New Techniques for PFO Closure

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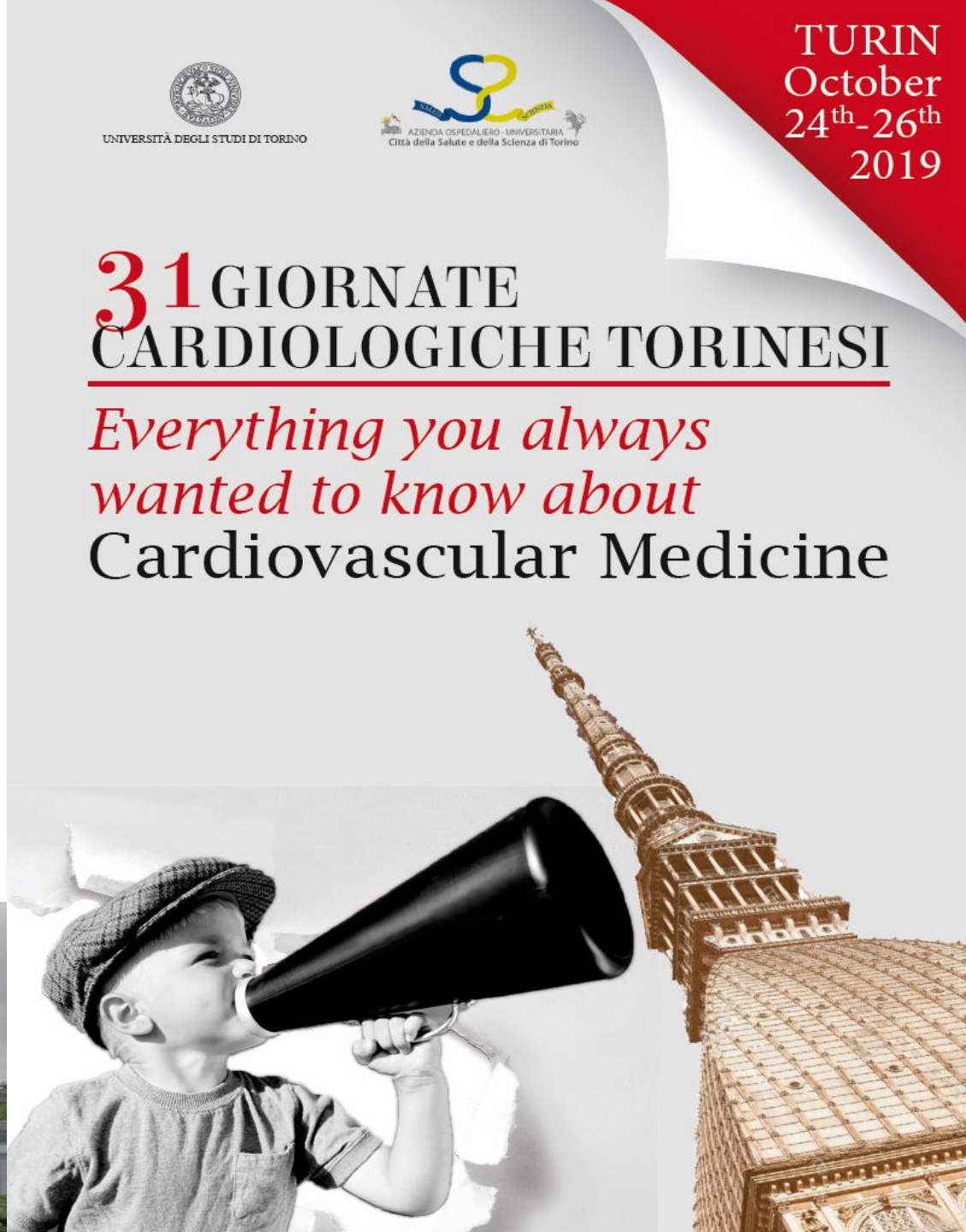

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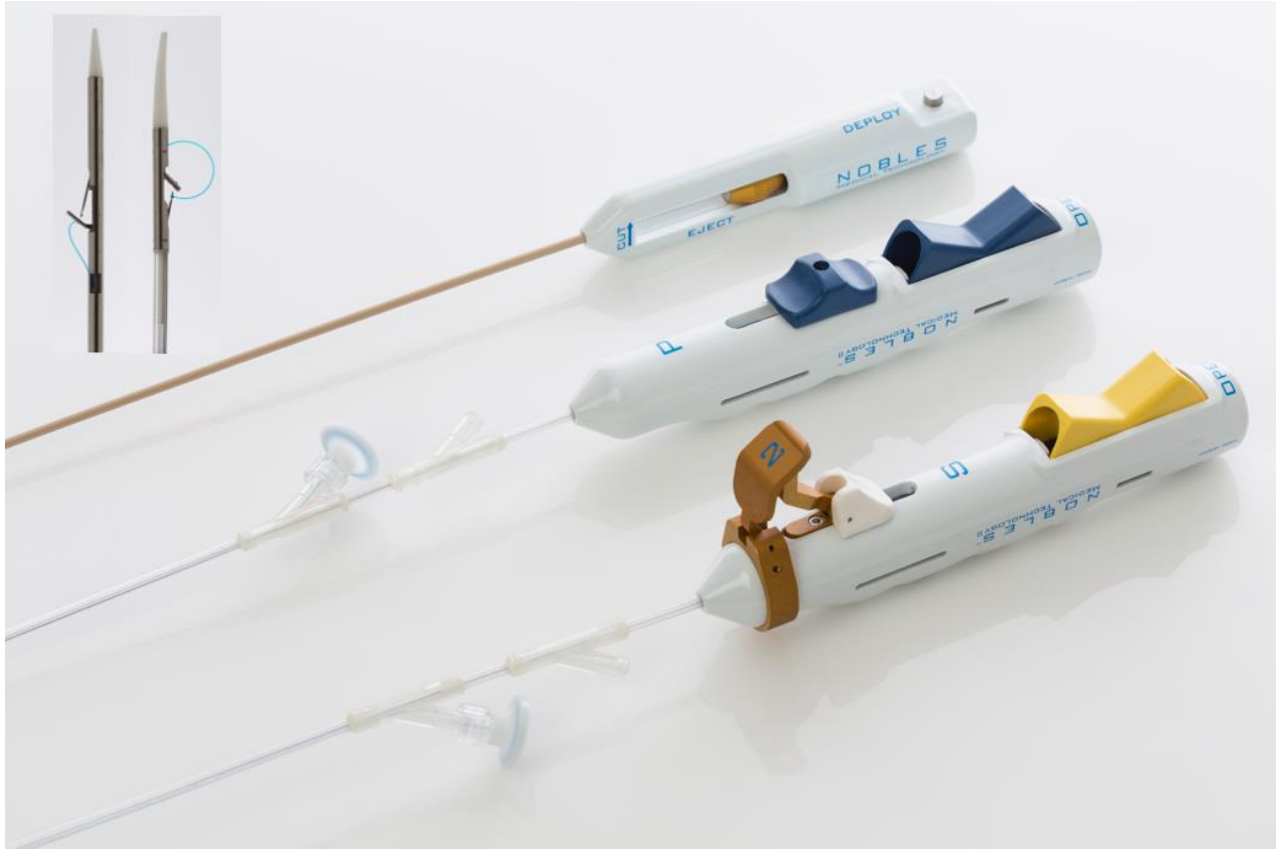
Ideal charachteristics of a PFO closure device

- Easy to Implant
- High Early Closure Rate
- No Obstruction of the Oval Fossa
- Percutaneous
- No DEVICE LEFT BEHIND
- Does not require long term anti-coagulation
- Does not migrate
- Does not erode
- Does not perforate
- Does not cause Atrial Fibrillation
- Provides Reliable Closure – Equivalent to Surgical Closure Results

NOBLESTITCH® EL

- Tecnologia innovativa per la sutura del Forame Ovale Pervio
- 3 delivery system 12 Fr
- Filo di polipropilene 4-0
- System ‘S’ : posiziona la sutura sul s. secundum
- System ‘P’ : posiziona la sutura sul s. primum
- KwiKnot™ : chiude il forame ovale con un sistema di bloccaggio in polipropilene



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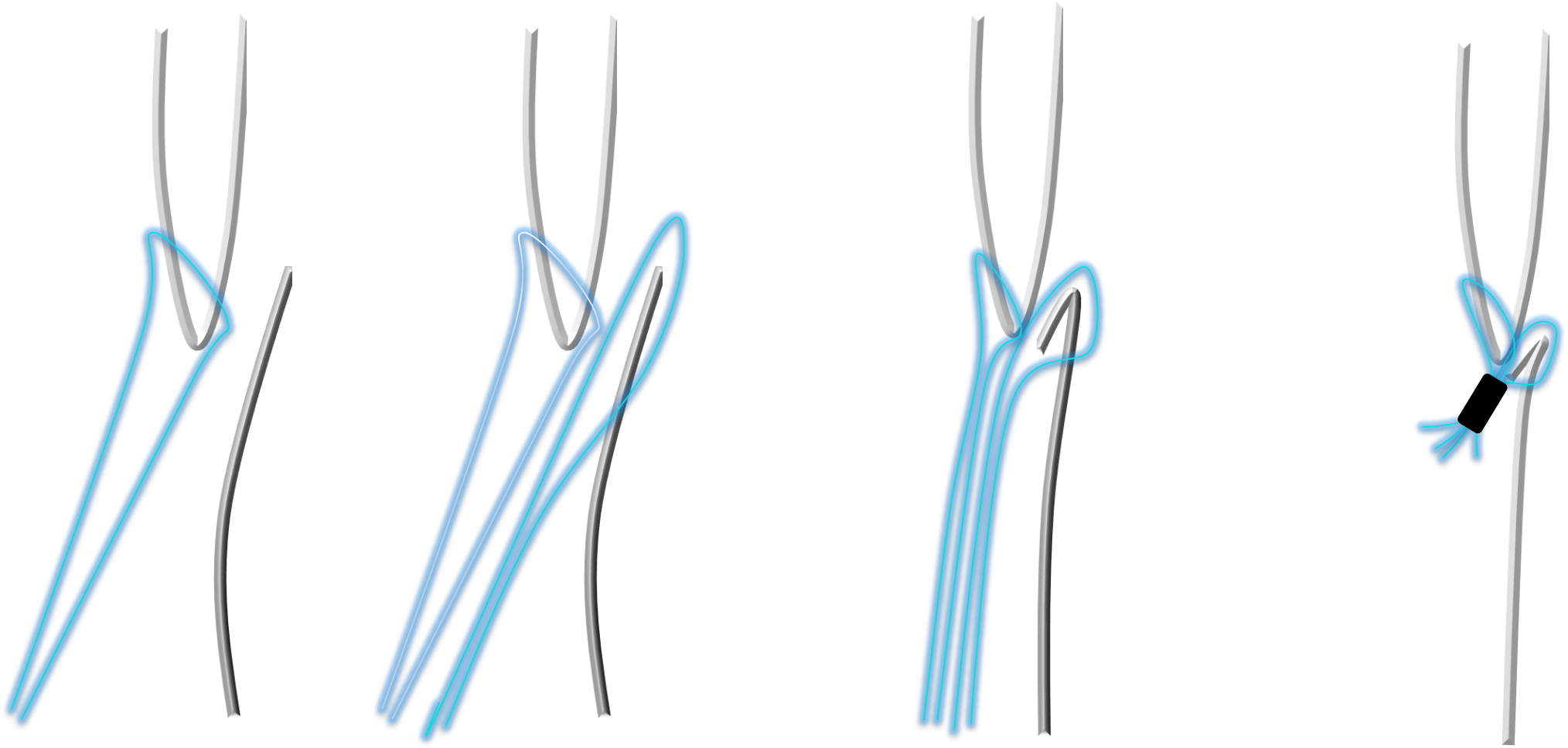
COME FUNZIONA



