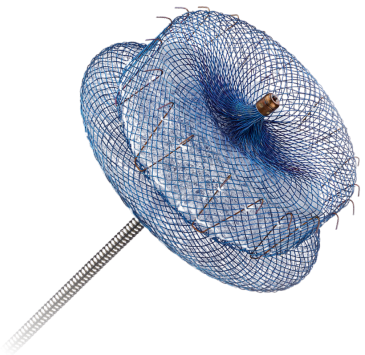
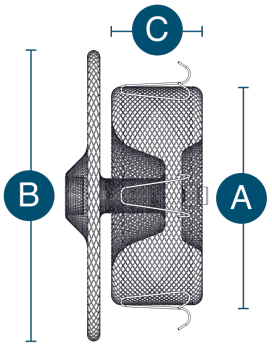
Abbott

AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER COPY



DIMENSIONES Y SELECCIÓN DEL DISPOSITIVO

Identifique y mida la orejuela auricular izquierda en la zona de despliegue (definida como unos 10-12 mm desde el orificio) para el lóbulo del dispositivo a fin de determinar el tamaño de dispositivo adecuado para ocluir la orejuela auricular izquierda.



MODEL SPECIFICATIONS

Model/Reorder No.	Tamaño de vaina recomendado	Diámetro del lóbulo A	Diámetro del disco B	Longitud del lóbulo C
9-ACP2-007-016	12F o 14F con adaptador	16 mm	22 mm	7.5 mm
9-ACP2-007-018	12F o 14F con adaptador	18 mm	24 mm	7.5 mm
9-ACP2-007-020	12F o 14F con adaptador	20 mm	26 mm	7.5 mm
9-ACP2-007-022	12F o 14F con adaptador	22 mm	28 mm	7.5 mm
9-ACP2-010-025	12F o 14F con adaptador	25 mm	32 mm	10 mm
9-ACP2-010-028	14F	28 mm	35 mm	10 mm
9-ACP2-010-031	14F	31 mm	38 mm	10 mm
9-ACP2-010-034	14F	34 mm	41 mm	10 mm

TECHNICAL PRODUCT INFORMATION

Condicional a RM

En ensayos preclínicos se ha demostrado que los dispositivos Amplatzer™ son de tipo Condicional a RM. Un paciente que tenga implantado un dispositivo Amplatzer™ puede someterse a exploraciones sin peligro inmediatamente después de la implantación, si se cumplen las siguientes condiciones:

- Campo magnético estático de 3 tesla o inferior
- Campo magnético de gradiente espacial de 720 G/cm o inferior
- Máxima tasa de absorción específica (SAR) comunicada para el sistema de RM promediada para todo el cuerpo de 3 W/kg para exploraciones de 15 minutos

Durante las pruebas, el dispositivo produjo un aumento de temperatura clínicamente no significativo a una máxima tasa de absorción específica (SAR) comunicada para el sistema de RM promediada para todo el cuerpo de 3 W/kg durante exploraciones de 15 minutos realizadas en un sistema de RM de 3 tesla con una bobina de cuerpo de transmisión/recepción.

La calidad de las imágenes de RM podría verse afectada si la zona de interés se encuentra exactamente en la misma posición que el dispositivo o relativamente cerca del mismo. Por tanto, podría ser necesario optimizar los parámetros de adquisición de imágenes de RM teniendo en consideración la presencia de este dispositivo.

#package_label#

RECOMMENDED ACCESSORIES

VAINA DE LIBERACION AMPLATZER™ TORQVUE™ 45° X 45°

Model/Reorder No.	Tamaño de vaina	Curva de punta	Diámetro interior de la vaina	Diámetro exterior de la vaina	Longitud útil
TV45x45- 12F-080	12 F	45° x 45°	4.00/0.16 mm/pulgadas	4.80/0.19 mm/pulgadas	80 cm
TV45x45- 14F-080	14 F	45° x 45°	4.80/0.19 mm/pulgadas	5.50/0.22 mm/pulgadas	80 cm

Model/Reorder No.	Uso para	Diámetro	Cuerpo	Longitud de la punta blanda	Descripción de la punta	Longitud útil
9-GW-002	LAAO/ASD/PFO	0.035 pulgadas	Super rígido	5 cm	1.5 mm, punta en J modificada	260 cm

VAINA DE LIBERACIÓN DIRIGIBLE AMPLATZER™

Model/Reorder No.	Tamaño de vaina	Diámetro interior	Diámetro exterior	Longitud útil	Longitud
ASDS-14F-075	14 F	4.7/0.184 mm/in	6.0/0.238 mm/in	75.0/29.5 mm/in	98.5/38.8 mm/in

INFORMACIÓN IMPORTANTE SOBRE SEGURIDAD

INDICATION FOR USE

The Amplatzer™ Amulet™ Left Atrial Appendage Occluder is a percutaneous transcatheter device intended to reduce the risk of thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation and who are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores, are suitable for short term anticoagulation therapy, and have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.

