

AMPLATZER™ PFO Occluder

Instructions for Use

Device Description

The AMPLATZER™ PFO Occluder is a self-expandable, double-disc device made from a Nitinol wire mesh. The 2 discs are linked together by a short connecting waist. In order to increase its closing ability, the discs contain thin polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread.

The device has radiopaque marker bands on the distal and proximal ends of the device. The device contains an end screw on the proximal end to facilitate delivery and deployment. The device is sterilized with ethylene oxide.

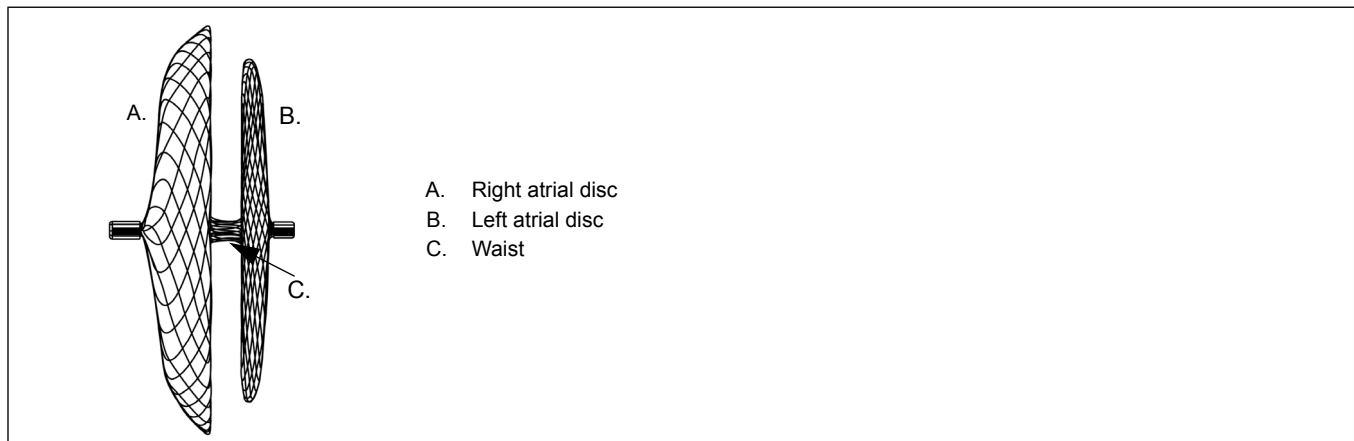


Figure 1. AMPLATZER™ PFO Occluder

Indications and Usage

The AMPLATZER™ PFO Occluder is intended for percutaneous, transcatheter closure of a patent foramen ovale (PFO) to prevent recurrent ischemic stroke in patients who have had a cryptogenic stroke due to a presumed paradoxical embolism.

Contraindications

- Patients with intra-cardiac mass, vegetation, tumor or thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the PFO is gained
- Patients whose vasculature, through which access to the PFO is gained, is inadequate to accommodate the appropriate sheath size.
- Patients with anatomy in which the AMPLATZER™ PFO device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.
- Patients with other source of right-to-left shunts, including an atrial septal defect and/or fenestrated septum.
- Patients with active endocarditis or other untreated infections.

STERILE EO



R ONLY



Does not contain
natural rubber
latex components



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Pat. <http://patents.sjm.com>

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Warnings

- Patients who are at increased risk for venous thromboembolic events should be managed with thromboembolic risk reduction regimen after the PFO Closure following state of care.
- Do not use this device if the sterile package is open or damaged
- Prepare for situations that require percutaneous or surgical removal of this device. This includes availability of a surgeon.
- Embolized devices must be removed as they may disrupt critical cardiac functions. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter or sheath.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- This device should be used only by physicians who are trained in standard transcatheter techniques
- Transient hemodynamic compromise may be encountered during device placement, which may require fluid replacement or other medications as determined by the physician.
- Do not release the device 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.
- Ensure there is sufficient distance from the PFO to the aortic root or SVC (typically defined as 9 mm or greater as measured by echo). See Figure 2. and Figure 3.

