AGA MEDICAL CORPORATION

AMPLATZER® Septal Occluder *and* Delivery System

Physician Manual

6000XX-001 (XX)

The AMPLATZER® Septal Occluder and Delivery System
Physician's Manual

Contents

Overview of Manual

This manual provides information on the AMPLATZER® Septal Occluder, Delivery System and Exchange System. This manual describes some items to discuss with your patient (and their parents) and explains how to register the patient's device. You will also find instructions for handling, storing, implanting, retrieving the device, as well as instructions for exchanging the delivery system if necessary during a procedure.

The manual is divided into the following sections:

- Brief Device Description
- Indications and Usage
- Contraindications
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Brief Device Description

The AMPLATZER Septal Occluder is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the ASD. In order to increase its closing ability, the discs and the waist are filled with polyester patches. The polyester patches are securely sewn to each disc by a polyester thread.

The AMPLATZER Delivery System was designed specifically to facilitate attachment, loading, delivery and deployment of the AMPLATZER Septal Occluder and is comprised of a delivery sheath, dilator, loading device, plastic vise and delivery cable.

The AMPLATZER Exchange System is intended for removal of an AMPLATZER Delivery Sheath and subsequent exchange for a sheath of equal or larger diameter. The components are identical to the Delivery System.

For a complete list of model numbers, refer to the Detailed Device Description section of this manual.

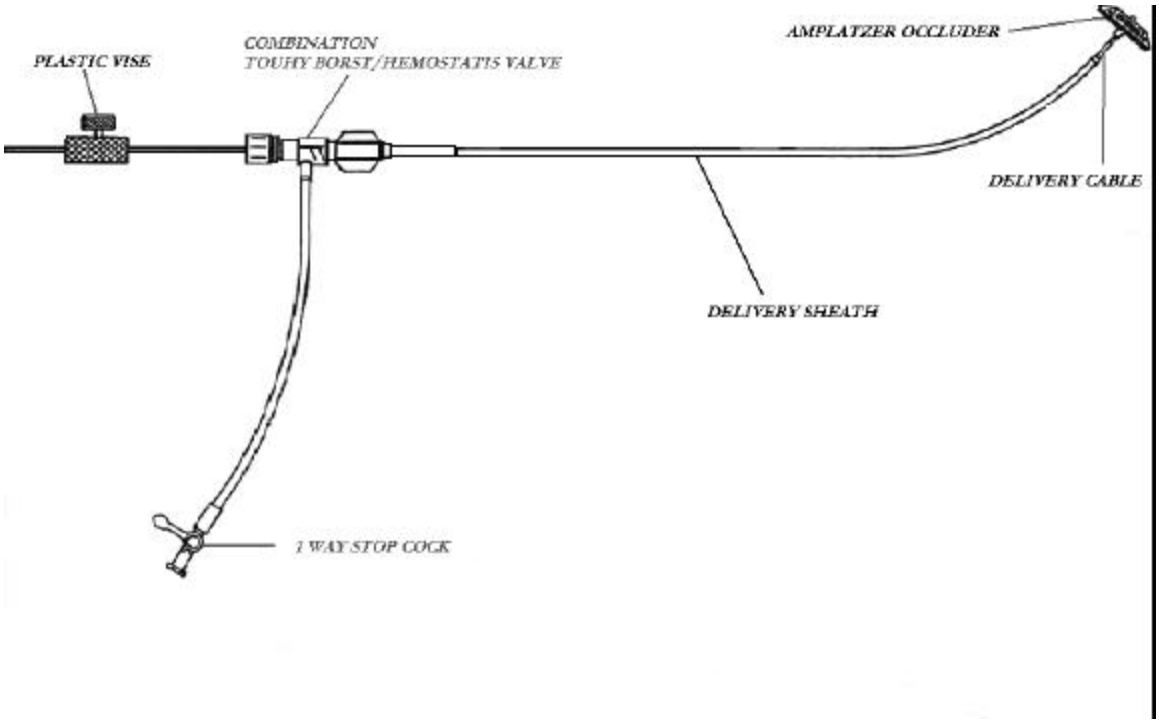

Figure 1. The AMPLATZER Septal Occluder and Delivery System

Indications and Usage

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. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (ie, 1.5:1 degree of left to right shunt or RV enlargement) or clinical symptoms such as paradoxical embolism or atrial dysrhythmia in the presence of a minimal shunt.

