013; 368: 1083 - 91. **4.** Mas J-L, Derumeaux G, Guillon B, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med* 2017;377:1011-21 and supplementary appendix. **5.** Lee PH, Song J-K, Kim JS, et al. Cryptogenic Stroke and High-Risk Patent Foramen Ovale: The DEFENSE-PFO Trial, *Journal of the American College of Cardiology* (2018), doi: 10.1016/j.jacc.2018.02.046. **6.** Heinrich P. Mattle, Stefan Evers, David Hildick-Smith, et al. Percutaneous closure of patent foramen ovale in migraine with aura, a randomized controlled trial, *European Heart Journal*, Volume 37, Issue 26, 7 July 2016, Pages 2029–2036. **7.** Based on internal lab testing. Data on file at Abbott. **8.** Søndergaard L, Kasner SE, Rhodes JF, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med* 2017; 377: 1033-42.

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION

℞ ONLY

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 a anticardiolipin antibody (IgG or IgM), Lupus anticoagulant, beta-2 glycoprotein-1 antibodies, or persistently elevated fasting plasma homocysteine despite medical therapy • Unable to take antiplatelet therapy • Atherosclerosis or other arteriopathy of the intracranial and extracranial vessels associated with a ≥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 n Index stroke of poor outcome (modified Rankin score greater than 3) n 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.

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 manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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