

# GET CLOSURE FOR YOUR PATIENTS: AMPLATZER™ PFO OCCLUDER

STRUCTURAL HEART THERAPY

The RESPECT Final Results presented at TCT 2016 reported the AMPLATZER™ PFO Occluder as more effective than medical therapy alone in reducing risk of a recurrent ischemic stroke.



## SAFE

Data from the RESPECT clinical trial showed low rates of Serious Adverse Events (SAEs) related to the device (2.0%) and procedure (2.4%) for the Device group.<sup>1</sup>

## EFFECTIVE

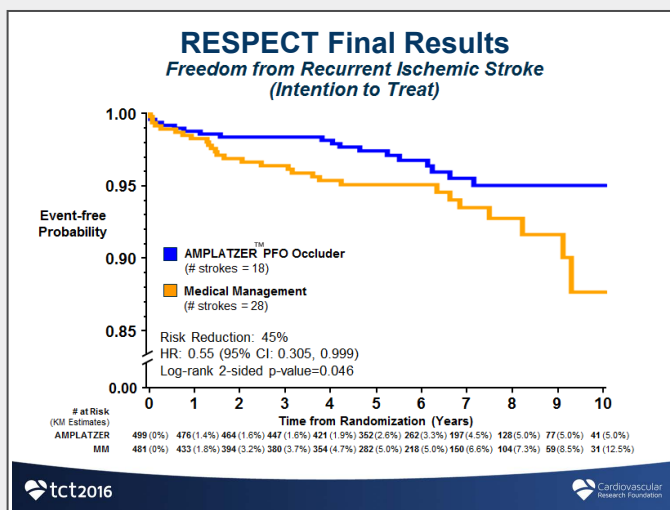
Long-term follow-up data (average 5.9 years) from the RESPECT clinical trial shows a statistically significant **45% RELATIVE RISK REDUCTION** (Figure 1) in favor of PFO closure with the AMPLATZER PFO device for reducing risk of any recurrent ischemic stroke, and a significant **62% RELATIVE RISK REDUCTION** (Figure 2) for reducing risk of recurrent ischemic stroke of unknown mechanism (cryptogenic).<sup>2</sup>

## REPRODUCIBLE

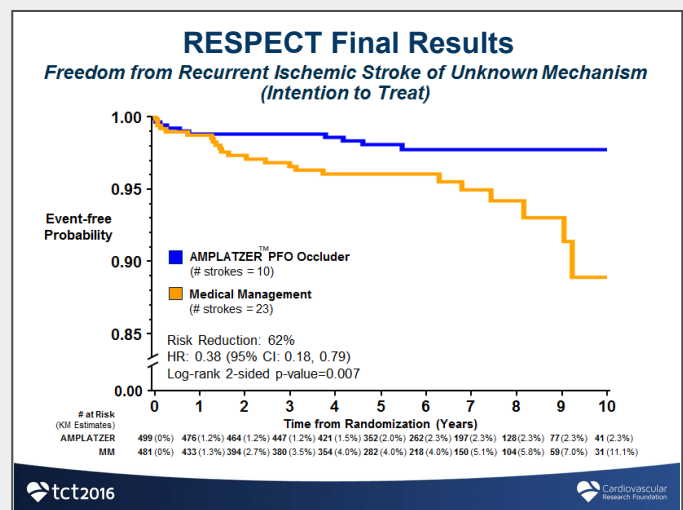
99.1% technical success and 96.1% procedural success<sup>1</sup>

## FDA APPROVED\*

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. The final analyses presented at TCT 2016, include additional follow-up beyond those on which FDA approval was based.



**Figure 1.** The RESPECT trial showed there was a 45% relative risk reduction for any recurrent ischemic stroke with the use of the AMPLATZER™ PFO Occluder.<sup>2</sup>



**Figure 2.** The AMPLATZER™ PFO Occluder also demonstrated a 62% relative risk reduction for recurrent ischemic stroke of unknown mechanism (cryptogenic).<sup>2</sup>

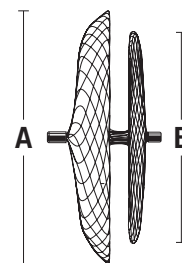
\* The AMPLATZER™ PFO device was approved by the FDA on October 28, 2016. FDA approval for the device was based on the RESPECT Trial data through the August 2015 data lock. The final analysis data presented at TCT 2016 includes additional follow-up beyond those on which FDA approval was based.

# Ordering Information

## SIZING AND DEVICE SELECTION

### AMPLATZER™ PFO Occluder

Model/Reorder Number	Right Atrial Disc Diameter [A]	Left Atrial Disc Diameter [B]	Minimum Recommended 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



Shortest Distance From Defect to Aortic Root, or Distance From Defect to Superior Vena Cava Orifice	Suggested AMPLATZER™ PFO Occluder Size
≥ 17.5 mm	35 mm
12.5-17.4 mm	25 mm
9-12.4 mm	18 mm
< 9 mm	Do not implant device

## 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

1. AMPLATZER™ PFO Occluder Instructions for Use. ARTUS600609-001 Rev B 2016-10

2. Thaler, D. E., Carroll, J. D., Saver, J. L., Smalling, R., MacDonald, L. A., Marks, D. S., & Tirschwell, D. L. (2016, Oct-Nov). "Long-Term Comparison of Patent Foramen Ovale (PFO) Closure versus Medical Therapy after Cryptogenic Stroke: Final Results of the RESPECT Trial." Presented at TCT 2016, Washington, DC.

#### 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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