Percutaneous ASD device closure : Insights from experience at NRI

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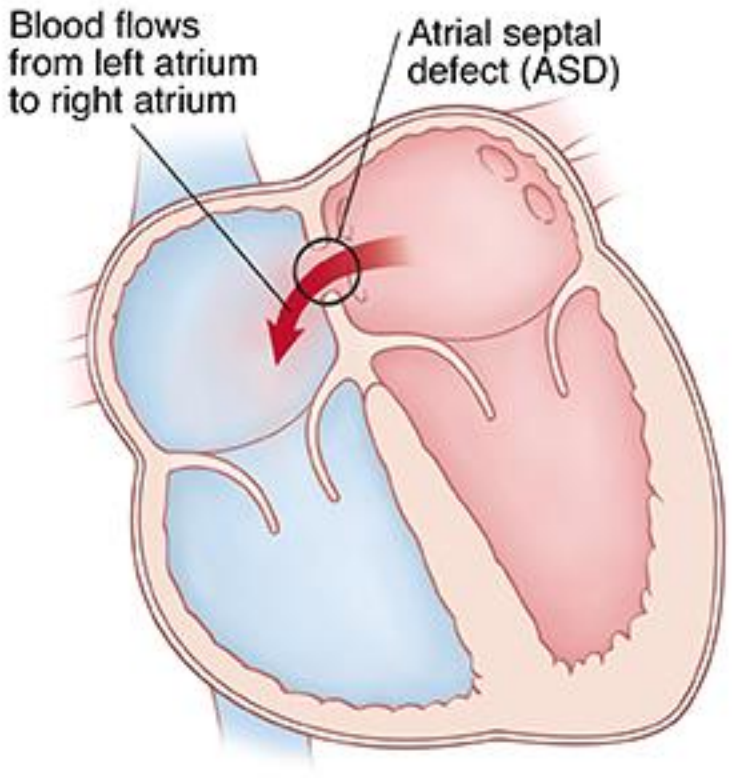
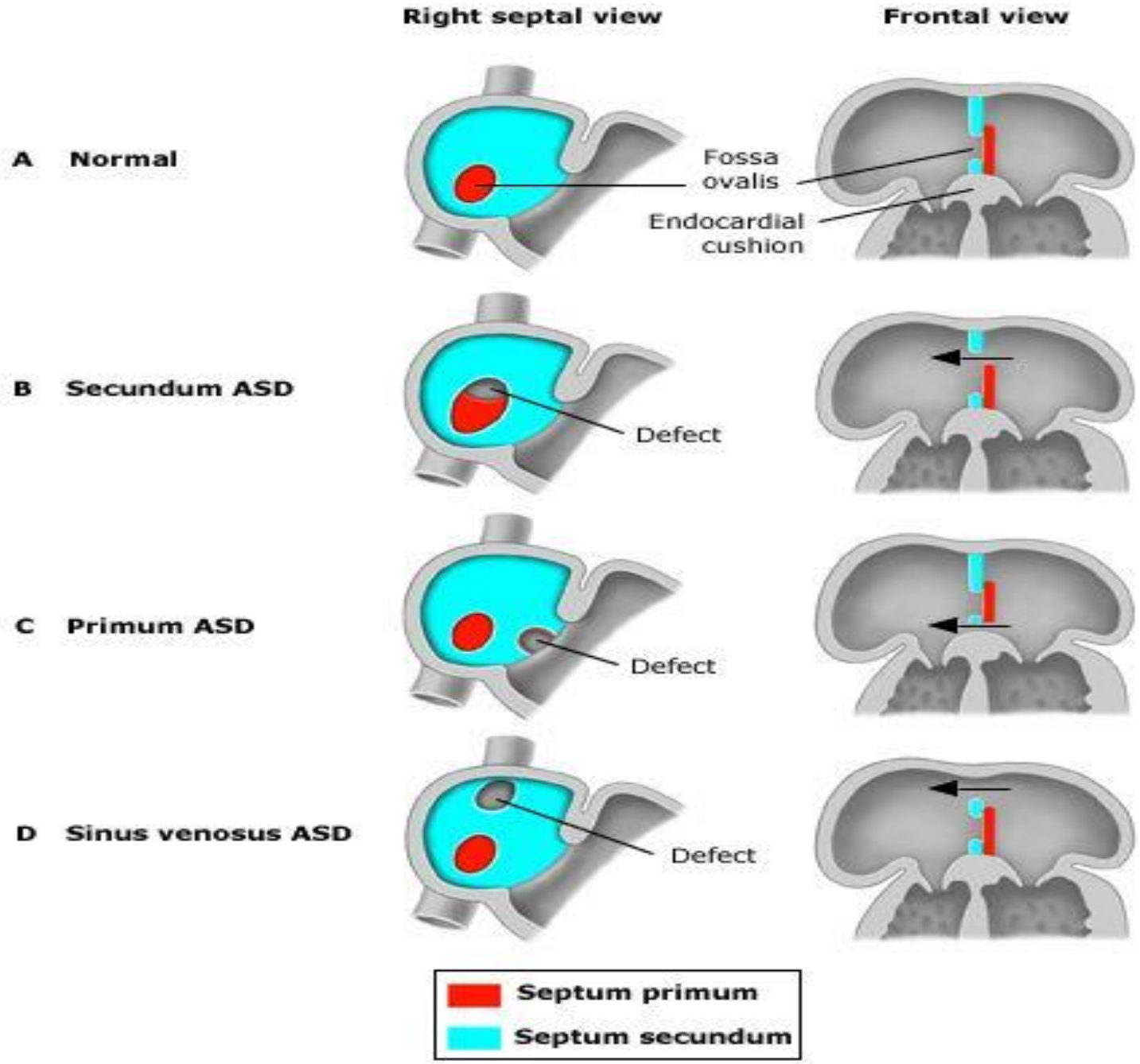
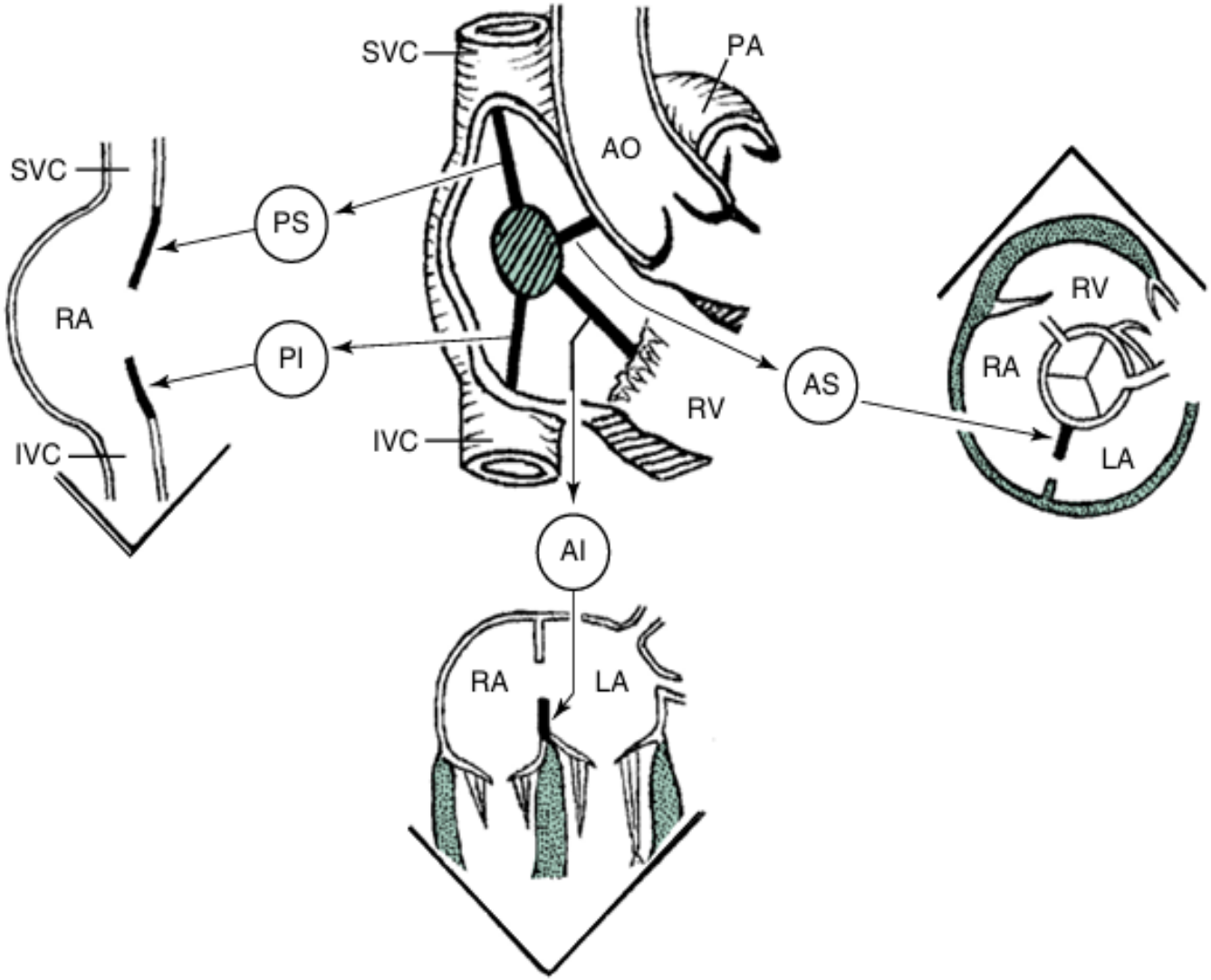
ASD: Atrial Septal Defect



- ASD is a defect in interatrial septum which allow communication between right and left atrial chambers
- Causes increased blood flow to lungs
- Leads to increased chances of pneumonia, arrhythmia, easy fatiguability and if uncorrected “Eisenmenger” (irreversible stage)


Right septal view
Frontal view
A Normal
Fossa ovalis
Endocardial cushion
B Secundum ASD
Defect
C Primum ASD
Defect
D Sinus venosus ASD
Defect
Septum primum
Septum secundum

OS ASD RIMS



NATURAL HISTORY OF OS ASD

1. ASD <3 mm in size Dx < 3 months of age, spontaneous closure occurs in 100% of patients at 1 - 1/2 y of age.

2. Spontaneous closure occurs > 80% of the times with defects 3 -8 mm before 1 - 1/2 y of age.

3. > 8 mm rarely closes spontaneously

4. Spontaneous closure is not likely to occur > 4 years of age

5. Most children with an ASD remain active and asymptomatic. Rarely, congestive heart failure (CHF) can develop in infancy.

