

How to deal with the MDR as a transcatheter interventionalist?



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New Devices:

Balloons

Stents

Occluders

Valves



from
2012

**The
Guardian**

Regulation (EU) 2017/745

From Wikipedia, the free encyclopedia

Regulation (EU) 2017/745 is a [regulation](#) of the European Union on the clinical investigation and sale of [medical devices](#) for human use. It repeals [Directive 93/42/EEC](#) (MDD), which concerns medical devices, and [Directive 90/385/EEC](#), which concerns active implantable medical devices, on 26 May 2021.

The regulation was published on 5 April 2017 and came into force on 25 May 2017.^{[1][2][3]} Originally approved medical devices will have a transition time of three years^{[4][5]} (until 26 May 2021) to meet new requirements.

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- [Scope and classification](#)
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- [Person responsible for regulatory compliance](#)
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- [European database on medical devices](#)
- [Medical Device Coordination Group](#)
- [Implementation date](#)
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Regulation

European Union regulation

**Title**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)

Made by

[Council](#)

Made under

TFEU/art 294 par 6



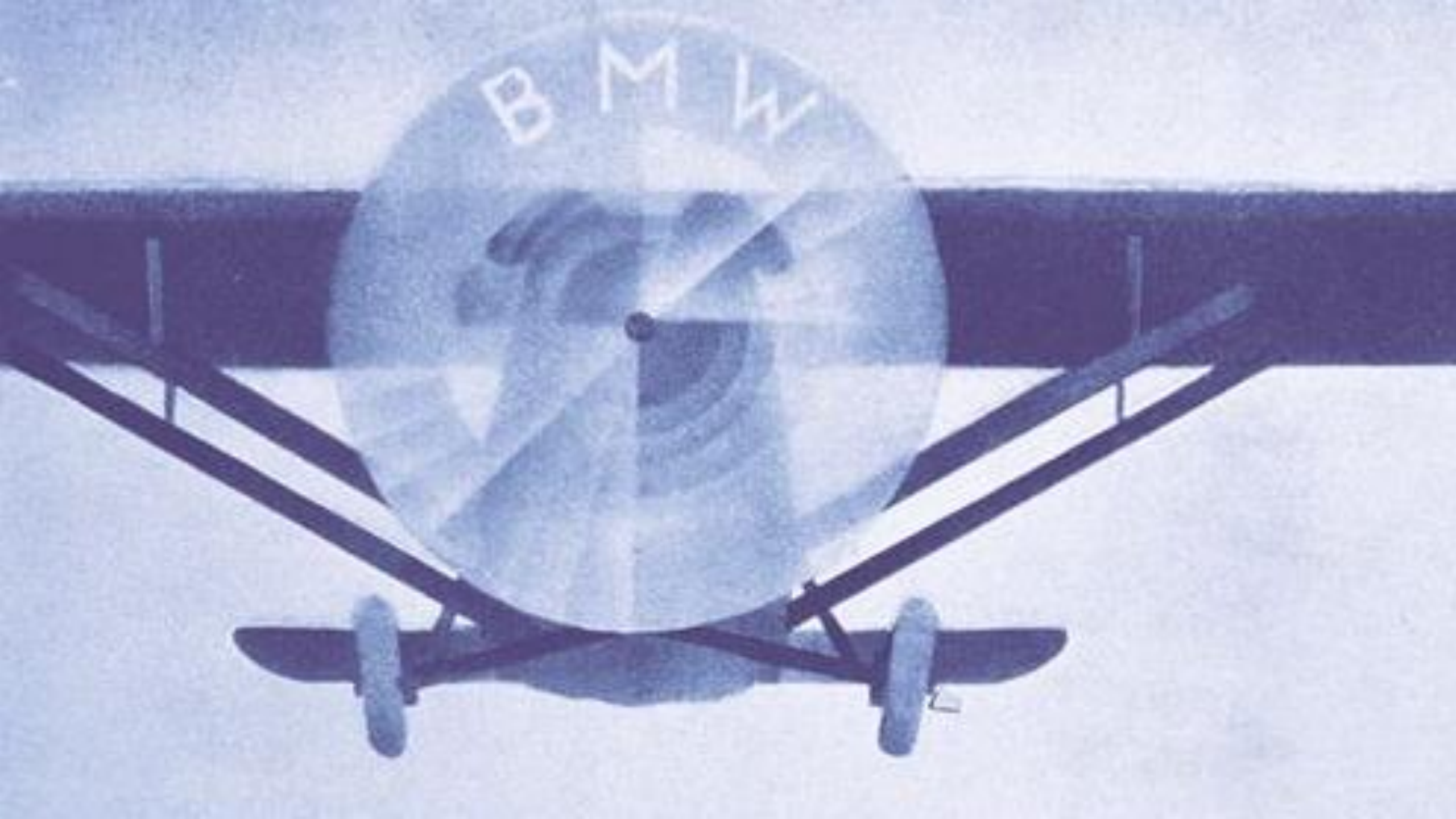
European Medicines Agency





7.03.2013

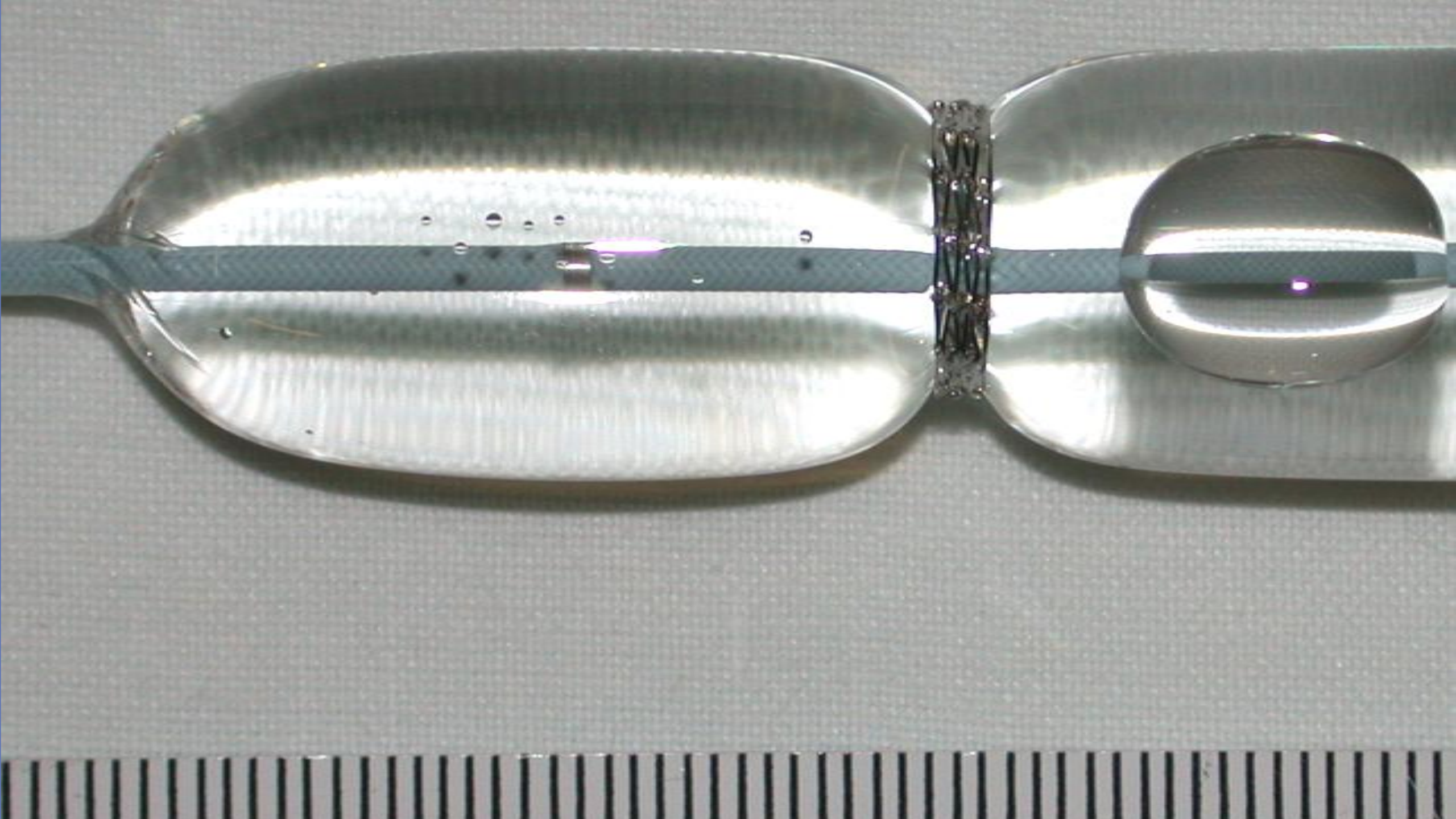


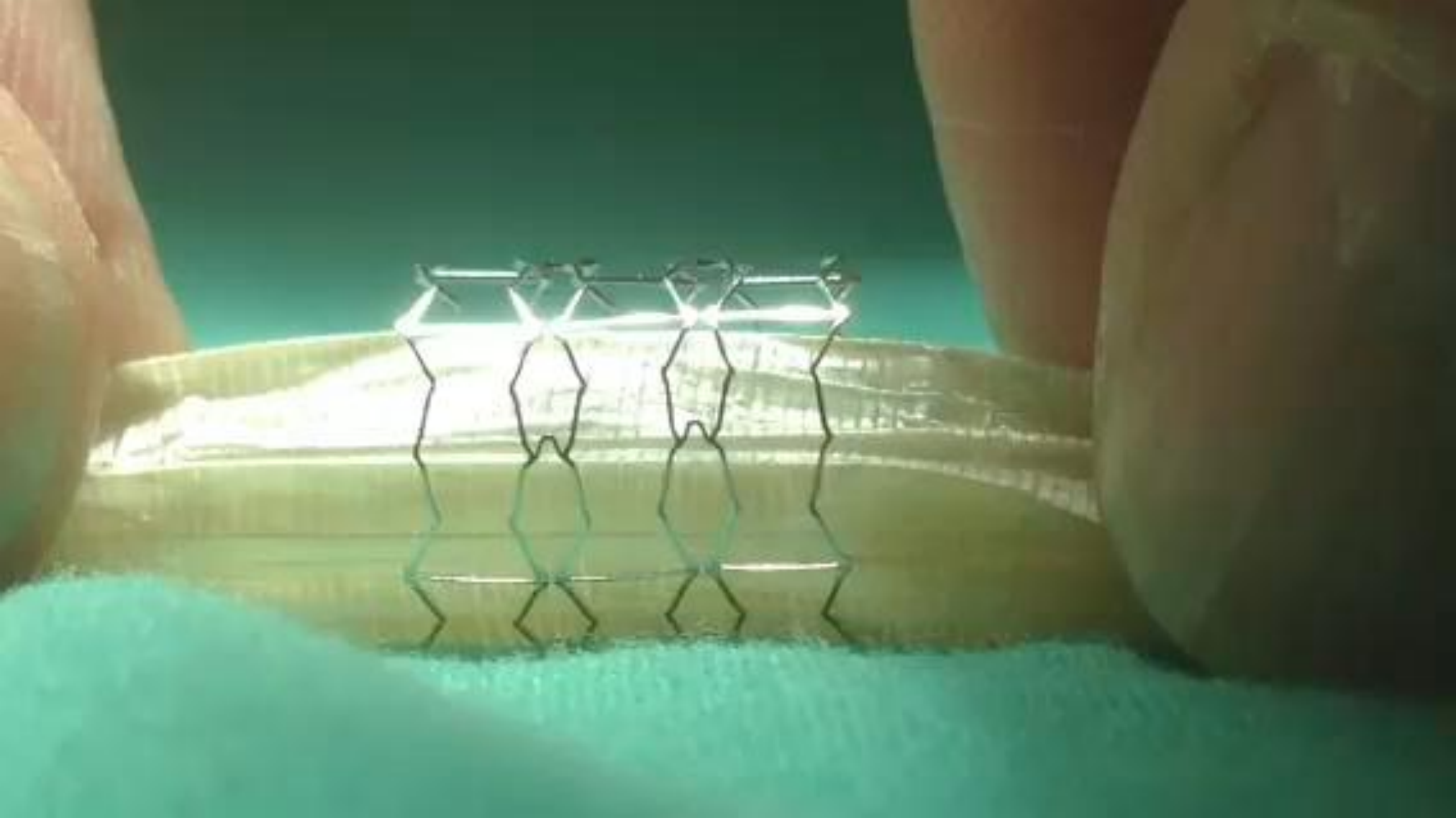














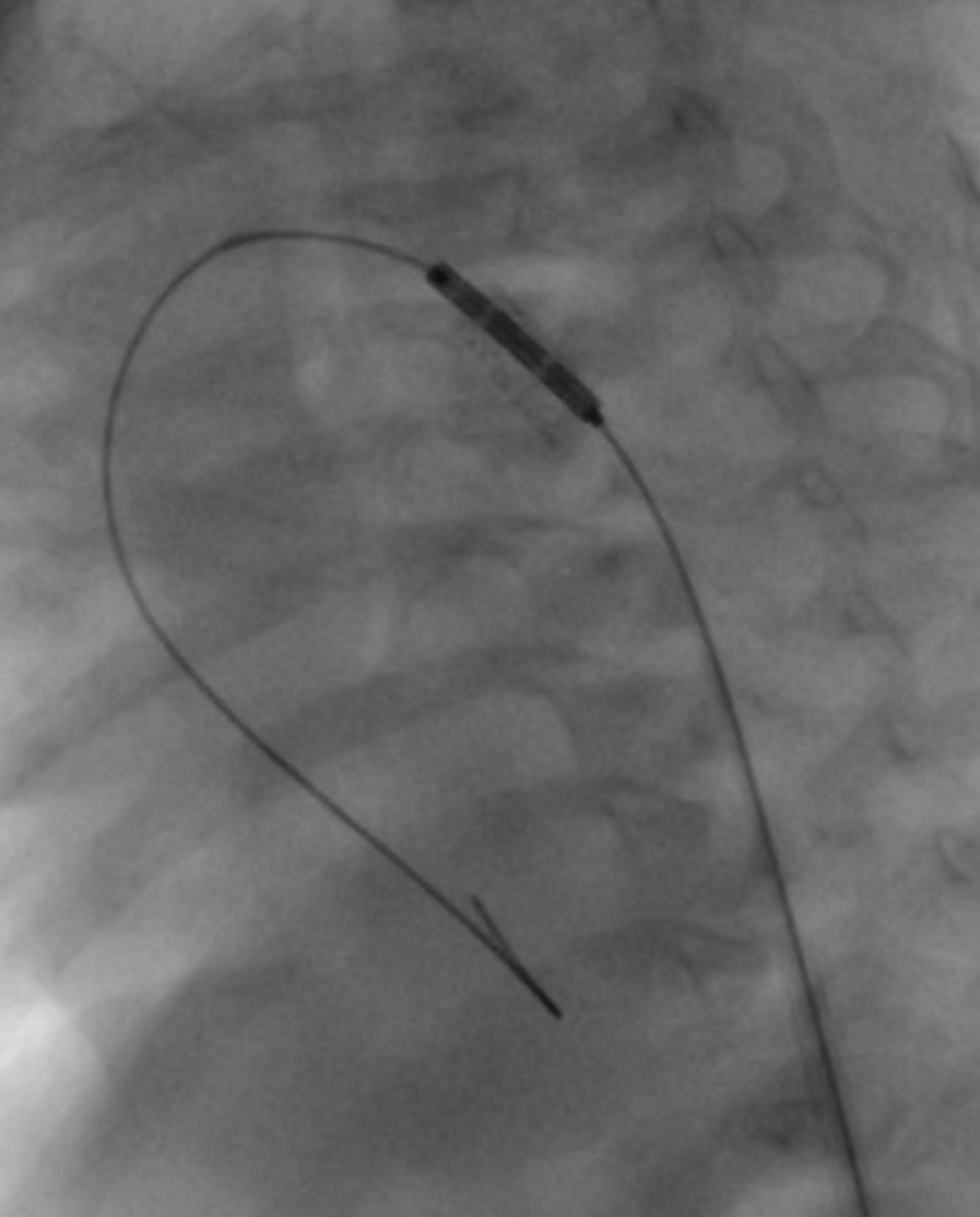
Preterm infant
715g BW

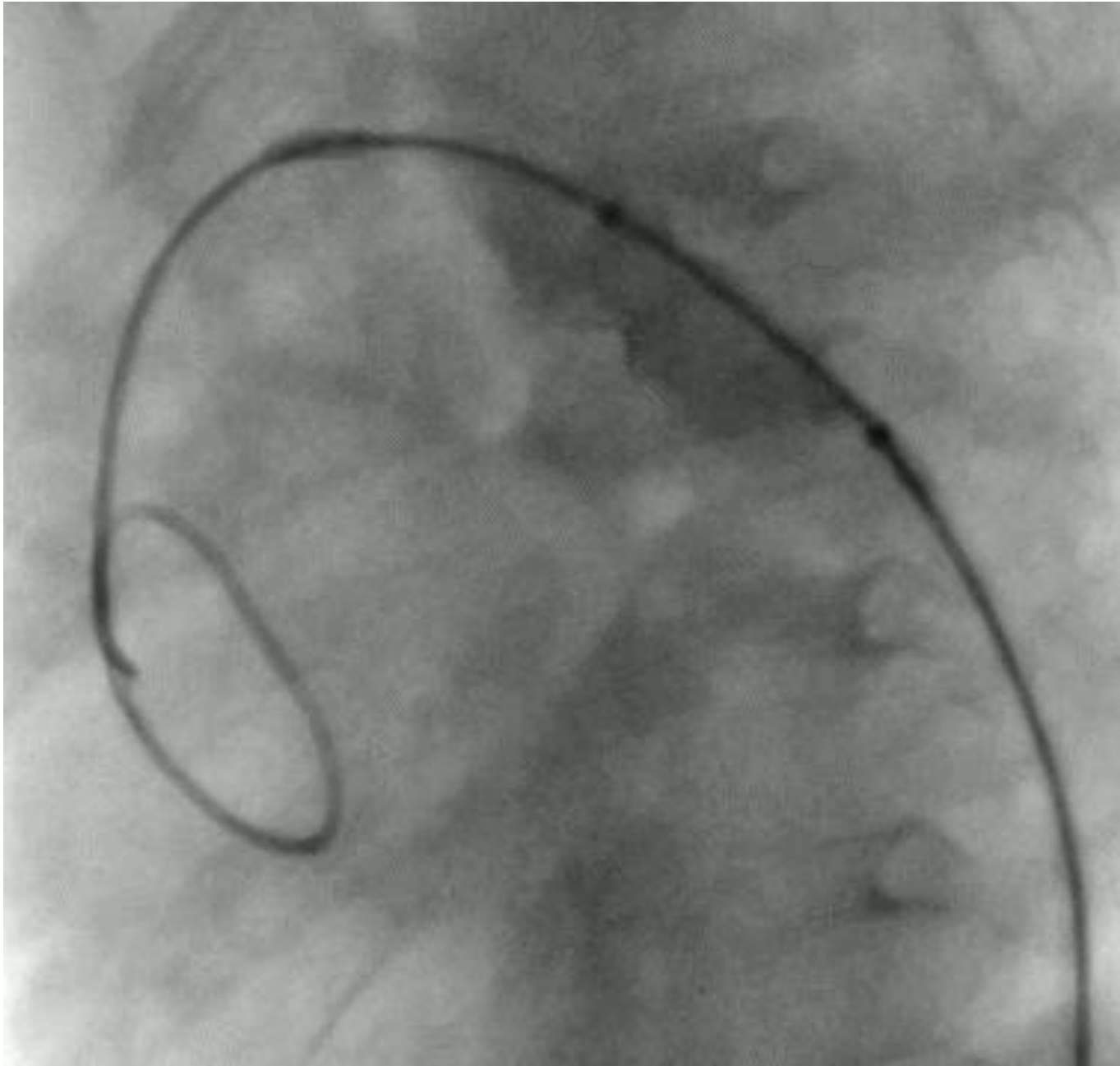


Preterm infant
715g BW

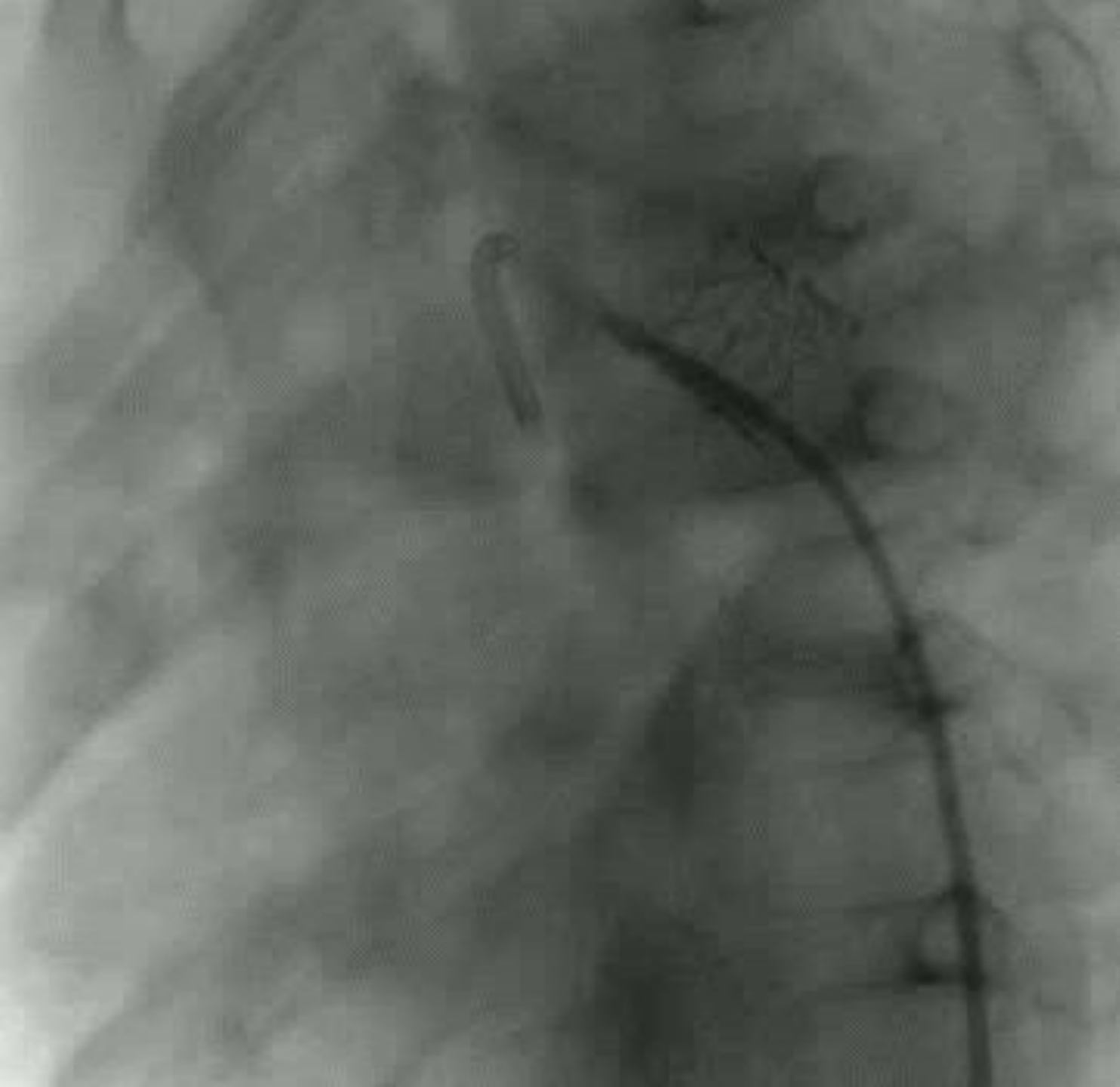


**Preterm infant
3 months later**

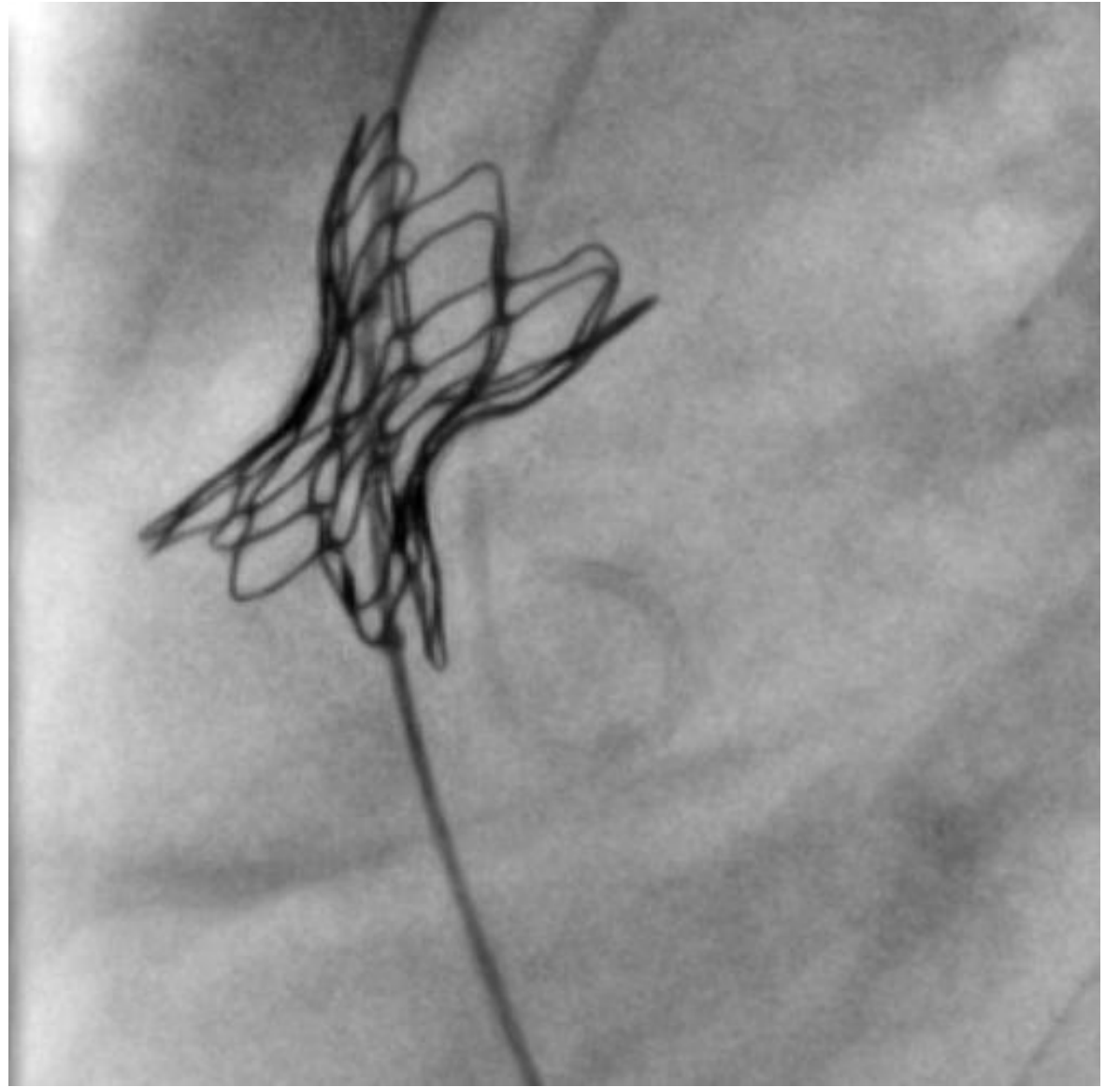
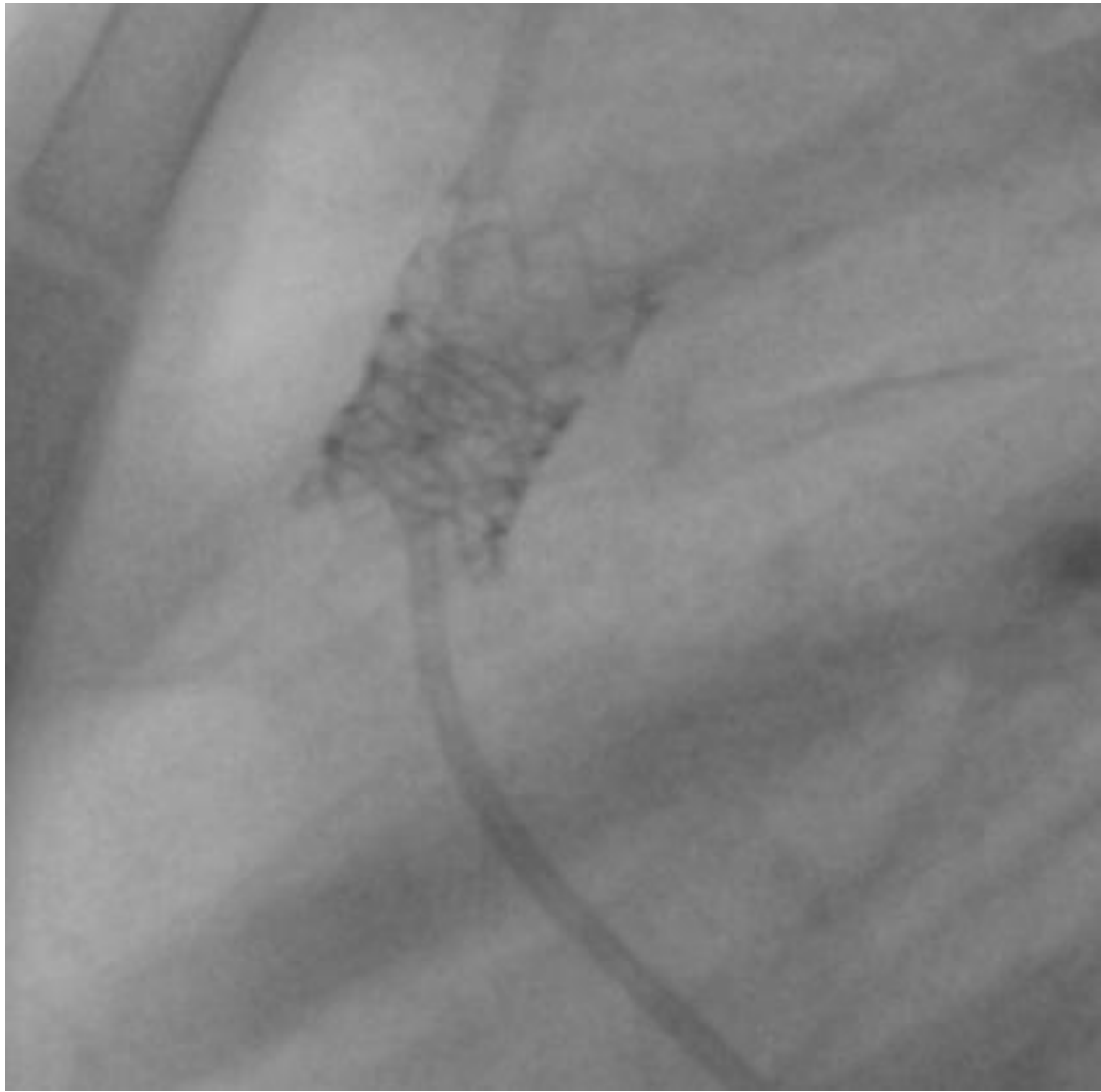




