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Amplatzer ASO device closure of secundum atrial septal defects and patent foramen ovale

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Abstract

Transcatheter closure of atrial septal defects and patent foramen ovale is now a well established therapeutic option. In this paper, we illustrate, step by step, the technique of Amplatzer ASO closure of these defects.

MeSH: Heart Defects, Congenital, Embolization, Therapeutic, Instrumentation, Heart Septal Defects, Heart Catheterization/Instrumentation, Atrial/Pathology/Therapy

Introduction

Atrial septal defects

Atrial septal defects (ASDs) are congenital deficiencies in the interatrial septum, and are most commonly found in the fossa ovalis. These lesions comprise 10% of all congenital heart defects.

The haemodynamic effects of ASDs are related to the degree of left to right shunting and its duration. Large defects cause volume overload of the right side of the heart with pulmonary hypertension, that is initially reversible, and later irreversible, with shunt reversal (right to left). At this stage, usually in middle age, survival is limited, and such individuals become cyanosed with reduced exercise tolerance and are at risk of atrial arrhythmias that may precipitate frank heart failure.

Small ASDs often close spontaneously in the first few years of life. Larger defects seldom do. Significant ASDs (Qp/Qs of > 1.5) are therefore closed surgically or by interventional catheter techniques before school age or at the time of diagnosis later in life.

Patent foramen ovale

In utero, the foramen ovale serves as a physiologic conduit for right to left shunting. After birth, the left atrial pressure is higher than that in the right atrium, resulting in functional closure of the foramen ovale, and later in anatomical closure. A patent

foramen ovale (PFO) is a persistent communication due to lack of anatomical closure.

A patent foramen ovale (PFO) is found in almost 50% of cryptogenic strokes and transient ischaemic attacks (TIA). In these individuals, the recurrence risk for stroke is 2-4% per annum, and for TIA the risk is 1-2% per annum. There is no consensus with regard to the ideal type or length of medical treatment for the prevention of such events. Indeed, it has been shown that there are no differences in risk reduction between different modes of anticoagulant or antiplatelet therapy with respect to recurrent stroke or TIA. On the other hand, a recent study with a mean of 15 months of followup showed that device closure of a PFO in individuals who have sustained a neurological event resulted in no strokes and a 1.7% per annum risk of TIA.¹

A wide variety of devices for transcatheter closure of ASDs and PFOs have been developed in the past few decades. We illustrate the technique of ASD/PFO closure using the Amplatzer ASO (atrial septal occluder) device (AGA Medical Corporation, 682 Mendelssohn Avenue, Golden Valley, MN 55427, USA).

This particular device consists of a collapsible meshwork of NITINOL (Nickel Titanium National Ordinance Ltd), an alloy that returns a device to its original shape after being collapsed into a sheath for delivery within the heart. The device shape is a self-expandable, double disk and the two disks are linked together by a connecting waist. Both discs and waist are filled with a polyester fabric in order to ensure complete closure of the defect.

Method

Transoesophageal echocardiography assessment of the defect is crucial

- It is important to have inferior and posterior rims.
- An anterior rim is not as important as the device will grasp the aorta.
- A superior rim is also not as important as the device will grasp the orifice of the superior vena cava.
- The defect should be well away from the pulmonary veins and mitral valve.
- A more detailed review of defect assessment by TOE with regard to device suitability will be the subject of another article.

Defect sizing

An MPA2 catheter is introduced into the femoral vein (FV), thence to right atrium (RA) and right ventricle (RV). If the pressure in the RV is elevated, make sure that there is no pulmonary stenosis by crossing the pulmonary valve into the main pulmonary artery, thereby checking for a gradient. Once in the vein, 50U/kg of heparin is administered as well as a dose of prophylactic antibiotic (e.g. ceftriaxone). The catheter is passed through the defect into the left atrium (LA) and is wedged in the left upper pulmonary vein (LUPV), pointing upward or downward. If it proves difficult to cross to the LA (e.g. very small PFO), use an exchange wire over the MPA catheter to probe the interatrial septum with the tip of the wire. Alternatively, a transeptal catheter may be used to cross to the LA with an exchange wire. An exchange wire is passed through the MPA catheter and wedged in a pulmonary vein for stability, preferably the left upper pulmonary vein.

The catheter can be seen on TOE crossing over from RA into LA across the ASD. The MPA catheter is now removed over the wire.

Figure 1 Catheter through defect into left upper pulmonary vein

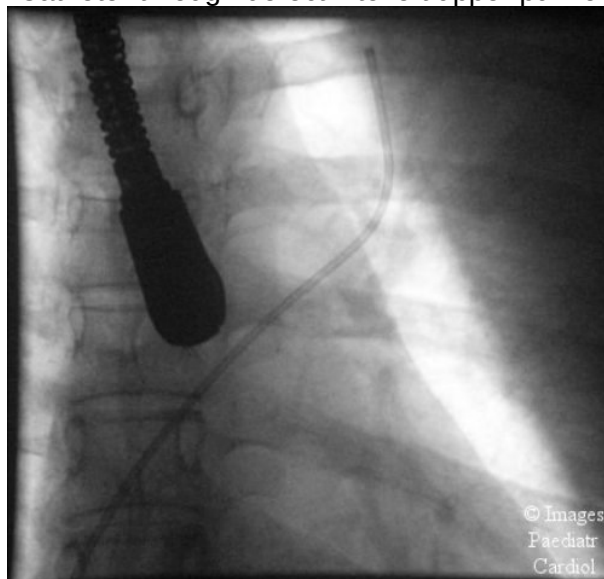


Figure 2 Catheter crossing a PFO from RA (below left) to LA (above right)



A suitably chosen Amplatzer sizing balloon is opened and flushed (24 / 34 mm diameter sizes – table 1). The balloon is held vertically pointing downward and is inflated with saline in order to remove all trapped air.

All ASDs/PFOs are stretched by the sizing balloon. The following guidelines may be helpful:

- Use a 24mm balloon for all adult PFOs and for children with transthoracic defect diameter <18mm.
- Use a 34mm balloon for all adult ASDs and for children with transthoracic defect diameter >18mm.

Table 1 Amplatzer sizing balloons

Delivery system	6F (pink)	7F (white)	8F (green)	9F (blue)	10F (red)	12F (orange)
Device size	4-9mm	10-17mm	18-20mm	22-24mm	26-30mm	32-40mm

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The balloon is then completely deflated. The standard short sheath is removed over the exchange wire and the sizing balloon is inserted over the wire.

