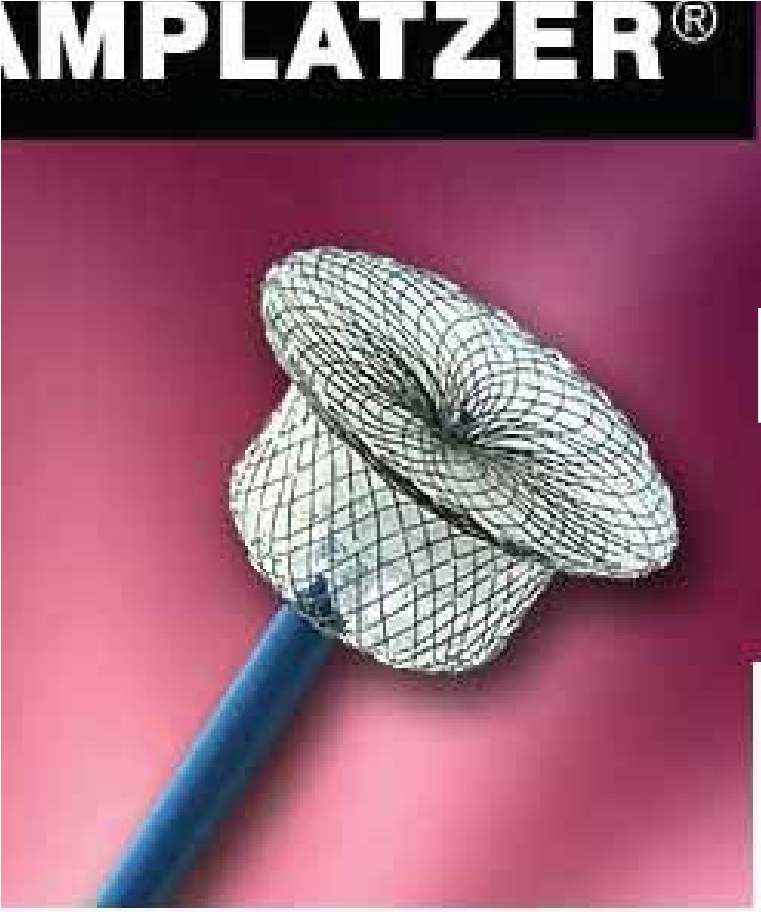
AMPLATZER®



Duct Occluder

Specifically Designed for the Non-Surgical Closure of Patent Ductus Arteriosus

Patent Ductus Arteriosus (PDA)

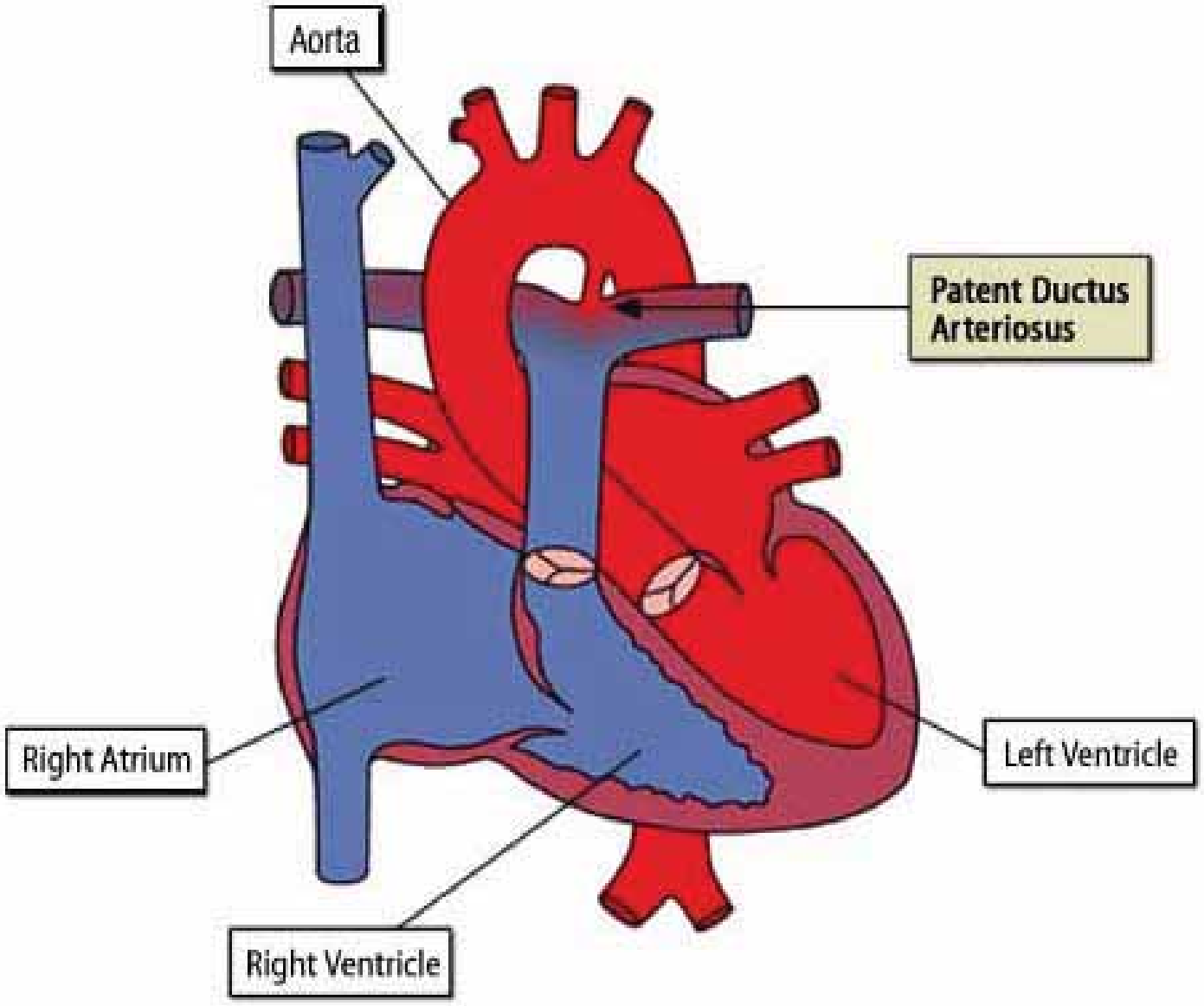
- Patent ductus arteriosus (PDA) is one of the best known of all congenital anomalies; it was the first to be treated via surgery. It represents about 8%-15% of all congenital heart disease, and is twice as frequent in females as in males.