Precautions

- This device has not been studied in patients with:
 - Age less than 18 years and greater than 60 years
 - Positive test for one of the following hypercoagulable states: Anticardiolipin antibody of the IgG or IgM, Lupus anticoagulant, B-2 glycoprotein-1 antibodies, or persistently elevated fasting plasma homocysteine despite medical therapy
 - Unable to take antiplatelet therapy
 - Atherosclerosis or other arteriopathy of the intracranial and extracranial vessels of greater than 50% of lumen Acute or recent (within 6 months) myocardial infarction or unstable angina
 - Left ventricular aneurysm or akinesis
 - Mitral valve stenosis or severe mitral regurgitation irrespective of etiology
 - Aortic valve stenosis (gradient greater than 40 mmHg) or severe aortic valve regurgitation
 - Mitral or aortic valve vegetation or prosthesis
 - Aortic arch plaques protruding greater than 4 mm into the lumen
 - Left ventricular dilated cardiomyopathy with left ventricular ejection fraction (LVEF) less than 35%
 - Chronic or intermittent atrial fibrillation or atrial flutter
 - Uncontrolled hypertension or uncontrolled diabetes mellitus
 - Diagnosis of lacunar infarct probably due to intrinsic small vessel as qualifying stroke event
 - Arterial dissection as cause of stroke
 - Index stroke of poor outcome (modified Rankin score greater than 3)
 - Pregnancy at the time of implant
 - Diagnosed with organ failure
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to re-sterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- The AMPLATZER™ PFO Occluder device consists of a 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 notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.
- Use clinical judgment in situations that use anticoagulants or antiplatelet medication before, during, and after this procedure.
- Store in a dry place.
- Pregnancy – Minimize radiation exposure to the fetus and the mother.
- Nursing mothers – There has been no quantitative assessment for the presence of leachables in breast milk.

MR Conditional

Non-clinical testing has demonstrated the AMPLATZER™ PFO Occluder is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient field less than or equal to 30 T/m
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for 15 minutes of scanning

In non-clinical testing the AMPLATZER™ PFO Occluder device produced a temperature rise of less than or equal to 1.79° C at a maximum whole-body averaged specific absorption rate (SAR) of 3.4 W/kg for 15 minutes of MR scanning in a 3.0 Tesla MR system (Siemens MAGNETOM Trio®, SYNGO® MR A35 4VA35A software, Erlangen, Germany).

In non-clinical testing the AMPLATZER™ PFO Occluder device produced a temperature rise of less than or equal to 1.61° C at a maximum whole-body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of MR scanning in a 1.5 Tesla MR system (Siemens MAGNETOM Espree®, SYNGO® MR B17 software, Erlangen, Germany).

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

Adverse Events

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

- Air embolus
- Allergic dye reaction
- Allergic drug reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bacterial endocarditis
- Bleeding
- Brachial plexus injury
- Cardiac perforation
- Cardiac tamponade
- Cardiac thrombus
- Chest pain
- Device embolization
- Device erosion
- Deep vein thrombosis
- Death
- Endocarditis
- Esophagus injury
- Fever
- Headache/migraine
- Hypertension/hypotension
- Myocardial infarction
- Pacemaker placement secondary to PFO device closure
- Palpitations
- Pericardial effusion
- Pericardial tamponade
- Pericarditis
- Peripheral embolism
- Pleural effusion
- Pulmonary embolism
- Reintervention for residual shunt/device removal
- Sepsis
- Stroke
- Transient ischemic attack
- Thrombus
- Valvular regurgitation
- Vascular access site injury
- Vessel perforation

Clinical Studies

Clinical Summary

The AMPLATZER™ PFO Occluder was evaluated in a prospective, randomized, multi-center, event driven study comparing device closure of a PFO with medical management alone in the prevention of recurrent ischemic stroke in those patients diagnosed with cryptogenic stroke and PFO. 980 patients were enrolled in the study with 499 patients randomized to the device group and 481 randomized to the medical group.