Figures 3 and 4 Removal of all trapped air from the balloon catheter

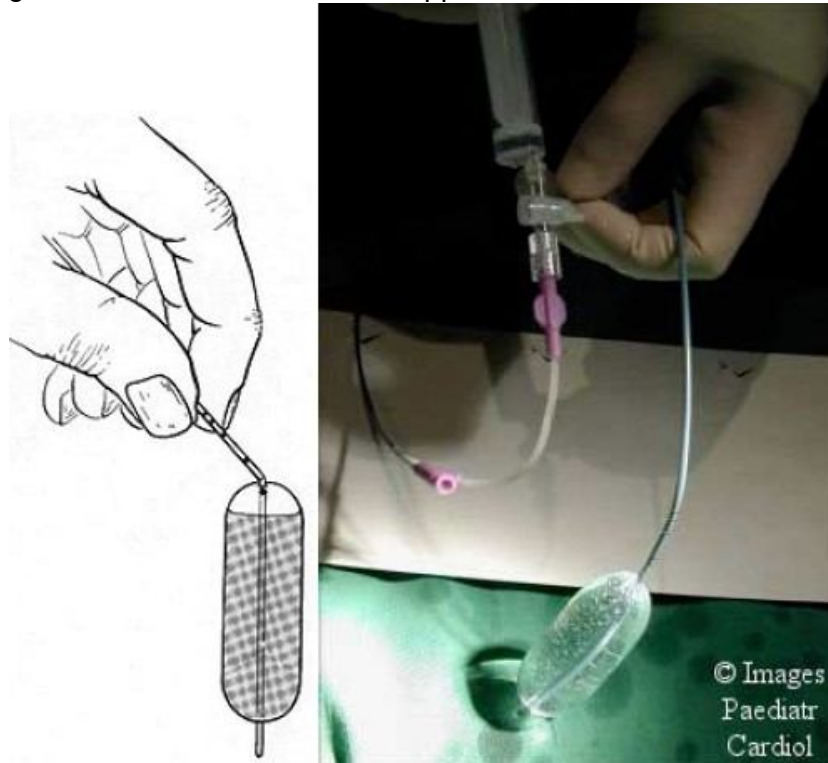


Figure 5 Balloon completely deflated



Figure 6 Catheter in over wire without sheath

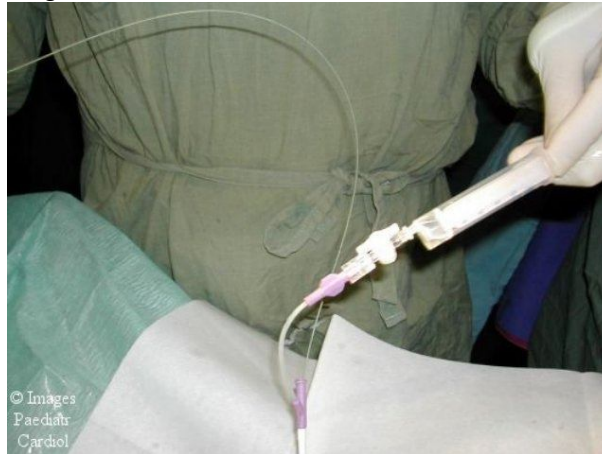
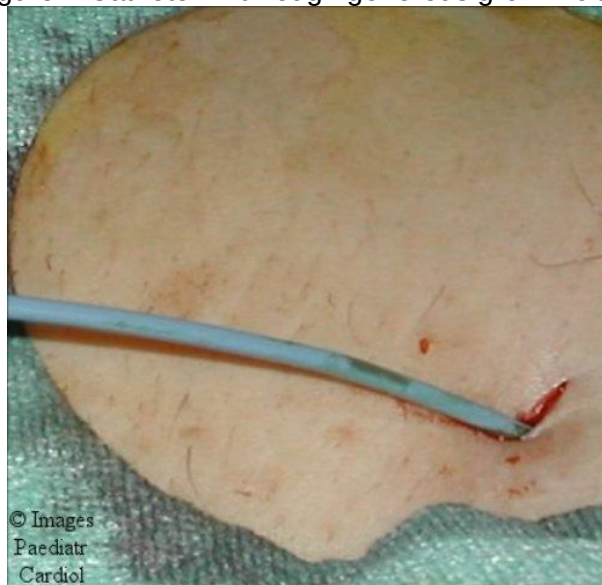


Figure 7 Catheter in through generous groin incision



The hole in the groin must be generous as the balloon catheter is 9F, and is inserted through the skin without a sheath.

The defect is situated approximately at the right border of the vertebral column in straight AP view.

The balloon is inflated across the defect with a 25% contrast solution. A good waist should be obtained without under/overdoing it.

The waist should be acquired and measured in the posteroanterior view and in the left anterior oblique view at an angle of about 15°. A suitable image is frozen on the slave monitor.

For calibration purposes, the sizing rings on the balloon shaft are spaced 10mm, 5mm and 2mm apart.

TOE is used to check that the defect is completely closed with the balloon, that no other defects in the interatrial septum (IAS) have been exposed, and the balloon diameter is measured. The best angle to view and measure the inflated balloon is at about 45 to 55°.

The volume of fluid injected in the balloon is noted and the balloon is now deflated. The balloon catheter is removed leaving the wire wedged in the LUPV. The balloon is now reinflated using the same volume as was used when the balloon was inflated across the defect.

