

AMPLATZER™ Duct Occluders

Structural Heart Therapy



INDICATIONS

The AMPLATZER Duct Occluder, AMPLATZER Duct Occluder II and AMPLATZER Duct Occluder II Additional Sizes are percutaneous, transcatheter occlusion devices intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

MRI SAFETY INFORMATION

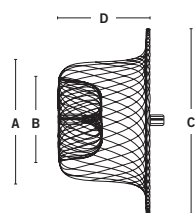
Through non-clinical testing, AMPLATZER devices have been shown to be MR Conditional. A patient with an implanted AMPLATZER device can be scanned under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning

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

DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

AMPLATZER Duct Occluder



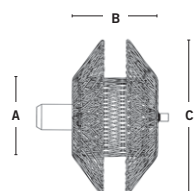
Model / Reorder Number	[A] Device Diameter at Descending Aorta (mm)	[B] Device Diameter at Pulmonary Artery (mm)	[C] Retention Skirt Diameter (mm)	[D] Device Length (mm)
9-PDA-003	5	4	9	5
9-PDA-004	6	4	10	7
9-PDA-005	8	6	12	7
9-PDA-006	10	8	16	8
9-PDA-007	12	10	18	8
9-PDA-008 ^a	14	12	20	8
9-PDA-009 ^a	16	14	22	8

AMPLATZER TorqVue™ 180° Delivery System

Model / Reorder Number	Minimum Recommended Sheath Size	Sheath Inner Diameter (mm [inch])	Sheath Outer Diameter (mm [inch])
9-ITV05F180/60	5 F	1.83 [0.072]	2.51 [0.099]
9-ITV06F180/60 or 9-ITV06F180/80	6 F	2.11 [0.083]	2.79 [0.110]
9-ITV07F180/80	7 F	2.44 [0.096]	3.18 [0.125]

a. Not available for sale in the U.S. Not available in all countries.

AMPLATZER Duct Occluder II^a



Model / Reorder Number	[A] Waist Diameter (mm)	[B] Device Length (mm)	[C] Disc Diameter (mm)
9-PDA2-03-04	3	4	9
9-PDA2-03-06	3	6	9
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-PDA2-06-04	6	4	12
9-PDA2-06-06	6	6	12

AMPLATZER TorqVue LP Delivery System^a

Model / Reorder Number	Minimum Recommended Catheter Size	Catheter Inner Diameter (mm [inch])	Catheter Outer Diameter (mm [inch])
9-TVLP4F90/060 or 9-TVLP4F90/080	4 F	1.17 [0.046]	1.40 [0.055]
9-TVLP5F90/060 or 9-TVLP5F90/080	5 F	1.50 [0.059]	1.73 [0.068]

a. Not available for sale in the U.S. Not available in all countries.

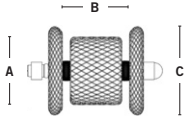


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AMPLATZER Duct Occluder II
Additional Sizes^a

AMPLATZER TorqVue LP Catheter^a



Model / Reorder Number	[A] Waist Diameter (mm)	[B] Length Between Retention Discs (mm)	[C] Disc Diameter (mm)
9-PDA2AS-03-02-L	3	2	4.00
9-PDA2AS-03-04-L	3	4	4.00
9-PDA2AS-03-06-L	3	6	4.00
9-PDA2AS-04-02-L	4	2	5.25
9-PDA2AS-04-04-L	4	4	5.25
9-PDA2AS-04-06-L	4	6	5.25
9-PDA2AS-05-02-L	5	2	6.50
9-PDA2AS-05-04-L	5	4	6.50
9-PDA2AS-05-06-L	5	6	6.50

Model / Reorder Number	Minimum Recommended Catheter Size	Catheter Inner Diameter (mm [inch])	Catheter Outer Diameter (mm [inch])
9-TVLPC4F90/080	4 F	1.17 [0.046]	1.40 [0.055]

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ANCILLARY PRODUCT SPECIFICATIONS

AMPLATZER Guidewire

Model / Reorder Number	Diameter (inch)	Body	Tip Description	Usable 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.

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Products referenced are approved for CE Mark. May not be available for sale in the U.S. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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