TAVR in Hong Kong – SAPIEN 3, Acurate Neo 2 and Evolut PRO+

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Disclosure

- Conflict of Interest – Nothing for Disclosure

TAVR in Hong Kong - Overview

Background Information

- Population = 7.7 million
- Special Administrative Region of China
- Medical System
  - Predominantly Public Hospital/Government Funding
  - Selected self-financed medical items
    - Eg. Balloon, OCT, IVUS, DES, PPM, Micra, ICD, TAVI, septal occluder, LAAO, Impella, Embolic Protection
- Patients
  - Local Hong Kong Residents
  - Referral from Mainland China/Macau
- Local Regulations
  - Registration under Department of Heath
  - Hospital Authority
    - if to be used under public health care system
    - special work group
- University
  - under research protocol
  - ethnic committee approval

Existing Safety Net

- Donation funding, named patient basis
- University funding
- Full coverage for Inoperable Symptomatic AS
  - Risk of death or irreversible morbidity of sAVR >= 50% at 30 days
  - Cardiologist, cardiac surgeons, CTSU anesthesiology
- Community Care Fund (CCF)

(c) Implantable Medical Devices Supported by the Programme "Subsidy for Eligible Patients of Hospital Authority to Purchase Specified Implantable Medical Devices for Interventional Procedures"

1. Transcatheter Valve Implantation (TVI)
2. MitraClip System
3. Percutaneous Pulmonary Valve Implantation (PPVI)
4. Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)
5. Impella
6. Transcatheter Tricuspid Valve Repair System

(c)「資助合資格的公立醫院病人購買指定的用於介入程序及在體內設置的醫療裝置」計劃涵蓋的醫療裝置

1. 經導管微創主動脈瓣植入術
2. 經導管二尖瓣修復術

有經濟困難的病人可以申請關愛基金的資助。基金會按照合資格的申請者的經濟情況作出全數或部分資助。

有關撒瑪利亞基金的詳情，可參閱醫院管理局互聯網內的撒瑪利亞基金網頁。

TAVI Journey in Hong Kong

First TAVI in Hong Kong was performed on December 6th, 2010 (Medtronic CoreValve, QEH HK)

The patient is now out to 7+ years follow-up.

心律 Cardiac Arrhythmia Today | 病友分享 | 陳伯伯

微創導管植入新心瓣

重獲新心　享受天倫之樂

隨著年紀漸長，心臟內的主動脈瓣可能會導致心衰竭、甚至死亡。每三個病人當中就有一位因為年紀大、身體弱而不能進行傳統開胸手術。

78歲的陳伯伯一向身體健康，還堅持每天做運動。2010年，發覺有氣喘情況。

First TAVI with Balloon Expandable Valve in Hong Kong was performed on December 10th, 2012 (Edwards SAPIEN XT, QMH HK)

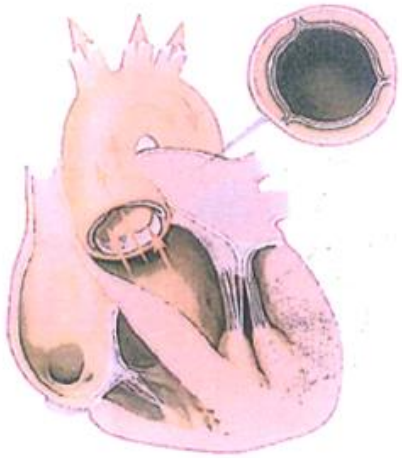
主動脈瓣狹窄
經導管主動脈瓣換置術

由於心瓣變得越來越狹窄並難以容許血液通過，一方面會令患者出現胸痛、疲勞、氣喘、頭暈、昏厥或運動困難等症狀；另一方面心室壁肌肉會受壓而增厚，嚴重時可導致心臟衰竭、心律失常、心肌供氧不足、低血壓和中風。

主動脈瓣狹窄主要經心臟超聲波診斷，患者發生心瓣膜病變時可能沒有外部症狀而難以察覺。

當主動脈瓣狹窄病變加重和繼續惡化時，則危及生命安全。一旦症狀開始出現而沒有接受治療，多達百分之五十患有重度主動脈瓣狹窄的病人會因病情惡化而可能在兩年內死亡，而五年的存活率僅為百分之二十。

主動脈瓣狹窄沒有藥物療法。但如果施行心瓣換置手術，很多人會繼續過上正常而健康的生活，大大提高存活率，緩解症狀並提高生活質量。傳統心瓣換置手術是主要的治療方法，但如果病者因手術風險因素而不適合進行開胸手術或評定為高風險，經導管主動脈瓣換置術 (Transcatheter Aortic Valve Implantation – TAVI) 亦是有效的治療方法。患者需經過心臟內科和外科醫生進行詳盡評估，從而定出最合適和有效的治療方案。



正常主動脈瓣

主動脈瓣狹窄常見原因包括先天性狹窄及老年性主動脈瓣鈣化。75 歲或以上的成年人患上中度至嚴重主動脈瓣狹窄的比例為百分之五，患上的機會並隨着年齡而增加。

主動脈瓣狹窄

First Established Region in Asia for SAPIEN 3

(First Case 2nd October 2015, QMH HK)

導管植人工心瓣 更精準

闢兩輸入路徑 風險低康復快

■瑪麗醫院去年新增TAVI的進入路徑。前左為梁女士，前右為鍾先生。（黃偉邦攝）

主動脈心瓣隨年紀增長退化，無法正常開合，需做手術植入人工心瓣。瑪麗醫院心臟診療團隊最近提升「導管主動脈心瓣替換手術（TAVI）」技術，新增兩條導管進入路徑，可直接於病人心臟外面做創落刀，經心主動脈或心尖，以導管植入人工心瓣後擴大心血管，較以往經由大腿股動脈運送，路程大大縮短且更接近替換位置，令醫生植入人工心瓣時更精準。

■瑪麗醫院提升導管主動脈心瓣替換手術的技術，讓植入人工心瓣位置更精準。

瑪麗醫院心臟內科顧問主管陳漢輝稱，主動脈心瓣疾病屬常見的心臟病之一，成因包括退化、先天性或感染等，令主動脈心瓣變得狹窄，或出現倒流，導致患者氣促、胸口痛或昏厥等，患者一旦有徵狀，若不更換心瓣，兩年內死亡率高達五成。

第三代心瓣切合亞洲人

傳統治療為病人進行開胸手術植入人工心瓣，但手術風險高。瑪麗醫院心臟內科副顧問醫生林祥智稱，該院近年引入的TAVI屬微創手術，創傷性較低及康復時間較短，以導管將人工心瓣經病人大腿股動脈運送到心臟，張開後取代原有心瓣，最新路徑是經心主動脈或心尖植入，位置可更精準，對象特別是需要再次更換人工心瓣的病人，當病人的股動脈、腹部大動脈狹小或病化，導管不能到達心臟時，新路徑為醫生及病人提供多一個選擇。

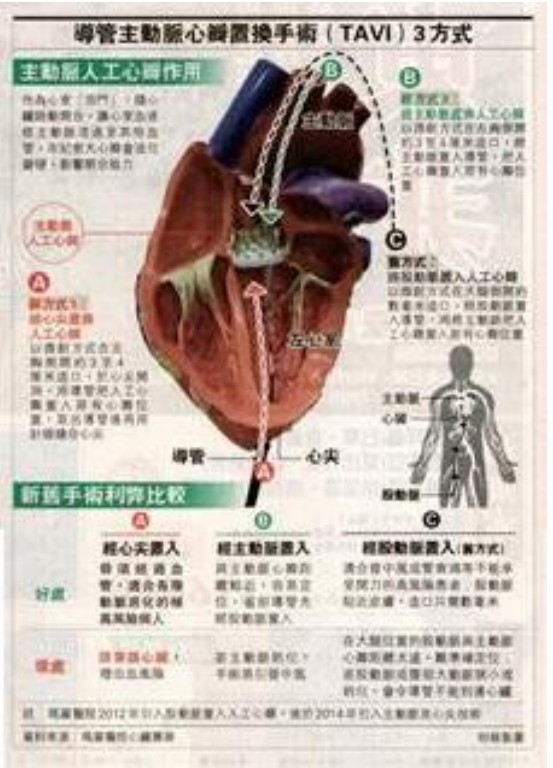
瑪麗醫院為亞洲首間醫院使用第三代人工心瓣，導管較上一代的直徑減少約三成四，只有二十至二十九毫米，可切合體形瘦削的亞洲病人需要，並加入褶腳設計，令人工心瓣可緊貼血管，減少術後心瓣倒流情況。

