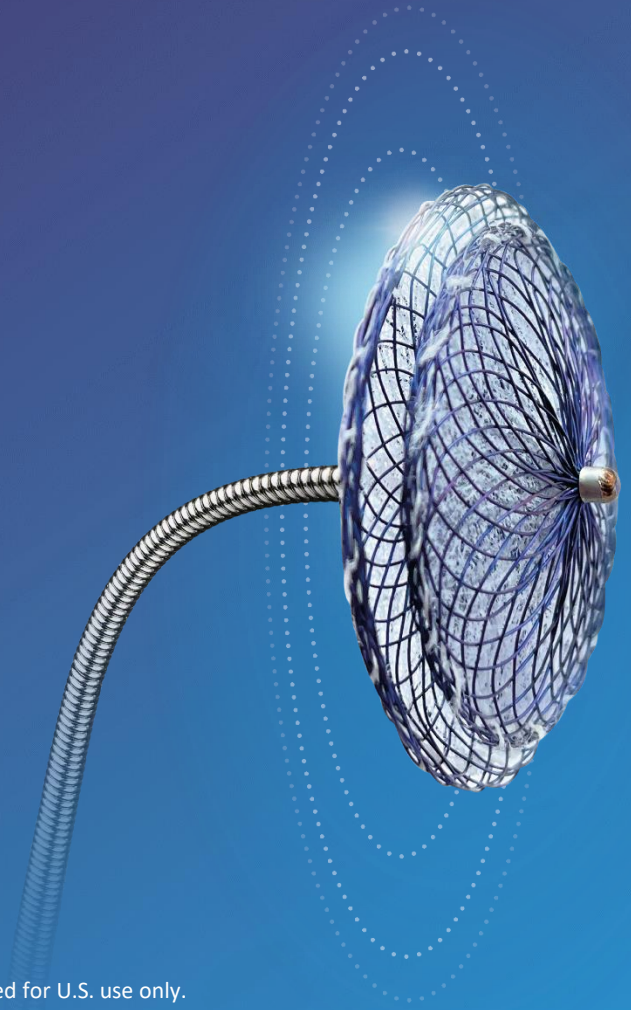
THE AMPLATZER™ TALISMAN™
PFO OCCLUSION SYSTEM

EFFECTIVE PFO CLOSURE **MADE EASIER**[1]



Abbott

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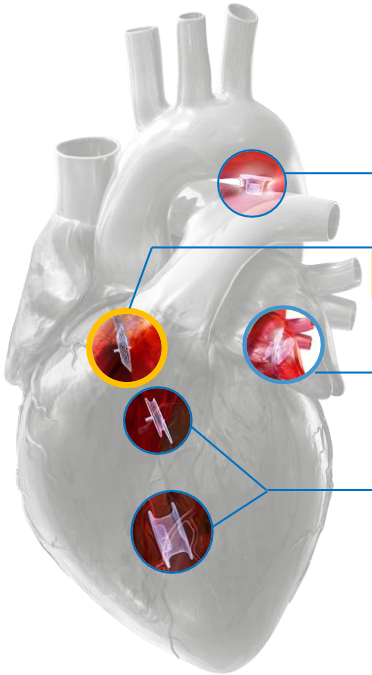
ABBOTT STRUCTURAL HEART

THE MOST COMPREHENSIVE PRODUCT PORTFOLIO



STRUCTURAL INTERVENTIONS

PATENT DUCTUS ARTERIOSUS

PATENT FORAMEN OVALE
AND
ATRIAL SEPTAL DEFECTS

LEFT ATRIAL APPENDAGE

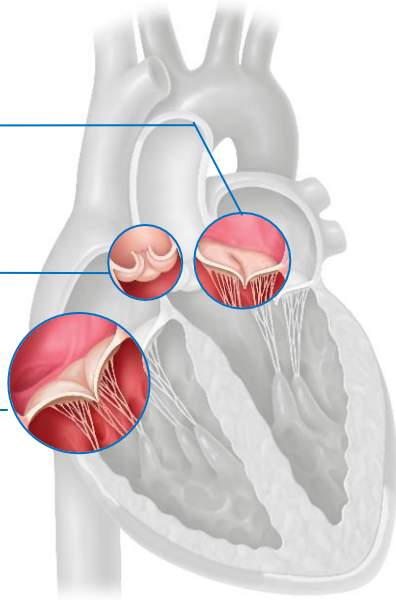
VENTRICULAR SEPTAL DEFECTS

VALVULAR SOLUTIONS

MITRAL VALVE
Surgical Repair/Replacement
Transcatheter Repair
Transcatheter Replacement