6. If a large defect is untreated -- CHF and pulmonary hypertension begin to develop in adults who are in their 20s and 30s.

Becomes common after 40 years of age.

7. With or without surgery, atrial arrhythmias (flutter or fibrillation) may occur in adults. (13% > 40 y).

8. *Infective endocarditis does not occur in patients with isolated ASDs.*

9. CVA, from paradoxical embolization through an ASD, is a rare complication.

HARDWARE - ASD DEVICE CLOSURE

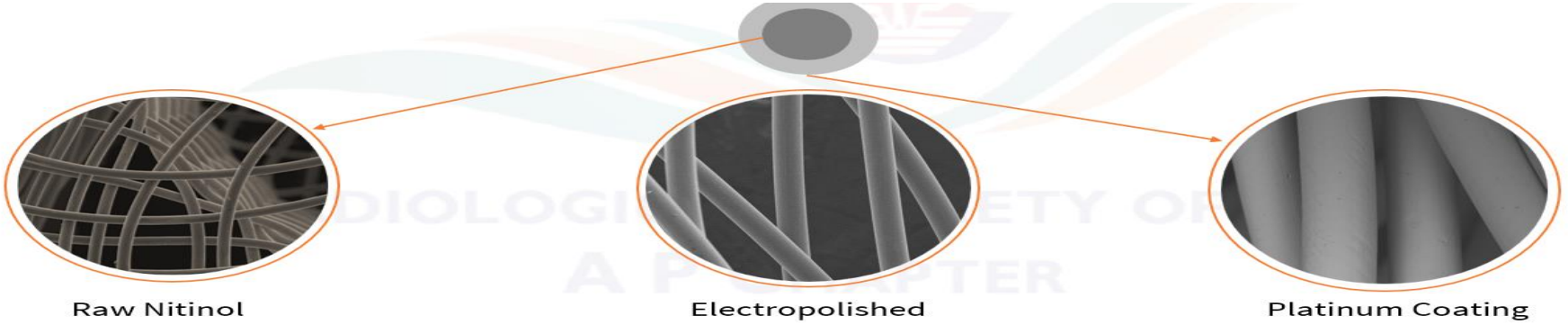
- TEE PROBE
- SUITABLE ASD CLOUSURE DEVICE
- SHEATH
- MULTIPURPOSE CATHETER/JR Catheter
- EXCHANGE LENGTH WIRE AMPLATZ
- DELIVERY CABLE
- NORMAL SALINE

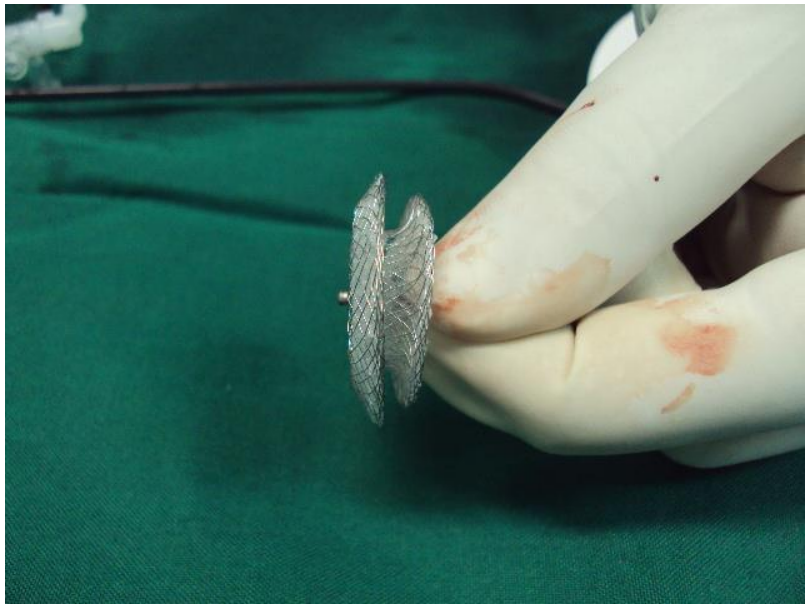
A self-expandable, double-disc device made up of nitinol wire with a Nanoplatinum coating.

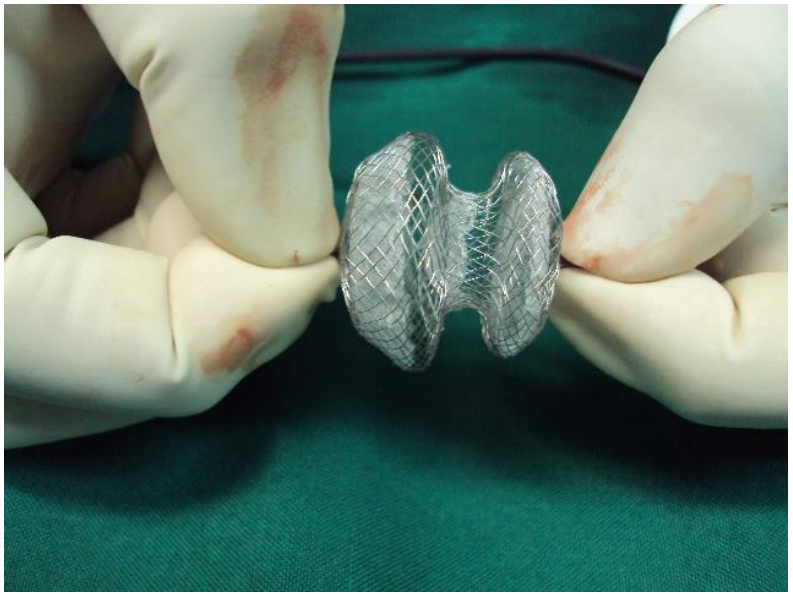
Nanoplatinum coating prevent the leaching of Nickel into the bloodstream and guards against the corrosion of the nitinol wire frame during long-term implants.

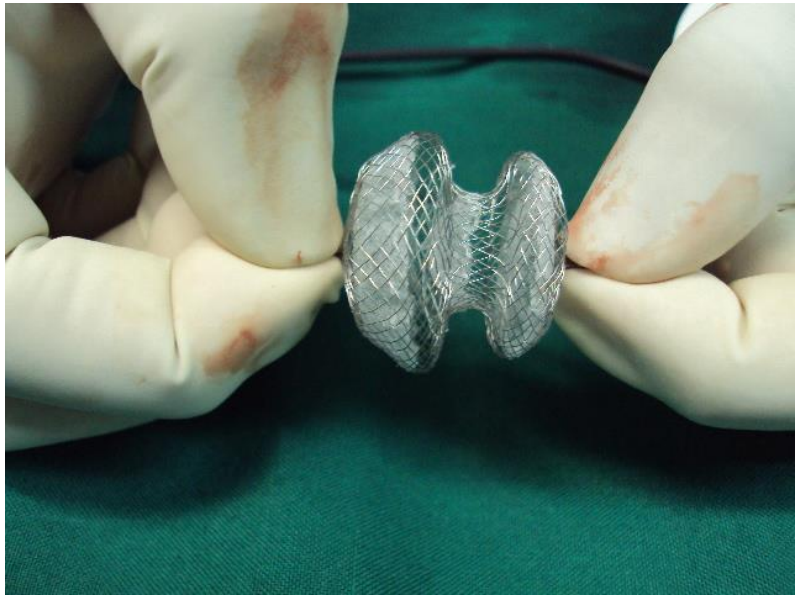
The device incorporates multiple polypropylene woven fabrics that expedite faster and complete closure of defects by inducing thrombogenicity

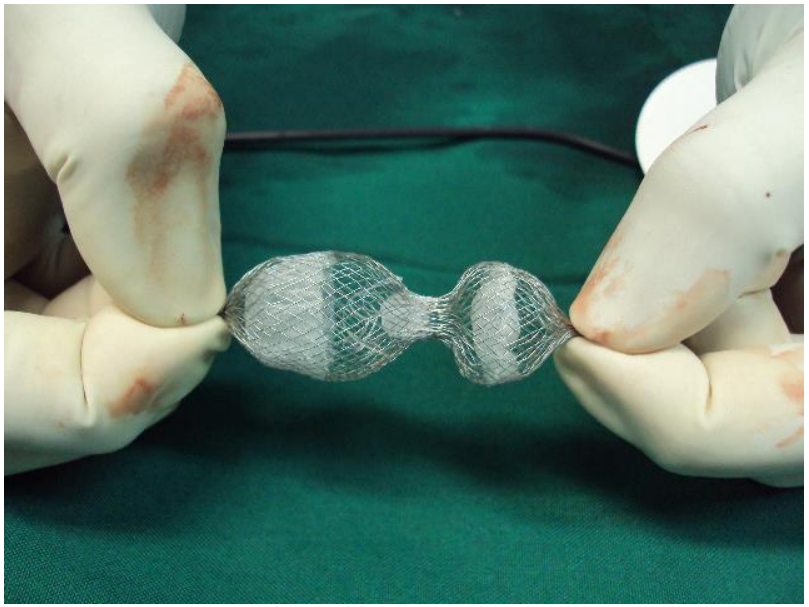
The smaller metal-to-disc ratio of the device makes it magnetic resonance imaging compatible and facilitates effortless recapture and repositioning during the procedure.





