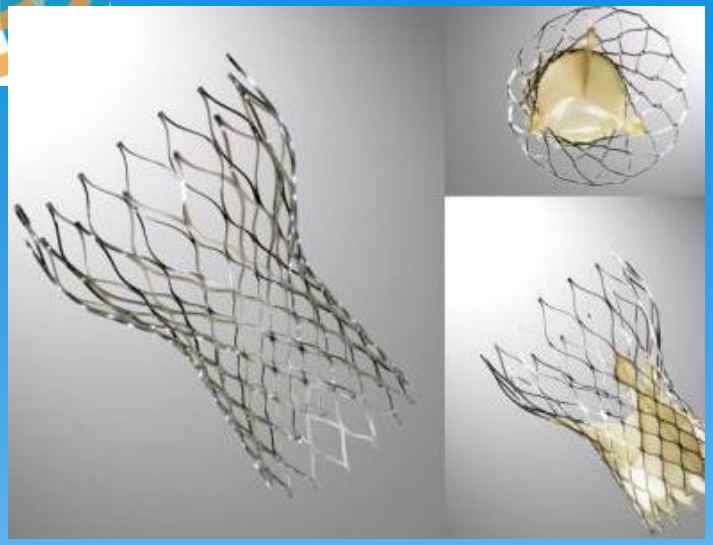
ECOCARDIOCHIRURGIA®
ECO-RM-TC
CHIRURGIA-INTERVENTISTICA

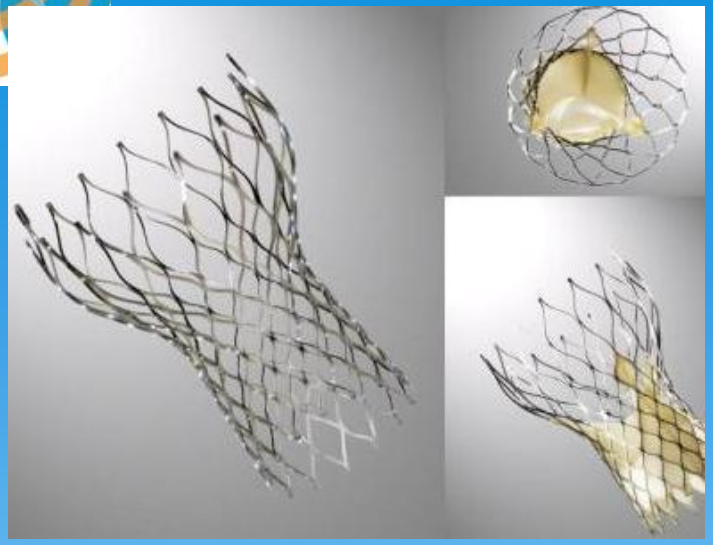
TRA COMPLICANZE PUBBLICATE ED ANEDDÒTICHE:

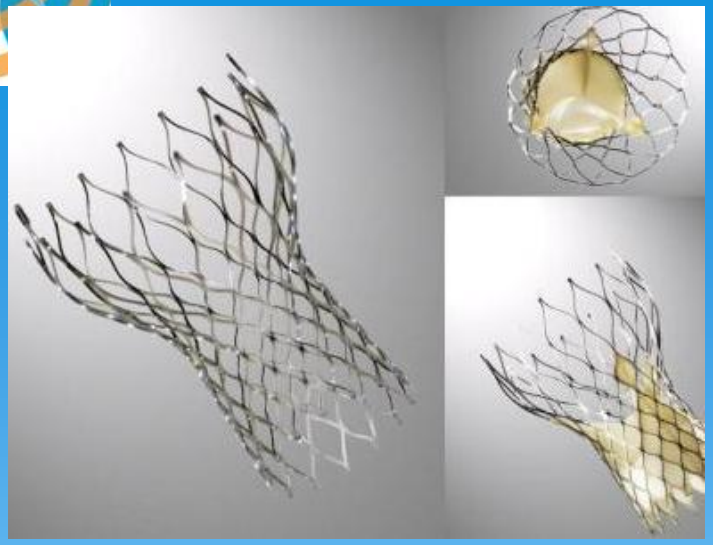
Quali veri rischi si celano dietro ad una procedura "semi-invasiva"

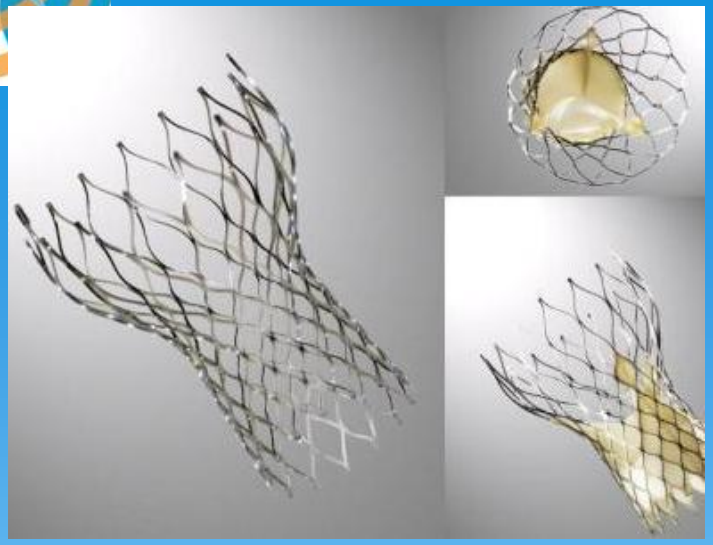
Paolo Danna, Milano

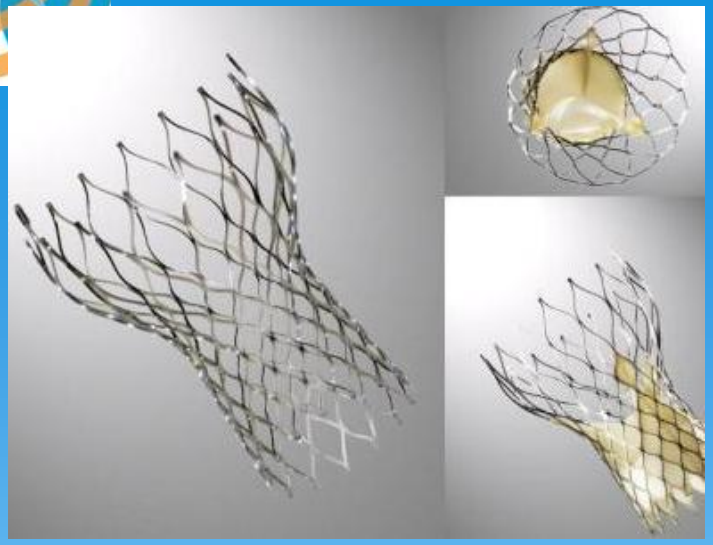
9 aprile 2015

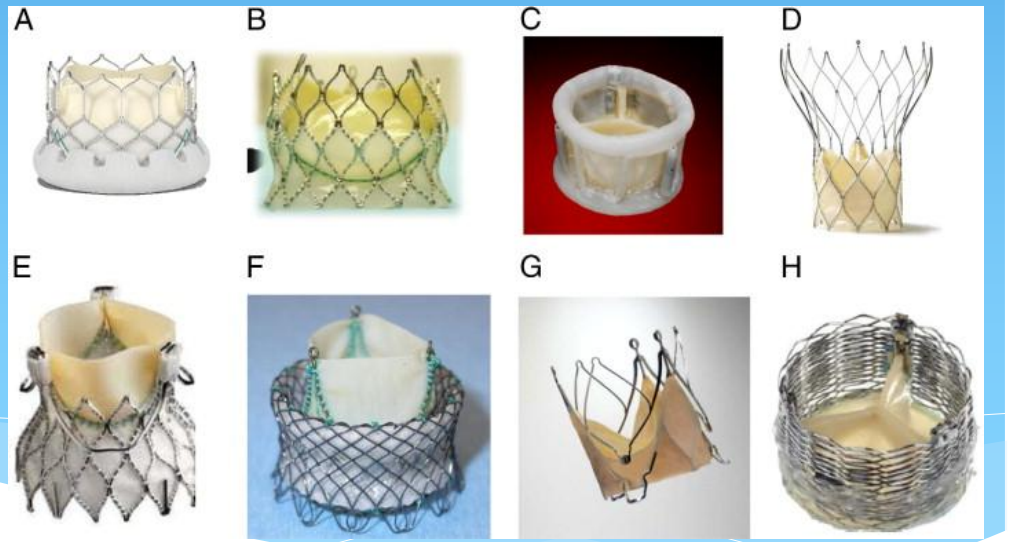











A
B
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D
E
F
G
H

The German Aortic Valve Registry (GARY): in-hospital outcome

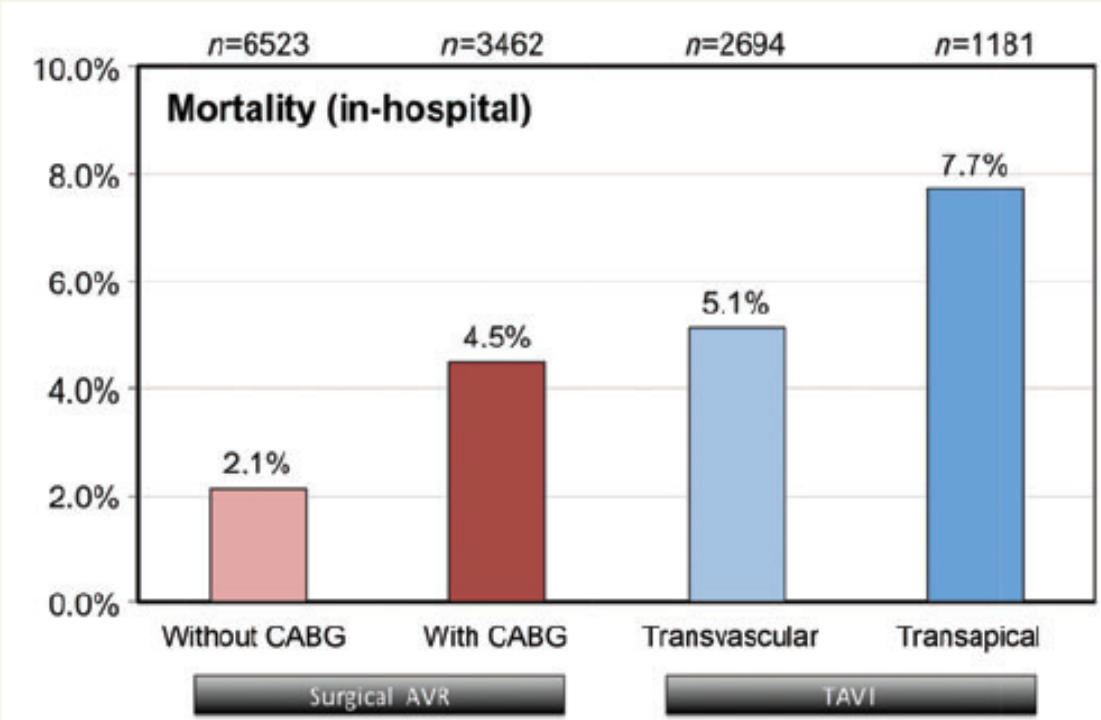

Figure 2 In-hospital outcome.

9985
SAVI

3875
TAVI

The German Aortic Valve Registry (GARY): in-hospital outcome

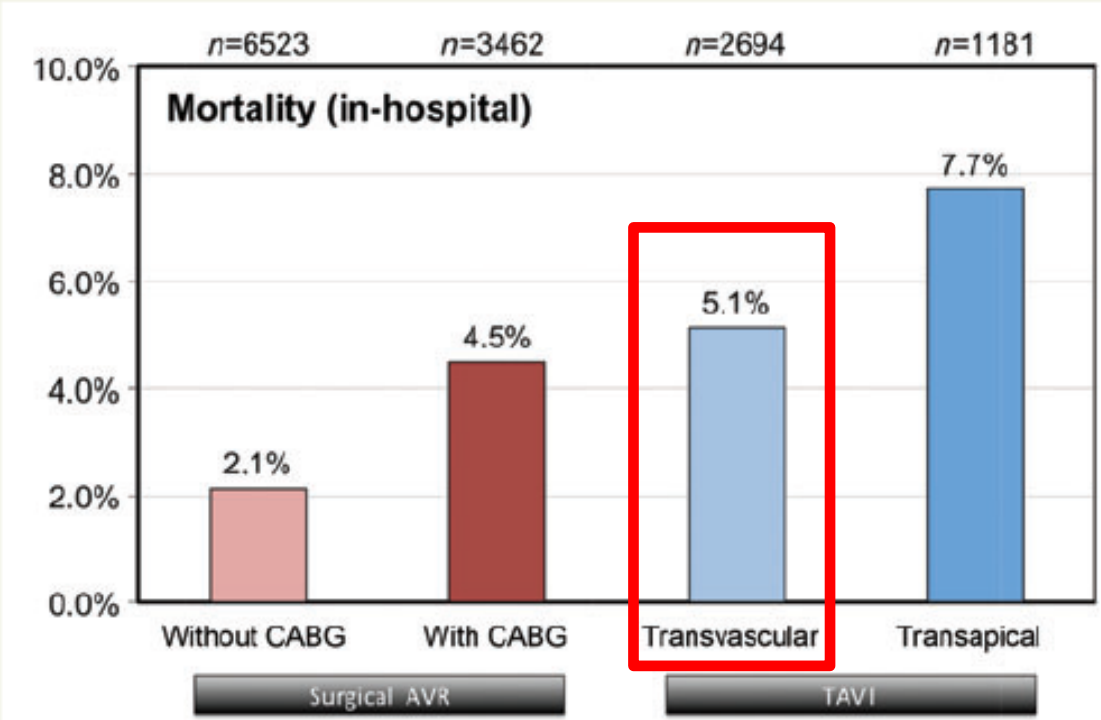

Figure 2 In-hospital outcome.

9987
SAVI

3876
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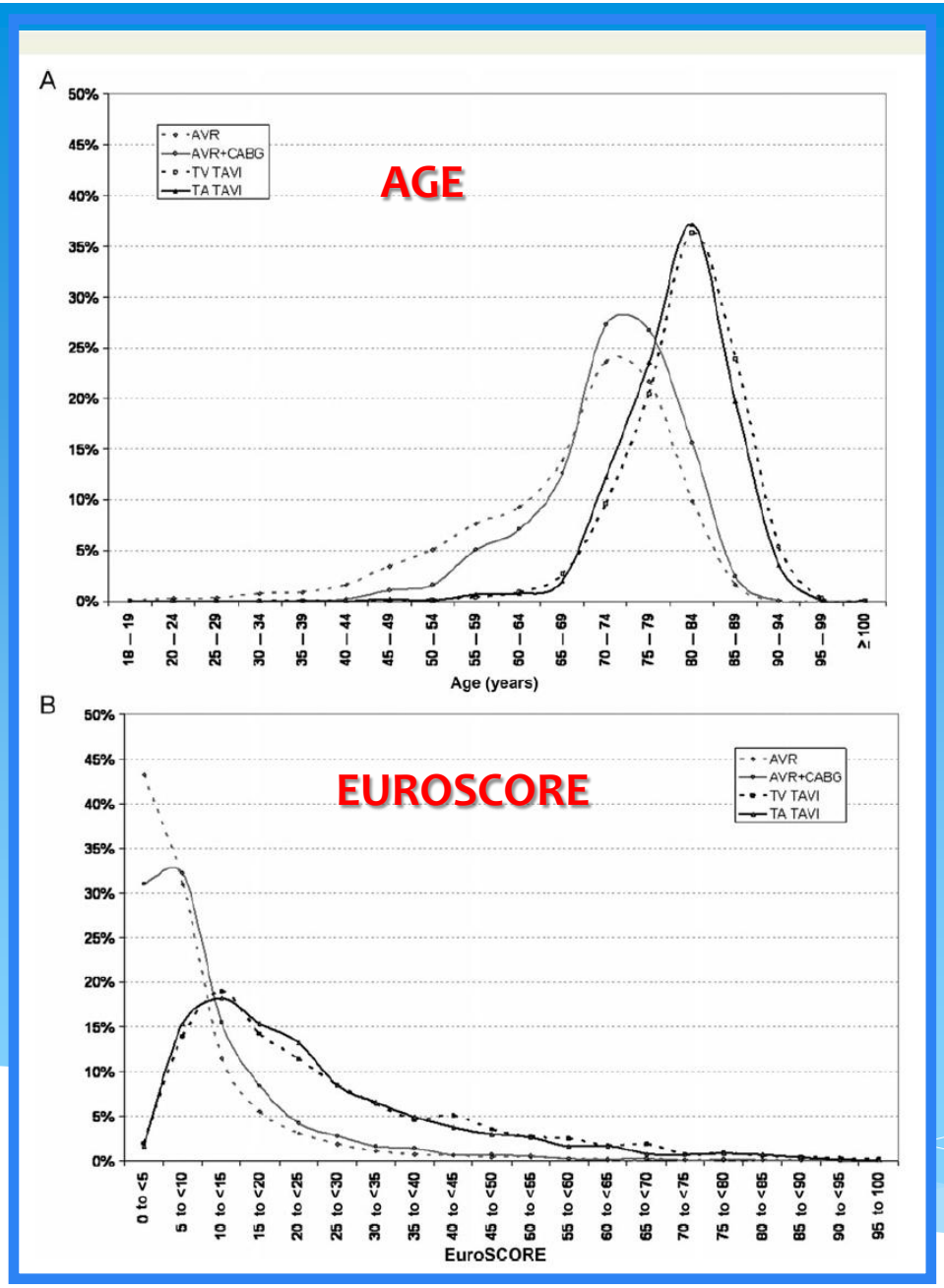
A
AGE
AVR
AVR+CABG
TV TAVI
TA TAVI
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
18 — 19
20 — 24
25 — 29
30 — 34
35 — 39
40 — 44
45 — 49
50 — 54
55 — 59
60 — 64
65 — 69
70 — 74
75 — 79
80 — 84
85 — 89
90 — 94
95 — 99
≥ 100
Age (years)
B
EUROSCORE
AVR
AVR+CABG
TV TAVI
TA TAVI
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
0 to <5
5 to <10
10 to <15
15 to <20
20 to <25
25 to <30
30 to <35
35 to <40
40 to <45
45 to <50
50 to <55
55 to <60
60 to <65
65 to <70
70 to <75
75 to <80
80 to <85
85 to <90
90 to <95
95 to 100
EuroSCORE