AORTIC VALVE
Surgical Replacement
Transcatheter Replacement

TRICUSPID VALVE
Transcatheter Repair



See Important Safety Information referenced within.

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

INNOVATION THROUGH COLLABORATION

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

CLINICAL TRIALS

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

SUPPORTING PEER-TO-PEER KNOWLEDGE EXCHANGE

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

EMPATHIC PATIENT SUPPORT

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

LARGEST PORTFOLIO

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

See Important Safety Information referenced within.

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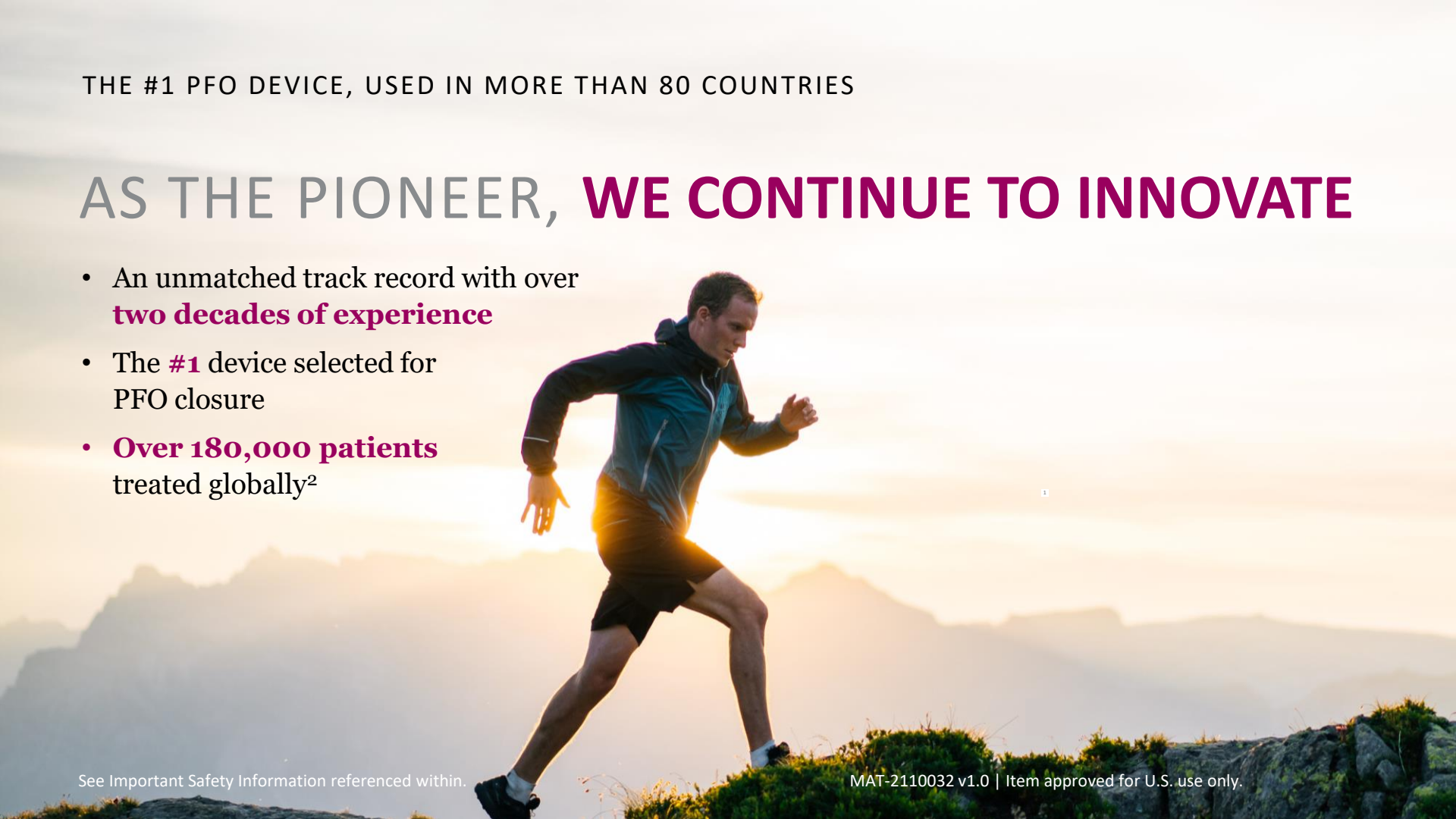
THE #1 PFO DEVICE, USED IN MORE THAN 80 COUNTRIES

