

AMPLATZER™ AMULET™

LEFT ATRIAL APPENDAGE OCCLUDER



INDICATION

The AMPLATZER™ Amulet™ left atrial appendage occluder is a percutaneous transcatheter device intended to prevent thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation.

PRODUCT BENEFITS

The AMPLATZER™ Amulet™ left atrial appendage occluder leverages the proven design of the AMPLATZER™ Cardiac Plug

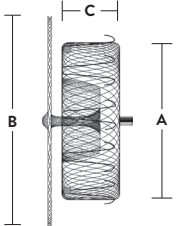
- Designed to completely seal the orifice of the LAA
- Provides secure placement in a shallow landing zone*
- Can be recaptured and repositioned

Second-generation platform intended to improve ease of preparation and device delivery.

- Pre-loaded design for simpler device preparation
- Longer waist designed to allow for more positional forgiveness in the LAA
- Broader size range to cover more LAA anatomy

DEVICE SPECIFICATIONS

AMPLATZER™ Amulet™ Left Atrial Appendage Occluder

	Model/Reorder Number	Size/Lobe Diameter (mm) (A)	Disc Diameter (mm) (B)	Lobe Length (mm) (C)	Waist Length (mm)
	9-ACP2-007-016	16	22	7.5	5.5
	9-ACP2-007-018	18	24	7.5	5.5
	9-ACP2-007-020	20	26	7.5	5.5
	9-ACP2-007-022	22	28	7.5	5.5
	9-ACP2-010-025	25	32	10	8
	9-ACP2-010-028	28	35	10	8
	9-ACP2-010-031	31	38	10	8
	9-ACP2-010-034	34	41	10	8

ACCESSORIES

AMPLATZER™ Amulet™ Delivery Sheath

Model/Reorder Number	Sheath Size
DS-TV45X45-12F-080	12 F
DS-TV45X45-14F-080	14 F

AMPLATZER™ Guidewire

Model/Reorder Number	Diameter (in)
9-GW-002	0.035

MRI CONDITIONAL INFORMATION

Through non-clinical testing, AMPLATZER™ devices have been shown to be MR Conditional. A patient with an implanted AMPLATZER device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 tesla or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

During testing, the device produced a clinically nonsignificant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-tesla MR system using a transmit/receive body coil.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

LATEX-FREE INFORMATION

Does not contain natural rubber latex components.

*Accomplished with a lobe designed to conform to the inner wall of the left atrial appendage, only requiring a minimum depth of 10-12 mm for deployment.

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