- The ductus arteriosus is an artery that allows blood in the fetus to bypass the lungs until the lungs expand at the time of birth. It normally closes soon after birth. When it remains open (patent) blood can flow from the aorta to the pulmonary artery.

- This defect over-works the heart, causes excess blood flow in the lungs, and can cause symptoms like fatigue, difficult or rapid breathing, failure to grow normally, or chronic respiratory infections. Large openings can lead to heart failure and death.

Patent Ductus Arteriosus

ustration of a Patent
uctus Arteriosus



PDA Classifications

PDAs Have Been Classified Into Five Types

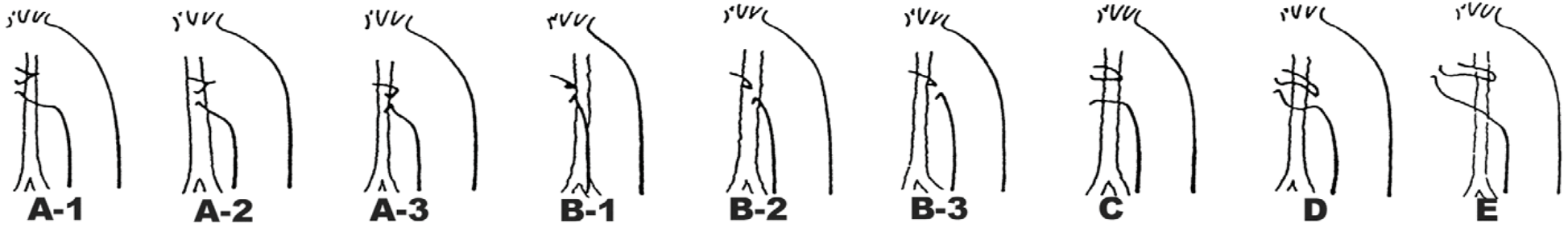
TYPE A- the most common (65% in one large series), a funnel-shaped ductus with a localized narrowing at the pulmonary artery junction.

TYPE B- the next most common (18%), includes funnel-shaped PDAs with an aortic ampulla.

TYPE C- tubular shape

TYPE D- oval shape with both aortic and pulmonary ampullae

TYPE E- other bizarre forms



Indications and Usage

The AMPLATZER Duct Occluder is indicated for the non-surgical closure of patent ductus arteriosus (PDA).

Contraindications for Use

- Patients weighing less than 6 kgs.
- Patients less than 6 months of age.
- 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.
- 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.

*Patients with pulmonary hypertension with pulmonary vascular resistance Of >8 woods units or Rp/Rs of >0.4.

AMPLATZER® Duct Occluder

LEGEND:

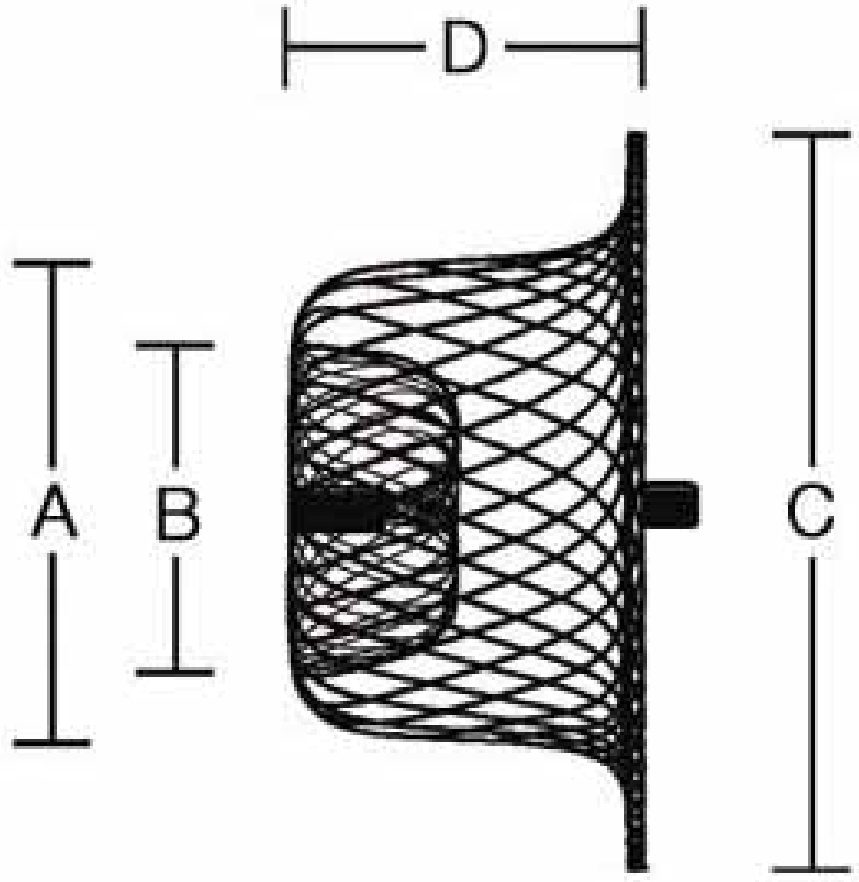
Device Size (A/B)

AO (A)

