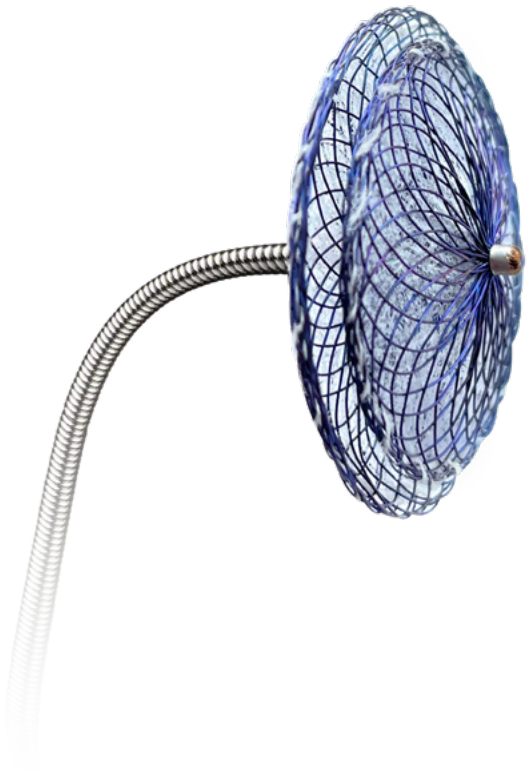
AMPLATZER™ TALISMAN™ PFO OCCLUDER



INDICATION FOR USE

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 who have had an ischemic stroke due to a presumed paradoxical embolism.

PRODUCT HIGHLIGHTS

MR Conditional Information

Non-clinical testing has demonstrated the Amplatzer™ Talisman™ PFO Occluder is MR Conditional. A patient with the Amplatzer™ Talisman™ PFO Occluder can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

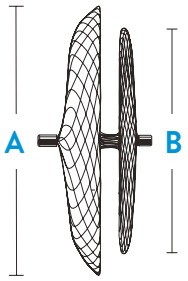
Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 3ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 16 mm from the Amplatzer™ Talisman™ PFO Occluder when imaged with a gradient echo pulse sequence in a 3.0T MR system.

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

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 25 mm 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 25 mm 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 25 mm 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[1], 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.

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.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, referencethe 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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Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA
www.structuralheart.abbott

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