

AMPLATZER®

Multi-Fenestrated Septal Occluder – “Cribriform”

Instructions for Use

Device Description

The AMPLATZER Multi-Fenestrated Septal Occluder – “Cribriform” (Cribriform Occluder) is a self-expanding double-disc nitinol mesh occlusion device. The 2 discs are connected by a short waist. Polyester fabric is securely sewn to each disc to increase occlusion. The device has radiopaque marker bands for use under fluoroscopy.

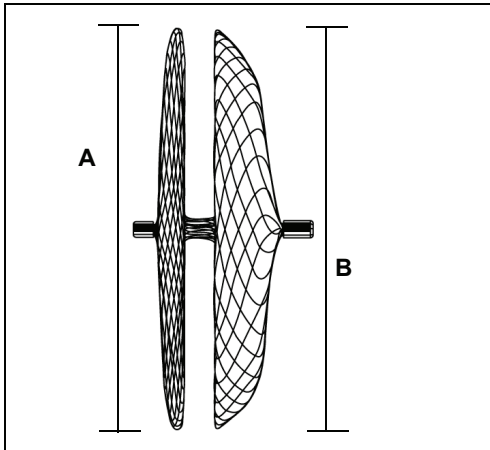


Figure 1. AMPLATZER Multi-Fenestrated Septal Occluder – “Cribriform” components.

- A. Left atrial disc.
- B. Right atrial disc.

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



ROnly

600218-004
08-2009 US

© 2007–2009 AGA Medical Corporation

AMPLATZER is a registered trademark of AGA Medical Corporation.

AGA Medical products and technologies for which patents are granted and/or pending in the USA and/or other countries are listed at www.amplatzer.com/patents

Not in any way connected with medical gas or equipment sold under the “AGA” brand by AGA AB or its successors.



AGA Medical
CORPORATION

Manufacturing Facility:
5050 Nathan Lane North
Plymouth, MN 55442 USA

+1.888.546.4407 Toll Free
+1.763.513.9227 Phone
+1.763.513.9226 Fax
www.amplatzer.com

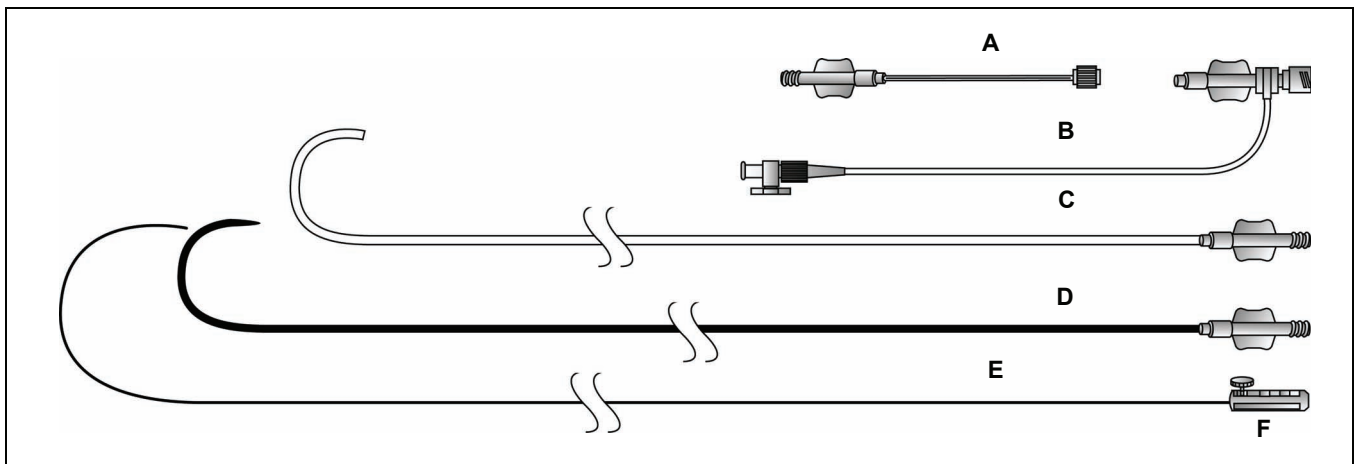


Figure 2. AMPLATZER Delivery System.

