

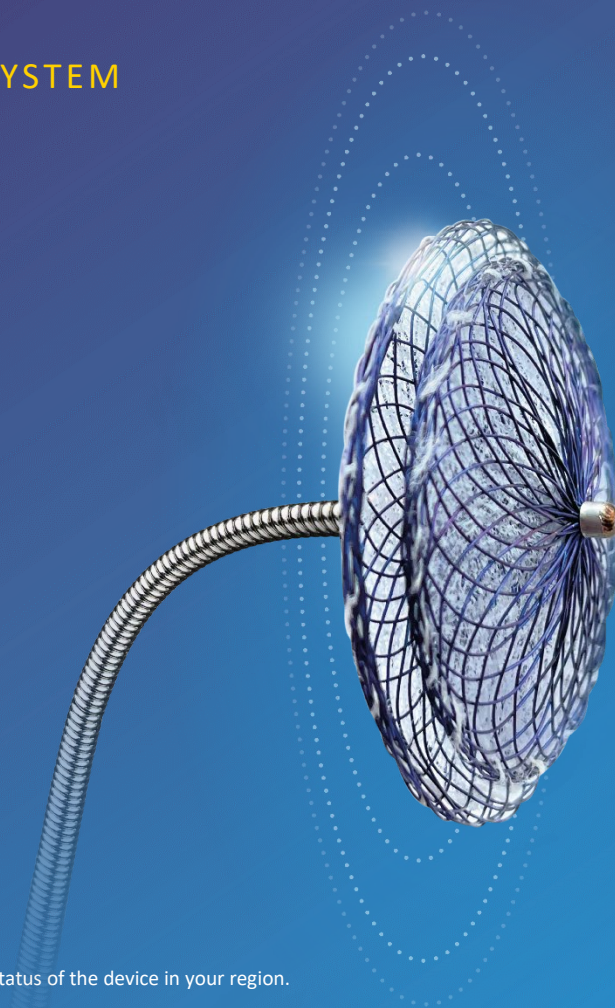
## THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

# EFFECTIVE PFO CLOSURE MADE EASIER<sup>1</sup>

**ABBOTT SALES TEAM:** Select from two custom slideshows by clicking a button below (must be in slideshow mode)

Experienced with Abbott PFO Occluders

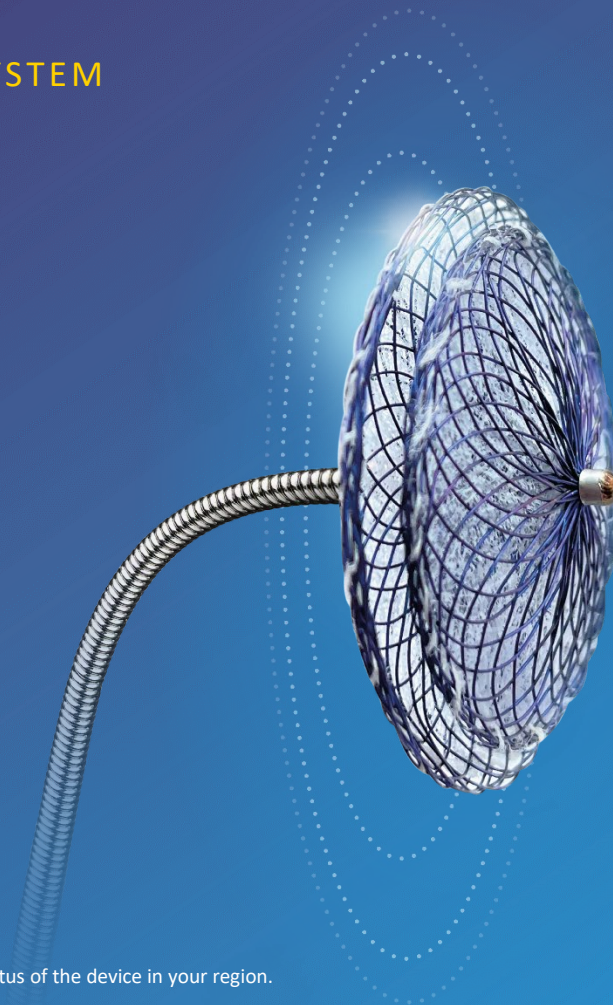
New to Abbott PFO Occluders



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THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

