AMPLATZER®

Septal Occluder and Delivery System

Instructions for Use

Device Description

The AMPLATZER Septal Occluder is a self-expanding double-disc nitinol mesh occlusion device. The 2 discs are connected by a short waist that relates to the defect size. Polyester fabric is securely sewn to each disc to increase occlusion. The device has radiopaque marker bands for use under fluoroscopy.

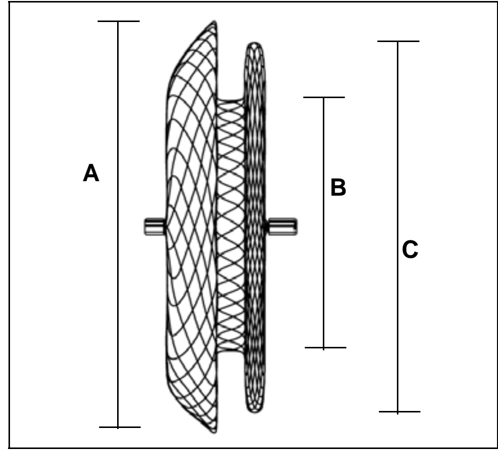

Figure 1. AMPLATZER Septal Occluder components.

A. Left atrial disc.
B. Device waist.
C. Right atrial disc.

The AMPLATZER Delivery System is intended to facilitate the attachment, loading, delivery, and deployment of the AMPLATZER Septal Occluder device. See Figure 2 for the delivery system components.

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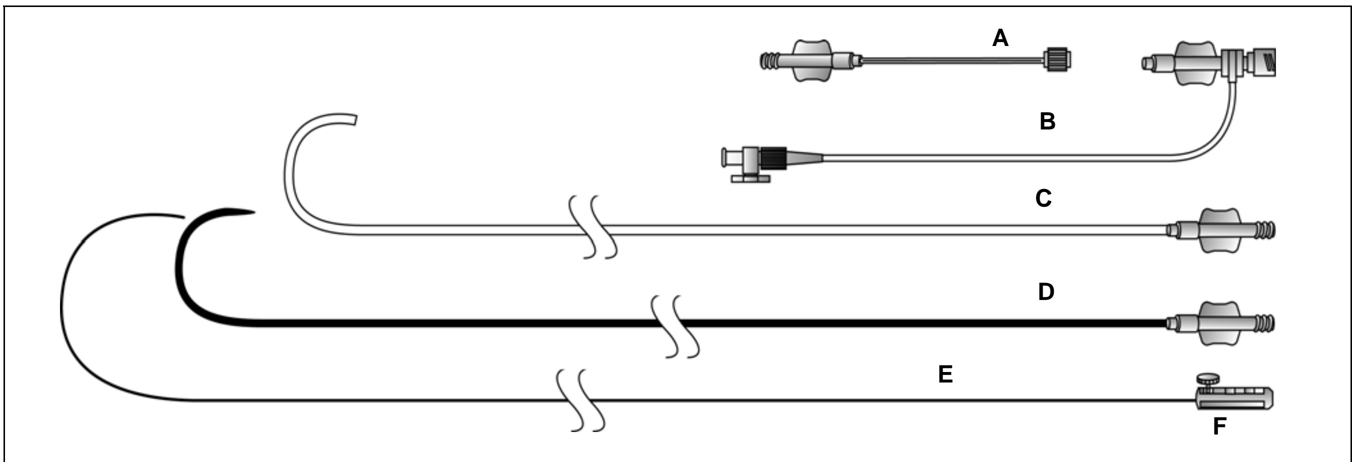

Figure 2. AMPLATZER Delivery System.

A. Loader – used to introduce the AMPLATZER Septal Occluder into the delivery sheath.
B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls back-bleeding.
C. Delivery sheath – Provides a pathway through which a device is delivered.
D. Dilator – used to ease penetration of tissue.
E. Delivery cable – the device is screwed onto the distal tip of the delivery cable, which allows for placement (and if necessary, retrieval) of the device.
F. Plastic vise (optional) – Attaches to the delivery cable, serving as a "handle" for detaching (unscrewing) the delivery cable from a device.

Indications for Use

The AMPLATZER Septal Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) 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 volume overload (i.e., 1.5:1 degree of left-to-right shunt or RV enlargement).

Contraindications

The AMPLATZER Septal Occluder is contraindicated for the following:

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- Any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another antiplatelet agent can be administered for 6 months.
- Any patient known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- Any patient whose size (i.e., too small for transesophageal echocardiography probe, catheter size, etc.) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.
- Any patient where the margins of the defect are less than 5 mm to the coronary sinus, AV valves, or right upper lobe pulmonary vein.