- A. Loader – used to introduce the AMPLATZER Cribriform Occluder into the delivery sheath.
- B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls blood backflow.
- 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 Cribriform Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the closure of multi-fenestrated (cribriform) atrial septal defects (ASD).

Patients indicated for ASD closure have echocardiographic evidence of fenestrated 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 right ventricular enlargement).

Contraindications

The AMPLATZER Cribriform Occluder is contraindicated for the following:

- Treatment of patients with Patent Foramen Ovale (PFO) defects. This device has not been studied in patients with PFO defects.
- Patients known to have extensive congenital cardiac anomaly, which can only be adequately repaired by way of cardiac surgery.
- Patients known to have sepsis within one month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Patients 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.
- Patients known to have demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- Patients whose size (i.e., too small for transesophageal echocardiography (TEE) probe, catheter size, vasculature size, etc.) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.
- Any patient where the radius of the device is greater than the distance from the central defect to the aortic root or superior vena cava.

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 Cribriform 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 transthoracic, transesophageal, or intracardiac echocardiographic imaging (TTE, TEE, or ICE) is required.

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 (see “Post-Procedure Instructions” on page 9). 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 less than a 9 mm distance from the central defect to the aortic root or superior vena cava orifice.

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.
- 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 Conditional¹

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

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

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3-tesla MR system using a transmit/receive body coil.

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

1. MR Conditional as defined in ASTM F 2503-05.

Adverse Events

Observed Adverse Events – Tissue Erosion/Perforation

The reported incidence of tissue erosion/perforation is approximately 1 in 1,000 patients treated with the AMPLATZER Septal Occluder. 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.

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
- Brachial plexus injury
- Cardiac perforation
- Death
- Device collapse due to structural failure
- Device embolization
- Device removal (due to embolization or misplacement)
- Erosion
- Fever
- Headache/migraines
- Hematoma/pseudoaneurysm including blood loss requiring transfusion
- Hypertension; hypotension
- Infection including endocarditis
- Infectious endocarditis
- Pericardial effusion
- Perforation of vessel or myocardium
- Phrenic nerve injury
- Stroke/transient ischemic attack
- Thrombus formation on the device surface with the risk of subsequent embolization
- Valvular regurgitation
- Vascular access site complications

Clinical Summary

The AMPLATZER Cribriform Occluder was evaluated in a multi-center, non-randomized, prospective clinical investigation comparing the device to a control group. This clinical investigation studied the 18 mm, 25 mm, and 35 mm device sizes; the 30 mm device size was not studied. A total of 20 subjects received 24 devices. A total of 49 subjects were evaluated in the Control Group.

Deaths

There were no device- or procedure-related deaths reported during the clinical investigation.

Observed Adverse Events

Table 1. Adverse Events

	Cribriform Subjects	Control Subjects	p-value	90% Confidence Interval
Major Complications ^a	0/24 (0.0%)	0/49 (0.0%)	--	(-5.23%, 10.13%)
Minor Complications ^b	4/24 (16.7%)	5/49 (10.2%)	0.4642	(-6.46%, 22.30%)
Overall Complications	4/24 (16.7%)	5/49 (10.2%)	0.4642	(-6.46%, 22.30%)

- a. **Major Complication:** 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, and death, which were listed in the protocol. Additionally, cardiac arrhythmias requiring permanent pacemaker placement or long term anti-arrhythmic medication and device embolizations requiring immediate surgical removal are included.
- b. **Minor Complication:** Device embolization with percutaneous retrieval, cardiac arrhythmia with treatment, phrenic nerve injury, hematoma, other vascular access site complications, retroperitoneal hematoma, surgical wound complications, and other procedural complications, as listed in the protocol. Additionally, pericardial effusion requiring medical management, evidence of device-associated thrombus formation without embolization (with or without treatment), and marker band embolization without known sequelae are included.