Figure 8 Sizing balloon catheter being deployed

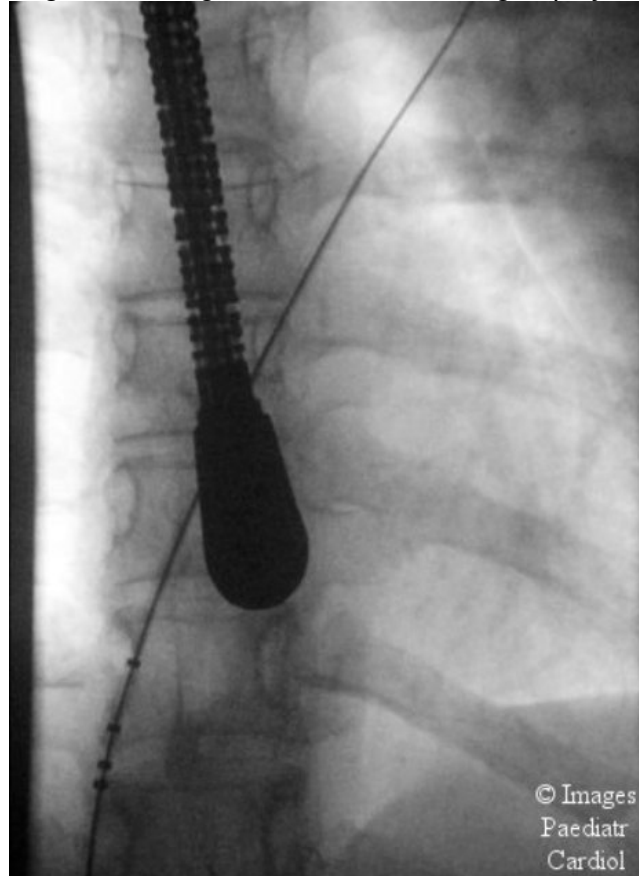


Figure 9 Schematic diagram showing inflated sizing balloon

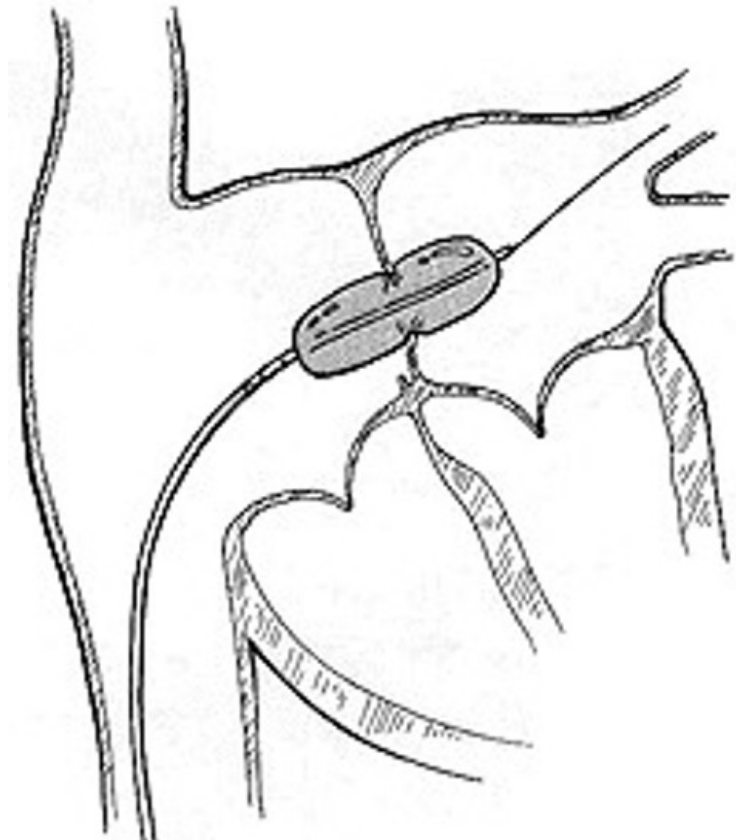


Figure 10 Sizing balloon inflated

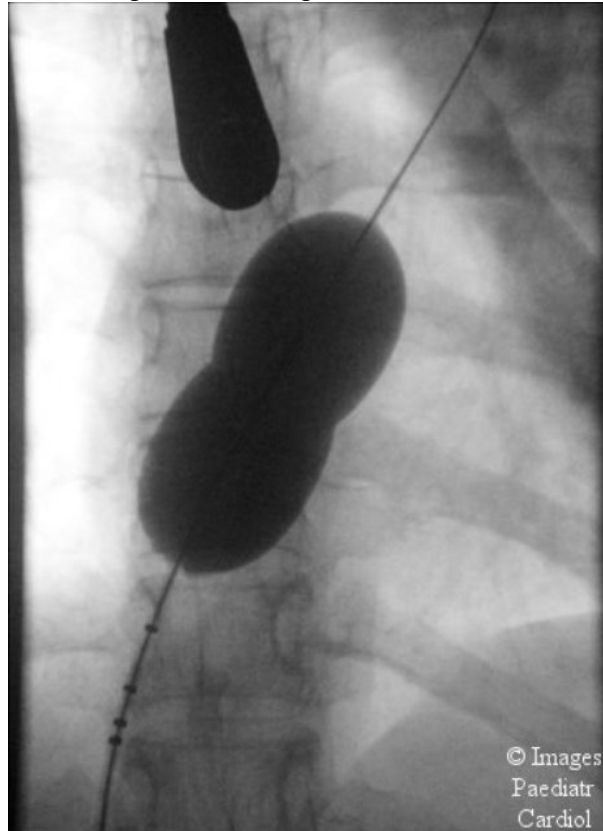


Figure 11 Sizing balloon at 15° of LAO



Figure 12 Schematic showing sizing rings on balloon shaft

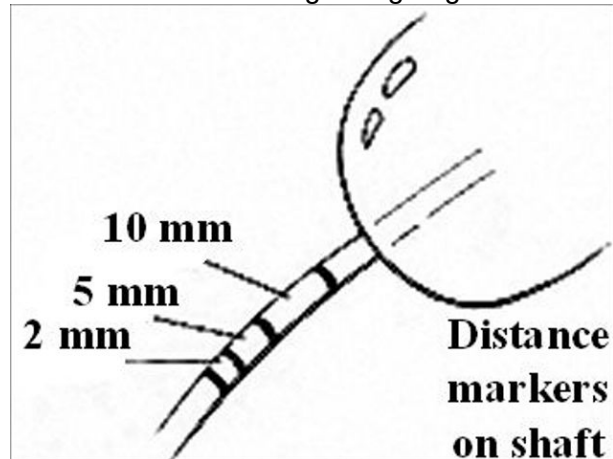


Figure 13 TOE showing inflated balloon



The balloon is now passed through the template sizing holes and the waist obtained is compared with that of the image on the slave monitor.

Visually check that waist obtained is about the same as that seen on the slave monitor.

In this way, the diameter of the defect (the waist of the inflated balloon) has been estimated by three methods: by radiology, by TOE, and externally.

Figure 14 Balloon though template - 1

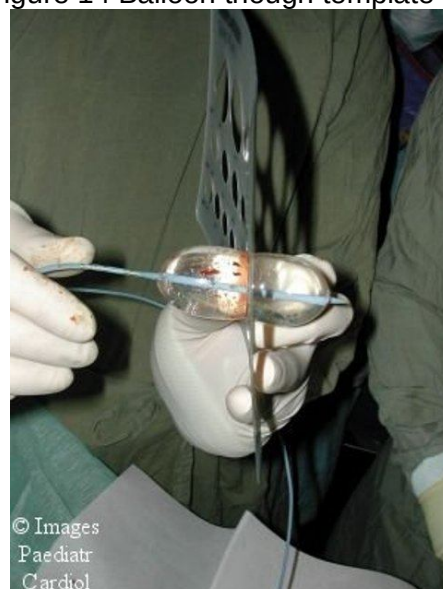


Figure 15 Balloon though template - 2

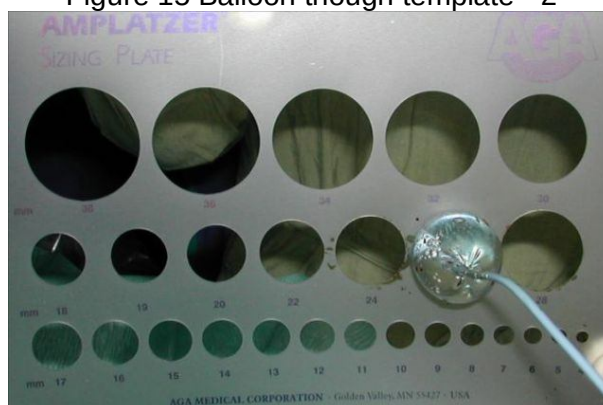


Table 2 Delivery systems for different Amplatzer ASO devices

Delivery system	6F (pink)	7F (white)	8F (green)	9F (blue)	10F (red)	12F (orange)
Device size	4-9mm	10-17mm	18-20mm	22-24mm	26-30mm	32-40mm

The appropriate sheath (table 2) and introducer pack are opened (sizes 45 by 60/80 cm), and both sheath and introducer are flushed while still mounted on the cardboard.

The loader is also flushed and the introducer is passed into the sheath. The sheath and introducer are now passed into the femoral vein, incidentally stopping bleeding from around the wire. The two piece loader is connected.

The loader is now flushed through the side port. The delivery wire is inserted through the loader.