Warnings

- Patients who are allergic to nickel may have an allergic reaction to this device.
- Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon.
- Embolized devices must be removed as they may disrupt critical cardiac functions. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within the sheath.
- Use on or before the last day of the expiration month noted on the product packaging.
- This device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
- Do not use the device if the packaging sterile barrier is open or damaged.

- Do not release the AMPLATZER Septal Occluder from the delivery cable if the device does not conform to its original configuration or if the device position is unstable. Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device.
- Implantation of this device may not supplant the need for Coumadin in patients with ASD and paradoxical emboli.
- The use of echocardiographic imaging (TTE, TEE, or ICE) is required.
- Balloon sizing should be used to size the atrial septal defect using a stop-flow technique. Do not inflate the balloon beyond the cessation of the shunt (i.e., stop-flow). DO NOT OVERINFLATE.
- Do not select a device size greater than 1.5 times the echocardiographic-derived ASD diameter prior to balloon sizing.

Precautions

- The use of this device has not been studied in patients with patent foramen ovale.
- Use standard interventional cardiac catheterization techniques to place this device.

Handling

- Store in a dry place.

Patient Selection

- Certain patients may be at higher risk for complications such as tissue erosion and device embolization. If higher risk patients have devices implanted, closer follow-up is warranted (reference section 12). Higher risk patients include the following:
  - Patients with deformation of the device at the aortic root.
  - Patients with high defects (minimal aortic and superior rims).
  - Patients with IVC rim deficiency (risk of device embolization).

Procedural

- This device should only be used by physicians who have been trained in transcatheter techniques and who should determine which patients are suitable candidates for procedures using this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.
- Aspirin (e.g., 81 mg or 325 mg) or an alternative antiplatelet/anticoagulant is recommended to be started at least 24 hours prior to the procedure. Cephalosporin therapy is optional.
- Maintain a recommended minimum active clotting time (ACT) of 200 seconds prior to device insertion and throughout the procedure.
- If TEE is used, the patient's esophageal anatomy must be adequate for placement and manipulation of the TEE probe.

Post-Implant

- Patients should take appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician.
- Patients should be treated with antiplatelet/anticoagulation therapy (such as aspirin) for 6 months post-implant. The decision to continue antiplatelet/anticoagulation therapy beyond 6 months is at the discretion of the physician.
- Use in Specific Populations
  - Pregnancy - Care should be taken to minimize the radiation exposure to the fetus and the mother.
  - Nursing Mothers - There has been no quantitative assessment of the presence of leachables from the device/ procedure in breast milk, and the risk to nursing mothers is unknown.
- MR Conditional

  Non-clinical testing has demonstrated that the AMPLATZER Septal Occluder device is MR Conditional. It can be scanned safely under the following conditions:
  - Static magnetic field of 3 tesla
  - Spatial gradient magnetic field of 720 G/cm or less
  - Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning.

  In non-clinical testing, the AMPLATZER Septal Occluder device produced a temperature rise of 1.1°C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.83 W/kg as assessed by calorimetry for 20 minutes of MR scanning in a 5-tesla Magnex Scientific MR scanner.

  The same device produced a temperature rise of 1.6°C at a maximum whole-body averaged SAR of 5.57 W/kg as assessed by calorimetry for 20 minutes of MR scanning in a 1.5-tesla Magnex Scientific MR scanner.

  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 of MR imaging parameters for the presence of this implant.

Potential Adverse Events

Potential adverse events may occur during or after a procedure placing this device may include, but are not limited to:

- Air embolus
- Allergic dye reaction
- Anesthesia reactions
- Apnea
- Death
- Fever
- Hypertension/hypotension
- Infection including endocarditis
- Perforation of vessel or myocardium
- Pseudoaneurysm including blood loss requiring transfusion
- Stroke
- Valvular regurgitation

Adverse Events

Clinical Summary

The AMPLATZER Septal Occluder was evaluated in a multi-center, non-randomized, pivotal study comparing the device to surgical closure of atrial septal defects; 423 patients received 433 devices with a total device exposure of 911.5 years. Individual patient exposure to the device averaged 25.6 months (ranging from 0 to 38.9).

A Registry group was also studied to evaluate the device in patients with other conditions appropriate for device closure. Forty-eight (48) patients with Fenestrated Fontan (communication in the baffle with at least 5 mm distance from the free atrial wall and central venous pressure less than 15 mm Hg) were enrolled in the study.

Deaths

There was one non-device or procedure-related death reported in the pivotal study and no deaths were reported in the Fenestrated Fontan Registry Group.