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[2]



See Important Safety Information referenced within.

WE RAISED THE BAR WITH THE LANDMARK RESPECT TRIAL

- RESPECT[3] 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[3]

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

WHAT'S NEW?

THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

EFFECTIVE PFO CLOSURE **MADE EASIER**[1]

See Important Safety Information referenced within.

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See Important Safety Information referenced within.

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THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

THE EASY-TO-USE **JUST GOT EASIER**[1]

- Added another size, so you have the **complete PFO portfolio for every case**
- Simplified the prep, making it **more intuitive**

See Important Safety Information referenced within.

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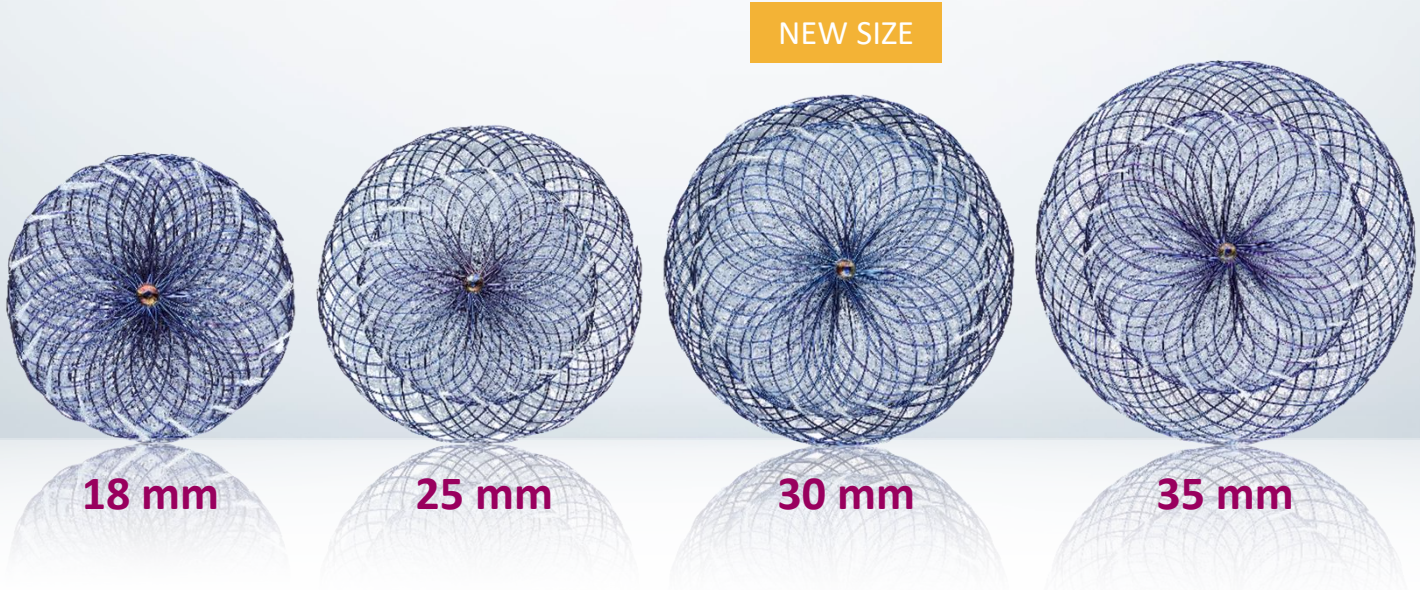
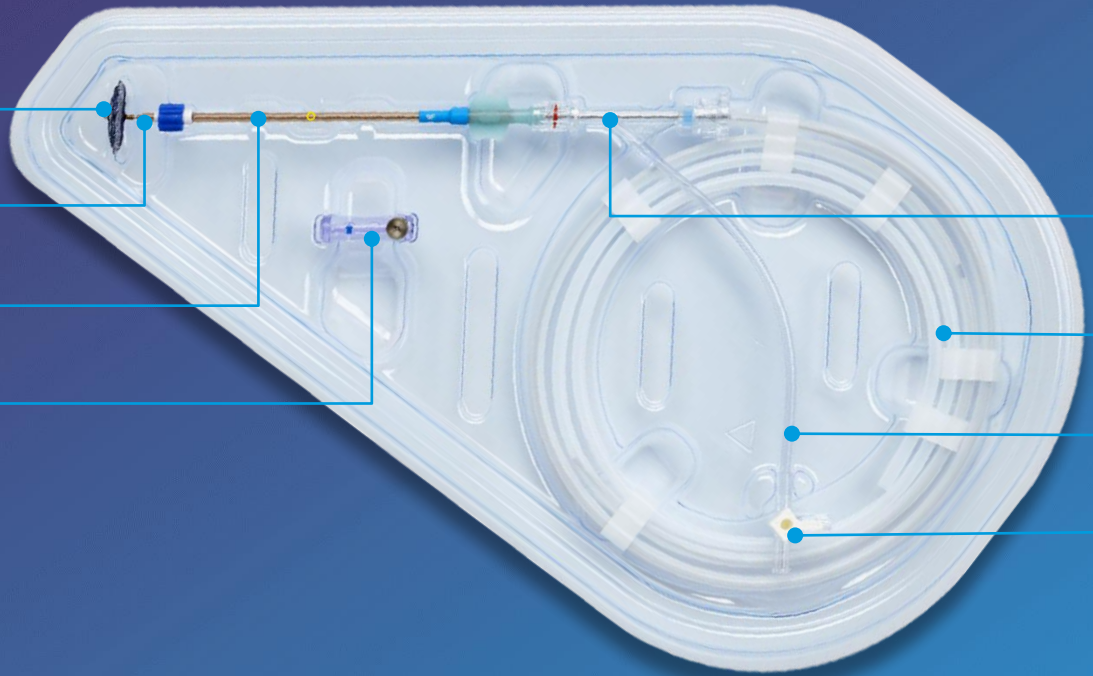
THE COMPLETE **RANGE OF SIZES**

The 30 mm Amplatzer™ Talisman™ PFO Occluder completes our portfolio so you have **the right size for every case.**



THE EASY-TO-USE JUST GOT EASIER

SIMPLIFIED PREP, INTUITIVE EXPERIENCE



See Important Safety Information referenced within.

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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[2]

+

Amplatzer™ Trevisio™ Delivery System

Provides precision in placement and predictability in release

=

Amplatzer™ Talisman™ PFO Occlusion System

Effective PFO closure made easier[1]

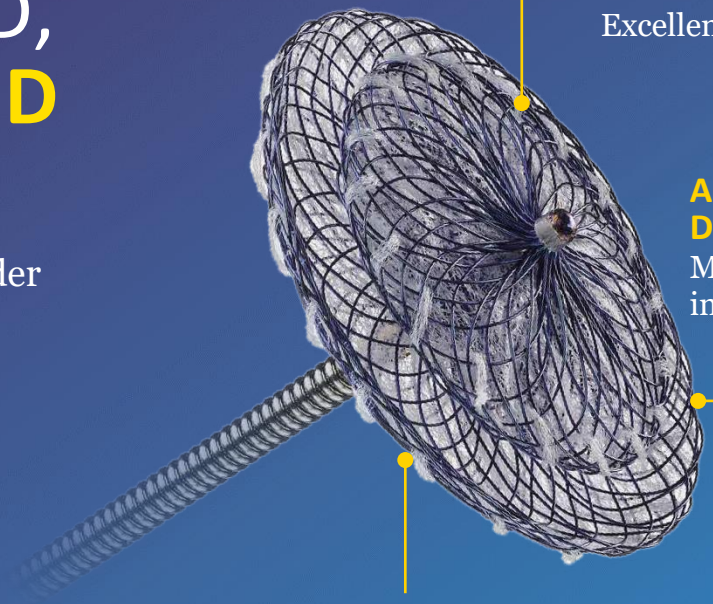
See Important Safety Information referenced within.