現年八十一歲的鍾先生，〇二年因主動脈心瓣狹窄而做開胸手術更換人工心瓣，去年人工心瓣退化導致心瓣倒流，他上周採用經心尖置入導管更換人工心瓣，昨午已可出院，較〇二年時需留院一個月，康復進度快。

術後一周出院 健步如飛

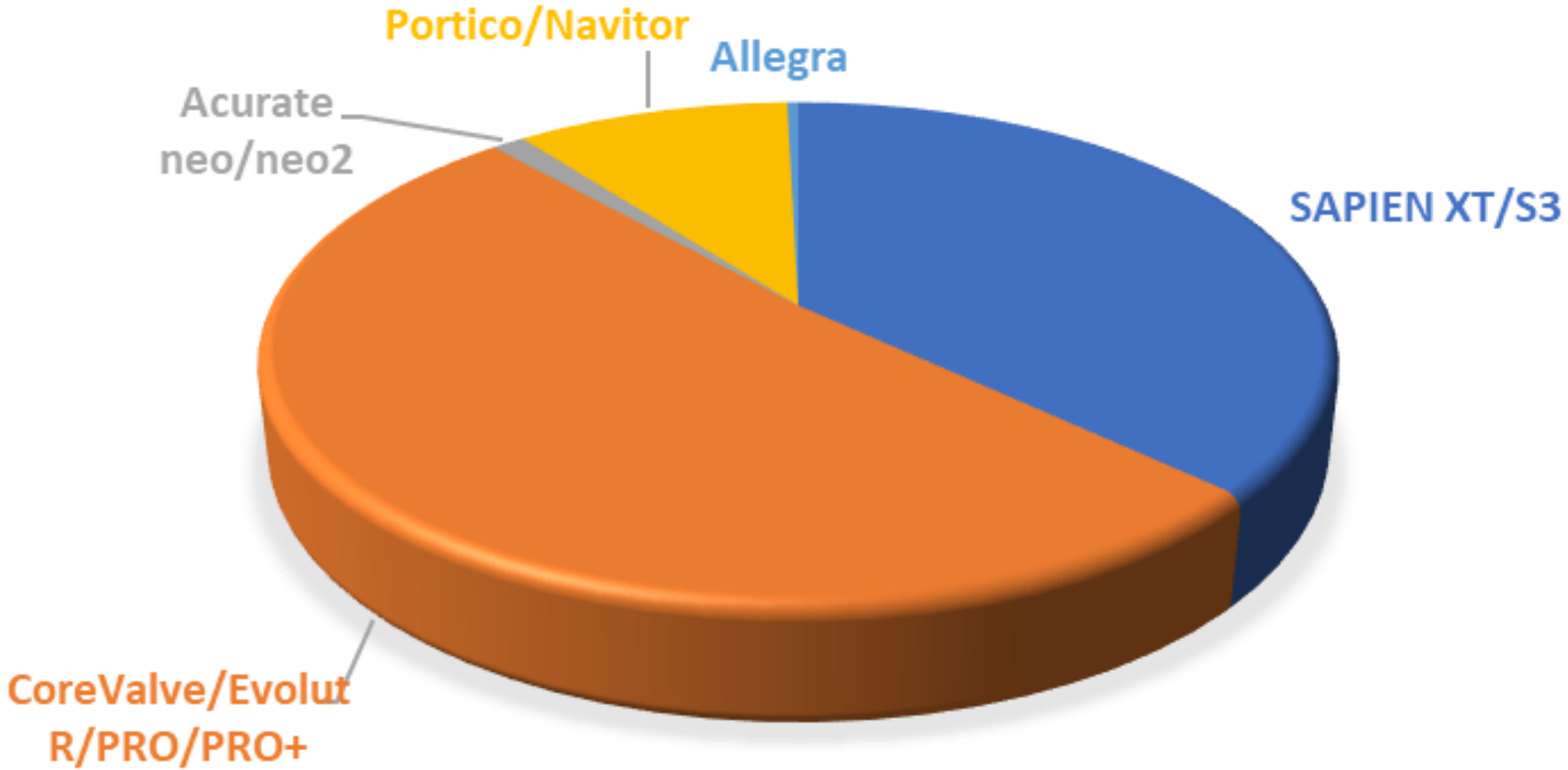
現年九十歲梁女士因患嚴重主動脈心瓣狹窄引致氣促，「行唔到路，講唔到嘢，」兩年前接受經股動脈進入的TAVI時，當年家人曾勸心手術風險而不建議做，但她「因太辛苦，自己話事同醫生講做手術」，她術後一周出院，現在健步如飛。

瑪麗醫院心胸外科顧問醫生陳泰良指出，該院心臟診療團隊會為病人進行血管造影、心臟超聲波等檢查，才決定病人採取的手術模式，低風險、身體機能良好的病人，建議採用微創開胸手術，而年長、曾進行心臟手術者則採取TAVI。