Methods

Patients were randomized to either receive the AMPLATZER™ PFO Occluder or standard of care medical management. The four medical therapy regimens allowed per protocol in the medical management (MM) group were: (a) Aspirin alone, (b) Coumadin alone, (c) Clopidogrel alone or (d) Aspirin combined with dipyridamole.

Device patients

Post device implant, patients were to take clopidogrel for 30 days and aspirin for 6 months. Additional medical therapy beyond six months was at the discretion of the treating physician. Patients were evaluated by transesophageal echocardiogram (TEE) at approximately 6 months post implant to assess PFO closure.

Patients Studied

Patients were enrolled in the study with diagnosis of cryptogenic stroke within 270 days as well as documented PFO. Exclusion criteria sought to ensure patients were fully screened and all other potential causes of stroke were ruled out. Exclusion criteria, also listed in the precautions section, included:

- Age < 18 or > 60 years
- Cerebral and cardiovascular conditions that suggest other risks for stroke
- Arterial hypercoagulable state
- Other sources of right to left shunt
- Infections, organ failure, uncontrolled diabetes mellitus or hypertension
- Contraindication to aspirin or clopidogrel
- Anatomical contraindications to device placement
- Progressive neurological dysfunction
- Any other reason to expect limited life expectancy, inability to attend follow-up visits, or inability to provide informed consent

Table 1. Subject Demographics and Baseline Characteristics

Variable	Device (N=499)	Medical Management (N=481)	p-value ¹
Age, years ²	492 45.7 (9.7) 46.7 [18.1, 61.0]	476 46.2 (10.0) 47.6 [18.4, 60.9]	0.491
Time from stroke to randomization, days	499 130 (70) 117 [10, 277]	481 130 (69) 121 [10, 286]	0.891
Sex, male	268 (53.7%)	268 (55.7%)	0.564
Previous myocardial infarction	5 (1.0%)	2 (0.4%)	0.452
Previous transient ischemic attack	58 (11.6%)	61 (12.7%)	0.626
Stroke prior to qualifying cryptogenic stroke	53 (10.6%)	51 (10.6%)	1.000
Substantial Shunt at Rest or Valsalva	247 (49.5%)	231 (48.0%)	0.655
Atrial septal aneurysm ³	180(36.1%)	170 (35.3%)	0.842

Continuous variables are reported as n, mean (SD), median [min, max] and categorical variables as n (%).

¹ 2-sample t-test (age), Wilcoxon-Mann-Whitney test (days from stroke to date randomized) and Fisher's Exact test.

² The IRB at one site (12 subjects) did not allow recording of subject birthdates on CRFs.

³ Defined as a total excursion of the septum primum ≥ 10 mm.

Table 2. Baseline PFO shunt assessment per TEE maximal grade: overall study population

Maximal shunt grade ^a	Device	Medical Management	All subjects	P value ^b
Grade 0	1/499 (0.2%)	9/481 (1.87%)	10/980 (1.02%)	0.0924
Grade I	108/499 (21.64%)	114/481 (23.7%)	222/980 (22.65%)	
Grade II	138/499 (27.66%)	121/481 (25.16%)	259/980 (26.43%)	
Grade III	247/499 (49.5%)	231/481 (48.02%)	478/980 (48.78%)	
Not assessed	5/499 (1%)	6/481 (1.25%)	11/980 (1.12%)	

Categorical variables are reported as n/N (%).

^a Maximal shunt grade was determined as the most severe grade between assessments at rest and at Valsalva. If only 1 assessment was available, that was used, if no assessments were available, it was listed as not assessed.

^b Based on a Chi-squared test.

Principal Effectiveness and Safety Results—RESPECT Clinical Trial

Primary Endpoint Analysis Results:

Results of analyses of the primary endpoint are summarized in Table 3. While the ITT analysis demonstrated a 50% relative risk reduction for the primary endpoint, the analysis did not achieve statistical significance (p=0.089). The PP analysis showed a

statistically significant relative risk reduction of 63% (p=0.034). These analyses support the conclusion that there is a true device effect on recurrent ischemic stroke, explained by elimination of a conduit through which venous source emboli can travel to the brain.

