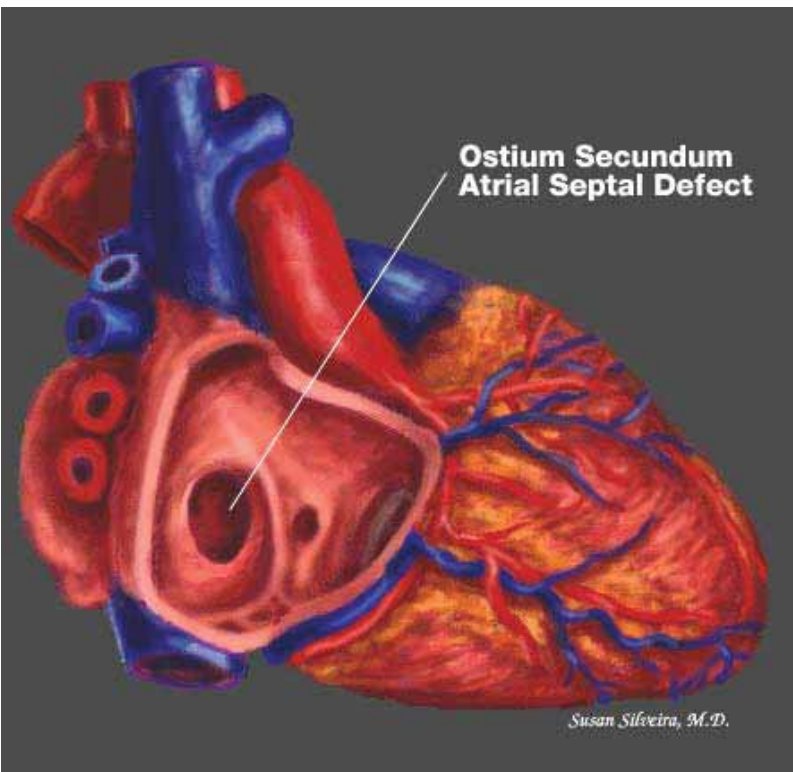


Septal Occluder

*The Answer to Effective
Transcatheter Treatment of
Atrial Septal Defects*

Understanding the Atrial Septal Defect



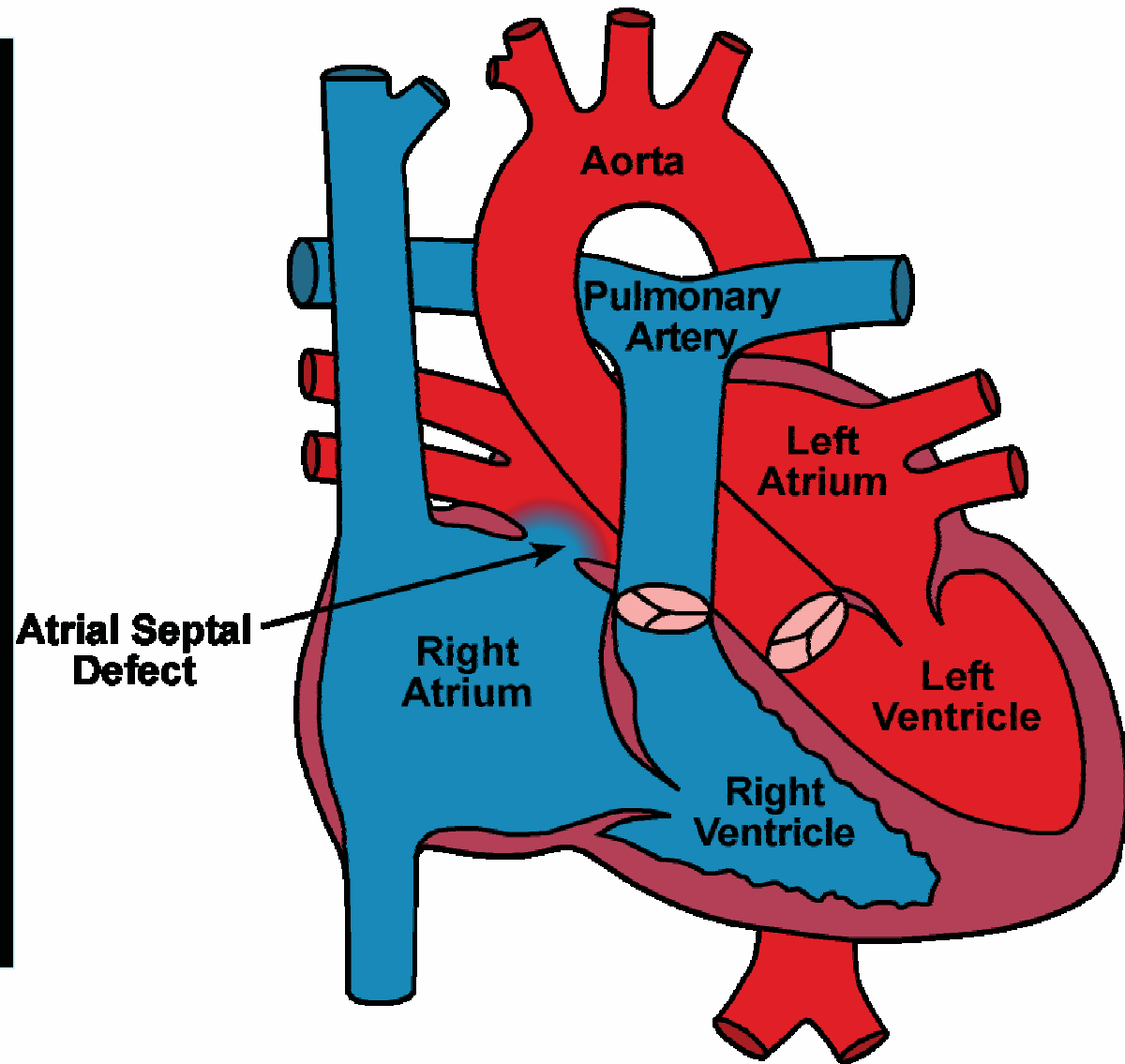
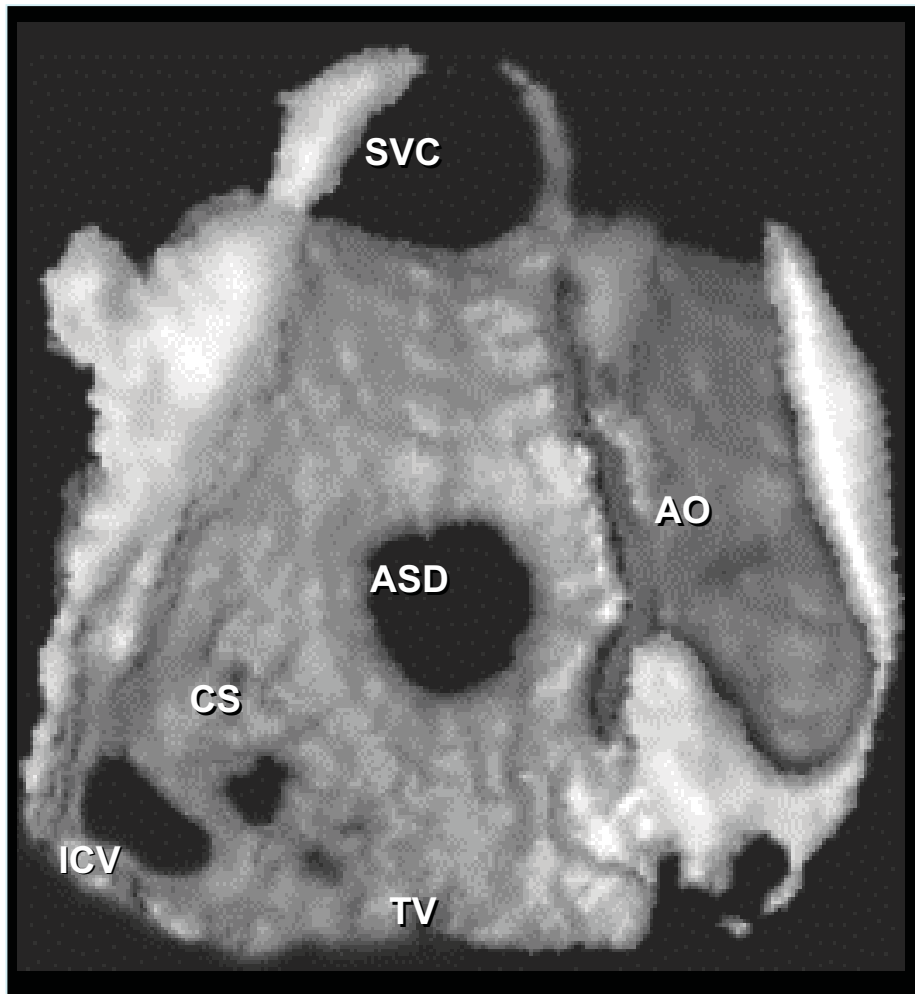
An Atrial Septal Defect (ASD) is a hole between the two upper chambers of the heart (atria), this occurs in 5 – 10% of congenital heart disease. In fetal development, the wall (septum) between the collecting chambers (atria) did not completely close and left a hole. Usually the hole is about in the middle, where the septal wall is thinnest. This is called a secundum defect.

In a normal heart, the right side pumps blood only to the lungs, where the oxygen is replenished. The left side pumps blood to the rest of the body, delivering the oxygen. For that reason, the left side needs to pump harder; generally, there's three to four times as much pressure on the left side. If there's an ASD, this pressure differential means that some blood flows through the hole from the left to the right side. This is one cause of "heart murmurs".

Because it's receiving so much extra blood, the left side of the heart does more than its normal share of work. It may have a tough time coping with the extra load. Plus, the blood is poorly oxygenated because the cycle is being "short circuited." This can cause symptoms like fatigue, difficult or rapid breathing, failure to grow normally, or chronic respiratory infections.

Larger holes can lead to heart failure and death. The severity of these symptoms depends on the size and location of the hole. Sometimes the symptoms appear in newborns. Sometimes they don't appear until much later in life. Each case is different.

The Atrial Septal Defect



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 or patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration.

Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left to right shunt or RV enlargement).

Contraindications

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- Any patient known to have sepsis within one month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Any patient known to have a bleeding disorder, untreated ulcer or any other contraindications to aspirin therapy, unless another 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 (i.e., too small for TEE probe, catheter size, etc) or condition (active infection, etc) would cause the patient to be a poor candidate for cardiac catheterization.
- Any patient where the margins of the defect are <5mm to the coronary sinus, AV valves or right upper lobe pulmonary vein.

