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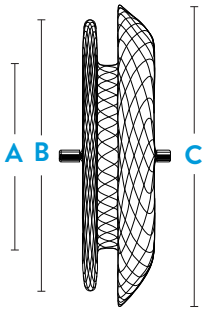
AMPLATZER™ Septal Occluder
Structural Heart Therapy

INDICATIONS

The AMPLATZER™ Septal Occluder is a percutaneous, transcatheter atrial septal defect closure device intended for the occlusion of atrial septal defects (ASDs) in secundum position or patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration.

Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular (RV) volume overload (i.e., 1.5:1 degree of left-to-right shunt or RV enlargement).



DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

AMPLATZER™ Septal Occluder					AMPLATZER™ TorqVue™ 45° x 45° Delivery System			
Model/Reorder Number	Device Size/Waist Diameter (mm) A	Right Atrial Disc Diameter (mm) B	Left Atrial Disc Diameter (mm) C	Waist Length (mm)	Model/Reorder Number	Minimum Recommended Sheath Size	Inner Diameter of Sheath (mm/inch)	Outer Diameter of Sheath (mm/inch)
9-ASD-004	4	12	16	3	9-ITV06F45/60	6 F, 45° Curve	2.11/0.08	2.79/0.11
9-ASD-005	5	13	17	3				
9-ASD-006	6	14	18	3				
9-ASD-007	7	15	19	3				
9-ASD-008	8	16	20	3				
9-ASD-009	9	17	21	3				
9-ASD-010	10	18	22	3				
9-ASD-011	11	21	25	4	9-ITV07F45/60 OR 9-ITV07F45/80	7 F, 45° Curve	2.44/0.10	3.18/0.13
9-ASD-012	12	22	26	4				
9-ASD-013	13	23	27	4				
9-ASD-014	14	24	28	4				
9-ASD-015	15	25	29	4				
9-ASD-016	16	26	30	4				
9-ASD-017	17	27	31	4				
9-ASD-018	18	28	32	4	9-ITV08F45/60 OR 9-ITV08F45/80	8 F, 45° Curve	2.69/0.11	3.45/0.14
9-ASD-019	19	29	33	4				
9-ASD-020	20	30	34	4	9-ITV09F45/80	9 F, 45° Curve	3.00/0.12	3.81/0.15
9-ASD-022	22	32	36	4				
9-ASD-024	24	34	38	4				
9-ASD-026	26	36	40	4	9-ITV10F45/80	10 F, 45° Curve	3.30/0.13	4.14/0.16
9-ASD-028	28	38	42	4				
9-ASD-030	30	40	44	4				

DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY CONT.

AMPLATZER™ Septal Occluder

Model/Reorder Number	Device Size/Waist Diameter (mm) A	Right Atrial Disc Diameter (mm) B	Left Atrial Disc Diameter (mm) C	Waist Length (mm)
9-ASD-032	32	42	46	4
9-ASD-034	34	44	50	4
9-ASD-036	36	46	52	4
9-ASD-038	38	48	54	4
9-ASD-040	40	50	56	4

AMPLATZER™ TorqVue™ 45° x 45° Delivery System

Model/Reorder Number	Minimum Recommended Sheath Size	Inner Diameter of Sheath (mm/inch)	Outer Diameter of Sheath (mm/inch)
9-ITV12F45/80	12 F, 45° Curve	3.99/0.16	4.80/0.19

ANCILLARY PRODUCT SPECIFICATIONS

AMPLATZER™ Sizing Balloon II

Model/Reorder Number	Maximum Defect Size (mm)	Maximum Inflation Volume (cc)	Balloon Length (cm)	Shaft Size	Useable Length (cm)	Guidewire (inch)
9-SB-018	20	15	3.5	6 F	70	0.035
9-SB-024	27	30	4.5	7 F	70	0.035
9-SB-034	40	90	5.5	8 F	70	0.035

AMPLATZER™ Guidewire

Model/Reorder Number	Diameter (inch)	Body	Floppy Tip Length (cm)	Tip Description	Useable Length (cm)
9-GW-002	0.035	Super Stiff	5	1.5 mm, Modified J-tip	260

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 safely immediately after placement of the device 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 non-significant 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 as 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 natural rubber latex components.

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 https://manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Information contained herein for **DISTRIBUTION in Europe, Middle East and Africa ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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