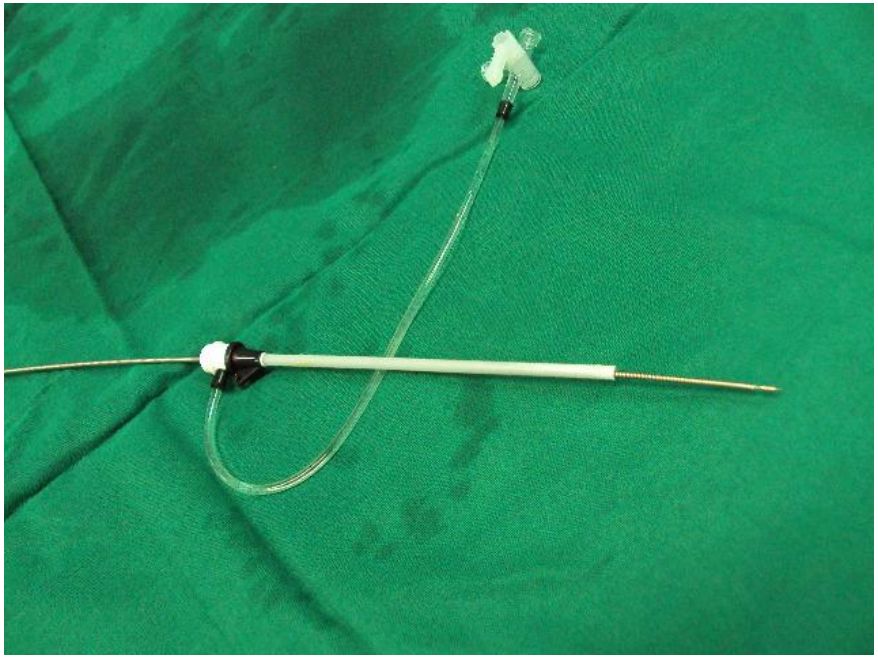


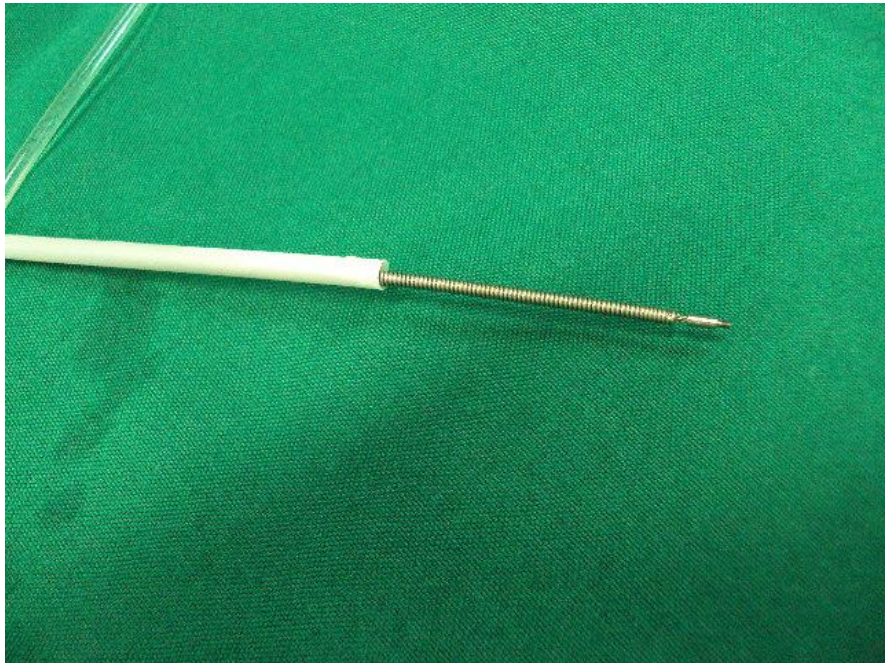




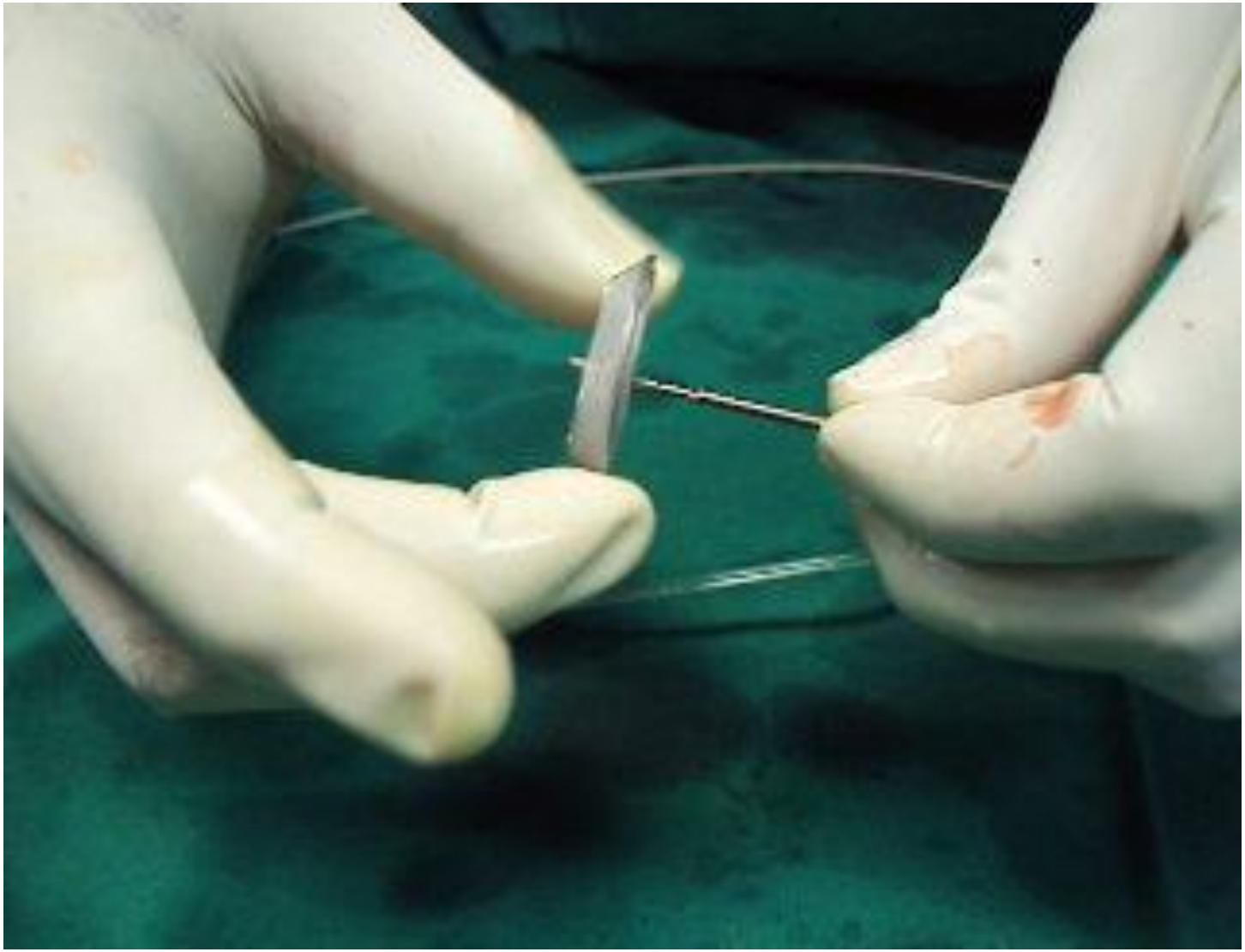
Stretched ASD Properties: Memory/Polypropylene threads

