Amplatzer™ Septal Occluder

Instructions for Use

Device Description

The Amplatzer™ Septal Occluder is a self-expanding double-disc nitinol mesh occlusion device. The two 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.

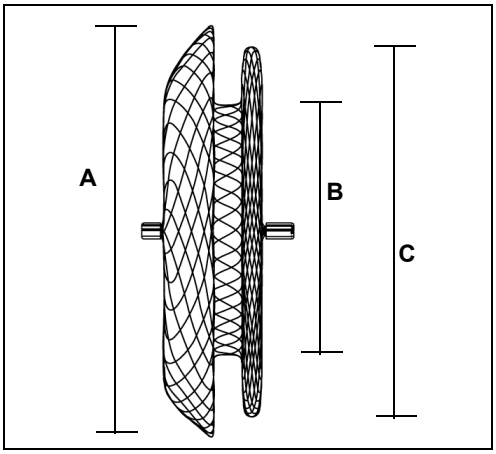

Figure 1. Amplatzer™ Septal Occluder Components

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

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STERILE EO

℞ ONLY

LATEX Not made with natural rubber latex

MR

Manufacturing facility:
Abbott Medical
5050 Nathan Lane North
Plymouth, MN
55442 USA

OR

St. Jude Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela Costa Rica

Abbott

Manufacturer:
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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.

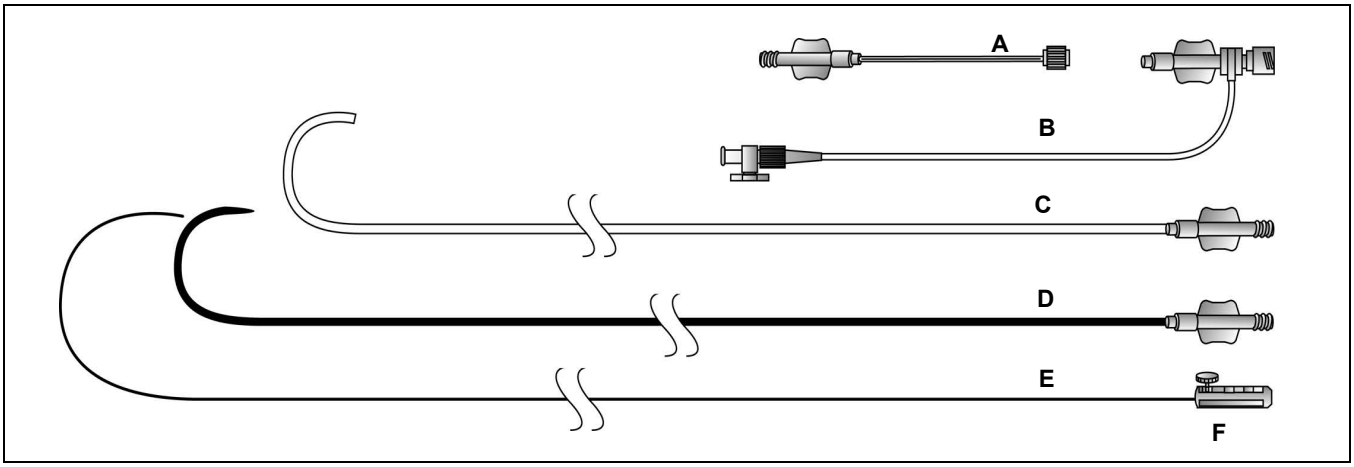


Figure 2. Amplatzer™ Delivery System

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 (such as, 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 (such as, too small for transesophageal echocardiography probe, catheter size) 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, inferior vena cava rim, AV valves, or right upper lobe pulmonary vein.

Warnings

- 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 expiration date 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 or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), aorta (AO)). Recapture the device and redeploy. If still unsatisfactory, recapture the device and either replace with a new device or refer the patient for alternative treatment.
- 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 (such as, stop-flow). DO NOT OVERINFLATE.
- Patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane, or patients in whom the device physically impinges on (i.e. indents or distorts) the aortic root, may be at increased risk of erosion.
- 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.
- Placement of the Amplatzer™ Septal Occluder may impact future cardiac interventions, for example transeptal puncture and mitral valve repair.
- This device contains nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to seek medical assistance immediately if they suspect they are experiencing an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data is currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.