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[3]



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%[1]

† Effective closure
* Note: Only the 18mm size is not asymmetric.

See Important Safety Information referenced within.

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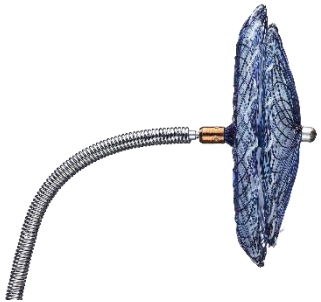
THE GOLD STANDARD FOR OVER 20 YEARS

MINIMIZING COMPLEXITY IN PFO CLOSURE

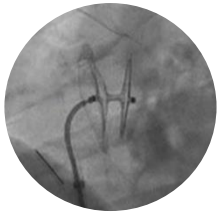
SIMPLIFIED PREP

Occluder comes assembled to 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

See Important Safety Information referenced within.

UNMATCHED CLINICAL EVIDENCE

DEMONSTRATED EXCELLENCE IN SAFETY AND EFFICACY

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

In **6 published trials**[3-8] 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.

See Important Safety Information referenced within.

THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

EFFECTIVE PFO CLOSURE **MADE EASIER**[1]

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

- Added a 30mm device, so there's the right-sized Amplatzer™ Talisman™ PFO Occluder for every case
- Simplified the prep, making it more intuitive

CONFIDENCE IN CLOSURE

In one complete portfolio — from the team who pioneered PFO treatment

See Important Safety Information referenced within.

MAT-2110032 v1.0 | Item approved for U.S. use only.

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

See Important Safety Information referenced within.