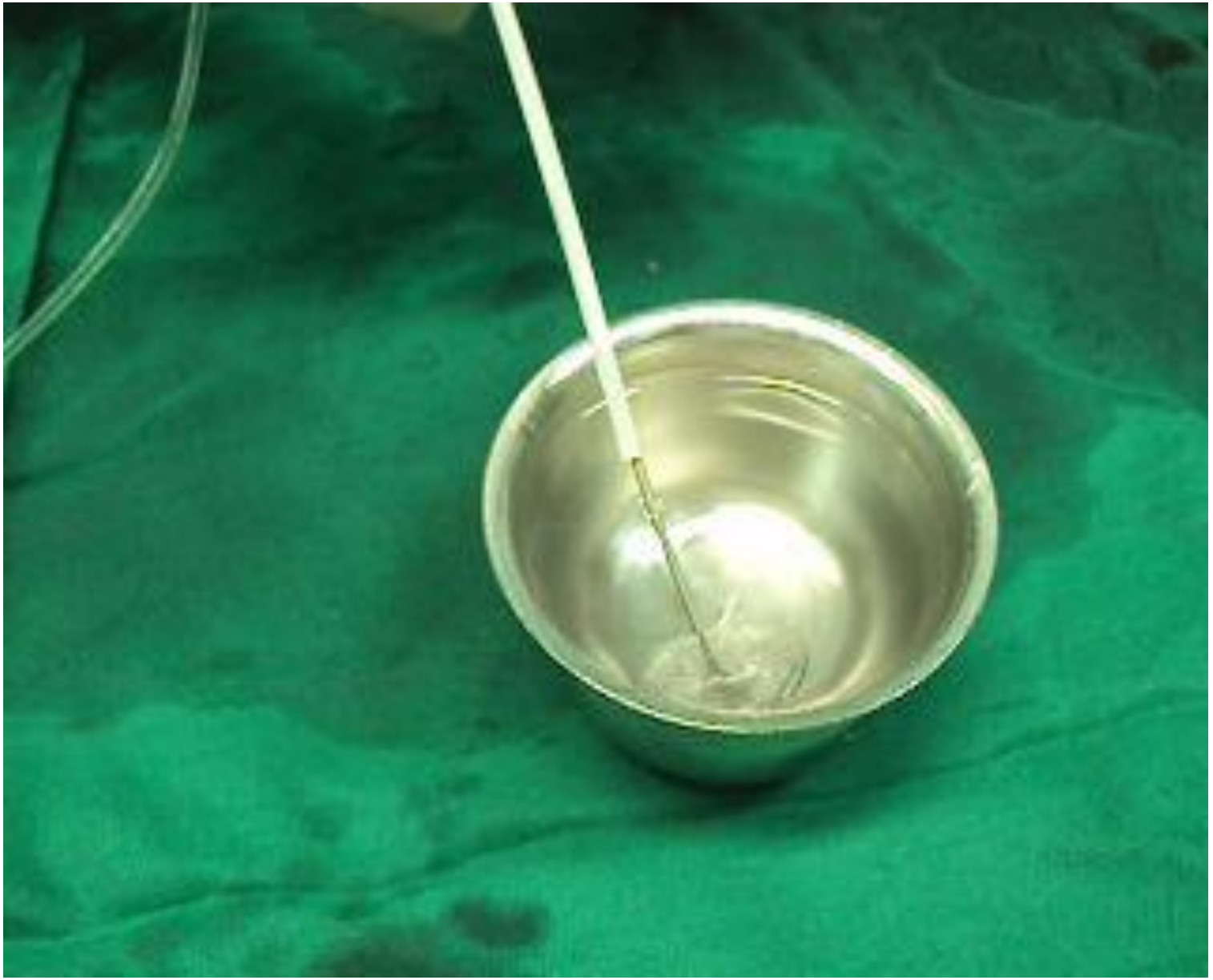
Loader & Delivery cable



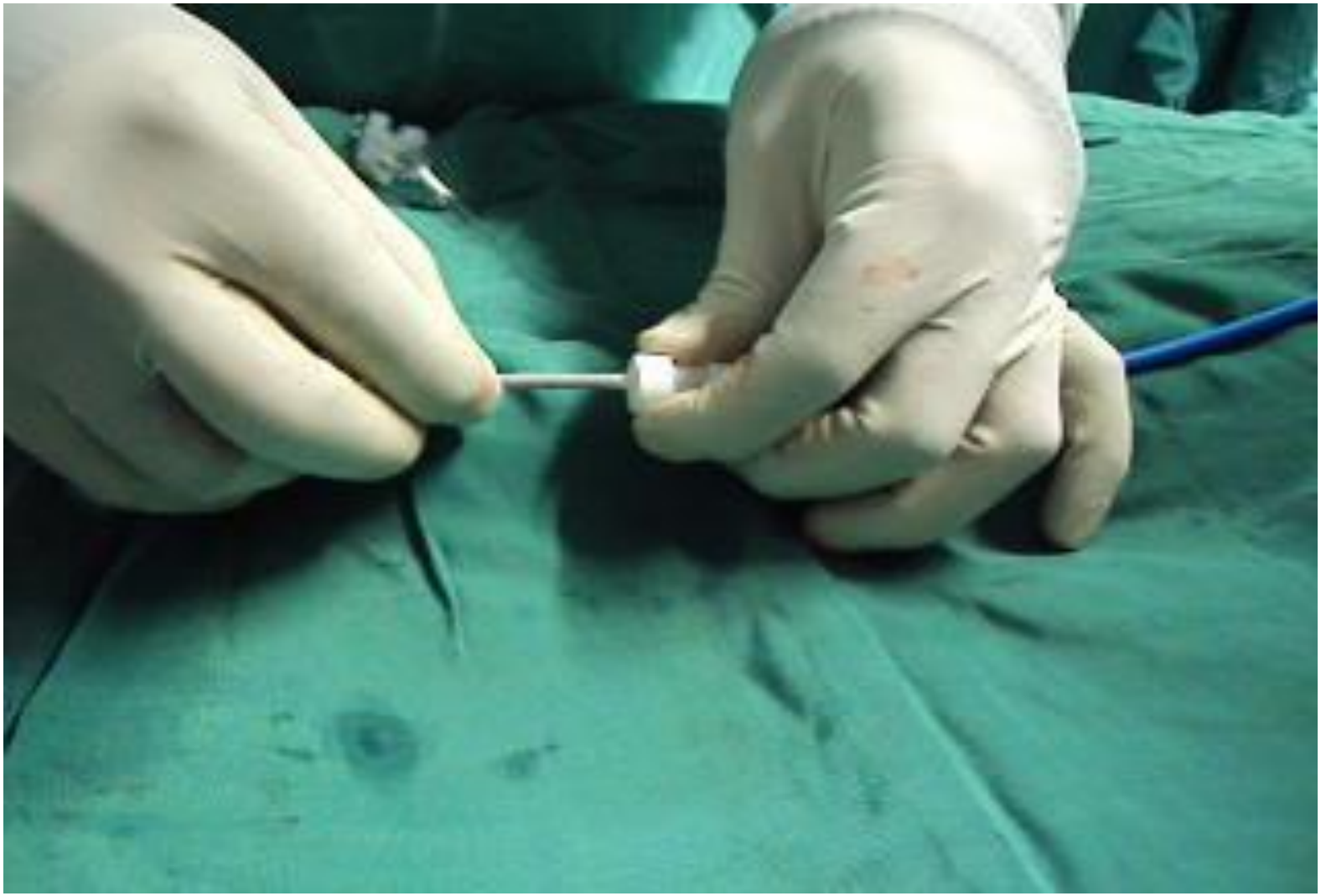


Loading of the ASD closure device

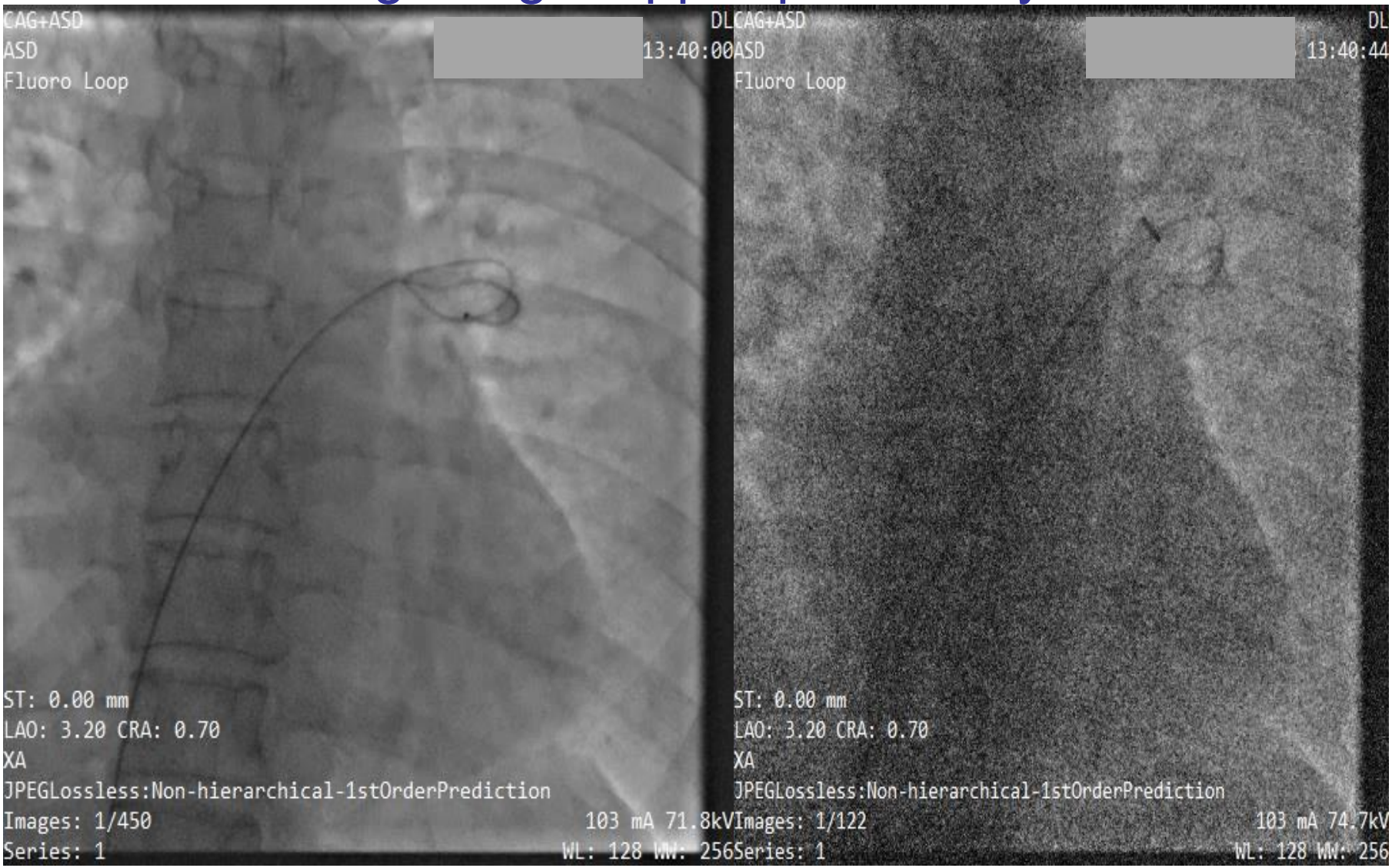




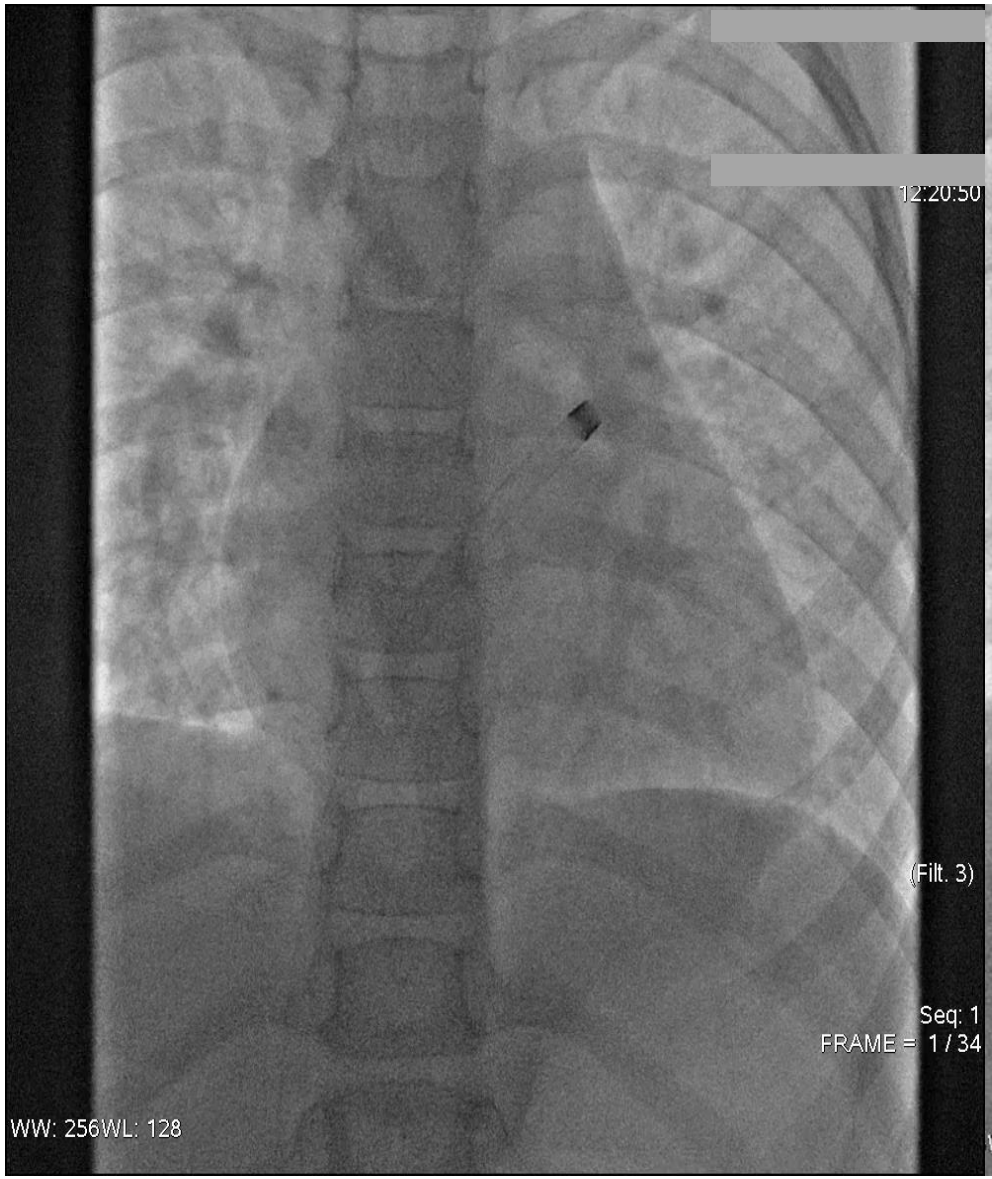
Insertion of the device in to the long sheath

