AMPLATZER™ DUCT OCCLUDERS

INDICATIONS

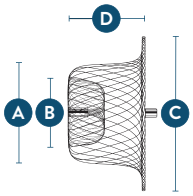
The Amplatzer™ Duct Occluder and Amplatzer™ Duct Occluder II are percutaneous, transcatheter occlusion devices intended for the nonsurgical closure of a patent ductus arteriosus (PDA) in patients with a weight of 6 kg or larger.

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

MRI SAFETY INFORMATION

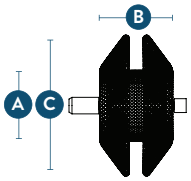
Through nonclinical testing, Amplatzer™ devices have been shown to be MR Conditional. Refer to the appropriate Instructions for Use to obtain more detailed MRI scanning information.

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.



DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

Amplatzer™ Duct Occluder					Amplatzer™ TorqVue™ 180° Delivery System			
Model/ Reorder Number	Device Diameter at Descending Aorta (mm) A	Device Diameter at Pulmonary Artery (mm) B	Retention Skirt Diameter (mm) C	Device Length (mm) D	Model/Reorder Number	Minimum Recommended Sheath Size	Sheath Inner Diameter (mm [inch])	Sheath Outer Diameter (mm [inch])
9-PDA-003	5	4	9	5	9-ITV05F180/60	5 F	1.83 [0.072]	2.51 [0.099]
9-PDA-004	6	4	10	7				
9-PDA-005	8	6	12	7	9-ITV06F180/80	6 F	2.11 [0.083]	2.79 [0.110]
9-PDA-006	10	8	16	8				
9-PDA-007	12	10	18	8				
9-PDA-008	14	12	20	8	9-ITV07F180/80	7 F	2.44 [0.096]	3.18 [0.125]
9-PDA-009	16	14	22	8				

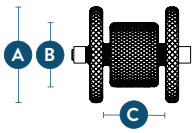


DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

Amplatzer™ Duct Occluder II

Amplatzer™ TorqVue™ LP Delivery System

Model/Reorder Number	Waist Diameter (mm) A	Device Length (mm) B	Disc Diameter (mm) C	Model/Reorder Number	Minimum Recommended Catheter Size	Catheter Inner Diameter (mm [inch])	Catheter Outer Diameter (mm [inch])
9-PDA2-03-04	3	4	9				
9-PDA2-03-06	3	6	9	9-TVLP4F90/060 or 9-TVLP4F90/080	4 F	1.17 [0.046]	1.40 [0.055]
9-PDA2-04-04	4	4	10				
9-PDA2-04-06	4	6	10				
9-PDA2-05-04	5	4	11				
9-PDA2-05-06	5	6	11	9-TVLP5F90/060 or 9-TVLP5F90/080	5 F	1.50 [0.059]	1.73 [0.068]
9-PDA2-06-04	6	4	12				
9-PDA2-06-06	6	6	12				



DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

Amplatzer Piccolo™ Occluder

Amplatzer™ TorqVue™ LP Catheter

Model/Reorder Number	Disc Diameter (mm) A	Waist Diameter (mm) B	Length between discs (mm) C	Model/Reorder Number	Minimum Recommended Catheter Size	Catheter Inner Diameter (mm [inch])	Catheter Outer Diameter (mm [inch])
9-PDAP-03-02-L	4.00	3.00	2.00				
9-PDAP-03-04-L	4.00	3.00	4.00				
9-PDAP-03-06-L	4.00	3.00	6.00				
9-PDAP-04-02-L	5.25	4.00	2.00				
9-PDAP-04-04-L	5.25	4.00	4.00	9-TVLPC4F90/080	4 F	1.17 [0.046]	1.40 [0.055]
9-PDAP-04-06-L	5.25	4.00	6.00				
9-PDAP-05-02-L	6.50	5.00	2.00				
9-PDAP-05-04-L	6.50	5.00	4.00				
9-PDAP-05-06-L	6.50	5.00	6.00				

ANCILLARY PRODUCT SPECIFICATIONS

Amplatzer™ Guidewire

Model/Reorder Number	Diameter (inch)	Body	Tip Description	Useable Length (cm)
9-GW-001	0.035	Super Stiff	7.5 mm, Modified J-tip	260

LATEX-FREE INFORMATION

These Amplatzer™ products do not contain latex.

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.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.
Always check the regulatory status of the device in your region.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.
Photo(s) on file at Abbott.

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