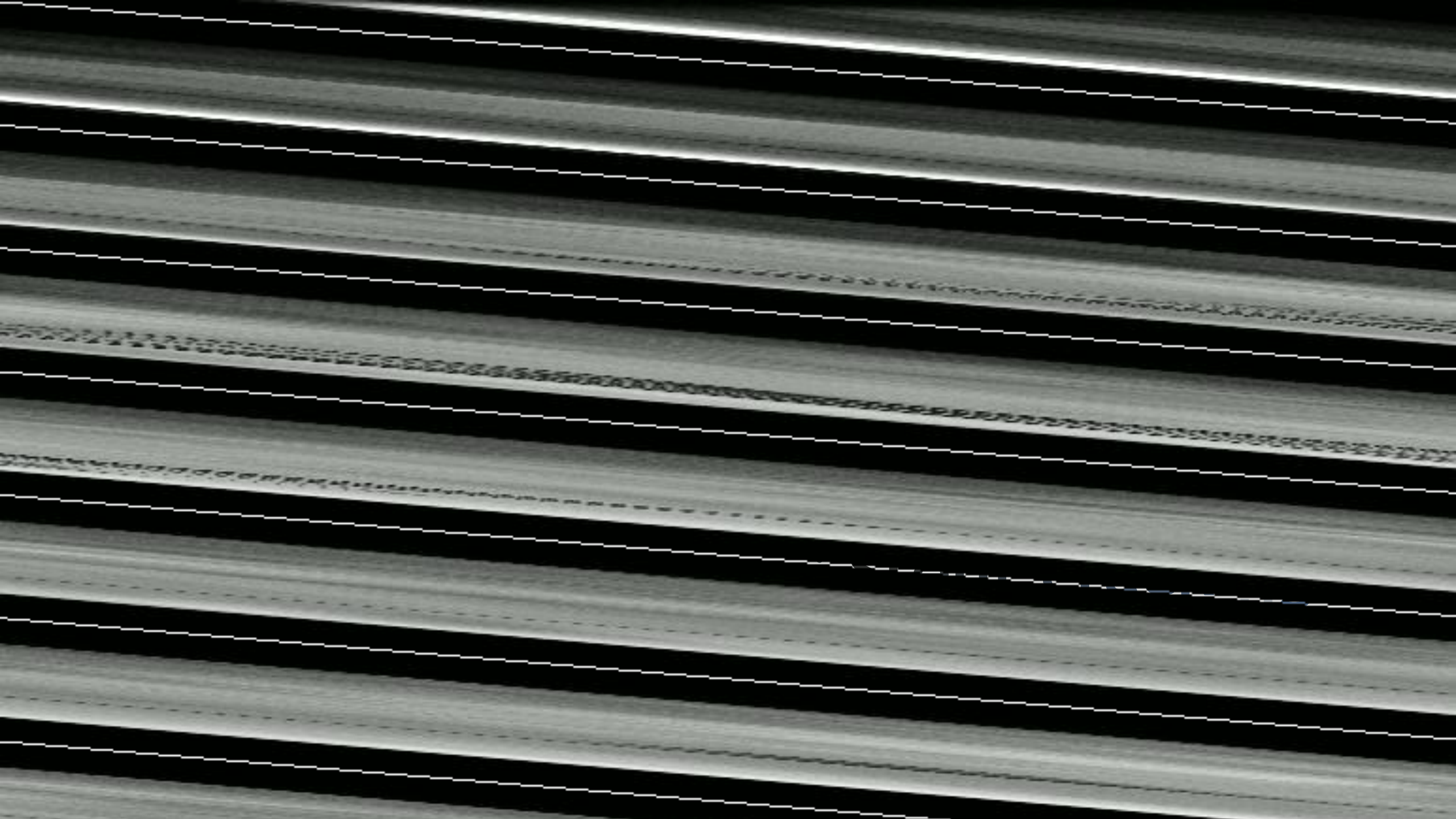
**Preterm infant
15 months later
7.7kg BW**



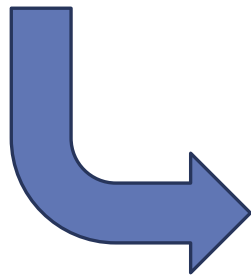
**Preterm infant
15 months later
7.7kg BW**



Valeo Stent in Palmaz Blue covered CP-Stent

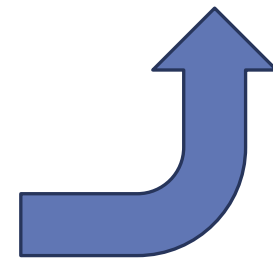
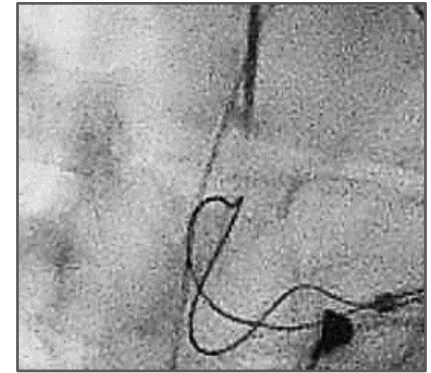


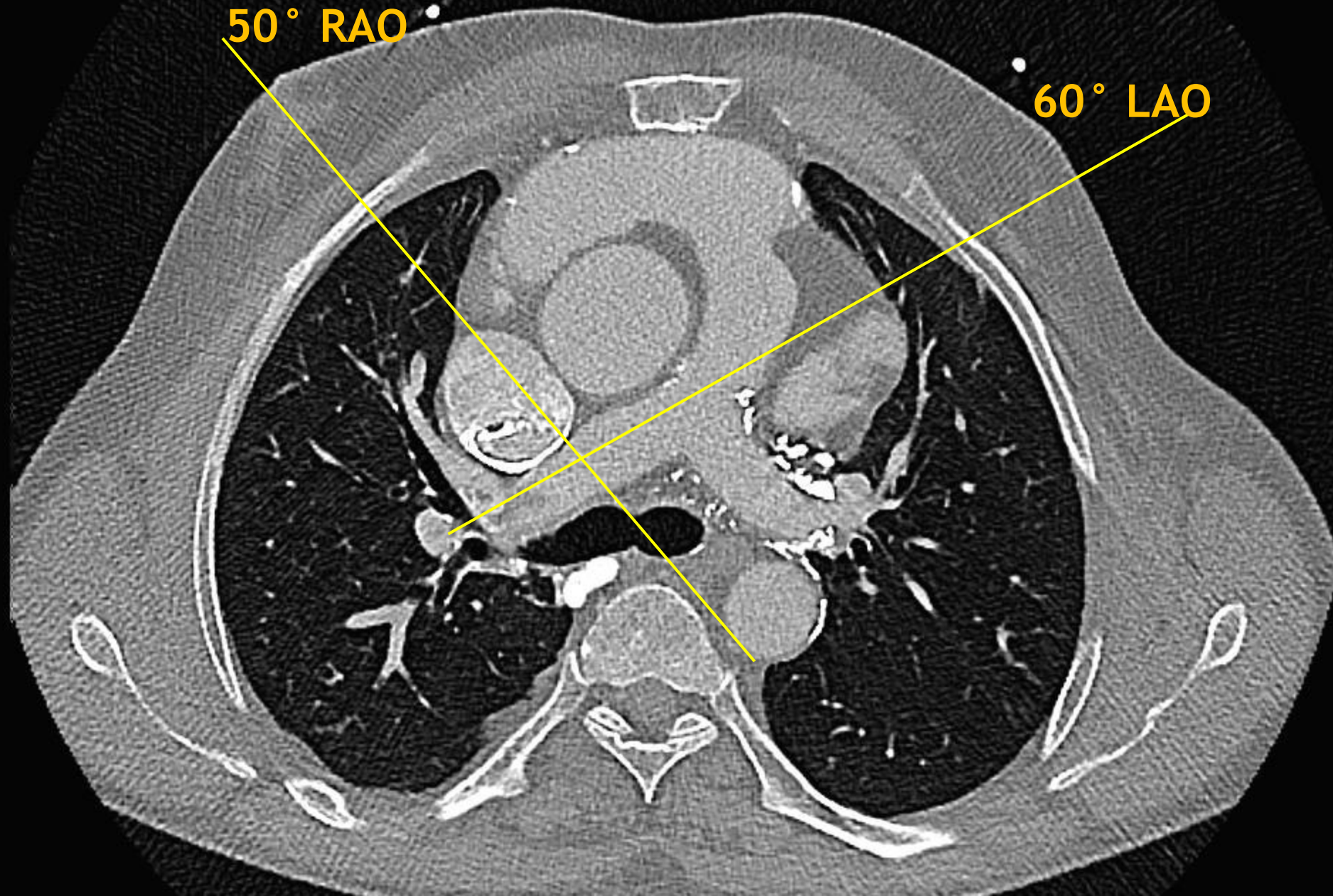
CT Scan



Development of the Transcatheter Strategy

**Transcatheter
Procedure**





50° RAO

60° LAO

FI_Cor_CTA 0.5 Bv36 3 65%
30.07.2021
10:08:21
SP F459,3

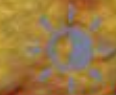
RFP [3]
[5] Punktionsstelle
||
[6] Punktion Stent

Manip Clip VRT
+C
KV 100
mAs/rot. 478
Bv36.3
P +90%
HR 62 BPM
RAO 5
CRAN 71
M 512x512