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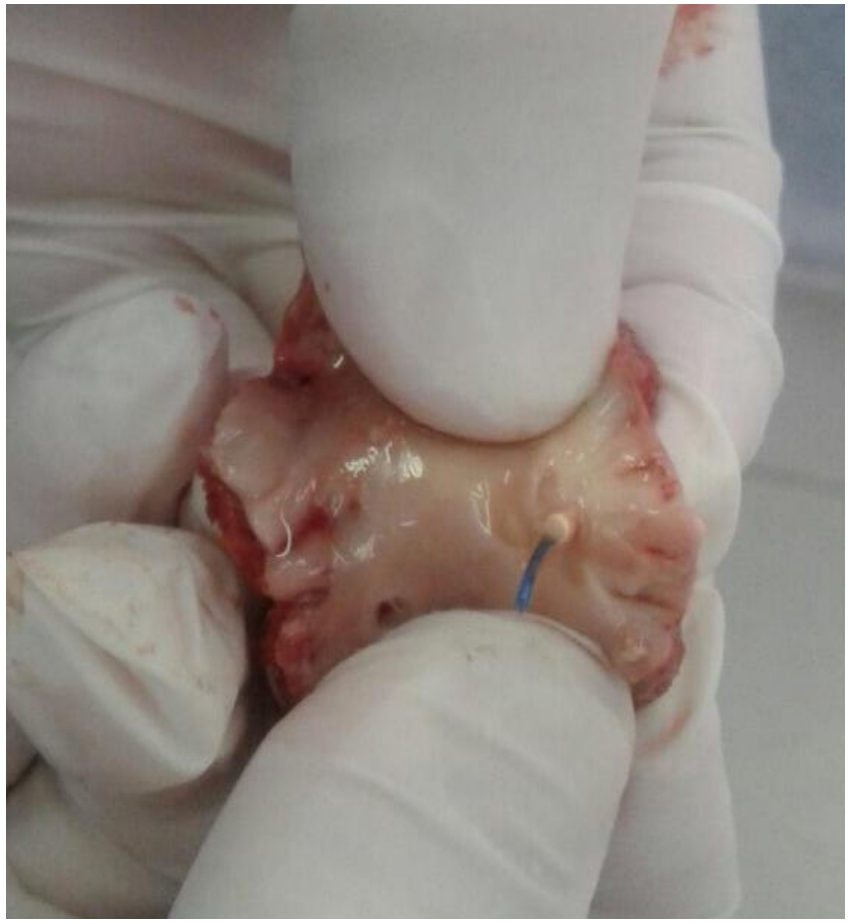
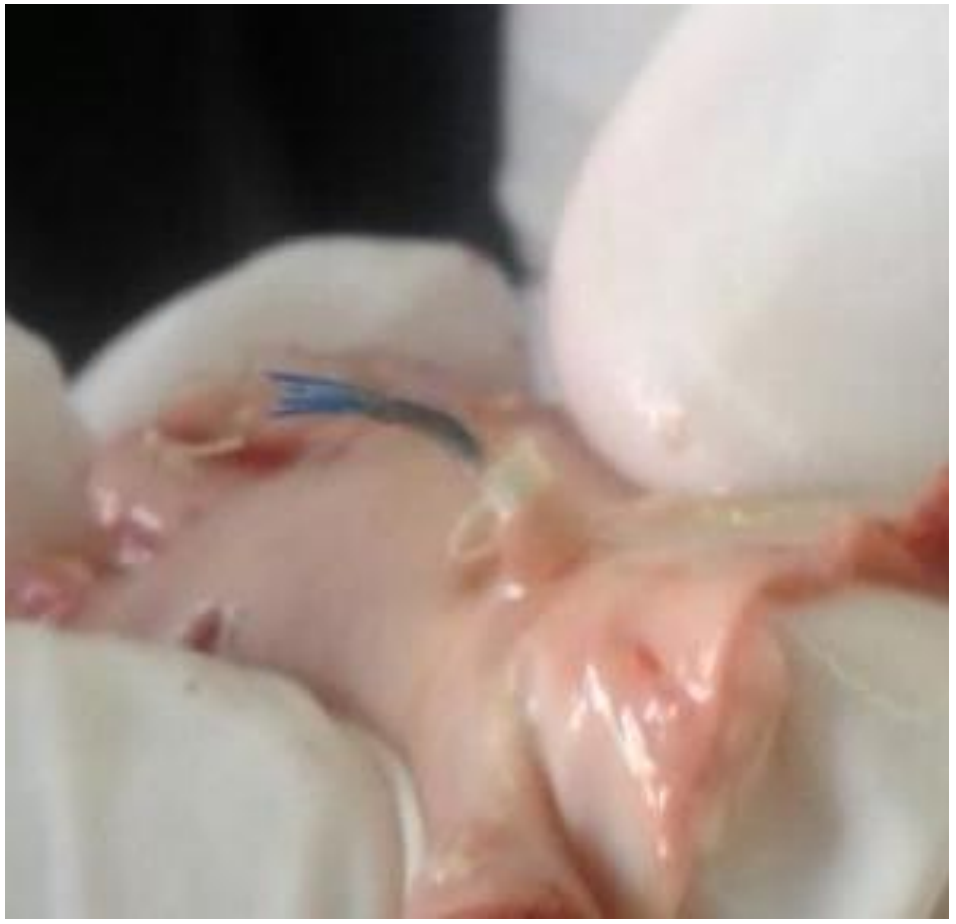
Suture Closure of PFO with NobleStitch

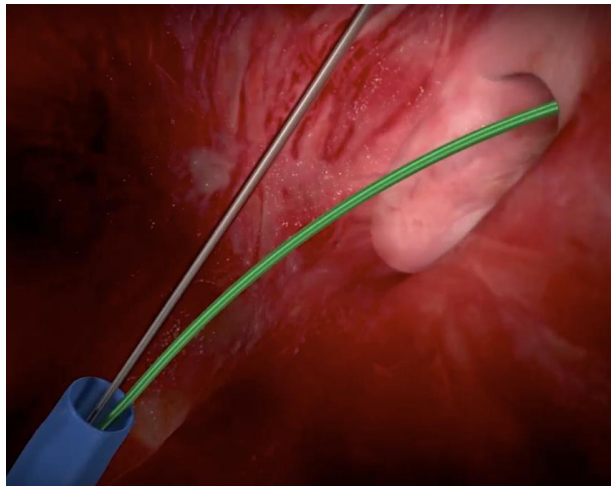
Polypropylene KwiKnot endothelialization

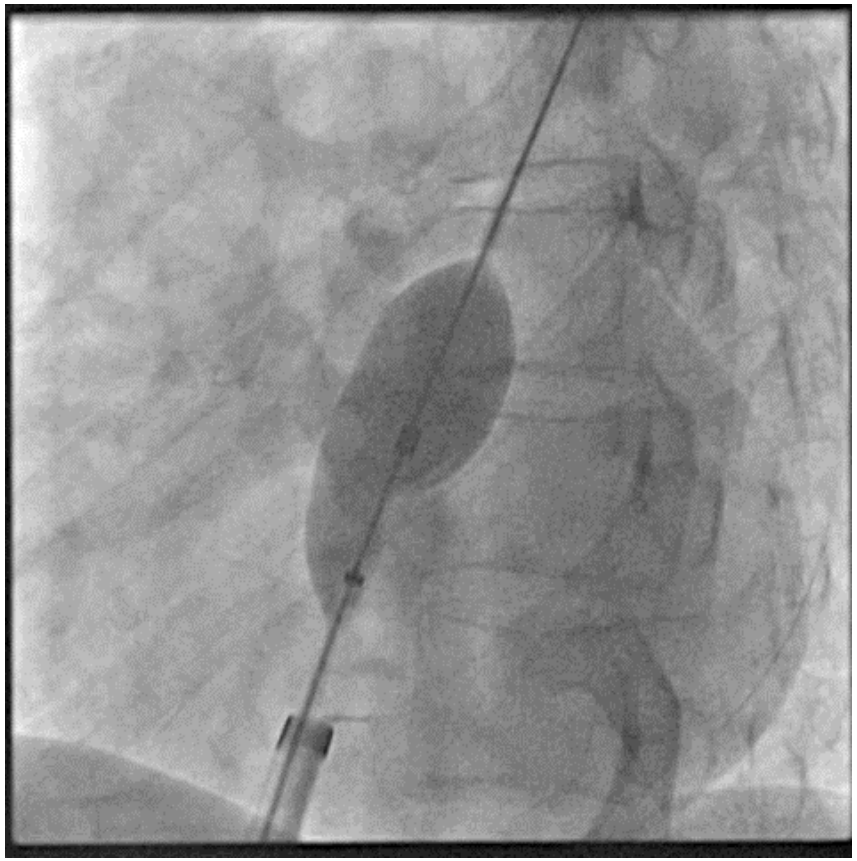




PROCEDURA – Balloon interrogation

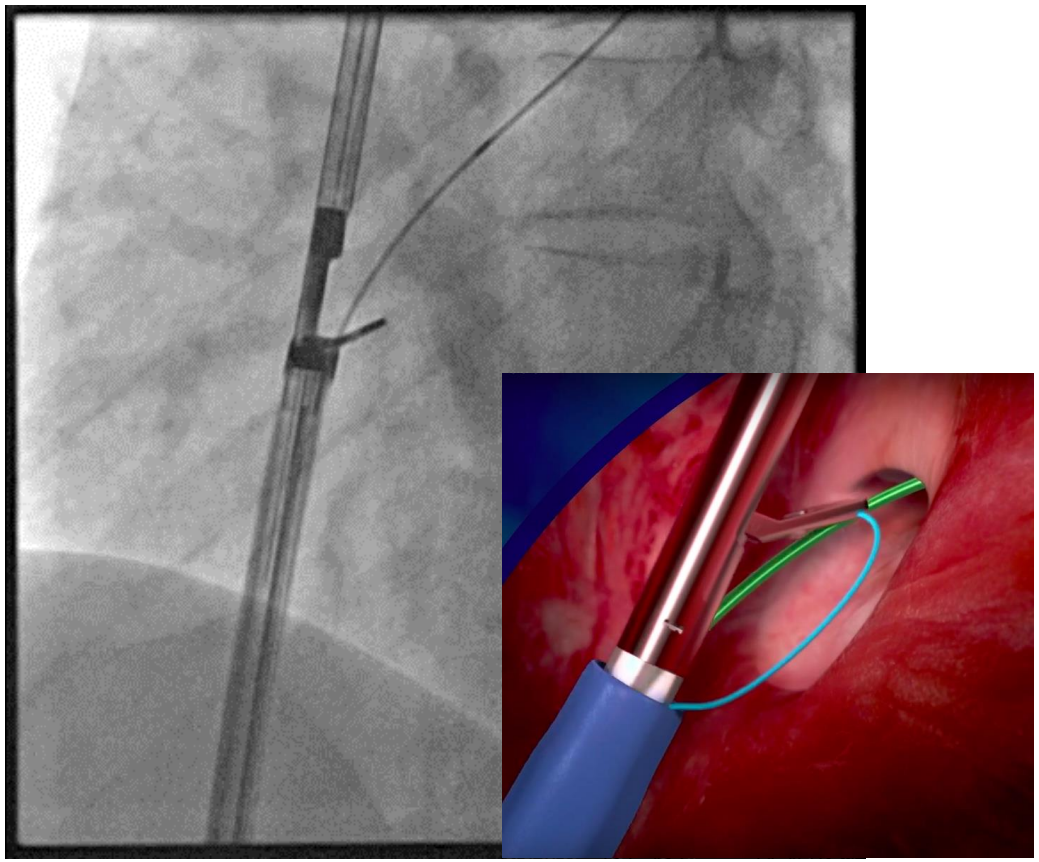
- LAO 60° - per tutta la durata della procedura
- Introduttore 14Fr – 63 cm
- Guida 0,018” in Vena Cava Superiore
- Guida 0,032” attraverso il forame ovale, in vena polmonare superiore sinistra