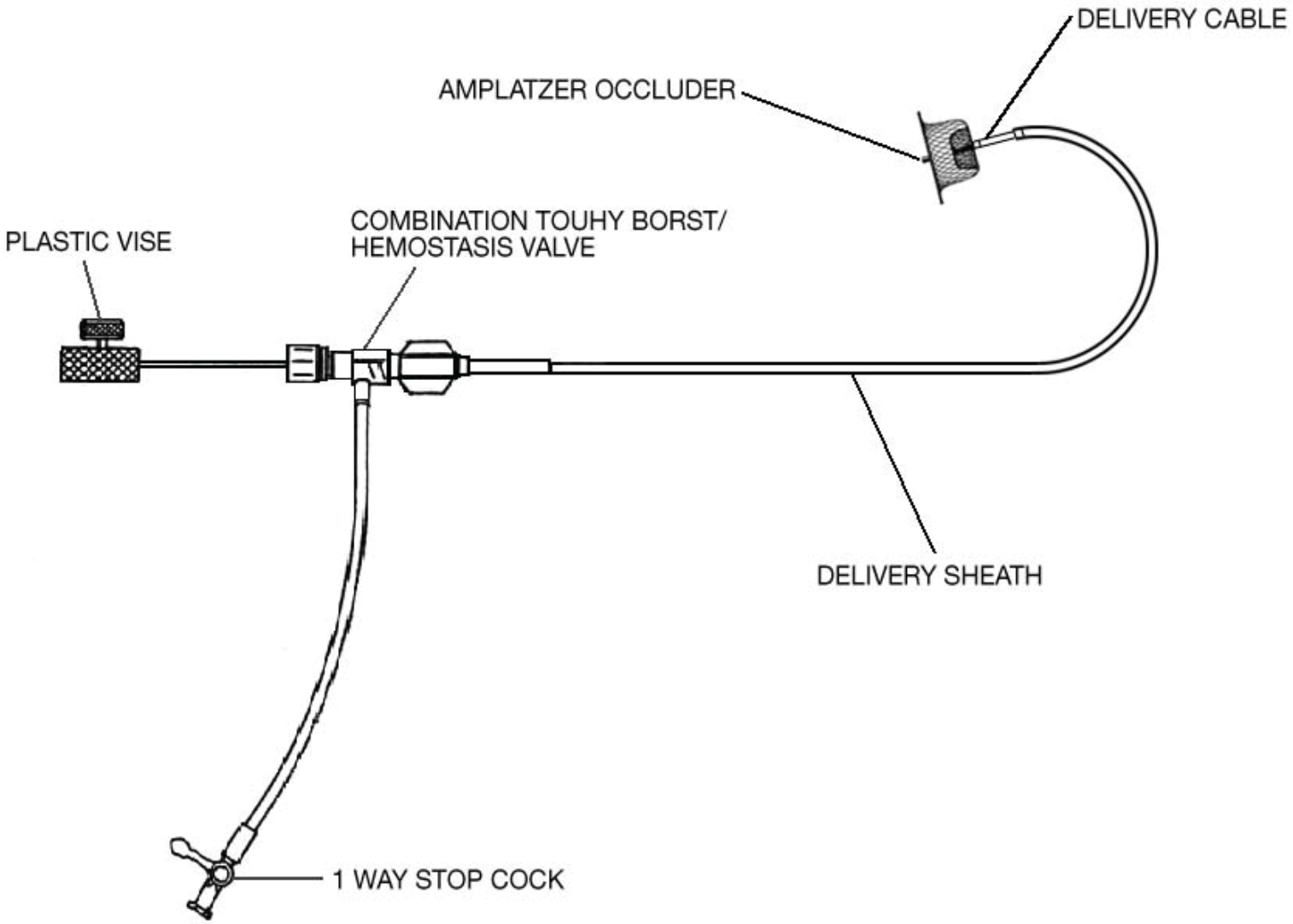
PA (B)

Retention Skirt = (C)

Length = (D)