Figure 16 Sheath and introducer flushed



Figure 17 The fully assembled delivery system with device attached

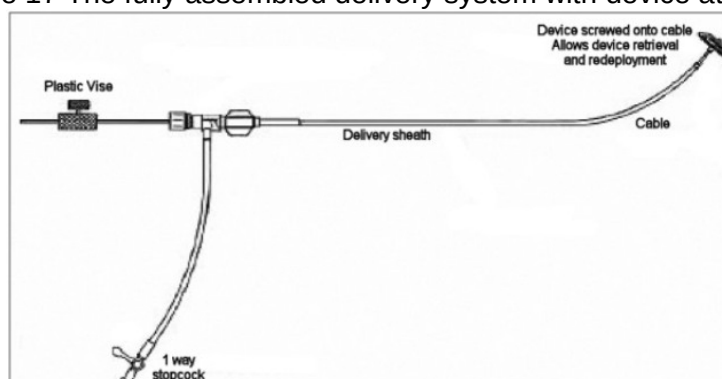


Figure 18 Loader being flushed



Figure 19 Loader being connected



Figure 20 Loader flushed through side port

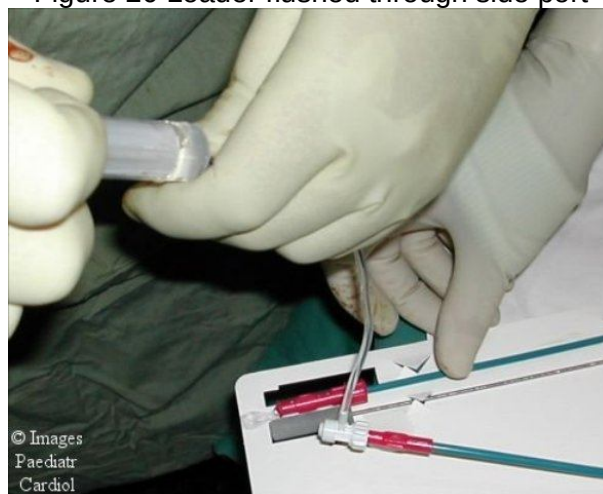


Figure 21 Delivery wire inserted into loader

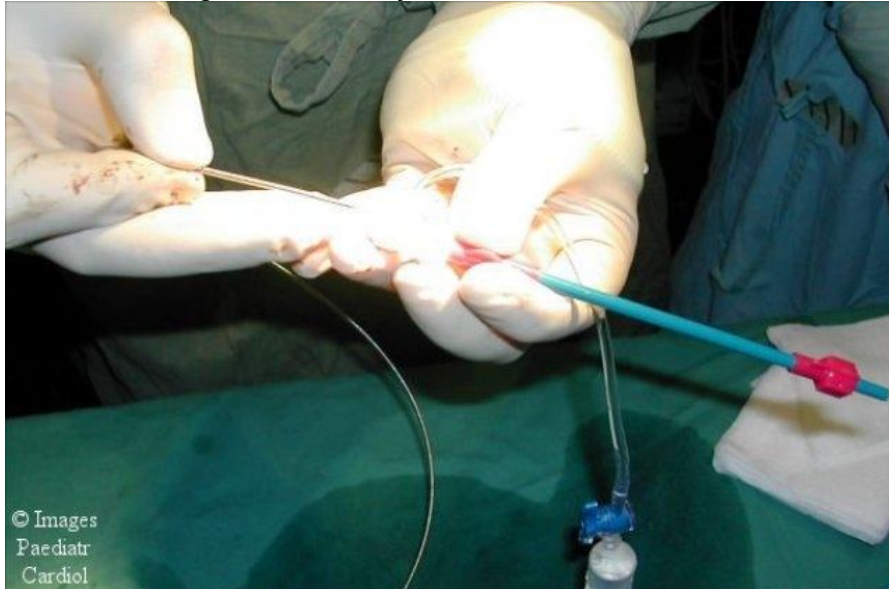
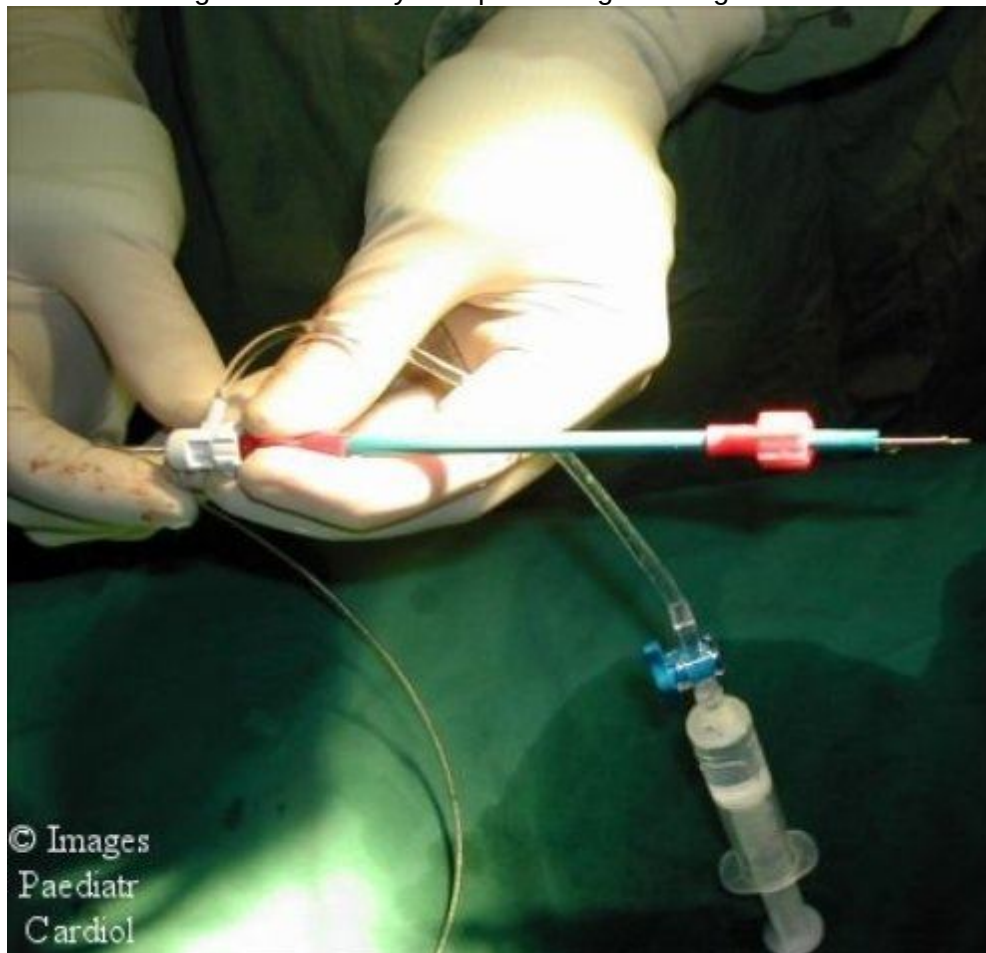


Figure 22 Delivery wire passed right through loader



The end of the delivery wire is pushed out of the other end of the loader. The Amplatzer device (table 3) is opened and the size advertised on the package labeling is checked with the template.

Table 3 Device properties

Device size (mm)	Left atrial disc diameter (mm)	Waist (mm)	Right atrial disc diameter (mm)
4	16	3	12
5	17	3	13
6	18	3	14
7	19	3	15
8	20	3	16
9	21	3	17
10	22	3	18
11	25	4	21
12	26	4	22
13	27	4	23
14	28	4	24
15	29	4	25
16	30	4	26
17	31	4	27
18	32	4	28
19	33	4	29
20	34	4	30
22	36	4	32
24	38	4	34
26	40	4	36
28	42	4	38
30	44	4	40
32	46	4	42
34	50	4	44
36	52	4	46
38	54	4	48

The device is now screwed clockwise onto the delivery wire. It is then untightened slightly until a click is felt.

The device is loaded under water and can be helped manually in order to avoid splay of the end of the loader.

If splay occurs, press around the end of the loader in order to decrease the degree of splay.

The side port of the loader is flushed with tip of loader under water to ensure removal of all air.

The loader is brought to the sheath. The wire is used to push the device out of the loader and into the sheath. The screw-on handle at the distal end of the wire is removed.

The loader is slid off the wire. The handle is reattached. The device is pushed to the end of the sheath.

The LA disk and the stalk are pushed out of the sheath into the LA.

The device is pulled back gently against the septum, and this is confirmed by feeling resistance on the wire and by TOE.

The right atrial (RA) disk is now deployed in the RA. If the deployed device appears perfect on fluoroscopy and on TOE, then it is very likely that both disks have been deployed in one atrium.

The device is given a 'Minnesota wiggle' in order to ensure that it is firmly deployed within the atrial septum. This is done by gently jerking the delivery wire in the sheath.

The device is now unscrewed off the wire.

Make sure to pull back the delivery wire back into the sheath immediately as the end of the wire is rigid and sharp and may produce trauma. The deployed device is acquired on cine in the posteroanterior view and with an angulation of 30° cranial with 30° LAO.

If necessary, the IAS can be profiled with a hand shot in LAO 40° and cranial 30° with the catheter in the RUPV.

The procedure information is recorded on the appropriate forms and the patient advised to take aspirin for six months. Antibiotic prophylaxis is also advised for 12 months.