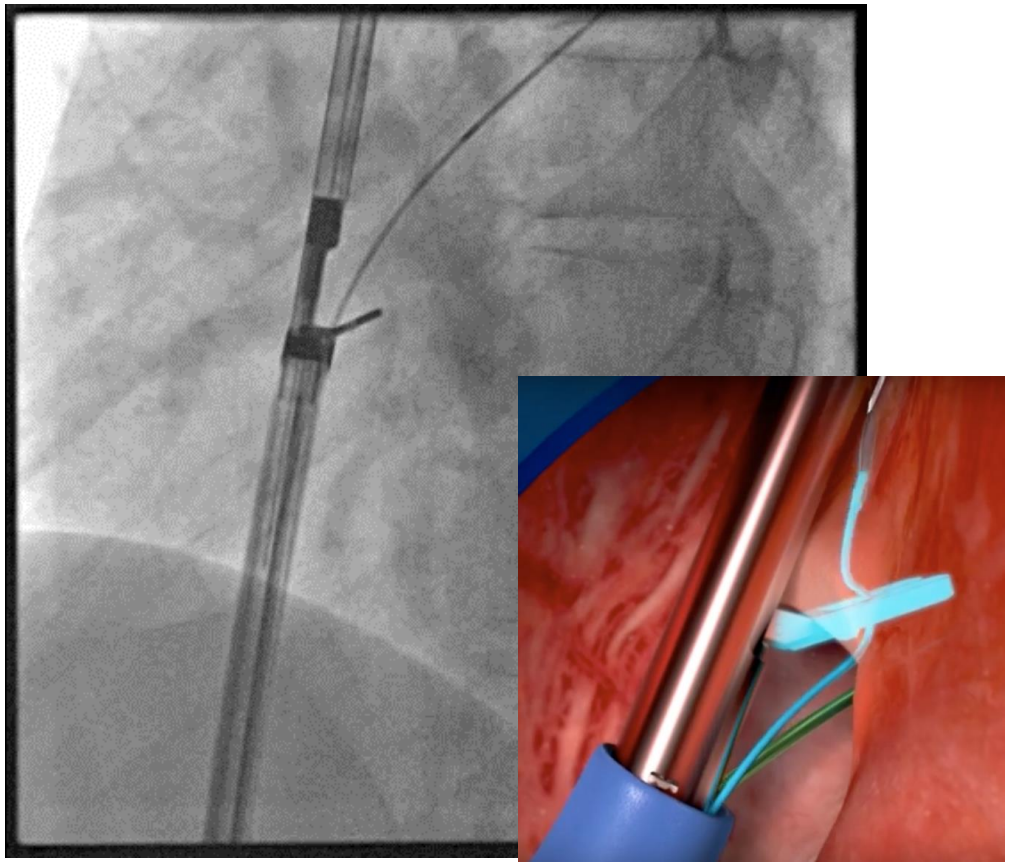


- Si definisce angiograficamente l’anatomia del s. primum e del s. secundum con l’utilizzo di un Sizing Balloon

PROCEDURA – Septum Secundum

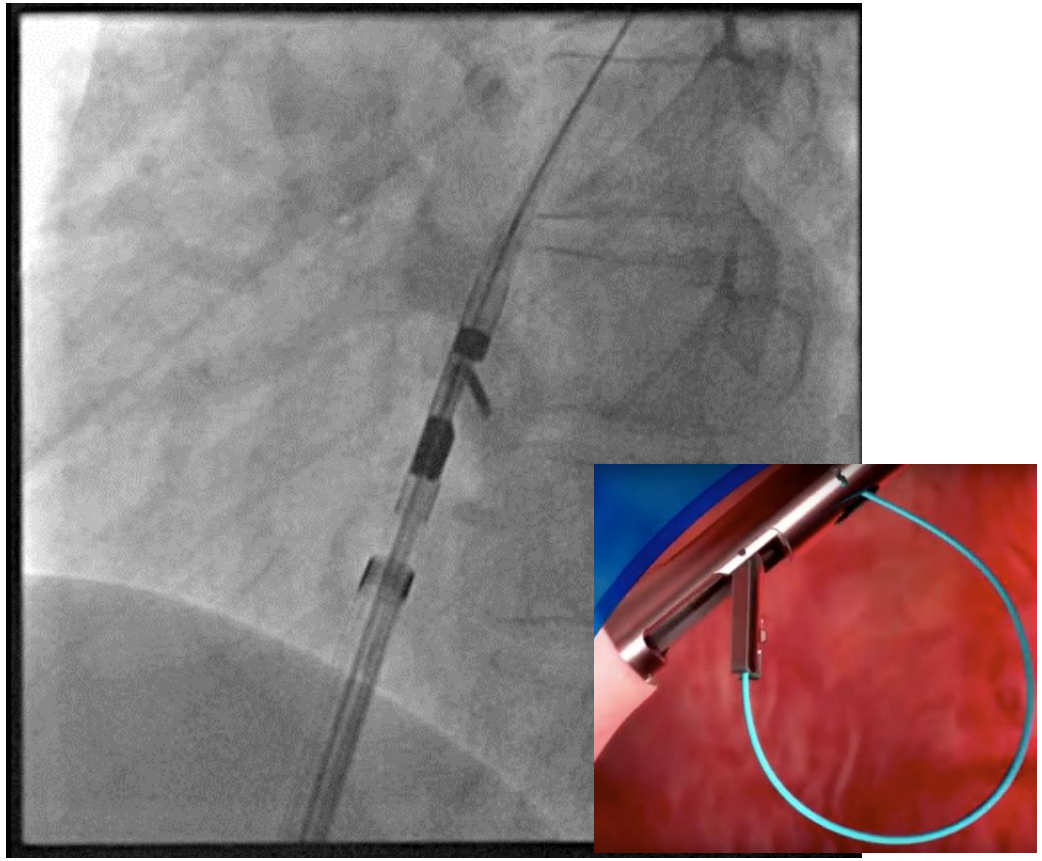


➢ Posizionamento corretto grazie alle due guide e all'introduttore

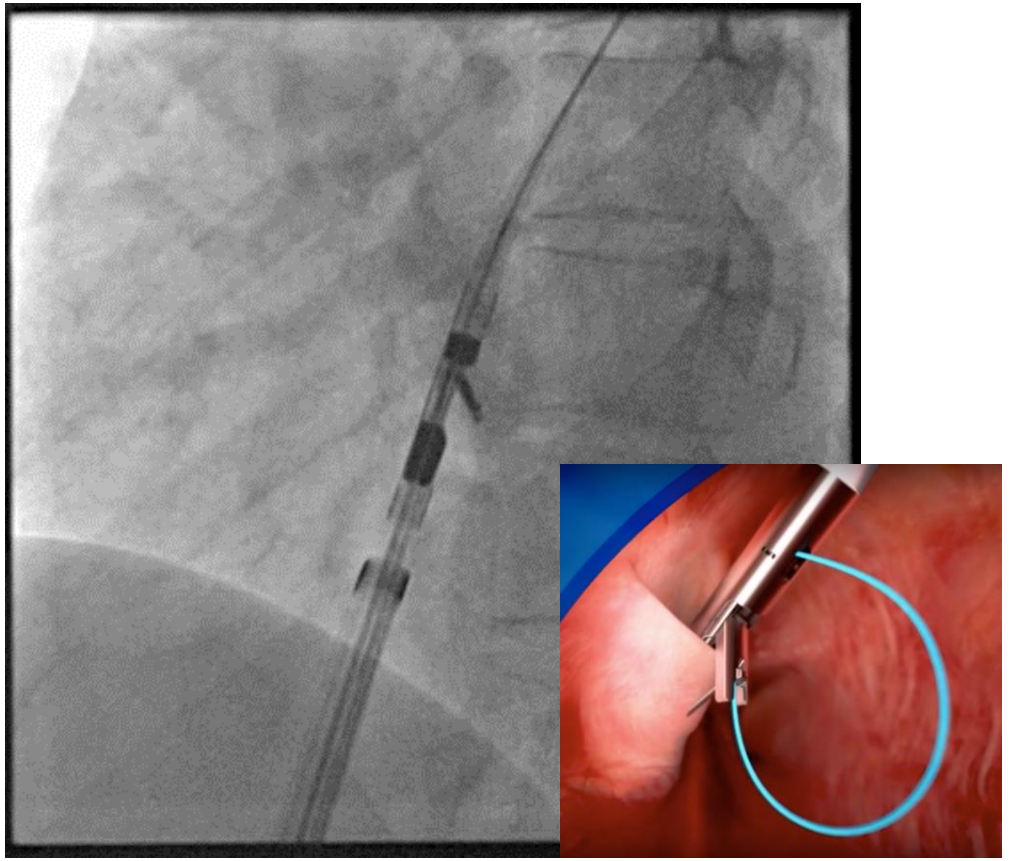


➢ L'ago cattura la sutura attraverso il septum secundum

PROCEDURA – Septum Primum



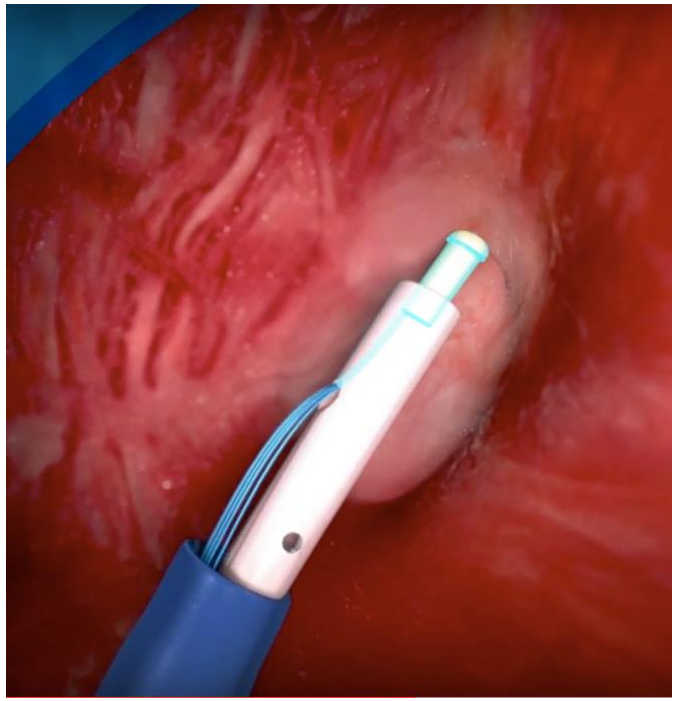
➢ Posizionamento corretto grazie ad un marker radiopaco