Table 1. Adverse Events – Pivotal Study

Adverse Events	AMPLATZER Patients	Surgical Control Patients	p-value
Major Adverse Events			
Cardiac arrhythmia requiring major treatment	2/442 (0.5%)	0/154 (0.0%)	1.00
Device embolization with surgical removal	3/442 (0.7%)	0/154 (0.0%)	0.57
Device embolization with percutaneous removal	1/442 (0.2%)	0/154 (0.0%)	1.00
Delivery system failure	1/442 (0.2%)	0/154 (0.0%)	1.00
Pericardial effusion with tamponade	0/442 (0.0%)	3/154 (1.9%)	0.017
Pulmonary edema	0/442 (0.0%)	1/154 (0.6%)	0.26
Repeat surgery	0/442 (0.0%)	2/154 (1.3%)	0.066
Surgical wound adverse events	0/442 (0.0%)	2/154 (1.3%)	0.066
Total Major Adverse Events (Patients)	**7/442 (01.6%)**	**8/154 (05.2%)**	**0.030**
Minor Adverse Events	**AMPLATZER Patients**	**Surgical Control Patients**	**p-value**
Anemia	0/442 (0.0%)	1/154 (0.6%)	0.26
Allergic reaction (drug)	2/442 (0.5%)	0/154 (0.0%)	1.00
Atelectasis	0/442 (0.0%)	1/154 (0.6%)	0.26
Cardiac arrhythmias minor treatment	15/442 (3.4%)	9/154 (5.8%)	0.23
Device embolization with percutaneous removal	1/442 (0.2%)	0/154 (0.0%)	1.00
Extremity tingling/numbness	1/442 (0.2%)	0/154 (0.0%)	1.00
Headaches/possible TIA	2/442 (0.5%)	0/154 (0.0%)	1.00
Delivery system failure	2/442 (0.5%)	0/154 (0.0%)	1.00
Pericardiotomy syndrome	0/442 (0.0%)	2/154 (1.3%)	0.066

Table 1. Adverse Events – Pivotal Study

Adverse Events	AMPLATZER Patients	Surgical Control Patients	p-value
Pericardial effusion	0/442 (0.0%)	6/154 (3.9%)	< 0.001
Pleural effusion	0/442 (0.0%)	1/154 (0.6%)	0.26
Pneumothorax	0/442 (0.0%)	3/154 (1.9%)	0.017
Staph infection	0/442 (0.0%)	1/154 (0.6%)	0.26
Surgical wound adverse events	0/442 (0.0%)	1/154 (0.6%)	0.26
Thrombus formation	3/442 (0.7%)	0/154 (0.0%)	0.56
Transfusions	0/442 (0.0%)	2/154 (1.3%)	0.066
Upper respiratory infection/fever	0/442 (0.0%)	2/154 (1.3%)	0.066
Urinary tract disturbance	1/442 (0.2%)	0/154 (0.0%)	1.00
Total Minor Adverse Events (Patients)	**27/442 (6.1%)**	**29/154 (18.8%)**	**< 0.001**

Registry Group – Fenestrated Fontan

Table 2. Adverse Events

Major Adverse Events	AMPLATZER Patients	Upper 95% Confidence Bound
Repeat surgery	1/48 (2.1%)	0.095
Hemothorax	1/48 (2.1%)	0.095
Minor Adverse Events		
Vomiting (required 2 nights in hospital)	1/48 (2.1%)	0.095
Atrial fibrillation/cardioversion	1/48 (2.1%)	0.095
Total Major Adverse Events	4/48 (8.3%)	0.181

Observed Adverse Events – Tissue Erosion/Perforation

The reported incidence of tissue erosion/perforation is approximately 1 in 1,000 patients. Tissue erosion, while rare, has led to cardiac tamponade and death. Tissue erosion/perforation refers to the erosion or abrasion of the tissue of the atrium, primarily in the area of the roof of the atrium near the aorta. Tissue erosion/perforation is understood to be caused by cardiac function in circumstances when the implanted device is oversized in relation to the ASD diameter. The risk is mitigated when the sizing recommendations and device size selection instructions are followed.

Clinical Studies

The AMPLATZER Septal Occluder was evaluated in a multi-center, non-randomized controlled study to compare the clinical performance of the device for ASD closure with that documented for the ASD Surgical repair procedure. Additionally, the device was studied in patients with uncommon conditions wherein transcatheter closure with the device may also be beneficial (Registry Group).