Directions for Use

- Patients should be fully heparinized throughout the procedure with a minimum activated clotting time (ACT) of 200 seconds prior to device insertion.
- 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 cranial angulation 35-45°, inject contrast medium 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 ASD

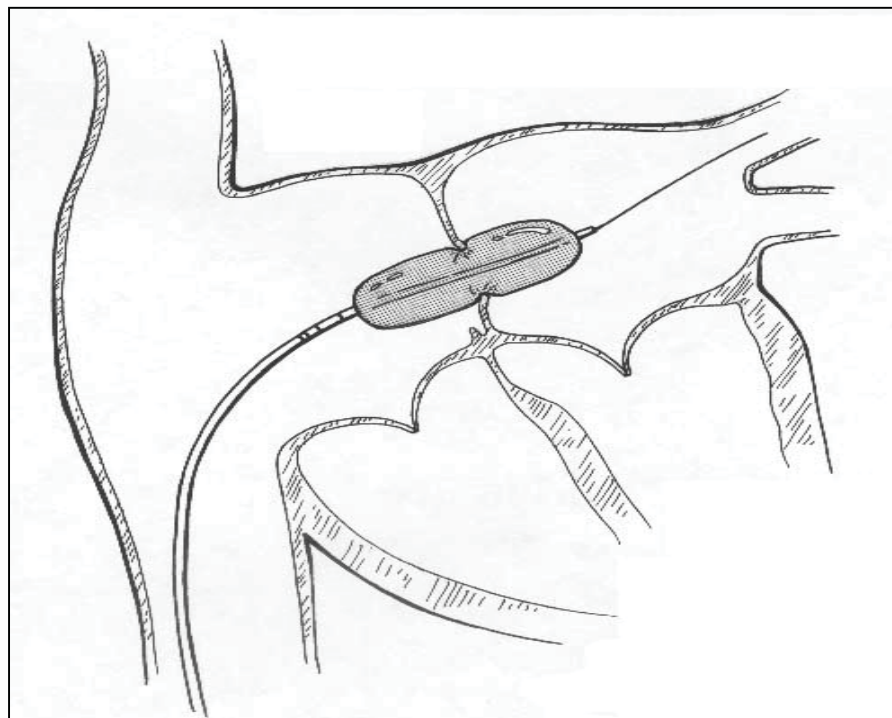
Two methods can be used:

- 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 CO₂ 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.
- 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 to the balloon catheter 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 ensure that the recommendations of the manufacturer are followed.*

AMPLATZER® Sizing Balloon

Provides Three Ways of Measuring Heart Defects

- Angiography (measure markers)
- TEE (clear indentation waist)
- Use of a sizing plate



Directions for Use

- 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. Flush via a side arm attached to the loader.
- Insert the dilator into the delivery sheath and secure to the sheath with the locking mechanism. Introduce the dilator/delivery sheath assembly through the groin. Once the delivery sheath has reached the inferior vena cava, remove the dilator to allow back bleeding to purge all air from the system then connect the hemostasis valve and flush with a syringe before the left atrium is entered.
- **WARNING:** Always use the luer lock adapter when connecting the hemostasis valve to the sheath when using the 12 French delivery system.
- 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 exchange wire and flush the sheath with saline.

AMPLATZER® Septal Occluder

- Self-Expandable
- Short-connecting Waist
- Nitinol Wire .004" - .008"
- Sizes: 4-38 mm

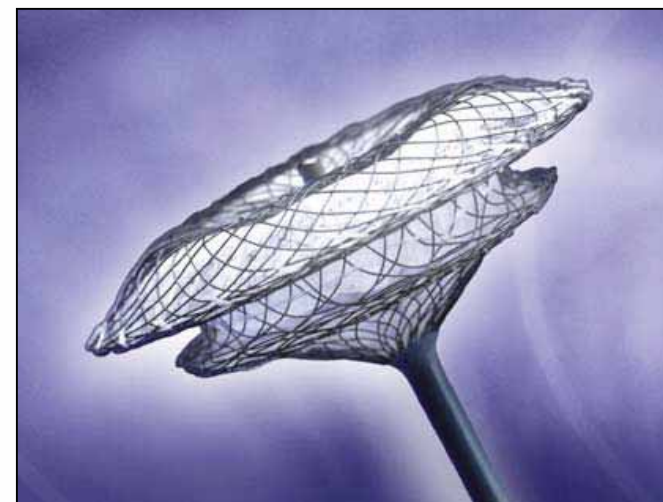
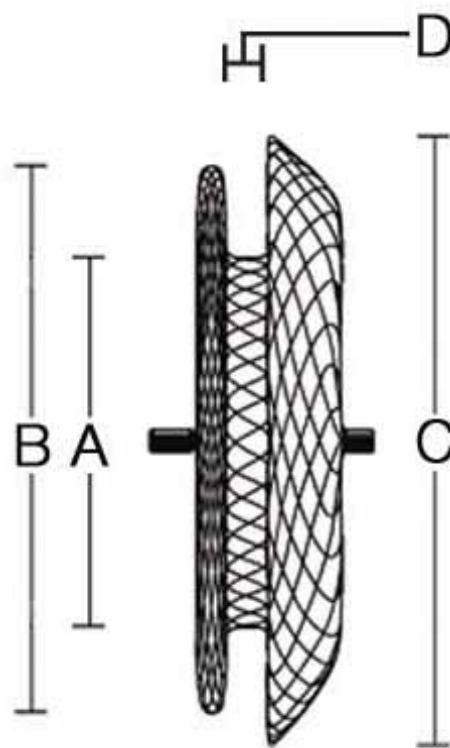
LEGEND:

Device Size (Waist = A)

RA Disc (B)

LA Disc (C)

Length of Waist = (D)



AMPLATZER® Sheath Selection Guide

Device and Delivery System Compatibility

6F: 60 cm, Device Size 4-10mm

7F: 60 or 80 cm, Device Size 11-17mm

8F: 60 or 80 cm, Device Size 18-20

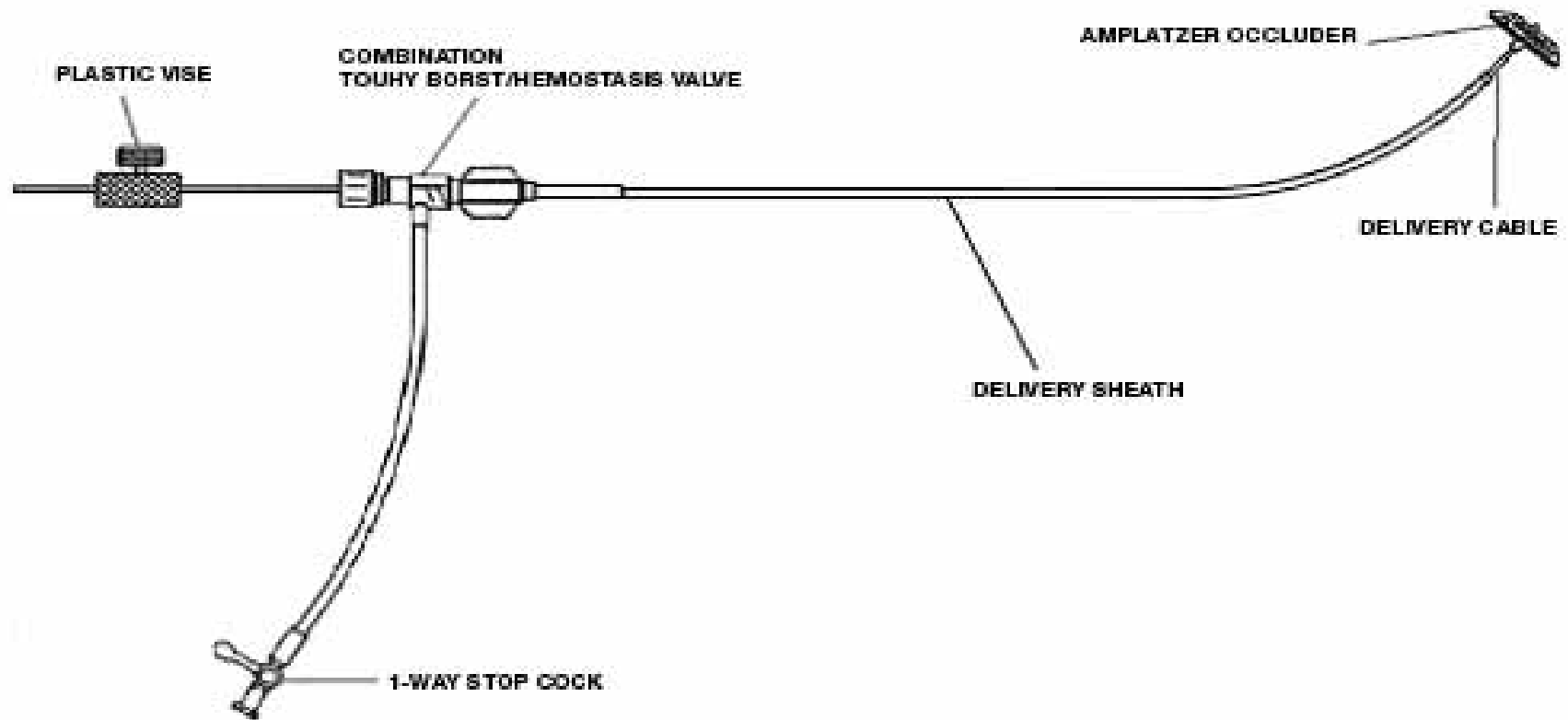
9F: 80cm, Device Size 22-24

10F: 80 cm, Device Size 26-30

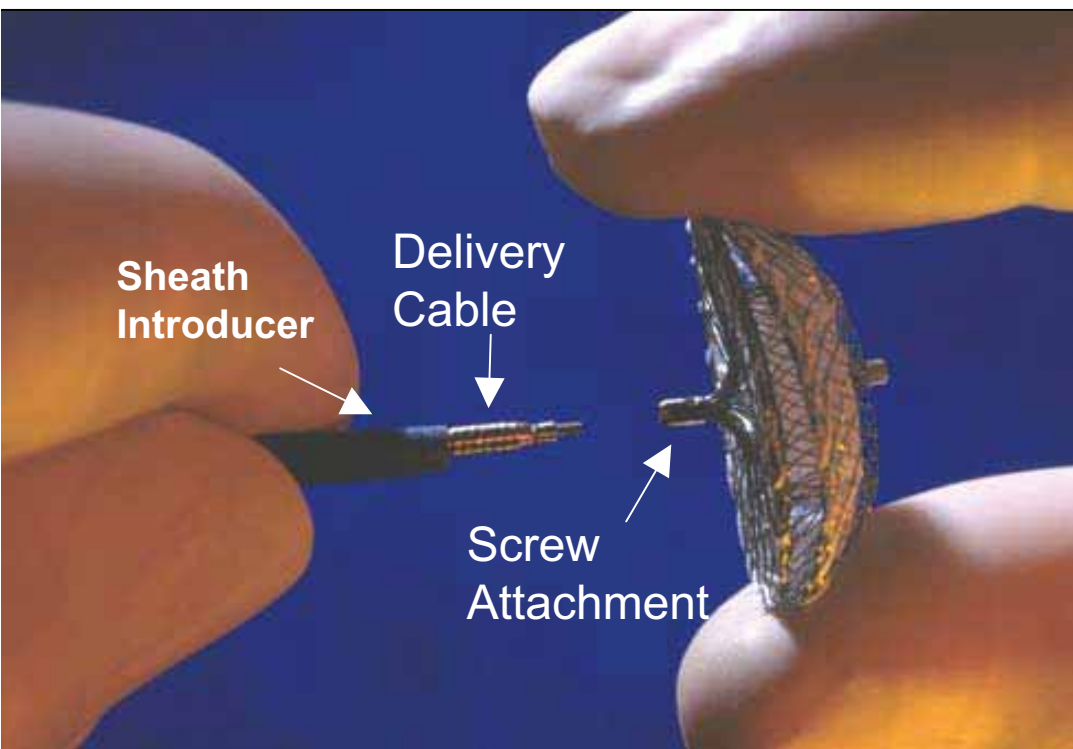
12F: 80 cm, Device Size 32-38

Color of Fr size is actual sheath color

AMPLATZER® Delivery System



AMPLATZER® Loading the Device



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



Attachment



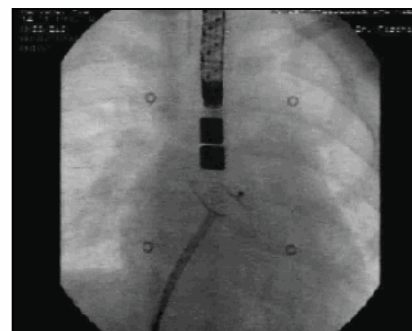
Loading



Transfer



Advancement



Deployment

AMPLATZER® Septal Occluder

How Are They Implanted?

- Under fluoroscopic and echocardiographic guidance, deploy the left atrial disc and part of the connecting waist (figure 1) and pull the device gently against the atrial septum (figure 2), 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 (figure 3). Pull the sheath back by approximately 5-10 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 disk to secure the device, which will facilitate detachment (figure 4).