Clinical Studies

The AMPLATZER Multi-Fenestrated Septal Occluder – “Cribriform” (Cribriform Occluder) was evaluated in a multi-center study. This clinical study evaluated the 18 mm, 25 mm, and 35 mm device sizes; the 30 mm device has not been studied.

The primary purpose of this study was to compare the clinical performance of the AMPLATZER Cribriform Occluder in subjects with multi-fenestrated ASDs with the clinical performance of the AMPLATZER Septal Occluder in subjects with multiple ASDs. This investigational plan did not include a statistical plan, hypotheses, or a control group.

Subjects with multiple ASDs reported in the AMPLATZER Septal Occluder clinical investigation (PMA P000039) were extracted and used as the “historical” control group for the AMPLATZER Cribriform Occluder clinical investigation. These subjects will be referred to as the Control Group within this document.

Patients studied

Device placement with the AMPLATZER Cribriform Occluder was attempted in 24 patients. Patients met the following eligibility criteria: echocardiographic evidence of multi-fenestrated ASD not amenable to closure with the AMPLATZER Septal Occluder (i.e. multiple defects where implantation of one or more devices will not result in adequate coverage of all communications), and 1.5:1 left-to-right shunting (or larger), right ventricular volume overload defined by any degree of right ventricle enlargement, or paradoxical embolism.

Exclusion criteria included:

- Presence of thrombus at the intended site of implant or documented evidence of venous thrombus in the vessels through which access to the defect is gained.
- Extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- Bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another anti-platelet agent can be administered for 6 months.
- Active endocarditis or other infections producing bacteremia.
- Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.
- The AMPLATZER Cribriform Occluder is not intended for closure of isolated PFO or PFO with a non-fenestrated atrial septal aneurysm.
- Anatomy in which the device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.
- Patients with intracardiac mass or vegetation.
- Inability to obtain informed consent.
- Patients who were unable to be followed for 6 months post-procedure.

Table 2. Patient Baseline Demographics

Variable		Cribriform Subjects	Control Patients	p-value
Age (years)	Mean ± s.d. (N)	25.8 ± 22.8 (24)	16.1 ± 18.2 (49)	0.0537
	[range]	[1.3, 65.8]	[1.6, 65.9]	
Gender	Female	19/24 (79.2%)	38/49 (77.6%)	1.0000
	Male	5/24 (20.8%)	11/49 (22.5%)	
Height (cm)	Mean ± s.d. (N)	137.9 ± 33.1 (24)	129.2 ± 33.3 (49)	0.2976
	[range]	[87.0, 188.0]	[77.0, 186.0]	
Weight (kg)	Mean ± s.d. (N)	51.3 ± 33.1 (24)	38.1 ± 27.9 (49)	0.0783
	[range]	[9.8, 103.0]	[8.6, 105.0]	

Table 2. Patient Baseline Demographics

Variable		Cribriform Subjects	Control Patients	p-value
Medical History	Chronic heart failure (CHF)	0/24 (0.0%)	1/49 (2.0%)	1.0000
	Failure to thrive	1/24 (4.2%)	0/49 (0.0%)	0.3288
	Coronary artery disease (CAD)	0/24 (0.0%)	0/49 (0.0%)	--
	Respiratory infections	3/24 (12.5%)	0/49 (0.0%)	0.0325
	Transient ischemic attacks (TIA)	1/24 (4.2%)	1/49 (2.0%)	1.0000
	Chronic obstructive pulmonary disease (COPD)	1/24 (4.2%)	0/49 (0.0%)	0.3288
	Hypertension	3/24 (12.5%)	2/49 (4.1%)	0.3229
	Stroke	2/24 (8.3%)	0/49 (0.0%)	0.1050
	Recurrent strokes/TIAs ^a	--	1/49 (2.0%)	--
	Diabetes	1/24 (4.2%) 2/24	0/49 (0.0%)	0.3288

a. Recurrent Strokes/TIA history was not collected in the Cribriform group.