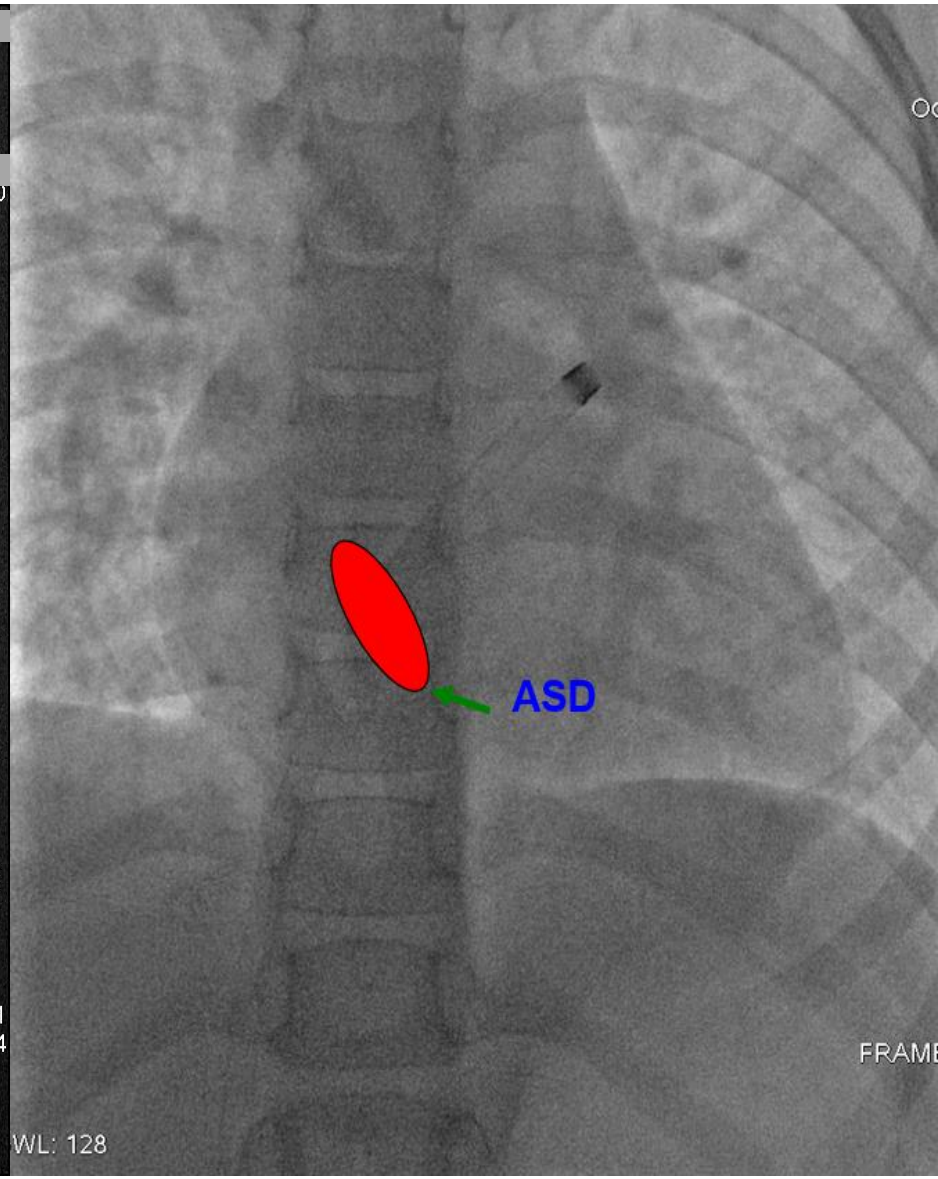


Hooking of right upper pulmonary vein

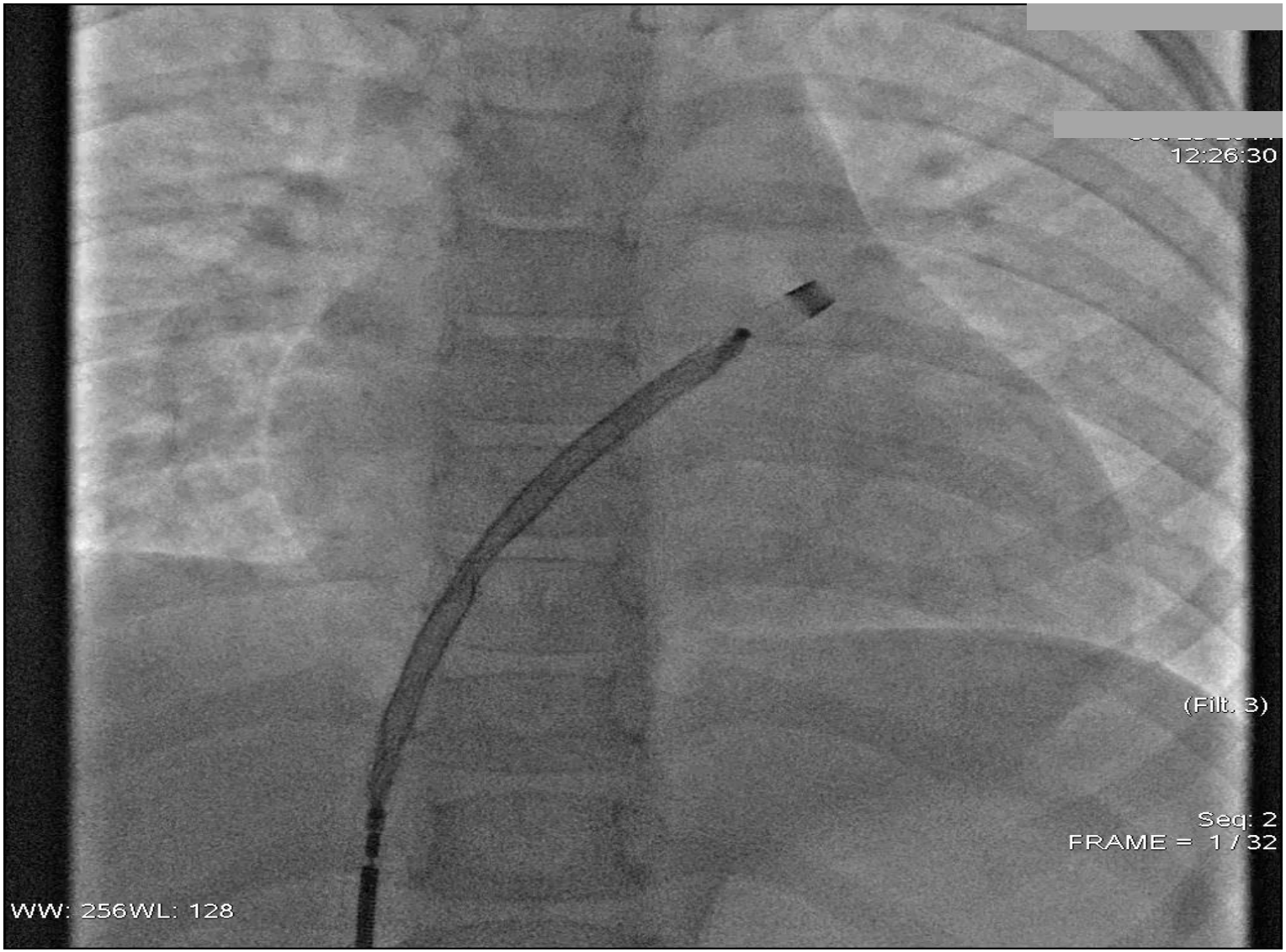


SHEATH ACROSS ASD

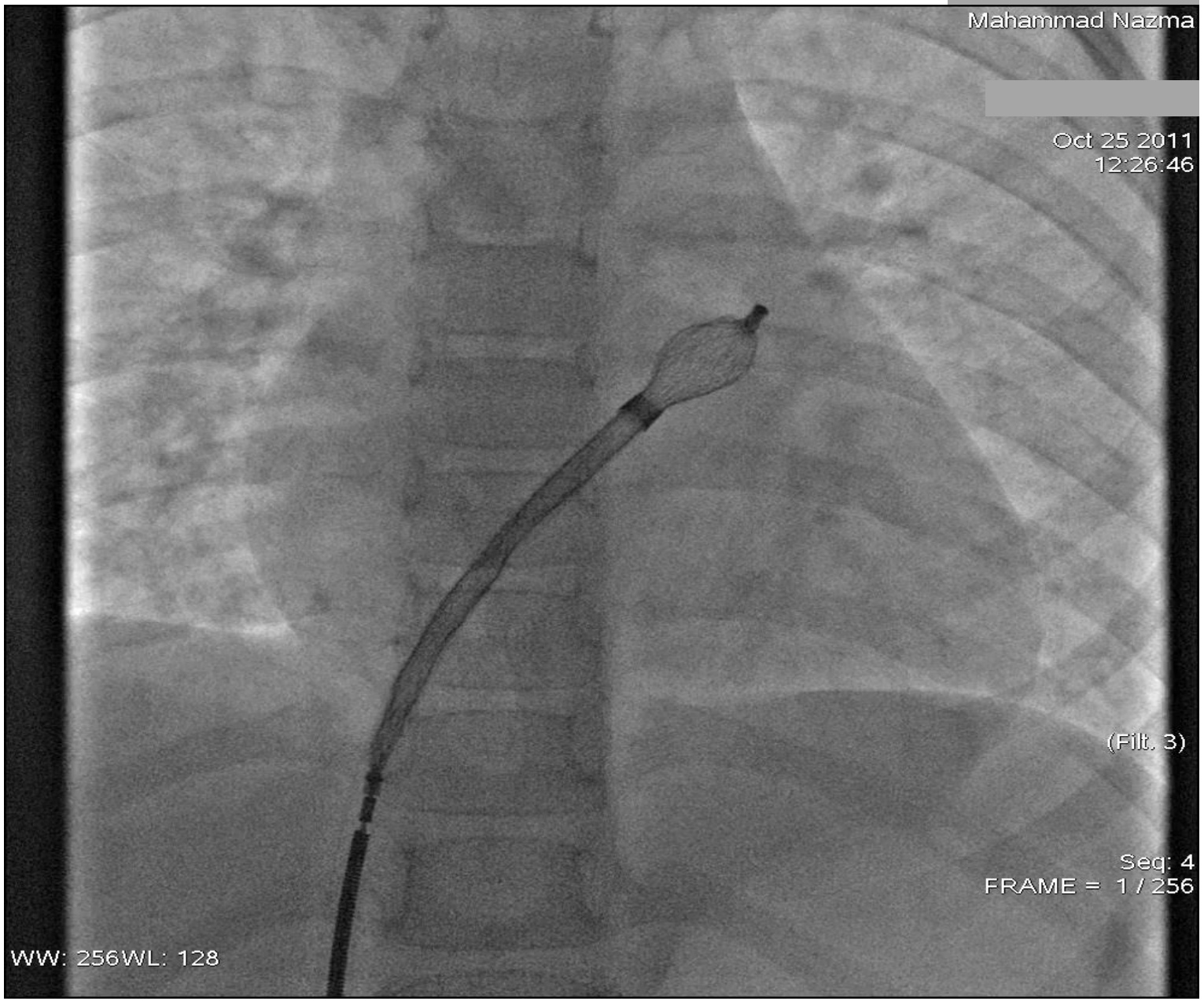




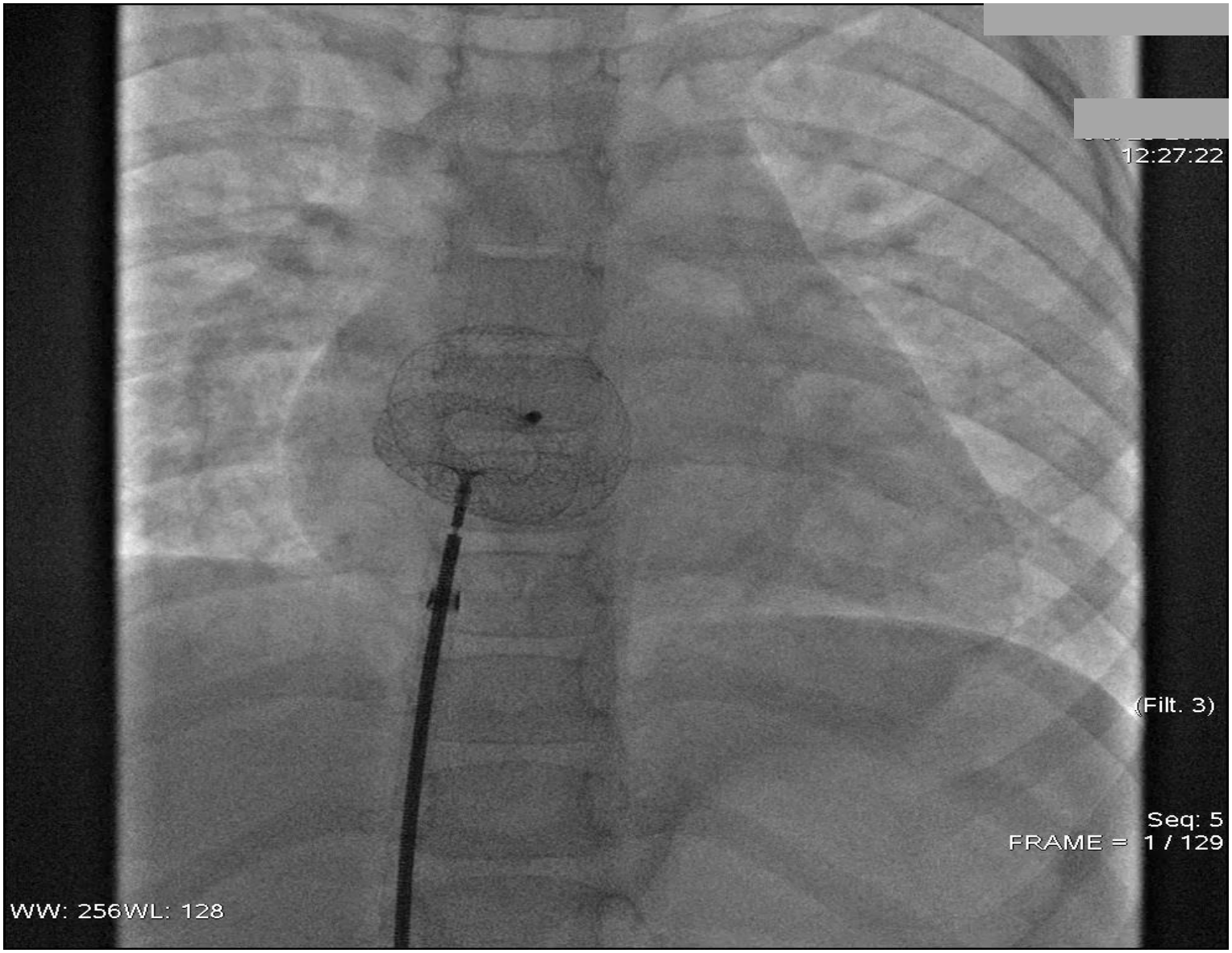
Device positioned Across ASD



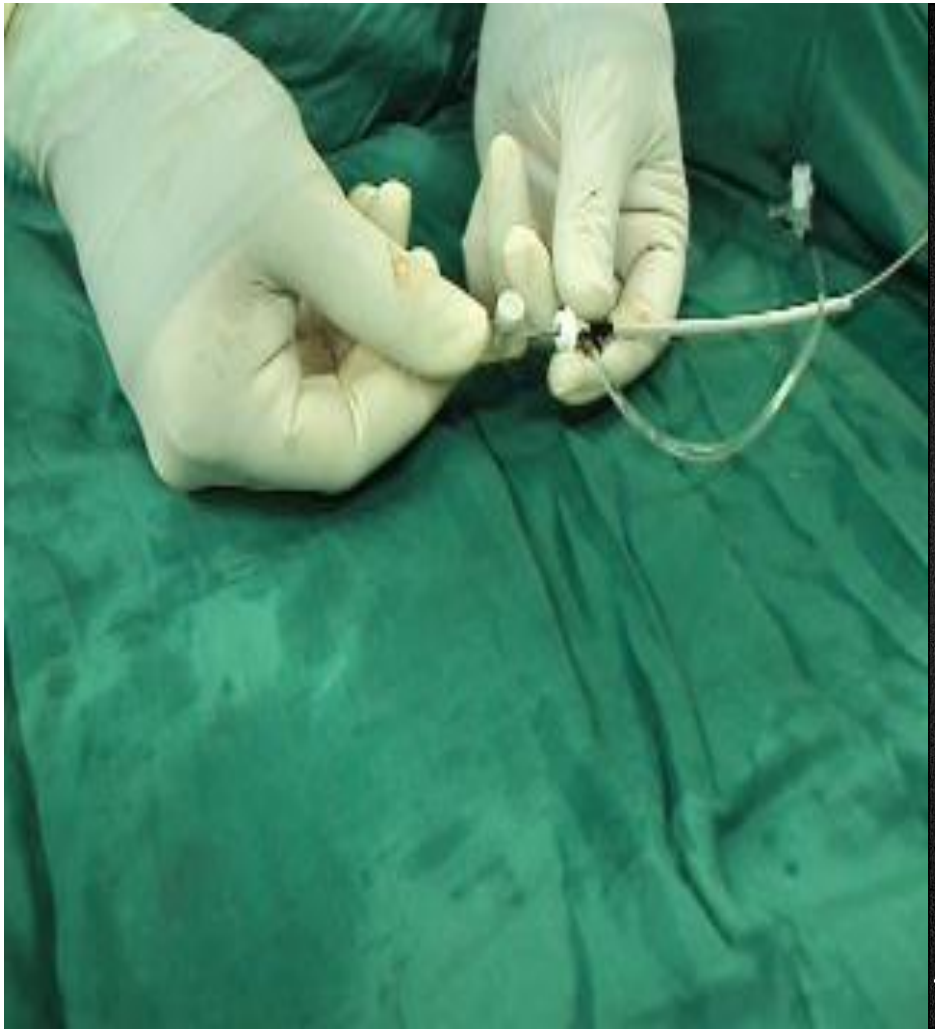
Unsheathing the Device

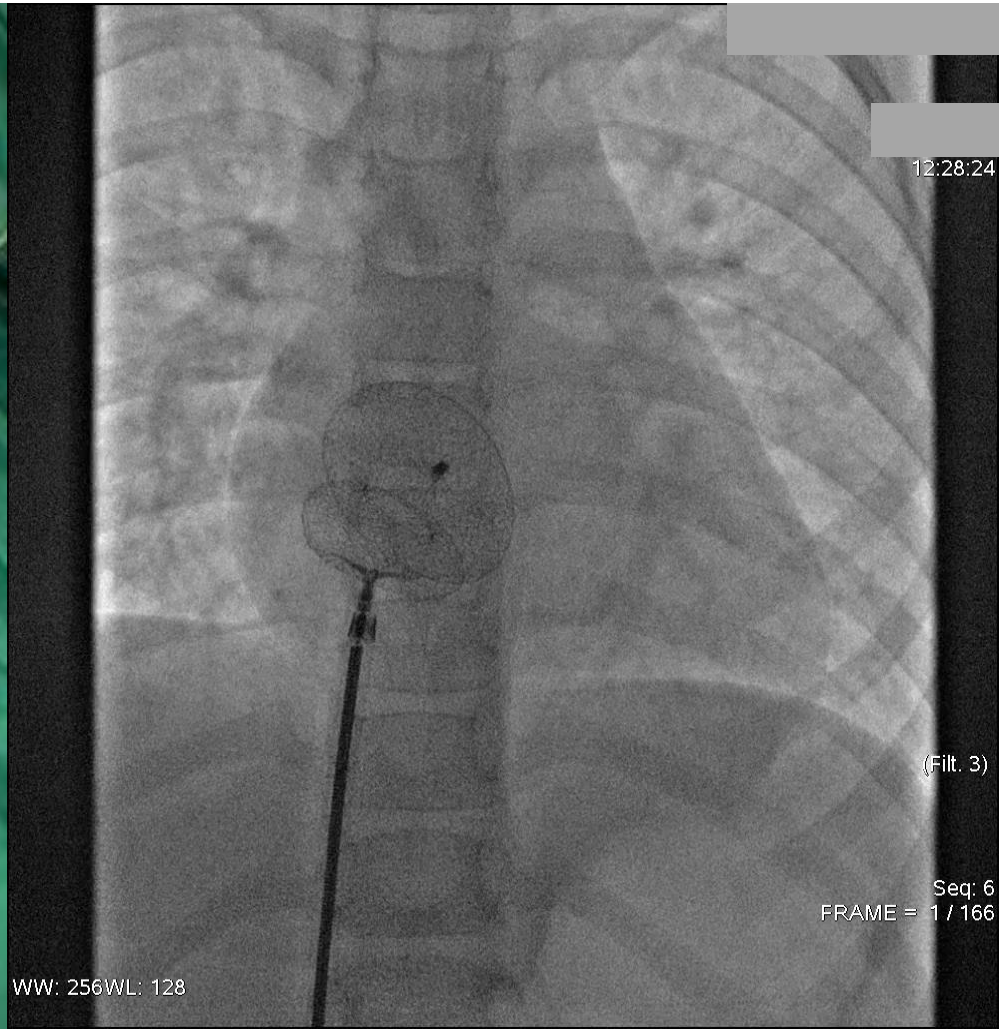


Minnesota Wiggle

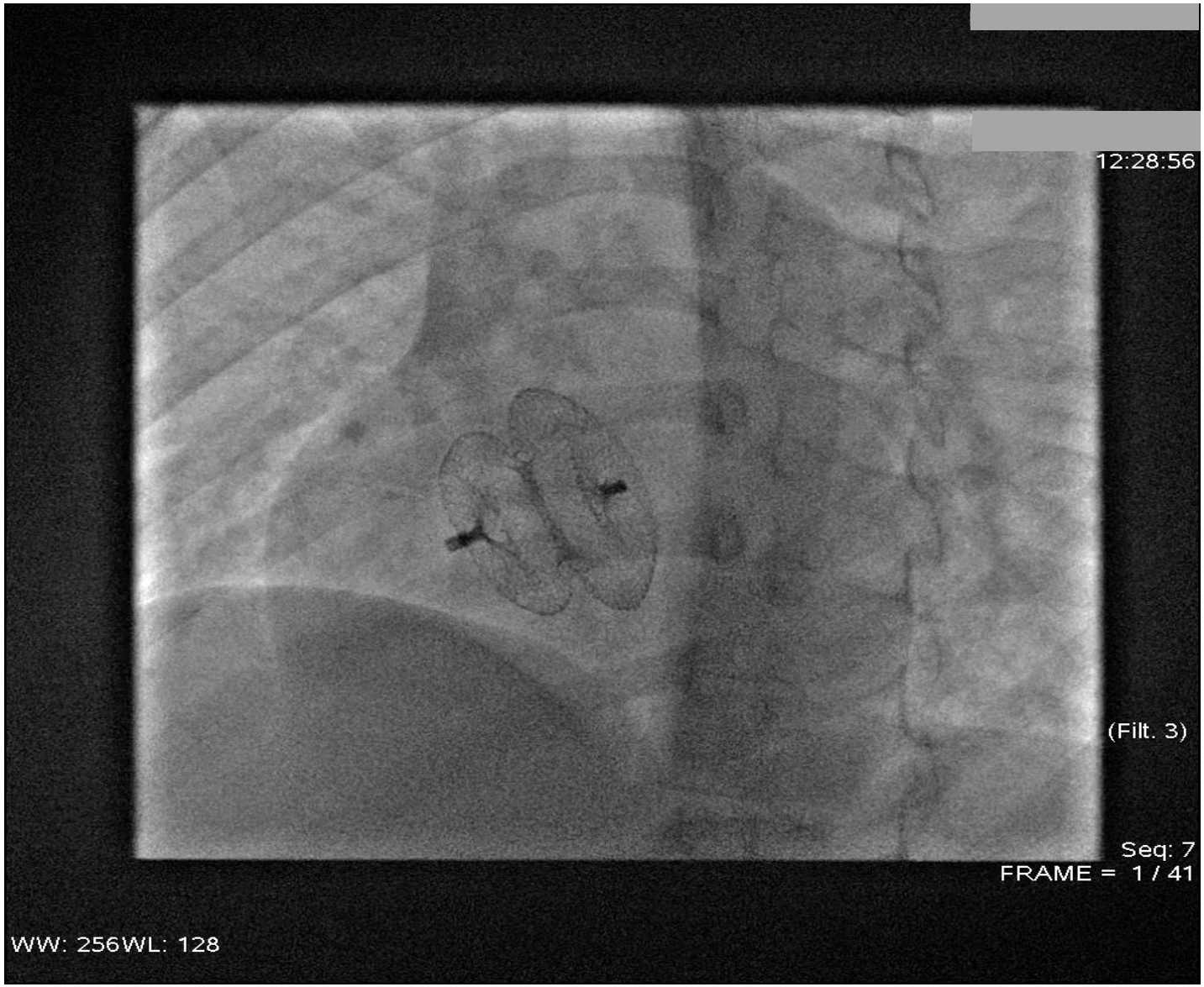


Device Release

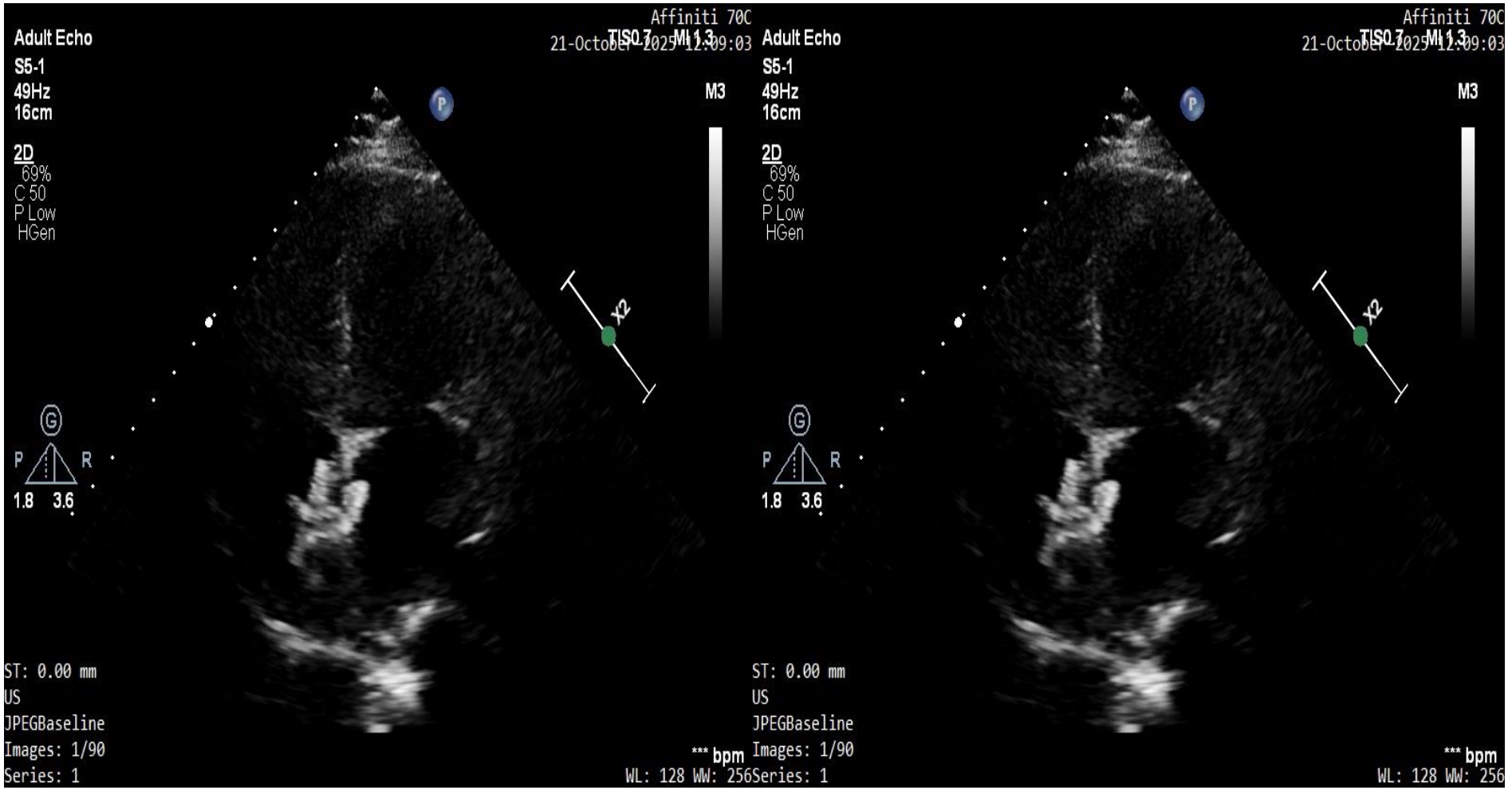




Device Final position check

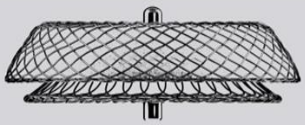


Device position in TTE



400
Indian patients with isolated secundum atrial septal defect

Transcatheter closure of atrial septal defects with **Cocoon Septal Occluder**



28 Children
(≤15 years)
Mean age:
8.14 ± 4.41 years

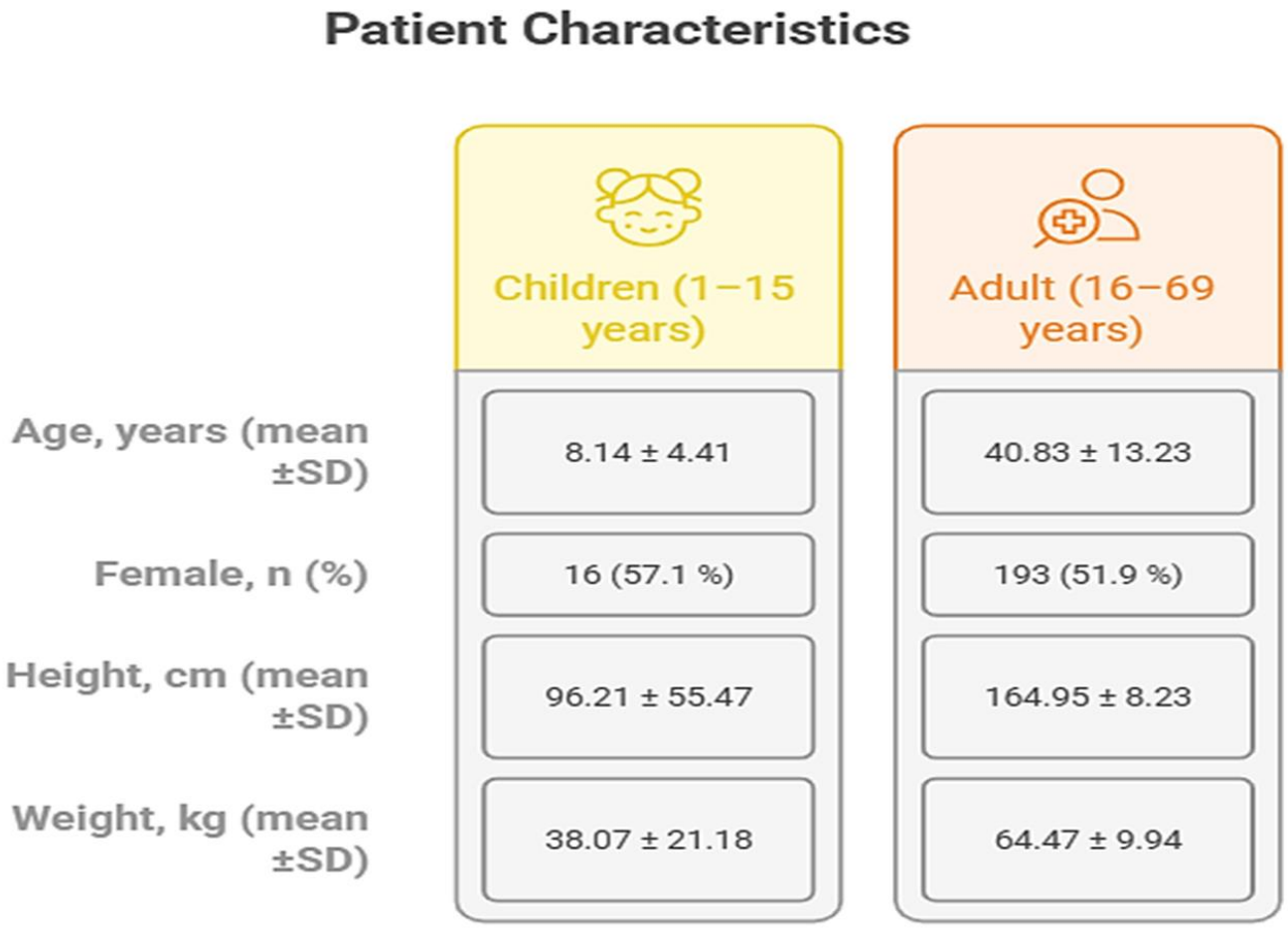
372 Adults
Mean age:
40.83 ± 13.23 years

ZERO Events
100% Complete closure

1 Year Follow-up

0%	Cardiac erosion
0%	Nickel allergy
0%	Stroke/transient ischemic stroke
0%	Migraine
0.5%	Atrial flutter/fibrillation
0.8%	Atrioventricular block
1.1%	Minor arrythmia
98.9%	Complete closures

BASELINE DEMOGRAPHICS



PROCEDURAL DETAILS

Patient Characteristics	Children (1–15 years) n =28	Adult (16–69 years) n =372
Procedural Details		
Qp/Qs Ratio, (mean ±SD)	1.68 ± 0.37	1.94 ± 0.43
Pulmonary Hypertension, n (%)		
Systolic, mmHg (mean ± SD)	36.93 ± 5.15	40.38 ± 8.00
Diastolic, mmHg (mean ± SD)	13.74 ± 1.68	13.60 ± 2.05
Size of Defect mm (mean ± SD)	16.75 ± 5.85	21.62 ± 6.87
Aortic Rim, n (%)		
Present	17 (60.7 %)	217 (58.3 %)
Deficient	11 (39.3 %)	155 (41.7 %)
Other Deficient Rims, n (%)		