Handling

Store in a dry place.

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 (for example, 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.
- Clinical follow-up with a cardiologist and echocardiograms are recommended at implant, 1 day post-implant, pre-discharge, and again at 1 week, 1 month, 6 months, and 12 months post-implant. Immediate follow-up with a cardiologist with the onset of any new symptoms suggestive of erosion or impending erosion, and routine clinical follow-up annually thereafter is also recommended.

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.

MRI Safety Information

	A patient with the Amplatzer™ Septal Occluder may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Device Name	Amplatzer™ Septal Occluder
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Field Spatial Gradient	19T/m (1900 gnauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	2.0W/kg whole-body-averaged SAR for 15 minutes of continuous scanning
MR Image Artifact	The presence of this implant may produce an image artifact.

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
- Arrhythmia
- Cardiac tamponade
- Death
- Embolization
- Fever
- Hypertension/hypotension
- Infection including endocarditis
- Need for surgery
- Pericardial effusion
- Perforation of vessel or myocardium
- Pseudoaneurysm including blood loss requiring transfusion
- Tissue erosion
- Thrombus formation on discs
- Stroke
- Valvular regurgitation

Tissue Erosion

Tissue erosion refers to the erosion or abrasion of the tissue of the atrium, primarily in the area of the roof of either or both atria, and or the adjacent aortic root (non-coronary sinus). The reported incidence of tissue erosion is approximately 1-3 per 1,000 patients[1]. Tissue erosion, while rare, is a surgical emergency due to the occurrence or impending risk of hemodynamic instability resulting from cardiac tamponade, and may lead to severe morbidity or death. Absence of the anterior superior (aortic) rim and device oversizing may be related to the causation of erosion due to the increased likelihood of device-tissue contact in the dynamic anatomic area at highest risk for erosion.

Clinical Summary

The Amplatzer™ Septal Occluder has been evaluated through both premarket and post-market clinical trials.

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 patients with fenestrated Fontans (communication in the baffle with a least a 5-mm distance from the free atrial wall and central venous pressure less than 15 mmHg) were enrolled in the study.

A post-approval study was conducted with 1000 patients to evaluate the incidence of hemodynamic compromise and obtain long-term survival data on subjects implanted with the Amplatzer™ Septal Occluder for occlusion of a secundum atrial septal defect.

Clinical Studies - Premarket Summary

Deaths

There was 1 non-device or procedure-related death reported in the pivotal study and no deaths were reported in the Fenestrated Fontan Registry Group.

1. Crawford GB, Brindis RG, Krucoff MW, et al. Percutaneous atrial Septal Occluder devices and cardiac erosion: A review of the literature. Article first published online: 2 MAY 2012. DOI: 10.1002/ccd.24347

Table 1. Adverse Events – Pivotal Study

Adverse Events	Amplatzer™ Device 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 (1.6%)	8/154 (5.2%)	0.030
Minor Adverse Events			
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
Minor Adverse Events			
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™ Device 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

Clinical Studies - Premarket Details

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).

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 kg.
- 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™ Device 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]	

Table 3. Patient Baseline Demographics (Continued)

Variable			Amplatzer™ Device Patients	Surgical Control Patients	P-value
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]

Table 4. Pre-closure – Fenestrated Fontan (Continued)

Variable		
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 1 acute embolization. Thus, 423 patients received 433 devices.

The patients were instructed to avoid strenuous activity for a period of 1 month and to take aspirin for 6 months post-placement (3–5 mg/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, patch closure is the preferred method. Different surgeons use different material for the patch. Most surgeons use pericardium; some surgeons use Gore-Tex‡ 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 closures of their ASDs. The surgical group required a 12-month visit.