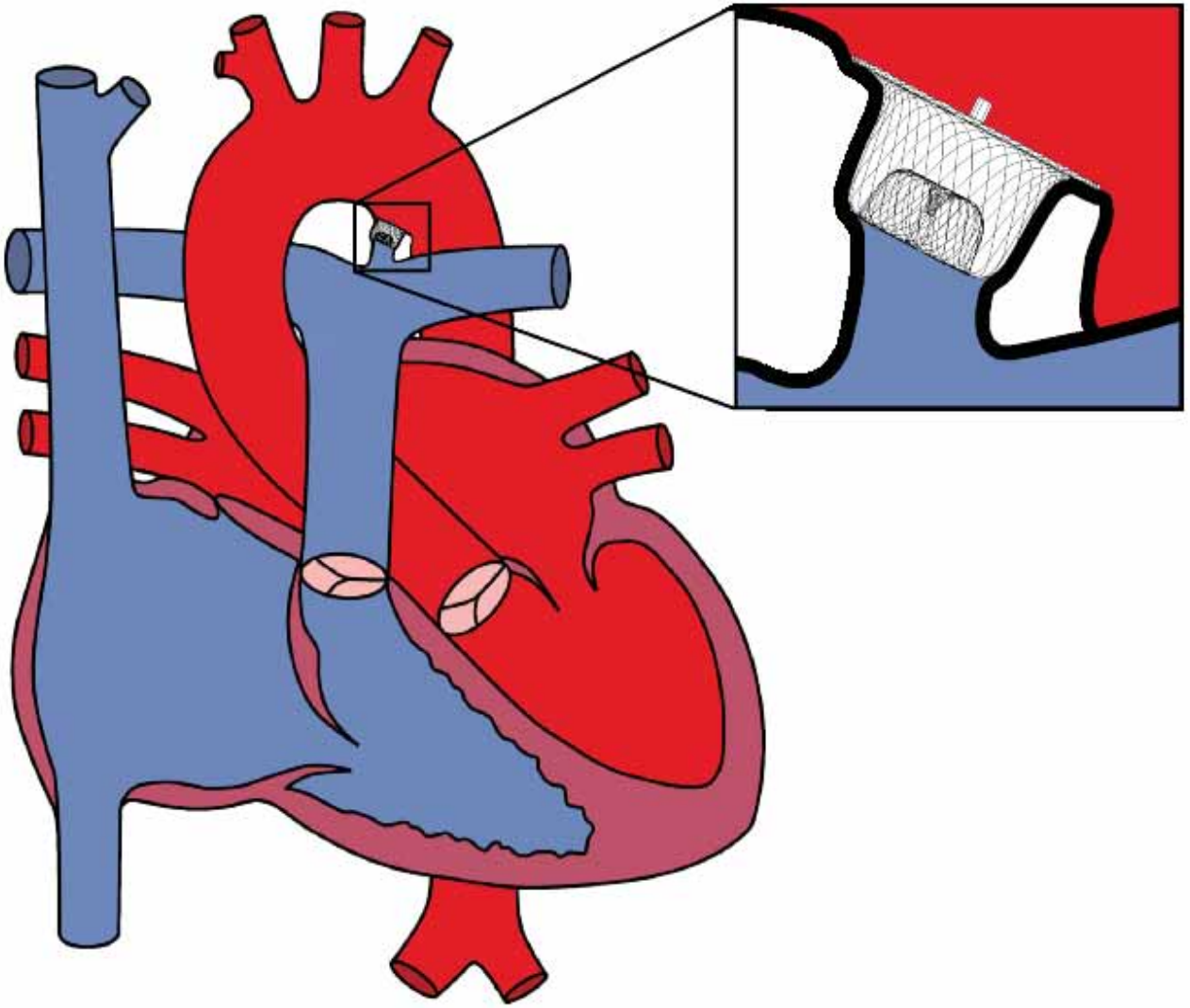


AMPLATZER® Delivery System



AMPLATZER® Duct Occluder

Device Implantation



AMPLATZER® Directions for Use

erform a right heart catheterization in routine fashion. There are two tions for angiographic demonstration of the patent ductus arteriosus. e first is to introduce an exchange guidewire through the ductus and ss a pigtail catheter with side holes in the communication. Perform a plane angiogram to opacify the PDA. The second option is to pass a gtail catheter into the proximal descending aorta via the femoral tery and perform the biplane angiogram to opacify the PDA.

lect an AMPLATZER Duct Occluder based on the smallest diameter easured in the PDA (refer to Figure 5 “B” measurement). It is commended to select a device so that the smaller end of the device at least 2-mm larger than the narrowest portion of the PDA. The vice size is a two-digit number. For example in the 8/6 device, the 8 fers to the diameter inside the retention skirt of the device, and the 6 fers to the opposite smaller end of the device. If the “B” easurement in the ductus is 4 mm, select the AMPLATZER Duct cluder with the smaller end of at least 6 mm. Therefore the 8/6 vice would be selected.

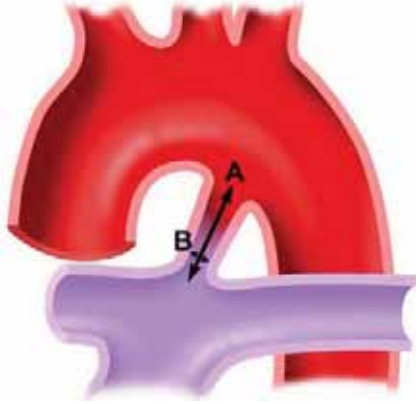


Figure 5

= Length

= Smallest Diameter

Introduce an exchange J-tipped guidewire. Remove the catheter. Advance the introducing sheath with dilator over the exchange wire into the aorta and position the sheath in the descending aorta while removing the dilator (Figure 6). Position can be confirmed by a test injection of contrast medium.

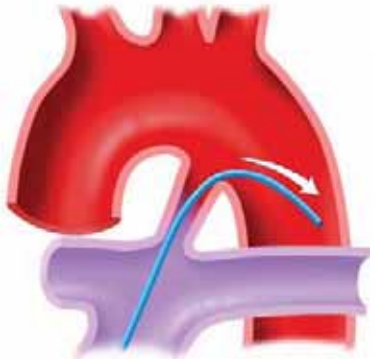


Figure 6

Pass the delivery cable through the loader and screw the AMPLATZER Duct Occluder clockwise onto the tip of the delivery cable (Figure 7).

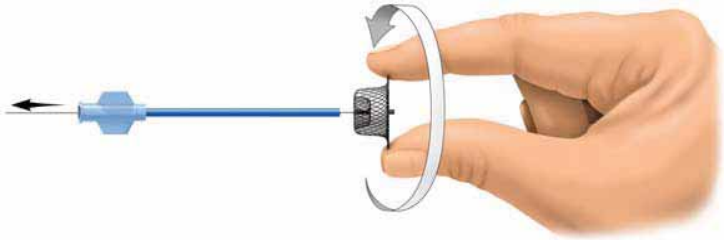


Figure 7

Immerse the device and the loader in saline solution and pull the AMPLATZER Duct Occluder into the loader.

Introduce the loader into the delivery sheath and without rotation, advance the device into the descending aorta (Figure 8).

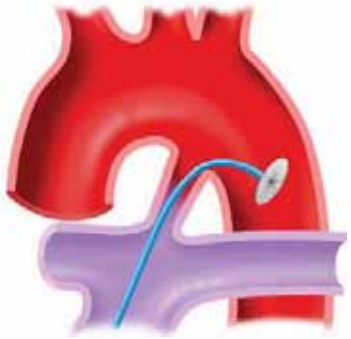


Figure 8

Deploy the retention skirt only and pull firmly against the orifice of the patent ductus arteriosus. This can be observed by fluoroscopy, or it can be clearly felt as a tugging sensation in synchrony with the aortic pulsation. The position of the device is confirmed with repeated angiograms in the aorta using the pigtail catheter. The device can be adjusted until the retention skirt is well seated in the ampulla. Retract the delivery sheath and deploy the cylindrical portion of the device securely in the patent ductus arteriosus while applying slight tension (Figure 9).

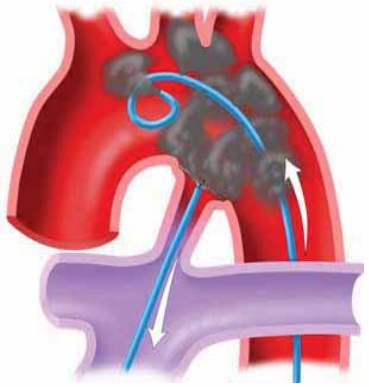


Figure 9

Perform an aortogram to verify correct position of the device. Perform and record on cine a power injection through the catheter using 1 cc per kilogram of contrast at 12 ml per second at 400 psi. To have optimal visualization of the anatomy, angulate the AP camera at 35 degrees LAO and 35 degrees cranial, and the lateral camera straight. These views will allow you to delineate the length of the device protruding into the pulmonary artery lumen.