Methods

Physical exams and Doppler transthoracic echocardiograms (TTE) were performed pre-procedure and at follow-up visits. Data was collected at the clinical sites and recorded on case report forms. Clinical follow-up was required pre-discharge, at 6 months, and at 12 months.

Devices available to investigators included the 18 mm, 25 mm, and 35 mm Cribriform Occluder sizes. The 30 mm device size was not included in this investigation. Investigators used the following device sizing recommendations (Table 3).

Table 3. Clinical Investigation Device Sizing Chart

Shortest Distance from Defect to Aortic Root or Distance from Defect to Superior Vena Cava Orifice (mm)	Suggested AMPLATZER Cribriform Occluder Size (mm)
Greater than or equal to 17.5	35
12.5 – 17.4	25
9 – 12.4	18
Less than 9	Do not implant device

Results

Table 4. Principal Efficacy Results^a

	Cribriform Subjects	Control Subjects	p-value	Upper 95% Confidence Bound
Technical success	20/24 (83.3%)	48/49 (98.0%)	0.0375	(3.50%, 30.42%)
Technical failure	4/24 (16.7%)	1/49 (2.0%)	0.0375	(-30.42%, -3.50%)
Procedure success	19/20 (95.0%)	45/48 (93.8%)	1.0000	(-10.50%, 13.82%)
Early composite success	20/24 (83.3%)	42/49 (85.7%)	1.0000	(-11.11%, 19.33%)
6-month closure success	20/20 (100.0%)	42/45 (93.3%)	0.5467	(-15.55%, 5.89%)

Table 4. Principal Efficacy Results^a

	Cribriform Subjects	Control Subjects	p-value	Upper 95% Confidence Bound
Primary efficacy success ^b (12-month closure success)	19/19 (100.0%)	39/41 (95.1%)	1.0000	(-13.72%, 8.00%)
12-month composite success	19/23 (82.6%)	39/43 (90.7%)	0.4346	(-5.50%, 25.06%)

a. Unit of analysis = Subject.

b. One subject missed the 12-month visit in the Cribriform group; five subjects missed the 12-month visit in the Control group and one subject did not have an echocardiogram done.

Technical Success: Subjects in whom successful deployment of the device was achieved.

Technical Failure: Subjects in whom the device was inserted, recaptured, or embolized and the procedure was aborted.

Procedure Success: Technical success subjects who had successful closure of the atrial septal defect immediately following the procedure. Successful closure of the defect was defined as less than or equal to 2 mm residual shunt.

Early Composite Success: Subjects in whom device placement was attempted who did not experience technical failure, a major adverse event within 30 days of the procedure, embolization, or major shunt at the 24-hour follow-up visit.

6-Month Closure Success: Technical success subjects who had shunt status evaluated at the 6-month follow-up visit and had successful closure of the atrial septal defect. Successful closure of the defect was defined as less than or equal to 2 mm residual shunt. Technical success subjects who did not have the shunt evaluated at the 6-month follow-up, but were classified as a failure at the shunt evaluation at their last follow-up interval, were classified as 6-month failures. Technical success subjects who did not have the shunt evaluated at the 6-month follow-up, but were classified as a successful closure at the shunt evaluation at their last follow-up interval, were classified as missing.

Primary Efficacy Outcome (12-month Closure Success): Technical success subjects who had shunt status evaluated at the 12-month follow-up visit and had successful closure of the atrial septal defect. Successful closure of the defect was defined as less than or equal to 2 mm residual shunt. Technical success subjects who did not have the shunt evaluated at the 12-month follow-up, but were classified as a failure at the shunt evaluation at their last follow-up interval, were classified as 12-month failures. Technical success subjects who did not have the shunt evaluated at the 12-month follow-up, but who were classified as a successful closure at the shunt evaluation at their last follow-up interval, were classified as missing.