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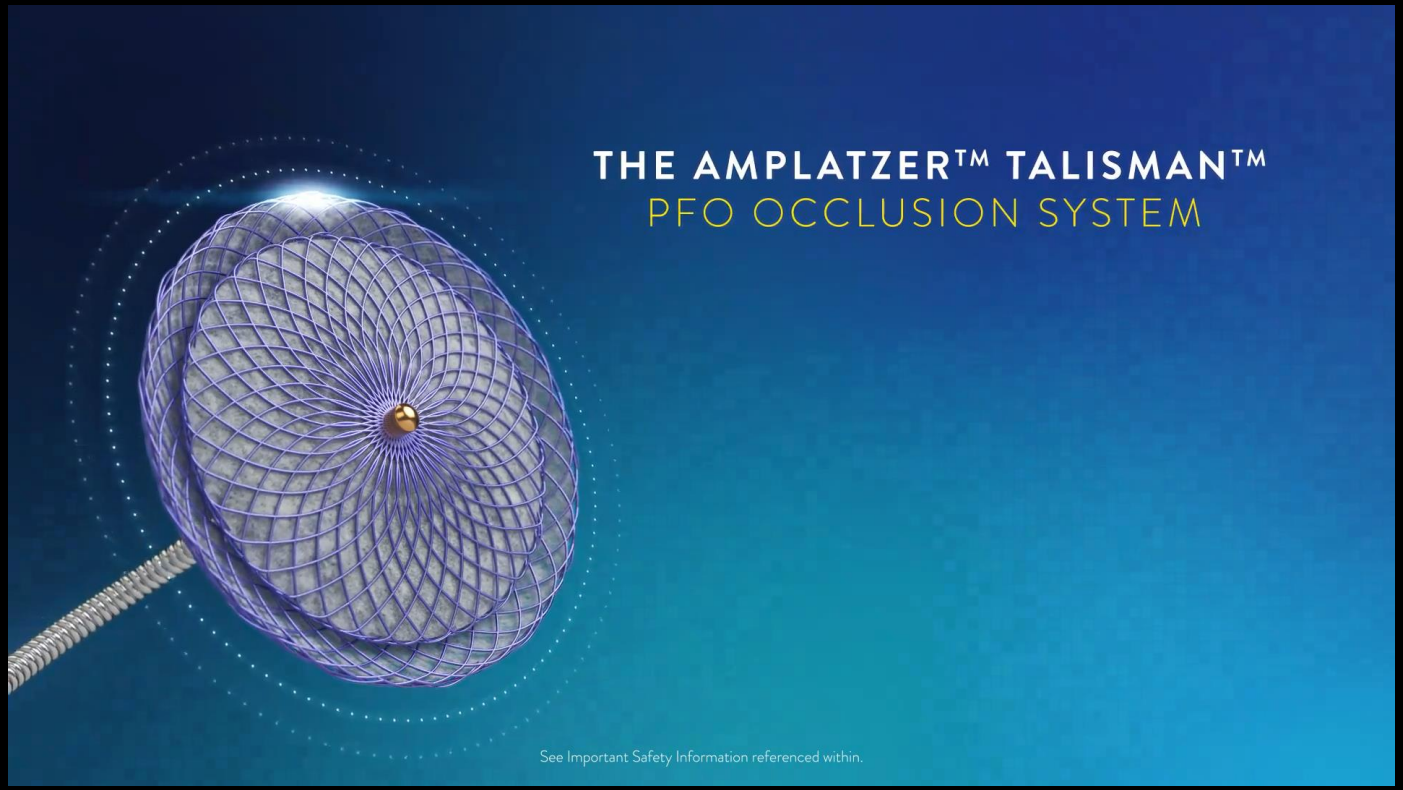


Play Video

Skip Video

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!

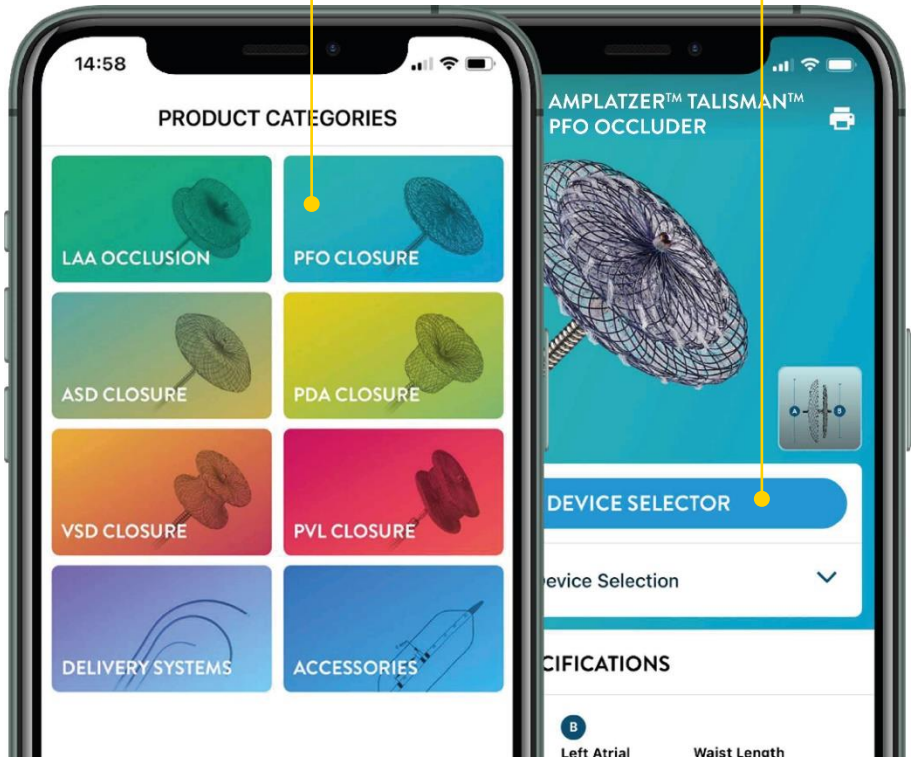
Download on the App Store

GET IT ON Google Play

See Important Safety Information referenced within.