Results

Table 5. Principal Effectiveness and Safety Results – Pivotal Study

	Amplatzer™ Device 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)
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 a 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™ Device 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)

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

	Amplatzer™ Device Patients	Surgical Control Patients	90% Confidence Interval
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™ Device 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™ Device 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”

Summary of the Post-Approval Study Methods

Study Objective

A post-approval study was conducted to evaluate the incidence of hemodynamic compromise and obtain long-term survival data on subjects implanted with the Amplatzer™ Septal Occluder for occlusion of a secundum atrial septal defect.

Study Design

Prospective, multi-center, non-randomized study.

Study Population

One thousand subjects indicated for implantation with the Amplatzer™ Septal Occluder for occlusion of a secundum atrial septal defect were enrolled in the study. The subject population included pediatric and adult subjects.

Table 9. Patient Baseline Demographics

Variable	Mean +/- SD (N) [Range] or n/N (%)
Age (years)	21.0 +/- 21.8 (1000) [0.3, 83.6]
Gender	
Male	351 / 1000 (35.1%)
Female	649 / 1000 (64.9%)
Height (cm)	135.3 +/- 33.8 (1000) [33.3, 198.1]
Weight (kg)	45.4 +/- 31.2 (1000) [4.5, 179.2]

Data Source

Sponsor clinical study

Key Study Endpoints

Primary Endpoint:

Subjects met the Primary Endpoint if they had one or more adverse events that led to hemodynamic compromise caused by the implantation or presence of the Amplatzer™ Septal Occluder device.

Co-Primary Endpoints:

Safety - The incidence of device and delivery system-related adverse events by subject.

Effectiveness - The percentage of subjects for whom closure success was achieved through two years.

Study visits and length of follow-up

The required length of follow-up for enrolled subjects was two years. Post-procedure follow-up visits occurred at pre-discharge, one month, one year, and two years.

Total number of Enrolled Study Sites and Subjects

A total of 1000 subjects were enrolled at fifty study sites

Follow-up Rate

The visit follow-up rate was calculated using the number of subjects available at the visit plus deaths that occurred prior to the visit in the numerator and the total number of study subjects in the denominator. The follow-up rate was 99.8% (998/1000) at the pre-discharge visit, 99.1% (991/1000) at the 1-month visit, 96.5% (965/1000) at the 12-month visit, and 93.1% (931/1000) at the 24-month visit.

Summary of the Post-Approval Study Results

Primary Endpoint

Hemodynamic compromise related to the device occurred in 6 subjects by 2 years (0.6% of 1000 evaluable subjects), due to dysrhythmia in 2, device embolization in 1, and cardiac erosion in 3. The rate of cardiac erosion was 0.3% at an average of 74 days from implant as reported by the site.

Table 10. Hemodynamic Compromise Related to the Device

Event	# of Events[a]	n/N (%) of Subjects[b]	Average Days from Implant to Event	Events per 100 Subject Years
Atrial Fibrillation	1	1 / 1000 (0.1%)	215	0.05
Cardiac Erosion[c]	3	3 / 1000 (0.3%)	74	0.15

Table 10. Hemodynamic Compromise Related to the Device (Continued)

Event	# of Events[a]	n/N (%) of Subjects[b]	Average Days from Implant to Event	Events per 100 Subject Years
Device Embolization	1	1 / 1000 (0.1%)	12	0.05
Pericardial Effusion	1	1 / 1000 (0.1%)	11	0.05
Sinus Bradycardia/Sinus Bradycardia (Cardiac Arrhythmia)	1	1 / 1000 (0.1%)	0	0.05
Total Major Adverse Events (Patients)	7	6 / 1000 (0.6%)	66	0.35

a. "# of Events" is the number of unique events that occurred.
b. "# (%) of Subjects" is the number of subjects with that event over the total subjects.
c. One event was originally reported as a pericardial effusion and was later determined to be caused by a cardiac erosion.

Co-Primary Effectiveness Endpoint

The co-primary effectiveness endpoint was defined as the percentage of subjects for whom closure success was achieved through two-years. Two criteria were required to meet this endpoint:

Technical Success - Successful deployment of the device percutaneously

Closure Success - Closure of the atrial septal defect (for example, a shunt < 2 mm) without the need for surgical repair

The analysis population for the co-primary effectiveness endpoint is all subjects who either reached their two-year visit or demonstrated closure of the atrial septal defect prior to or at their two-year visit. The closure success rate at two years was 966/ 987 (97.87%).