The device is also indicated in those patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration.

Contraindications

- 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 local or generalized sepsis, 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 anti-platelet 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 or condition would cause the patient to be a poor candidate for cardiac catheterization.

- Any patient where the margins of the defect are <5mm to the coronary sinus, AV valves and right upper lobe pulmonary vein.

Warnings

- The AMPLATZER Septal Occluder and Delivery System should only be used by those physicians trained in transcatheter defect closure techniques.

- Physicians must be prepared to deal with urgent situations which require removal of embolized devices that result in critical hemodynamic compromise.

- Embolized devices must be removed. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath.

- Do not use if the sterile barrier has been compromised in any way.

Precautions

Handling

- The AMPLATZER Septal Occluder and Delivery System are for single use only. Do not reuse or resterilize.

Sizing

- Accurate defect sizing is crucial to AMPLATZER Septal Occluder device selection. The use of a compliant balloon catheter to determine defect size is recommended. Device selection should be equal to, or slightly larger than, the balloon stretched diameter of the defect.

Procedural

- Aspirin (3-5 mg/kg/day) is to be started at least 24 hours prior to the procedure. In the rare case of aspirin intolerance, two times 200 mg of Ticlopidin are given. Cephalosporin therapy is optional.
- Patient should fully heparinized throughout the procedure with a minimum active clotting time (ACT) of 200 seconds prior to device insertion.
- Transesophageal echocardiography (TEE) or similar imaging equipment is recommended as an aid in placing the AMPLATZER Septal Occluder. If used, the patient's esophogeal anatomy must be adequate for placement and manipulation of the TEE probe.
- 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.

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.

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 5mm distance from the free atrial wall and central venous pressure less than 15Hg) were enrolled in the study.

Deaths

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

Observed Adverse Events

Pivotal Clinical Study

Table 1 Complications – Pivotal Study

Major Complication	AMPLATZER Patients	Surgical Control Patients	p-value
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 Complication	0/442 (0.0%)	2/154 (1.3%)	0.066
Total Major Complications Patients	7/442 (1.6%)	8/154 (5.2%)	0.030

Table 1 Complications – Pivotal Study (continued)

Minor Complications	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
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 Complications	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	1/424 (0.2%)	0/154 (0.0%)	1.00
Total Minor Complications (Patients)	27/442 (6.1%)	29/154 (18.8%)	<0.001

Registry Group – Fenestrated Fontan

Table 2: Complications -FF

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

Potential Adverse Events

Placement of the AMPLATZER Septal Occluder involves using standard interventional cardiac catheterization techniques. The following adverse events (listed in alphabetical order) might be expected from interventional cardiac catheterization techniques.

- Air embolus
- Allergic dye reaction
- Anesthesia reactions
- Apnea

- Fever
- Hypertension/hypotension
- Infection including endocarditis
- Perforation of vessel or myocardium
- Pseudoaneurysm including blood loss requiring transfusion
- Valvular regurgitation

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 $\leq$ 38mm) 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 Woods units or a right-to-left shunt at the atrial level with a peripheral arterial saturation < 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 < 1 month prior to procedure.
- Malignancy where life expectancy was < 2 years.
- Demonstrated intracardiac thrombi on echocardiography.
- Weight < 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 2D Color Doppler Transthoracic Echo (TTE).

Table 3: Patient Baseline Demographics

Variable	AMPLATZER Patients	Surgical Control Patients	p-value
Age (years) Mean±s.d.(N) [range]	18.1 ± 19.3 (442) [0.6, 82.0]	5.9 ± 6.2 (154) [0.6, 38.2]	<0.001
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) [range]	134.6 ± 32.0 (440) [58,188]	105.5 ± 26.9 (151) [60,178]	<0.001
Weight (kg) Mean±s.d (N) [range]	42.3 ±27.3 (440) [6.3,130]	20.6 ± 15.2 (153) [4.8,78.4]	<0.001
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/TIA's	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