Patients Studied

Pivotal Study – Atrial Septal Defects

Attempt to treat was initiated in 442 device patients and 154 surgical patients. Enrolled patients had echocardiographic evidence of ostium secundum atrial septal defect (device group: defect size less than or equal to 38 mm) and clinical evidence of right ventricular volume overload or had clinical symptoms such as paradoxical embolism or atrial dysrhythmia in the presence of a minimal shunt. Exclusion criteria included:

- Patients with multiple defects that could not be adequately covered by the device (device group only).
- Associated congenital cardiac anomalies requiring surgery.

- Ostium primum or sinus venosus atrial septal defects.
- Partial anomalous pulmonary venous drainage.
- Pulmonary vascular resistance above 7 Wood units or a right-to-left shunt at the atrial level with a peripheral arterial saturation less than 94%.
- Patients with recent myocardial infarction, unstable angina and decompensated congestive heart failure.
- Patient with right and/or left ventricular decompensation with ejection fraction < 30%.
- Sepsis (local/generalized).
- History of repeated pulmonary infection.
- Any type of serious infection less than 1 month prior to procedure.
- Malignancy where life expectancy was less than 2 years.
- Demonstrated intracardiac thrombi on echocardiography.
- Weight less than 8 Kilograms.
- Inability to obtain informed consent.
- Patient with gastritis, gastric ulcer, duodenal ulcer, bleeding disorders etc and other contraindications to aspirin therapy unless other anti-platelet agents could not be administered for 6 months.
- Patients underwent physical examination which included: heart murmur classification; an electrocardiogram, chest x-ray, and 2-D Color Doppler transthoracic echocardiogram (TTE).

Table 3. Patient Baseline Demographics

Variable			AMPLATZER Patients	Surgical Control Patients	p-value
Age (years)		Mean ± s.d. (N)	18.1± 19.3 (442)	5.9 ± 6.2 (154)	< 0.001
		[range]	[0.6, 82.0]	[0.6, 38.2]	
Gender	Female		299/442 (67.6%)	94/154 (61.0%)	0.14
	Male		143/442 (32.4%)	60/154 (39.0%)	
Height (cm)		Mean ± s.d. (N)	134.6 ± 32.0 (440)	105.5 ± 26.9 (151)	< 0.001
		[range]	[58,188]	[60,178]	
Weight (kg)		Mean ± s.d. (N)	42.3 ± 27.3 (440)	20.6 ± 15.2 (153)	< 0.001
		[range]	[6.3, 130]	[4.8, 78.4]	
Medical History	CHF		11/442 (2.5%)	7/154 (4.5%)	0.27
	Failure to thrive		14/442 (3.2%)	13/154 (8.4%)	0.012
	CAD		9/442 (2.0%)	0/154 (0%)	0.12
	Respiratory infections		7/442 (1.6%)	13/154 (8.4%)	< 0.001
	TIA		6/442 (1.4%)	1/154 (0.6%)	0.68
	COPD		1/442 (0.2%)	0/154 (0%)	1.00
	Hypertension		16/442 (3.6%)	0/154 (0%)	0.016
	Stroke		13/442 (2.9%)	0/154 (0%)	0.026
	Recurrent strokes/TIAs		5/442 (1.1%)	1/154 (0.6%)	1.00
	Diabetes		4/442 (0.9%)	0/154 (0%)	0.58

Registry Group – Fenestrated Fontan

Table 4. Pre-Closure – Fenestrated Fontan

Variable			
Age (years)		Mean ± s.d (N)	7.8 ± 6.9 (48)
		[range]	[1.6, 44.9]
Gender	Female		29/48 (60.4%)
Height (cm)		Mean ± s.d (N)	114.5 ± 25.2 (46)
		[range]	[78,168]
Weight (kg)		Mean ± s.d (N)	22.4 ± 13.5 (48)
		[range]	[9.7,68.7]
Medical history	CHF		1/48 (2.1%)
	Failure to thrive		1/48 (2.1%)
	Stroke		2/48 (4.2%)
	Heart murmur		26/47 (55.3%)
	Pulmonary ejection murmur		2/47 (4.3%)
	Mid Diastolic Murmur		1/47 (2.1%)
	Right axis deviation		11/45 (24.4%)
	Peaked p waves		1/45 (2.2%)
	Cardiomegaly		20/45 (44.4%)

Methods

Device Patients

Device placement was attempted in 442 patients. The patients underwent cardiac catheterization. Position and size of the defect were confirmed by angiography. The size of the defect was determined by obtaining the “stretched” diameter of the defect with a compliant balloon catheter. If the size and position of the defect were determined to be feasible for transcatheter closure, device placement was attempted. Nineteen (19) patients did not receive the device due to anatomical conditions. There was one acute embolization. Thus 423 patients received 433 devices.