Co-Primary Safety Endpoint:

The incidence of device and delivery system-related adverse events by subject was 61/930 (6.56%).

Table 11. Device-Related Serious Adverse Events

Event	# of Events[a]	n/N (%) of Subjects[b]	Average Days from Implant to Event	Events per 100 Subject Years
Atrial Ectopic Beats/Premature Atrial Beats/Premature Atrial Contractions/ Ectopic Atrial Rhythm	1	1 / 1000 (0.1%)	12	0.05
Atrial Fibrillation	3	3 / 1000 (0.3%)	87	0.15
Atrial Flutter	1	1 / 1000 (0.1%)	27	0.05
Cardiac Erosion	3	3 / 1000 (0.3%)	74	0.15
Device Embolization	3	3 / 1000 (0.3%)	4	0.15
Headache	1	1 / 1000 (0.1%)	11	0.05
Migraine	2	2 / 1000 (0.2%)	10	0.10
Numbness	1	1 / 1000 (0.1%)	24	0.05
Pericardial Effusion	1	1 / 1000 (0.1%)	11	0.05
Surgical Closure of ASD	2	2 / 1000 (0.2%)	53	0.10
Tingling	1	1 / 1000 (0.1%)	24	0.05
Visual Disturbance	1	1 / 1000 (0.1%)	24	0.05
Total	20	14 / 1000 (1.4%)	38	1.01

a. "# of Events" is the number of unique events that occurred
b. "# (%) of Subjects" is the number of subjects with that event over the total subjects

Table 12. Procedure Related Serious Adverse Events

Event	# of Events	n/N (%) of Subjects	Average Days from Implant to Event	Events per 100 Subject Years
Abnormal Lab Value	1	1 / 1000 (0.1%)	1	0.05
Air Embolus	1	1 / 1000 (0.1%)	0	0.05
Arteriovenous (AV) Fistula	1	1 / 1000 (0.1%)	8	0.05
Aspiration Pneumonia/Necrotizing Pneumonia/Aspiration of Vomitus	1	1 / 1000 (0.1%)	0	0.05
Atrial Fibrillation	2	2 / 1000 (0.2%)	0	0.10
Atrial Flutter	1	1 / 1000 (0.1%)	0	0.05
Bleeding	2	2 / 1000 (0.2%)	0	0.10
Breath Holding Spell	1	1 / 1000 (0.1%)	0	0.05
Device Embolization	3	3 / 1000 (0.3%)	1	0.15
Elective Surgery	1	1 / 1000 (0.1%)	90	0.05
First Degree Heart/AV Block/Cardiac Arrhythmia - 1st degree AV Block	1	1 / 1000 (0.1%)	0	0.05
Hypotension	2	2 / 1000 (0.2%)	0	0.10
Hypoxemia	1	1 / 1000 (0.1%)	0	0.05
ST Segment Changes	1	1 / 1000 (0.1%)	0	0.05
Stridor	1	1 / 1000 (0.1%)	0	0.05
Surgical Closure of ASD	4	4 / 1000 (0.4%)	42	0.20
VASC Pseudoaneurism	1	1 / 1000 (0.1%)	22	0.05
Vaso Vagal Response	1	1 / 1000 (0.1%)	0	0.05
Totals	26[a]	16 / 1000 (1.6%)	11	1.31

[a]Eleven of the 26 procedures related serious adverse events listed were reported for three subjects and occurred on the date of the procedure.

Device Sizing

The hemodynamic compromise event rate for patients with appropriately sized devices was 1/518 (0.19%) and for patients with undersized or oversized devices the hemodynamic compromise event rate was 5/356 (1.4%).

High/Low Implanting Physicians

The hemodynamic compromise event rate was 1/307 (0.33%) for high implanting physicians and 4/583 (0.69%) for low implanting physicians based on historical experience. In addition no statistically significant difference in physician implant rate per year was demonstrated between subjects who did and did not have a device-related hemodynamic compromise event.