KM i.v. 70/3.5 50/3.5
52 bpm, 79 %, 66 ms

Aorta

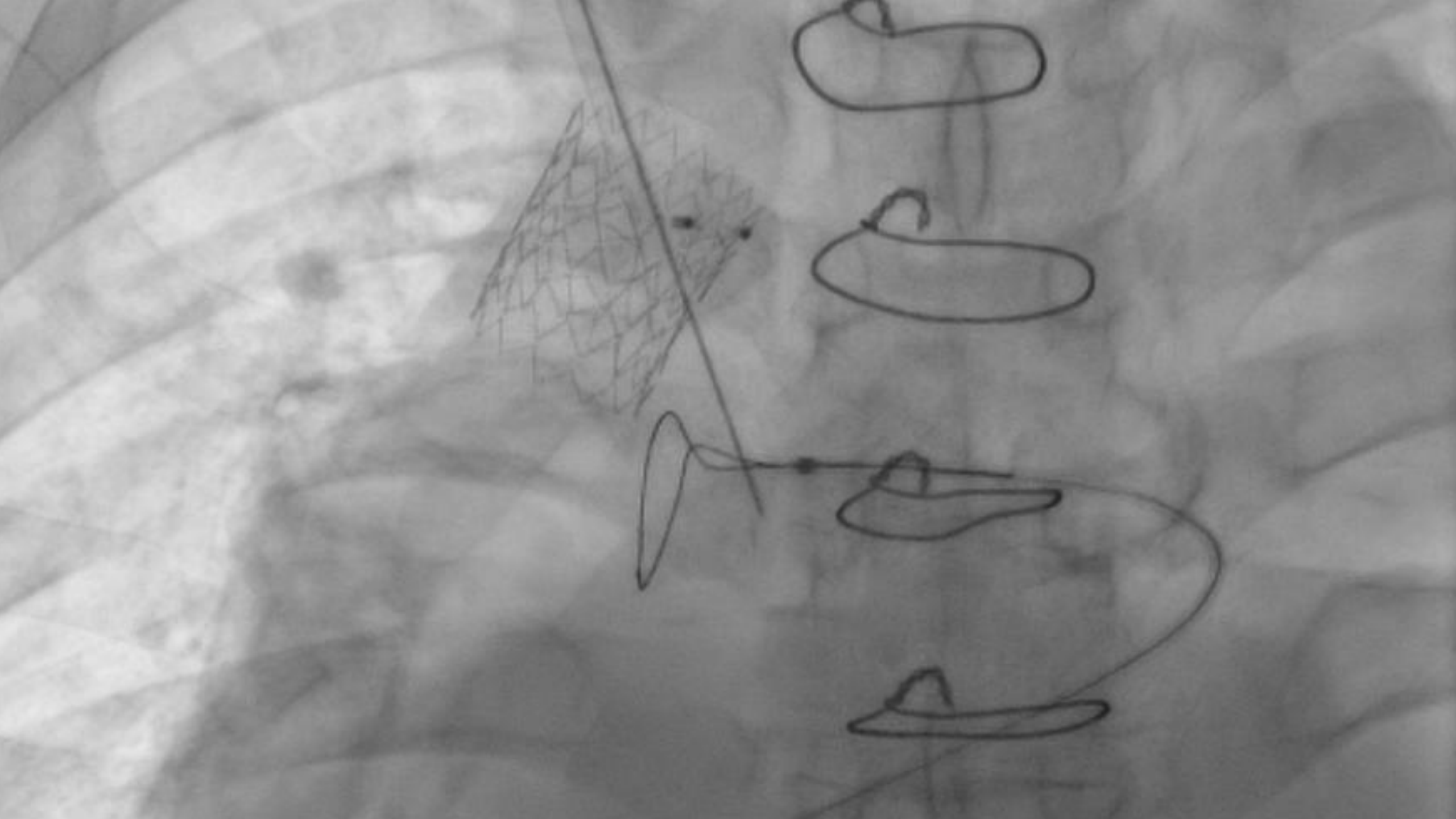
5cm

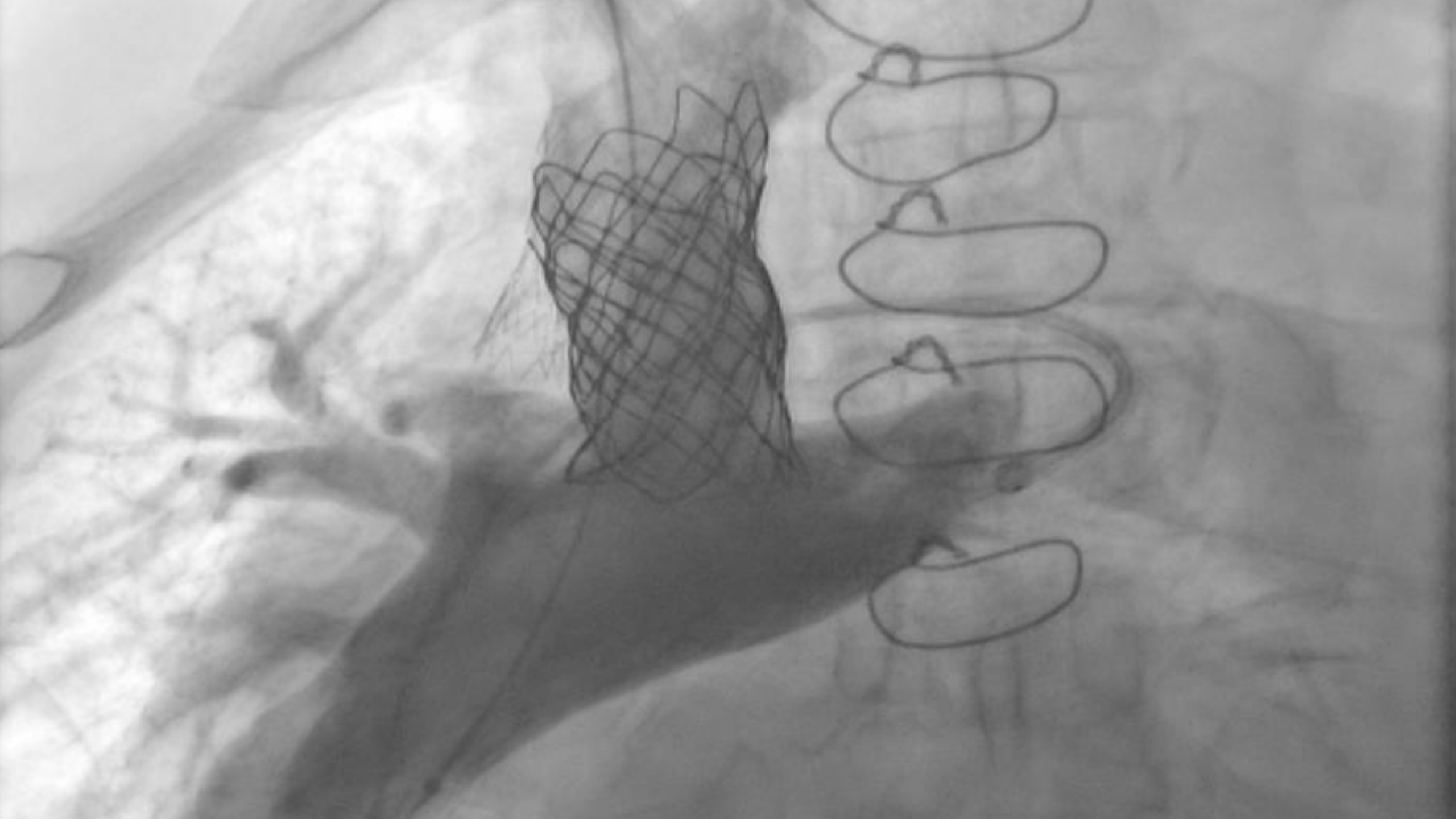


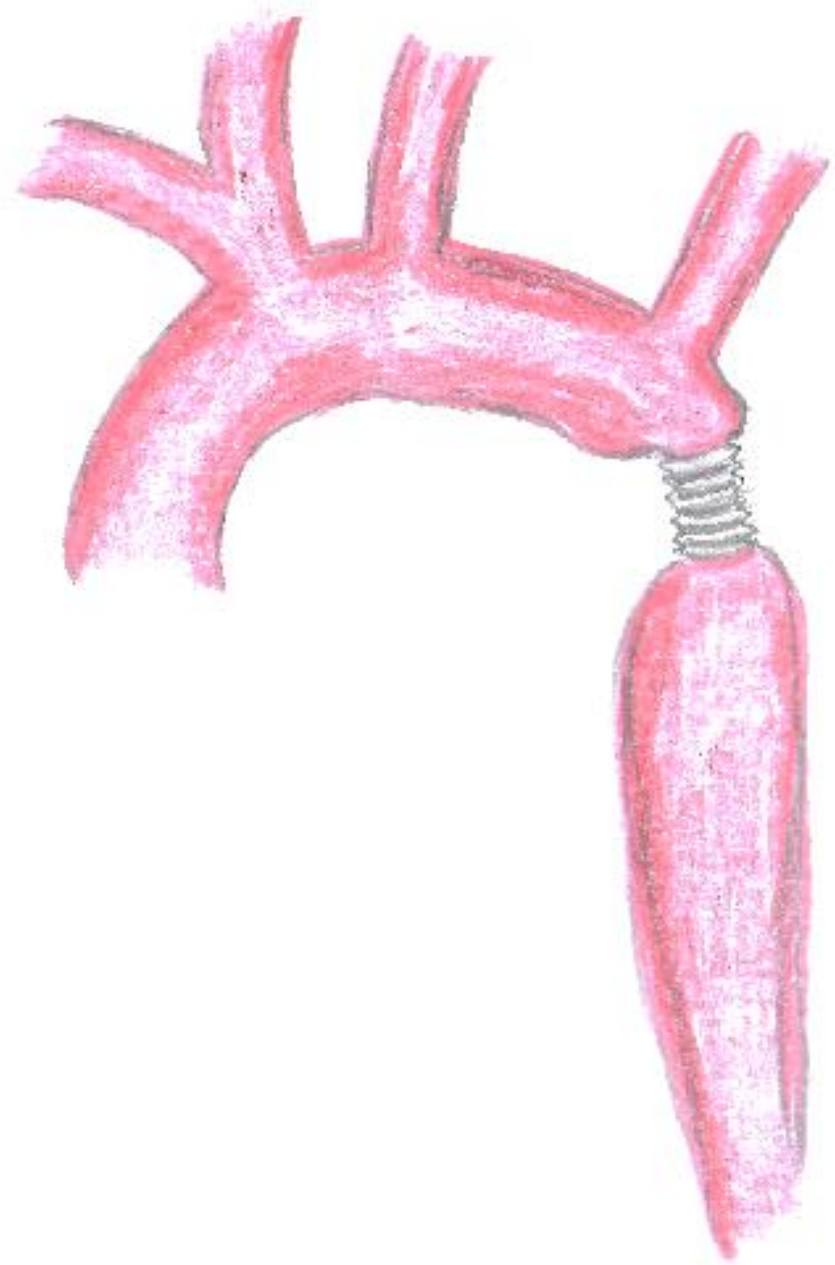
cking



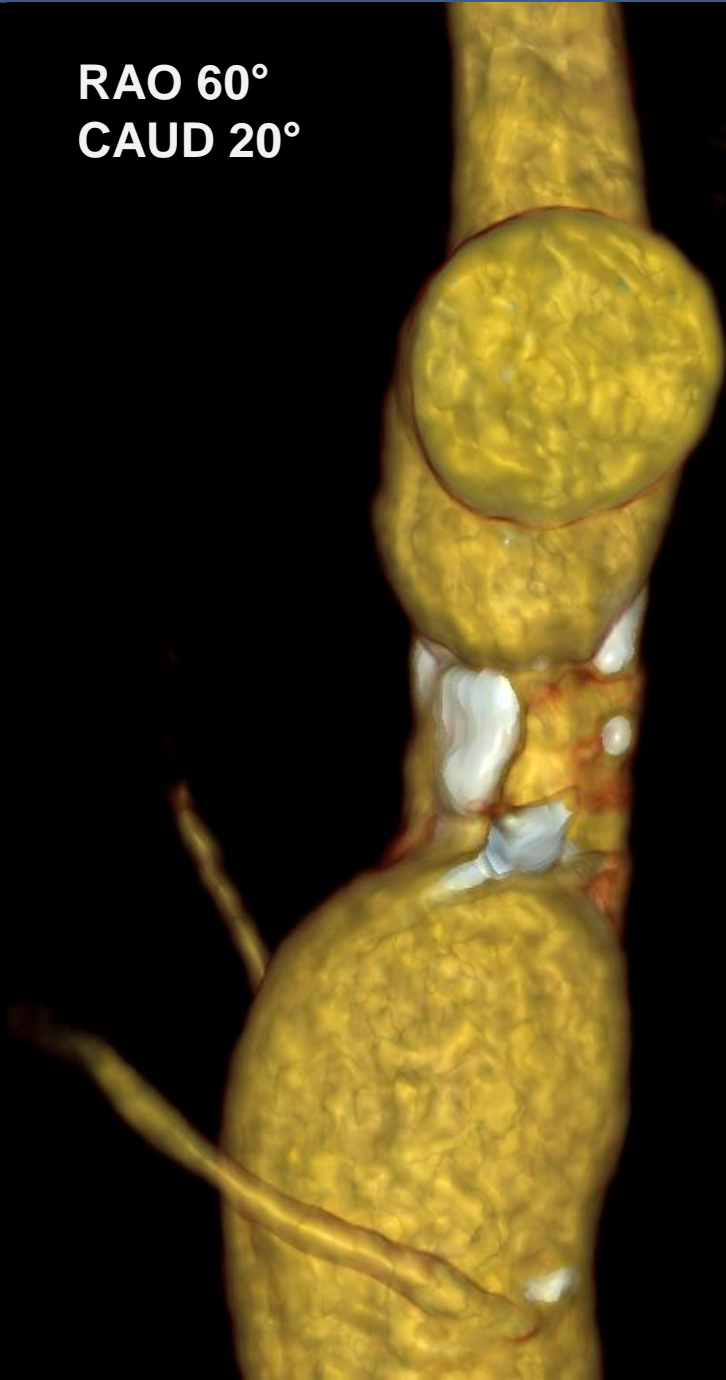
SOS







RAO 60°
CAUD 20°



LAO 30°
CAUD 30°



8652
.12.1977, M, 42Y
RRENT
04.2020

Deutsches Herzz