Age (years) Mean±s.d (N) [range]	7.8 ± 6.9 (48) [1.6, 44.9]
Gender: Female	29/48 (60.4%)
Height (cm) Mean±s.d.(N) [range]	114.5 ± 25.2 (46) [78,168]
Weight (kg) Mean±s.d (N) [range]	22.4 ± 13.5 (48) [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 (anatomical, defect too large, etc); and an acute embolization occurred in another. 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[1]	Surgical Control Patients	90% Confidence Interval
Technical Success	423/442 (95.7%)	154/154 (100.0%)	(-0.084,-0.010)
Procedure Success	413/423 (97.6%)	154/154 (100.0%)	(-0.059, +0.008)
Early (≤ 30 days) Composite Success	401/442 (90.7%)	148/154 (96.1%)	(-0.111, -0.005)
12-month Composite Success	311/362 (85.9%)	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 Success	326/331 (98.5%)	149/149 (100%)	(-1.052, 0.017)
Principal Safety Measures			
Major Complications 12-months	7/442 (1.6%)	8/154 (5.2%)	(-0.090, -0.002)
Minor Complications 12-months	27/442 (6.1%)	29/154 (18.8%)	(-0.200, -0.070)
12-month Composite Success (K-M)	0.889	0.938	[-0.101, +0.003]
Survival at 30 days (K-M)	0.909	0.956	[-0.091, -0.003]
Survival at 180 days (K-M)	0.902	0.947	[-0.092, +0.002]

[1]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 ($\leq$ 2 mm residual shunt)

Composite Success: All device placement attempts without a major complication, surgical reintervention, embolization, technical failure or major shunt (defined as > 2 mm).

Closure Success: among patients that were technical successes, closure of the atrial septal defect (defined as a shunt $\leq$ 2mm) without the need for surgical repair.

Major Complications: 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 Complications: Device embolization with percutaneous retrieval, cardiac arrhythmia with treatment, phrenic nerve injury, hematoma, other vascular access site complications, retroperitoneal hematoma, surgical wound complications, other procedural complications, 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 Efficacy Results—FF

	AMPLATZER Patients	Lower 95% Confidence Bound
Technical Success	46/48 (95.8%)	0.875
Procedure Success	46/46 (100.0%)	0.937
Early Composite Success	44/48 (91.7%)	0.819
6 month Success	38/38 (100.0%)	0.924
Primary Efficacy Outcome (12 month Success)	32/32 (100.0%)	0.911
Hospital days Mean±s.d. (N) [range]	1.2± 0.7 (39) [0.0, 4.0]	(0.95, 1.41)

Table 7: Principal Safety Results – FF

	AMPLATZER Patients[1]	Upper 95% Confidence Bound
Major complications	2/48 (4.2%)	0.125
Minor Complications	2/48 (4.2%)	0.125
Total complications	4/48 (8.3%)	0.181

[1]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.
- Device placement should only be done with the assistance of TEE or similar imaging equipment.
- Device size selection should be the same size (or slightly larger than) the stretched 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** – Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

Directions For Use

This section outlines the basic steps of the suggested procedure for implanting an AMPLATZER Septal Occluder.

- Following percutaneous puncture of the femoral vein, perform a standard right heart catheterization.

- Perform an angiogram in order to demonstrate the atrial communication. Catheterize the left atrium using a 45° LAO position and with cranial angulation, inject contrast medium into the left atrium or into the right upper lobe pulmonary vein.

- Introduce a .035" exchange "J" tip guidewire into the left atrium. Insert a compliant balloon catheter over the exchange wire into the left atrium and determine the stretched diameter of the defect.

- Sizing the defect – Two methods can be used:
  a) Pull technique: Using a round compliant balloon, inflate the catheter with various increments of carbon dioxide or contrast medium (for patients not allergic to contrast media) and pull across the atrial communication. There should be only a slight deformity of the sizing balloon to determine the stretched diameter. If using a sizing plate, remove the sizing balloon and reinflate with the identical amount of CO_2 or contrast medium. Pass the inflated balloon through various openings of the sizing plate to determine the stretched diameter of the defect. Sizing of the defect is very important for appropriate selection of the occlusion device, therefore repeat sizing of the defect is encouraged. Alternatively, determination of the balloon can also be established using echocardiographic or radiographic measurements.
  b) Static technique: Using a balloon specifically designed for sizing atrial communications (i.e. 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. Measurements can then be made identical to the pull technique.