Study Strengths and Weaknesses

Strengths - The post-approval study involved 1000 patients; availability of patient follow-up data was very high and results are applicable to real world application of the technology.

Weaknesses - The study did not have an active control group.

Erosion - Additional Analysis

McElhinney et al.[1] conducted a retrospective case-control investigation to identify potential risk factors associated with erosion in patients who were implanted with the Amplatzer™ Septal Occluder for occlusion of a secundum atrial septal defect. One hundred twenty-five (125) cases of erosion reported between 2002 and 2014 following ASD closure with an ASO were matched

in a 2:1 fashion to controls who had ASD closure with an ASO, but did not develop erosion. The median duration from implant to erosion diagnosis was 14 days and was ≤one day in approximately one-third of patients (n=40).

Deficiency of aortic or SVC rims, i.e. aortic rim < 5 mm or SVC rim < 5 mm stop flow technique used, the balloon-sized ASD diameter, the difference between sized and static ASD diameters, the absolute ASO device size, patient age:device size and weight:device size ratios, and the device size-static ASD diameter difference were significantly associated with erosion in the univariate analysis (p<0.05). Details on the results of this analysis are provided below (Table 13.) Another possible risk factor for erosion noted following implantation of the ASO device was indentation of aortic sinus (Odds ratio: 4.8 (95% Confidence interval: 1.4-17.3, p=0.016)).

Table 13. Basic Details of Erosion and Control Cohorts (Table 2 McElhinney et al.)

	Control (n=250)	Erosion (n=125)	OR (95%CL)	P Value
Age at procedure y	28.7 ± 18.6	27.4±18.0 [117]	0.9 (0.7-1.1)	0.49
Female	172 (69)	83 (72) [116]	2.2 (0.7–7.5)	0.21
Weight, kg	60.6±27.2	55.6±25.7 [78]	0.99 (0.96–1.01)	0.25
Deficient rim(s)				
Any rim	64 (26)	84 (97) [87]	103 (14–741)	<0.001
Aortic rim	61 (24)	82 (94) [87]	51 (12–208)	<0.001
SVC rim	2 (1)	14 (17) [84]	27 (3.6–206)	<0.001
Both aortic and SVC rim	0 (0)	12 (14) [84]	156 (0.9-27333)	0.055
ASD size				
Static (native) ASD diameter, mm	15.7±6.3	16.6±5.0 [96]	1.03 (0.99–1.08)	0.19
BS performed	249 (99)	71 (96) [74]	0.01 (0–154)	0.34
Stop-flow technique used	248 (99)	34 (58) [59]	0.02 (0–0.23)	0.006
BS ASD diameter, mm	19.0±6.7	21.2±5.2 [92]	1.07 (1.03–1.12)	0.003
BS diameter–static diameter difference, mm	3.3±3.7	4.3±3.7 [86]	1.11 (1.03–1.20)	0.007
BS diameter >5 mm more than static diameter	62 (26)	36 (44) [95]	3.2 (1.6–6.1)	<0.001
ASO device-related details				
Device size, mm	20.3±7.4	22.6±5.6 [121]	1.07 (1.03–1.11)	0.001
Patient age:device size ratio, y/mm	1.50±1.10	1.21±0.84 [115]	0.03 (0.01–0.22)	<0.001
Patient weight:device size ratio, kg/mm	3.23±1.71	2.52±1.39 [78]	0.01 (0.00–0.10)	<0.001
Device size–static diameter difference, mm	4.5±4.0	5.8±3.8 [94]	1.12 (1.04–1.20)	0.003
Device diameter >5 mm more than static diameter	83 (34)	49 (52) [95]	2.7 (1.6–4.8)	<0.001
Device size–BS diameter difference, mm	1.33±2.15	1.52±1.85 [95]	1.1 (0.9–1.2)	0.33
Device size >3 mm more than BS diameter	37 (15)	18 (18) [97]	1.3 (0.6–2.2)	0.51

Data are presented as number (% of patients with available data) or mean±standard deviation, along with the [number of patients with available data]. ASD indicates atrial septal defect; ASO, Amplatzer septal occluder; BS, balloon-sized or balloon-sizing; CI, confidence interval; OR, odds ratio; and SVC, superior vena cava.