FIRST, select PFO Closure

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

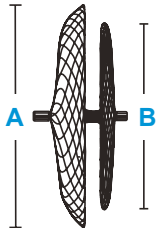


DEVICE SPECIFICATIONS

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

See Important Safety Information referenced within.

DEVICE SPECIFICATIONS

DEVICE SIZING GUIDELINES

PFO Morphology	Example Anatomical Characteristics	Suggested Amplatzer™ Talisman™ PFO Occluder Size (mm)
Simple PFO or PFO with a non-prominent ASA 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
Complex PFO 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
PFO with small anatomy 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[3], 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.

AMPLATZER™ TALISMAN™ PFO OCCLUDER

IMPORTANT SAFETY INFORMATION

Rx ONLY

INDICATIONS AND USAGE

The Amplatzer™ Talisman™ 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 stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude other causes of ischemic stroke.

CONTRAINDICATIONS

- Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained.
- Patients with intra-cardiac thrombus, mass, vegetation, or tumor.
- 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 required Amplatzer™ Talisman™ PFO device size would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.
- Patients with another source of right-to-left shunts, including an atrial septal defect and/or fenestrated septum.
- Patients with active endocarditis or other untreated infections.
- Patients who are unable to tolerate intra-procedural anticoagulation or post-procedural anti-platelet therapy.

WARNINGS

- Do not use an open or damaged pouch; do not use a damaged device.
- 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.
- The safety and effectiveness of the Amplatzer™ Talisman™ PFO Occluder has not been established in patients with a hypercoagulable state.
- Prepare for situations that require percutaneous or surgical removal of this device. This includes availability of a surgeon and access to operating room.
- 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.
- The Amplatzer™ Talisman™ 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.
- Transient hemodynamic compromise may be encountered during device placement, which may require fluid replacement or other medications as determined by the physician.
- Prior to device detachment, evaluate the position of the device relative to the free atrial wall and the aortic root using echocardiography.
- Use echocardiography to ensure that the device does not impinge on the free atrial wall or aortic root.
- 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 consider alternative treatments.
- DO NOT use the Amplatzer™ Talisman™ PFO Occluder after the Use-by date stated on the package label.
- This device was sterilized with ethylene oxide and is for single use only. Never reuse or re-sterilize the system. Use of expired, reused, or re-sterilized devices may result in infection. This device should be used only by physicians who are trained in standard transcatheter techniques.

PRECAUTIONS FOR SPECIAL POPULATIONS

- Pregnancy: The safety and effectiveness of this occluder has not been established during pregnancy. Fluoroscopic x-ray guidance is used during placement of the device. The risk of increased X-ray exposure for patients who are pregnant must be weighed against the potential benefits of this technique.
- Nursing mother: The safety and effectiveness of this occlude has not been established in lactating mothers. There has been no quantitative assessment for the presence of leachables in breast milk.
- Pediatric Population: The safety and effectiveness of this occluder has not been established in a pediatric population.

PRECAUTIONS

- Aspirin (325 mg/day) (or alternative antiplatelet/anticoagulant, if patient has aspirin intolerance) is recommended to be started at east 24 hours prior to the procedure.
- Antibiotics should be administered peri-procedurally.
- Patients should be fully heparinized throughout the procedure using adequate dosing so as to keep the activated clotting time (ACT) greater than 200 seconds. CAUTION: Intracardiac echocardiography (ICE) or transesophageal echocardiography (TEE) is recommended as an aid in evaluating the PFO and placing the Amplatzer™ Talisman™ PFO Occluder. If TEE is used, the patient's esophageal anatomy must be adequate for placement. CAUTION: Be cautious when using fluoroscopic X-ray guidance, which may be used during placement of the device. CAUTION: Do not use a power injection system to put contrast solution through the sheath.
- The safety and effectiveness of the Amplatzer™ Talisman™ 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 despit 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
  - Index stroke of poor outcome (modified Rankin score greater than 3)
  - Pregnancy at the time of implant
  - Multi-organ failure