Ref.:
syngo.via

49S01P000331127
36.43.86
H60,2

PHL

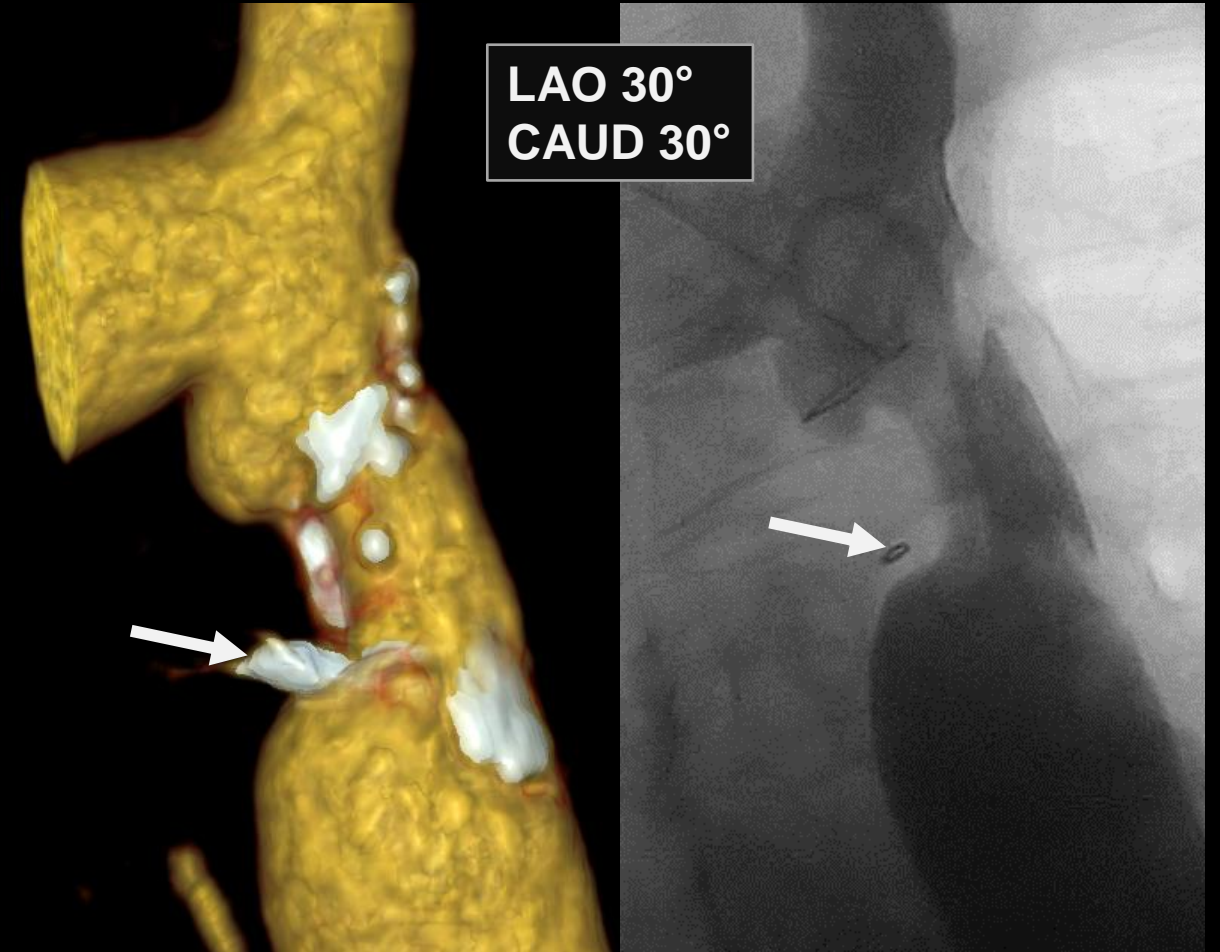
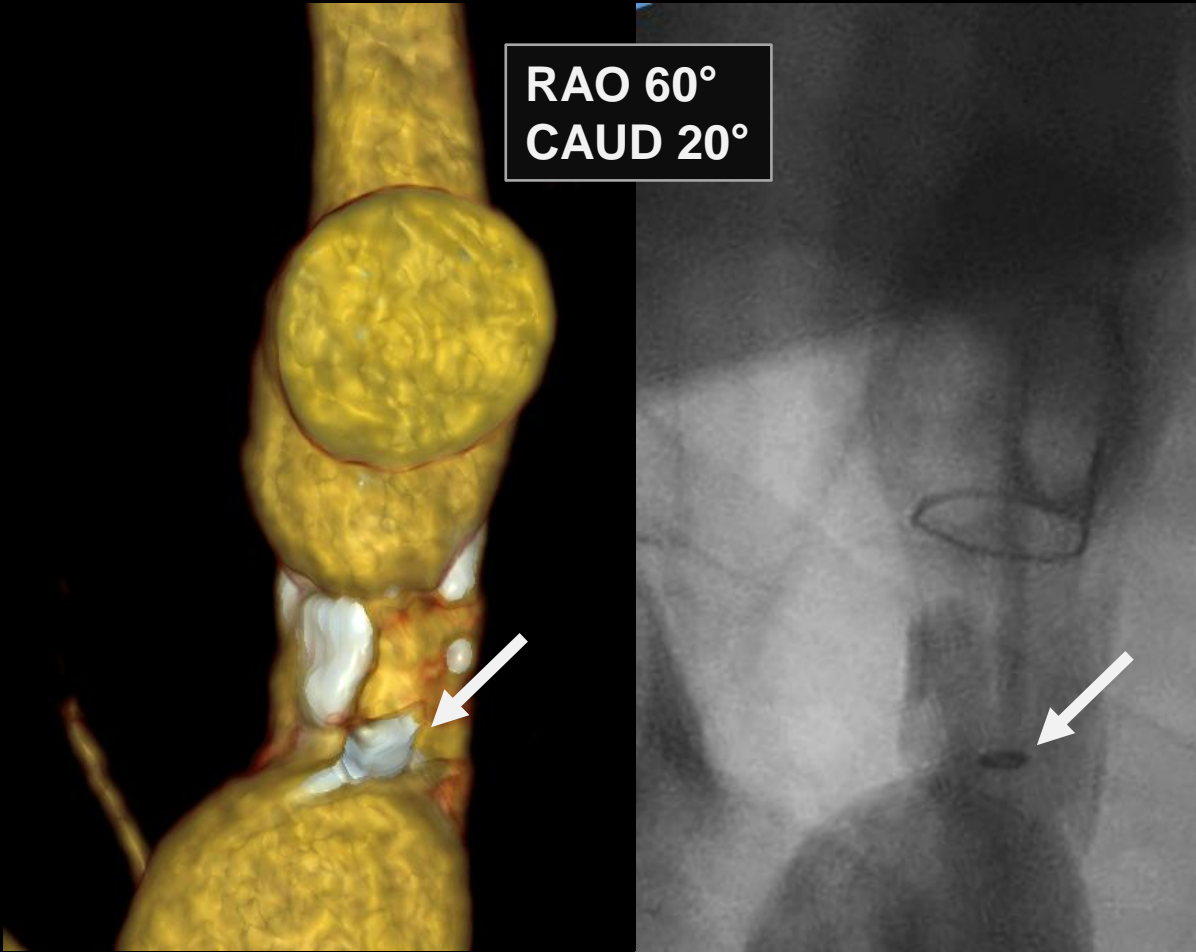
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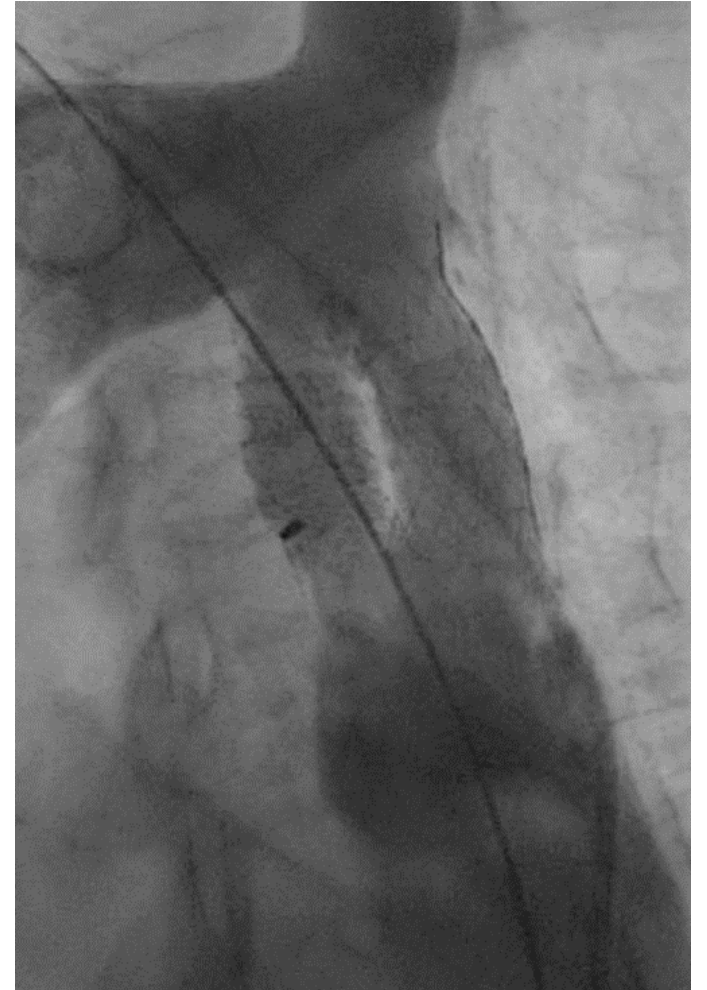
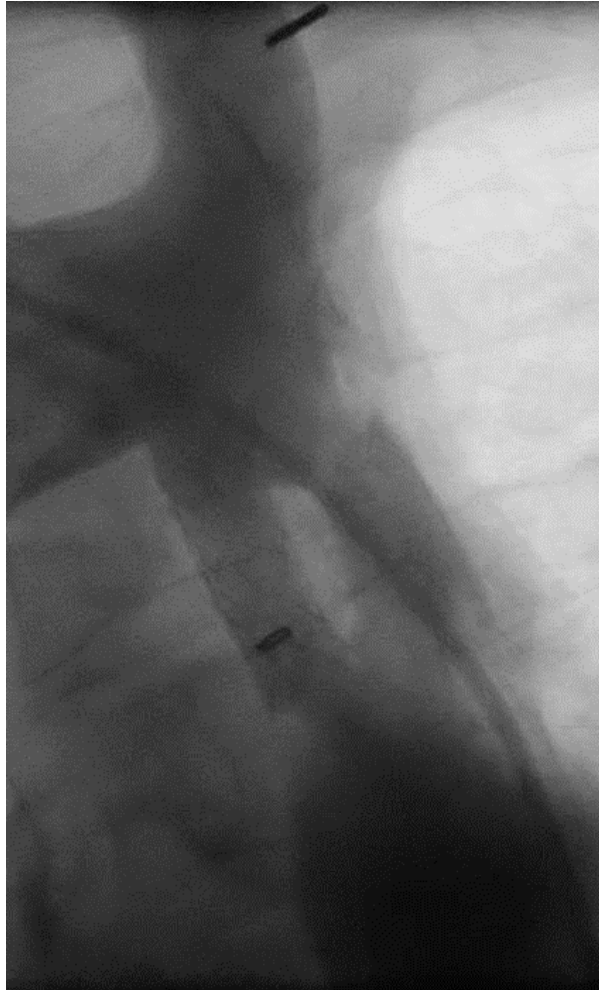
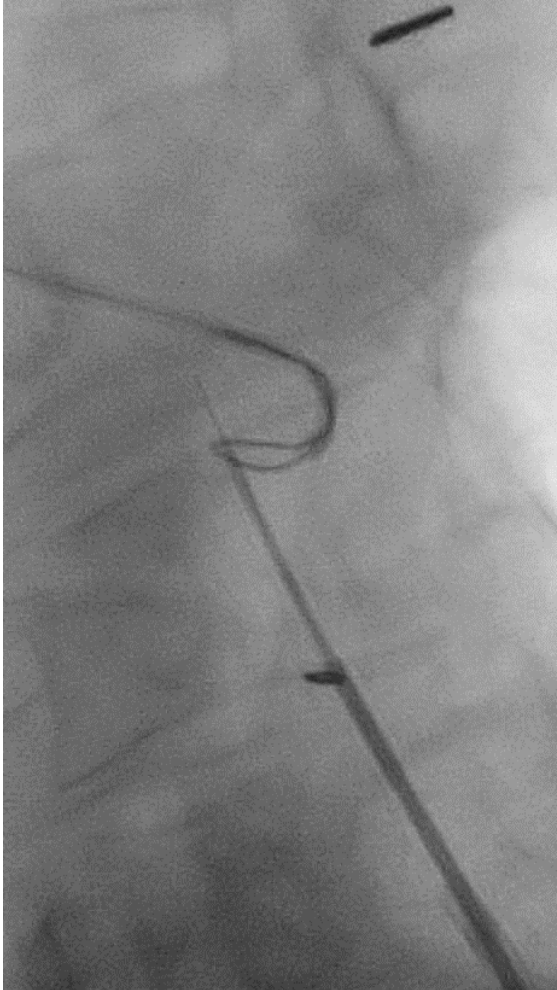
nip Clip VRT