In the multivariate analyses, deficiency of aortic or SVC rims, balloon size diameter > 5 mm more than static (native) ASD diameter, and low patient weight to device size ratio were found to be significantly associated with erosion(p<0.05). Details on the results of this analyses are provided below (Table 14.)

Table 14. Multivariable Conditional Logistic Regression Models for Association with Erosion (Table 3 McElhinney et al.)

	OR (95% CI)	P Value
Model 1		
Any rim deficient	71 (8–682)	<0.001
BS diameter >5 mm more than static	4.4 (1.1–17.2)	0.036

1. McElhinney et al., Relative Risk Factors for Cardiac Erosion Following Transcatheter Closure of Atrial Septal Defects A Case-Control Study (DOI: 10.1161/CIRCULATIONAHA.115.019987)

Table 14. Multivariable Conditional Logistic Regression Models for Association with Erosion (Table 3 McElhinney et al.) (Continued)

	OR (95% CI)	P Value
Patient weight:device size ratio, log kg/mm	0.004 (0.001–855)	0.044
Model 2		
Aortic rim deficient	45 (7–292)	<0.001
BS diameter >5 mm more than static	5.4 (1.3–22.2)	0.02
Patient weight:device size ratio, log kg/mm	0.002 (0.00–0.400)	0.022

BS indicates balloon-sized; CI, confidence interval; and OR, odds ratio.

NOTE: Physicians should consider these risk factors for erosion at implant and in selection of device size and placement.

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.
- Echo guidance: The procedure should be performed under echo guidance to allow for comprehensive assessment of all rims (with specific emphasis on adequacy of the anterior-superior rim) and cardiac structures to enable appropriate placement and position of the ASD device, and to assess whether acute ASD closure has been achieved without pathologic interference or impingement on important surrounding cardiac structures.

Patients with Multiple SDs

Closure of multiple ASDs should only be attempted by those physicians who have gained sufficient experience (greater than 10–15 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 (such as 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 Device Specifications/ Recommended Sheath Sizes (Table 15) for recommended delivery system sheath sizes. See Figure 1 for the device illustration.

Table 15. Device Specifications/Recommended Sheath Sizes

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

Table 15. Device Specifications/Recommended Sheath Sizes (Continued)

Device Order Number	B Device Size (= ASD) (mm)	A LA Disc Diameter (mm)	Width of Connecting Waist (mm)	C RA Disc Diameter (mm)	Smallest Recommended Sheath Size (French)
9-ASD-009	9	21	3	17	6–7
9-ASD-010	10	22	3	18	6–7
9-ASD-011	11	25	4	21	7
9-ASD-012	12	26	4	22	7
9-ASD-013	13	27	4	23	7
9-ASD-014	14	28	4	24	7
9-ASD-015	15	29	4	25	7
9-ASD-016	16	30	4	26	7
9-ASD-017	17	31	4	27	7
9-ASD-018	18	32	4	28	8–9
9-ASD-019	19	33	4	29	8–9
9-ASD-020	20	34	4	30	8–9
9-ASD-022	22	36	4	32	9
9-ASD-024	24	38	4	34	9
9-ASD-026	26	40	4	36	10
9-ASD-028	28	42	4	38	10
9-ASD-030	30	44	4	40	10
9-ASD-032	32	46	4	42	10
9-ASD-034	34	50	4	44	12
9-ASD-036	36	52	4	46	12
9-ASD-038	38	54	4	48	12

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 (for example, Amplatzer™ Sizing Balloon II) 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 1 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 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 or interferes with any adjacent cardiac structure (such as SVC, PV, MV, CS, AO). Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace it with a new device, or refer the patient for alternative treatment.