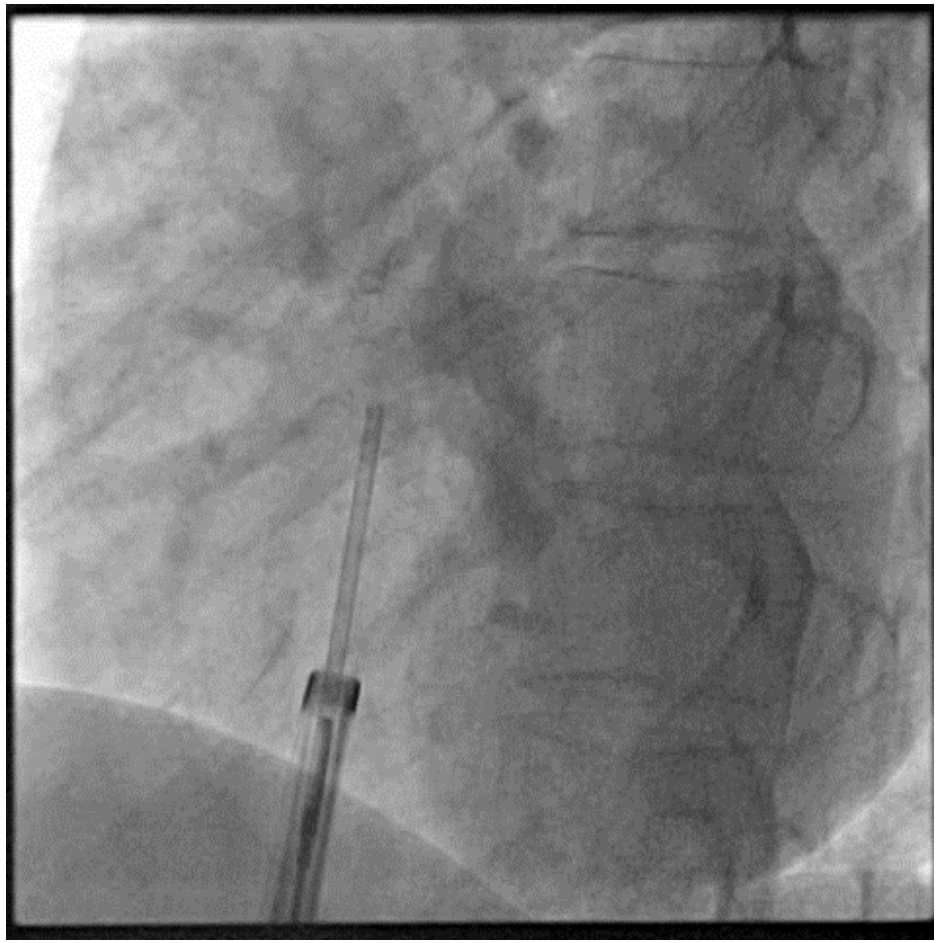


➢ L'ago cattura la sutura attraverso il septum primum

PROCEDURA - Kwiknot™

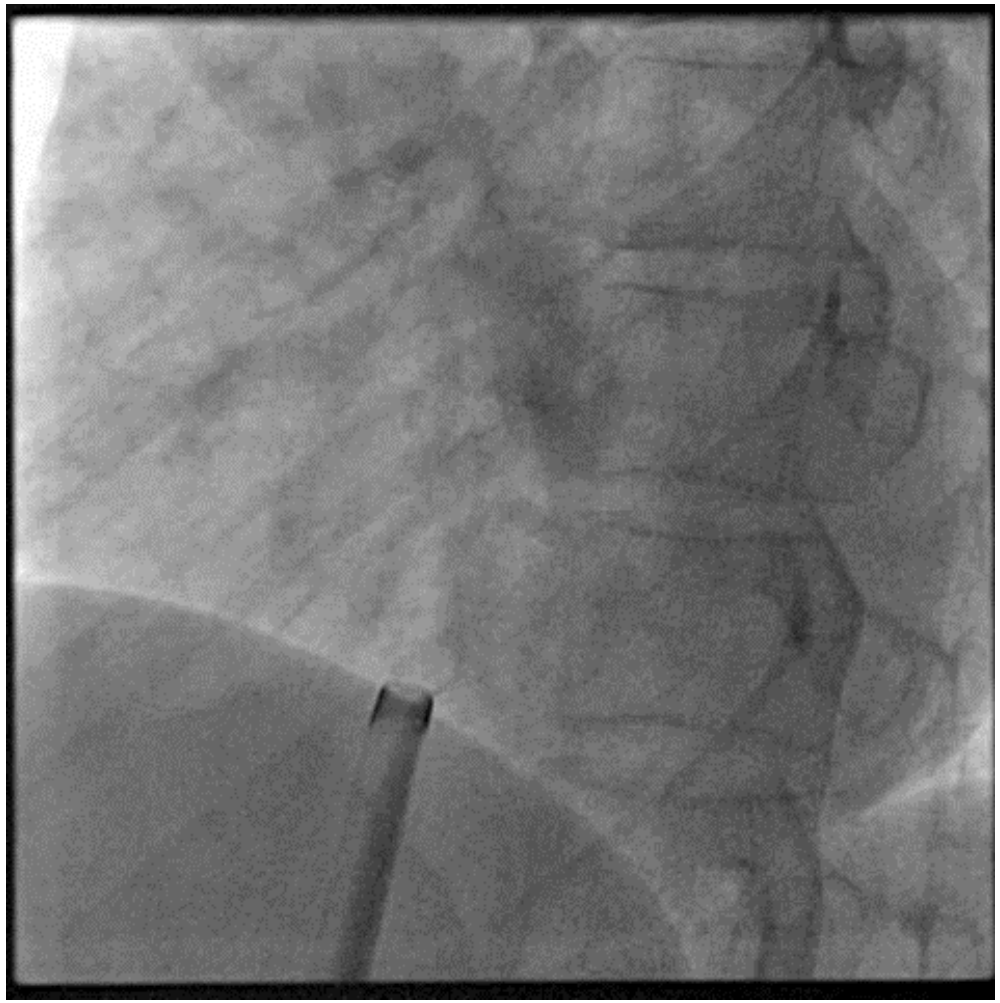
- Chiusura con dispositivo KwiKnot





PROCEDURA – ANGIO FINALE

- Risultato finale in angiografia



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PERCHÈ NOBLESTITCH?

- ✓ Nessuna protesi metallica impiantata
- ✓ Non è richiesta terapia antiaggregante o altra terapia medica
- ✓ Nessun rischio di dislocazione ed erosione
- ✓ Nessun rischio di trombosi
- ✓ Non inibisce future procedure transettali
- ✓ Non induce allergie dovute a nickel, farmaci, etc
- ✓ TEE e anestesia totale non obbligatorie

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CHI TRATTARE?

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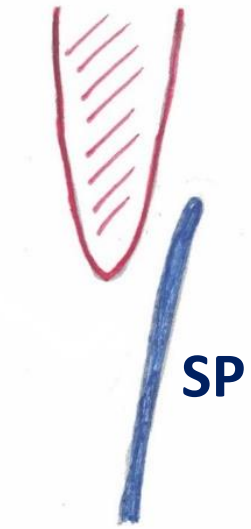
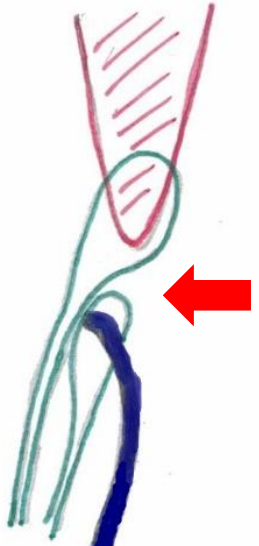
Ideal

SS

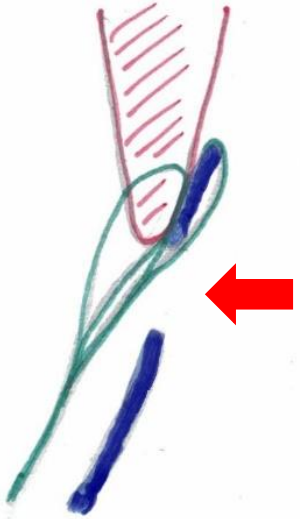
SP



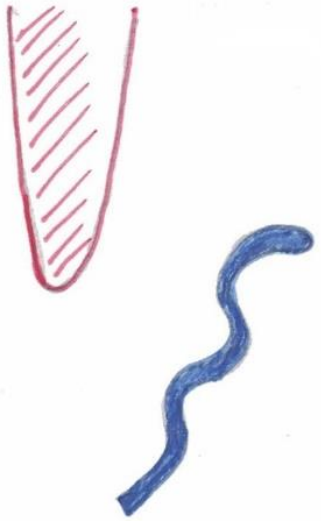
ASD PFO-type with basal L-R Shunt

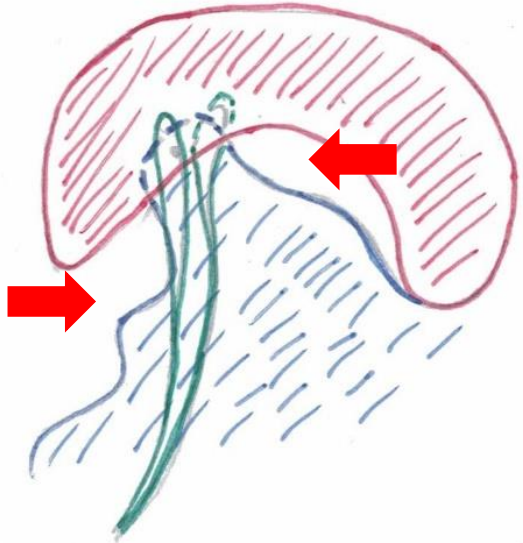


Fenestrated SP



Floppy Giant Aneurysm with basal L-R shunt





Sutures (4 wires)