Newspaper 7.2016

TAVI DEVICE USE IN HONG KONG

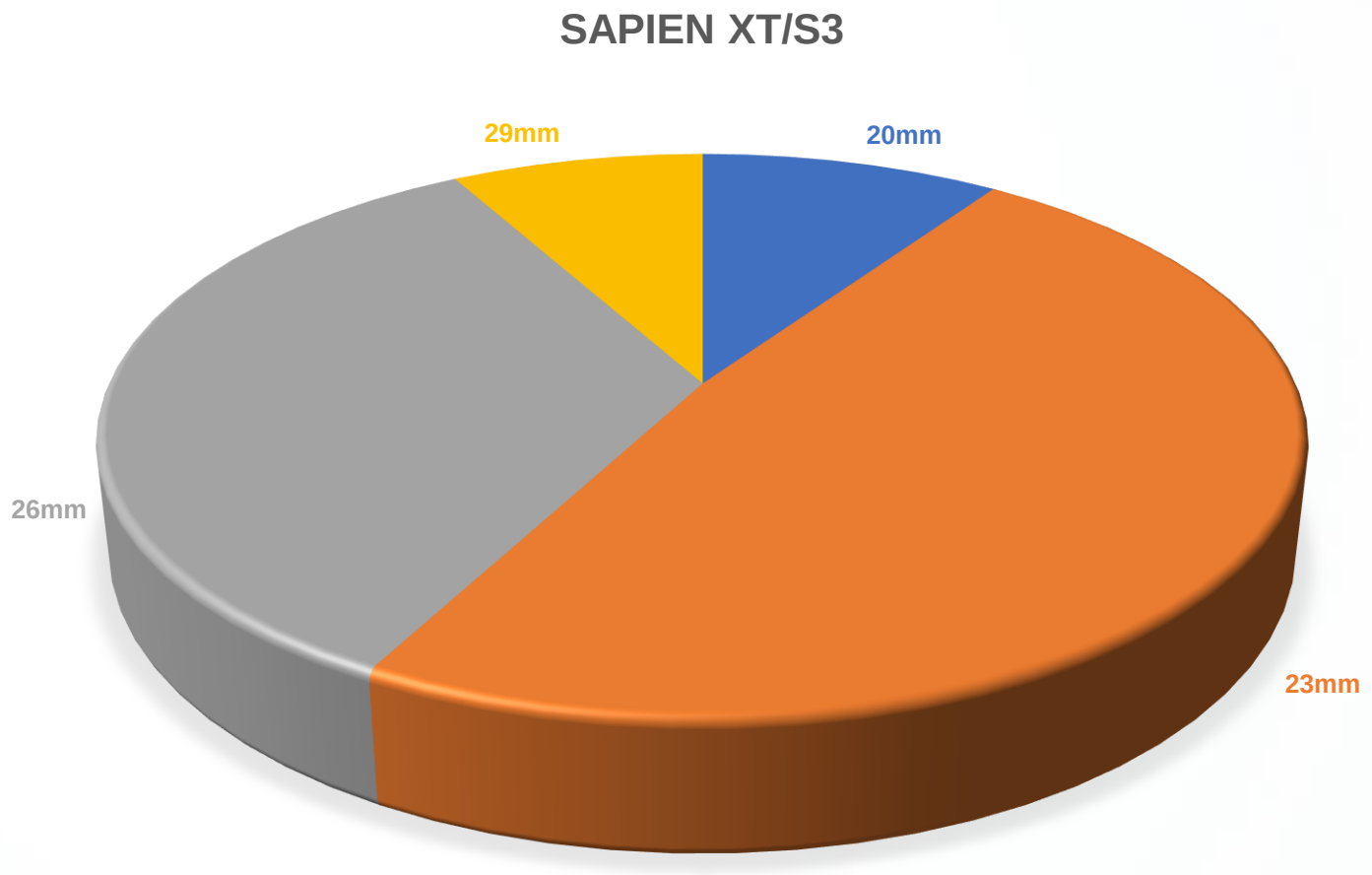


TAVR in Hong Kong – S3, ACURATE neo2, Evolut PRO+

Edwards SAPIEN 3

Size Selection and Range Distribution

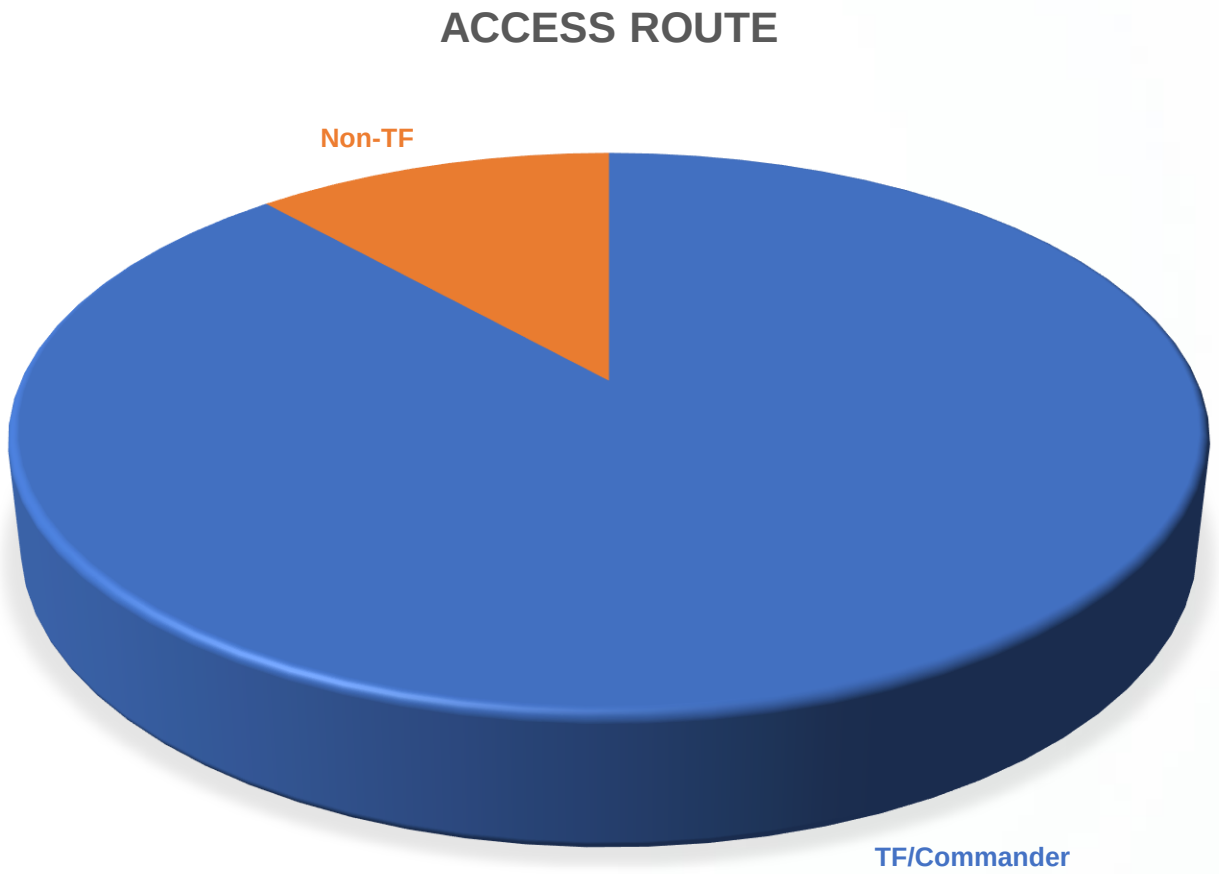
- Size of THV Used
  - 20mm – 8.6%
  - 23mm – 43.3%
  - 26mm – 30.6%
  - 29mm – 7.3%



Edwards SAPIEN 3

Access Route Distribution

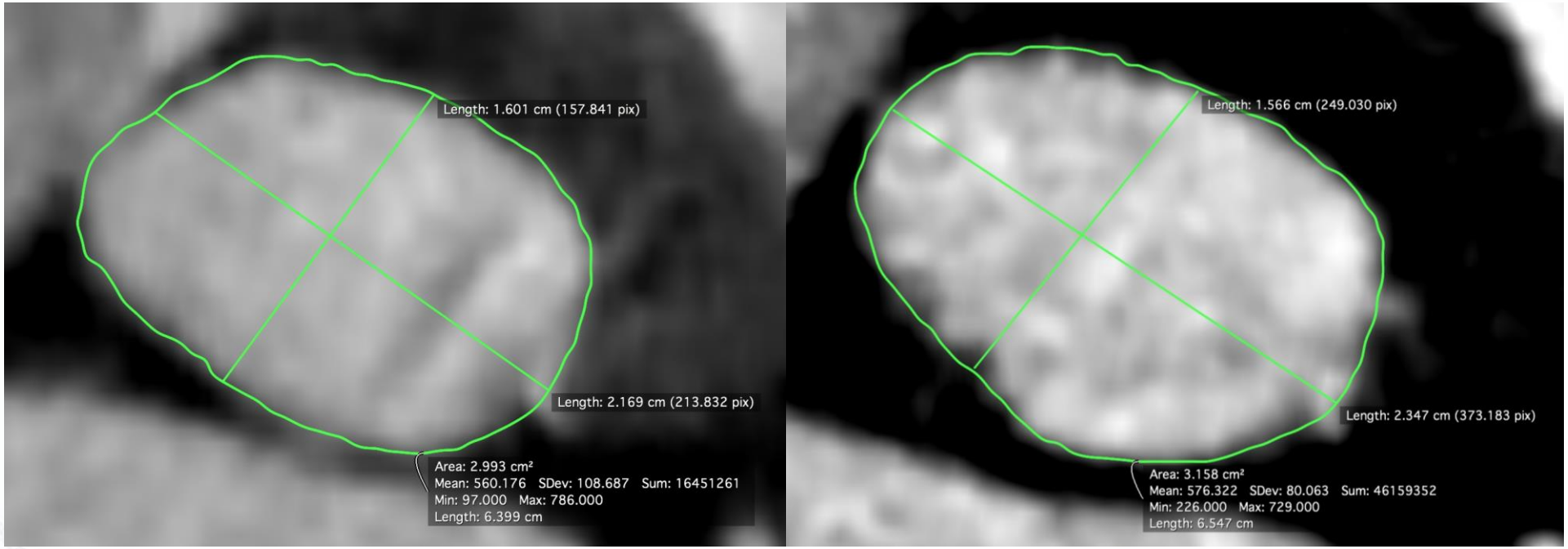
- Access Route
  - Transfemoral – 88%
  - TA/Alternative Route – 12%