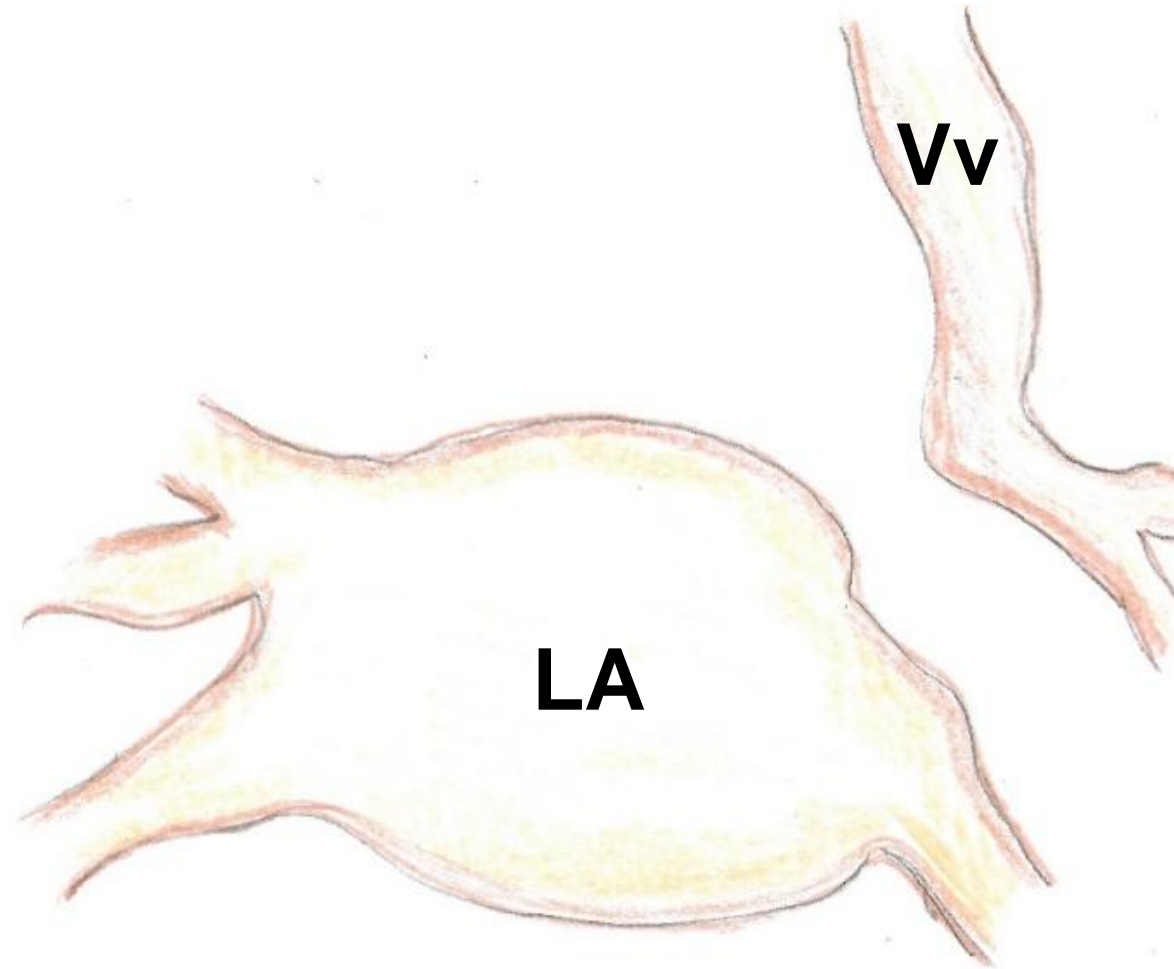
KMI.v. 70/4 60/4
88 bpm, 45 %, 66 ms

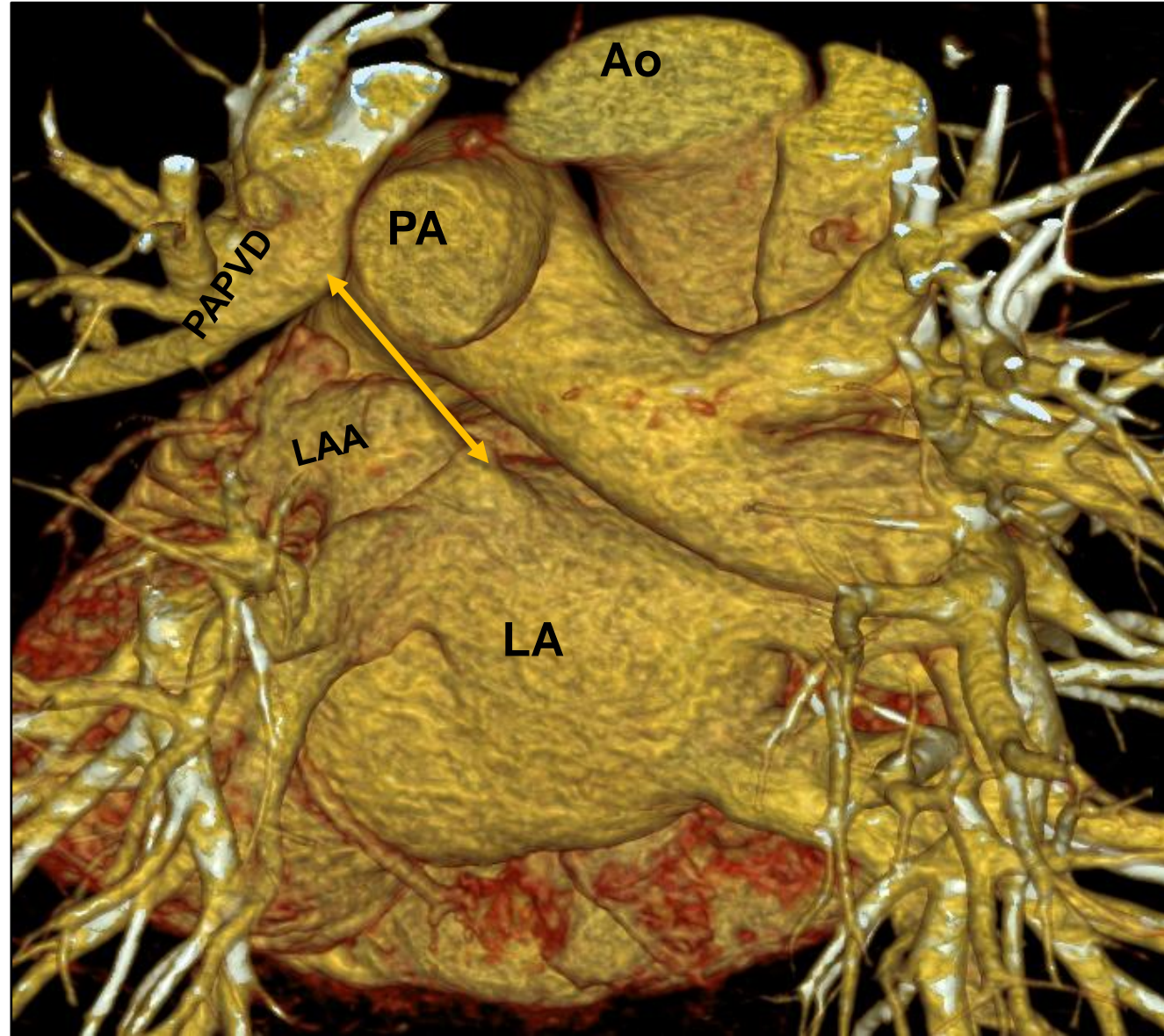
[12] o.p.

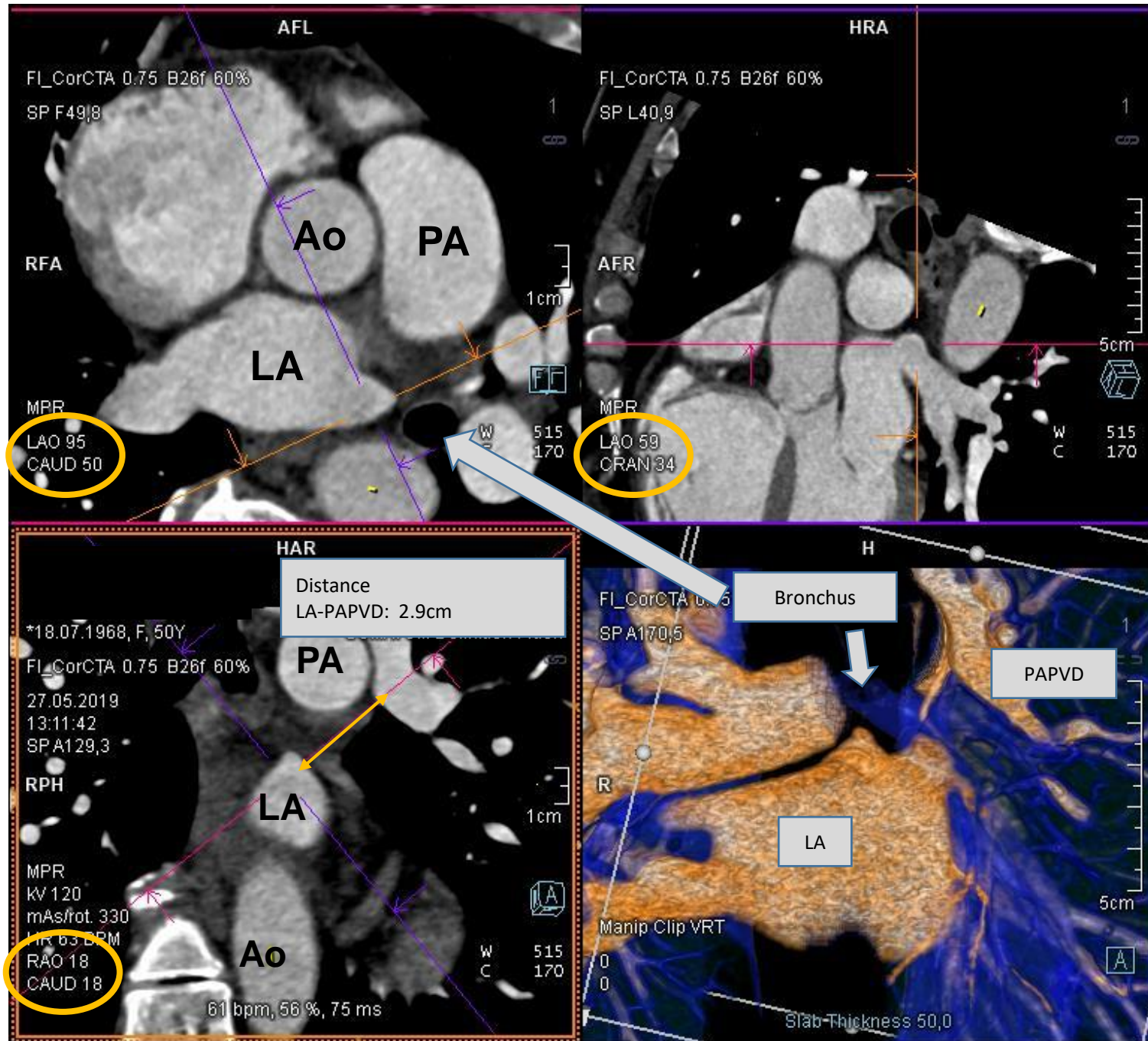


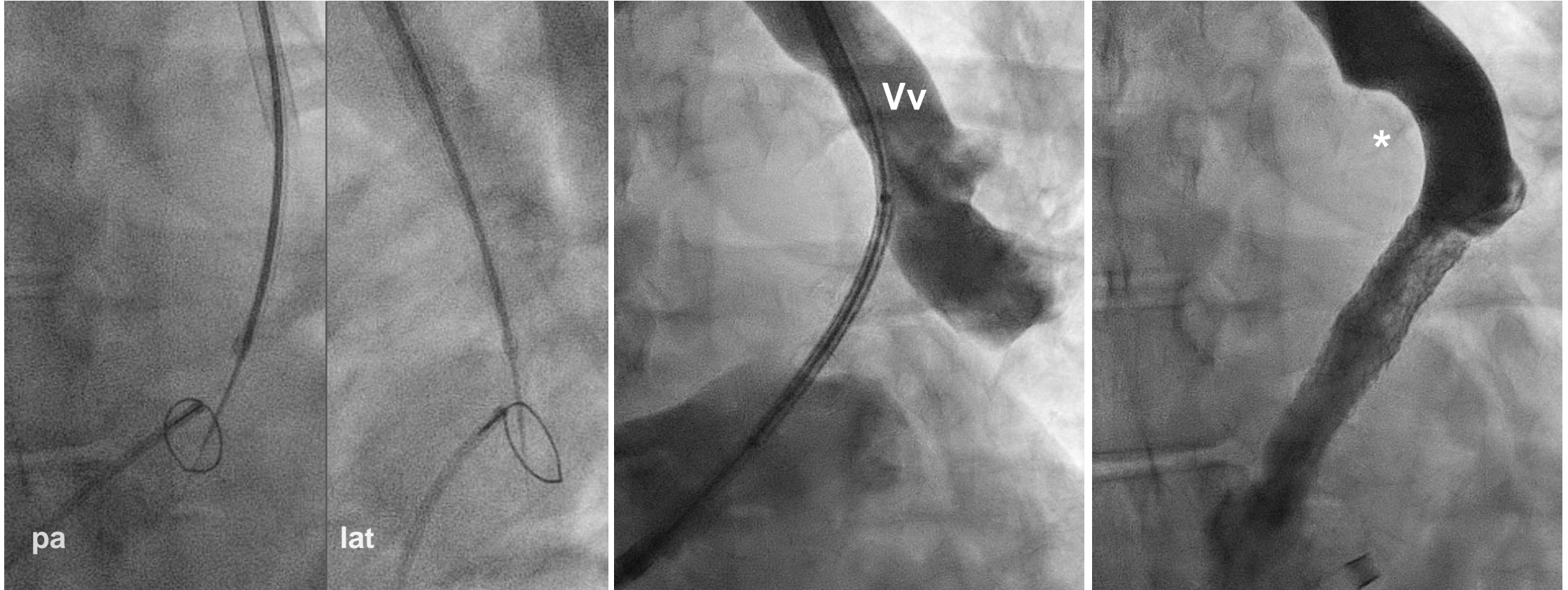


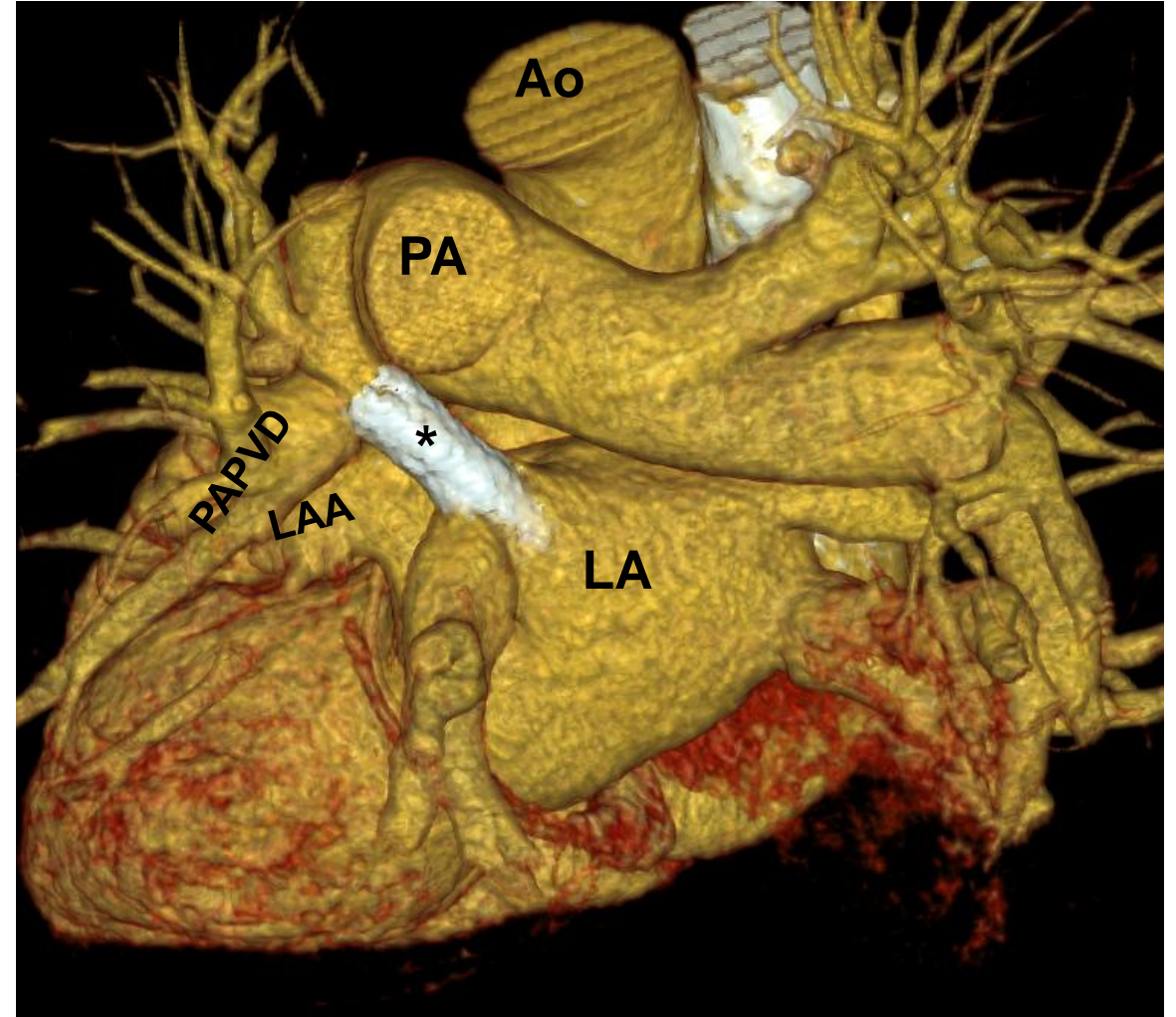
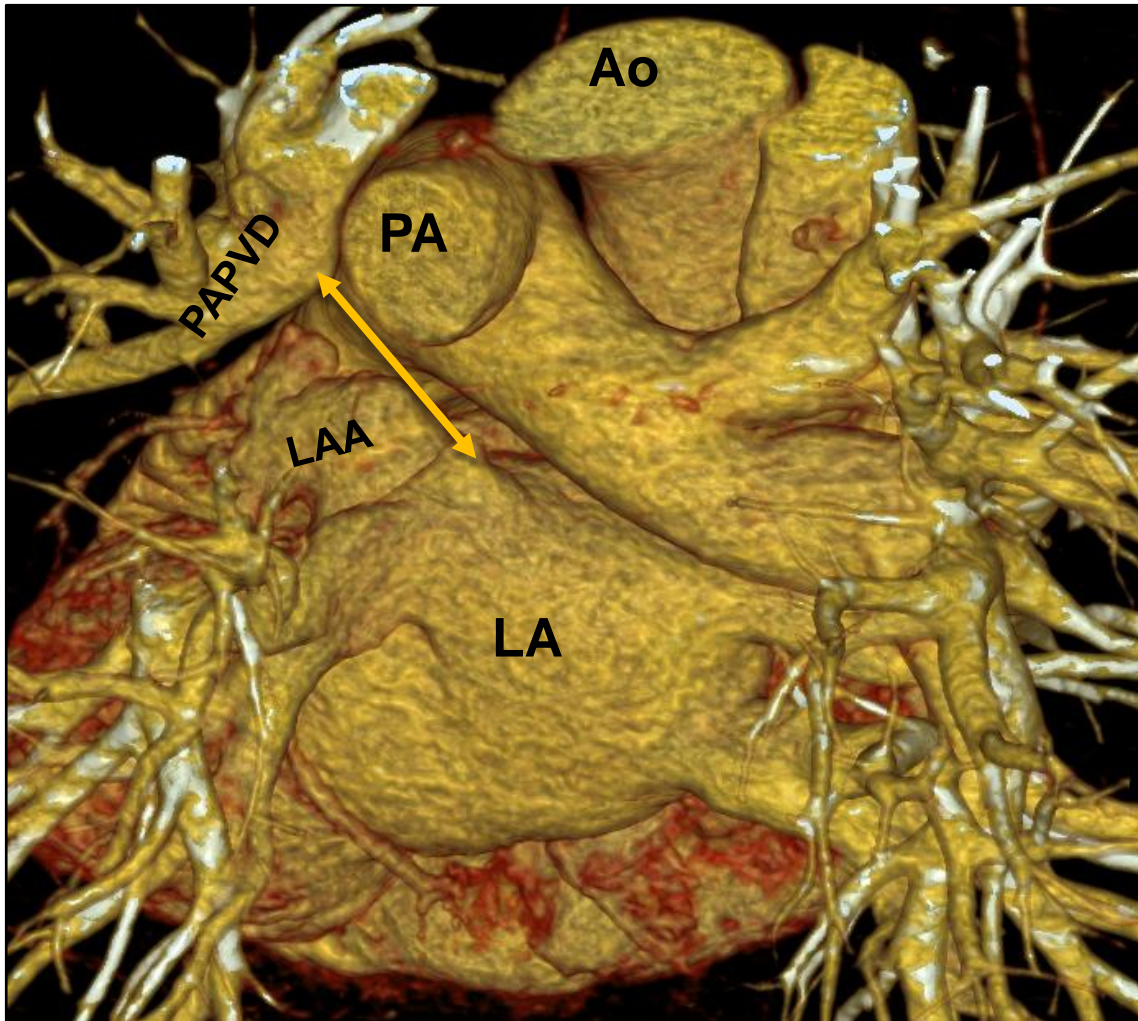