ANCHE NELLE MIGLIORI CONDIZIONI, LA TAVI E' UNO DEGLI INTERVENTI CON MORTALITA' PERIPROCEDURALE PIU' ELEVATA FRA QUELLI CHE SI EFFETTUANO IN UN LABORATORIO DI EMODINAMICA

Box 1 Composite endpoints according to Valve Academic Research Consortium-2 (VARC-2)[2]

Device success

- Absence of procedural mortality AND
- Correct positioning of a single prosthetic heart valve into proper anatomical location AND
- Intended performance of the prosthetic heart valve (no prosthesis–patient mismatch and mean aortic valve gradient <20 mm Hg or peak velocity <3 m/s) AND
- No moderate or severe prosthetic valve regurgitation

Early safety (at 30 days)

- All cause mortality
- All strokes (disabling and non-disabling)
- Life threatening bleeding
- Acute kidney injury (stage 2 or 3, including renal replacement therapy)
- Coronary artery obstruction requiring intervention
- Major vascular complication
- Valve related dysfunction requiring repeat procedure (balloon valvuloplasty, transcatheter aortic valve implantation (TAVI), or surgical aortic valve replacement)

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COMPLICANZE DELLA TAVI

Complicanze legate all'accesso (vascolare, trans-apicale)

Tamponamento cardiaco

Rottura della radice aortica

Ostruzione coronarica

Insufficienza aortica residua

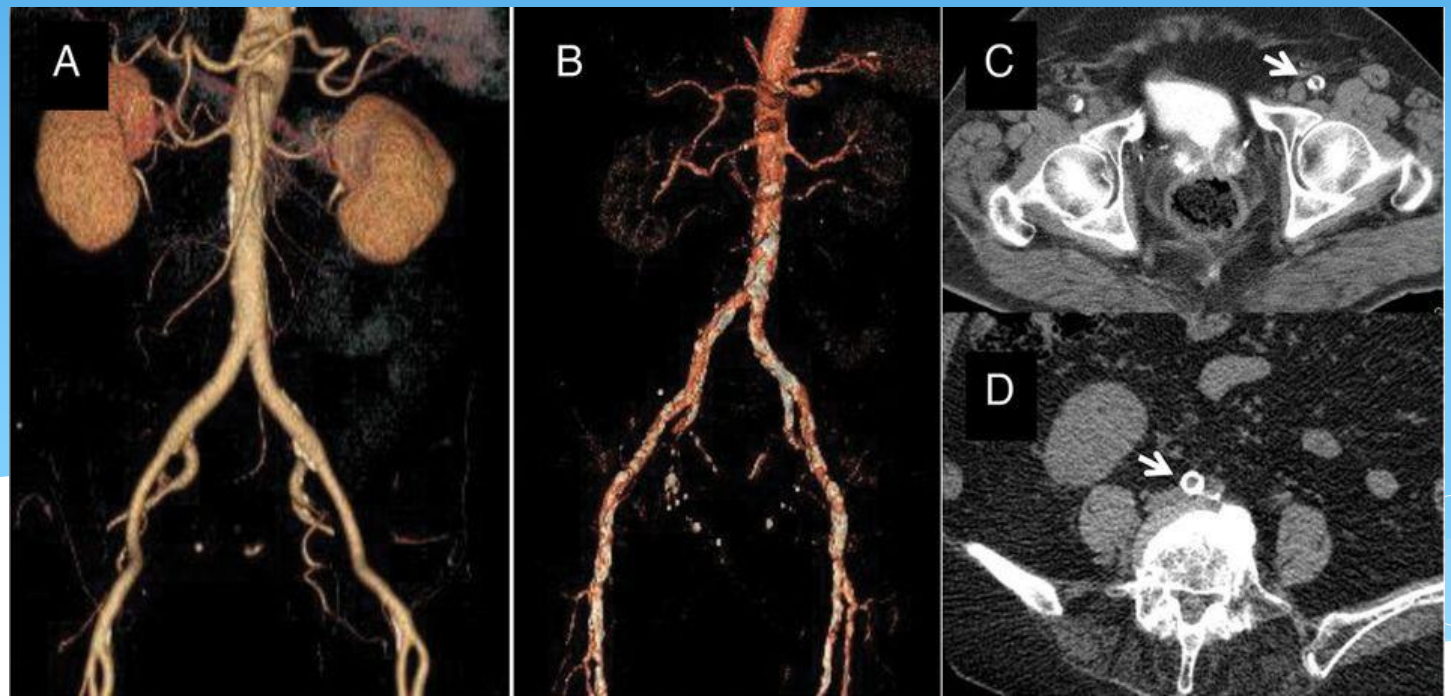
Necessità di un pacemaker permanente

Insufficienza renale

Eventi cerebrovascolari

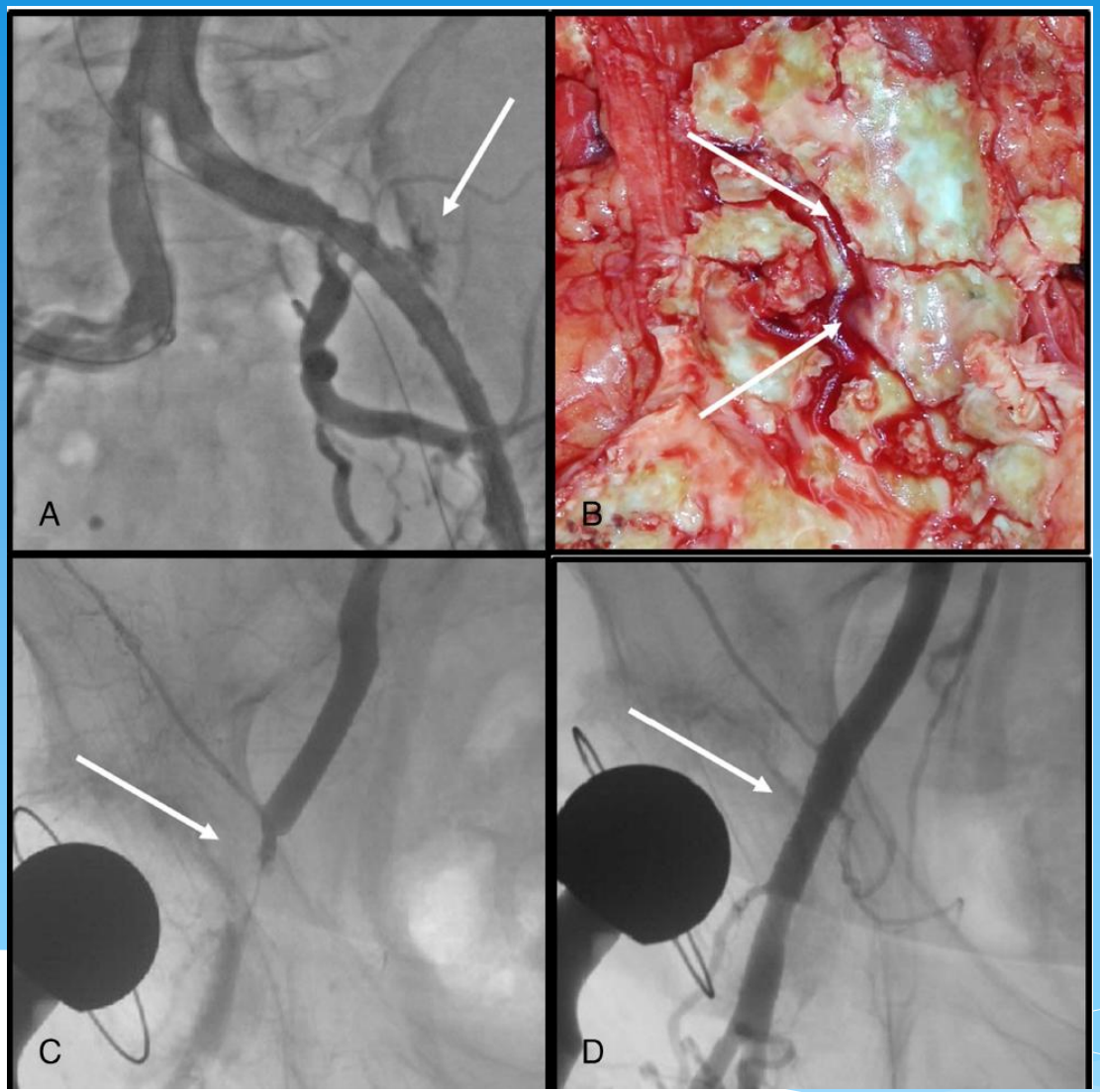
COMPLICANZE LEGATE ALL'ACCESSO

Complicanze Vascolari: 16% di tutte le procedure. Come evitarle? Non ostinarsi a voler escludere in tutti i pazienti un accesso chirurgico minimale; accessi «alternativi» rispetto a quello femorale.



ESSENZIALE LA COLLABORAZIONE CON RADIOLOGI SENZIBILIZZATI, INTERESSATI E COINVOLTI NELLA PIANIFICAZIONE DELLE PROCEDURE

Rottura o dissezione occlusiva



L'importante è mantenere l'accesso!

TAMPONAMENTO CARDIACO

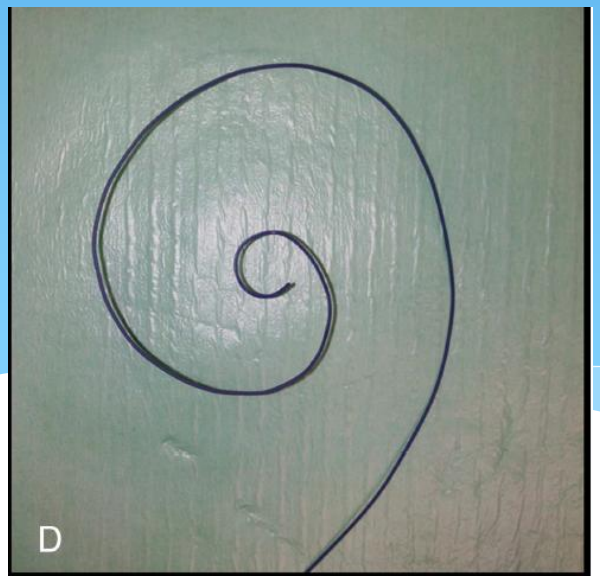
Si verifica da 0.2 a 4.3% delle procedure. Meccanismi:

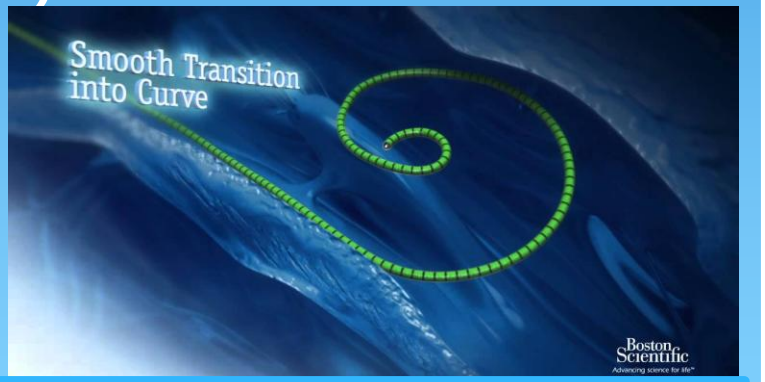
1) Filoguida «stiff» nel ventricolo sinistro
2) Catetere stimolatore in ventricolo destro
3) Rottura «libera» della radice aortica con fistola aorto-pericardica

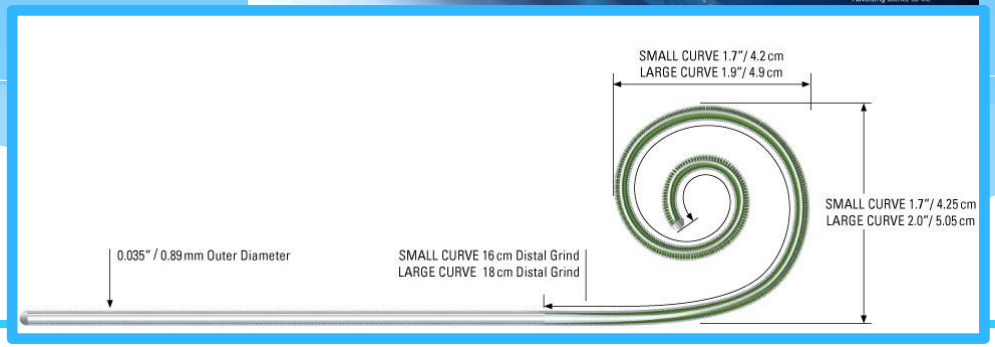
FILOGUIDA «STIFF» NEL VS

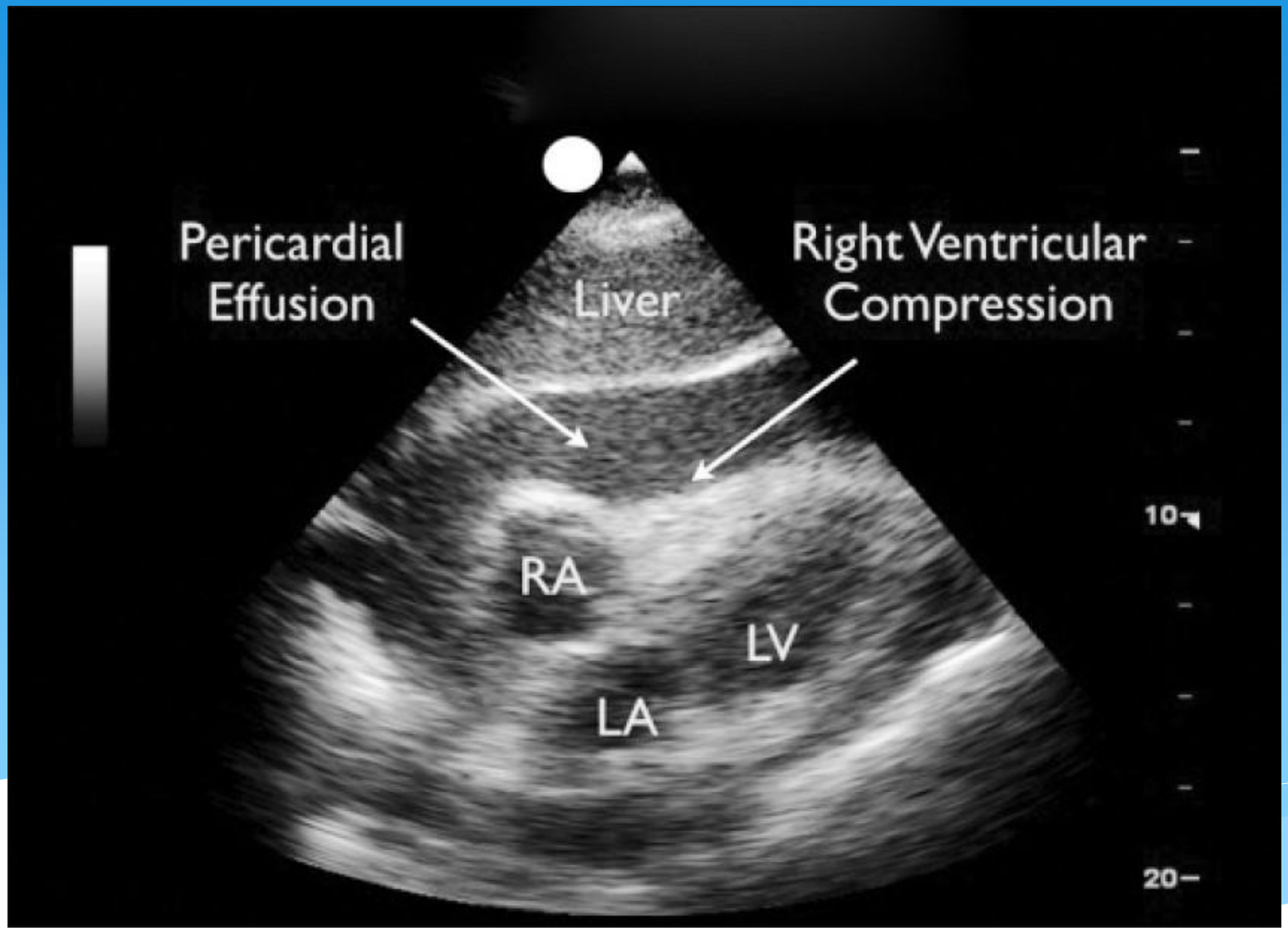
Necessario per permettere il transito della valvola protesica fino all'aorta ascendente ed il passaggio della stessa attraverso la valvola nativa stenotica e calcifica.