# EFFECTIVE PFO CLOSURE **MADE EASIER<sup>1</sup>**

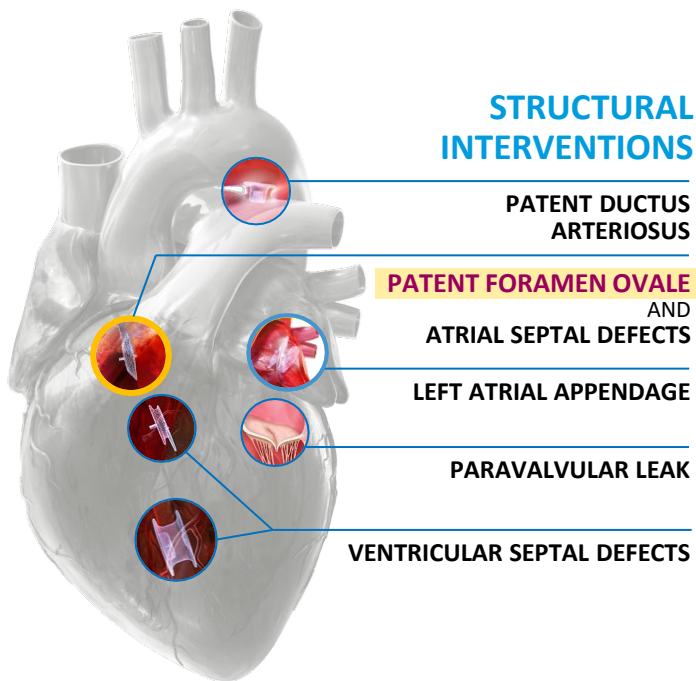


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ABBOTT STRUCTURAL HEART

# THE MOST COMPREHENSIVE PRODUCT PORTFOLIO



## VALVULAR SOLUTIONS

### MITRAL VALVE

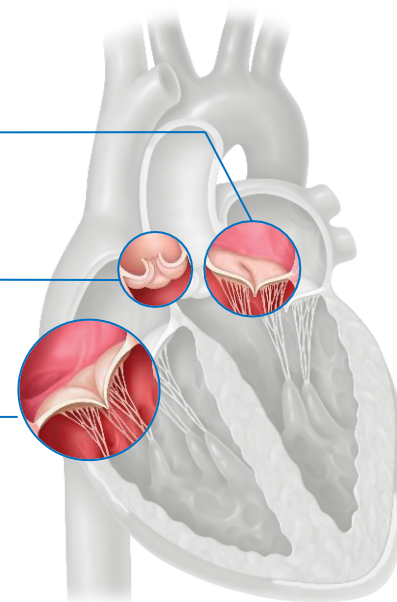
Surgical Repair/Replacement  
Transcatheter Repair  
Transcatheter Replacement

### AORTIC VALVE

Surgical Replacement  
Transcatheter Replacement

### TRICUSPID VALVE

Transcatheter Repair



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BUILT FOR BETTER

# GOING BEYOND BETTER PRODUCTS FOR YOU AND YOUR PATIENTS

## WORLD-CLASS EDUCATION AND SUPPORT

Providing expert instruction to ensure your team has convenient access to the latest training



## SUPPORTING PEER-TO-PEER KNOWLEDGE EXCHANGE

Creating forums and other opportunities to share ideas and foster new connections to take therapies further



## INNOVATION THROUGH COLLABORATION

Proactively co-designing patient-focused solutions with physicians to address unmet needs



## EMPATHIC PATIENT SUPPORT

Providing world-class patient materials and resources to ensure positive experiences



## CLINICAL TRIALS

Ongoing world-class research to balance risk/benefit ratio, improve safety and advance standard-of-care



## LARGEST PORTFOLIO

Offering the broadest product portfolio focused on helping people live fuller, healthier lives



AMPLATZER™ PFO OCCLUDER: THE #1 MOST-STUDIED IN THE WORLD

# AS THE PIONEER, **WE CONTINUE TO INNOVATE**

- An unmatched track record with over **two decades of experience**
- The **#1** device selected for PFO closure
- **Over 180,000 patients** treated globally<sup>2</sup>



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## UNMATCHED CLINICAL EVIDENCE

# WE RAISED THE BAR WITH THE LANDMARK RESPECT TRIAL

- RESPECT<sup>3</sup> is the largest long-term trial for PFO closure with 5,810 patient-years of data — **almost 2x more** than other PFO trials
- RESPECT is the only trial to include patients on either antiplatelet or anticoagulation therapy — a **real-world cross-section** of patients

## The RESPECT Trial<sup>3</sup>

Device Used	Amplatzer™ PFO Occluder
Patients	<b>980</b>
Follow-Up Patient Years	<b>5,810</b> (median 5.9 yrs)
Anticoagulant Allowed in Control Group?	<b>Yes</b>
Relative Risk Reduction	<b>62%</b> (Recurrent ischemic stroke of unknown mechanism)
Effective Closure	<b>94.2%</b> Freedom from >9 bubbles (Evaluated after 6 months)

WHAT'S NEW?

# THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

EFFECTIVE PFO CLOSURE  
MADE EASIER<sup>1</sup>



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Over 20 years ago, we pioneered PFO closure with the Amplatzer™ PFO Occluder to reduce the risk of recurrent PFO-associated stroke.

We continue to advance the gold standard, with input from you.

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## THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

# YOU ASKED. WE DELIVERED.

### **“Can device prep be simpler, faster?”**

The device comes assembled to the flexible Amplatzer™ Trevisio™ delivery cable, making it more intuitive

### **“Can we ensure the left atrial disc fits better into surrounding structures?”**

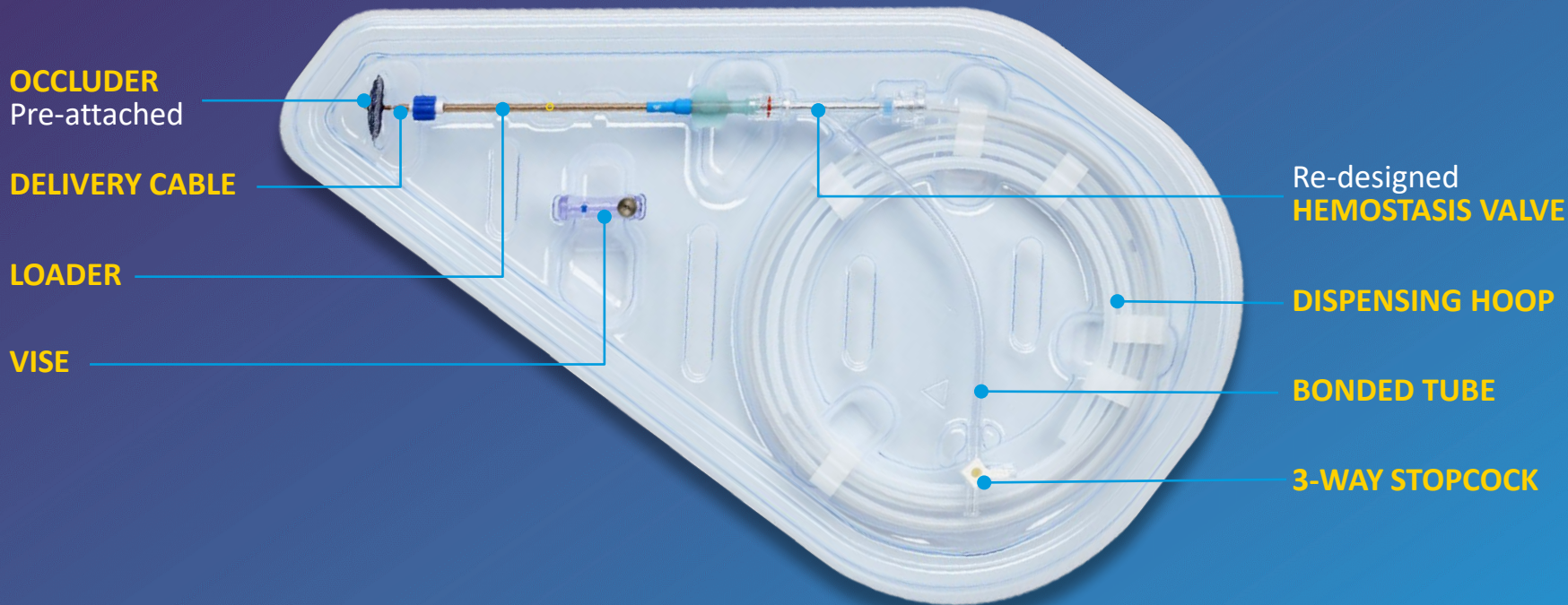
We refined the 30mm device to have a smaller left atrial disc



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THE EASY-TO-USE JUST GOT EASIER