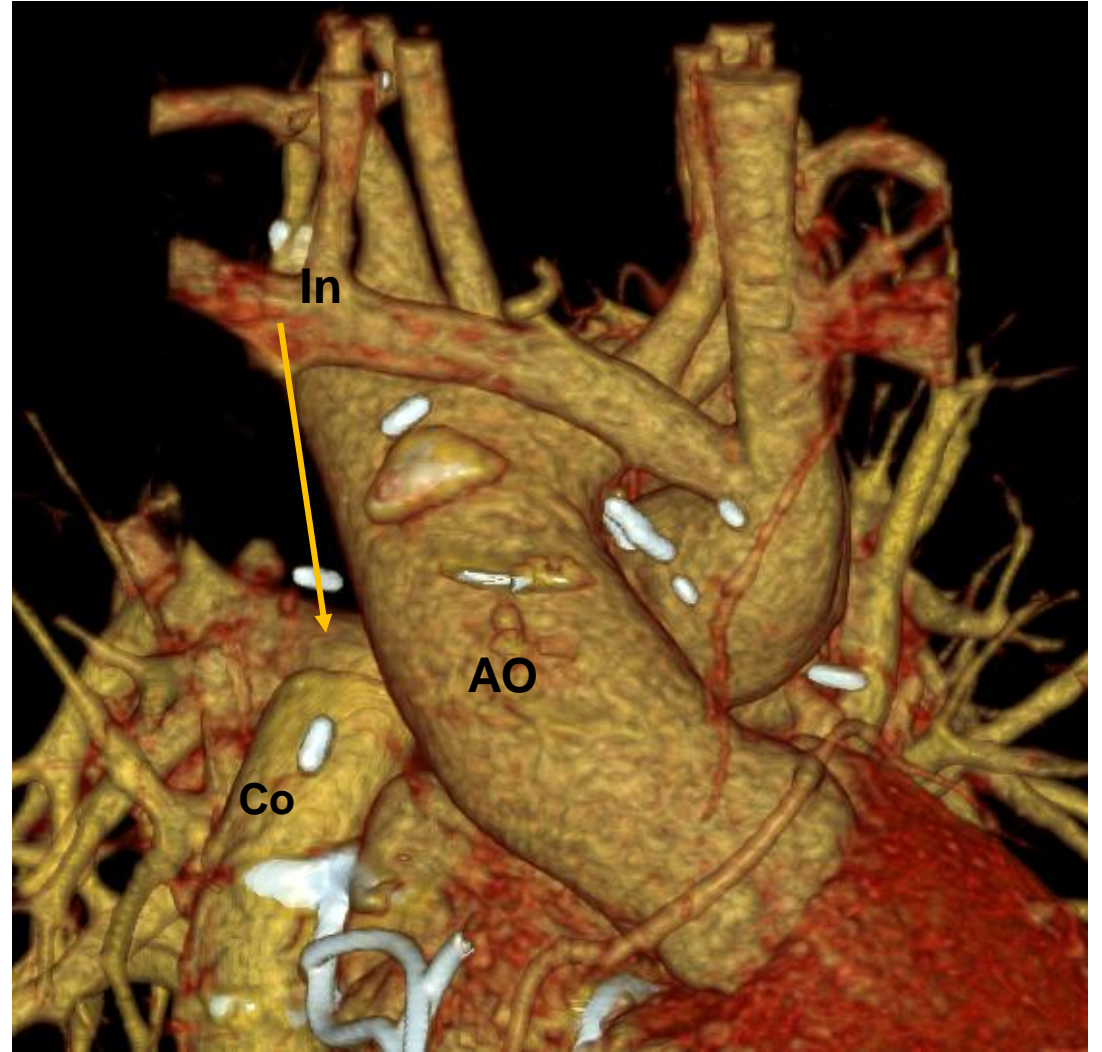
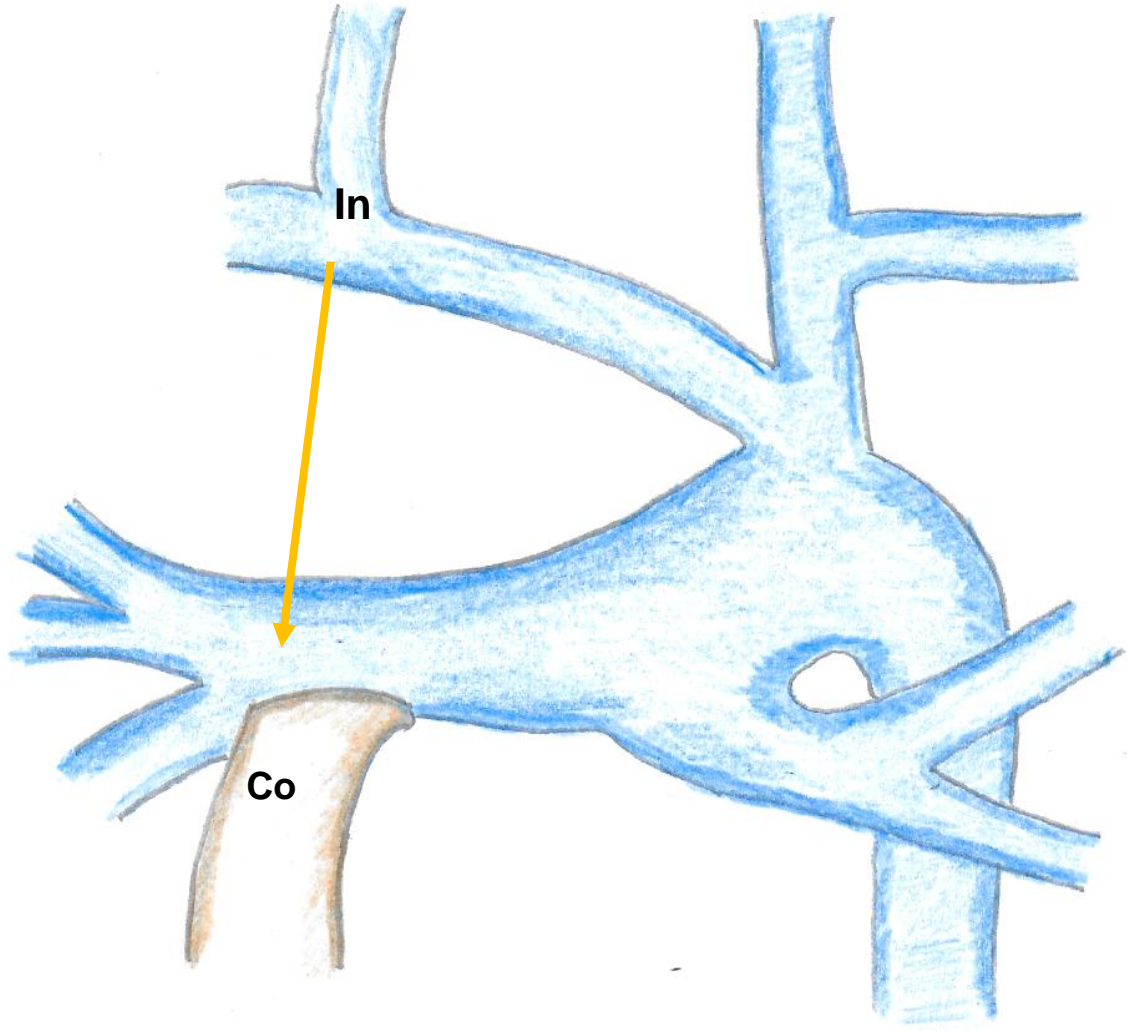