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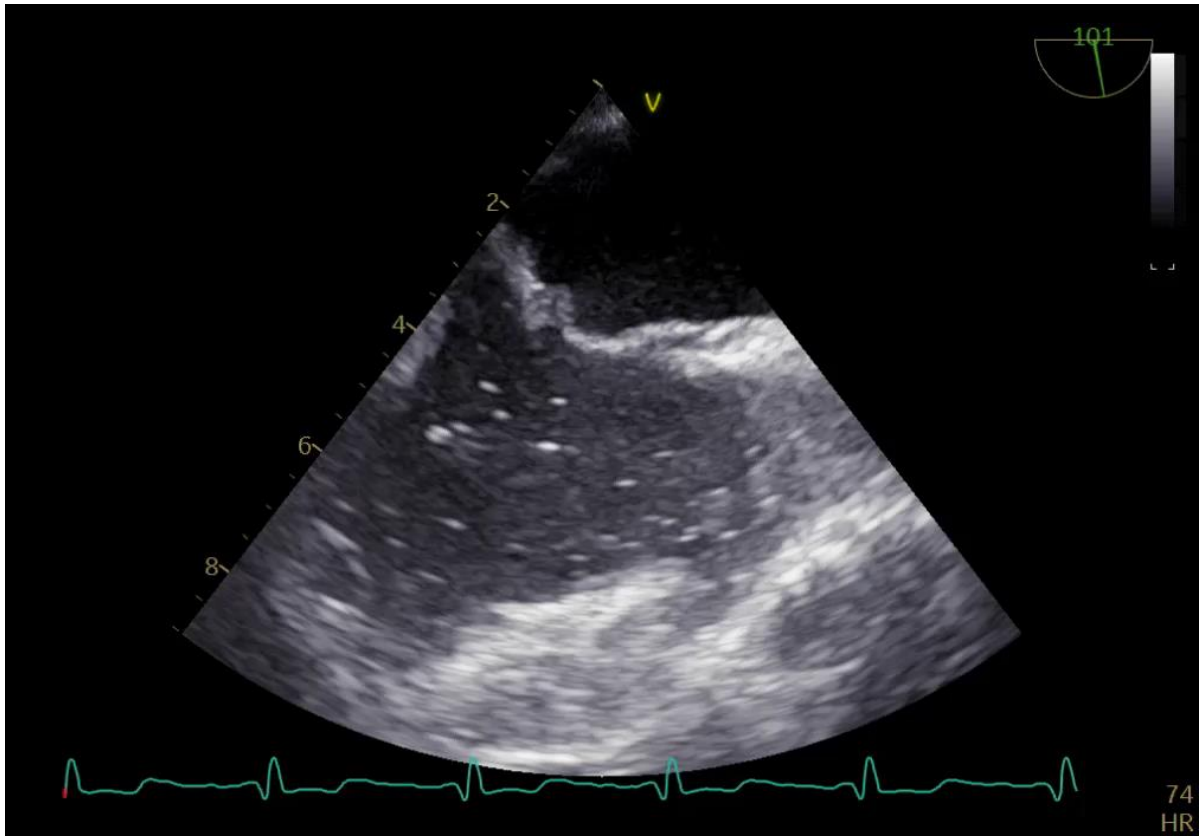
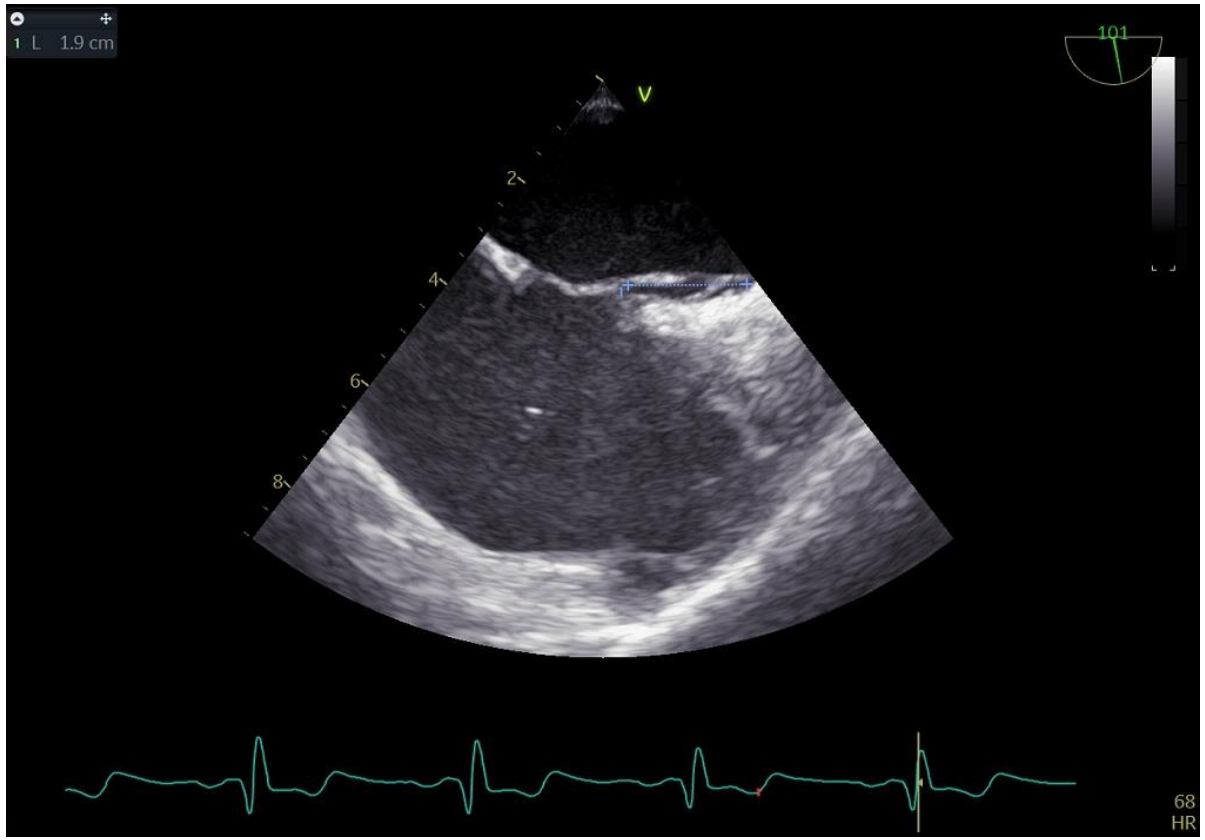
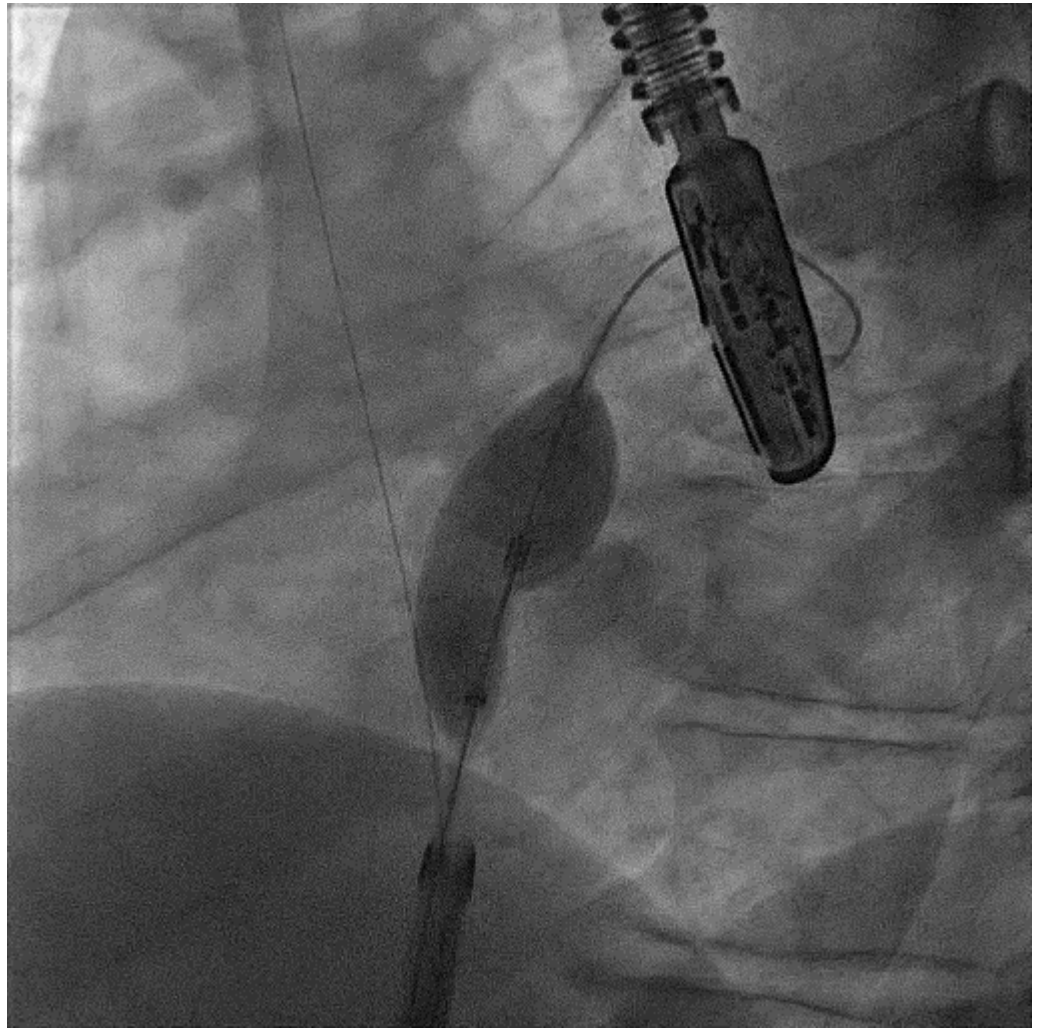
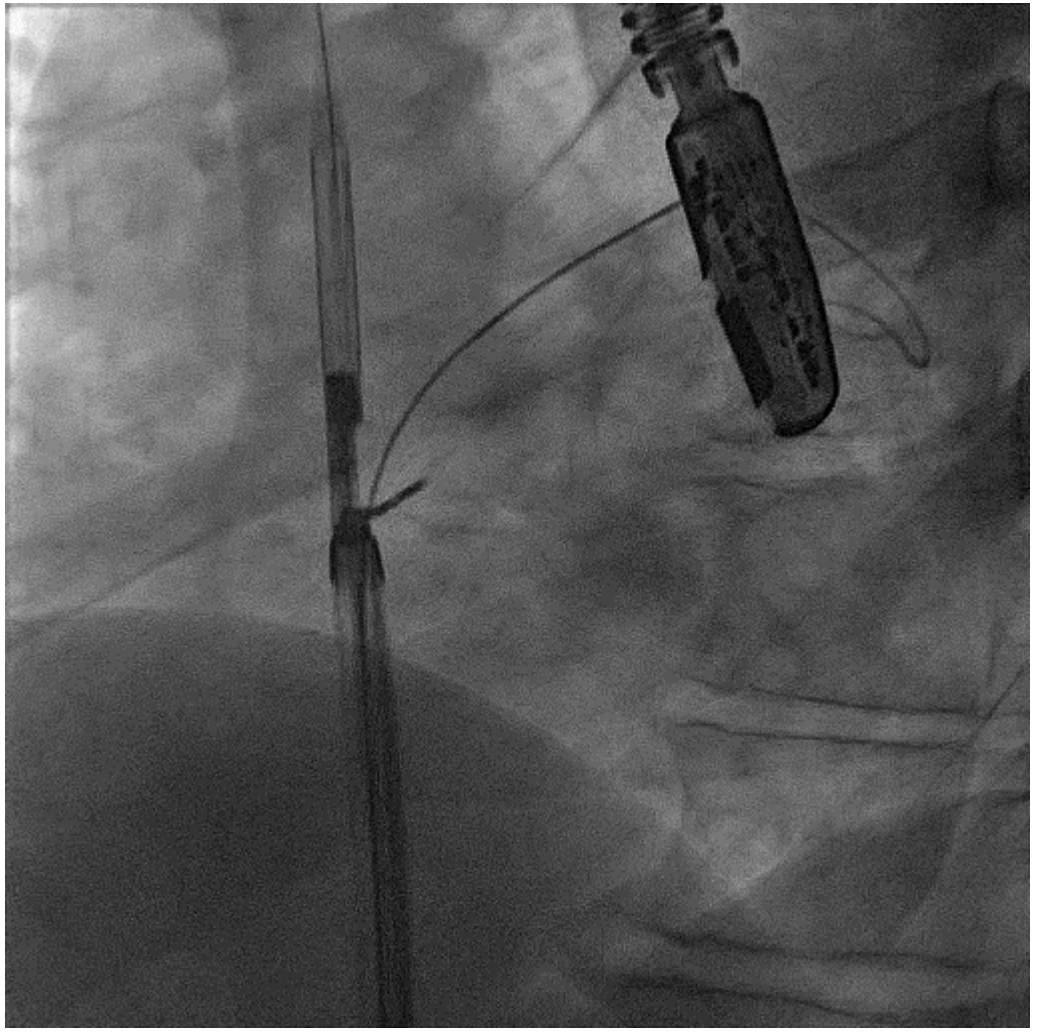
TTE pre-procedura