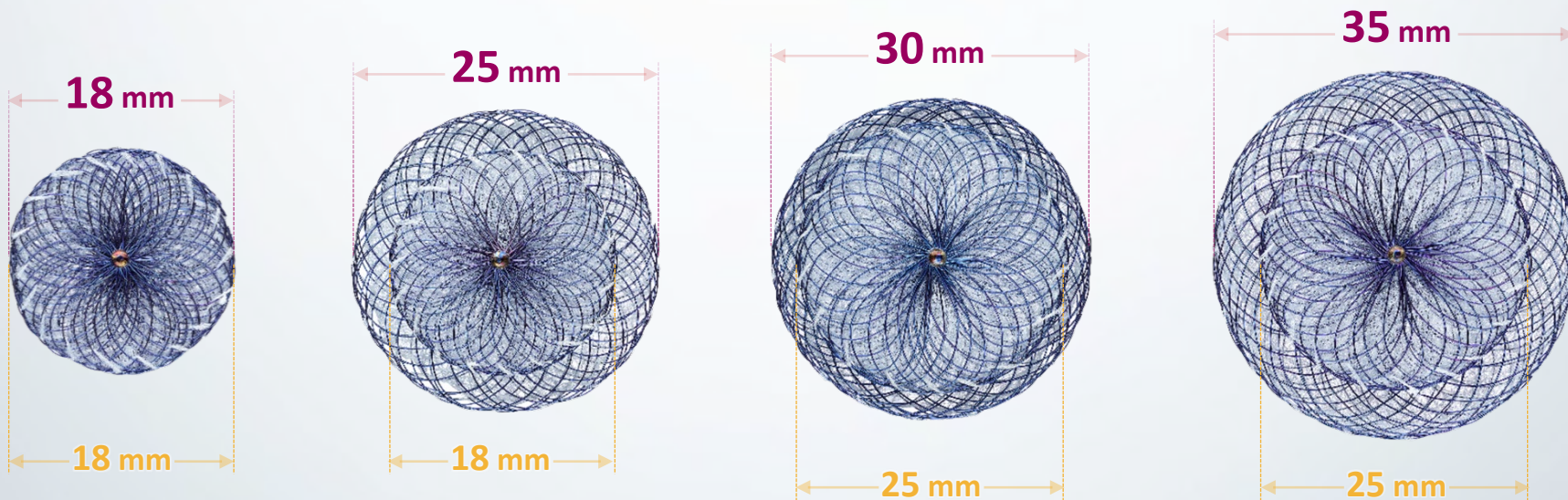
# SIMPLIFIED PREP, **INTUITIVE EXPERIENCE**



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OFFERING A WIDE RANGE OF DEVICE SIZES

# OPTIMIZED FOR MOST ANATOMIES



We re-engineered the 30 mm size with a **SMALLER LEFT ATRIAL DISC** to better avoid interference with surrounding structures

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ADVANCING THE GOLD STANDARD

# BUILT OFF A LEGACY OF EXCELLENCE

## **Amplatzer™ PFO Occluder**

Most-studied, with more  
than 180,000 patients  
treated worldwide<sup>2</sup>



## **Amplatzer™ Trevisio™ Delivery System**

Flexible cable provides  
precision in placement and  
predictability in release

---

## **Amplatzer™ Talisman™ PFO Occlusion System** **Effective PFO closure made easier<sup>1</sup>**



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THE GOLD STANDARD FOR OVER 20 YEARS

# OFTEN IMITATED, NEVER MATCHED

Unique design features set the  
Amplatzer™ Talisman™ PFO Occluder  
apart from the rest

**>94%**

**CLOSURE RATE†**  
at 6 months in  
RESPECT trial<sup>3</sup>

† Effective closure

\* Note: Only the 18mm size is not asymmetric.