Figure 24 Device loaded underwater



Figure 25 Pressing around the loader end to diminish splay

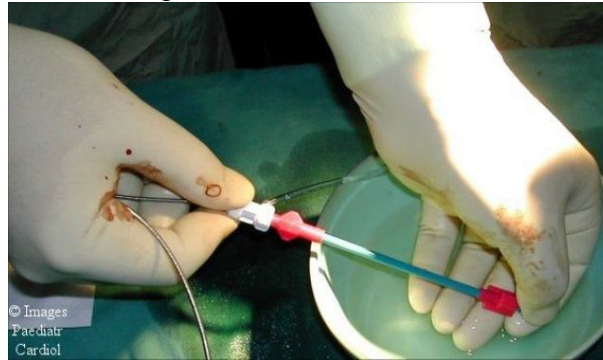


Figure 26 Flush loader underwater

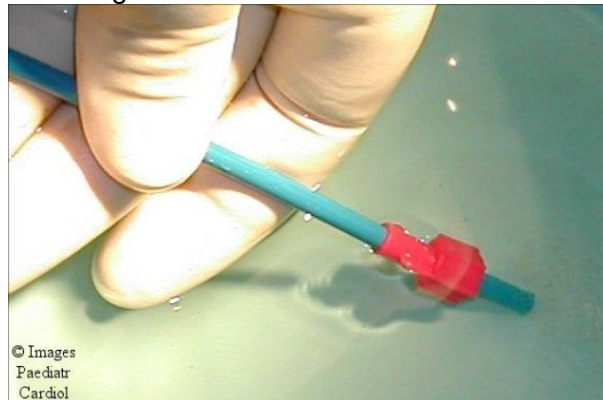


Figure 27 Introducer removed leaving sheath well in LA

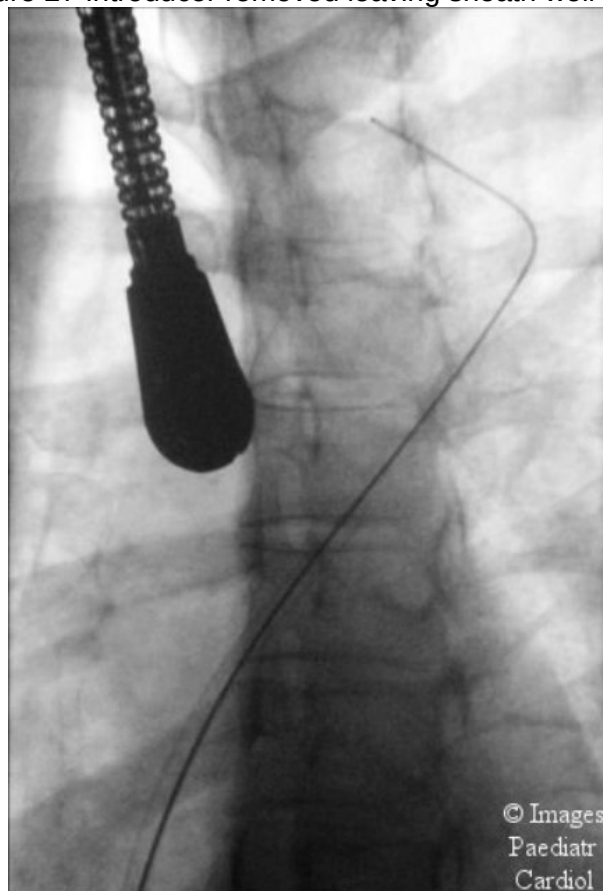


Figure 28 Loader brought to sheath



Figure 29 Wire used to push in device



Figure 30 Handle removed



Figure 31 Loader removed



Figure 32 Handle reattached to wire



Figure 33 Device pushed to sheath tip

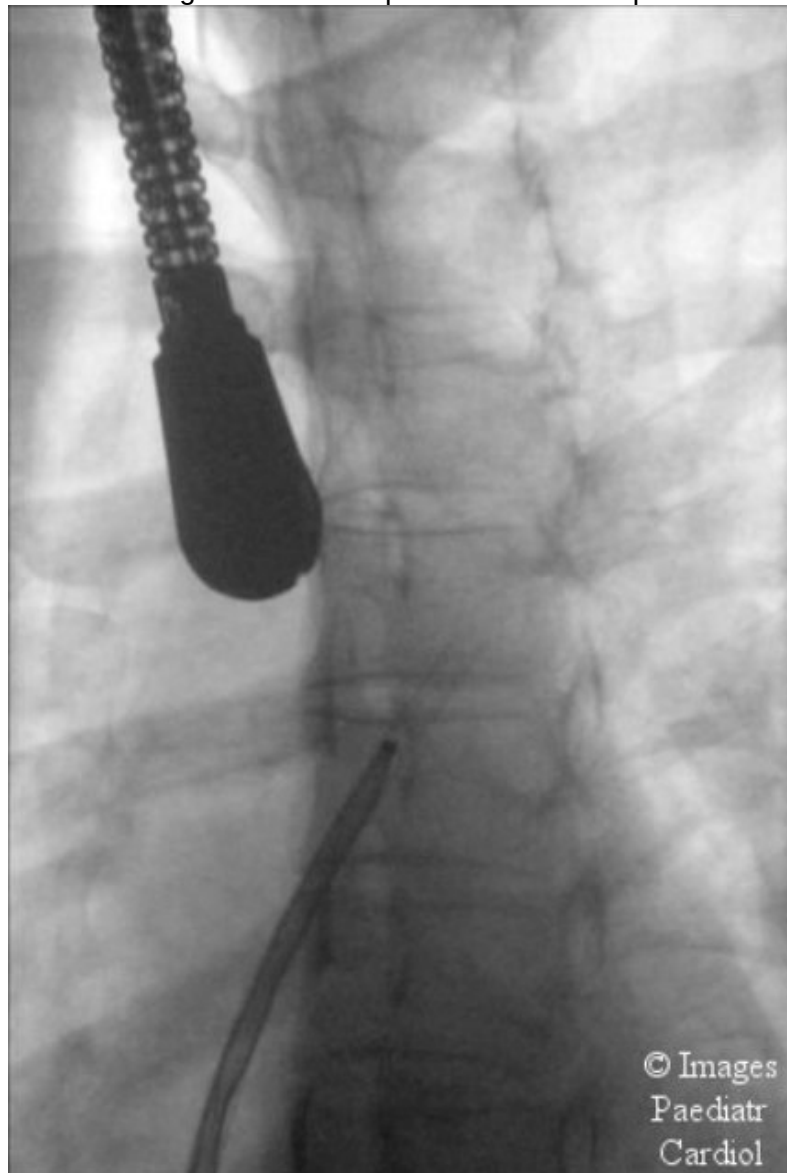


Figure 34 In vitro demonstration of device opening

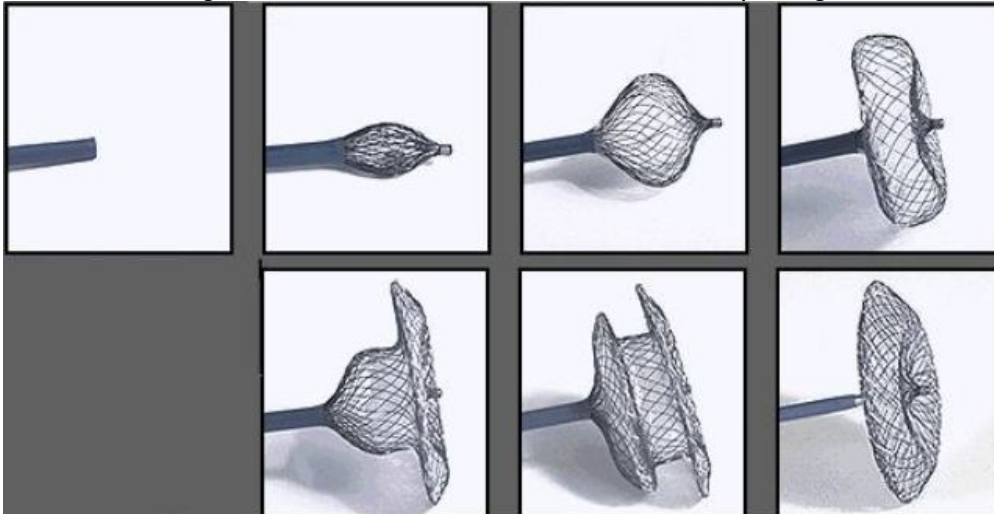


Figure 35 Distal (LA) disk being deployed

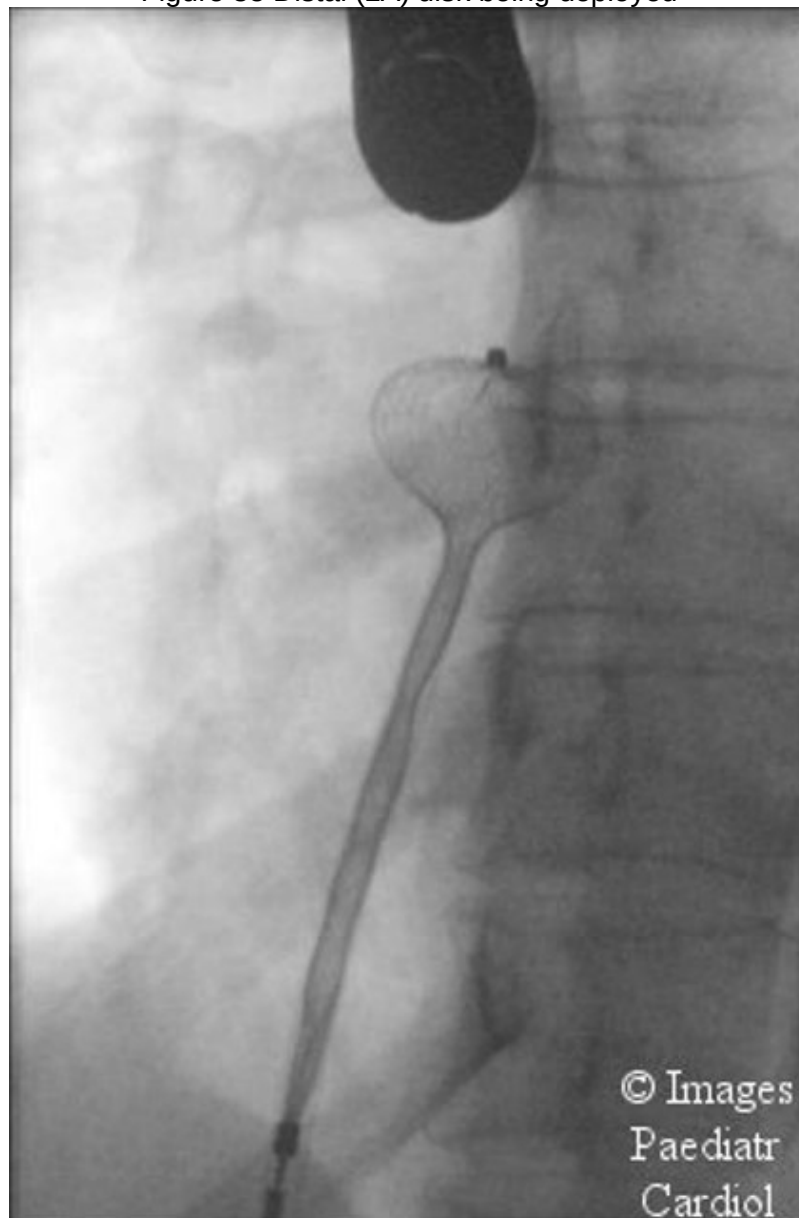


Figure 37 Device being pulled back against IAS

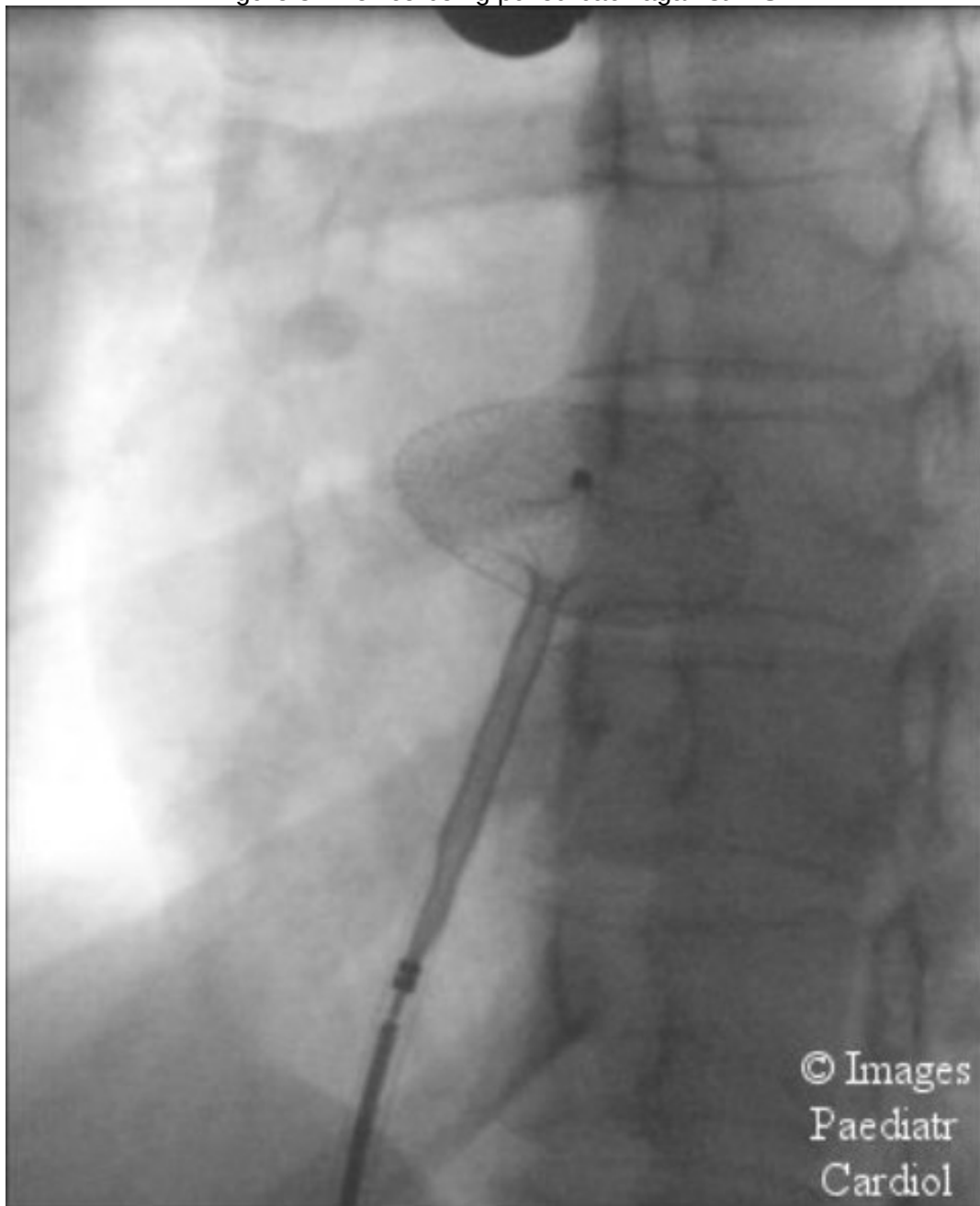


Figure 38 RA disk also deployed

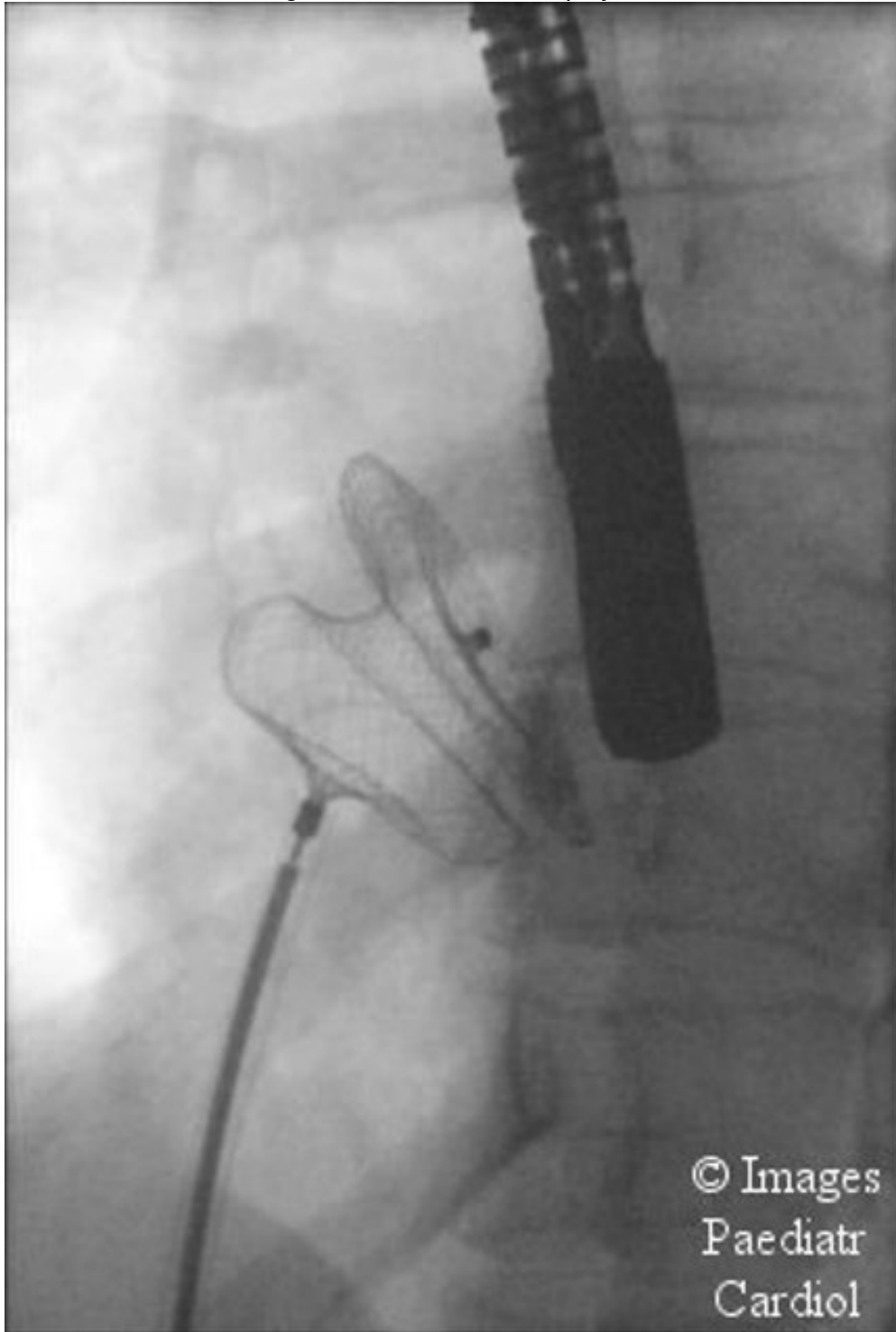


Figure 40 Device released

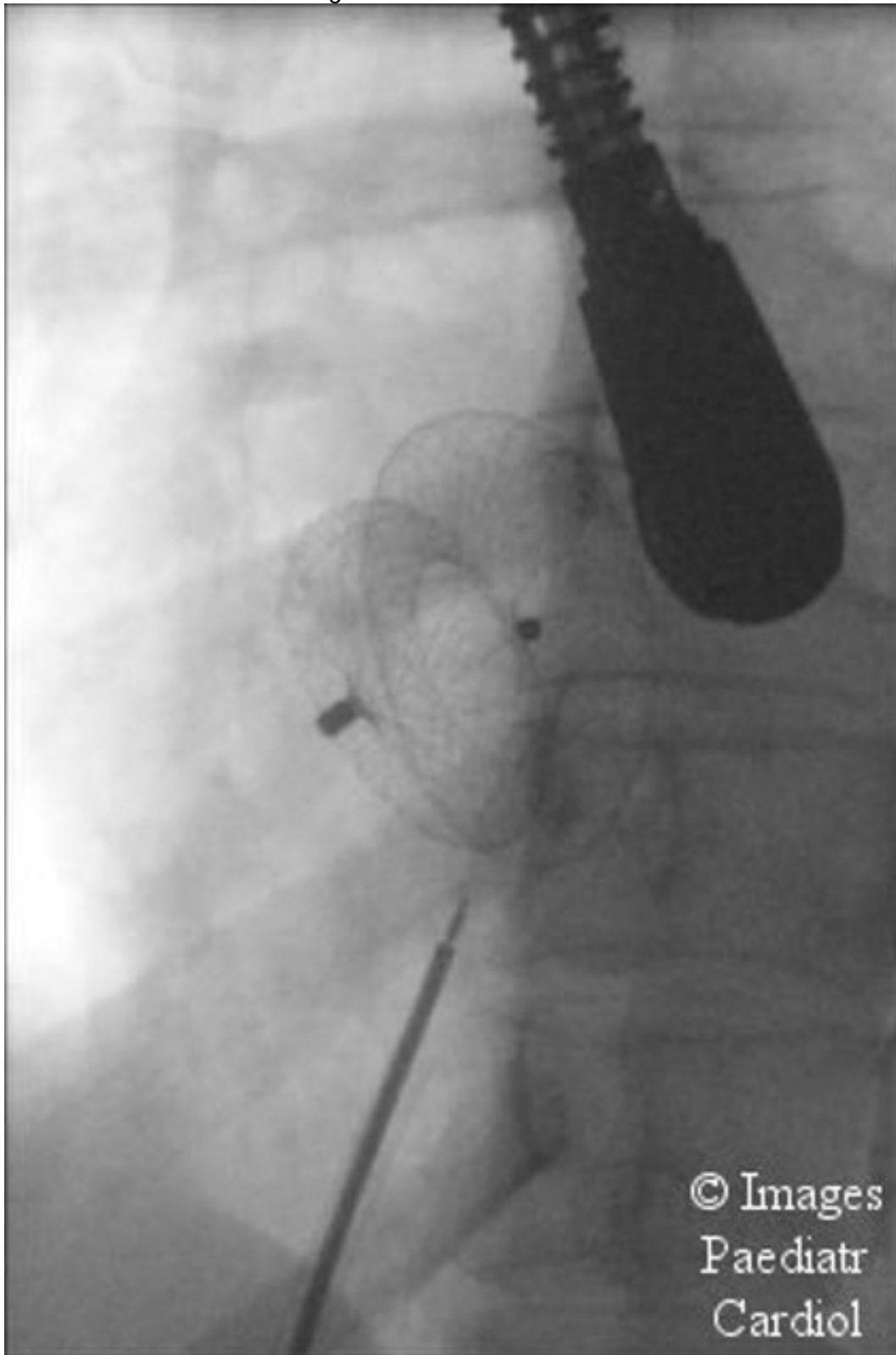