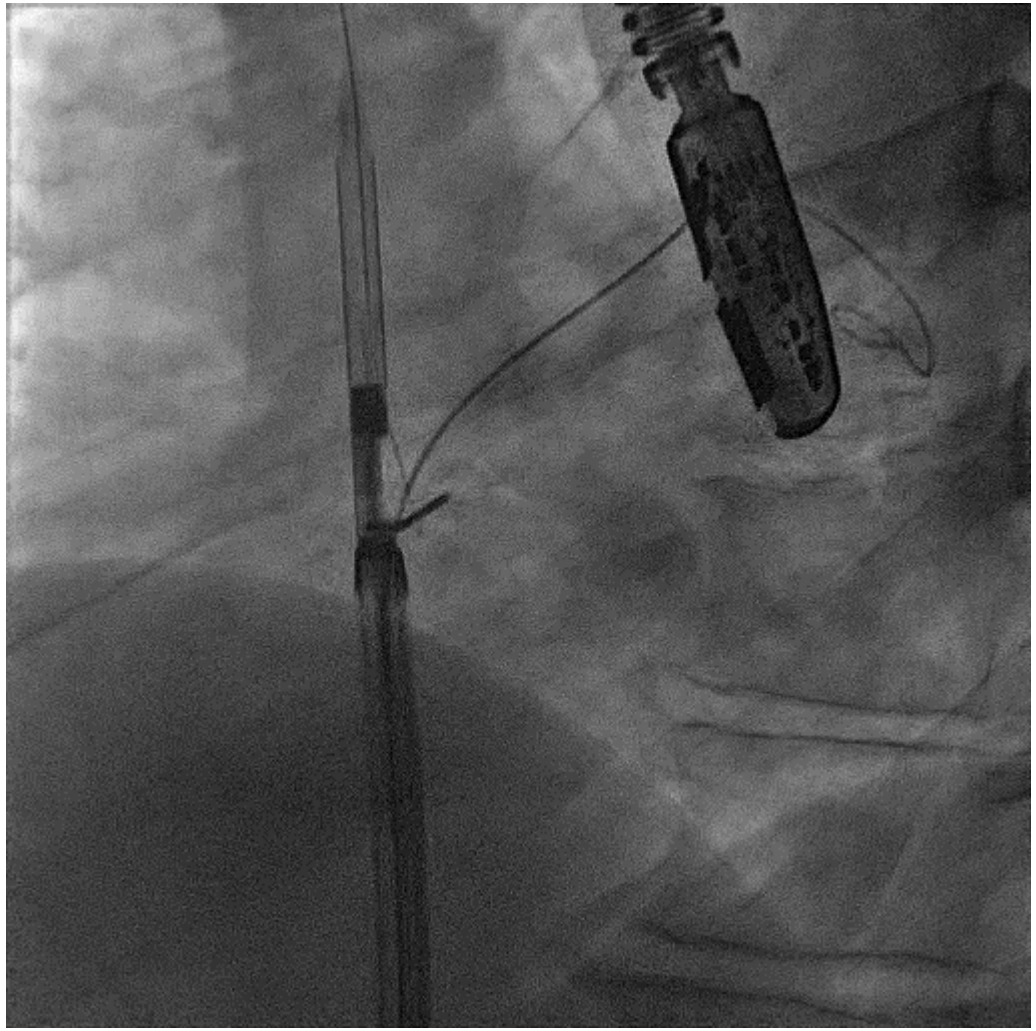


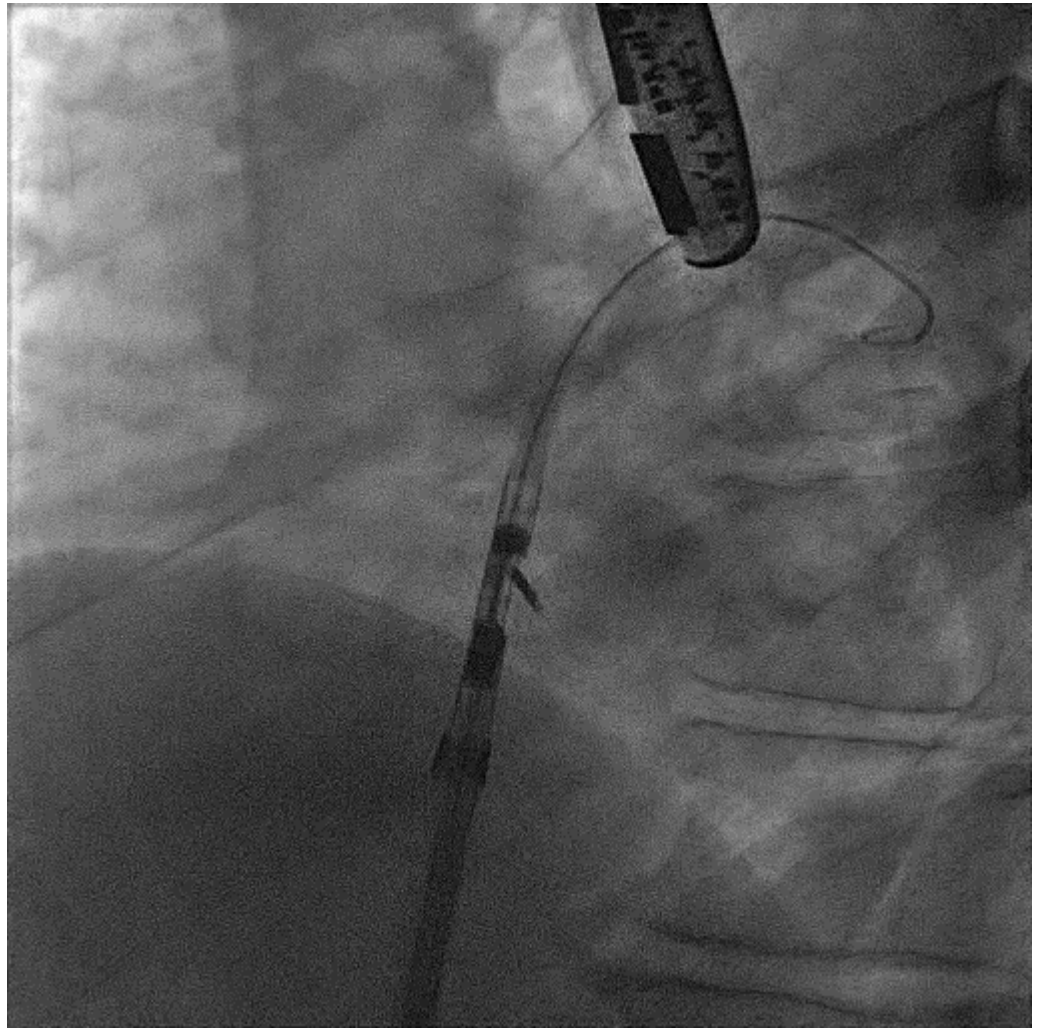
Procedura





Procedura





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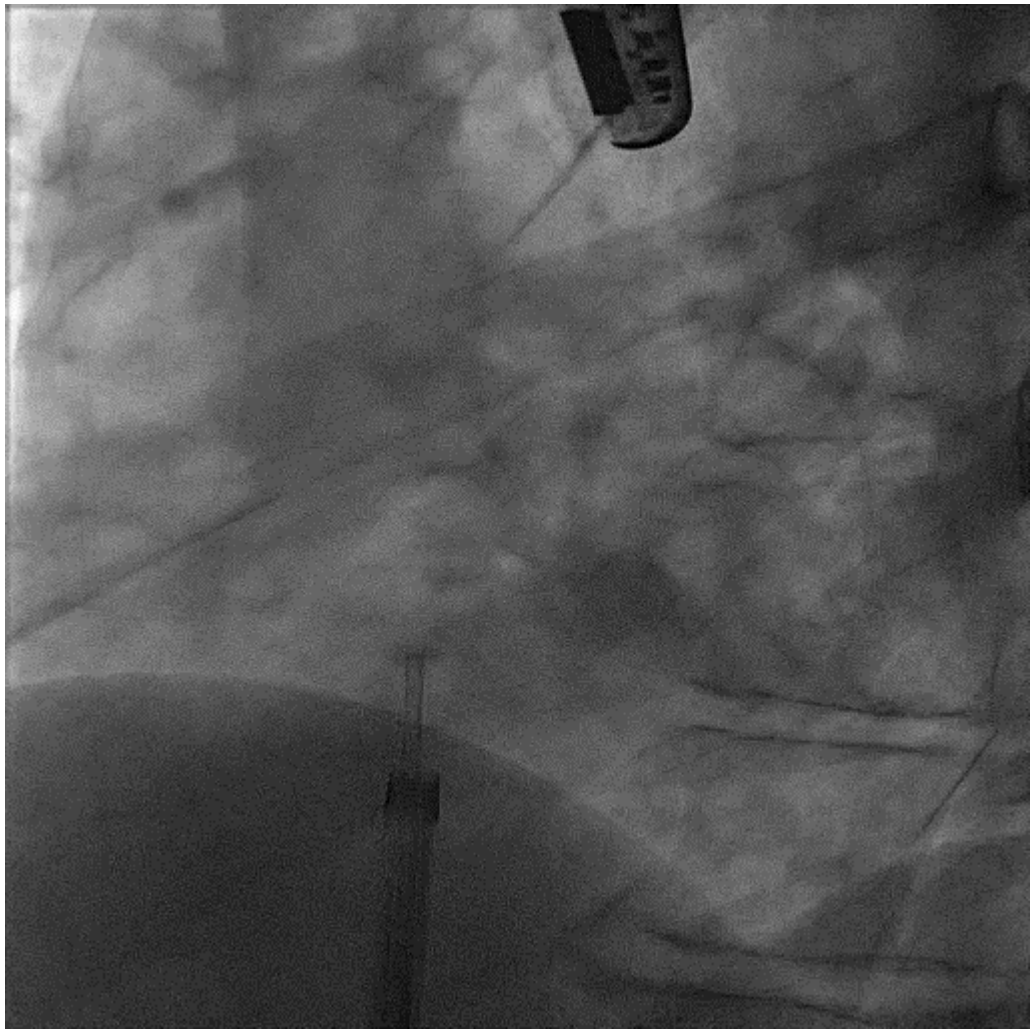
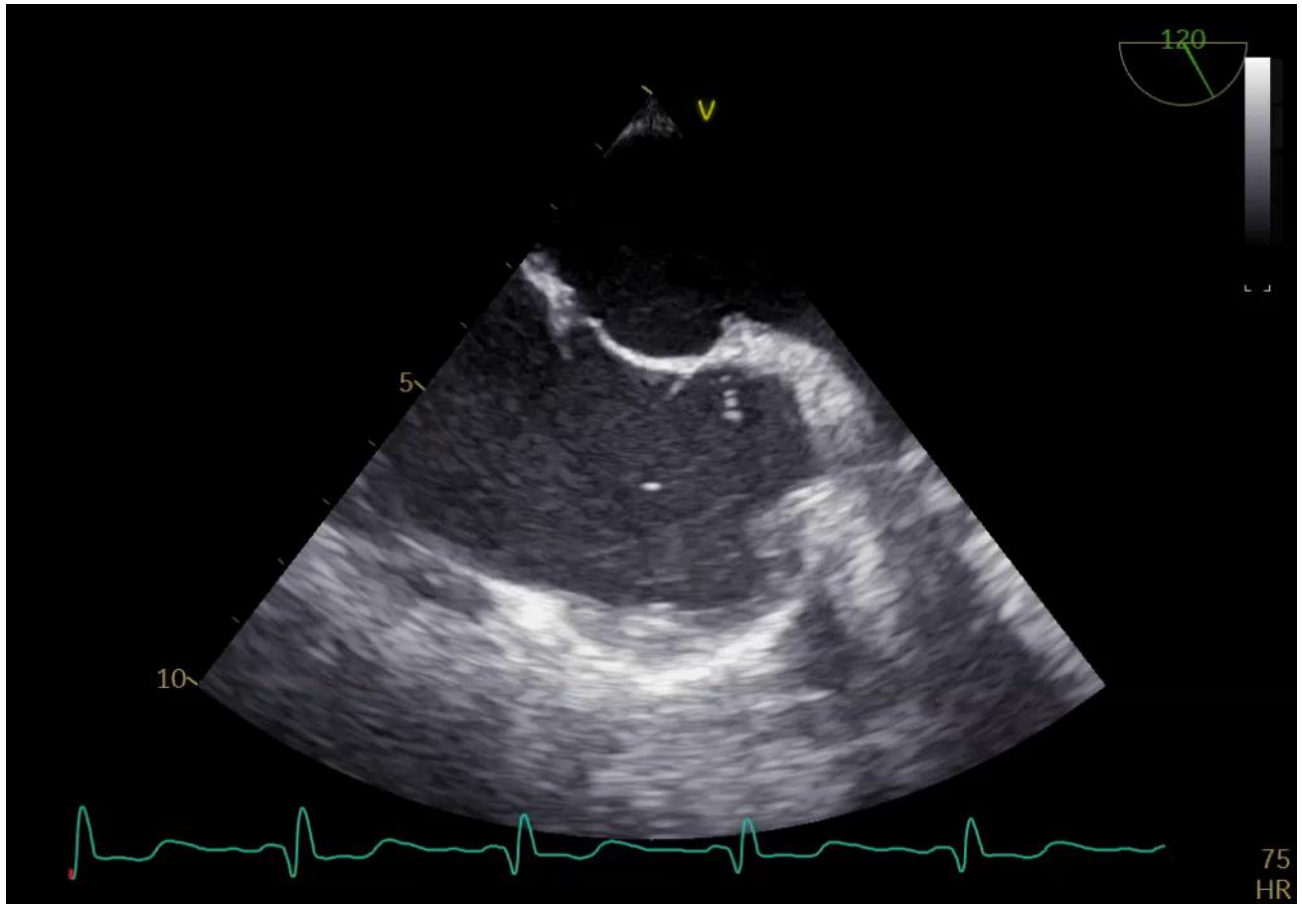
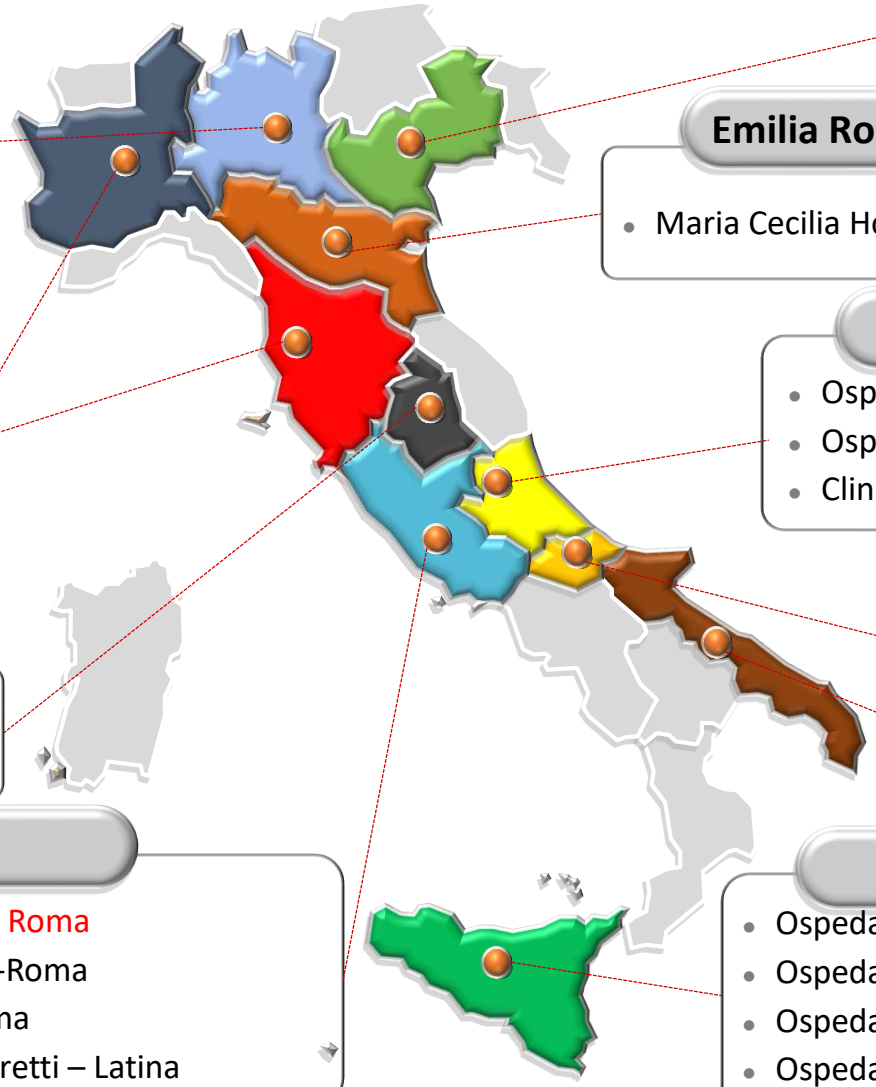