1) Tecnica per il posizionamento del filoguida in VSx
2) Uso di filiguida dedicati (Safari)







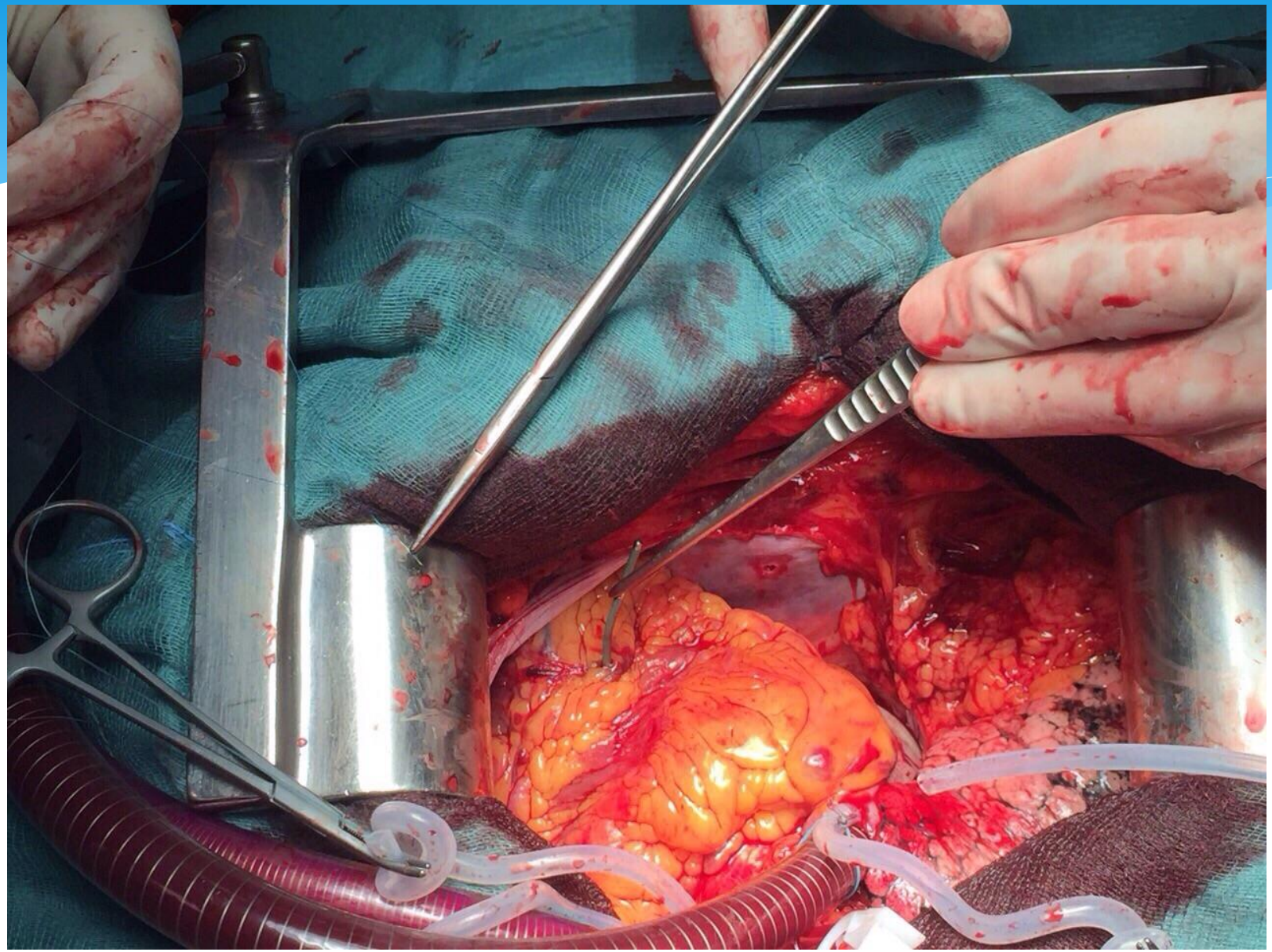

Pericardial
Effusion
Liver
Right Ventricular
Compression
RA
LV
LA
10
20

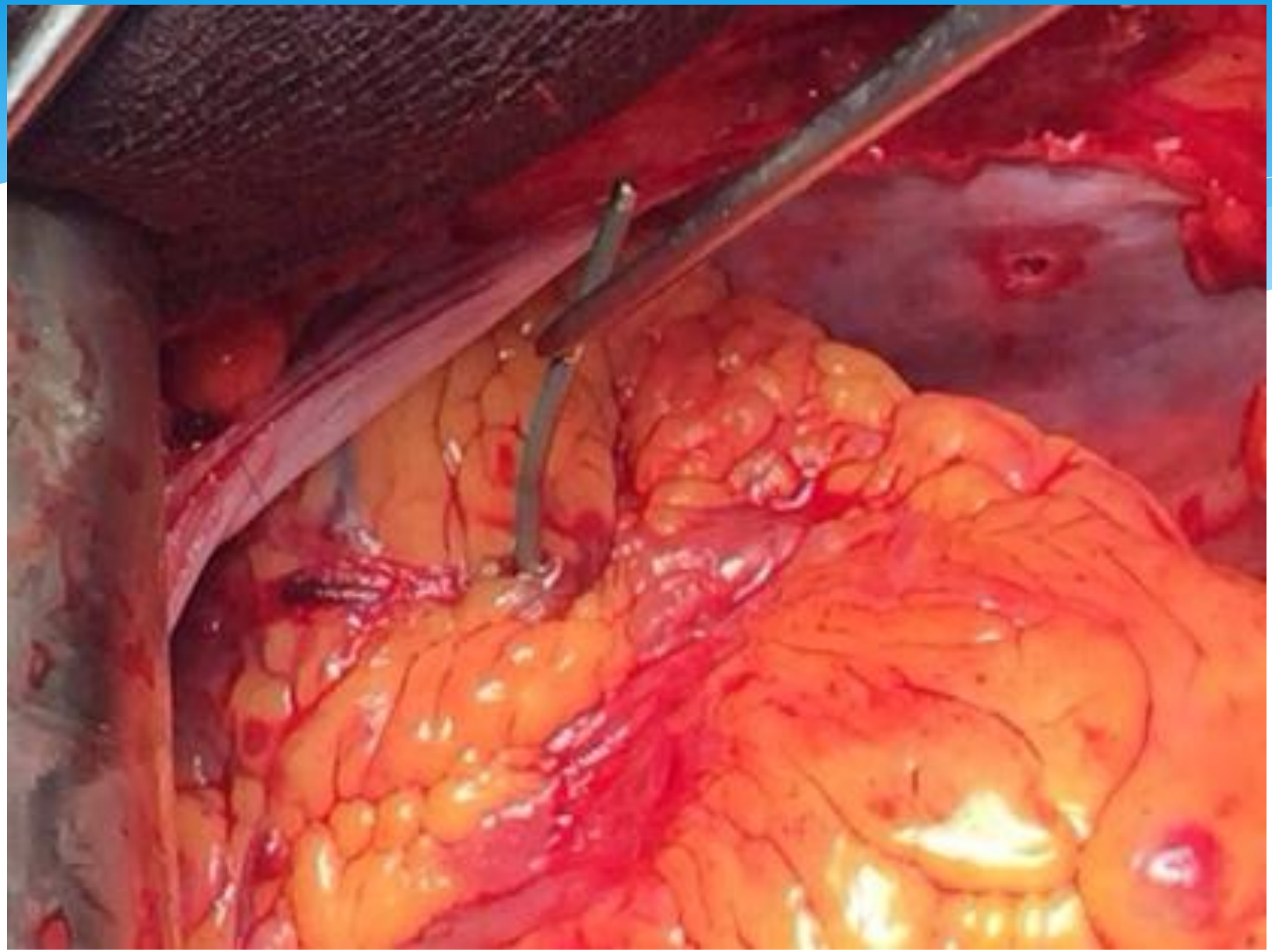
CATETERI STIMOLTORI NEL VD (rapid pacing)

Necessario per poter ridurre al minimo l'eiezione cardiaca durante la fase di impianto del device

1) **Tecnica di posizionamento (accesso dai vasi femorali o dai vasi brachio-cervicali)**

2) **Tipo di catetere stimolatore (morbido, rigido, con palloncino)**





ROTTURA DELLA RADICE AORTICA

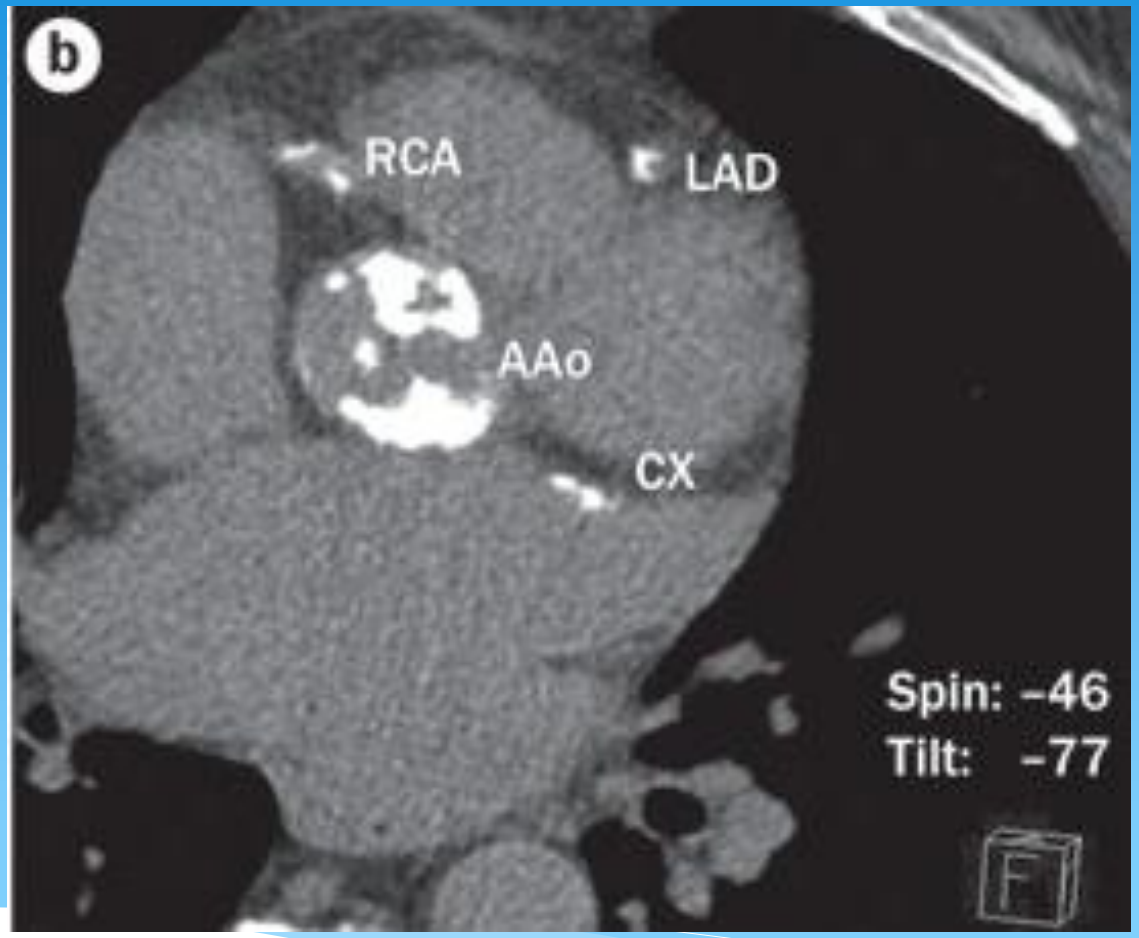
Complicanza rara: 1% delle procedure

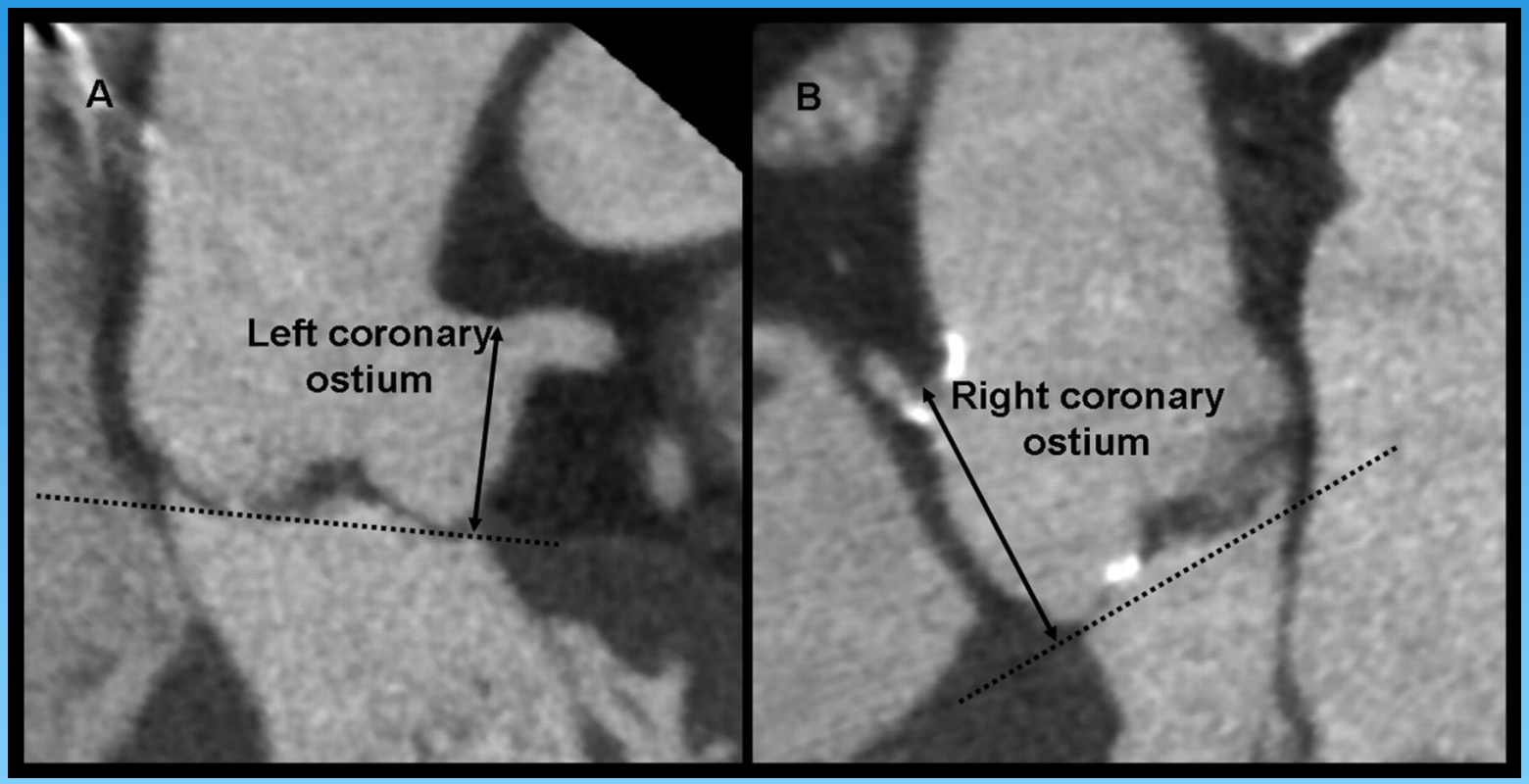
1) **Si verifica sia con i dispositivi autoespansibili (forza radiale, eccessivo oversizing, annulus non circolare) che con quelli balloon-expandable.**
2) **Studio preoperatorio della radice aortica con CT cardiosincronizzata (calcificazioni).**
3) **Evitare postdilatazioni aggressive per ottimizzare un risultato già accettabile (IAO 1+)**