Table 3. Summary of Primary Endpoint Analyses Results

Analysis Type	Analysis Population	# Subjects (# Events)		Kaplan-Meier Estimate at 5 years		Hazard Ratio (Relative Risk Reduction)	Two-sided p-value (Device vs MM)
		Device group	MM group	Device group	MM group		
Pre-specified in protocol	Intent-to-treat	499 (9)	481 (16)	0.021	0.059	0.50 (50%)	0.089
Pre-specified in protocol	Per-Protocol	463 (6)	474 (14)	0.012	0.059	0.37 (63%)	0.034

Results of analyses through extended follow-up at 5 and 8 years are shown in Table 4. As subjects aged, strokes of traditional mechanism emerged, motivating a separate post-hoc analysis to characterize device effect. Strokes in which a disease was adjudicated to be present and likely to be the potential cause of the stroke by ASCOD phenotyping (*Overlap of Diseases Underlying Ischemic Stroke: The ASCOD Phenotyping* by Sirimarco et al 2013) were excluded. Such strokes are unlikely to be due to the PFO. This analysis showed a relative risk reduction of 54% for stroke (p = 0.042).

Table 4. Kaplan-Meier event rates at 5 years and 8 years, hazard ratio estimates and log-rank p-value (post-hoc analyses)

ITT Analysis	# Subjects (# Subjects with Events)		Kaplan-Meier Estimate At 5 years At 8 years		Hazard Ratio (Relative Risk Reduction)	p-value (Device vs MM)
	Device group	MM group	Device group	MM group		
Freedom from stroke of undetermined mechanism	499 (10)	481 (19)	0.021 0.025	0.041 0.052	0.46 (54%)	0.042

Safety Evaluation

There were 386 SAEs in 189 patients in the Device arm and 298 SAEs in 168 patients in the MM arm. The proportions of patients experiencing an SAE in the two arms were similar (37.9% in the Device arm and 34.9% in the MM arm; Table 5). The

proportion of patients experiencing an SAE related to the procedure was 2.4% and the proportion of patients experiencing an SAE related to the device was 2.0%. No unanticipated adverse device effects (UADE) were reported in the trial.

Table 5. Overall Rate of SAEs - Extended Follow-up

	Device (N=499, 2769 patient-years)		Medical Management (N=481, 2376 patient-years)	
	n (%)	Events (rate per 100 patient-years)	n (%)	Events (rate per 100 patient-years)
Any SAE	189 (37.9%)	386 (13.9)	168 (34.9%)	298(12.5)
Unanticipated adverse device effect	0 (0.0%)	0 (0.0%)	N/A	N/A
Deaths related to procedure or device	0 (0.0%)	0 (0.0%)	N/A	N/A
Related to procedure	12 (2.4%)	12 0.4)	N/A	N/A
Related to device	10 (2.0%)	13 (0.5)	N/A	N/A

Twelve (12) procedure-related SAEs occurred in 12 patients (2.4%), and are summarized in Table 6.

Table 6. Procedure- Related SAEs in the Device Arm (N = 467)

Event	n (%)
Cardiac perforation (<i>required pericardiocentesis</i>)	2 (0.4%)
Cardiac perforation (<i>no treatment required</i>)	2 (0.4%)
Access site bleeding (<i>1 required a stitch, 1 required transfusion, 1 required no treatment</i>)	3 (0.6%)
Right atrial thrombus (<i>detected during procedure - procedure abandoned</i>)	1 (0.2%)
Deep vein thrombus	1 (0.2%)
Atrial fibrillation (<i>successfully cardioverted</i>)	1 (0.2%)
Other (<i>allergic drug reaction - vasovagal response</i>)	2 (0.4%)

Thirteen (13) device-related SAEs occurred in 10 patients (2.0%), and are summarized in Table 7.