WARNING: Remove the device if >3mm extends into the pulmonary artery, or if more than half of the left pulmonary artery lumen is occupied by the device. In questionable cases, perform transthoracic echocardiography before release of the device with Doppler measurement of left pulmonary artery flow velocity. The device should be removed if left pulmonary artery flow is >3.0 M/s (or >75% greater than the LPA velocity before cardiac catheterization).

If position is not satisfactory, recapture the device into the sheath by pulling back on the delivery cable.

NOTE: 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.

Screw the plastic vise on the delivery cable and detach the device by rotating the cable counter clockwise as indicated by the arrow on the vise (Figure 10). Repeat aortogram.

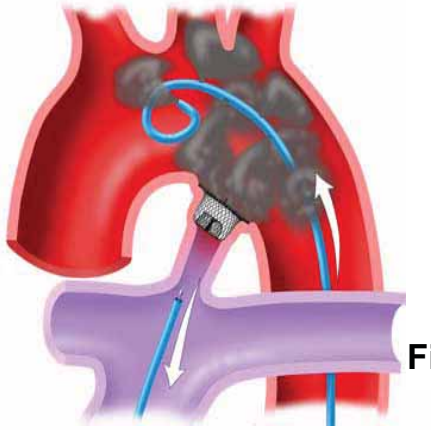
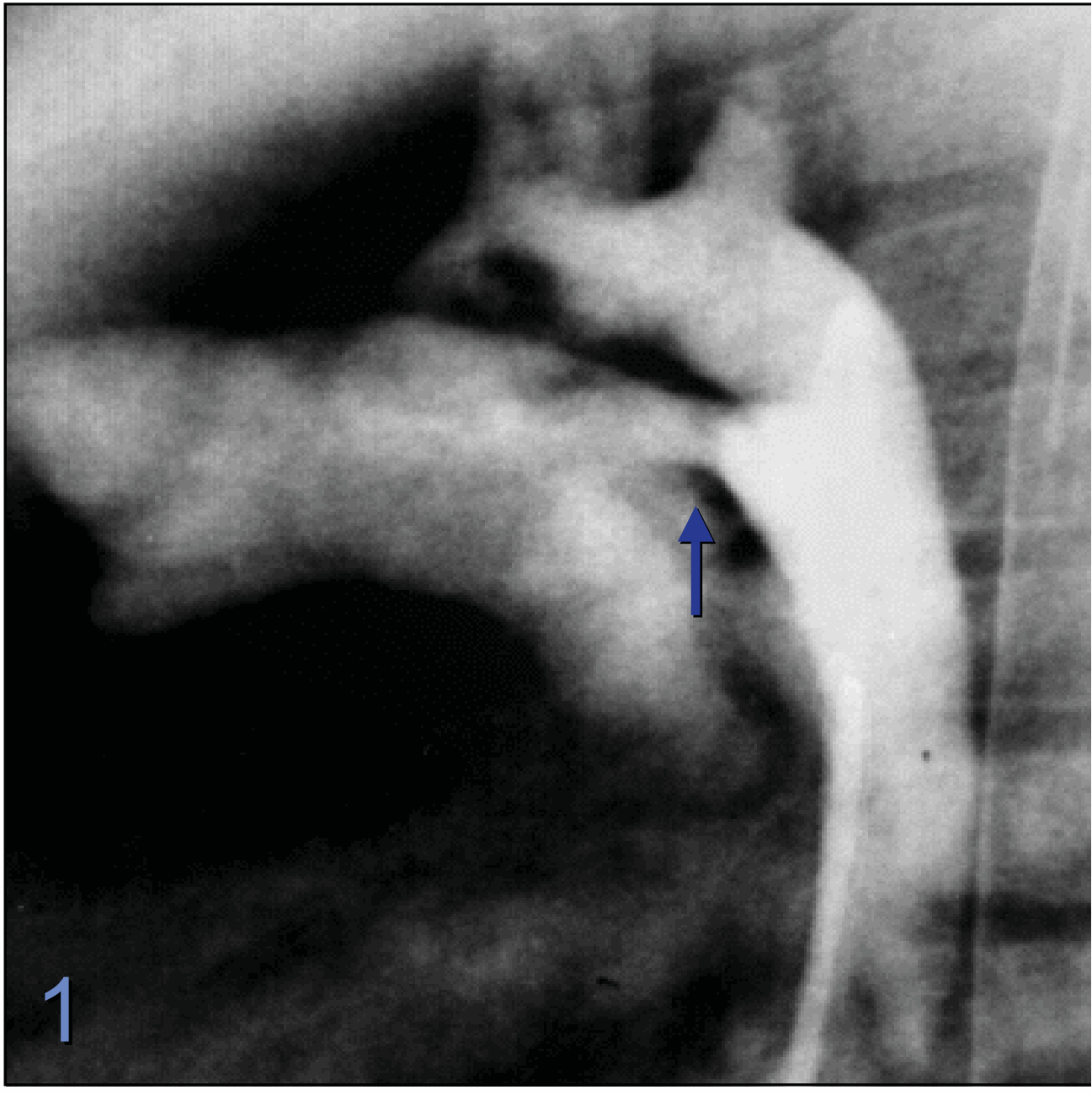