PIÙ DI 600 PAZIENTI TRATTATI



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EVIDENZE CLINICHE

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Novel percutaneous suture-mediated patent foramen ovale closure technique: early results of the NobleStitch EL Italian Registry

Achille Gaspardone[1]*, MD, MPhil; Federico De Marco[2], MD, PhD; Gregory A. Sgueglia[1], MD, PhD; Antonella De Santis[1], MD; Maria Iamele[1], MD; Emanuela D'Ascoli[1], MD; Maurizio Tusa[2], MD; Anca Irina Corciu[2], MD; Michael Mullen[3], MD, FRCP; Anthony Nobles[4], PhD; Mario Carminati[3], MD; Francesco Bedogni[2], MD

192 pazienti in 12 centri italiani

Age (years)	**44 ± 12**
Gender (F/M)	**114/78**
Baseline RTL shunt at Valsalva	
Grade 2	**53.2%**
Grade 3	**46,8%**
TEE echo guidance	**53,8%**
Fluo time (min)	**16.1 (13.0-22.5)**
Procedure time (min)	**58 (40-75)**
Radiation dose (Gy/cm²)	**87 (52-125)**
Contrast medium (ml)	**200 (150-270)**

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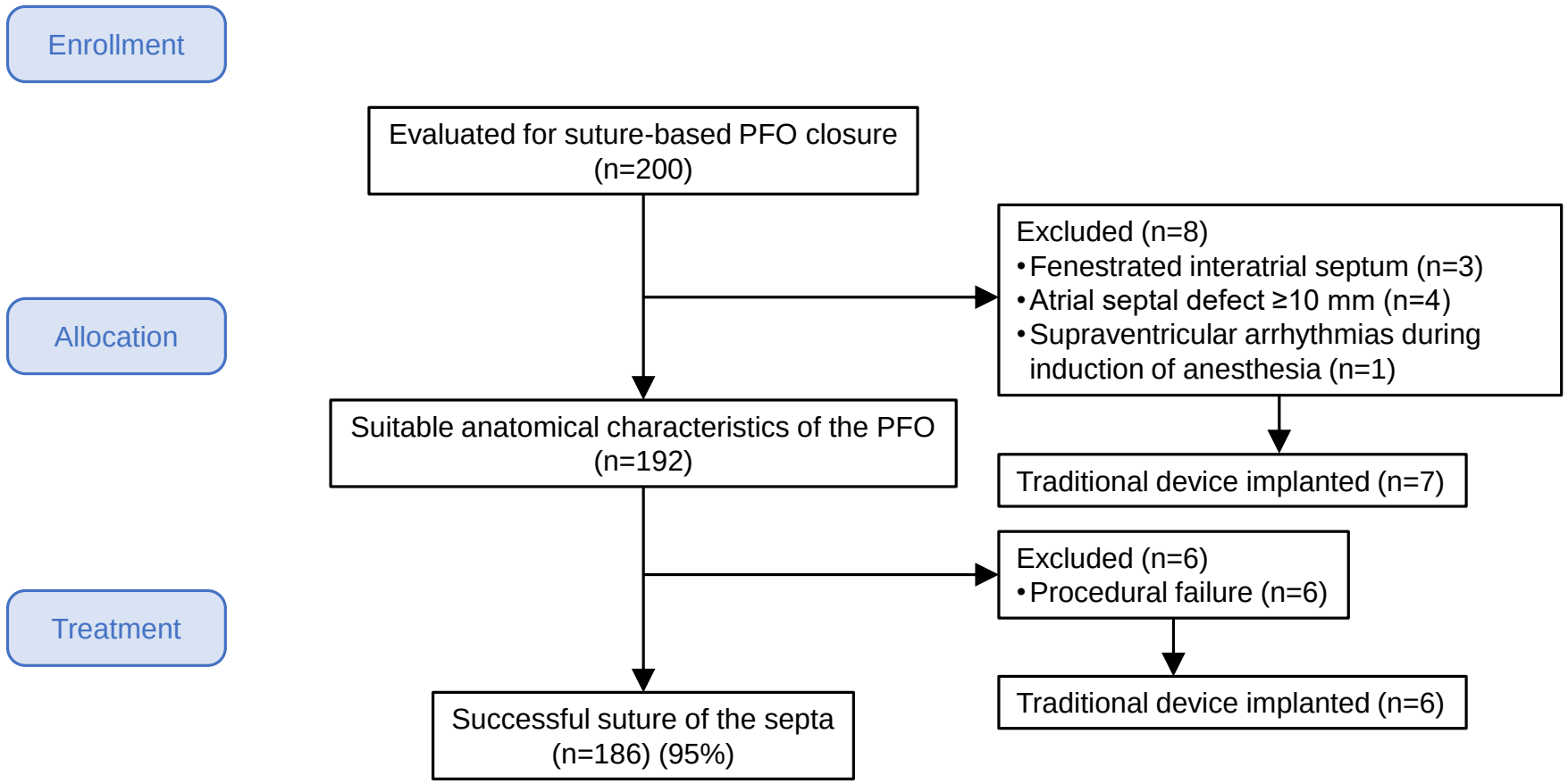
Registry Flow Chart

June 2016-October 2017



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Patient Characteristics

Table 1. General characteristics of the 192 patients submitted to suture-mediated patent foramen ovale closure.

Age (years)	44±12
Gender (F/M)	114/78
Medical history	
Stroke	108 (56.3%)
Transient ischemic attack	68 (35.4%)
Intractable migraine	10 (5.2%)
Decompression sickness	5 (2.6%)
Platypnea-orthodeoxia	1 (0.5%)
RoPE Score	7.6±1.3

