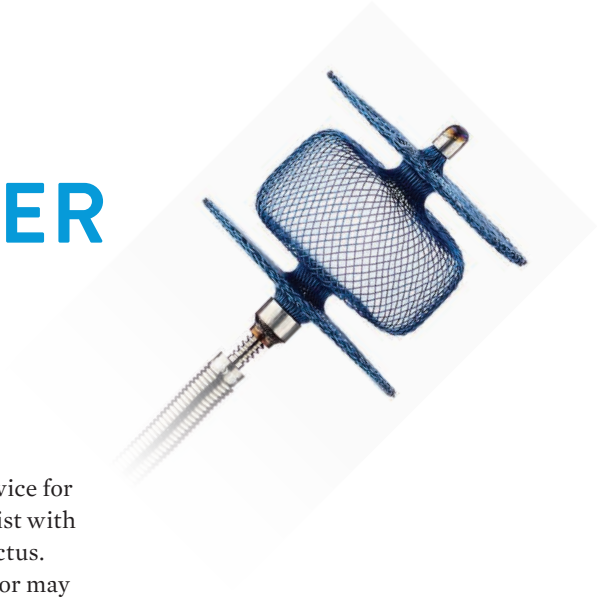
AMPLATZER PICCOLO™ OCCLUDER



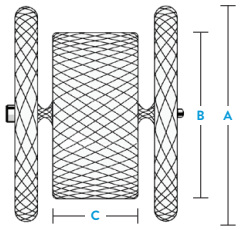
DEVICE DESCRIPTION

The Amplatzer Piccolo™ Occluder is a self-expanding, nitinol mesh occlusion device for use in a patent ductus arteriosus (PDA). The device configuration is a central waist with two retention discs. The central waist is designed to be positioned within the ductus. The retention discs are deployed in the pulmonary and aortic ends of the ductus or may be deployed completely within the duct when treating small infants. The device may be delivered via an anterograde (venous) or a retrograde (arterial) approach. Radiopaque marker bands at each end of the occluder permit visibility during fluoroscopy.

INDICATIONS AND USAGE

The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA). For patients with a weight 700 grams and up at time of the procedure.

DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY



Amplatzer Piccolo™ Occluder

Model Number	A Retention Disc Diameter mm (in)	B Waist Diameter mm (in)	C Length Between Retention Discs mm (in)
9-PDAP-03-02-L	4.00 (0.157)	3.00 (0.118)	2.00 (0.079)
9-PDAP-03-04-L	4.00 (0.157)	3.00 (0.118)	4.00 (0.157)
9-PDAP-03-06-L	4.00 (0.157)	3.00 (0.118)	6.00 (0.236)
9-PDAP-04-02-L	5.25 (0.207)	4.00 (0.157)	2.00 (0.079)
9-PDAP-04-04-L	5.25 (0.207)	4.00 (0.157)	4.00 (0.157)
9-PDAP-04-06-L	5.25 (0.207)	4.00 (0.157)	6.00 (0.236)
9-PDAP-05-02-L	6.50 (0.256)	5.00 (0.197)	2.00 (0.079)
9-PDAP-05-04-L	6.50 (0.256)	5.00 (0.197)	4.00 (0.157)
9-PDAP-05-06-L	6.50 (0.256)	5.00 (0.197)	6.00 (0.236)

Amplatzer™ TorqVue™ LP Catheter

Model Number	Profile	Inner Diameter mm (in)	Outer Diameter mm (in)
9-TVLPC4F90/080	4 F	1.17 (0.046)	1.4 (0.055)

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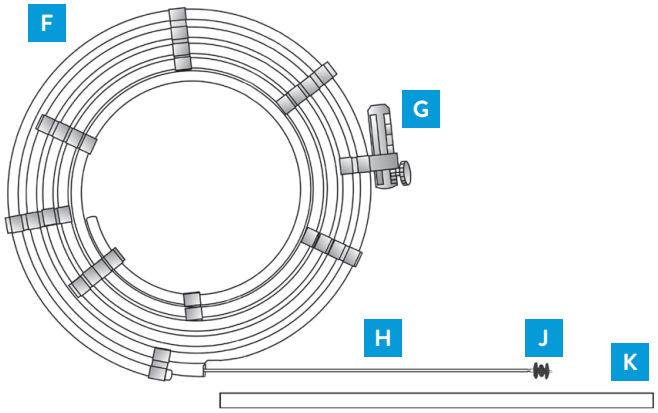
PACKAGING INFORMATION



F. Hoop dispenser
G. Vise
H. Delivery wire
J. Occluder
K. Occluder protector tube

Note that the device and the delivery system are being sold separately.

ASSOCIATED PRODUCT

Amplatzer™ Guidewire

Model Number	Outer Diameter mm (in)	Body Type	Tip Guidewire Type	Length cm
9-GW-001	0.035	Extra-stiff	7,5mm modified J-TipFixed Body	260

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the Amplatzer™ device is MR Conditional. A patient with an implanted Amplatzer™ device can be scanned safely in an MR system 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 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

These Amplatzer™ products do not contain latex.

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