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**DURABLE NITINOL WIRE MESH  
WITH POLYESTER FABRIC THREAD**

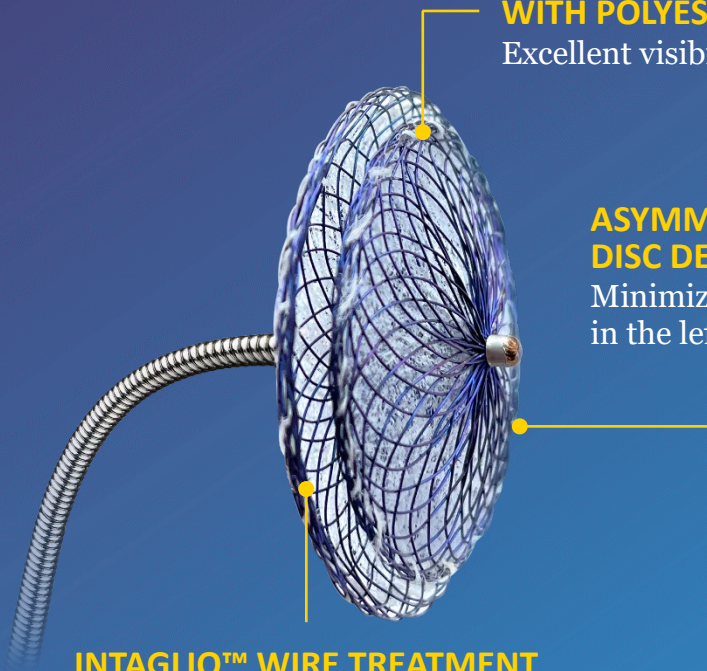
Excellent visibility under fluoro

**ASYMMETRIC DOUBLE  
DISC DESIGN\***

Minimizes material  
in the left atrium

**INTAGLIO™ WIRE TREATMENT**

Reduces nickel leaching by more than 97%<sup>1</sup>

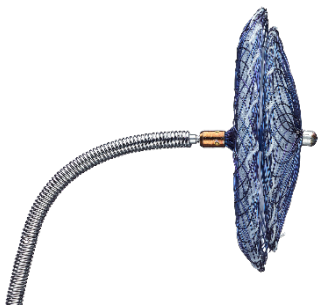


THE GOLD STANDARD FOR OVER 20 YEARS

# MINIMIZING COMPLEXITY IN PFO CLOSURE

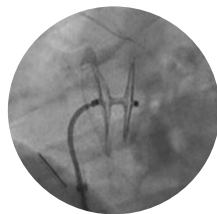
## SIMPLIFIED PREP

Occluder comes assembled to the flexible Trevisio™ delivery cable, ready to use



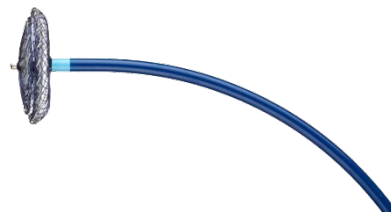
## RECAPTURABLE AND REPOSITIONABLE

Self-expanding discs align to the PFO without an additional “locking” step and can be adjusted for ideal placement



## LOW-PROFILE DELIVERY

8 F and 9 F introducer sheaths enable treatment of patients with smaller vasculature



UNMATCHED CLINICAL EVIDENCE

# DEMONSTRATED EXCELLENCE IN SAFETY AND EFFECTIVENESS

Trusted and relied upon **by thousands of physicians** around the world

---

In **6 published trials**<sup>3-8</sup> with **990\*** patients, the Amplatzer™ PFO Occluder showed:

**ZERO**

- Device erosions
- Device thrombus
- Device embolization events
- Wire frame fractures

\* Patients in device group of each trial implanted with the Amplatzer™ PFO Occluder:  
RESPECT = 465, PREMIUM = 119, PC = 191, CLOSE = 121, DEFENSE = 53, PRIMA = 41.

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THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

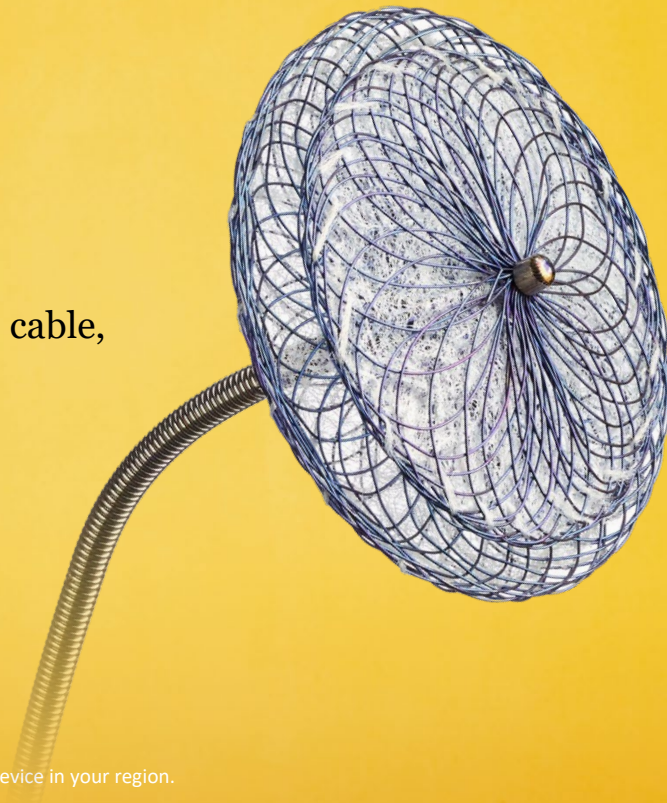
# EFFECTIVE PFO CLOSURE MADE EASIER<sup>1</sup>