Superior vena cava	8 (28.6 %)	81 (21.8 %)
Anterior	13 (46.4 %)	148 (39.8 %)
IVC Posterior	7 (25.0 %)	138 (37.1 %)
IVC Flimsy	0 (0.0 %)	5 (1.3 %)

Patient Characteristics	Children (1–15 years) n =28	Adult (16–69 years) n =372
Device Diameter, mm (mean ± SD)	20.43 ± 6.24	24.94 ± 7.28
10 mm	1 (3.6 %)	0 (0.0 %)
12 mm	0 (0.0 %)	10 (2.7 %)
14 mm	4 (14.3 %)	27 (7.3 %)
16 mm	4 (14.3 %)	16 (4.3 %)
18 mm	5 (17.9 %)	20 (5.4 %)
20 mm	3 (10.7 %)	55 (14.8 %)
22 mm	3 (10.7 %)	20 (5.4 %)
24 mm	2 (7.1 %)	41 (11.0 %)
26 mm	3 (10.7 %)	59 (15.9 %)
28 mm	1 (3.6 %)	40 (10.8 %)
30 mm	0 (0.0 %)	9 (2.4 %)
32 mm	0 (0.0 %)	23 (6.2 %)
34 mm	0 (0.0 %)	5 (1.3 %)
36 mm	2 (7.1 %)	11 (3.0 %)
38 mm	0 (0.0 %)	14 (3.8 %)
40 mm	0 (0.0 %)	22 (5.9 %)

VARIATIONS !

- Patients underwent cardiac catheterization pre procedure to assess LVEDP.

Intra procedurally –

- LUPV hooked in 380 patients
- RUPV in 20 patients
- LLPV in 5 patients
- Cobra formation was seen in 3 patients – resolved by pull back
- BAT in 4 patients

In-hospital Outcomes

IN CHILDREN (1-15 years) n=28	
28 (100%)	Complete Closure
2 (7.1%)	Vascular Bleeding
1(3.6%)	Type-I Atrio-ventricular block
0%	Device Embolization Device Withdrawal Perforation Thrombus Formation Atrial Arrhythmia Stroke/Transient ischaemic attack Type-II Atrio-ventricular block Complete atrio-ventricular block

In Adult (16-69 years) n=372	
369 (99.2 %)	Complete Closure
2 (0.5 %)	Device Embolization
1 (0.3 %)	Device Withdrawal
1 (0.3 %)	Perforation
8 (2.2 %)	Vascular Bleeding
5 (1.3 %)	Atrial Arrhythmia
7 (1.9 %) 2 (0.5 %)	Atrio-ventricular block Type-I Atrio-ventricular block Type-II
