

AMPLATZER PICCOLO™ OCCLUDER



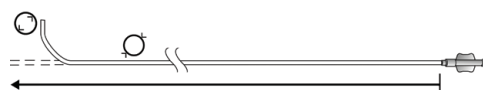
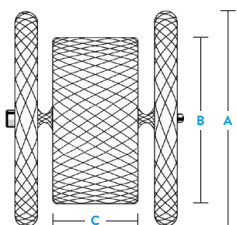
DEVICE DESCRIPTION

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 antegrade (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

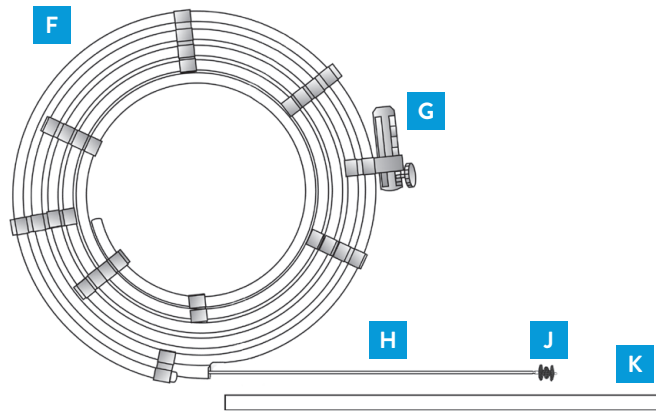


Amplatzer Piccolo™ Occluder

Amplatzer™ TorqVue™ LP Catheter

Model Number	A Retention Disc Diameter mm (in)	B Waist Diameter mm (in)	C Length Between Retention Discs mm (in)	Model Number	Profile	Inner Diameter mm (in)	Outer Diameter mm (in)
9-PDAP-03-02-L	4.00 (0.157)	3.00 (0.118)	2.00 (0.079)	9-TVLPC4F90/080	4 F	1.17 (0.046)	1.4 (0.055)
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)				

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

Under the scan conditions defined above the Amplatzer™ device is expected to produce a maximum temperature rise of less than 2.5 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 0.9 cm from the implant when imaged with a gradient echo pulse sequence and a 3.0T MRI system and 0.6 cm when imaged with a gradient echo pulse sequence and a 1.5T MRI system.

LATEX-FREE INFORMATION

These Amplatzer™ products do not contain latex.

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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. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott. Information contained herein for DISTRIBUTION in Europe, Middle East and Africa ONLY. Please check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force.

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