Legend for Figures 3–6

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

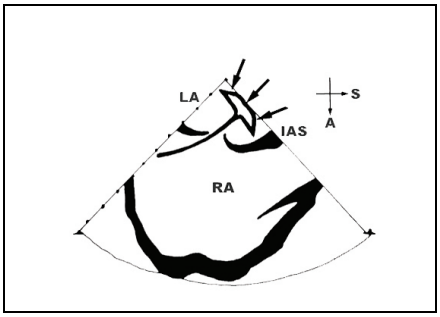


Figure 3. Transesophageal echocardiogram during placement of the Amplatzer™ Septal Occluder

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 three arrows) is deployed by pushing on the delivery cable.

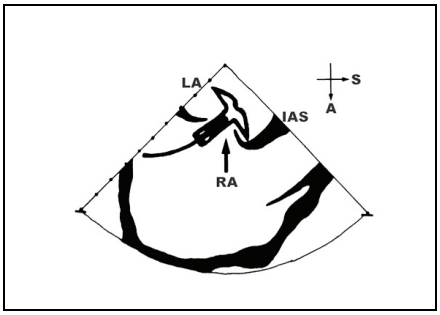


Figure 4. Deployed device waist

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.

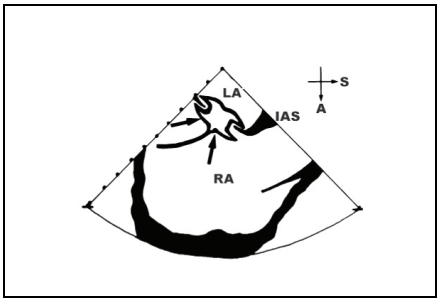


Figure 5. Deployed right atrial disc

The right atrial disc (indicated by the two 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 does not reconfigure to its original shape, is unstable or interferes with any adjacent cardiac structure (such as SVC, PV, MV, CS, AO), advance the sheath while retracting the delivery cable to recapture the device into the sheath and redeploy or replace with a new device. See Figure 6 for an example of acceptable placement.

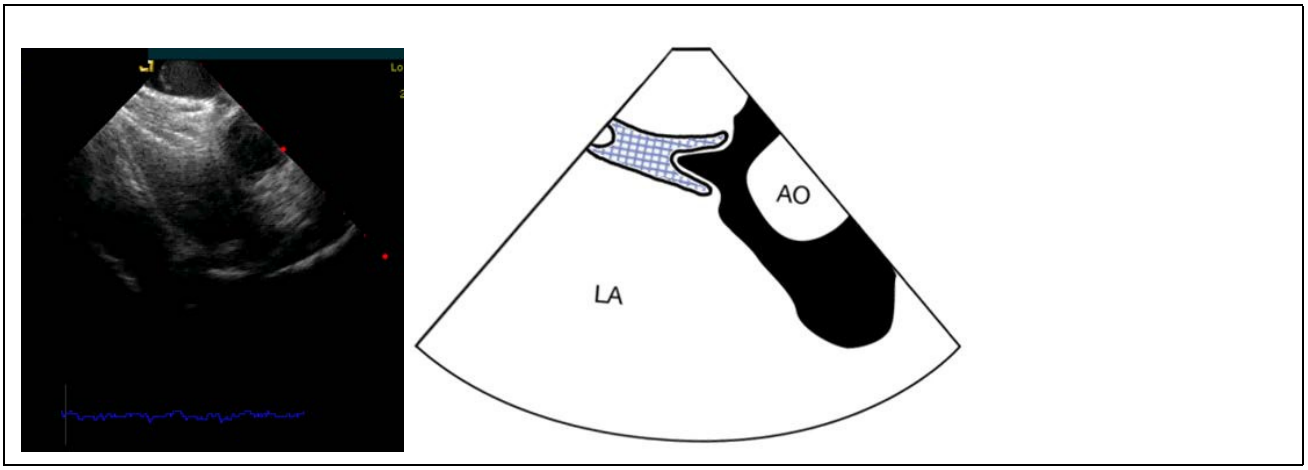


Figure 6. Acceptable placement

Figure 7 shows impingement of the device on the aortic root – please note patients in whom the device physically impinges on (in other words, indents or distorts) the aortic root, may be at increased risk of erosion.