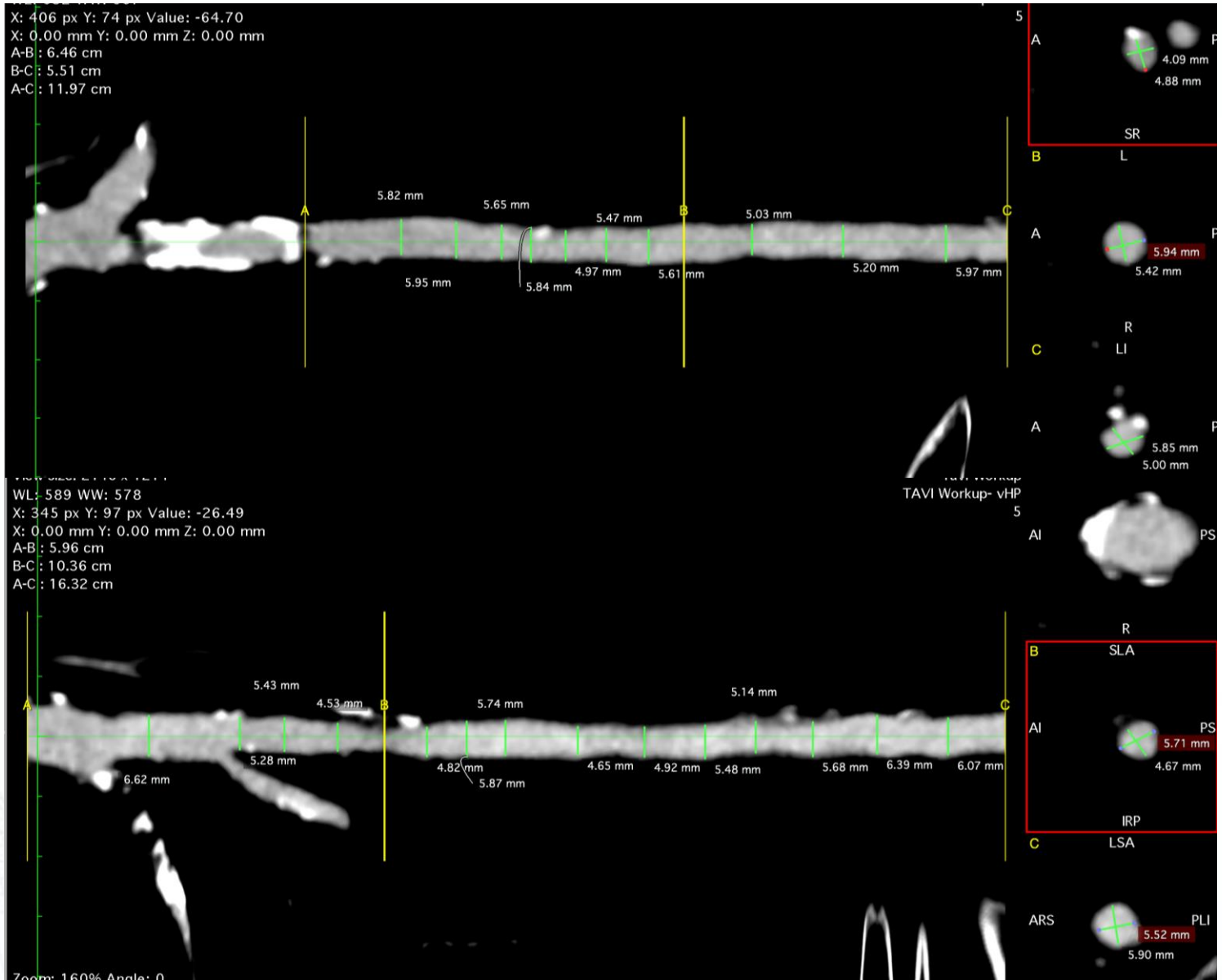
Case Spectrum – Small Annulus

75% - Area 299.3mm
Dia 16.0x21.6mm

40% - 315.8mm;
Dia 15.6x23.4mm



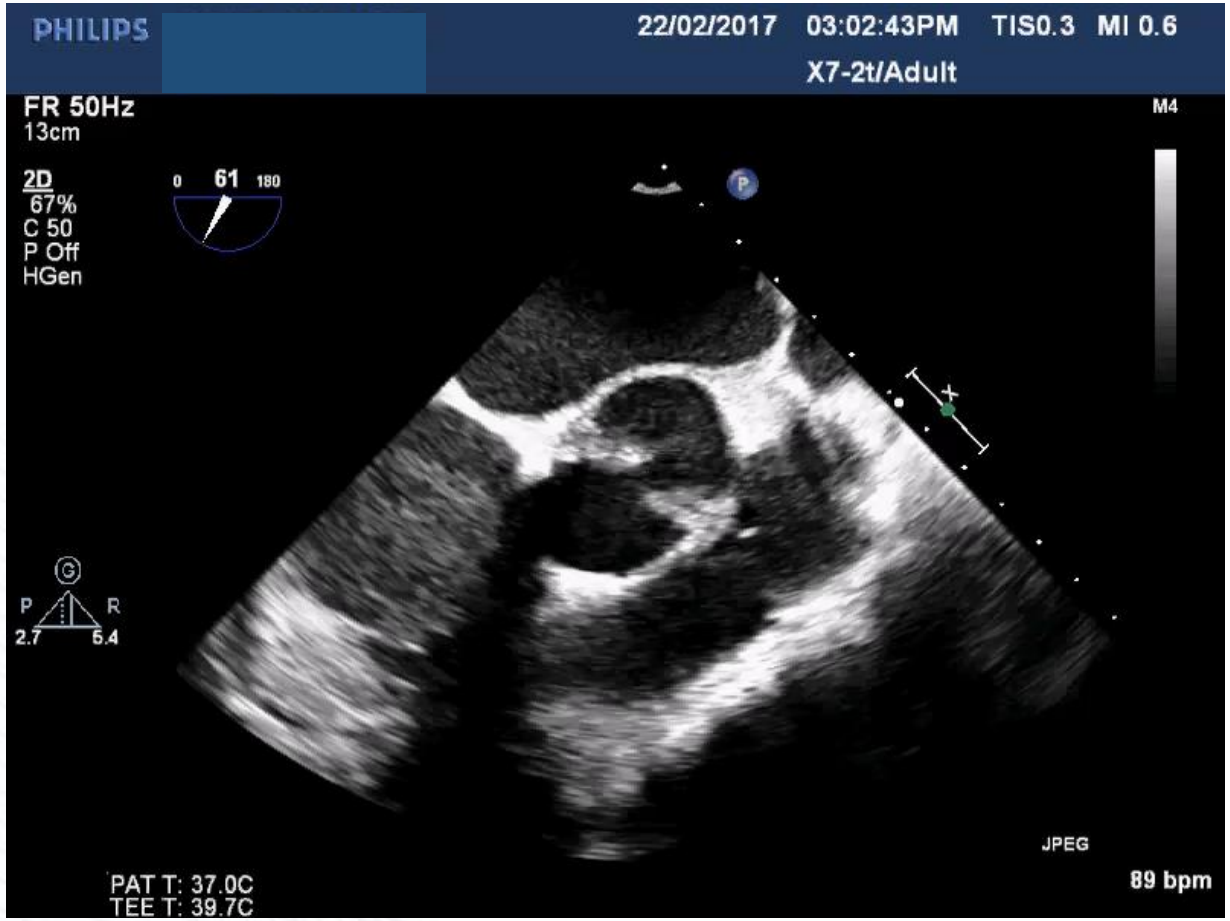
Case Spectrum – Small Femoral Access