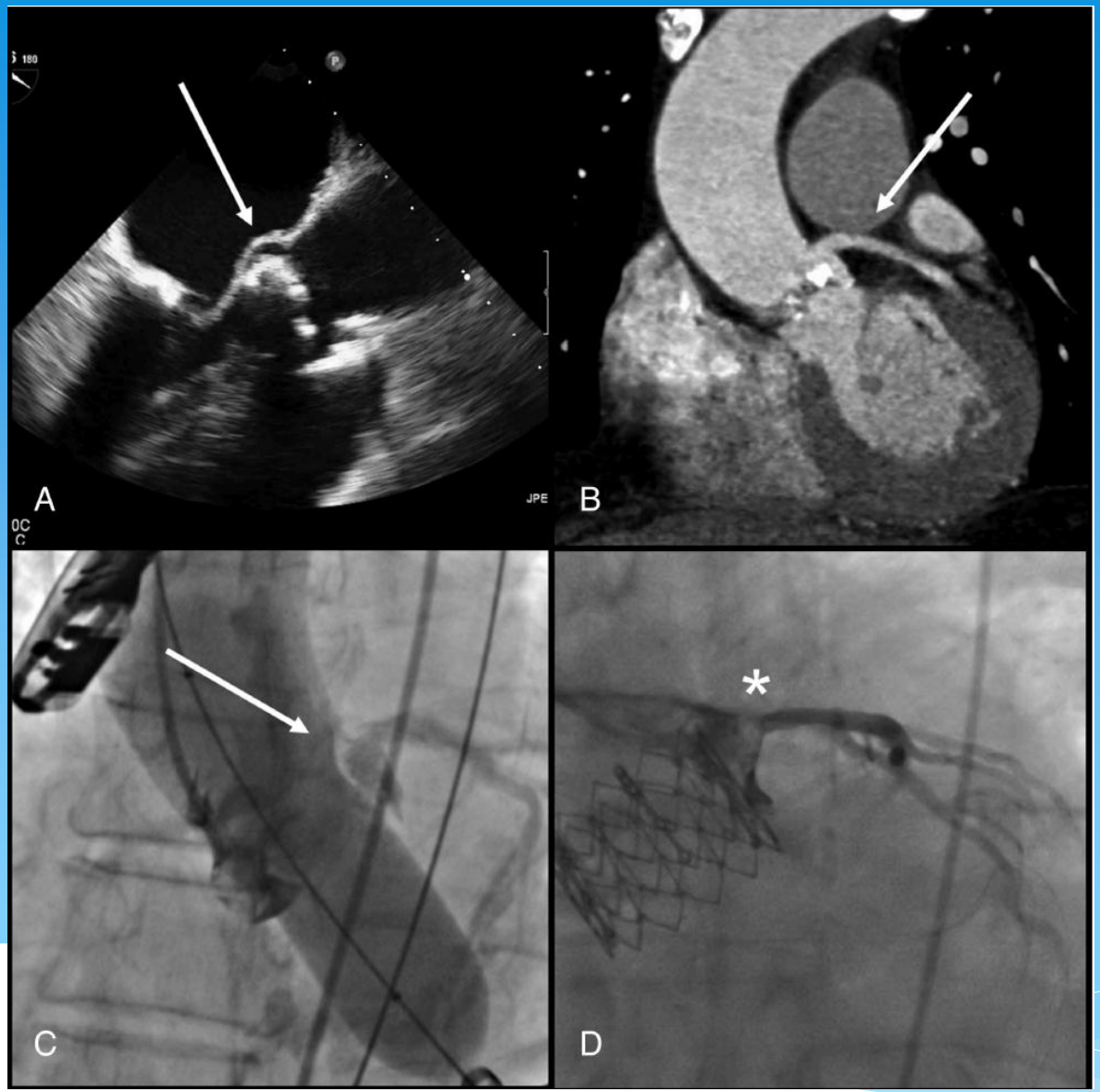
OSTRUZIONE CORONARICA

Complicanza rara: 0,2-0.4% delle procedure

1) **Riportata più di frequente con i dispositivi balloon-expandable che con quelli autoespansibili.**
2) **Studio preoperatorio della radice aortica con CT cardiosincronizzata per identificare i fattori di rischio: calcificazioni voluminose delle cuspidi, ostii coronarci «bassi», seni di Valsalva poco profondi.**


b
RCA
LAD
AAo
CX
Spin: -46
Tilt: -77

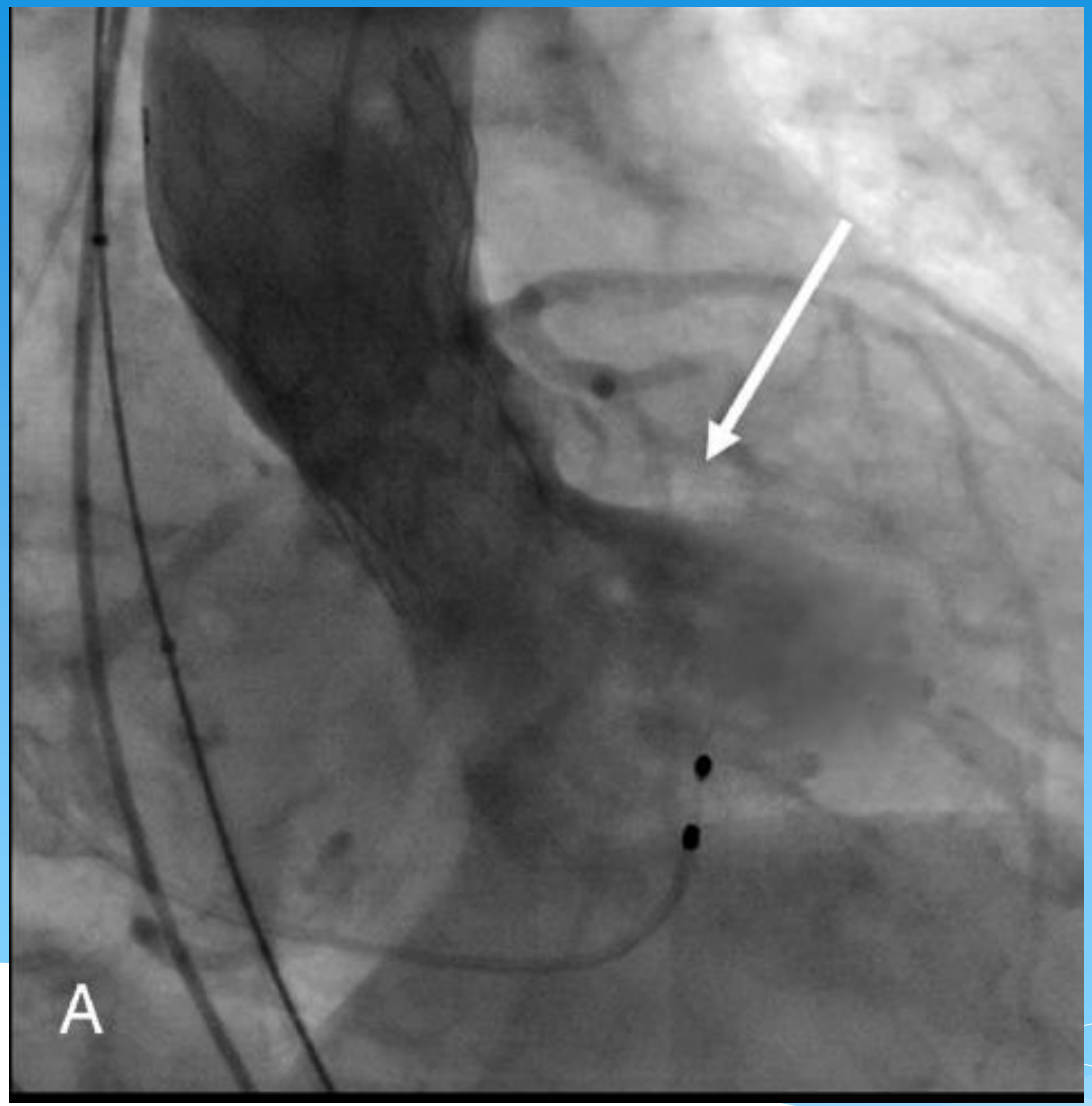

A
Left coronary ostium
B
Right coronary ostium


A
B
C
D
*

INSUFFICIENZA AORTICA RESIDUA

Complicanza COMUNE: 4-35% delle procedure

1) **Riportata più di frequente con i dispositivi autoespansibili che con quelli balloon-expandable.**
2) **Quasi sempre paraprotesica: annulus non circolare, calcificazioni, malposizionamento delle protesi.**
3) **Fattore prognostico negativo importante. Dati GARY: IAO 1+ 60%, 2+ 7%, 3% <1%. NB: IAO post chirurgica ~0%.**
4) **Dispositivi di seconda generazione (?)**


A

PACEMAKER DEFINITIVO

Complicanza COMUNE: 15-33% delle procedure

1) Riportata più di frequente con i dispositivi autoespansibili che con quelli balloon-expandable.
2) Danno da compressione diretta sul sistema di conduzione. Fattori predittivi: BBDx (ma non BBSx) pre-esistente, impianto profondo nel LVOT, sovra-dimensionamento eccessivo.
3) Non predittiva di mortalità a medio termine.
4) Costo complessivo dellla procedura!

INSUFFICIENZA RENALE

Complicanza COMUNE: 7% delle procedure

1) **IRC spesso presente come co-morbidità nei pazienti TAVI.**
2) **Multifattoriale: mezzo di contrasto (TAC, coronarografia, procedura), ipotensione peri-procedurale, sanguinamento, trasfusioni.**
3) **Fattore indipendente predittivo di mortalità ad 1 anno.**

ICTUS

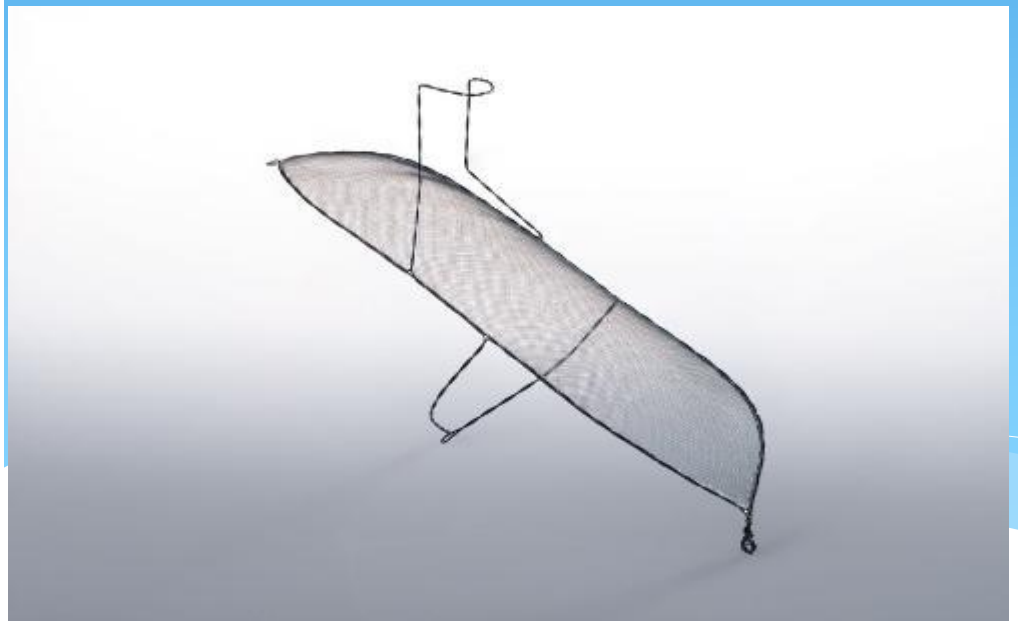
Complicanza NON COMUNE: 1.3-1.8% delle procedure

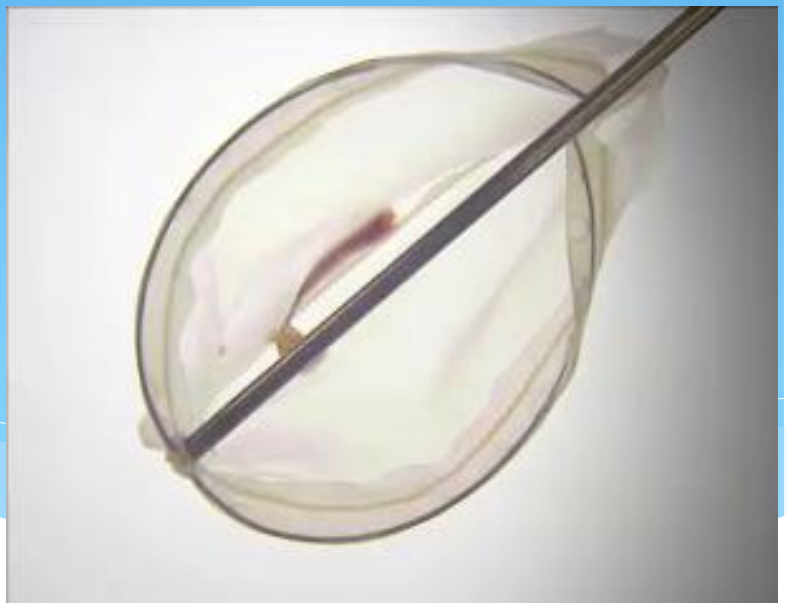
1) **Complicanza GRAVE: predittiva di mortalità complessiva (5x) e cardiovascolare (4x) (P<0.001).**
2) **Registro GARY: 1.8% in-hospital, 3.0% 30 gg.**
3) **Caveat: nuove lesioni diffusion-weighted MRI sono presenti in 84% dei pazienti TAVI (significato clinico?) Migrazione di frammenti dall'arco aortico o dalla valvola verso il territorio sovra-aortico.**

ICTUS

1) Prevenzione: minimizzare manipolazione della valvola, pre-dilatare e post-dilatare il meno possibile, usare nuovi dispositivi a basso profilo (da dimostrare).
2) Sistemi di protezione cerebrali: Claret, Embrella, Triguard EDD, Embol-X: dispositivi promettenti ma esperienza clinica limitata. Manipolazione dei TSA.


A





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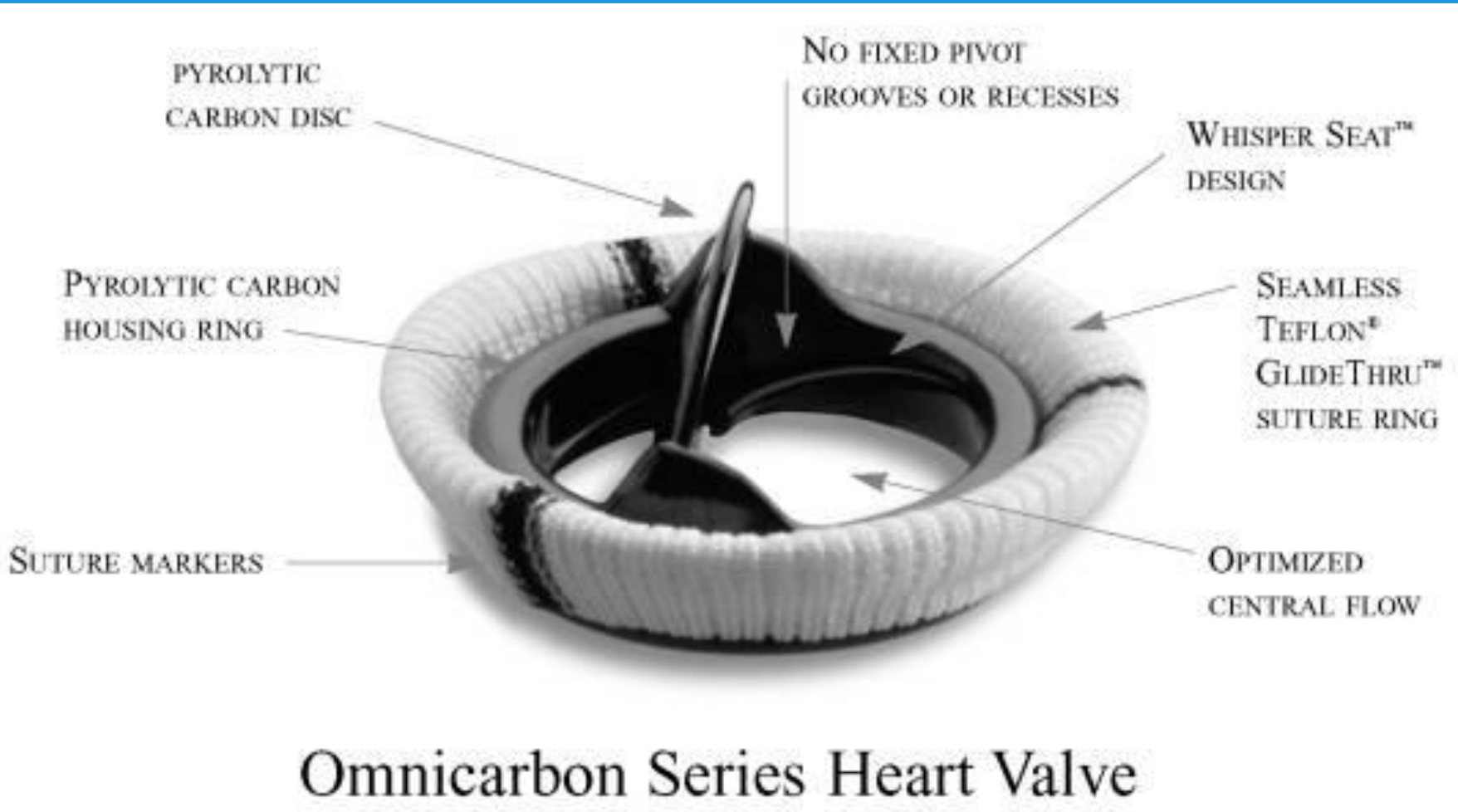
UNA COMPLICANZA «ANEDDÒTICA»

Patient presentation

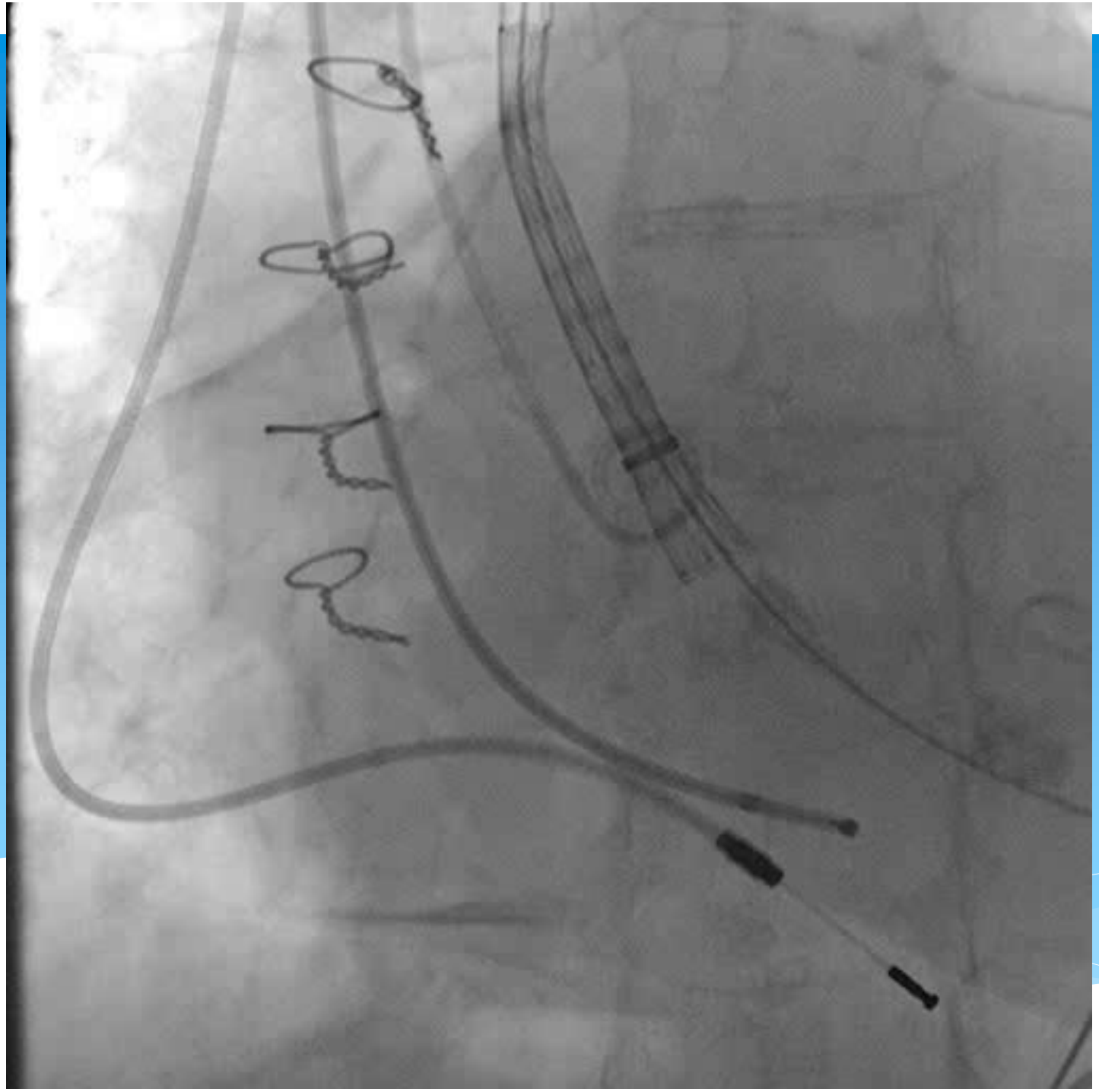
79 yo woman s/p mitral valve replacement (1992, Omnicarbon 27) and VVI pacemaker for slow AF. Stable until 2011, when she developed progressive DOE.