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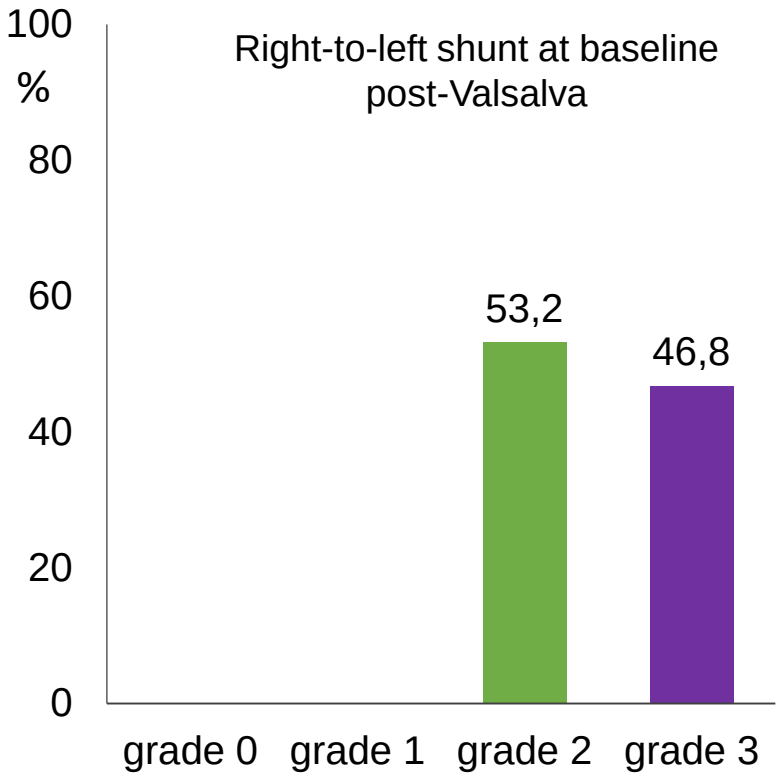
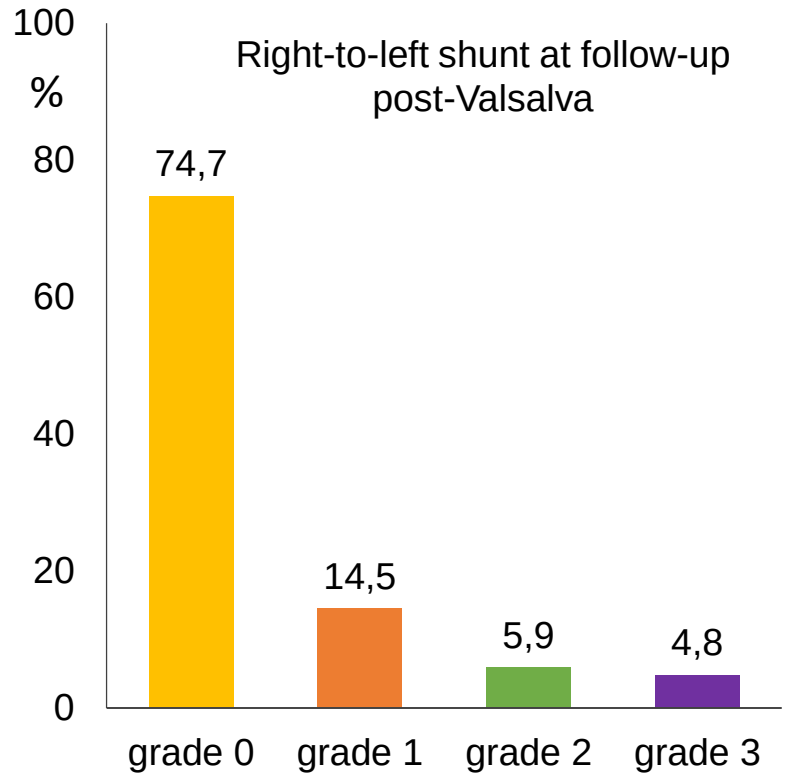
Table 2. Functional, anatomical and procedural characteristics of the 186 patients who completed the procedure.

Baseline right-to-left-shunt spontaneously	
0	53 (28.5%)
1	57 (30.6%)
2	55 (29.6%)
3	21 (11.3%)
Baseline right-to-left-shunt during Valsalva maneuver	
0	0 (0%)
1	0 (0%)
2	99 (53.2%)
3	87 (46.8%)
Patent foramen ovale diameter (mm)	6.0 (4.0-7.3)
Tunnel length (mm)	6.7 (4.1-9.0)
Atrial septum aneurysm	50 (26.9%)
Proctored procedure	125 (67.2%)
Transesophageal echocardiography guidance	100 (53.8%)
Fluoroscopy time (min)	16.1 (13.0-22.5)
Procedure time (min)	58 (40-75)
Radiation dose (Gy.cm^2)	87 (52-125)
Contrast medium (ml)	200 (150-270)

Closure Rate at last Follow Up

Mean follow up length (N=186) = 206 ± 130 days
N= 42 (22.6%) 12 month follow up ; N= 116 (63.4%) 6 months follow up





Trans thoracic echo

grade 0 = no bubbles ; grade 1 = 1-10 bubbles ; grade 2 = 11 – 20 ; grade 3 = more than 20 bubbles

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Table 3. Characteristics of the patients with and without significant right-to-left shunt at follow-up.

	RLS grade ≤1 (n=166)	RLS grade ≥2 (n=20)	p
Age (years)	44±13	43±12	0.52
Male gender	64 (38.6%)	10 (50%)	0.32
Medical history			
Stroke	92 (55.4%)	12 (60%)	
Transient ischemic attack	59 (35.5%)	8 (40%)	
Intractable migraine	10 (6%)	0 (0%)	0.74
Decompression sickness	4 (2.4%)	0 (0%)	
Platypnea-orthodeoxia	1 (0.6%)	0 (0%)	
RoPE Score	7.6±1.3	7.5±1.6	0.84
Baseline RLS during Valsalva maneuver			
2	94 (56.6%)	7 (35%)	0.11
3	72 (43.4%)	13 (65%)	
Patent foramen ovale diameter (mm)	5.5 (4.0-7.0)	6.7 (6.0-8.0)	0.14
Tunnel length (mm)	7.0 (4.0-9.0)	6.0 (4.3-10.0)	0.91
Atrial septum aneurysm	43 (25.9%)	7 (35%)	0.39
Proctored procedure	114 (68.7%)	11 (55%)	0.22
Transesophageal echocardiography guidance	84 (50.6%)	13 (65%)	0.22
Fluoroscopy time (min)	16.1 (12.9-22.2)	18.7 (14.0-25.2)	0.30
Procedure time (min)	55 (40-73)	65 (51-82)	0.22
Radiation dose (Gy.cm^2)	87 (52-119)	90 (53-168)	0.40
Contrast medium (ml)	200 (150-270)	230 (200-365)	0.66

RLS = right-to-left shunt

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Safety

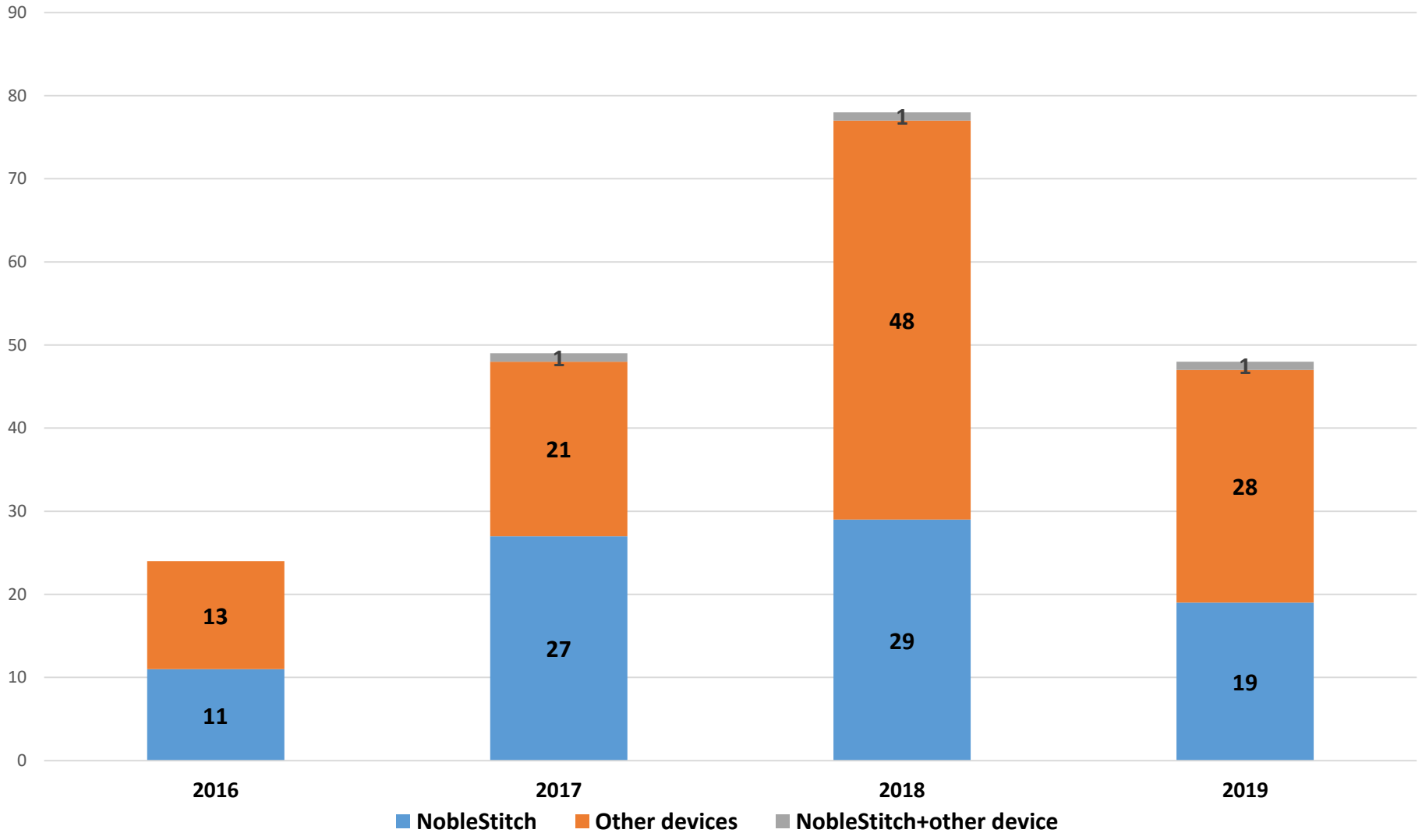
- No device related complications
- No clinical arrhythmia at follow-up
- No recurrent neurologic events

PSD experience

	Total population (n = 196 pts)	NobleStitch (n= 86 pts; 43.8 %)	Other devices (n= 110 pts; 56.2%)
Mean age (yrs)	48± 12	48± 11	49± 12
Female gender (%)	92 (46.7%)	41 (47.7%)	51(46.3%)
Main indications to PFO closure			
Transient ischemic attack (%)	85 (43.3%)	39 (46%)	46 (41.8%)
Cryptogenic stroke (%)	65 (33.1%)	22 (26.4%)	43(38.9%)
Decompression sickness (%)	16 (8.2 %)	10 (11.8%)	6 (5.4%)
Disabling migraine (%)	27 (14 %)	13 (14.5%)	14 (15.4%)
Other indications (%)*	3 (1.5%)	1 (1.1%)	2 (1.8%)

* 1 acute myocardial infarction due to paradoxical embolism, 1 before bariatric surgery, 1 before neurological surgery

PSD experience- temporal distribution of all procedures



+3 REDO for significant residual shunt at FU

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Aim of the study

To compare the feasibility, safety and efficacy of percutaneous PFO closure using two different techniques, the NobleStitch EL system and traditional devices (Amplatzer, GORE).

FEASIBILITY AND SAFETY/EFFICACY PROFILE OF THE PERCUTANEOUS PATENT FORAMEN CLOSURE: NOBLESTITCH EL VS. OTHER DEVICES

Intra-procedural data

	Group A (n= 63 pts)	Group B (n=84 pts)
	Noble Stich	Other devices
Successful closure system deployment	37 (100%)	40 (100%)
Major complications	0	0
Minor complications	2*	1**
End procedure residual shunt		
grade ≤1	10 (15.8%)	12 (14.2%)
grade>2	1 (1.58%) ***	

* 1 acute atrial fibrillation onset during induction of anesthesia, 1 groin hematoma
** 1 groin hematoma

*** underwent PFO closure with device in the same procedure

FEASIBILITY AND SAFETY/EFFICACY PROFILE OF THE PERCUTANEOUS PATENT FORAMEN CLOSURE: NOBLESTITCH EL VS. OTHER DEVICES

	Group A (NobleStitch), n= 62 pts	Group B (other devices), n= 84 pts
FU period (days)	191±131	189± 141
RLS grade ≤1	60 pts (96,7%)	84 pts (100%)

	Group A (NobleStitch), n= 62 pts	Group B (other devices), n= 84 pts
RLS ≥2	2 pts *	0 pts
Device-related complications	1 stroke in the first post-operative day	1 symptomatic thrombosis of the device at 60 days FU

* the patients underwent the second procedure with device implantation

Conclusions

Percutaneous PFO closure with NobleStitch EL in favorable atrial septal anatomies is an effective closure, with excellent safety profile at medium term follow-up when compared to traditional devices.