  NOTE: *Always refer to the Instructions for use that accompany each balloon catheter to insure that the recommendations of the manufacturer are followed.*

- Once the stretched diameter of the defect has been determined, select an occlusion device equal or, if the identical size is not available, slightly larger than the defect. Therefore, the device should be stenting the defect.

- Remove the balloon catheter leaving the .035" exchange guidewire in place.

- 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 saline solution and pull the device into the loader with a jerking motion.

- 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. 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 injection of contrast medium. Remove the exchange wire and flush the sheath with saline.

- Attach the loading device to the delivery sheath. Advance the device into the sheath by pushing (not rotating) the delivery cable.

NOTE: *REFER TO DIAGRAMS FOLLOWING THIS SECTION*

- Under fluoroscopic and echocardiographic guidance, deploy the left atrial disc and waist and pull the device gently against the atrial septum, which can be felt and also observed by ultrasonography. With tension on the delivery cable, pull the sheath back and deploy the right atrial disk. Pull the sheath back by approximately 15 cm. 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 ultrasound.

  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.**

- Confirm correct placement. If device placement is unsatisfactory or if the device does not reconfigure to its original shape, retract the device into the sheath and redeploy or replace with a new device.

- 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 as indicated by the arrow. 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.

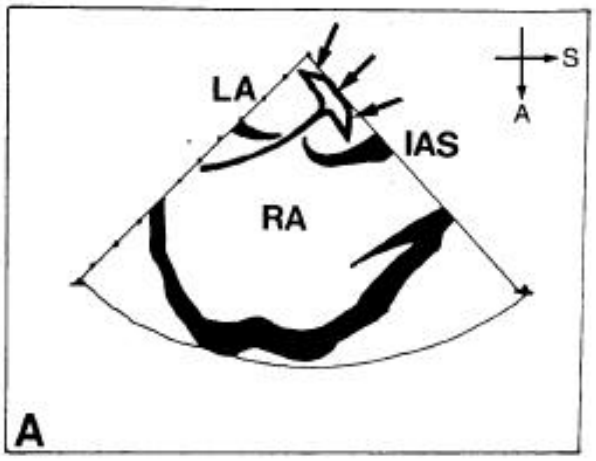

Figure A

Transesophageal echocardiogram during placement of the AMPLATZER™ Septal Occluder. The study is recorded in a vertical plane with the subjects 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 (three arrows) deployed by advancing the delivery cable

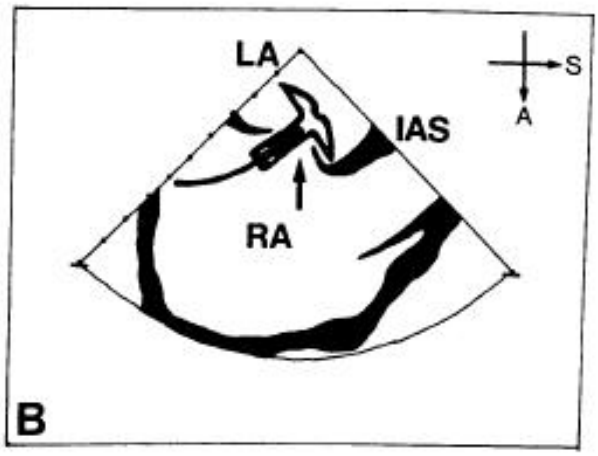

Figure B

The middle centering portion of the device (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 left atrial disc is against the atrial septum.