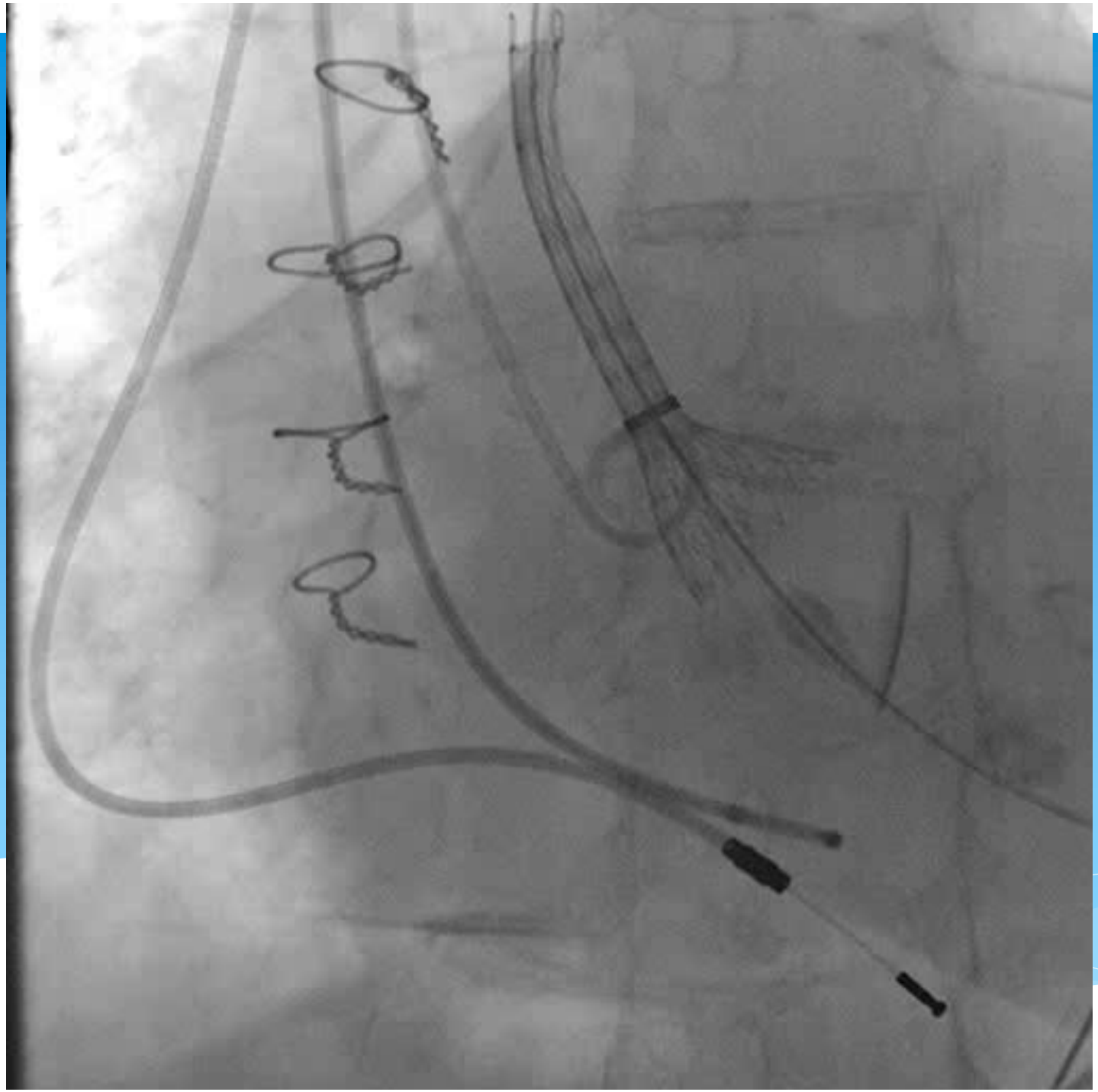
9/2012: NYHA III heart failure due to severe Aortic Stenosis (valve area 0.7 cm2, mean gradient 55mmHg). Normal LV function, normal mitral prosthetic valve function.

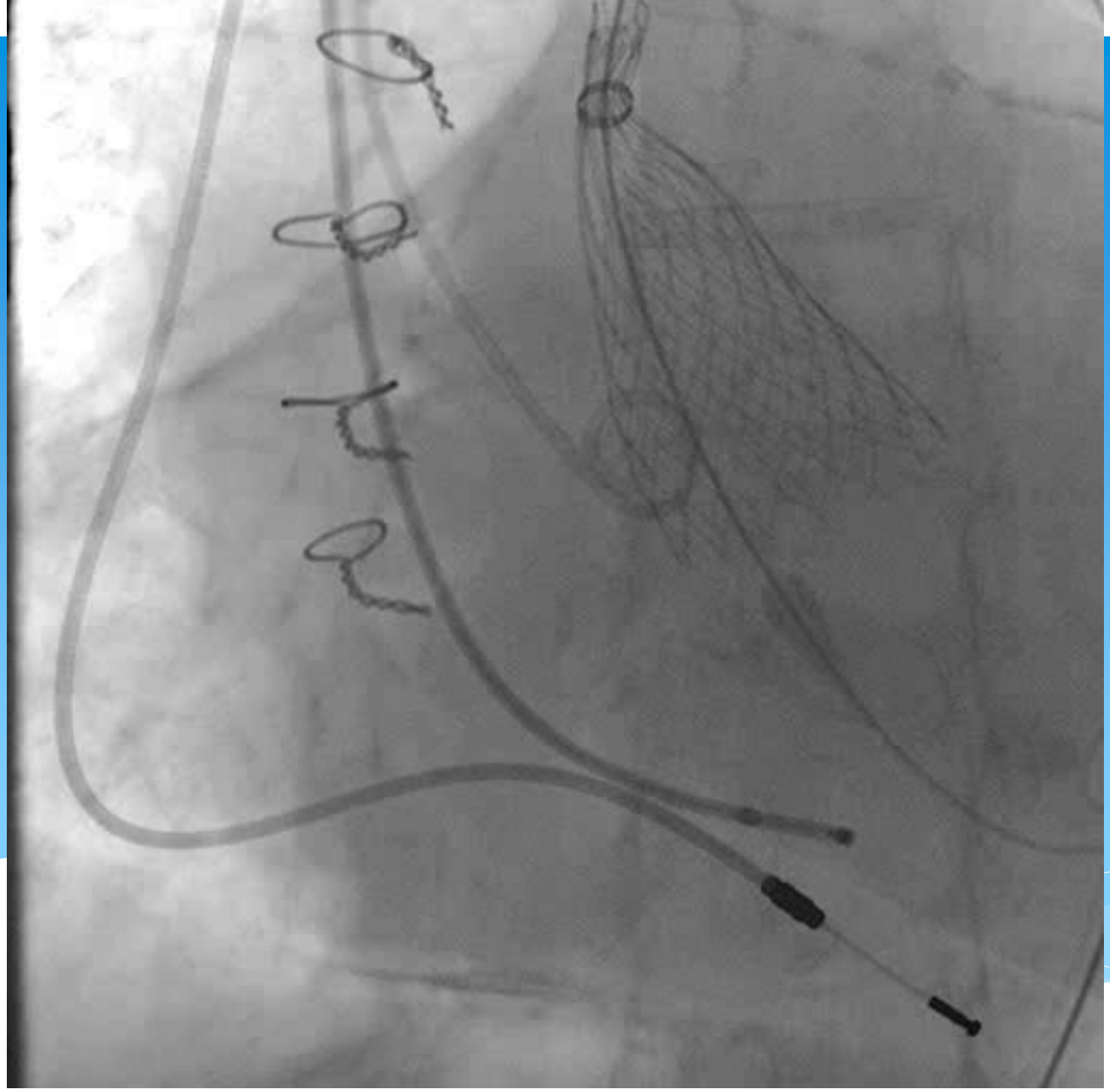
Procedure planned: TAVI with Corevalve 29 (annulus size, 22x24 mm on CT) after valvuloplasty with 22 mm balloon.