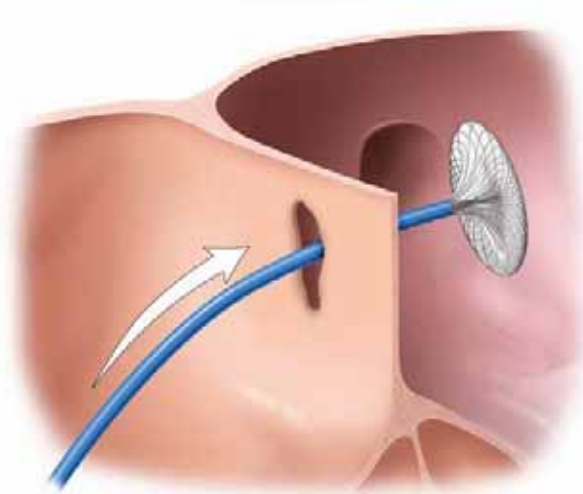


Figure 1

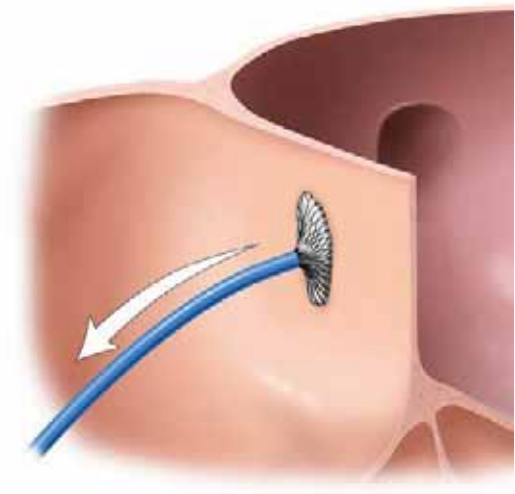


Figure 2

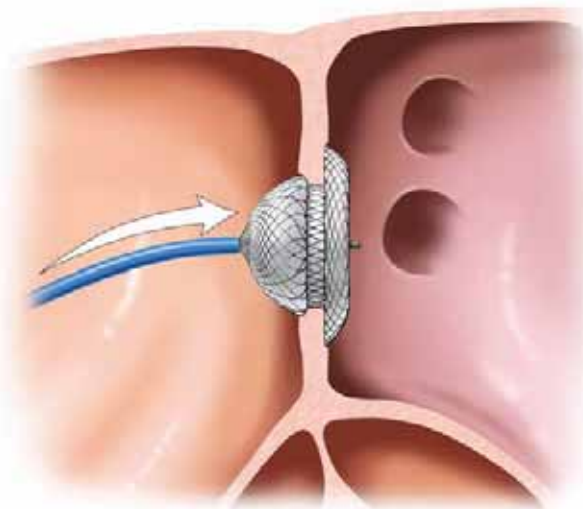


Figure 3

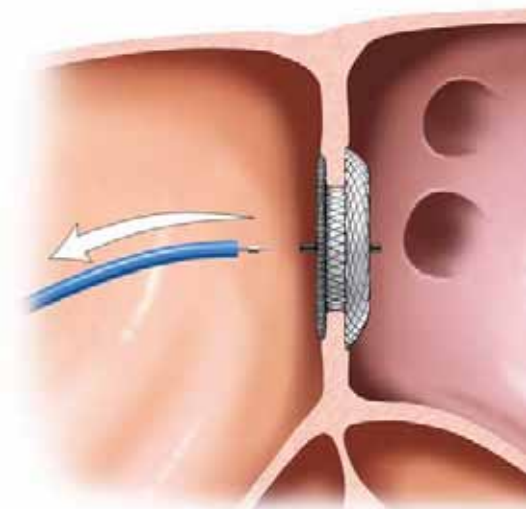
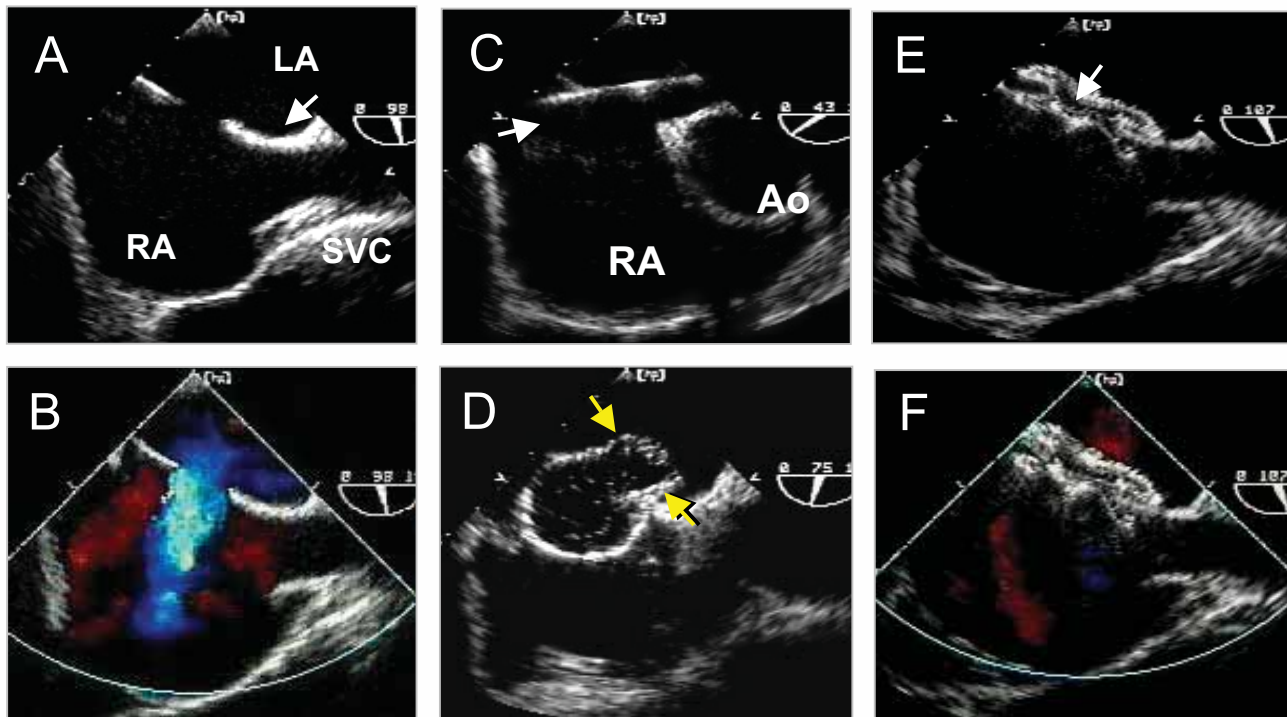


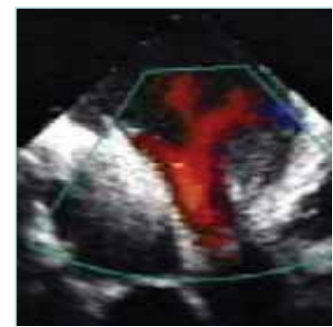
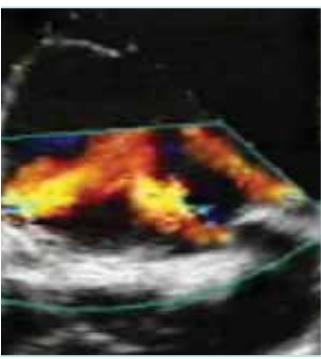
Figure 4