12-Month Composite Success: Subjects in whom device placement was attempted who did not experience technical failure, a major adverse event within 12 months of the procedure, embolization, or major shunt at the 12-month follow-up visit. Subjects who were technical successes and did not have a major adverse event within 12 months and did not have the shunt evaluated at the 12-month follow-up, but were classified as a failure at the shunt evaluation at their last follow-up interval, were classified as 12-month composite failures. Technical success subjects with no major adverse event within 12 months who did not have the shunt evaluated at the 12-month follow-up, but were classified as a successful closure at the shunt evaluation at their last follow-up interval, were classified as missing.

Individualization of Treatment

Patient Selection

Device placement should only be attempted in those patients with sufficient distance from the central defect to the aortic root and superior vena cava orifice (greater than or equal to 9 mm distance).

Device Size Selection and Placement

Device size selection and placement (i.e. targeted communication for closure of the fenestrated defects) is based on the location of the defects. The use of transesophageal echocardiography (TEE) or similar imaging equipment (e.g., intracardiac echocardiography, etc.) is mandatory as an aid in positioning the sheath through the most suitable defect to achieve complete closure of the communications. Refer to “Directions for Use” on page 8 for device sizing instructions.

Table 5. Device and Sheath Size Recommendations

Device Order Number	Left Atrial Disc Diameter	Right Atrial Disc Diameter	Minimum Delivery Sheath Size
9-ASD-MF-018	18 mm	18 mm	8 French
9-ASD-MF-025	25 mm	25 mm	8 French
9-ASD-MF-030	30 mm	30 mm	8 French

Table 5. Device and Sheath Size Recommendations

Device Order Number	Left Atrial Disc Diameter	Right Atrial Disc Diameter	Minimum Delivery Sheath Size
9-ASD-MF-035	35 mm	35 mm	9 French

How Supplied

The AMPLATZER Cribriform Occluder is packaged separately from the AMPLATZER Delivery System. Refer to the following section for the recommended Delivery System sizes.

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 0.889 mm (0.035 inch) exchange “J” tip guidewire into the left atrium.
5. Device size and placement (the fenestration in which the device will be placed) is based on the location of the fenestrations. The use of transesophageal echocardiography or intracardiac echocardiography is mandatory in positioning the sheath in the most centrally-located fenestration. Once the most centrally-located defect has been crossed, measurements should be made to determine the distance to the outer rim of the farthest fenestration; and the device size selected should be 2:1 of this measurement. The device selected must completely cover all fenestrations.
6. Transesophageal echocardiography (TEE) or similar imaging equipment (e.g., intracardiac echocardiography) is required to measure the distance from the most centrally-located defect to the aortic root and to the superior vena cava orifice.
7. Select a device size such that the radius of the discs will not exceed the lesser of the two measurements from the centrally located defect to the aortic root and the superior vena cava orifice.

Table 6. Device Size Selection

Shortest Distance from Defect to Aortic Root or Distance from Defect to Superior Vena Cava Orifice (mm)	Suggested AMPLATZER Cribriform Occluder Size (mm)
Greater than or equal to 17.5	35
12.5 – 14.9	30
12.5 – 17.4	25
9 – 12.4	18
Less than 9	Do not implant device

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.
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 solution.
11. Attach the loader 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 ultrasonography. With tension on the delivery cable, pull the sheath back and deploy the right atrial disc. Pull the sheath back by approximately 5 cm-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 ultrasound.

WARNING: Do not release the AMPLATZER Cribriform Occluder 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.

13. Confirm correct placement of the device:

- 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.
- If device placement is satisfactory, attach the plastic vise to the delivery cable by tightening the screw on the plastic 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.

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 should be followed more closely, including the following:
 - Clinical follow-up with echocardiogram 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
	EU authorized representative
	Product serial number
	Product lot number
	Use by date (do not use the device after the end of the month shown)
	Do not reuse
	Sterilized using ethylene oxide

	Consult operating instructions
	Keep dry
	Do not use if package is damaged
	Latex-free
	Inner diameter
	Outer diameter
	Length
	Usable length
	Hydrophilic coating
	Indication of conformity with the essential health and safety requirements set out in European Directives
	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).