Table 7. Device-Related SAEs in the Device Arm (N = 467)

Event	n (%)
Ischemic stroke (<i>primary endpoint</i>)	2 (0.4%)
Pulmonary embolization	2 (0.4%)
Thrombus in right atrium (<i>not attached to device</i>)	1 (0.2%)
Atrial fibrillation	2 (0.4%)
Explant/surgical intervention	1 (0.2%)
Residual shunt requiring closure	1(0.2%)
Other (<i>chest tightness, atrial flutter, non-sustained ventricular tachycardia, sepsis</i>)	4 (0.8%)

Technical Success

Technical success, defined as successful delivery and release of the device for subjects in whom delivery system entered the body, was 99.1%.

Procedural Success

Procedural success, defined as successful implantation with no reported in-hospital SAEs in device subjects, was 96.1%.

Directions for Use

Materials recommended for use with this device

- 0.035-inch AMPLATZER™ Guidewire (9-GW-002)
- AMPLATZER™ TorqVue™ 45

Preprocedure care

- Aspirin (325 mg/day) (or alternative antiplatelet/anticoagulant, if patient has aspirin intolerance) is recommended to be started at least 24 hours prior to the procedure.
- Antibiotics can be administered periprocedurally.
- Patients should be fully heparinized throughout the procedure using adequate dosing so as to keep the activated clotting time (ACT) greater than 200 seconds.

Procedure

CAUTION: Transesophageal echocardiography (TEE) or similar imaging equipment (ie, intracardiac echocardiography) is recommended as an aid in evaluating the PFO and placing the AMPLATZER™ PFO Occluder. If TEE is used, the patient’s esophageal anatomy must be adequate for placement and manipulation of the probe. (moved from Precautions)

CAUTION: Fluoroscopic x-ray guidance may be used during placement of the device.(moved from Precautions)

1. Puncture the femoral vein and perform a standard right-heart catheterization.
2. Perform an angiogram to demonstrate the PFO. Catheterize the left atrium using a 45° LAO position and cranial angulation of 35°–45°. Inject contrast medium into the right upper lobe pulmonary vein.

Note: Occluder size and placement are based on the locations of the PFO.

3. Use the J-tip guidewire to gain access through the PFO.
4. Use transesophageal echocardiography (TEE) or similar imaging equipment (ie, intracardiac echocardiography) to measure the distance from the PFO to the aortic root, and the distance from the PFO to superior vena cava orifice.

Note: If TEE imaging is used, Steps 4-7 can happen prior to femoral access, if desired

5. Obtain two linear measurements by TEE or intra-cardiac echocardiography (ICE) as shown below:

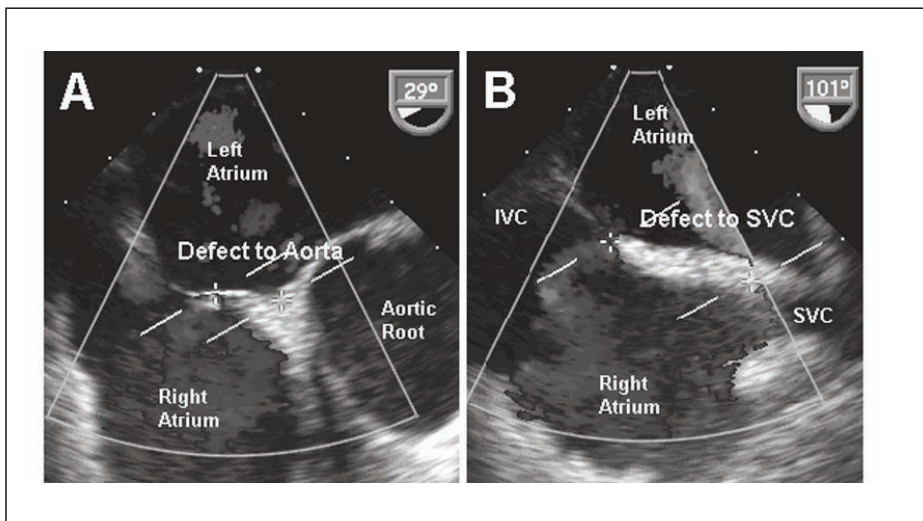


Figure 2.