Transcatheter Closure of Secundum ASD

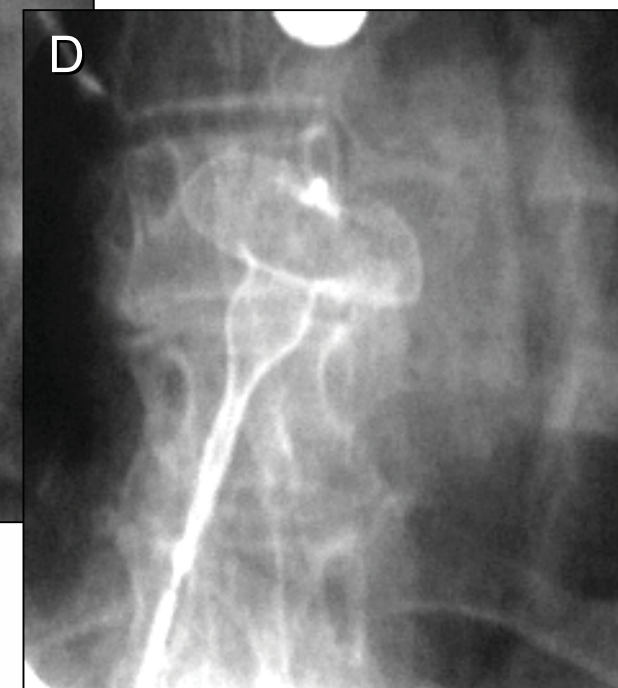
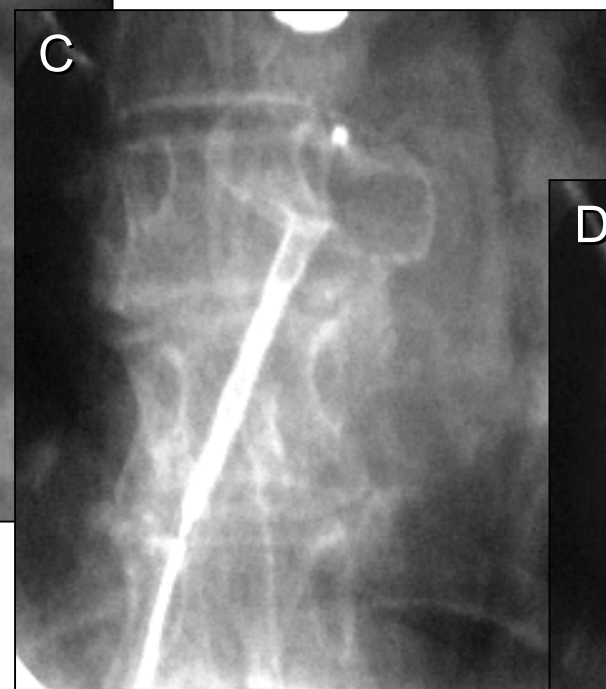
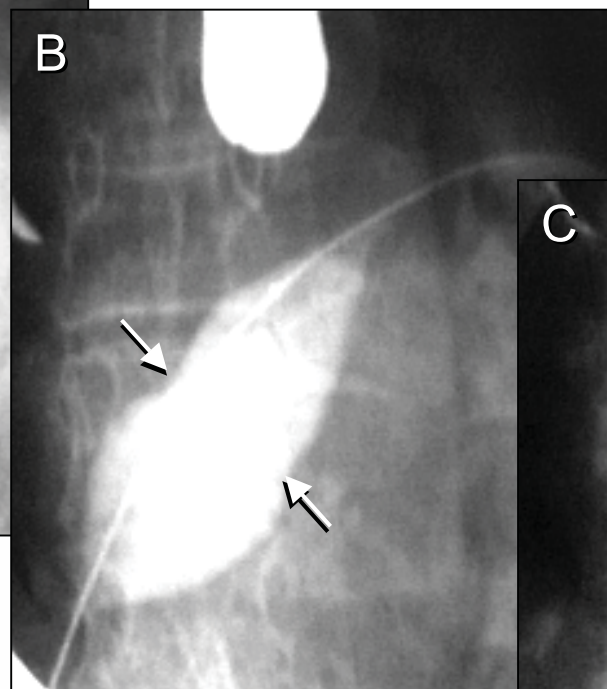
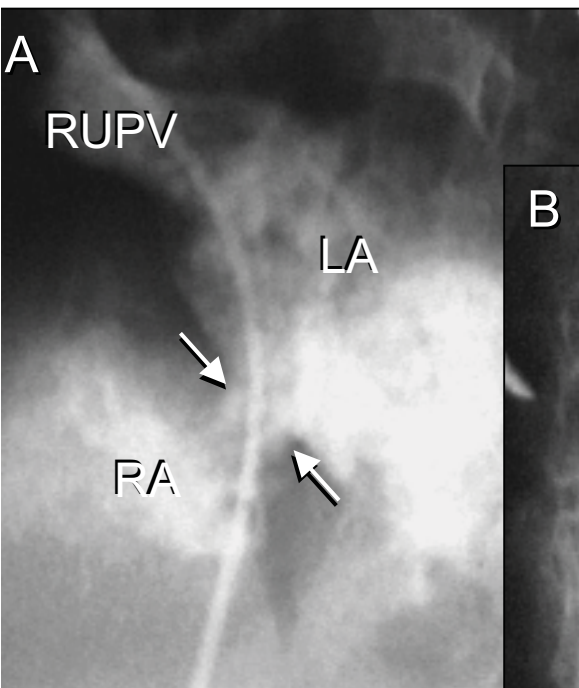
TEE Guidance