Figure 10

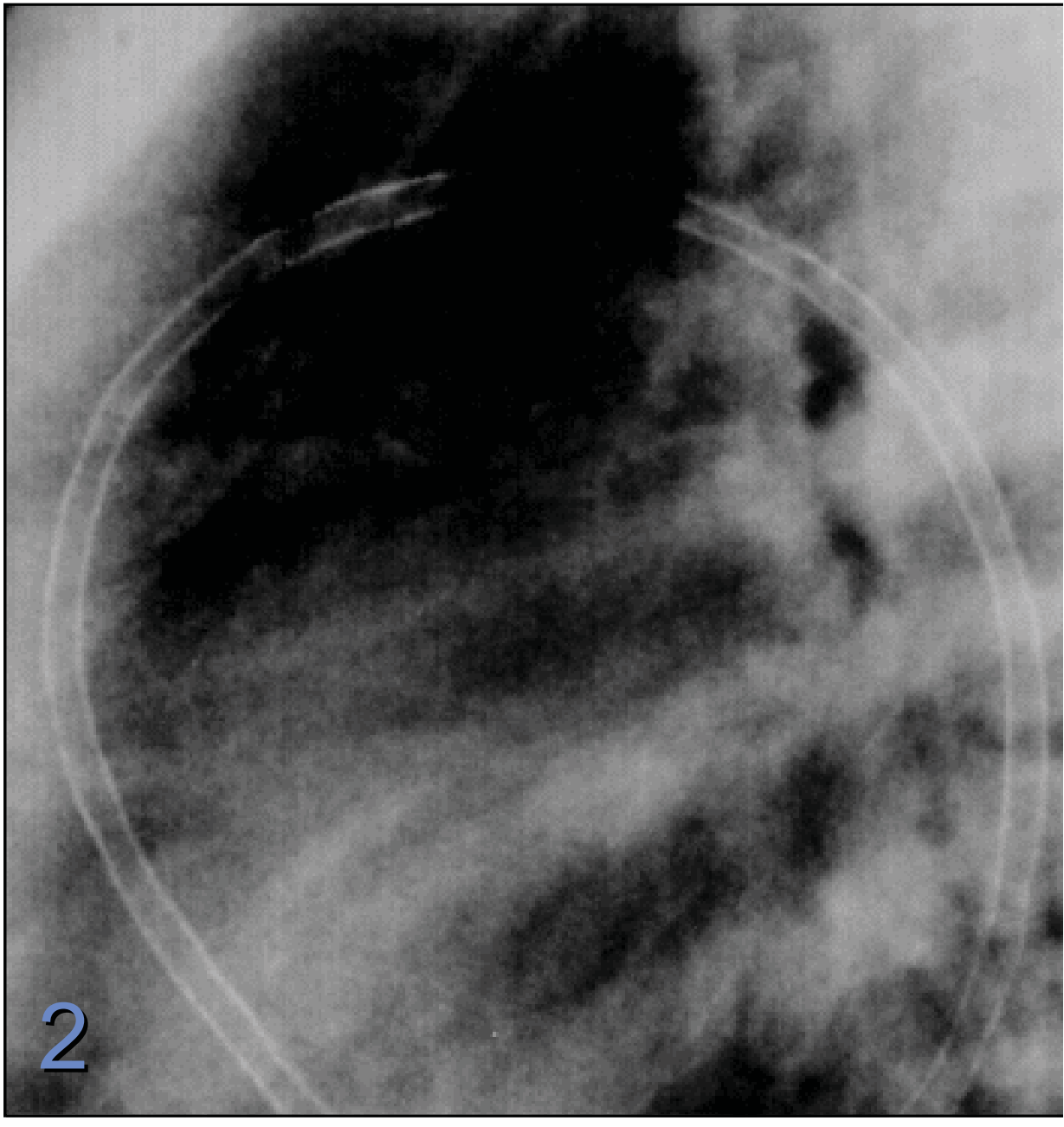
AMPLATZER® Duct Occluder

ngiogram in the descending aorta
the lateral projection revealing a
.6mm PDA, angiographic type A
arrow)



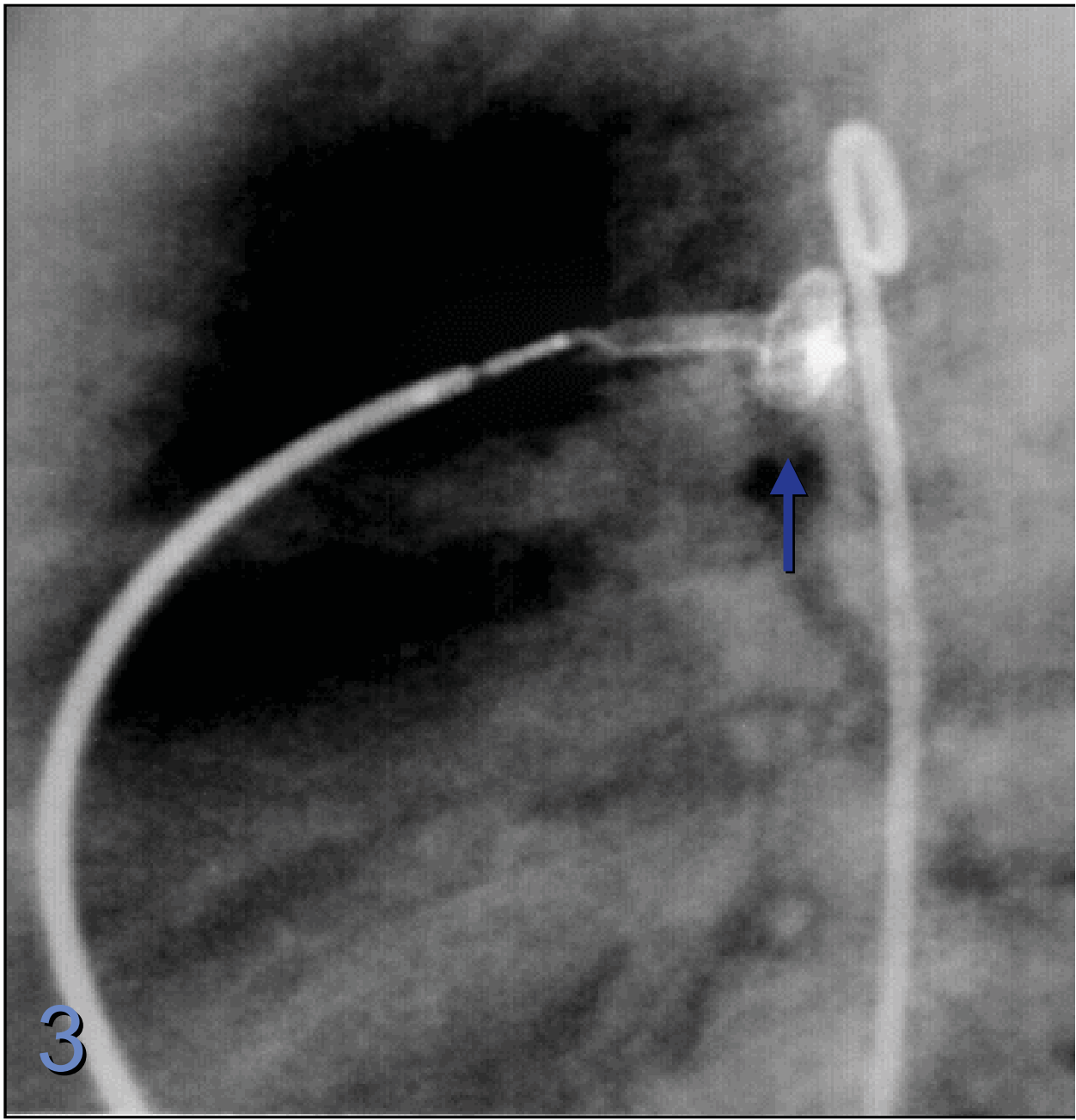
AMPLATZER® Duct Occluder

ine spot film demonstrating the 6 Fr.
ong sheath crossing the ductus and
ositioned in the descending aorta.