0%	Thrombus Formation Stroke/Transient ischaemic attack Complete atrio-ventricular block

One-year Follow-up Outcomes

CHILDREN (1-15 years) n=28	
28 (100%)	Complete Closure
0%	Embolization Cardiac Erosion Nickel Allergy Pericardial Effusion/Cardiac-Tamponade Endocarditis Thrombus Formation Haemolysis Atrio-ventricular block Stroke/Transient ischaemic attack Minor Atrial Arrhythmia Atrial Flutter/Fibrillation Migraine/Headache

ADULT (16-69 years) n=372	
368 (99.2 %)	Complete Closure
1 (0.3 %)	Embolization
3 (0.8 %)	Pericardial Effusion/Cardiac Tamponade
2 (0.5 %)	Thrombus Formation
3 (0.8 %)	Atrio-ventricular block
4 (1.1 %)	Minor Atrial Arrhythmia
2 (0.5 %)	Atrial Flutter/Fibrillation
0%	Cardiac Erosion Nickel Allergy Endocarditis Haemolysis Stroke/Transient ischaemic attack Migraine/Headache

THROMBOPROPHYLAXIS

Device size >30 mm

- Aspirin 75 mg & clopidogrel 75 mg for 3 months.
- F/b Aspirin 75 mg for 5 months.

Smaller devices:

- Aspirin 75 mg for 6 months for >10 y

- <10 yrs
- Aspirin 3-5 mg/kg daily for 6 months .

LIMITATIONS OF THE STUDY

- Retrospective non randomized – re call bias .
- Single centre experience.
- Follow up of 1 year.
- In corporation of 3D & 4D would have further refined .

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Original Article

Safety and one-year follow-up analysis of percutaneous ASD closure at a tertiary care hospital

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ABSTRACT

Aim: This study was designed to evaluate the safety and effectiveness of the Cocoon Septal Occluder device (Vascular Innovations Co. Nonthaburi, Thailand) for transcatheter closure of isolated secundum type atrial septal defect (ASD) in Indian patients.