Transcatheter Closure of Secundum ASD CE Guidance



Transcatheter Closure of Secundum ASD



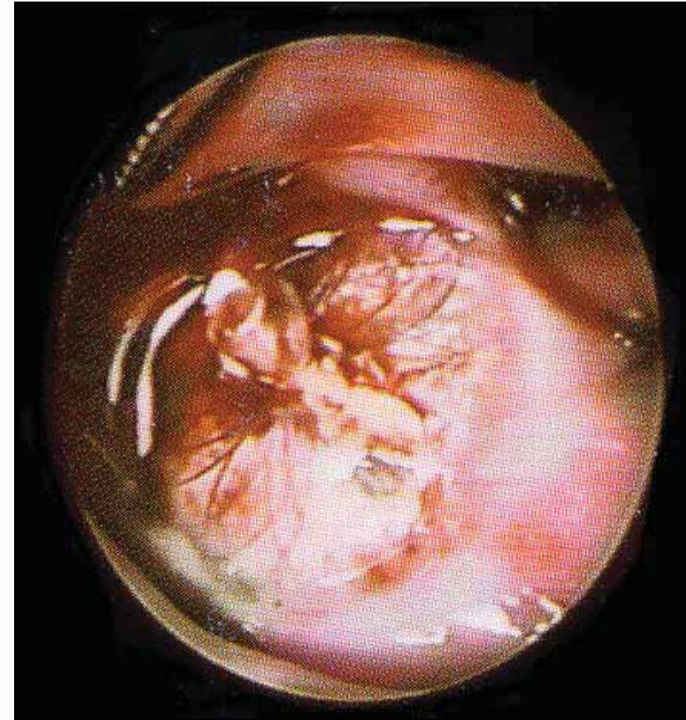
Anatomical Implantation Views



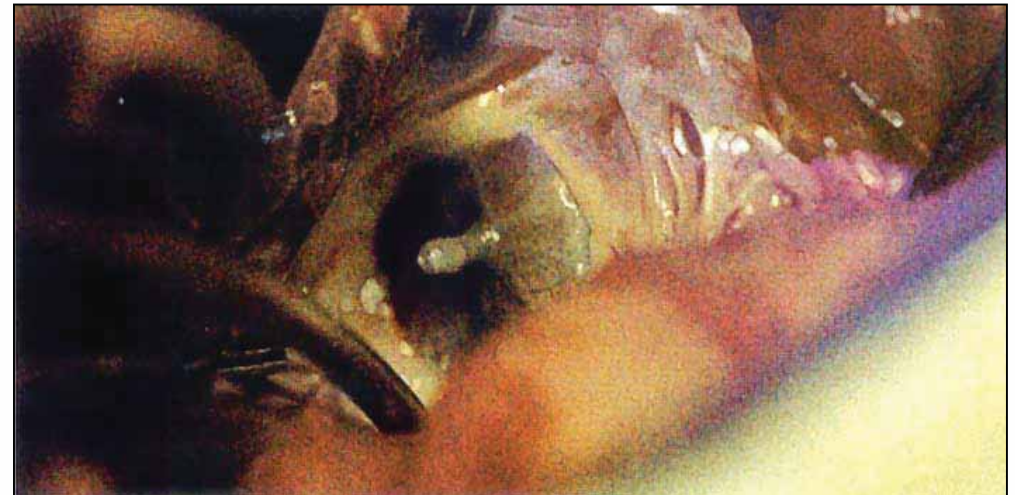
Seven weeks post implant



Six weeks post implant



Right atrial view of a 6mm /
one month post implant



Seven months post implant

AMPLATZER® Septal Occluder

Ordering Information

Order Number	Device Size	Smallest Recommended Sheath	Order Number	Device Size	Smallest Recommended Sheath
9-ASD-004	4 mm	6-7 French, 45° curve	9-ASD-017	17 mm	7 French, 45° curve
9-ASD-005	5 mm	6-7 French, 45° curve	9-ASD-018	18 mm	8-9 French, 45° curve
9-ASD-006	6 mm	6-7 French, 45° curve	9-ASD-019	19 mm	8-9 French, 45° curve
9-ASD-007	7 mm	6-7 French, 45° curve	9-ASD-020	20 mm	8-9 French, 45° curve
9-ASD-008	8 mm	6-7 French, 45° curve	9-ASD-022	22 mm	9 French, 45° curve
9-ASD-009	9 mm	6-7 French, 45° curve	9-ASD-024	24 mm	9 French, 45° curve
9-ASD-010	10 mm	6-7 French, 45° curve	9-ASD-026	26 mm	10 French, 45° curve
9-ASD-011	11 mm	7 French, 45° curve	9-ASD-028	28 mm	10 French, 45° curve
9-ASD-012	12 mm	7 French, 45° curve	9-ASD-030	30 mm	10 French, 45° curve
9-ASD-013	13 mm	7 French, 45° curve	9-ASD-032	32 mm	10 French, 45° curve
9-ASD-014	14 mm	7 French, 45° curve	9-ASD-034	34 mm	10 French, 45° curve
9-ASD-015	15 mm	7 French, 45° curve	9-ASD-036	36 mm	10 French, 45° curve
9-ASD-016	16 mm	7 French, 45° curve	9-ASD-038	38 mm	12 French, 45° curve