## WE TOOK THE DEVICE TRUSTED FOR DECADES AND MADE IT BETTER:

- The occluder comes assembled to the Amplatzer™ Trevisio™ cable, so prep is simpler and more intuitive
- Refined the 30mm device to have a smaller left atrial disc

## CONFIDENCE IN CLOSURE

The PFO solution you've asked for, from the team who pioneered PFO treatment



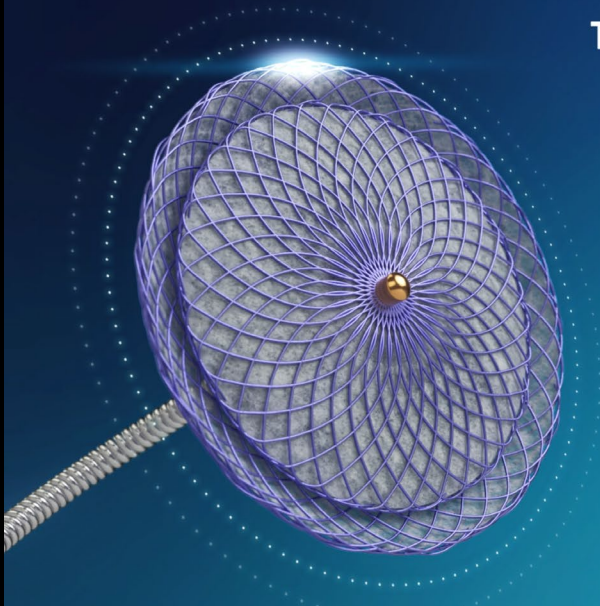
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THE AMPLATZER™ TALISMAN™  
PFO OCCLUSION SYSTEM IS OUR  
**MOST ADVANCED**  
PFO CLOSURE DEVICE YET



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# THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM



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## THE AMPLATZER™ PORTFOLIO APP

# DEVICE SELECTION MADE EASIER

The Amplatzer Portfolio App assists you in choosing the optimal Amplatzer™ Talisman™ PFO Occluder for your patient.