Methods: This was a single-center, retrospective, observational study which included patients who underwent transcatheter closure of isolated secundum ASD using the Cocoon Septal Occluder between April 2014 and May 2023. Follow-up assessments up to one-year were conducted through review of hospital medical records, clinic visits, or via telephonic communication with primary care physicians.

Results: A total of 400 patients were included in the study, consisting of 28 paediatric (aged ≤15 years, 8.14 ± 4.41 years) and 372 adult patients (40.83 ± 13.23 years). The mean defect diameter and device size were 16.75 ± 5.85 mm and 20.43 ± 6.24 mm for paediatric patients, and 21.62 ± 6.87 mm and 24.94 ± 7.28 mm for adult patients, respectively. The device was successfully implanted in all paediatric patients, achieving 100 % closure of the defect with no complications, which persisted through one-year follow-up. In the adult cohort, complete ASD closure was achieved in 99.2 % of patients, with two cases of device embolization and one case of device withdrawal. At one-year follow-up, adult patients experienced 0.3 % late device embolization, 0.8 % pericardial effusion/cardiac tamponade, 0.5 % atrioventricular block, and 0.5 % atrial flutter/fibrillation. No cases of endocarditis, haemolysis, nickel allergy, stroke/transient ischemic attack, or migraine were reported in either paediatric or adult patients.

Conclusion: The results demonstrate that Cocoon Septal Occluder is safe and effective in closing isolated secundum ASD during one-year follow-up.

Thank you...