CONTRAINDICATIONS

The Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder is contraindicated for patients:

• with the presence of intracardiac thrombus.

• with active endocarditis or other infections producing bacteremia.

• where placement of the device would interfere with any intracardiac or intravascular structures.

WARNINGS

• If the device is retracted while it is in the sheath, the device and the sheath must both be removed and replaced. Failure to replace both the device and the sheath may result in sheath and/or device malfunction.

• If the device is retracted farther than the radiopaque markers (fully recaptured), the device and the sheath must both be removed and replaced. Failure to replace both the device and the sheath may result in sheath and/or device malfunction.

• Physicians must be prepared to deal with urgent situations, such as pericardial effusion or device embolization, which can require removal of the device.

• 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.

• Late pericardial effusion events were observed in the clinical study. The use of post-procedure anticoagulation therapy may be associated with an increased potential for a late pericardial effusion. Physicians should monitor for signs and symptoms of pericardial effusion and obtain appropriate imaging when indicated. Physicians should also consider routine echocardiography to screen for pericardial effusion.

• Remove embolized devices. Do not remove an embolized device unless the device is fully captured inside a sheath.

• The Amplatzer™ Amulet™ device contains 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 120 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 seek medical assistance immediately if they suspect they are experiencing an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.

• Do not use this device if the sterile package is open or damaged.

• The 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.

• Use on or before the expiration date that is printed on the product packaging label.

PRECAUTIONS

• The physician should exercise clinical judgment in situations that involve the use of antithrombotic drugs before, during, and/or after the use of this device.

• The physician should exercise caution if implanting a device in a patient who has an implantable cardioverter defibrillator (ICD) or pacemaker leads.

• The physician should have the guidewire in the left upper pulmonary vein when making exchanges in the left atrium.

• Ensure that the vasculature is adequate for the sheath size being selected.

• The physician should exercise caution if performing ablation at or near the implant site after the device is implanted.

• Use standard interventional cardiovascular catheterization techniques when using Amplatzer™ products.

• Use in specific populations

- Pregnancy – Minimize the radiation exposure to the fetus and the mother.

- Nursing mothers – There has been no quantitative assessment for the presence of leachables in breast milk.

MRI Safety Information

Non-clinical testing has demonstrated that the Amplatzer™ Amulet™ Left Atrial Appendage Occluder device is MR Conditional.

A patient with the Amplatzer™ Amulet™ device can be safely scanned in an MR system under the following conditions:

- Static magnetic fields of 1.5 Tesla (1.5T) and 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 4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 20 mm from the device when imaged with a gradient echo pulse sequence in a 3.0T MR system.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the device or implant procedure include, but are not limited to, the following:

• Air embolism
• Airway trauma
• Allergic reaction
• Anemia
• Anesthesia reaction (nausea, vasovagal reaction, confusion/altered mental status or other)
• Arrhythmia
• Atrial septal defect
• Bleeding
• Cardiac arrest
• Cardiac tamponade
• Chest pain/discomfort
• Congestive heart failure
• Death
• Device embolization
• Device erosion
• Device malfunction
• Device malposition
• Device migration
• Device related thrombus
• Fever
• Hematuria
• Hypertension/hypotension
• Multi-organ failure
• Myocardial infarction
• Perforation
• Pericardial effusion
• Pleural effusion
• Renal failure/dysfunction
• Respiratory failure
• Seizure
• Significant residual flow
• Stroke
• Thrombocytopenia
• Thromboembolism: peripheral and pulmonary
• Thrombus formation
• Transient ischemic attack
• Valvular regurgitation/insufficiency
• Vascular access site injury (hematoma, pseudoaneurysm, arteriovenous fistula, groin pain or other)
•Vessel trauma/injury