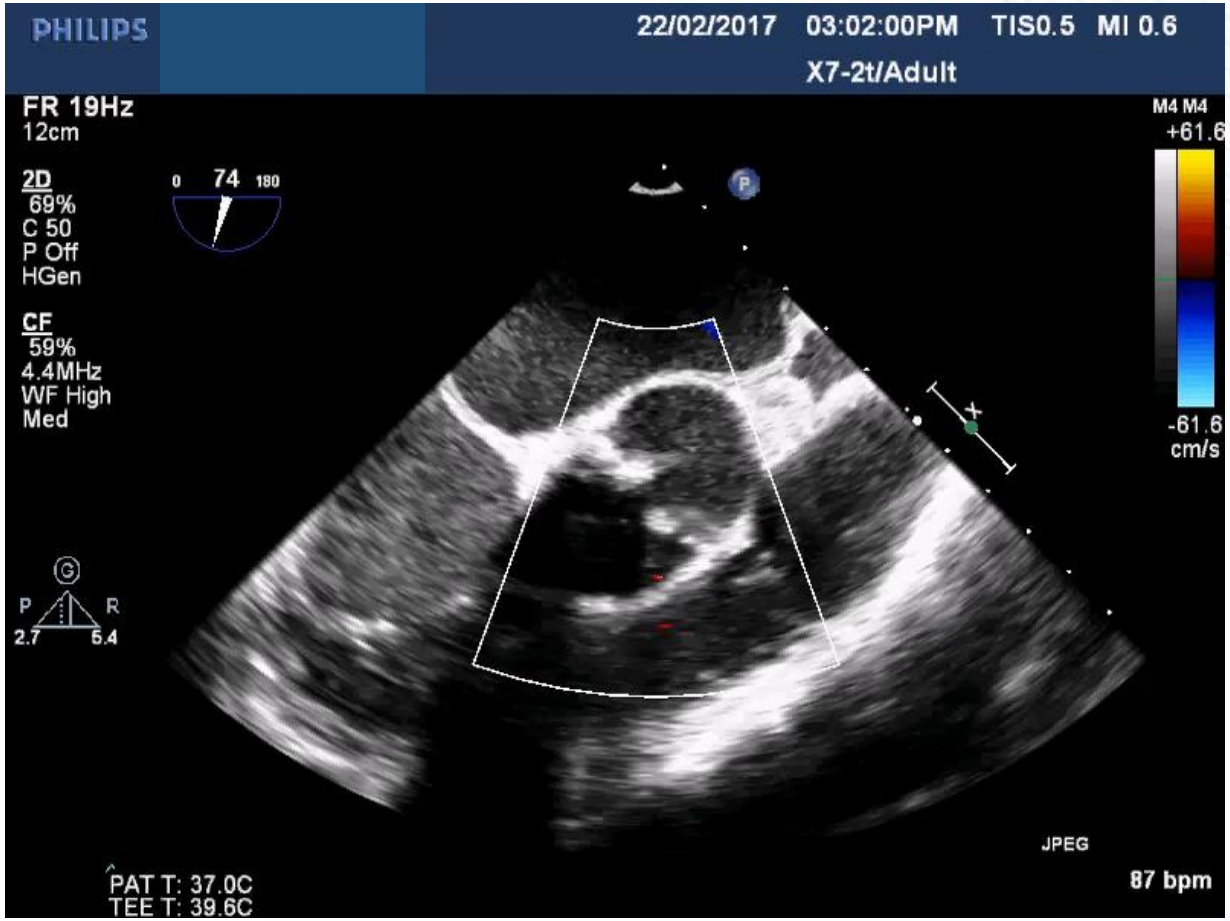


Right

Left

Case Spectrum
– TAVI Bicuspid AV (Direct Implantation)





Im: 1/267
Se: 19

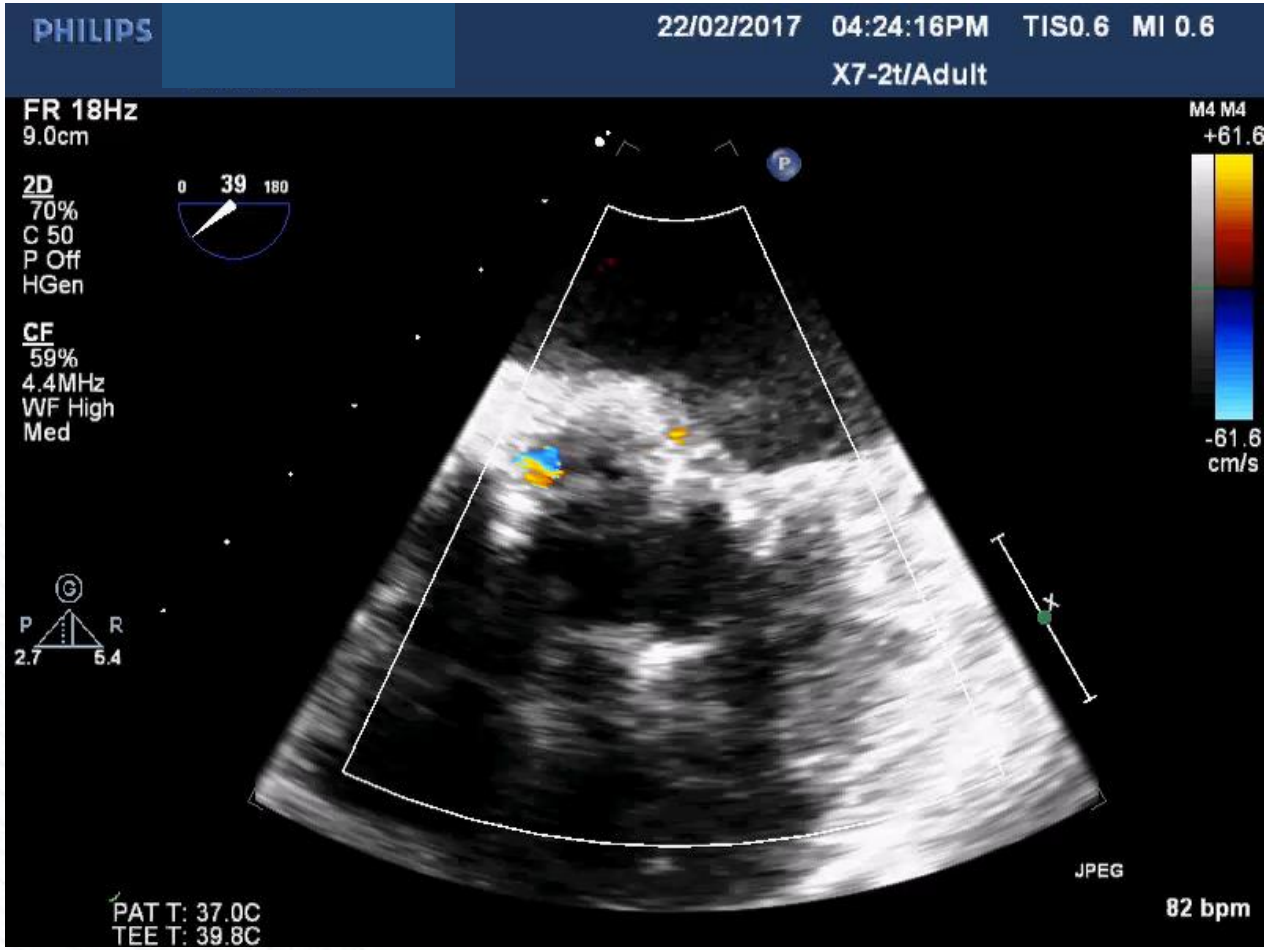
9/21/1928 M
QUEEN MARY HOSPITAL
CG170056