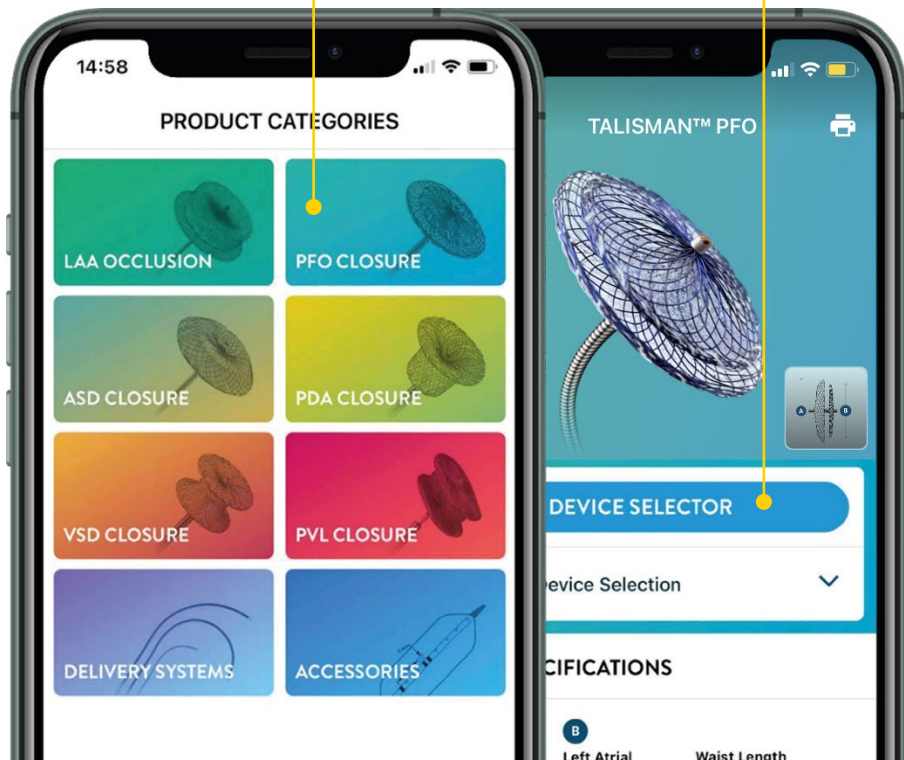
**DOWNLOAD NOW!**



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**FIRST**, select  
PFO Closure

**NEXT**, tap the Device Selector, and  
choose the appropriate PFO morphology



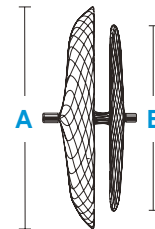
# THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

## DEVICE SPECIFICATIONS

### SIZING AND DEVICE SELECTION

#### Amplatzer™ Talisman™ PFO Occluder

Model/Reorder Number	Right Atrial Disc Diameter A	Left Atrial Disc Diameter B	Recommended Sheath Size
9-PFO-1818	18 mm	18 mm	8 F; 45° curve
9-PFO-2518	25 mm	18 mm	8 F; 45° curve
9-PFO-3025	30 mm	25 mm	9 F; 45° curve
9-PFO-3525	35 mm	25 mm	9 F; 45° curve



### DELIVERY SHEATH

#### Amplatzer™ Talisman™ Delivery Sheath

Model/Reorder Number	Sheath Size	Tip Angle	Sheath Inner Diameter	Sheath Outer Diameter	Usable Length
9-TDS-08F45-80	8F	45°	2.69 mm	3.45 mm	80 cm
9-TDS-09F45-80	9F	45°	3.00 mm	3.81 mm	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

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## SIZING THE AMPLATZER™ TALISMAN™ PFO OCCLUDER

# DEVICE SPECIFICATIONS

### DEVICE SIZING GUIDELINES

PFO Morphology	Example Anatomical Characteristics	Suggested Amplatzer™ Talisman™ PFO Occluder Size (mm)
<b>Simple PFO or PFO with a non-prominent ASA</b> PFO where a secure device position and effective PFO closure can be achieved when using the 25mm device size	1. Absence of ASA, long tunnel, and thickened septum secundum 2. Non-prominent ASA (< 20 mm total excursion) without a long tunnel (≥ 10 mm length) and without a thickened septum secundum (≥ 10 mm thickness)	25
<b>Complex PFO</b> PFO with one or more anatomical characteristics that may complicate the ability to achieve a secure device position and effective PFO closure when using the 25mm device size	1. ASA (≥ 10 mm excursion) with long tunnel (≥ 10 mm length) 2. ASA (≥ 10 mm excursion) with thickened septum secundum (≥ 10 mm thickness) 3. Prominent ASA with excessive mobility (≥ 20 mm total excursion) 4. Lipomatous hypertrophy of septum secundum (≥ 15 mm thickness)	30 or 35
<b>PFO with small anatomy</b> Anatomy not suitable for 25mm device size secondary to interference with adjacent cardiac structures	1. Septal primum length < 20 mm	18

Note: Evaluate the position of the device after deployment, but before detachment. Use echocardiography to ensure that the device does not impinge on the free atrial wall or aortic root. If the device interferes with an adjacent cardiac structure (such as free atrial wall or aortic root), recapture the device and redeploy. If device position remains unsatisfactory, recapture the device and either replace with a smaller device (18 mm or 25 mm) or refer the patient for alternative treatment.

The presence of an ASA alone does not necessarily prevent successful PFO closure with a 25 mm device size. In RESPECT<sup>3</sup>, 180 patients (36%) in the device closure group had an ASA. The 25 mm device size was used in the majority of patients with an ASA (77%) to close the PFO, and at 6-months post-implant, effective closure was achieved in 95% of these patients. There were no cases of device embolization in any patient in the study.

## REFERENCES

1. Tests performed by and data on file at Abbott.
2. Abbott Internal Sales Data: 1998-2021.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.

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 [eifu.abbottvascular.com](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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