The patients were instructed to avoid strenuous activity for a period of one month and to take aspirin for 6 months post placement (3-5mg/kg/day). Additionally, patients were examined and a transthoracic Echocardiogram (TTE) was conducted at 24 hours, 6 months and 1 year.

Surgical Control Group

Surgical repair of an atrial septal defect requires sternotomy, cardiopulmonary bypass, aortic cross clamp and right atriotomy. If the defect is small, primary repair by suturing the defect is feasible, however, if the defect is large, then patch closure is the preferred method. Different surgeons use different material for the patch. Most surgeons use pericardium, however, some surgeons use Goretex® to repair the ASD. At the end of the operation, the surgeon inserts chest tubes to drain any blood. The chest tubes last for 24-48 hours after which they are removed. The patient spends 3-5 days at the hospital after which they go home. A total of 154 patients underwent surgical closure of their ASD. The surgical group required a 12 month visit.

Results

Table 5. Principal Effectiveness and Safety Results – Pivotal Study

	AMPLATZER Patients[a]	**Surgical Control Patients**	**90% Confidence Interval**
Technical success	423/442 (95.7%)	154/154 (100%)	(-0.084, -0.010)
Procedure success	413/423 (97.6%)	154/154 (100%)	(-0.059, +0.008)
Early (≤ 30 days) composite success	401/442 (90.7%)	148/154 (96.1%)	(-0.096, +0.019)
12-month composite success	331/362 (91.4%)	146/154 (94.8%)	(-0.153, -0.033)
24-hour closure success	404/418 (96.7%)	154/154 (100%)	(-0.073, -0.001)
6-month closure success	376/387 (97.2%)	154/154 (100%)	(-0.068, +0.003)
12-month closure	326/331 (98.5%)	149/149 (100%)	(-0.052, 0.017) [Presumably, second value should be a +]
Principal Safety Measures			
Major adverse events 12-months	7/442 (1.6%)	8/154 (5.2%)	(-0.090, -0.002)
Minor adverse events 12-months	27/442 (6.1%)	29/154 (18.8%)	(-0.200, -0.070)
12-month composite success (K-M)	0.934	0.938	[-0.044, +0.036]
Survival at 30 days (K-M)	0.939	0.956	[-0.052, +0.036]
Survival at 180 days (K-M)	0.936	0.947	[-0.048, +0.026]

a. Unit of analysis = Patient. Although 10 patients had 2 defects each treated with an AMPLATZER Septal Occluder, all patients with multiple AMPLATZER implants were successfully treated.

Technical Success – Successful deployment of the device, or the successful completion of the surgical procedure.

Procedure Success – Successful closure of the defect as measured immediately following the procedure (less than or equal to 2 mm residual shunt).

Composite Success – All device placement attempts without a major adverse event, surgical reintervention, embolization, technical failure or major shunt (defined as greater than 2 mm).

Closure Success – Among patients that were technical successes, closure of the atrial septal defect (defined as a shunt less than or equal to 2 mm) without the need for surgical repair.

Major Adverse Events – Events that are life threatening, prolong hospitalization or have long term consequences or need for ongoing therapy. These include but are not limited to cerebral embolism, cardiac perforation with tamponade, endocarditis, pericardial effusion with tamponade, repeat surgery, death, cardiac arrhythmias requiring permanent pacemaker placement or long term anti-arrhythmic medication and device embolizations requiring immediate surgical removal.

Minor Adverse Events – Device embolization with percutaneous retrieval, cardiac arrhythmia with treatment, phrenic nerve injury, hematoma, other vascular access site adverse events, retroperitoneal hematoma, surgical wound adverse events, other procedural adverse events, pericardial effusion requiring medical management, evidence of device associated thrombus formation without embolization (with or without treatment) and marker band embolization without known sequelae.

Table 6. Principal Effectiveness and Safety Results – Patient Age Less Than 20 Years

	AMPLATZER Patients	Surgical Control Patients	90% Confidence Interval
Technical success	315/328 (96.0%)	149/149 (100%)	(-0.086, -0.005)
Procedure success	306/315 (97.1%)	149/149 (100%)	(0.074, + 0.005)
Early (≤ 30 days) composite success	295/328 (89.9%%)	143/149 (95.9%)	(-0.124, -0.007)
12-month composite success	256/281 (91.1%)	142/149 (95.3%)	(-0.108, + 0.013)
24-hour closure success	301/310 (97.1%)	149/149 (100%)	(-0.075, + 0.005)
6-month closure success	270/278 (97.1%)	149/149 (100%)	(-0.077, + 0.006)
12-month closure	246/251 (98.0%)	149/149 (100%)	(-0.068, + 0.014)
Principal Safety Measures			
Major adverse events 12-months	6/328 (1.8%)	7/149 (4.7%)	(-0.086, + 0.008)
Minor adverse events 12-months	16/328 (4.9%)	29/149 (19.5%)	(-0.221, -0.085)
12-month composite success (K-M)	0.930	0.944	[-0.055, + 0.027]
Survival at 30 days (K-M)	0.933	0.954	[-0.059, + 0.017]
Survival at 180 days (K-M)	0.930	0.954	[-0.062, + 0.014]