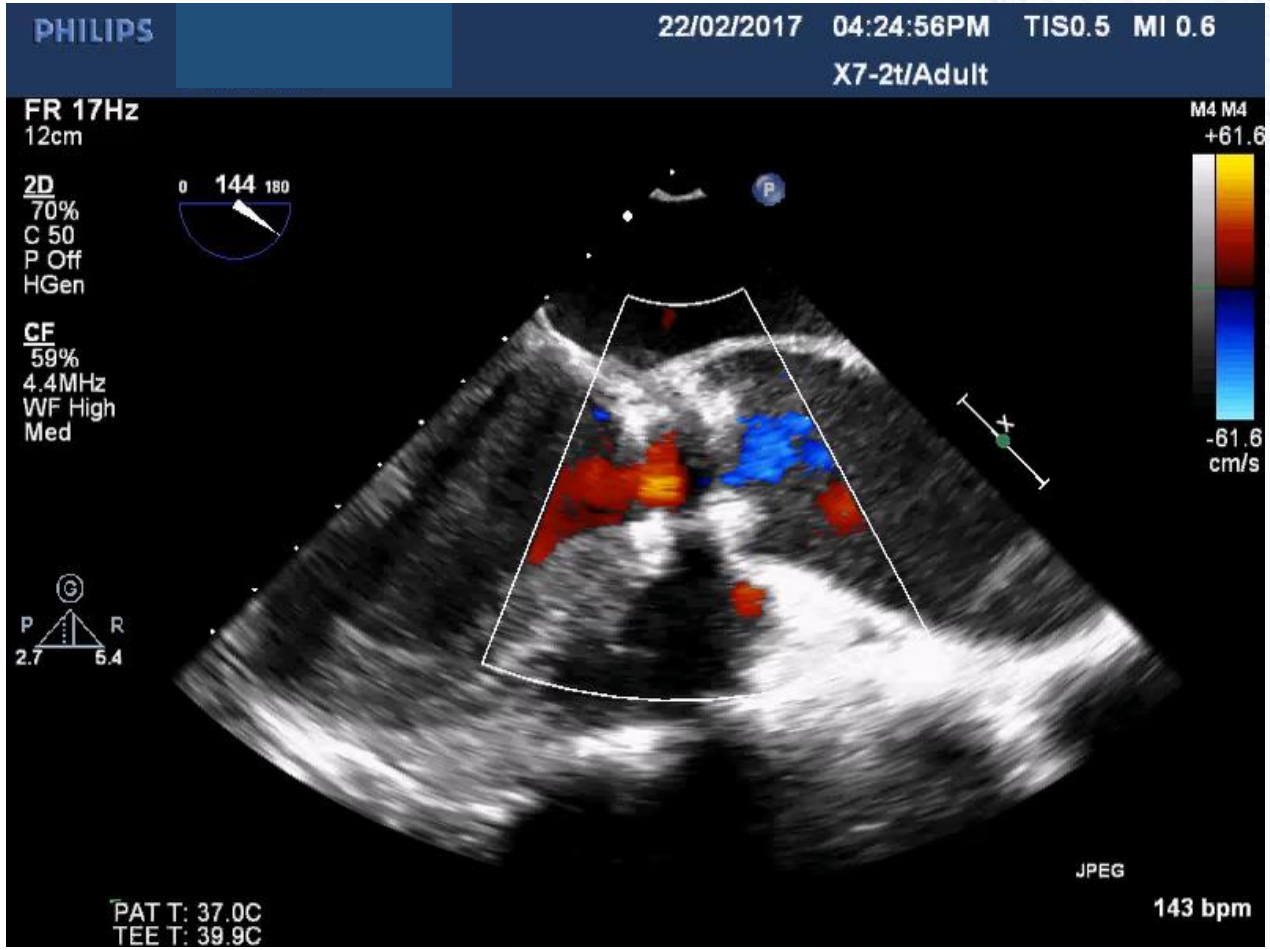
Left Coronary 15 fps

WL: 128 WW: 256 [D]
LAO: 12 CAU: 12

2/22/2017 4:08:22 PM

TEE


PHILIPS
22/02/2017 04:24:16PM TIS0.6 MI 0.6
X7-2t/Adult
FR 18Hz
9.0cm
2D
70%
C 50
P Off
HGen
CF
59%
4.4MHz
WF High
Med
0 39 180
M4 M4
+61.6
-61.6
cm/s
P R
2.7 5.4
JPEG
PAT T: 37.0C
TEE T: 39.8C
82 bpm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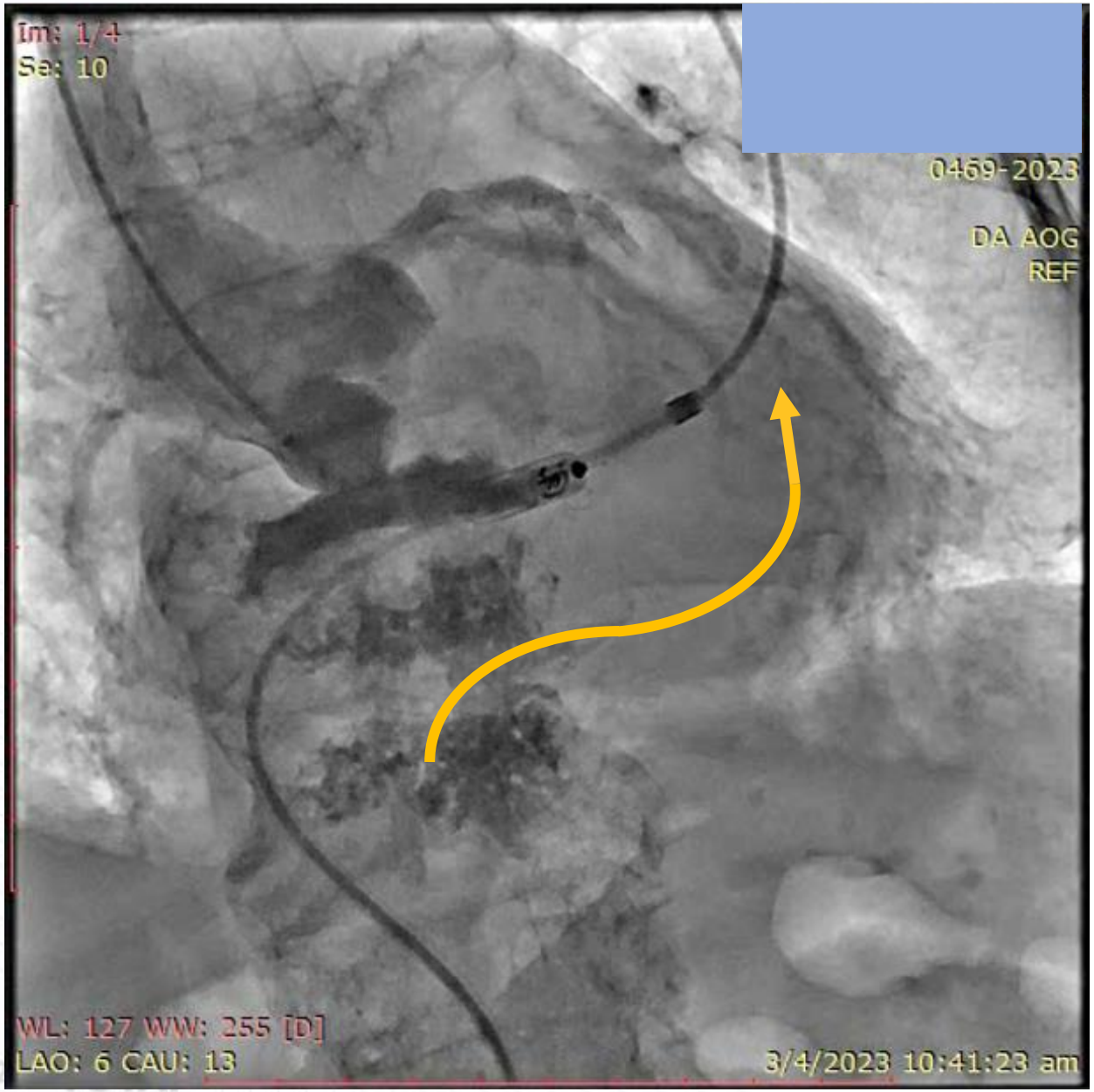
X7-2t/Adult
FR 17Hz
12cm
2D
70%
C 50
P Off
HGen
CF
59%
4.4MHz
WF High
Med
0 144 180
M4 M4
+61.6
-61.6
cm/s
P R
2.7 5.4
JPEG
PAT T: 37.0C
TEE T: 39.9C
143 bpm