A	Distance from the PFO to aortic root in the 30 degree view (range 0 to 45 degrees to visualize the aortic root en face); and
B	Distance from the PFO to the orifice of the superior vena cava (SVC) in the bicaval 90 degree view (range 80 to 125 degrees to minimize foreshortening of the SVC).

Note: If Imaging cannot clearly localize the PFO, place a wire through the PFO to help with identification.

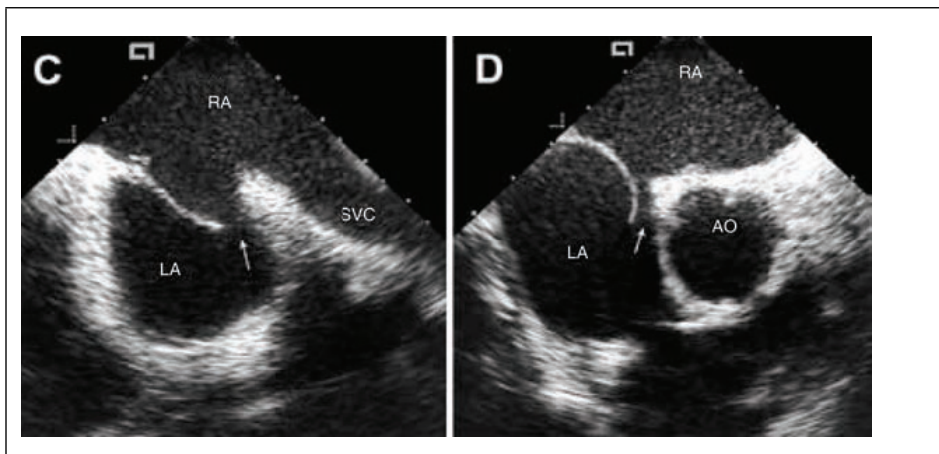


Figure 3.

C	PFO as assessed by ICE in long axis view
D	PFO as assessed by ICE in short axis view

- Size the device such that the radius of the right atrial disc will not exceed the lesser of the two measurements, except in the case of an atrial septal aneurysm, where consideration should be given to placing a larger occluder in an effort to cover the aneurysm (refer to Table 8 and Table 9 for sizing guidelines and device selection). Check SVC, inferior vena cava (IVC) and coronary sinus (CS) flows after device deployment, but before detachment.

WARNING: Do not implant a device if the distance from the PFO to the Aortic Root or SV is less than 9 mm (as measured by echocardiography).

Table 8. Device Sizing Guidelines

Shortest Distance from PFO to Aortic Root or Distance from PFO to Superior Vena Cava Orifice (mm)	Suggested AMPLATZER™ PFO Occluder Size (mm)
Greater than or equal to 17.5	35

Table 8. Device Sizing Guidelines

Shortest Distance from PFO to Aortic Root or Distance from PFO to Superior Vena Cava Orifice (mm)	Suggested AMPLATZER™ PFO Occluder Size (mm)
12.5 – 17.4	25
9.0 – 12.4	18
Less than 9.0	Do not implant device

Note: See Table 9 for device specifications and recommended sheath size.

Table 9. AMPLATZER™ PFO Occluder Specifications and Recommended Sheath Sizes

Device Order Number	Right Atrial Disc Diameter	Left Atrial Disc Diameter	Recommended Sheath Size
9-PFO-018	18 mm	18 mm	8 Fr
9-PFO-025	25 mm	18 mm	8 Fr
9-PFO-035	35 mm	25 mm	9 Fr

7. Prepare the delivery system according to the manufacturer's instructions for use.
8. Insert the dilator into the delivery sheath and tighten the rotating luer. Advance the dilator and delivery sheath over the guidewire, through the communication, and into the left atrium, confirming correct movement via echo and/or fluoroscopy.

CAUTION: Do not use a power injection syringe to put contrast solution through the sheath.

