AMPLATZER™ PFO OCCLUDER

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

Abbott

A PIONEERING DEVICE 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]

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.** Check the regulatory status of the device in areas where CE marking is not the regulation in force.

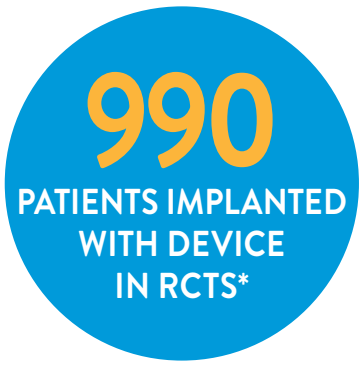
WHY IS AMPLATZER PFO OCCLUDER RELIED UPON BY THOUSANDS OF PHYSICIANS AROUND THE WORLD?

WE SET THE STANDARD

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

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



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.

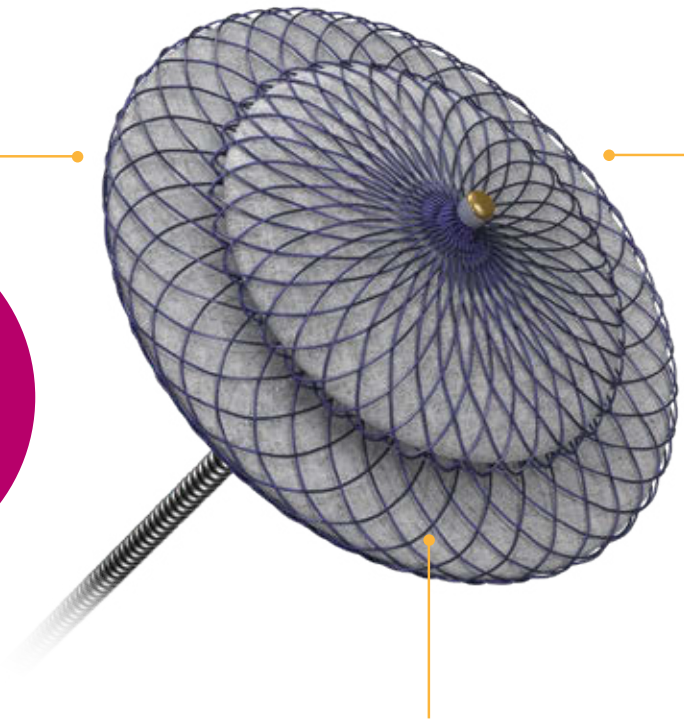
DESIGN ADVANTAGES THAT MAKE THE DIFFERENCE

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]

*On commonly used sizes (25mm and 35mm devices)
†Effective Closure

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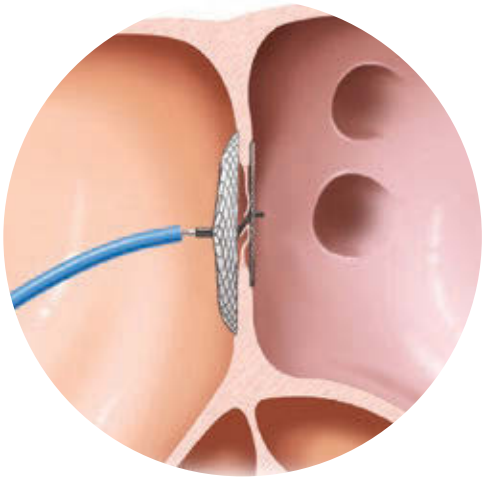
ONE STEP AHEAD: MINIMIZING COMPLEXITY IN CLOSURE

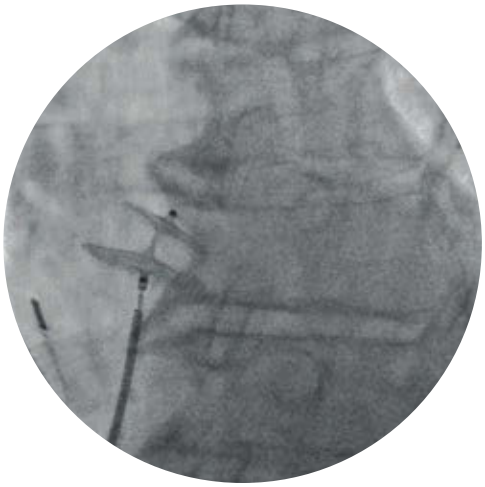


UNIQUE SELF-EXPANDING DISCS

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.

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

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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.

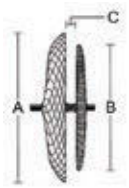
AMPLATZER™ PFO OCCLUDER

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-030	30 mm	30 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

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.

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