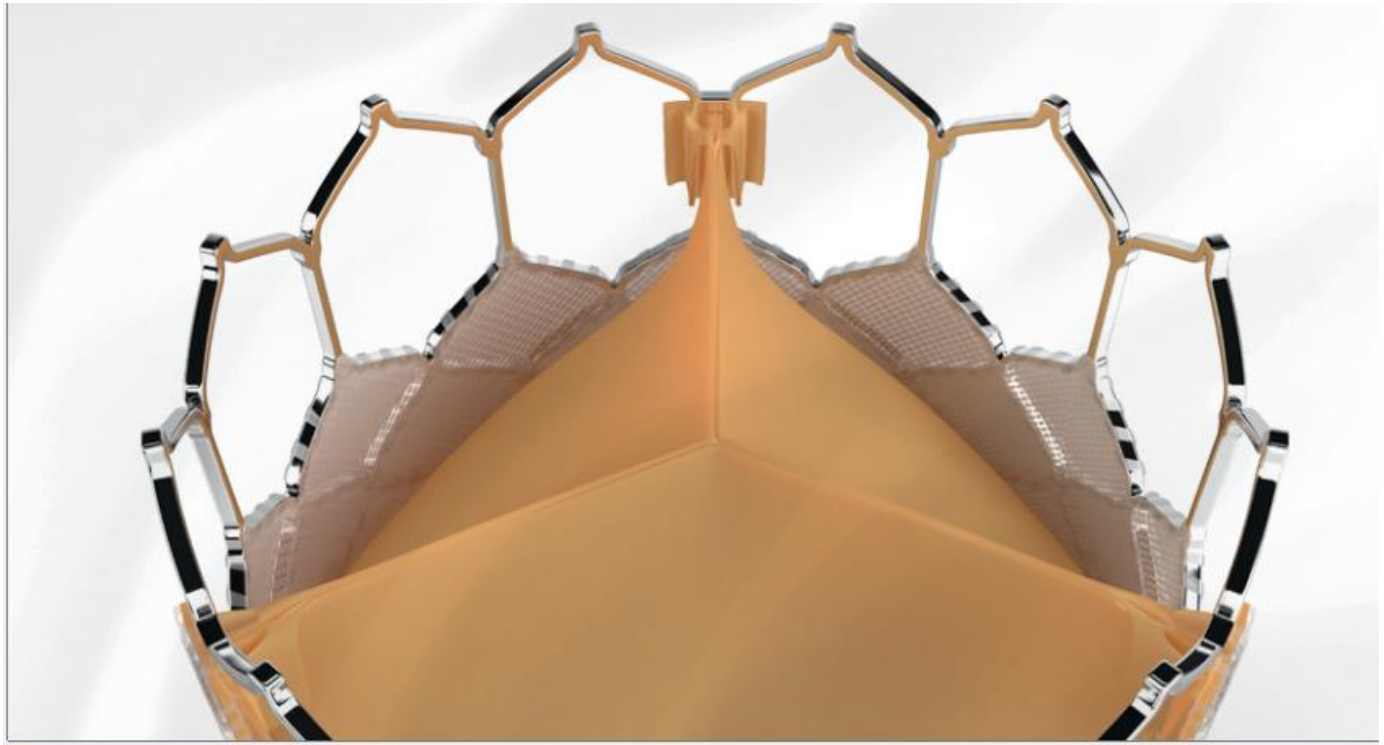
Case Spectrum




Im: 1/185
Se: 21
0469-2023
DA AOG
WL: 127 WW: 255 [D]
LAO: 6 CAU: 13
3/4/2023 11:10:54 am


Im: 1/55
Se: 23
0469-2023
DA AOG
WL: 127 WW: 255 [D]
LAO: 8 CAU: 20
3/4/2023 11:15:30 am

S3 Ultra RESILIA Valve



See Important Safety Information inside.

SAPIEN 3 Ultra RESILIA valve

- Builds on the benefits of the proven SAPIEN 3 platform
- Addresses calcification, the leading cause of tissue valve failure*[1]
- Fully addresses the vital considerations for optimal lifetime management
  - Superior outcomes†[4]
  - Facilitates future treatment options‡[5]
  - Durability that stands up to SAVR§[6]

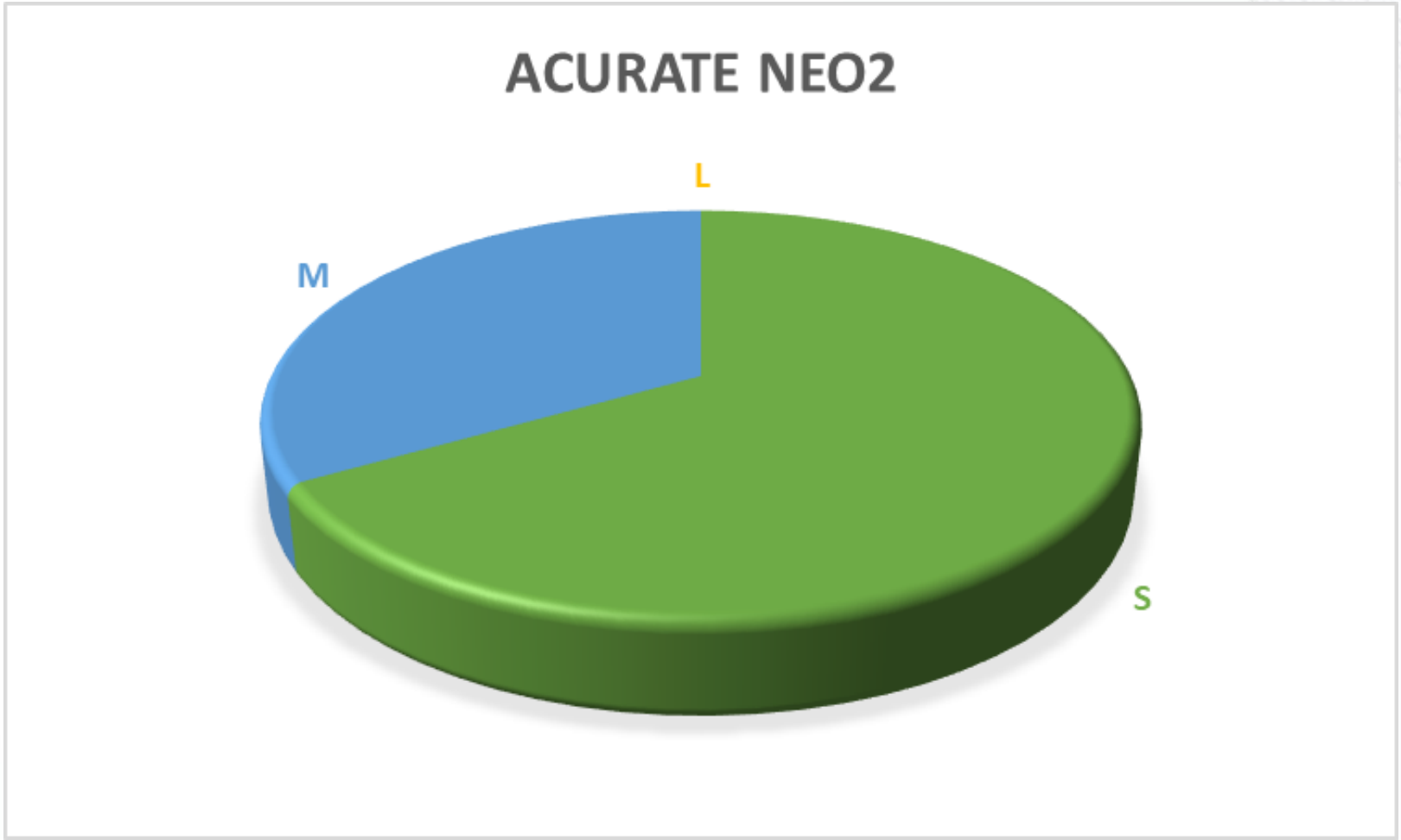
Discover how to take your patients farther.

Learn more about SAPIEN 3 Ultra RESILIA valve at **SAPIEN3UltraRESILIA.com**

Acurate Neo/Neo 2

Access Route Distribution

- Size of Device Used
  - S
  - M
  - L



[redacted]

Acurate NEO S – 23mm

Boston Scientific

Aortic annulus (3D% plane)
min 18.7mm
max 22.7mm
average 20.7mm
area derived 20.4mm
perimeter derived 20.7mm

perimeter
65.0mm

Relatively smaller than CTA annulus size
Not too much calcium

(Sinus big - ✓)

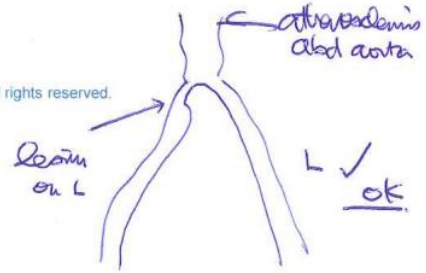
ACURATE *neo*™
Aortic Valve

Valve Size	S – 23 mm	M – 25 mm	L – 27 mm
Order Number	SYM-SV23-002	SYM-SV25-002	SYM-SV27-002
Aortic annulus diameter* (mm)	21mm ≤ annulus Ø ≤ 23 mm	23mm < annulus Ø ≤ 25 mm	25mm < annulus Ø ≤ 27 mm
Aortic annulus perimeter (mm)	66 mm ≤ annulus ⟳ ≤ 72 mm	72 mm < annulus ⟳ ≤ 79 mm	79 mm < annulus ⟳ ≤ 85 mm

right cor
- 16.0mm
Left cor
- 14.2mm ✓

Equal –

* CT based measurement: Perimeter derived annulus.