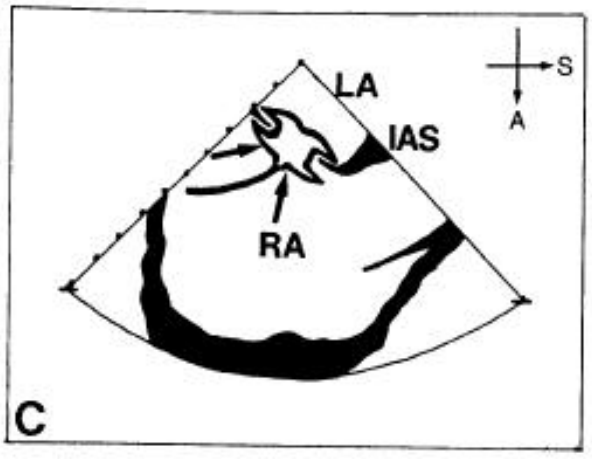

Figure C

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

LEGEND: A=anterior; S=superior
IAS=level of the interatrial septum

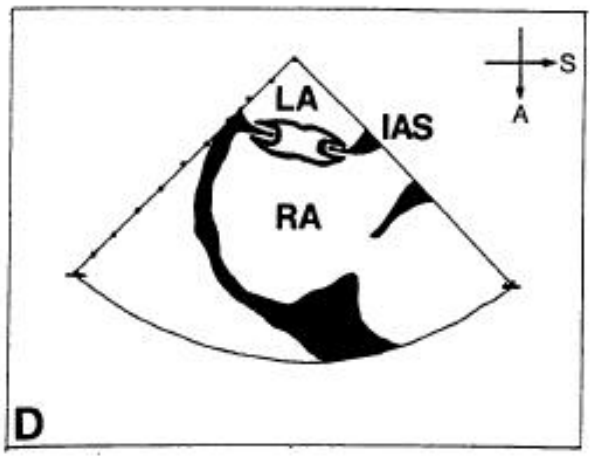

Figure D

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

LA=left atrium; RA=right atrium;

To exchange the delivery sheath

The AMPLATZER Exchange System is a delivery system especially adapted for use in conjunction with the AMPLATZER family of occlusion devices. The system components are identical to the AMPLATZER Delivery System, with the exception of the dilator, which incorporates an enlarged inner lumen for passage over an AMPLATZER delivery cable.

The AMPLATZER Exchange system is used to exchange the delivery sheath during a procedure. It may become necessary to exchange the sheath for a larger size.

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- Peel open the package and flush the delivery sheath, dilator and loader using sterile heparinized normal saline or a similar isotonic solution by connecting a syringe to the luer hub of each component.
- Insert the dilator into the delivery sheath and secure with the locking mechanism
- Screw the delivery cable to the capsule located on the proximal end of the original delivery cable thus doubling its length.

- Once securely attached, remove the original delivery sheath from the patient and discard.
- Introduce the dilator/delivery sheath exchange assembly over the lengthened cable 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.
- Advance the delivery sheath over the cable through the communication and disconnect the secondary cable.
- Proceed with device recapture and/or deployment according to the instructions provided with the AMPLATZER Occlusion device.

Patient Counseling Information

The patient and family should be advised of the known risks of the implantation procedure and follow-up as discussed in other sections of this manual, as well as the potential benefits. The patient should also be advised to read *A Patient's Guide to Transcatheter closure of an Atrial Septal Defect Using the AMPLATZER® Septal Occluder System.*

Patient Registration

Inside the shipping container for each AMPLATZER Septal Occluder is an implant registration form that creates a permanent record of your patient's implant. It is important that you complete the form and promptly return the original to AGA Medical Corporation. Copies are provided for the patient's medical records.

AGA Medical will transfer vital information to a wallet-sized laminated identification card and will mail it directly to the patient. A temporary identification card provided on the form for the patient's use until the permanent card arrives.

Physician Training

Proctoring is required prior to implanting the device for the first time. Physicians are required to contact AGA Medical Corporation and request a referral to a physician experienced in the implantation techniques of the AMPLATZER Septal Occluder. A minimum of three patients are required for the proctoring session. A copy of the patients' echocardiograms and any other pertinent information must be sent to the proctor prior to the proctoring session to verify patient suitability for the procedure.

Physicians should be thoroughly familiar with the AMPLATZER System supporting material including all product labeling and education and training materials.

How Supplied

The AMPLATZER Septal Occluder, Delivery System and Exchange System are all packaged separately from the AMPLATZER Delivery System.
NOTE: The contents of the inner package are **STERILE**.