Omnicarbon Series Heart Valve

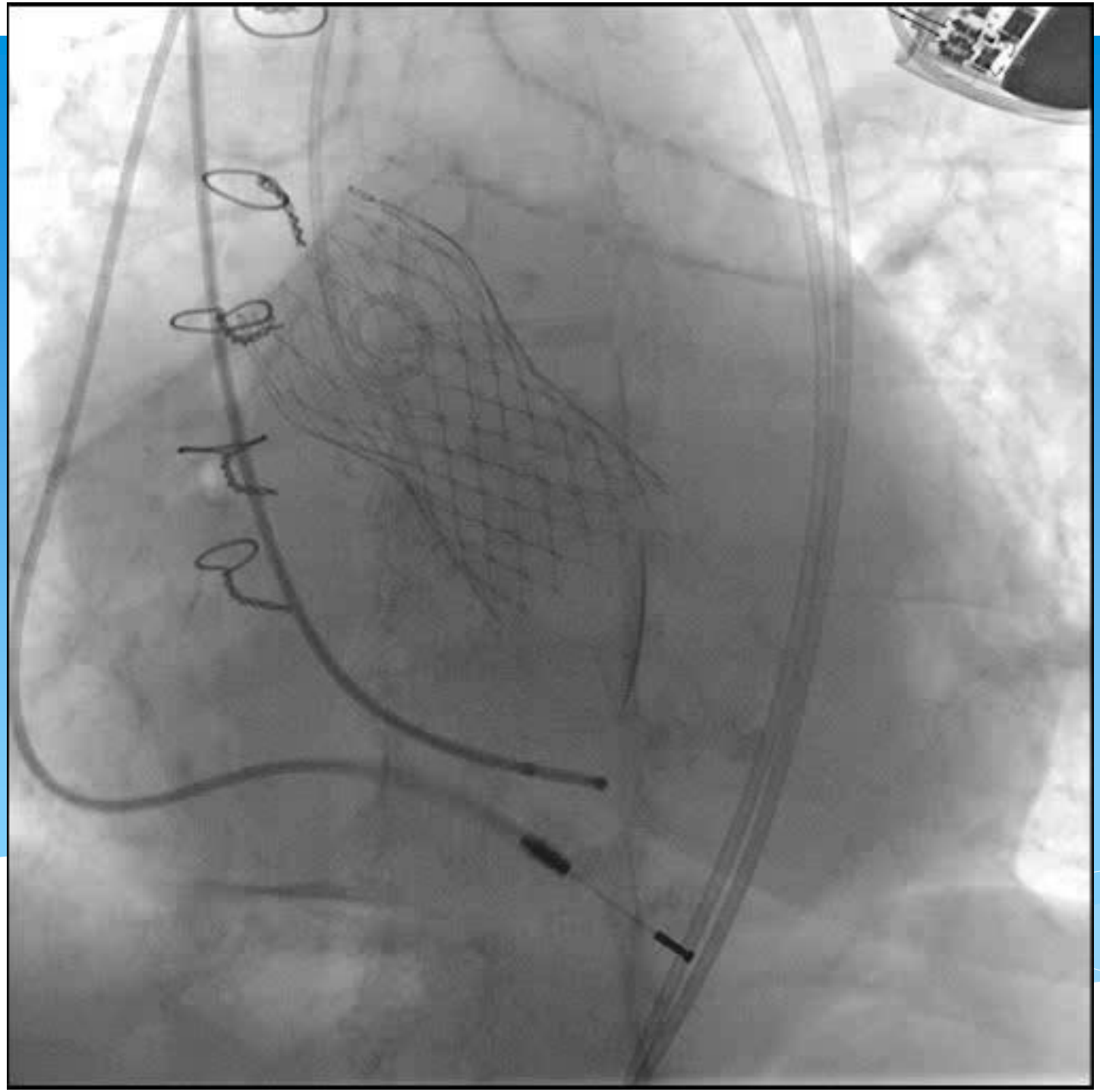




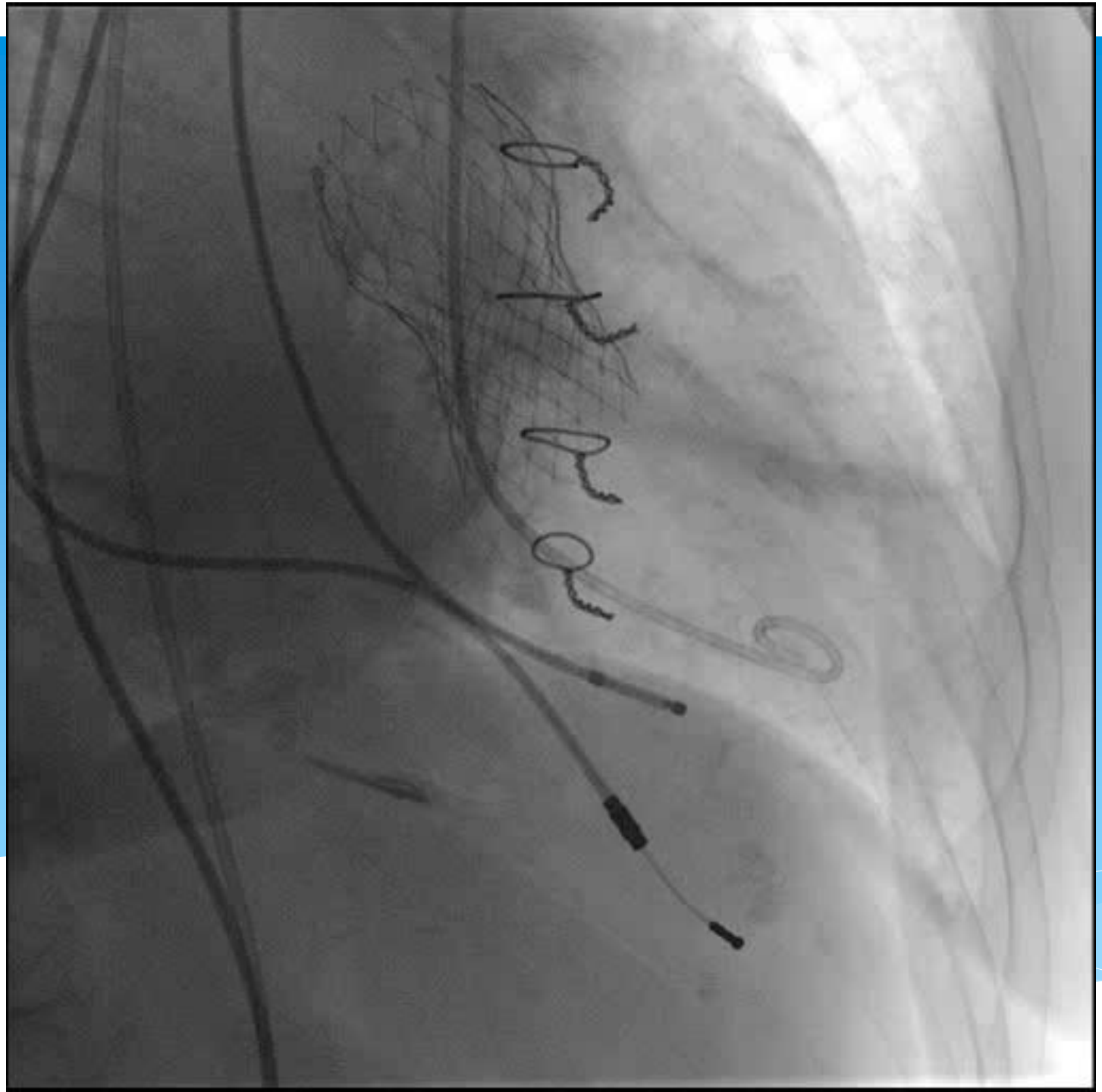


After valve deployment

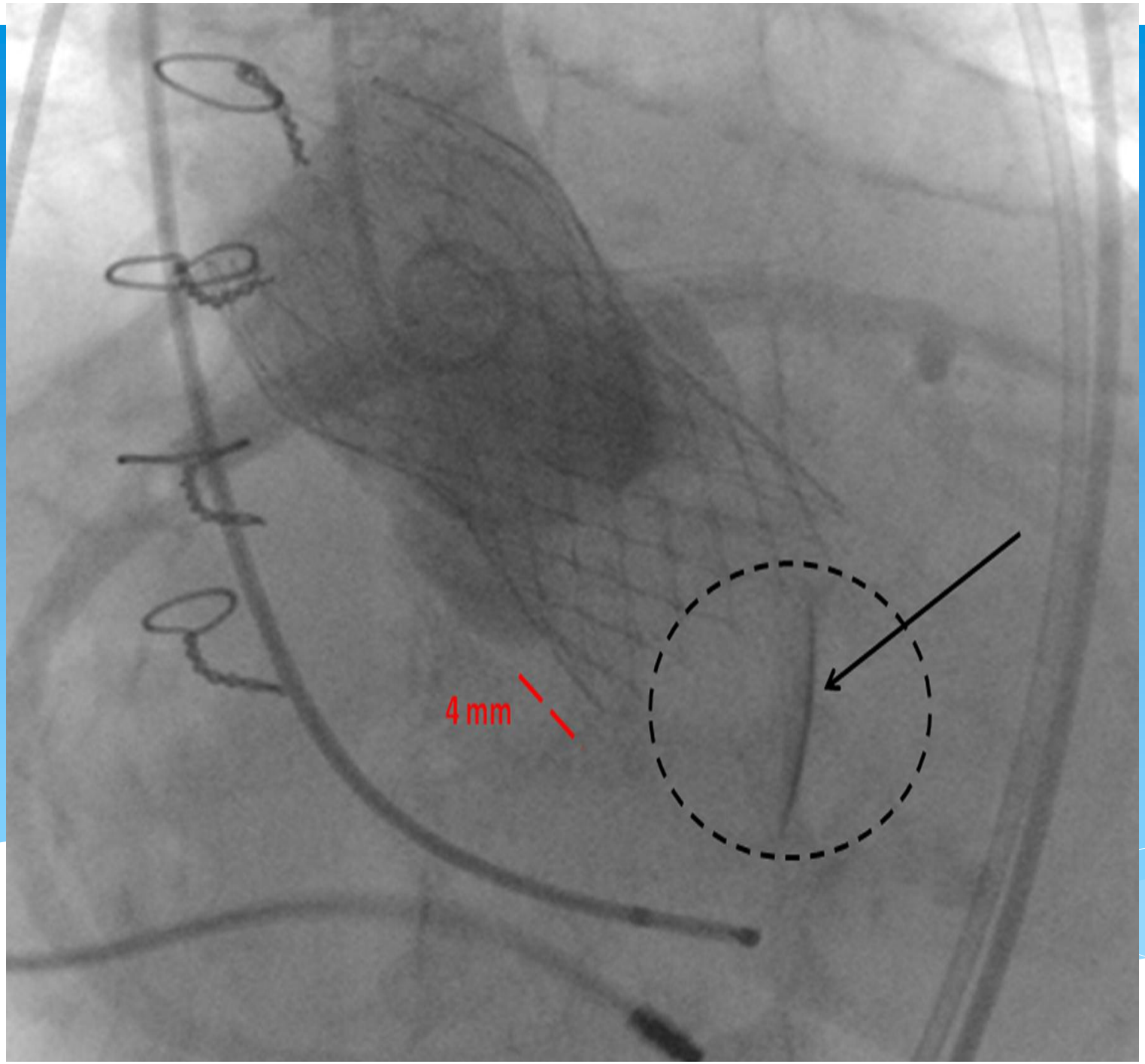
Sudden onset of severe hypotension (60/30 mmHg), dyspnea and progressively worsening pulmonary oedema

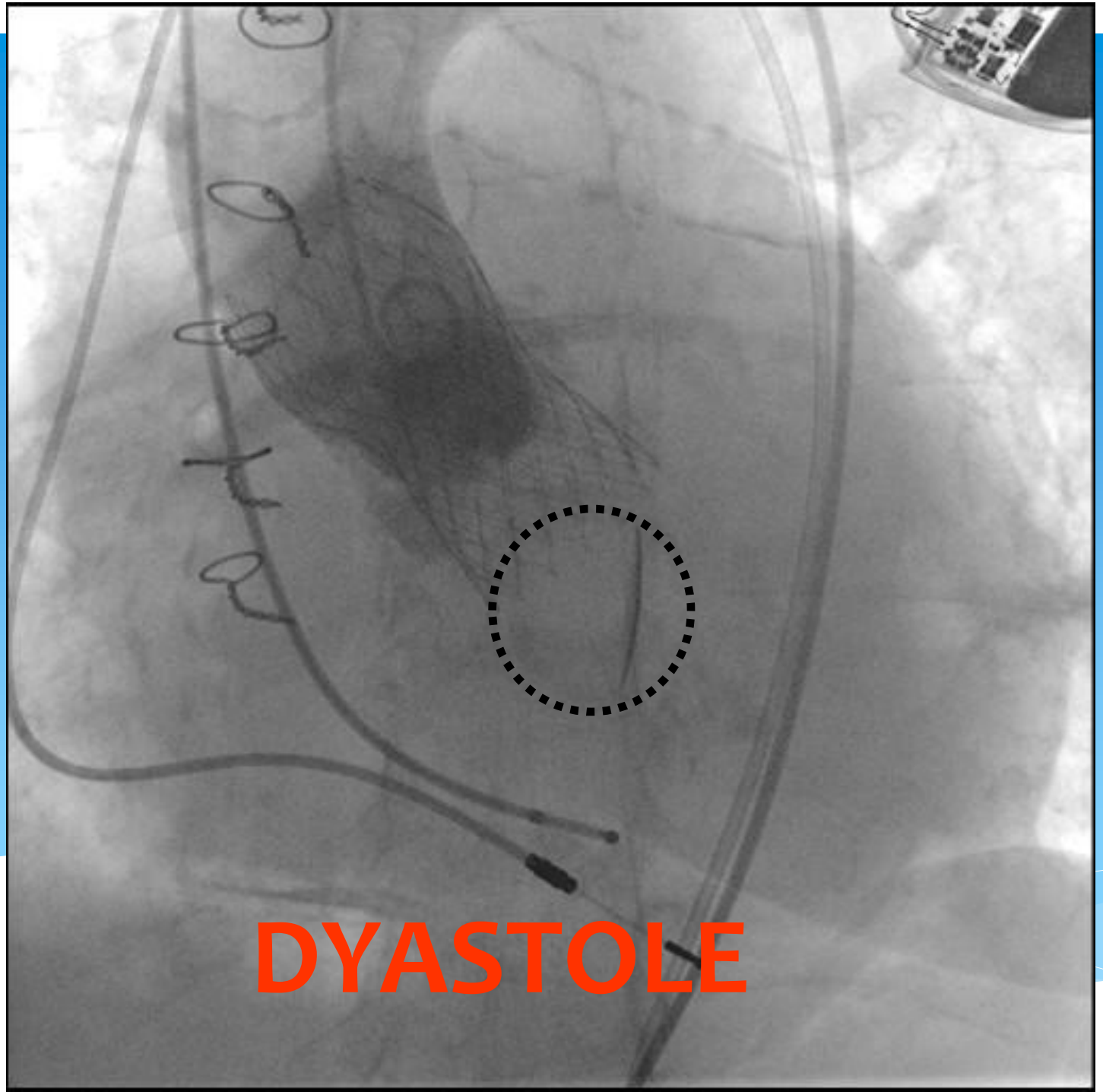


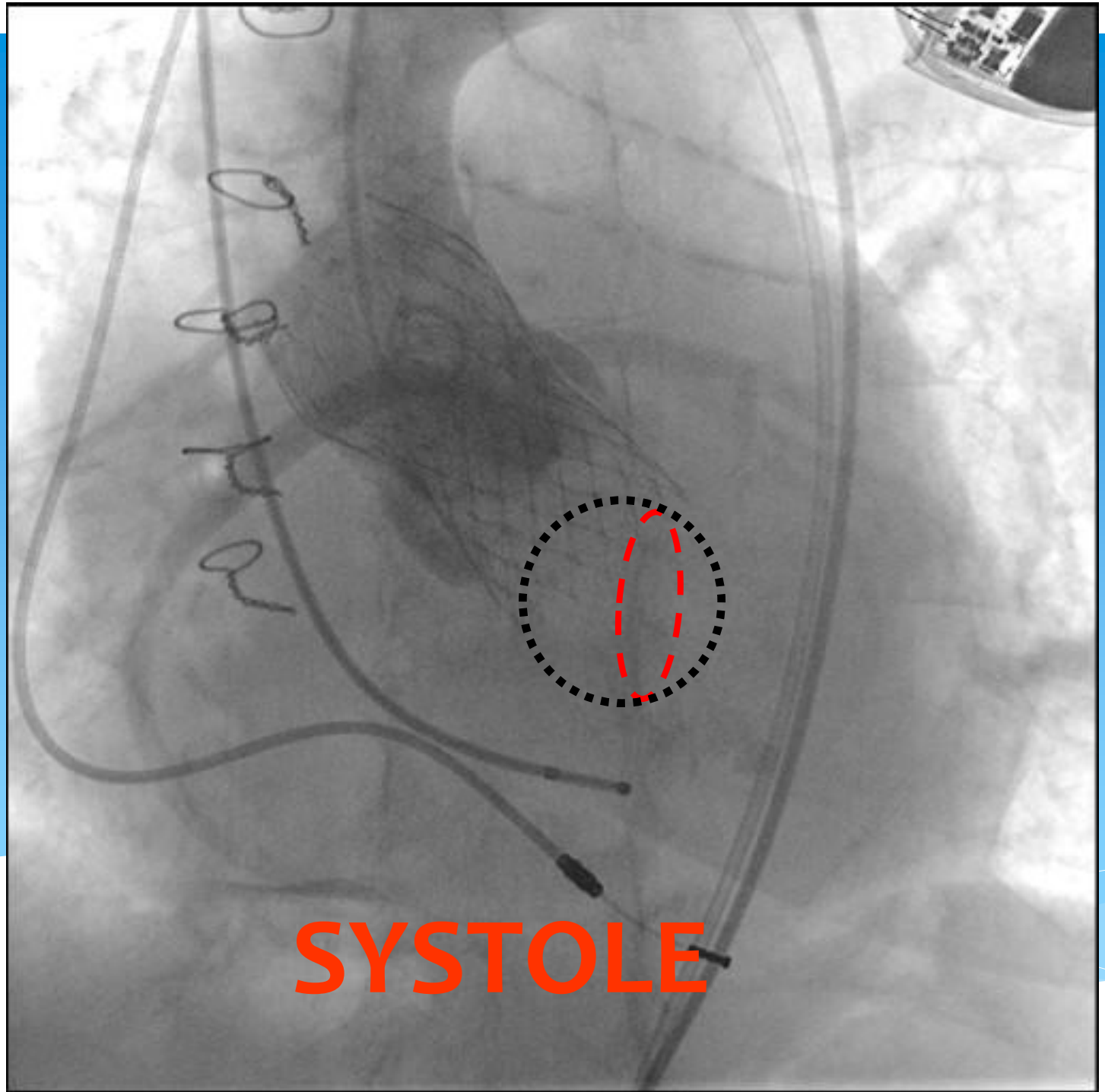
After administration of inotropes, suspecting interference of the Corevalve with the Omnicarbon, we advanced the pigtail in the LV and performed ventriculography, which showed *Massive Mitral Regurgitation*



The Corevalve frame (too deep in the ventricle on the mitral side, although "within range" on the right aortic cusp side) prevented *effective systolic closure of the disc* of the mitral prosthesis


4 mm

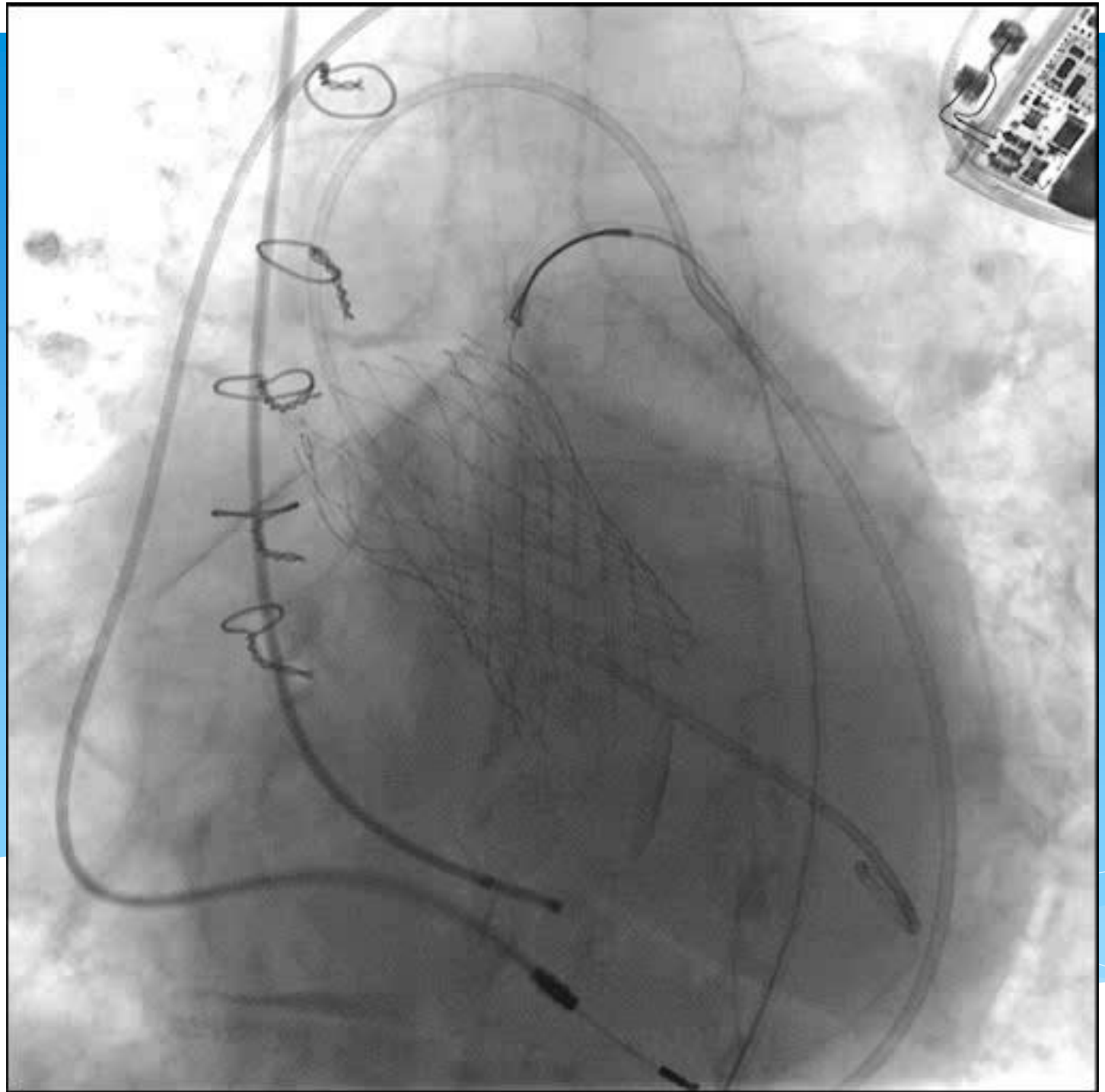

DYASTOLE


SYSTOLE

Patient “in extremis”- What to do?

20 mm snare, “gentle traction” in an attempt to move the Corevalve cranially:

unsuccessful!



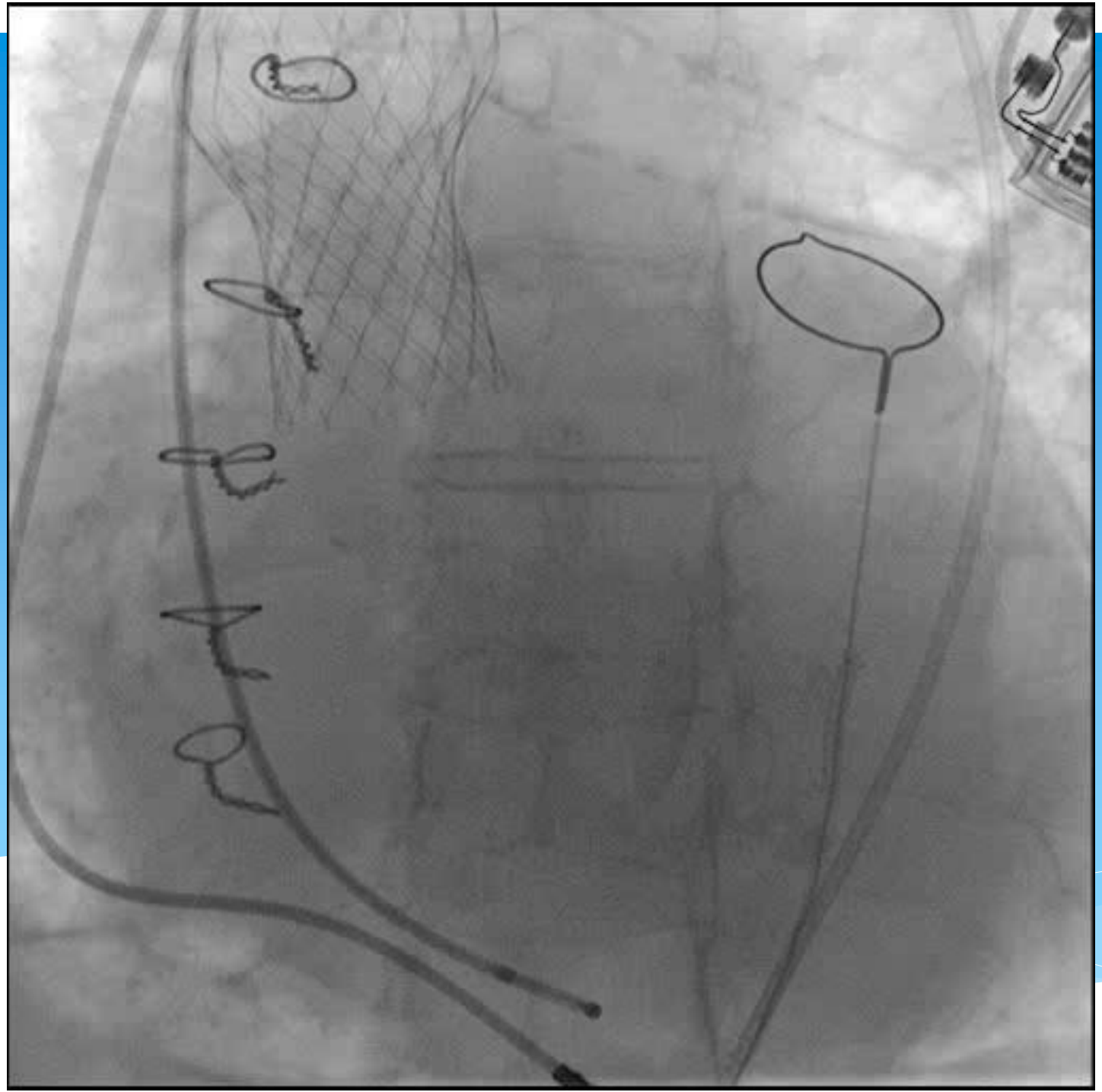
Patient “in extremis”- What to do?