Registry Group – Fenestrated Fontan

Table 7. Principal Efficacy Results – Fenestrated Fontan

		AMPLATZER Patients	Upper 95% Confidence Bound
Technical success		46/48 (95.8%)	0.875
Procedure success		46/46 (100%)	0.937
Early composite success		44/48 (91.7%)	0.819
6-month success		38/38 (100%)	0.924
Primary efficacy outcome (12-month success)		32/32 (100%)	0.911
Hospital days	Mean ± s.d. (N)	1.2 ± 0.7 (39)	(0.95, 1.41)
	[range]	[0.0, 4.0]	

Table 8. Principal Safety Results – Fenestrated Fontan

	AMPLATZER Patients[a]	Upper 95% Confidence Bound
Major adverse events	2/48 (4.2%)	0.125
Minor adverse events	2/48 (4.2%)	0.125
Total adverse events	4/48 (8.3%)	0.181

a. Unit of analysis = “patient”

Individualization of Treatment

Patient Selection

Device placement should only be attempted in those patients with sufficient rim around the defect to allow stable seating of the device.

Patients with Multiple ASDs

Closure of multiple ASDs should only be attempted by those physicians who have gained sufficient experience (greater than10-15 cases) to undertake more technically challenging procedures.

- If there are two large ASDs separated by more than a 7 mm rim of tissue, then implantation of two devices may be justified.
- If there are multiple ASDs that are close to each other, one device may be used to cover all defects when placed in the largest defect.

Device Placement and Size Selection

- Device placement should only be done with the assistance of TEE or similar imaging equipment (i.e., intracardiac echocardiography).
- Device size selection should be the same size or one size larger than the diameter of the defect.

Use in Specific Populations

- Pregnancy – Care should be taken to minimize the radiation exposure to the fetus and the mother.
- Nursing Mothers – There has been no quantitative assessment of the presence of leachables in breast milk.

Patient Information

Refer to AMPLATZER® Septal Occluder: A Patient’s Guide.

How Supplied

The AMPLATZER Septal Occluder is packaged separately from the AMPLATZER Delivery System. Refer to Table 9 in the following section for the recommended Delivery System sizes.

Table 9. Device Specifications/Recommended Sheath Sizes (Refer to Figure 1)

Order Number	B Device Size (=ASD)	A LA Disc Diameter	Width of Connecting Waist	C RA Disc Diameter	Smallest Recommended Sheath Size
9-ASD-004	4 mm	16 mm	3 mm	12 mm	6-7 French
9-ASD-005	5 mm	17 mm	3 mm	13 mm	6-7 French
9-ASD-006	6 mm	18 mm	3 mm	14 mm	6-7 French
9-ASD-007	7 mm	19 mm	3 mm	15 mm	6-7 French
9-ASD-008	8 mm	20 mm	3 mm	16 mm	6-7 French
9-ASD-009	9 mm	21 mm	3 mm	17 mm	6-7 French
9-ASD-010	10 mm	22 mm	3 mm	18 mm	6-7 French
9-ASD-011	11 mm	25 mm	4 mm	21 mm	7 French
9-ASD-012	12 mm	26 mm	4 mm	22 mm	7 French

Table 9. Device Specifications/Recommended Sheath Sizes (Refer to Figure 1)

Order Number	B Device Size (=ASD)	A LA Disc Diameter	Width of Connecting Waist	C RA Disc Diameter	Smallest Recommended Sheath Size
9-ASD-013	13 mm	27 mm	4 mm	23 mm	7 French
9-ASD-014	14 mm	28 mm	4 mm	24 mm	French
9-ASD-015	15 mm	29 mm	4 mm	25 mm	7 French
9-ASD-016	16 mm	30 mm	4 mm	26 mm	7 French
9-ASD-017	17 mm	31 mm	4 mm	27 mm	7 French
9-ASD-018	18 mm	32 mm	4 mm	28 mm	8-9 French
9-ASD-019	19 mm	33 mm	4 mm	29 mm	8-9 French
9-ASD-020	20 mm	34 mm	4 mm	30 mm	8-9 French
9-ASD-022	22 mm	36 mm	4 mm	32 mm	9 French
9-ASD-024	24 mm	38 mm	4 mm	34 mm	9 French
9-ASD-026	26 mm	40 mm	4 mm	36 mm	10 French
9-ASD-028	28 mm	42 mm	4 mm	38 mm	10 French
9-ASD-030	30 mm	44 mm	4 mm	40 mm	10 French
9-ASD-032	32 mm	46 mm	4 mm	42 mm	10 French
9-ASD-034	34 mm	50 mm	4 mm	44 mm	12 French
9-ASD-036	36 mm	52 mm	4 mm	46 mm	12 French
9-ASD-038	38 mm	54 mm	4 mm	48 mm	12 French