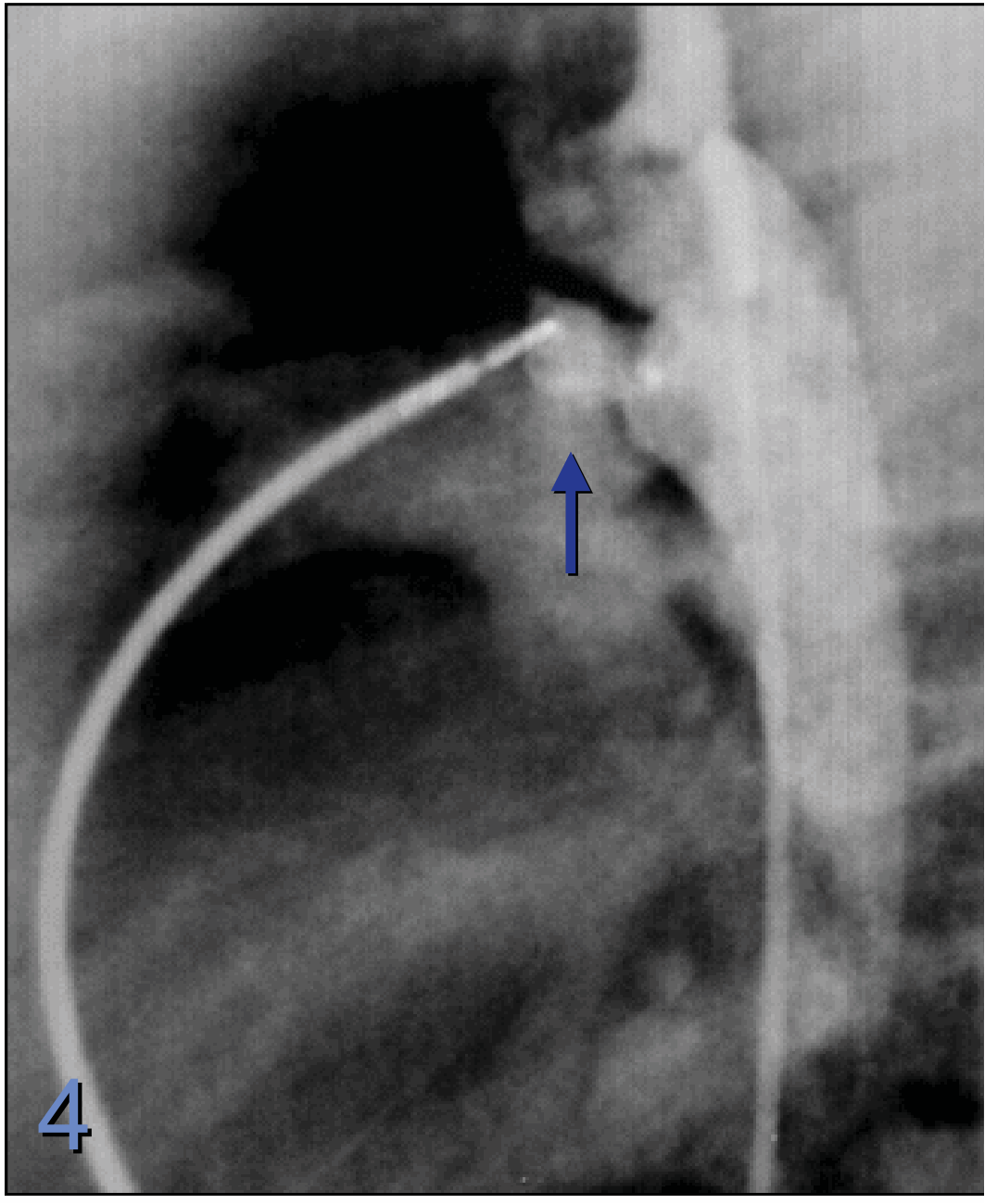
AMPLATZER® Duct Occluder

ine spot film demonstrating opening
the retention disc (arrow) in the
escending aorta just outside the
mpulla.