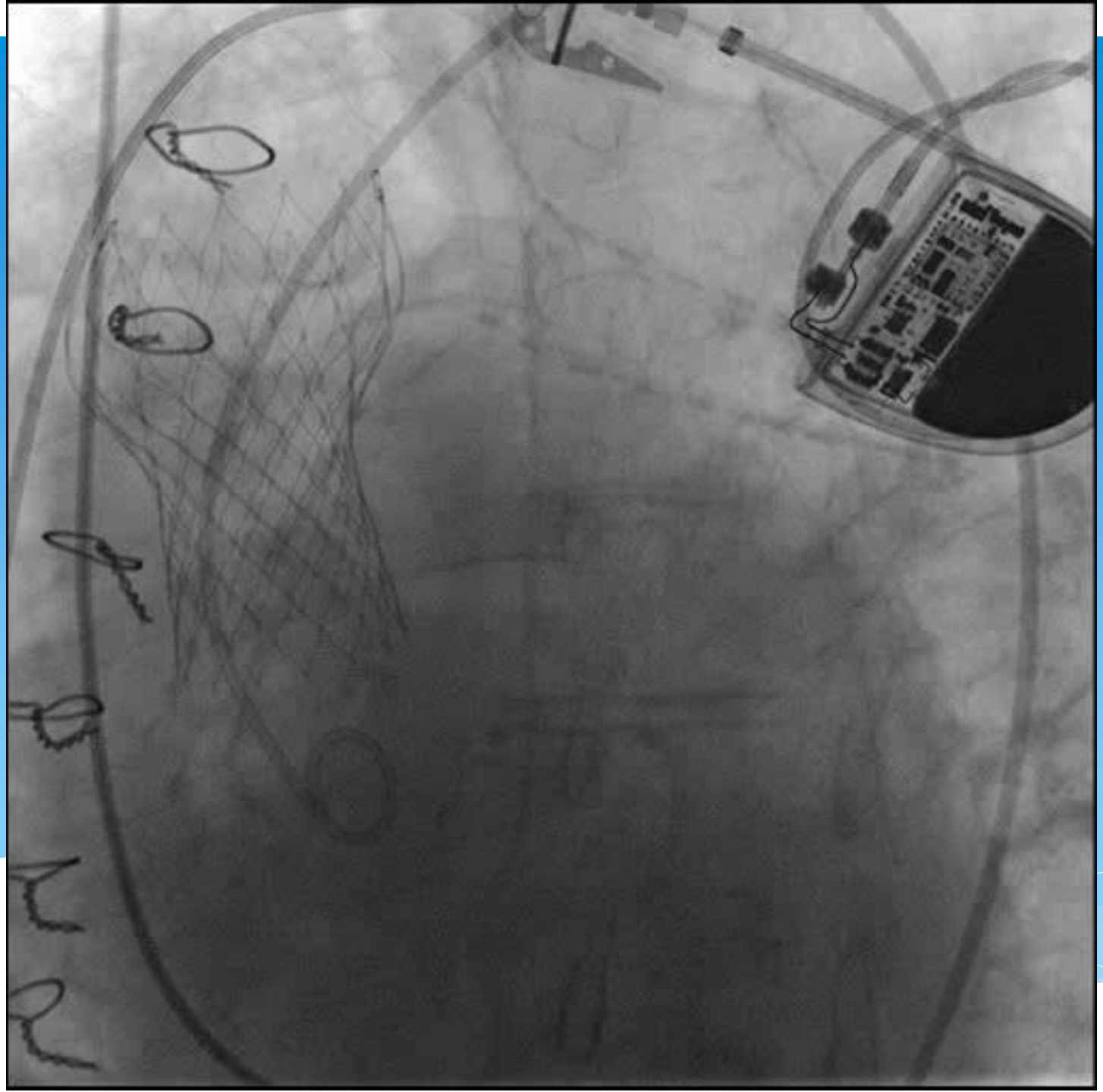
20 mm snare, “very determined” traction

valve “pop-up” in ascending aorta

IMMEDIATE HEMODYNAMIC IMPROVEMENT

with increase in blood pressure and oxygenation.





Patient stabilized- What to do next?

1) Position a second Corevalve aiming for a higher implant?

2) Position a Sapien valve?

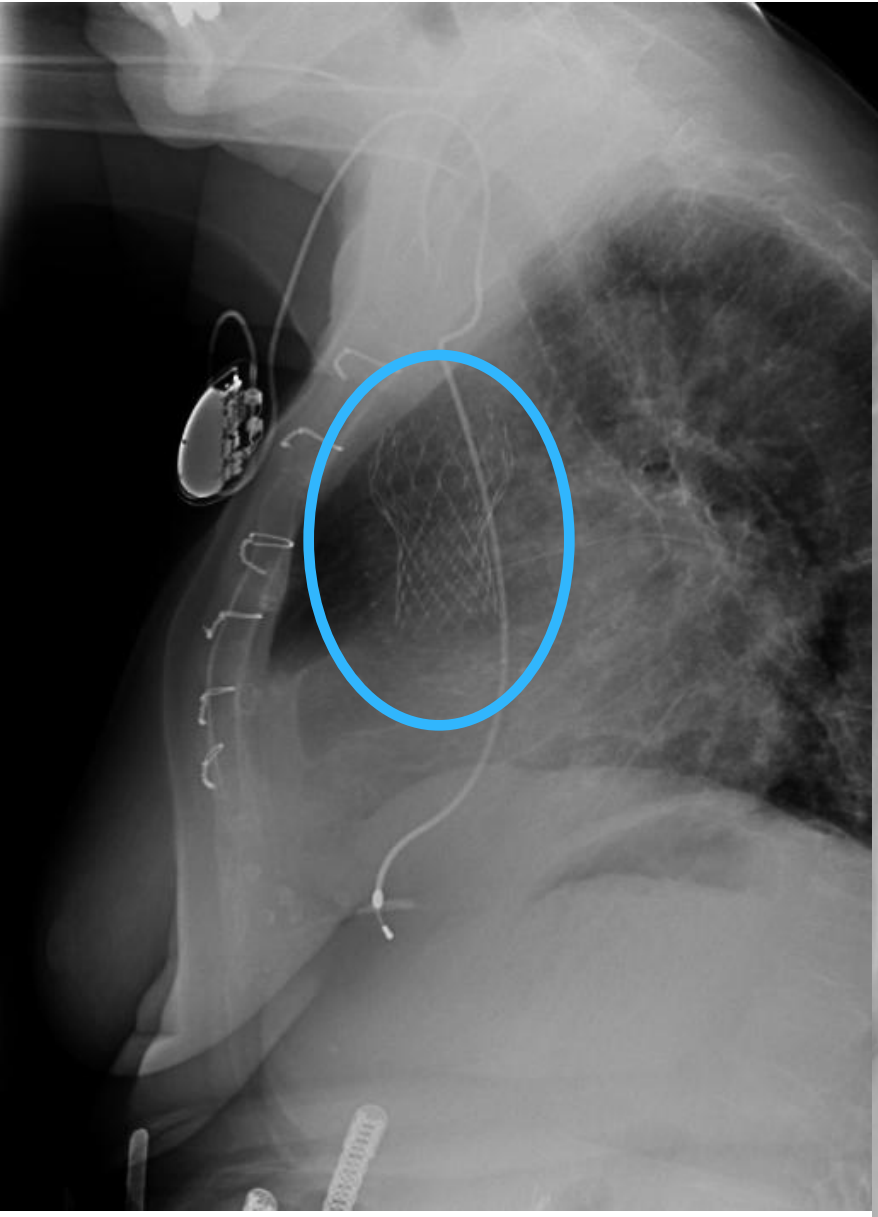
3) Assess valve hemodynamics (balloon valvuloplasty has been performed), ensure Corevalve does not interfere with flow in coronaries and arch vessels, conclude the procedure and closely follow the patient ("watchful waiting")?

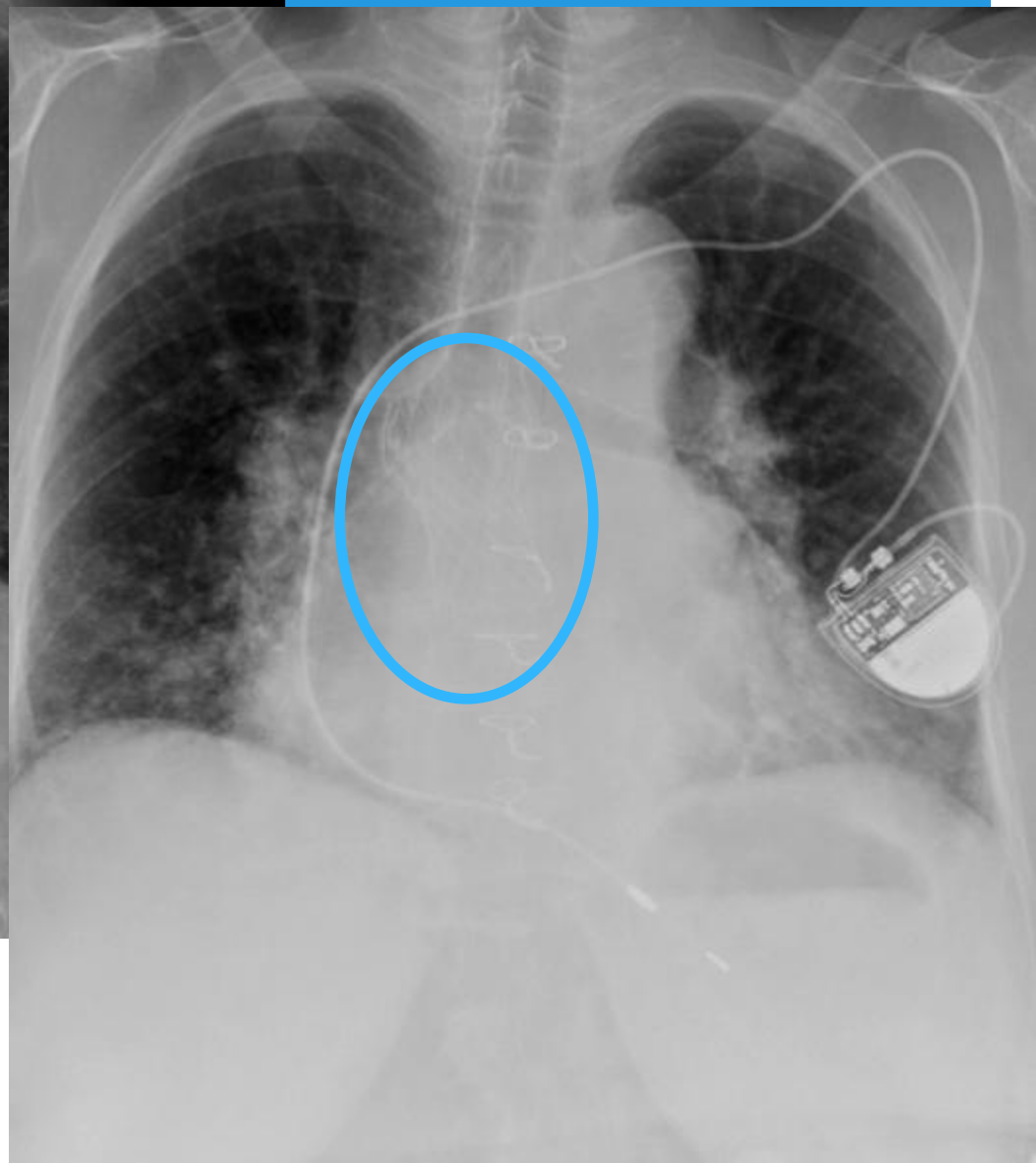
We felt that we had pushed our luck far enough for the day. Trans-aortic mean gradient was 18 mmHg, Aortic Insufficiency was 1/2+, the patient was stable and we thought wise to close the procedure leaving the valve in the ascending aorta.

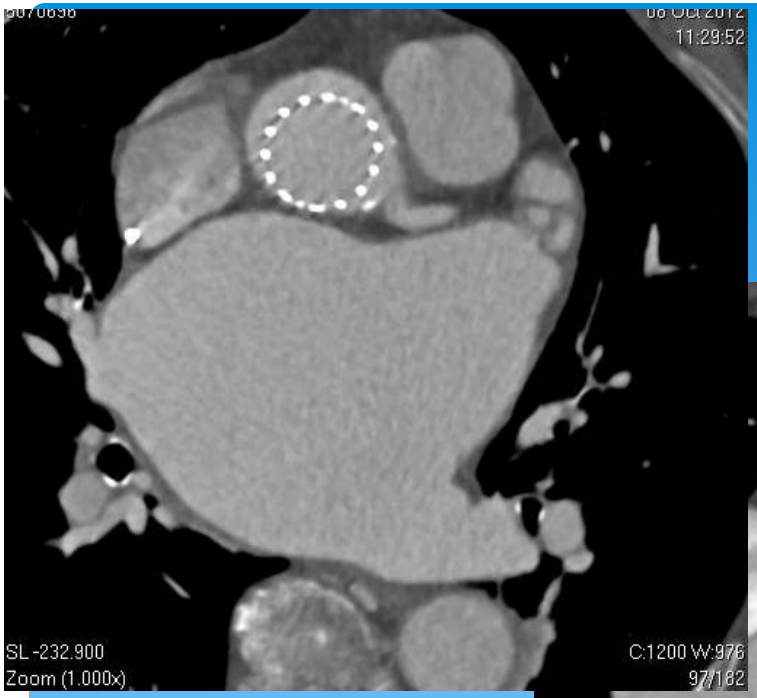
The patient was discharged home 48 h later in good clinical condition, on DAPT.

She was doing well at 1 mo. and 2 mo. f-u. At 3 mo. post procedure she complained of worsening SOB. Echocardiography showed an increase in the mean trans-aortic gradient to 48 mmHg.

We decided to perform a second TAVI procedure, implanting a 26 mm Sapien Valve.



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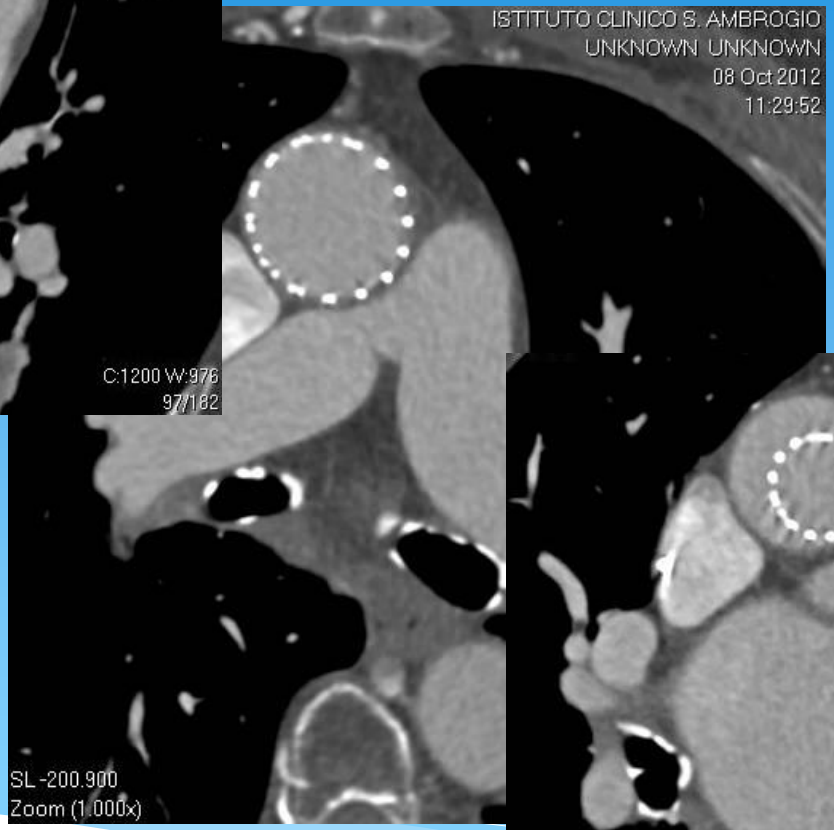
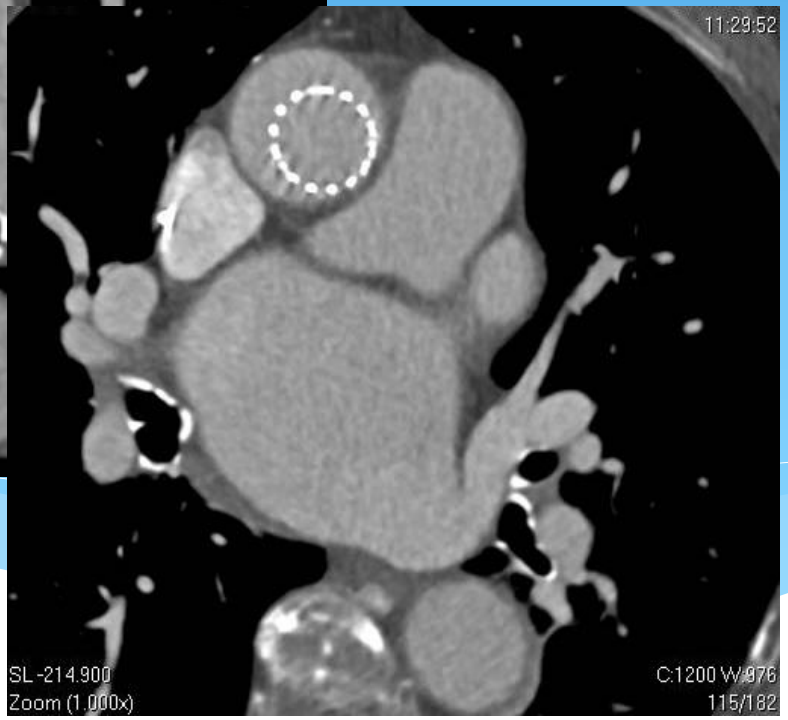
Zoom (1.000x)
C:1200 W:976
97/182