PATIENT COUNSELING INFORMATION

Physicians should review the following information when counselling patients about the Amplatzer™ Talisman™ PFO Occluder and the implant procedure:

- The safety and effectiveness of PFO closure with the Amplatzer™ Talisman™ PFO Occluder in combination with the required postimplant antiplatelet therapy.
- PFO closure with the Amplatzer™ Talisman™ PFO Occluder can only reduce the risk for a recurrent stroke due to a paradoxical embolism through a PFO.
- With aging, there is an increased likelihood that non-PFO related risks for stroke may develop and cause a recurrent ischemic stroke independent of PFO closure.
- The procedural risks associated with Amplatzer™ Talisman™ PFO Occluder.
- The need for adherence to a defined adjunctive antithrombotic therapy following implantation of the Amplatzer™ Talisman™ PFO Occluder.
- Patients with a history of DVT or PE may benefit from continuation or resumption of anticoagulation therapy following implantation of the Amplatzer™ Talisman™ PFO Occluder to reduce the risk of recurrent DVT or PE.
- It is recommended that the medical team (neurologist and cardiologist) and the patient engage in a shared decision-making process and discuss the risks and benefits of PFO closure in comparison to using antithrombotic therapy alone, while taking into account the patient's values and preferences.

POTENTIAL 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 reaction/toxic effect due to: anesthesia, contrast media, medication, or metal
- Arrhythmia
- Arteriovenous fistulae
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Death
- Deep vein thrombosis
- Device embolization
- Device erosion
- Endocarditis
- Esophagus injury
- Fever
- Headache/migraine
- Hematoma
- Hypertension/hypotension
- Infection
- Myocardial infarction
- Pacemaker placement secondary to PFO device closure
- Pain
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pseudoaneurysm
- Pulmonary embolism
- Reintervention for residual shunt/device removal
- Stroke
- Transient ischemic attack
- Thrombus formation
- Valvular regurgitation
- Vascular access site injury
- Vessel perforation

AMPLATZER™ TALISMAN™ DELIVERY SHEATH

IMPORTANT SAFETY INFORMATION

Rx ONLY

INDICATIONS AND USAGE

The Amplatzer™ Talisman™ Delivery Sheath is indicated to provide a pathway through which an Amplatzer™ PFO Occluder is introduced for patent foramen ovale closure.

CONTRAINDICATIONS

- None known.

WARNINGS

- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use this device if the sterile package is open or damaged. Inspect all components before use. Do not use if the package or items appear to be damaged or defective.
- DO NOT use the Amplatzer™ Talisman™ Delivery Sheath after the Use-by date stated on the package label.
- This device should be used only by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that use this device.
- Use a hemostasis valve to impede blood backflow during the implant procedure.

PRECAUTIONS FOR SPECIAL POPULATIONS

- The physician should exercise clinical judgment in situations that involve the use of antithrombotic drugs before, during, and/or after the use of the delivery sheath.
- Use caution and rely on imaging guidance when advancing the sheath and dilator to minimize the risk of cardiovascular injury or interference with previously implanted medical devices. Whenever possible, advance the sheath and dilator over a guidewire.
- Do not attempt to use a guidewire larger than the maximum diameter specified in the Directions for Use.
- Do not use a power injection system to put contrast solution through the sheath.
- Remove the dilator and sheath from the patient slowly to prevent an ingress of air.

POTENTIAL ADVERSE EVENTS

- Potential adverse events that may occur during or after a procedure using this delivery sheath may include, but are not limited to:
- Allergic reaction/toxic effects due to hypersensitivity to contrast
- agent, anesthesia, device materials, or drugs used to minimize blood clot formation
- Arrhythmia
- Arteriovenous fistulae
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Cardiovascular injury
- Death
- Dissection
- Embolism (air, foreign body, and peripheral)
- Hematoma
- Infection
- Myocardial infarction
- Pericardial effusion
- Thromboembolism
- Thrombosis
- Vascular access site injury

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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 or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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