Figure 41 Device reviewed from different angles

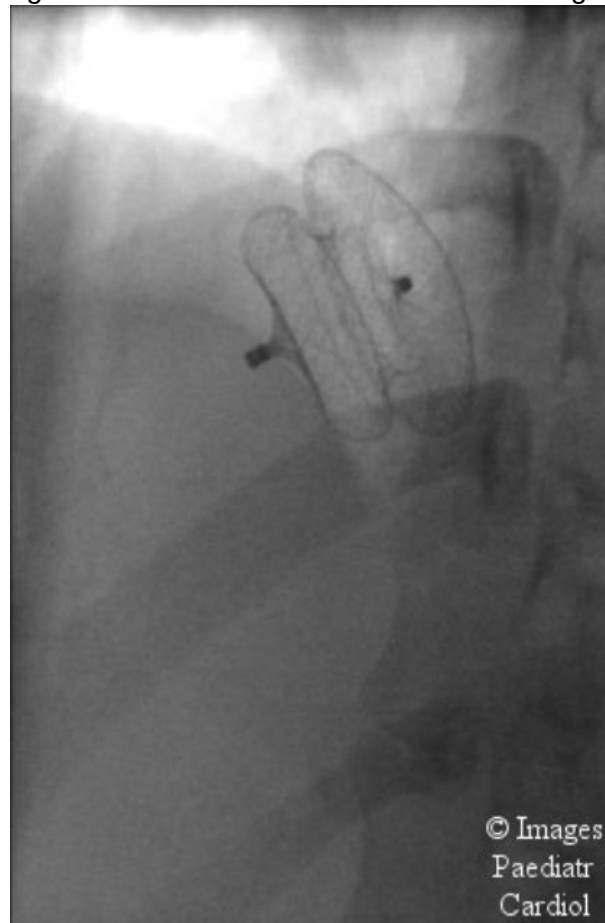


Figure 42 Profiling the IAS - 1

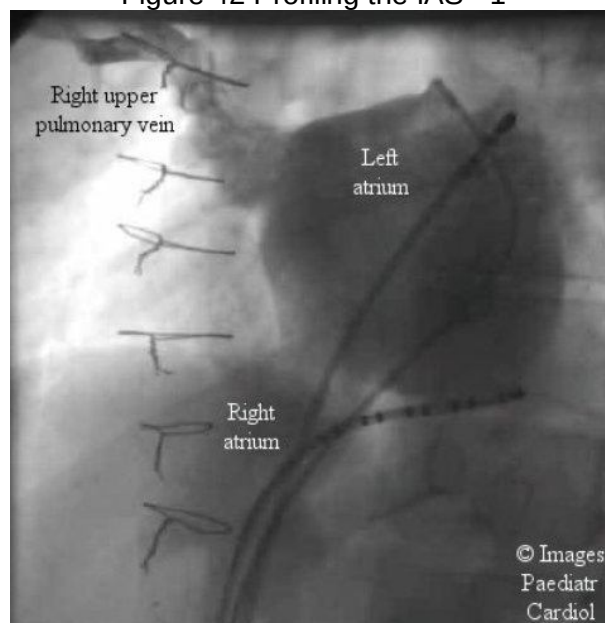
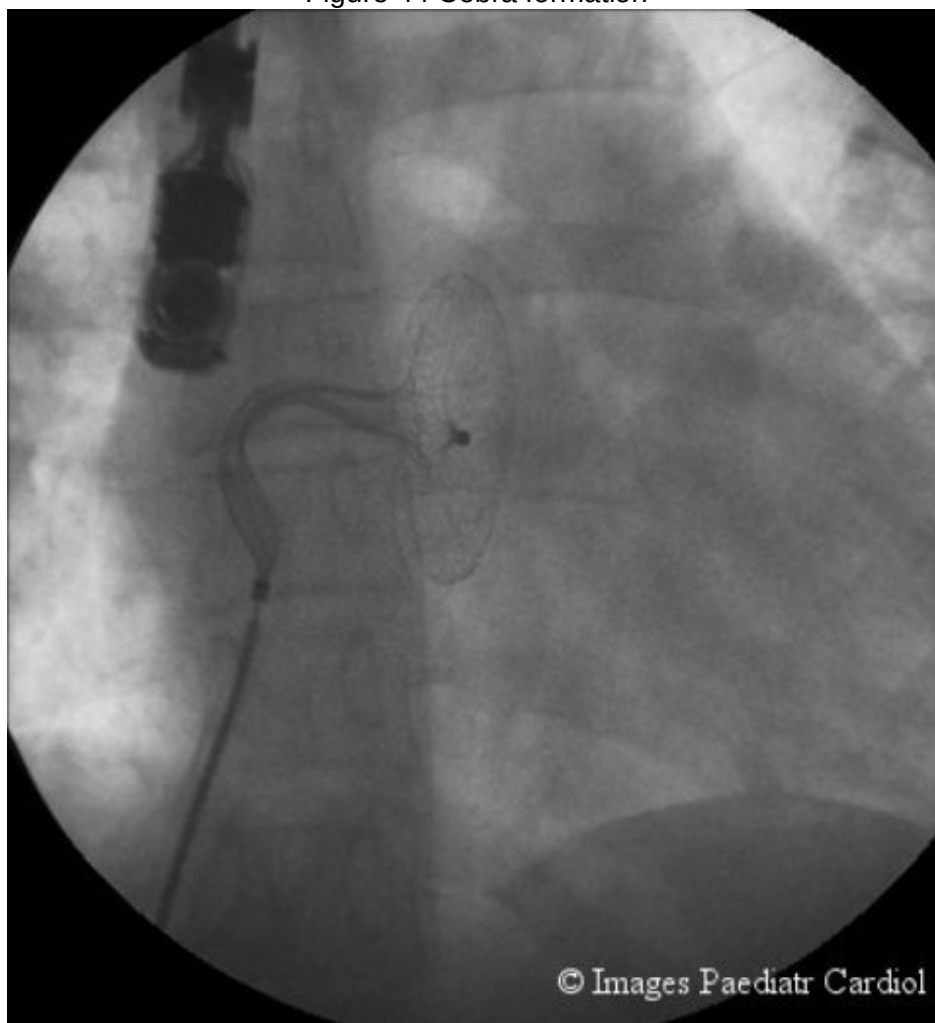


Figure 44 Cobra formation



Points to ponder

The device size refers to the central stalk. Roughly, the actual rim is 5mm for device sizes up to 19mm i.e. the actual device diameter is the device size plus 10mm. For 20mm devices and larger, the rim is 7mm. It is therefore important to ensure that the IAS can accommodate the required device size. If necessary, the size of the entire IAS can be measured on TOE. However, TOE foreshortens the length of the IAS, and such measurements are better done during transthoracic echocardiography.

The LA disk (and occasionally also the RA disk) may be deployed in a distorted manner (cobra formation). This may be due to a faulty device or the device may actually be catching on an intracardiac structure. If the