ISTITUTO CLINICO S. AMBROGIO
UNKNOWN UNKNOWN
08 Oct 2012
11:29:52
SL -200.900
Zoom (1.000x)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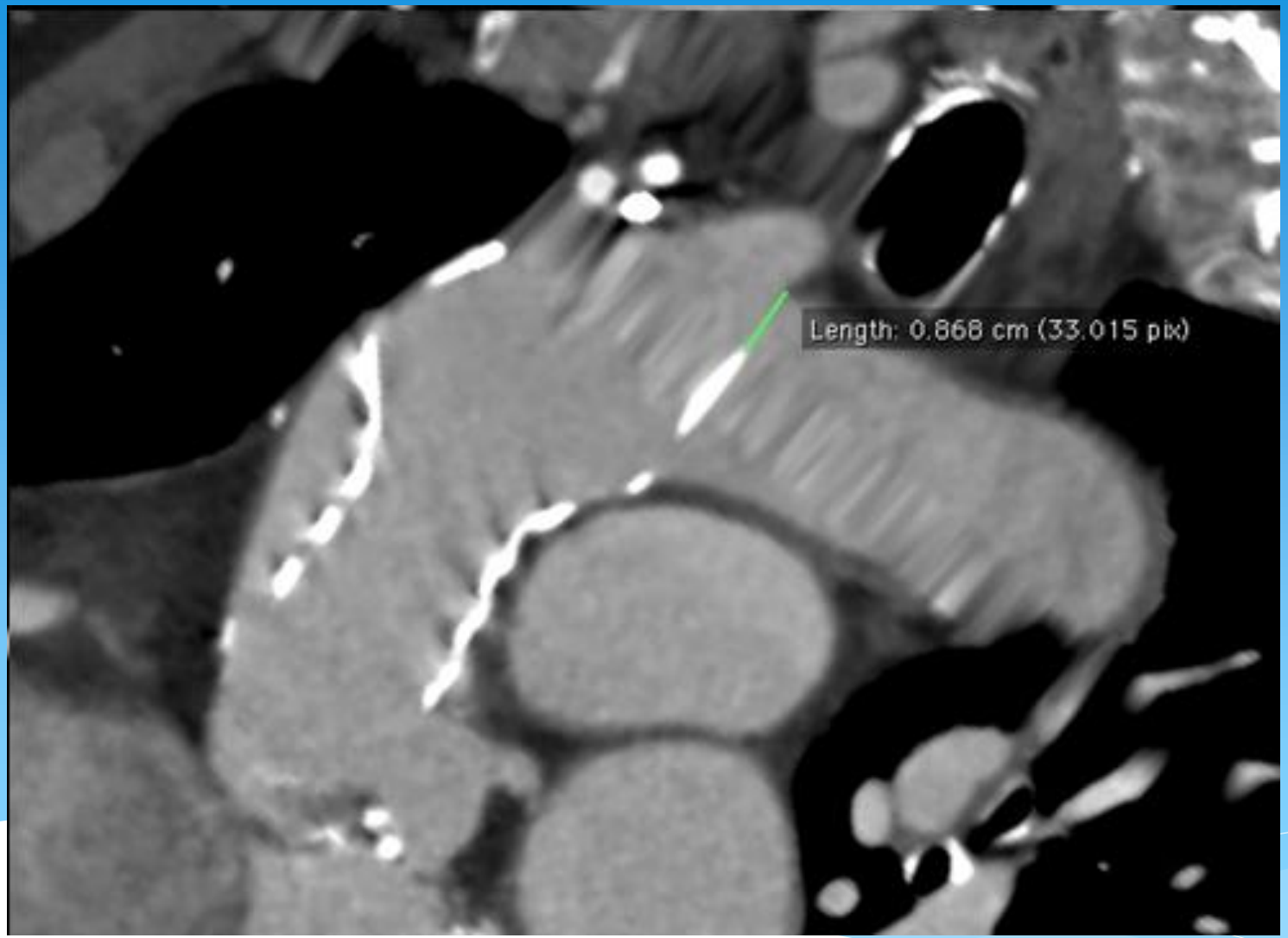
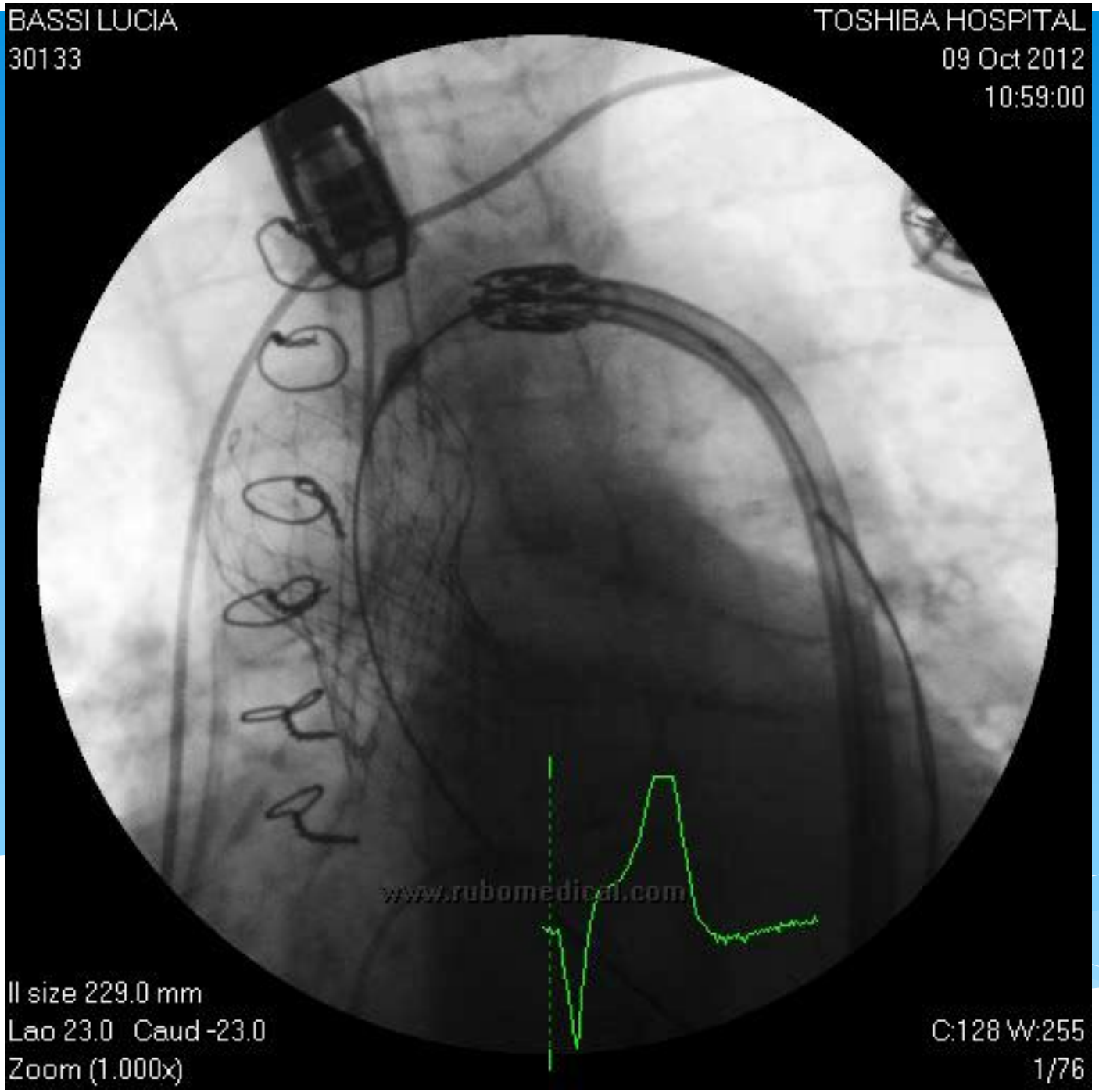
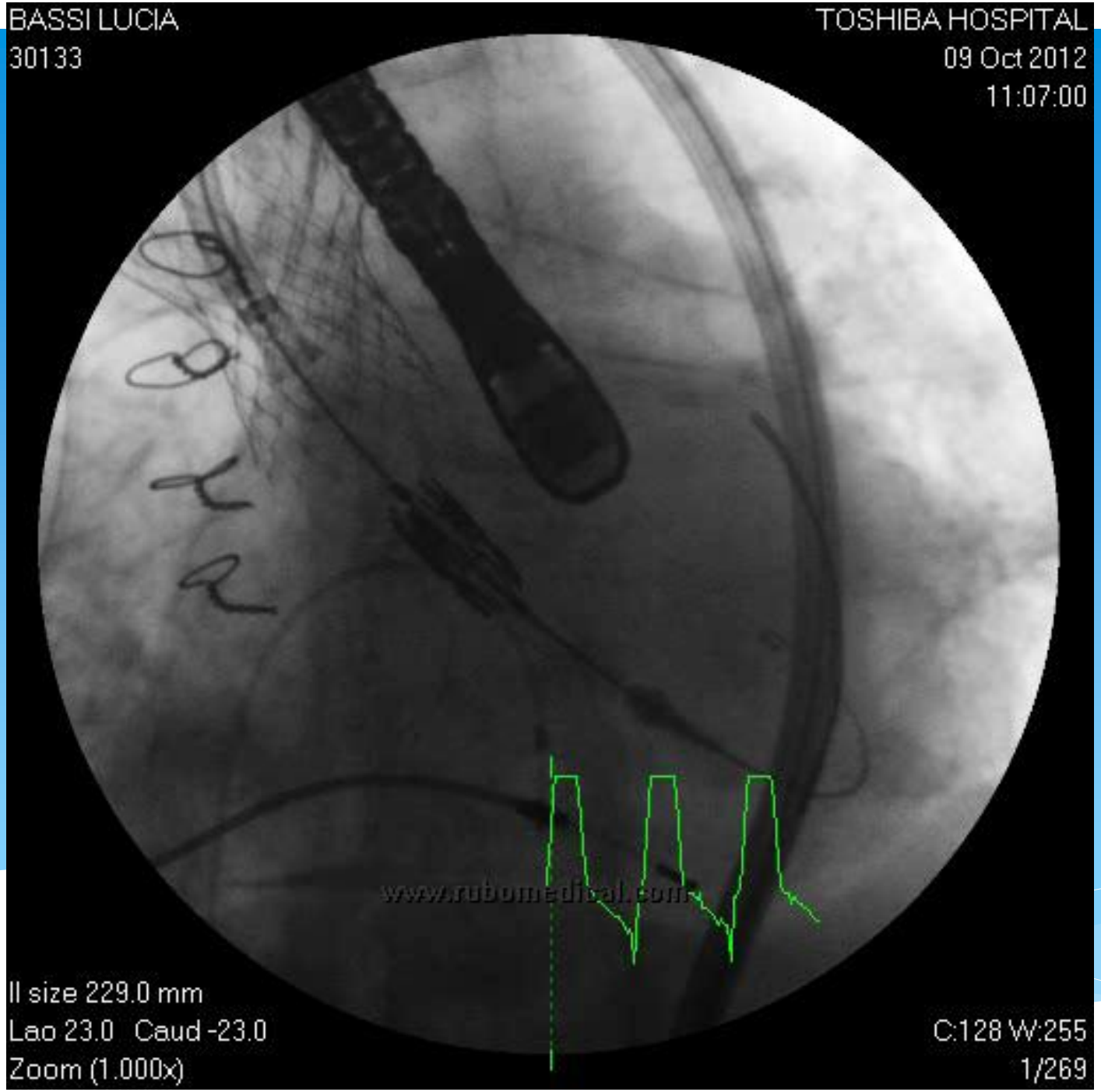
115/182


Length: 0.868 cm (33.015 pix)


BASSI LUCIA
30133
TOSHIBA HOSPITAL
09 Oct 2012
10:59:00
www.rubomedical.com
II size 229.0 mm
Lao 23.0 Caud -23.0
Zoom (1.000x)
C:128 W:255
1/76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30133
TOSHIBA HOSPITAL
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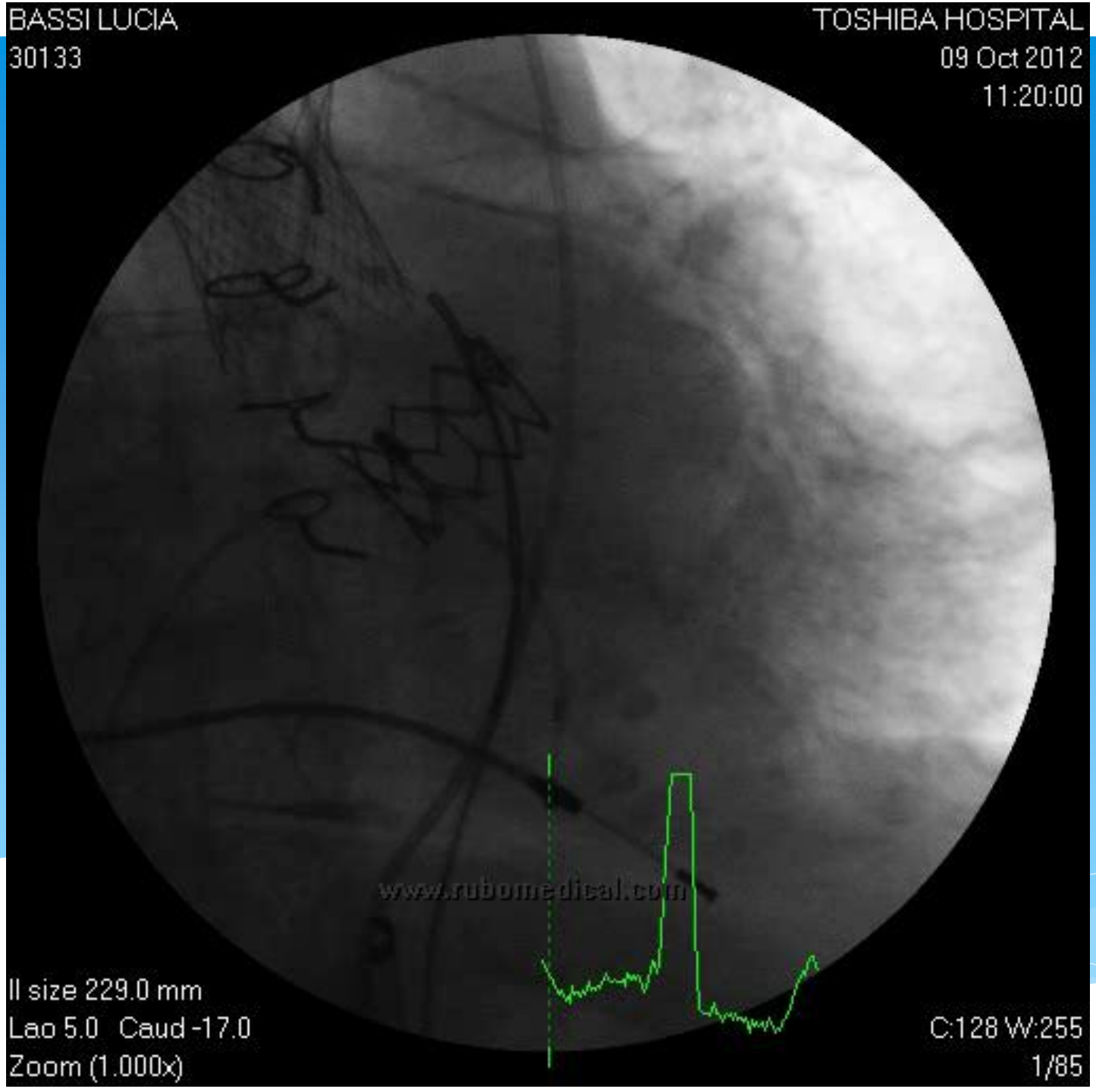
1/269


BASSI LUCIA
30133
TOSHIBA HOSPITAL
09 Oct 2012
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www.rubomedical.com
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Lao 5.0 Caud -17.0
Zoom (1.000x)
C:128 W:255
1/85

CONCLUSIONS (I)

The fact that a complication is not reported in the literature does not mean it will not happen.

In a case like this, probably the initial choice of a Sapien valve would have been wiser. After searching the literature, we decided a Corevalve would be safe and used it, because of institutional constraints.

Conclusions (II)

A large-volume center should be equipped and comfortable with multiple models of transcatheter first- and second-generation valves.

This case highlights the major potential advantages offered by second generation, fully retrievable, fully repositionable devices.

Thanks for your attention!