WARNING: Do not advance the delivery system if resistance is felt. Slowly remove the guidewire and dilator to prevent ingress of air. Allow blood backflow to purge all air from the system. Flush the delivery sheath with sterile saline.
9. Prepare the device for use.
 - Inspect the sterile pouch.

CAUTION: Do not use the device if the sterile pouch is open or damaged.

 - Open the sterile pouch. Inspect the device.

CAUTION: Do not use the device if it is damaged.
10. Pass the delivery cable through the loader. Attach the device to the distal end of the delivery cable by rotating the device clockwise approximately 5 turns until the device is secure. Then, rotate the device counterclockwise 1/8 of one turn to facilitate release of the device.
11. Immerse the device and loader in sterile saline and pull back on the delivery cable to retract the device inside the loader
12. Flush the loader with sterile saline through the hemostasis valve.
13. Attach the loader to the delivery sheath and tighten the rotating luer to lock the components together.
14. Attach the loader firmly to the sheath to ensure that there are no gaps between the inner surfaces of the 2 components. Advance the delivery cable and device through the delivery sheath until the device reaches the tip of the sheath. Do not rotate the cable.

CAUTION: Do not advance the delivery cable and device if resistance is felt.
15. Use angiography and echocardiography for guidance. Hold the delivery cable in place while retracting the delivery sheath to deploy the left atrial disc and part of the connecting waist. Pull the device gently against the atrial septum. This can be felt and observed by echocardiography.
16. Maintain a slight tension on the delivery cable while retracting the delivery sheath approximately 5–10 cm to deploy the right atrial disc.
17. Confirm correct placement. Use angiography and echocardiography to confirm that the device is in place and evaluate for residual shunt or valve insufficiency.
18. If the position of the device is unsatisfactory:
 - Stabilize the delivery cable and re-advance the delivery sheath until the device is completely within the sheath.
 - Reposition the device and deploy it again, or remove the device from the patient. The device may be repositioned and recaptured up to 3 times.
19. 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. Detach the device from the delivery cable by turning the delivery cable counterclockwise (indicated by the arrow on the plastic vise). In the unlikely event that this should not be possible, advance the delivery sheath against the right atrial disc to secure the device and to facilitate detachment

Note: When the procedure is complete, slowly remove the sheath and delivery cable from the patient.

WARNING: When the procedure is complete, slowly remove the delivery cable and delivery sheath from the patient. Remove the sheath slowly to prevent an ingress of air.

Post-procedure care

- It is up to the physician discretion whether patient should be kept overnight. Regardless of hospital length of stay, patient should have a TTE prior to discharge.
- Patients with any observed pericardial effusion following the device implantation should be closely monitored with serial echocardiograms performed until the pericardial effusion resolves.
- Clinical follow-up with a cardiologist and echocardiograms are recommended at implant, 1 day post-implant, pre-discharge, and again at 1 week, 6 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 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 antithrombotic therapy (such as aspirin) for 6 months post-implant. The decision to continue antithrombotic therapy beyond 6 months is at the discretion of the physician.
- Patients should be instructed to avoid strenuous activity for a minimum of 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.
- If a left-sided thrombus is identified, the patient should be evaluated for a hypercoagulable state and aggressive anticoagulant therapy should be initiated. Thrombolysis and surgical removal should be considered if the patient does not respond to anticoagulant therapy.
- For patients with a history of PE or DVT additional anticoagulation should be considered.

Post-procedure Instructions

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

Disposal

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

Warranty















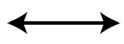




St. Jude Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. St. Jude 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 St. Jude Medical Corporation and after confirmed to be defective by the manufacturer.

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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
	Reference number
	Product serial number
	Product lot number
	Use by date (Use on or before the last day of the expiration month noted on the product packaging.)
	Do not reuse
	Sterilized using ethylene oxide
	Consult operating instructions
	Keep dry
	Do not use if package is damaged
	Does not contain natural rubber latex components
	Inner diameter
	Outer diameter
	Length
	Usable length
	Recommended delivery sheath/catheter dimensions
	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).

	Date of manufacture
	Quantity