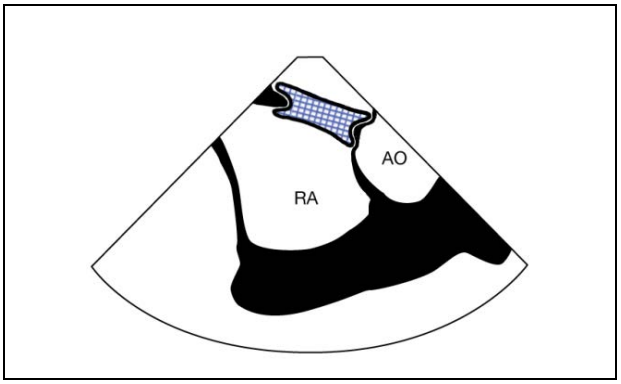


Figure 7. Impingement on the aortic root (patients with this placement may be at increased risk of erosion)

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 is not possible, advance the sheath against the right atrial disc to secure the device, which will facilitate detachment.

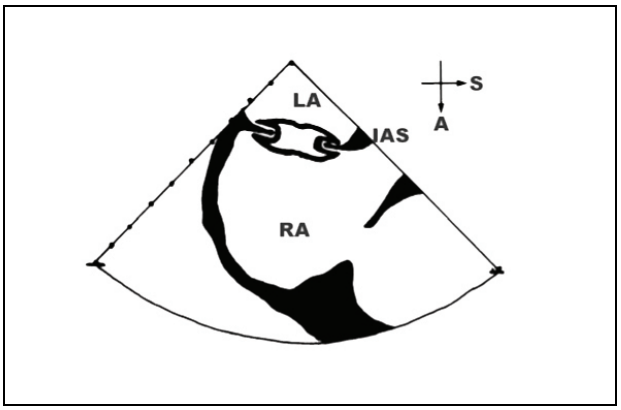


Figure 8. The device is released by unscrewing the delivery cable with the vise, and moves to a neutral position no longer tethered to the cable.

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.
- Clinical follow-up with a cardiologist and echocardiograms are recommended at implant, one day post-implant, pre-discharge, and again at one week, one month, six months, and 12 months post-implant. Clinical follow-up with a cardiologist annually thereafter is also recommended.
- Patients should be educated to seek immediate medical attention that includes an echocardiogram, if they develop signs or symptoms of hemodynamic instability such as chest pain, arrhythmia, fainting, or shortness of breath.
- Patients should be instructed to avoid strenuous activity for a minimum 1 month post-device implant or as directed by physician. Strenuous activities may lead to the increased risk of adverse events including erosion. Patients should be reminded that if they experience any symptoms of shortness of breath or chest pain at any time, and especially after strenuous activity, they should seek medical care immediately.
- Registration form – An implant registration form is located in each device box. Complete the patient information section and send the form to Abbott Medical.

Disposal

- The carton and IFU are recyclable. Dispose of all packaging materials as appropriate.
- Use solid biohazard waste procedures to discard devices.

Warranty

Abbott Medical 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. Abbott Medical'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 Abbott Medical and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, ABBOTT MEDICAL 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.

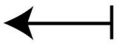
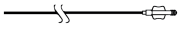
State of California (USA) Only:

⚠ **WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.**

Symbol Definitions

The following symbols may appear on the device packaging.

Symbol	Definition
	Caution, consult accompanying documents
	Manufacturer
	Reference number
	Serial number
	Batch Code
	Use-by date
	Do not re-use

STERILE EO	Sterilized using ethylene oxide
UDI	Unique device identification
	Consult instructions for use
	Keep dry; keep away from rain
	Do not use if package is damaged
	Not made with natural rubber latex
	MR Conditional
	Inner diameter
	Outer diameter
	Length
	Usable length
	Recommended delivery sheath/catheter dimensions
	Federal law restricts this device to sale by or on the order of a physician.
	Quantity
	Date of manufacture
Septal Occluder	Septal Occluder
	Manufacturing facility
	Follow instructions for use on this website