latter, the device should be retrieved back in the sheath and deployed fully at a different angulation in the LA. Very occasionally, the device persists in deploying in this abnormal fashion and may have to be replaced.

If the device embolises and the patient is stable, the device can be removed surgically or pulled back into a large sheath by means of a goose necked snare. If the device cannot be retrieved or if the device is still attached to the delivery cable but cannot be brought back into the sheath then an AGA Bale Out kit may be employed. This kit consists of a cable that screws on to the back of the delivery cable converting it into an exchange length. The Bale Out sheath is wide enough to go over the cable. If a Bale Out Kit is not available, then remove the original sheath, open a larger sheath and use its cable to screw to the back of the cable inside the patient. Then cut

the tip of the dilator to allow the cable to pass through as the cable is larger than 0.035”.

If there are two atrial septal defects, balloon size both and assess not only the size and location of the defects, but also the distance between them. This will allow a decision as to whether to close the defects by using one oversized device or use two separate devices. If two devices are used, it is logical to first close the smaller defect so that when closing the larger defect, the larger device will overlap the smaller device.

If there is a large ASD in association with significant pulmonary stenosis, it is best to first close the ASD, leaving it attached to the delivery wire, and then balloon the pulmonary valve, releasing the device afterward. There is a significant risk of acute pulmonary oedema if pulmonary valvar stenosis is dilated before closure of the defect.

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Further reading

http://www.amplatzer.com/medical_professionals/index.html

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