Directions for Use

1. Administer heparin to achieve a recommended activated clotting time of greater than 200 seconds throughout the procedure.
2. Following percutaneous puncture of the femoral vein, perform a standard right heart catheterization.
3. Perform an angiogram in order to demonstrate the atrial communication. Catheterize the left atrium using a 45° LAO position and cranial angulation 35-45°, inject contrast medium into the right upper lobe pulmonary vein.
4. Introduce a 0.035 inch exchange “J” tip guidewire into the left atrium. Insert a compliant balloon catheter over the exchange guidewire into the left atrium and determine the diameter of the defect.
5. Sizing the defect
   - If balloon sizing is performed in addition to echocardiographic measurements, a stop-flow technique should be used.
   - Stop-flow technique: Using a balloon specifically designed for sizing atrial communications (e.g., AMPLATZER Sizing Balloon) the catheter is passed over the exchange guidewire directly through the skin. To facilitate this percutaneous entry, an assistant should apply forceful negative pressure with an attached syringe. Under fluoroscopic and echocardiographic guidance, the balloon catheter is placed across the defect and inflated with diluted contrast medium until the left-to-right shunt ceases as observed by echocardiography. The balloon is deflated until flow is seen, and then re-inflated until the shunting ceases. Measurements can then be made using echocardiographic imaging, fluoroscopy or by using the sizing plate.

   WARNING: Do not inflate the balloon beyond the “stop-flow” point or beyond the balloon's maximum inflation volume. Inflation beyond the stop-flow point may cause distention of the defect (resulting in inaccurate sizing of the defect) and/or balloon damage.

   Note: A waist in the balloon could appear without the cessation of flow. This would occur if there is more than one ASD. Sizing should occur based on stop-flow, not the appearance of a waist.

   Note: Always refer to the Instructions for Use that accompany each balloon catheter to insure that the recommendations of the manufacturer are followed.

6. Once the diameter of the defect has been determined, select an occlusion device equal to or, if the identical size is not available, one size larger than the defect.
7. Remove the balloon catheter leaving the 0.035 inch exchange guidewire in place.
8. Pass the delivery cable through the loader and screw the device to the tip of the delivery cable. Once securely attached, immerse the device and loader in cold (less than 5°C) sterile saline solution and pull the device into the loader with a jerking motion. Flush the device via the side arm.
9. Insert the dilator into the delivery sheath and secure to the sheath with the locking mechanism. Introduce the dilator/ delivery sheath assembly through the groin. Once the delivery sheath has reached the inferior vena cava, remove the dilator to allow back bleeding to purge all air from the system then connect the hemostasis valve and flush with a syringe before the left atrium is entered.

   WARNING: Always use the luer lock adapter when connecting the hemostasis valve to the sheath when using the 12 French delivery system.
10. Advance the sheath over the guidewire through the communication into the left upper pulmonary vein. Verify the correct position of the delivery sheath by a test hand injection of contrast medium or by echocardiography. Remove the guidewire and flush the sheath with sterile saline.
11. Attach the loading device to the delivery sheath. Advance the device into the sheath by pushing (not rotating) the delivery cable.
12. Under fluoroscopic and echocardiographic guidance, deploy the left atrial disc and part of the connecting waist and pull the device gently against the atrial septum, which can be felt and also observed by echocardiography. With tension on the delivery cable, pull the sheath back and deploy the right atrial disc. Pull the sheath back by approximately 5-10 cm. Position the frontal camera into the same projection as the angiogram to profile the atrial septum. A gentle "to and fro" motion with the delivery cable assures a secure position across the atrial septal defect, which can also be observed by echocardiography.

    WARNING: Do not release the device from the delivery cable if the device does not conform to its original configuration or if device position is unstable. Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device or abort the procedure.