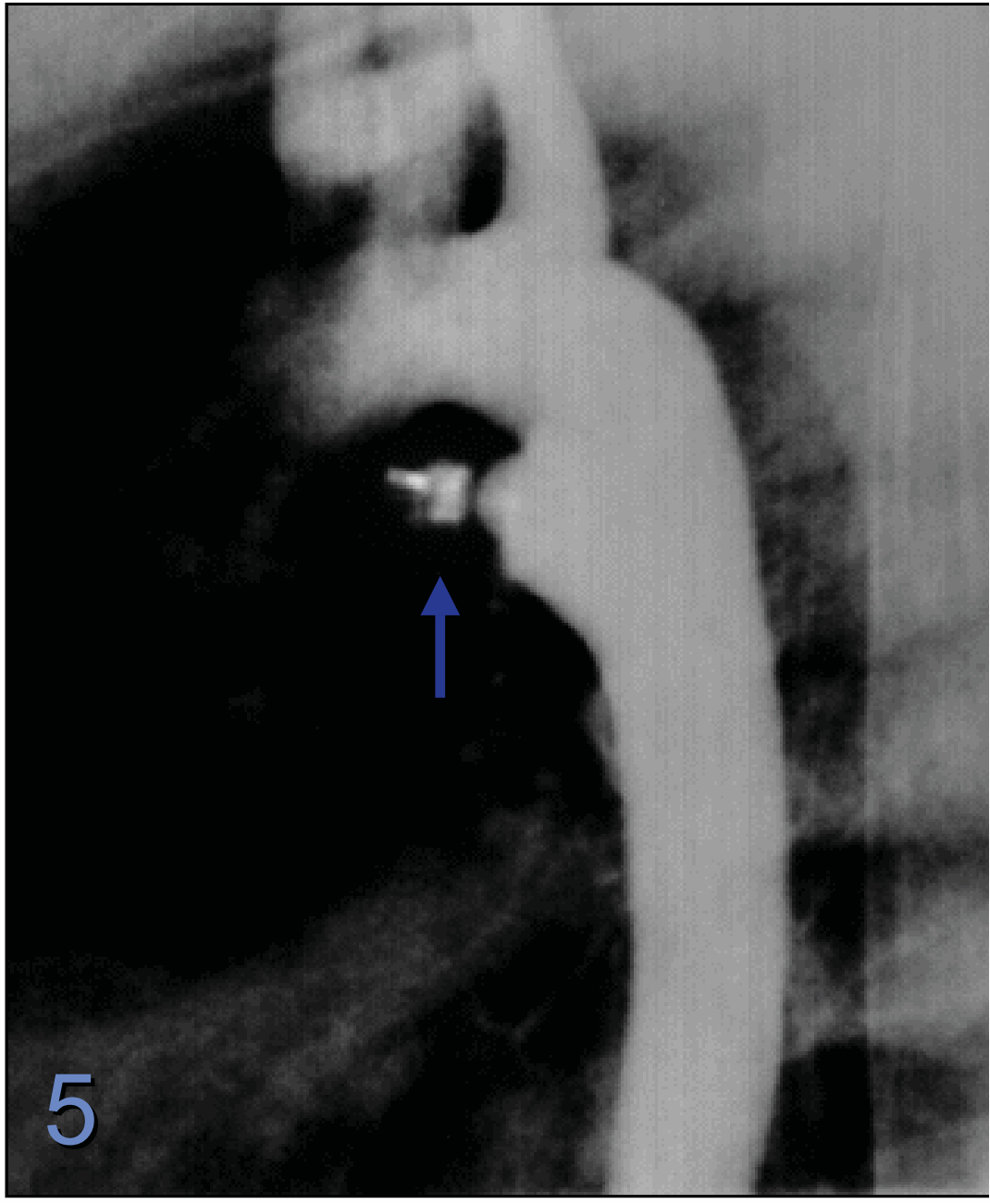
AMPLATZER® Duct Occluder

ortogram after opening the tubular part of
e prosthesis in the narrow part of the ductus
nd prior to device release to confirm position
rrow). Note, there is still left-to-right shunt.



AMPLATZER® Duct Occluder

epeat aortogram 15 minutes after release
emonstrating good device position (arrow)
nd complete closure



Post Implant

- Endocarditis prophylaxis is carried out for 6 months according to the recommendation of the American Heart Association. The decision to continue endocarditis prophylaxis beyond six months is at the discretion of the physician.

- Any patient who has a residual shunt will undergo an echo cardiographic evaluation of the residual shunt until complete closure of the defect has been confirmed.

- Lung perfusion scan should be completed if flow through is > 3M/sec, or if the Z-score is –2 for the left pulmonary artery diameter.

- Caution should be used if an MRI is performed with a magnetic field > 1.5 Tesla.

AMPLATZER® Duct Occluder

Ordering Information

Order Number	Device Size	Retention Skirt Diameter	Length	Recommended Sheath Size
9-PDA-003	5/4 mm	9 mm	5 mm	5 French, 180° curve
9-PDA-004	6/4 mm	10 mm	7 mm	5 French, 180° curve
9-PDA-005	8/6 mm	12 mm	7 mm	6 French, 180° curve
9-PDA-006	10/8 mm	16 mm	8 mm	6 French, 180° curve
9-PDA-007	12/10 mm	18 mm	8 mm	6 French, 180° curve
*9-PDA-008	14/12 mm	20 mm	8 mm	7 French, 180° curve
*9-PDA-009	16/14 mm	22 mm	8 mm	7 French, 180° curve
RECOMMENDED GUIDEWIRE				
Order Number	**Wire Size**	**Description**	**Tip Type**	**Usable length**
9-GW-001	.035	Super Stiff	3mm J-Tip	260CM

*The 14/12 and 16/14 mm AMPLATZER Duct Occluders are currently for investigational use only in the United States of America.

AMPLATZER® Duct Occluder

Principal Safety and Efficacy Results

Principal Efficacy	Patient #
Acute Procedure Success	390/393 (99.2%)
Acute Efficacy	303/393 (78.4%)
6 Month Efficacy	312/317 (98.4%)
12 Month Efficacy	205/208 (98.6%)

Acute Procedure Success- Of the number of patients where the device was attempted, those who successfully received a device.

Acute Efficacy- Of the number of patients where the device was attempted, those who had complete closure of the ductus at procedure.

6 Month Efficacy- Complete closure of the ductus at the 6 month visit in the attempted patients.

12 Month Efficacy- Complete closure of the ductus as measured by echocardiography at the 12 month visit.

AMPLATZER® Duct Occluder

Safety Summary

Total Serious and Major Adverse Events	5/393 (1.2%)
Serious Adverse Event	
Death	1/393 (0.3%)
Major Adverse Events	
Device Embolization with Percutaneous Removal	1/393 (0.3%)
Thrombus on Device	1/393 (0.3%)
Partial Obstruction of Pulmonary Artery	1/393 (0.3%)
Pseudoaneurysm	1/393 (0.3%)
Minor Adverse Events	
Hematoma of the groin	7/393 (1.7%)
Other	6/393 (1.5%)
Loss of peripheral pulse	4/393 (1.0%)
Cardiac arrhythmia requiring cardioversion or medication	2/393 (.5%)
Total Adverse Events	**23/393 (5.9%)**

One patient had a Major and Minor Adverse event. 23 patients had adverse events.

Patients less than 6 months of age, and less than 6 kgs. are not included in this analysis.

Air embolism, allergic reaction, blood loss/no transfusion, laryngospasm, respiratory arrest, thrombus on device.