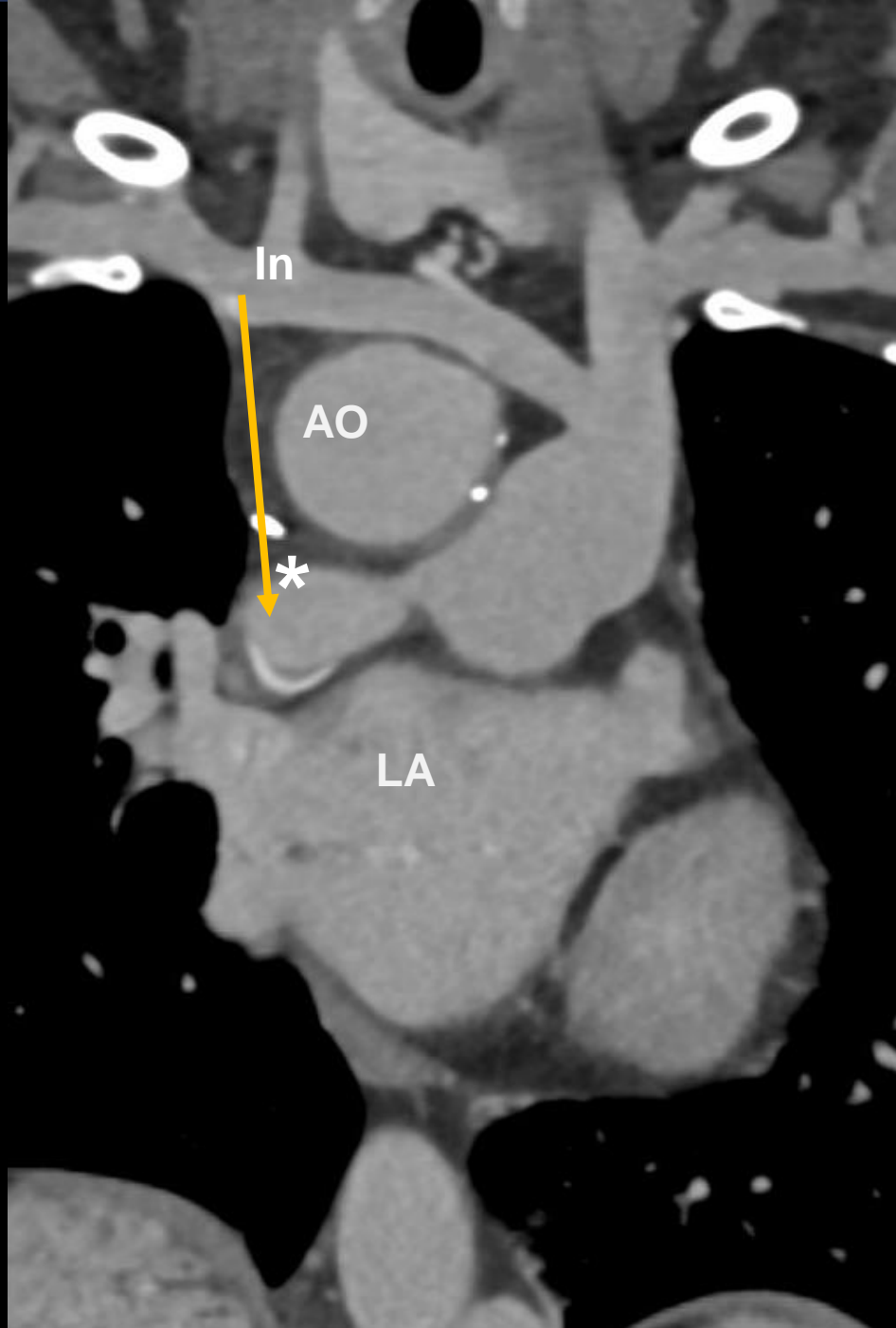


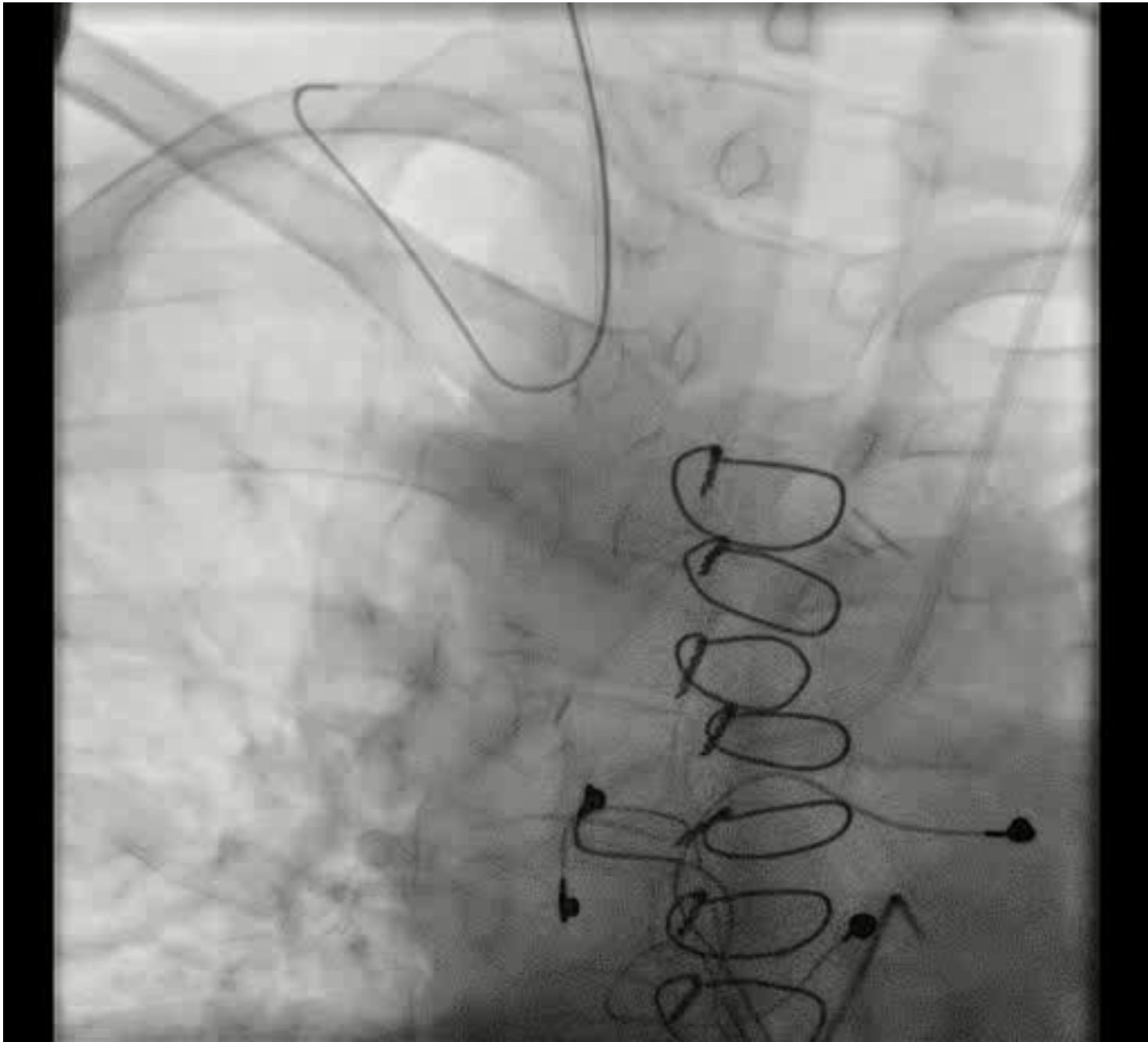


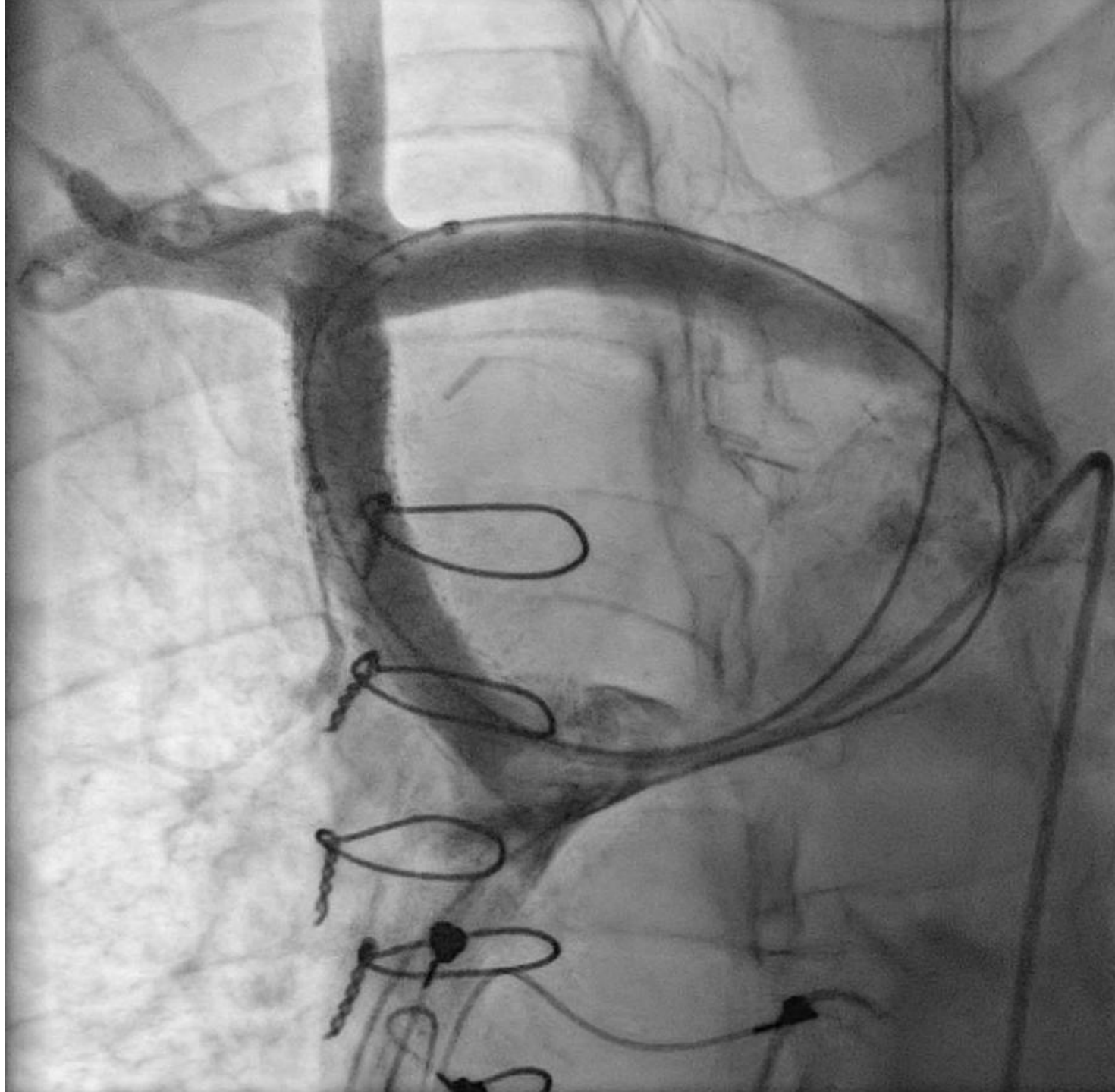


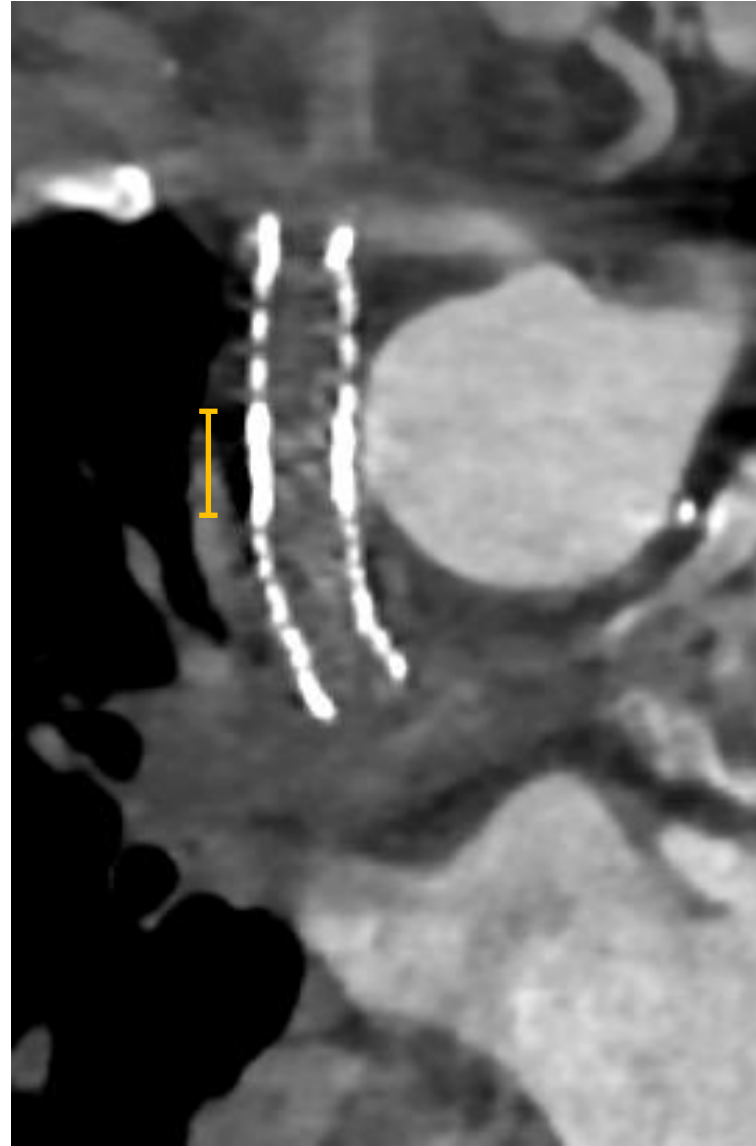
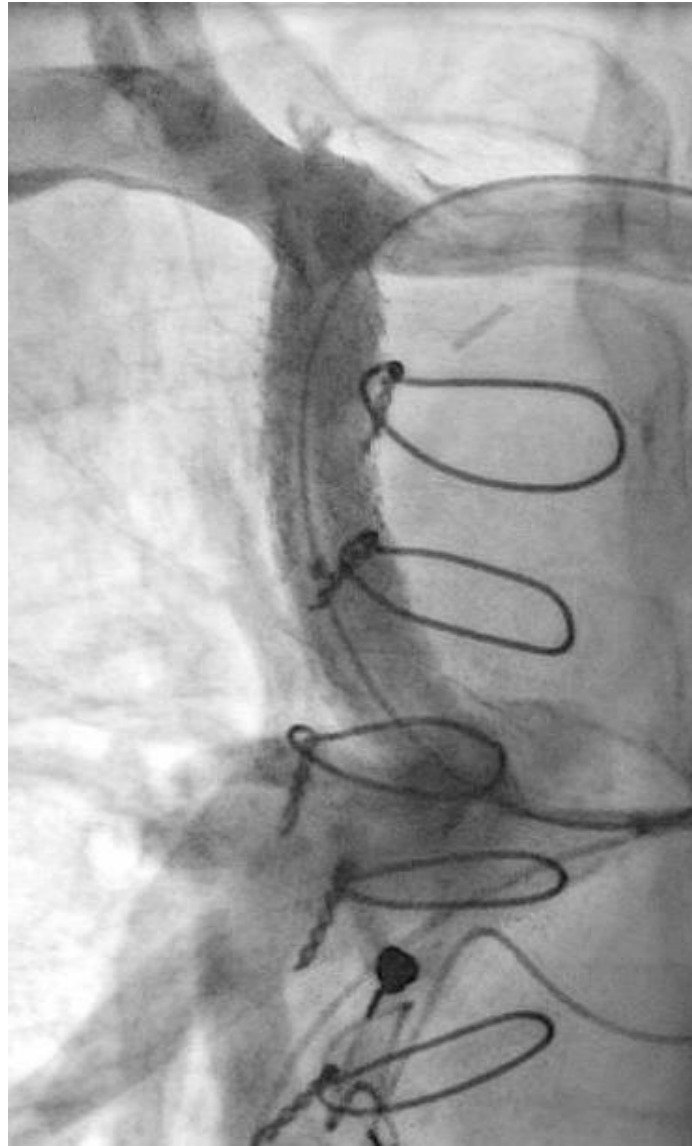










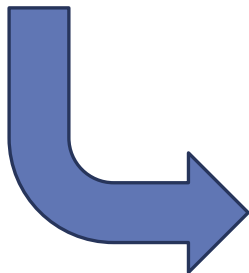


Extravascular Implantation of Covered Stents

CT Scan

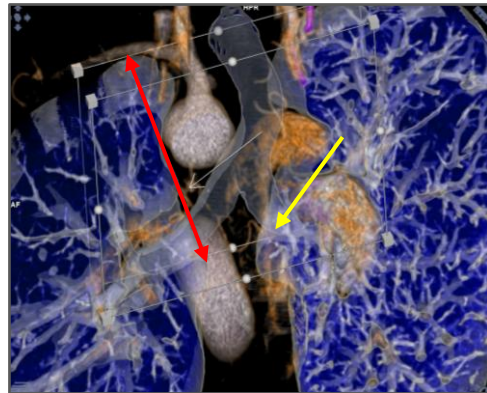


3D Dataset



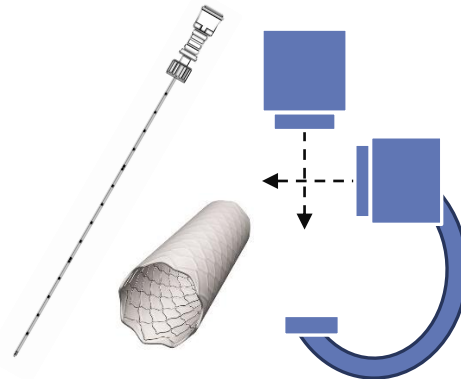
Development of the Transcatheter Strategy

Processing & Analysis



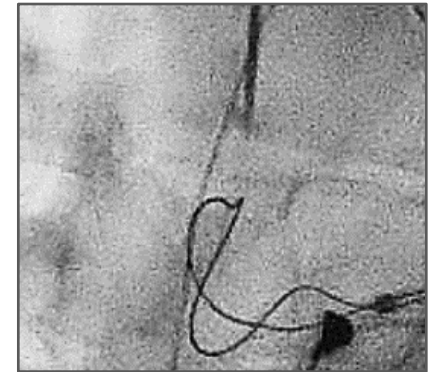
3D Topography
Extravascular Anatomy
Landmarks
Angulations

Equipment & Materials



Fluoroscopic Views
Needle Punctures
Materials
Procedural Steps

Transcatheter Procedure



Extravascular Catheterization



*When others were closing the holes in heart
this man became famous for creating one!*



William Rashkind

How to deal with the MDR as a transcatheter intervention

“...The initial response to this report varied between admiration and horror...”

(Charles E. Mullins, 1998)

Make Lemonade!



How to deal with the MDR as a transcatheter interventionalist?



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