Legend for Figures 3 – 6

A	anterior
S	superior
IAS	level of the inner atrial septum
LA	left atrium
RA	right atrium

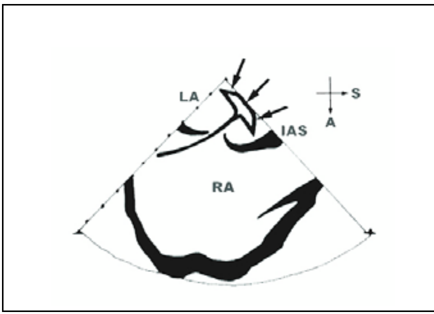

Figure 3. Transesophageal echocardiogram during the placement of the AMPLATZER Septal Occluder. The study is recorded in a vertical plane with the subject's head to the right of the image. The delivery catheter has been advanced across the atrial septum into the mid-left atrium and the left atrial disc (indicated by the 3 arrows) is deployed by pushing on the delivery cable.

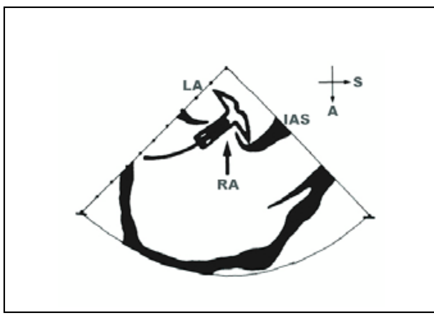

Figure 4. The waist of the device (indicated by the arrow) is deployed in the left atrium by pulling the delivery catheter back over the cable and withdrawn through the atrial defect until the left atrial disc is against the atrial septum.

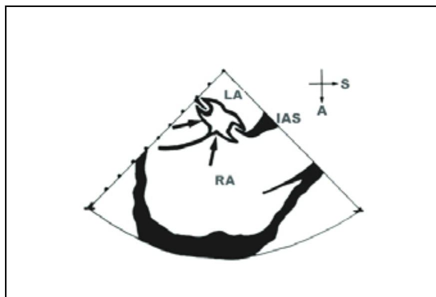

Figure 5. The right atrial disc (indicated by the 2 arrows) is deployed by further withdrawing the delivery catheter over the cable. The device is still attached to the delivery cable.

13. Confirm correct placement. If device placement is unsatisfactory or if the device does not reconfigure to its original shape, advance the sheath while retracting the delivery cable to recapture the device into the sheath and redeploy or replace with a new device.
14. Release the device. Attach the plastic vise to the delivery cable by tightening the screw on the vise. Release the device by rotating the vise counterclockwise. In the unlikely event that this should not be possible, advance the sheath against the right atrial disc to secure the device, which will facilitate detachment.

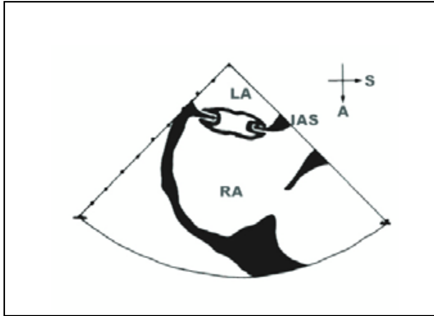

Figure 6. The device is released by unscrewing the delivery cable with the vise, and moves to a neutral position no longer tethered to the cable.

Post-Procedure Instructions

All patients should be kept overnight for observation. A transthoracic echocardiogram (TTE) should be performed prior to discharge.

Patients with any observed small pericardial effusion following device implantation should be closely monitored with serial echocardiograms performed until resolution of the pericardial effusion.

Higher risk patients (refer to “Patient Selection” on page 10) should be followed more closely, including the following:

- Clinical follow-up with echocardiogram one (1) week following device implantation.
- Education of patients about the higher risk and the need for echocardiography with symptoms (i.e., chest pain or shortness of breath).

Temporary Patient ID Card – Go to www.amplatzer.com/tempIDcard to print the temporary patient identification card. Complete this card and give it to the patient.

Registration Form – An implant registration form is located in each device box. Complete the patient information section and send the form to AGA Medical Corporation.

Warranty

AGA Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. AGA Medical Corporation's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to AGA Medical Corporation and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, AGA MEDICAL CORPORATION DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

See the Terms and Conditions of Sale for further information.

Symbol Definitions

The following symbols may appear on the device packaging:

Symbol	Definition
	Manufacturer
EC REP	EU authorized representative
SN	Product serial number
LOT	Product lot number
	Use by date (do not use the device after the end of the month shown)
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
	Consult operating instructions
	Keep dry
	Do not use if package is damaged
LATEX	Latex-free
	Inner diameter
	Outer diameter
	Length
	Usable length

HPC	Hydrophilic coating
CE 0473	Indication of conformity with the essential health and safety requirements set out in European Directives
Rx Only	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).