Detailed Device Description

AMPLATZER Septal Occluder
The AMPLATZER Septal Occluder is a self-expandable, double disc device made from a nickel-titanium (Nitinol) wire mesh. The two discs are linked together by a short connecting waist. In order to increase its closing ability, the discs and the waist are filled with polyester patches. The polyester patches are securely sewn to each disc by a polyester thread

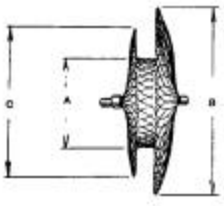

Table 8 - Device Specifications/Recommended sheath sizes

ORDER NUMBER	A DEVICE SIZE (=STRETCHED ASD)	B LA DISC DIAMETER	WIDTH OF CONNECTING WAIST	C RA DISC DIAMETER	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
9-ASD-013	13 mm	27 mm	4 mm	23 mm	7 French
9-ASD-014	14 mm	28 mm	4 mm	24 mm	7 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

AMPLATZER Delivery System

The AMPLATZER Delivery System was designed specifically to facilitate attachment, loading, delivery and deployment of the AMPLATZER Septal Occluder and is comprised of:

- Delivery sheath with Touhy-Borst adapter - used to deliver the device.
- Dilator – used to ease penetration of tissue.
- Loading Device – used to introduce the AMPLATZER Septal Occluder into the delivery sheath.
- Plastic Vise – facilitates direction control and serves as the "handle" for disconnecting (unscrewing) the delivery cable from the device.
- 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.

ORDER NUMBER	SHEATH SIZE	TIP ANGLE	USABLE LENGTH
9-DEL-6F-45/60	6 French	45°	60
9-DEL-7F-45/60	7 French	45°	60
9-DEL-7F-45/80	7 French	45°	80
9-DEL-8F-45/60	8 French	45°	60
9-DEL-8F-45/80	8 French	45°	80
9-DEL-9F-45/80	9 French	45°	80
9-DEL-10F-45/80	10 French	45°	80
9-DEL-12F-45/80	12 French	45°	80

AMPLATZER Exchange System

The AMPLATZER Exchange System is comprised of the identical components as the Delivery System, and is available in the following configurations:

Order #	**French**	**Curve**	**Length**
9-EXCH-9F-45/80	9	45°	80 cm
9-EXCH-12F-45/80	12	45°	80 cm

Glossary

ASD - Atrial Septal Defect

CAD - Coronary Artery Disease

CHF - Congestive Heart Failure

Closure Success - The successful closure of the atrial septal defect (defined as < 3mm residual shunt)

Composite Success- Closure (either device placement or surgery) without a major complication, surgical reintervention, embolization or significant shunt

COPD - Chronic Obstructive Pulmonary Disease

Fenestrated Fontan - Procedure performed to allow right to left shunting in patients with complex congenital heart disease to reduce right sided cardiac failure and pleural effusion

Hemodynamically insignificant shunts- Those shunts that are trivial (<1mm) and small ($\leq$ 2 mm)

Hemodynamically significant shunts- Those shunts that are moderate (>2 - 4mm) and large (> 4 mm)

Large Shunt - Echocardiographic evidence of residual shunt measuring more than 4mm. This is hemodynamically significant

Moderate Shunt - Echocardiographic evidence of residual shunt measuring between 3 and 4mm. This is hemodynamically significant

Multiple Devices - Patients who currently have more than one device

Small shunt - Echocardiographic evidence of residual shunt measuring between 1 and 2 mm. This is not hemodynamically significant

Qp/Qs - The ratio of pulmonary to systemic flow

TEE - Transesophageal echocardiogram

TIA - Transient Ischemic Attack

Trivial Shunt - Echocardiographic evidence of residual shunt measuring less than 1mm. This is not hemodynamically significant

TTE - Transthoracic echocardiogram

Warranty Information

The AMPLATZER Septal Occluder and Delivery System may be damaged by improper handling or use. AGA Medical Corporation disclaims all warranties, both express and implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. AGA Medical Corporation shall not be liable to any person for entity for any medical expenses or any direct, incidental or consequential damages caused by any defect, failure or malfunction of the system, whether a claim for such damage is based upon warranty, contract, tort or otherwise.