Best alignment angle =
(3-months)

EDUCARE

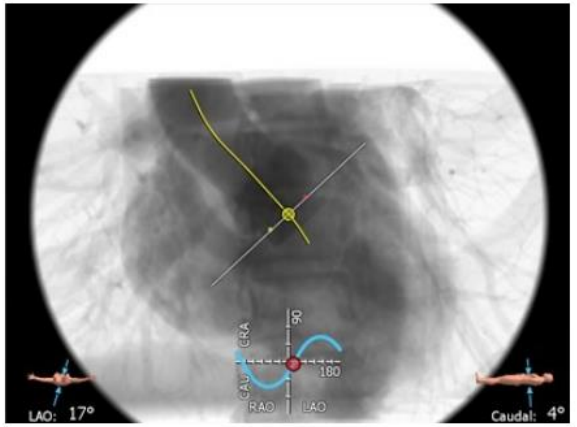
LAO 17°
CAU 4°

Perimeter 65.0mm

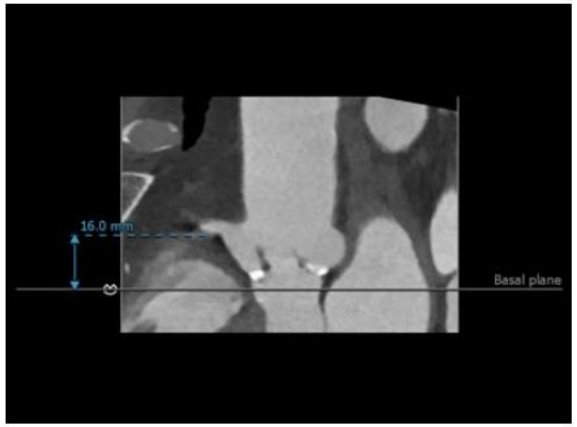
Average 20.7mm

Perpendicular Plane

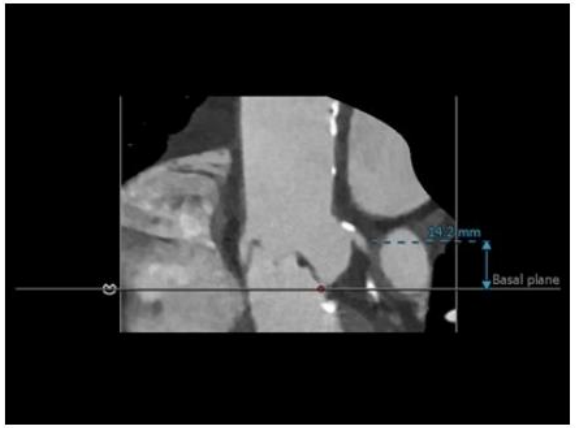
Angio



Stretched Vessel

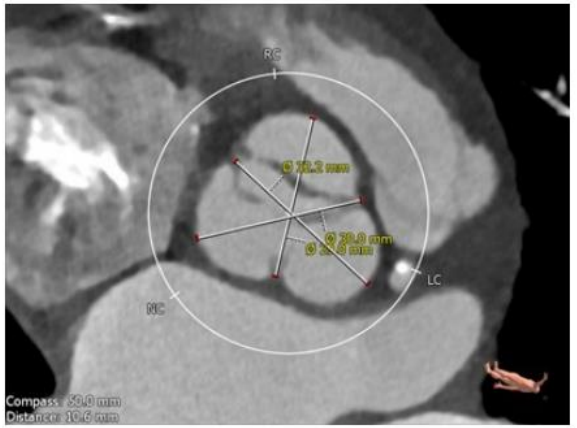


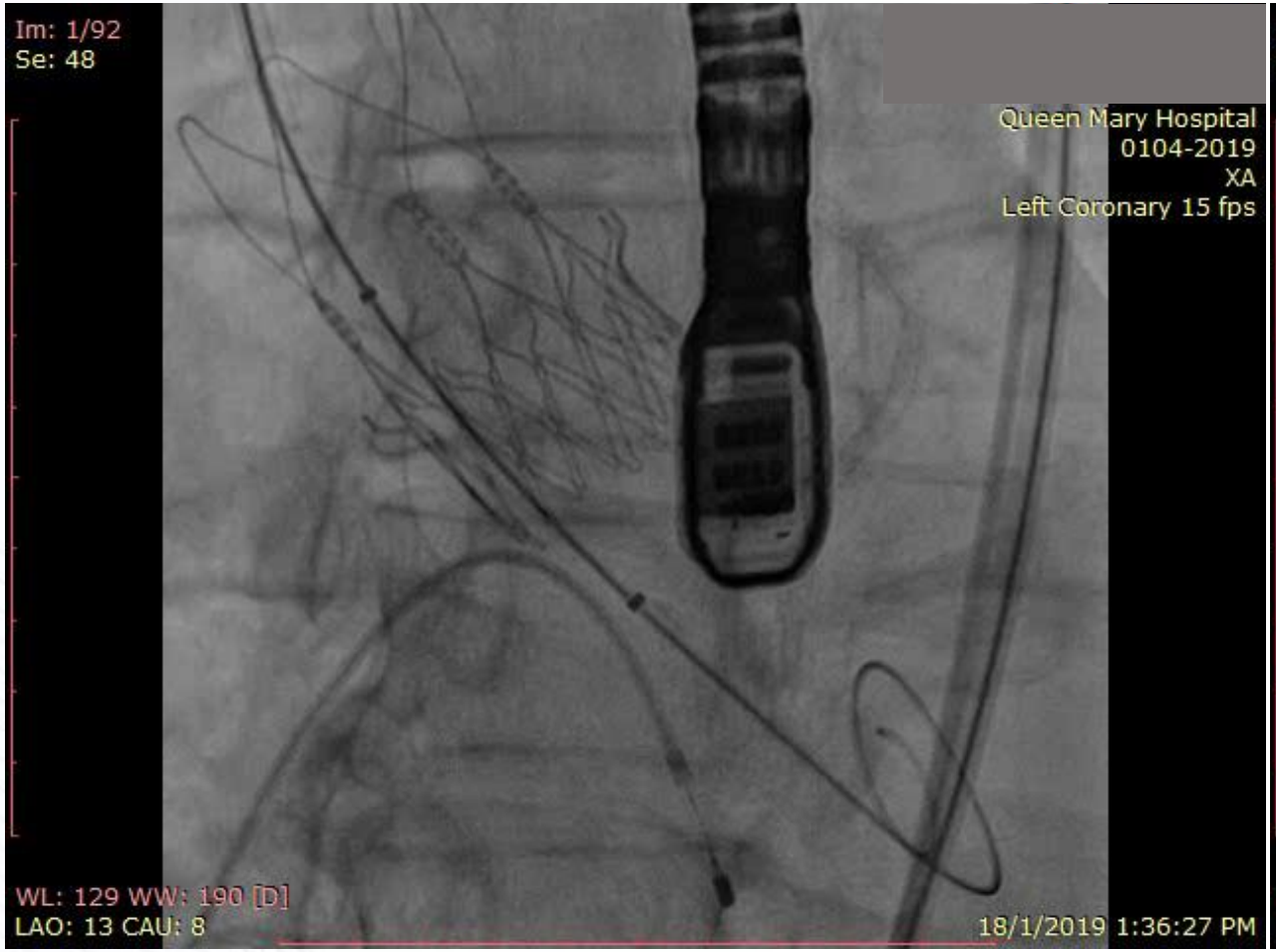
Stretched CMPR (Phase 30.0%)

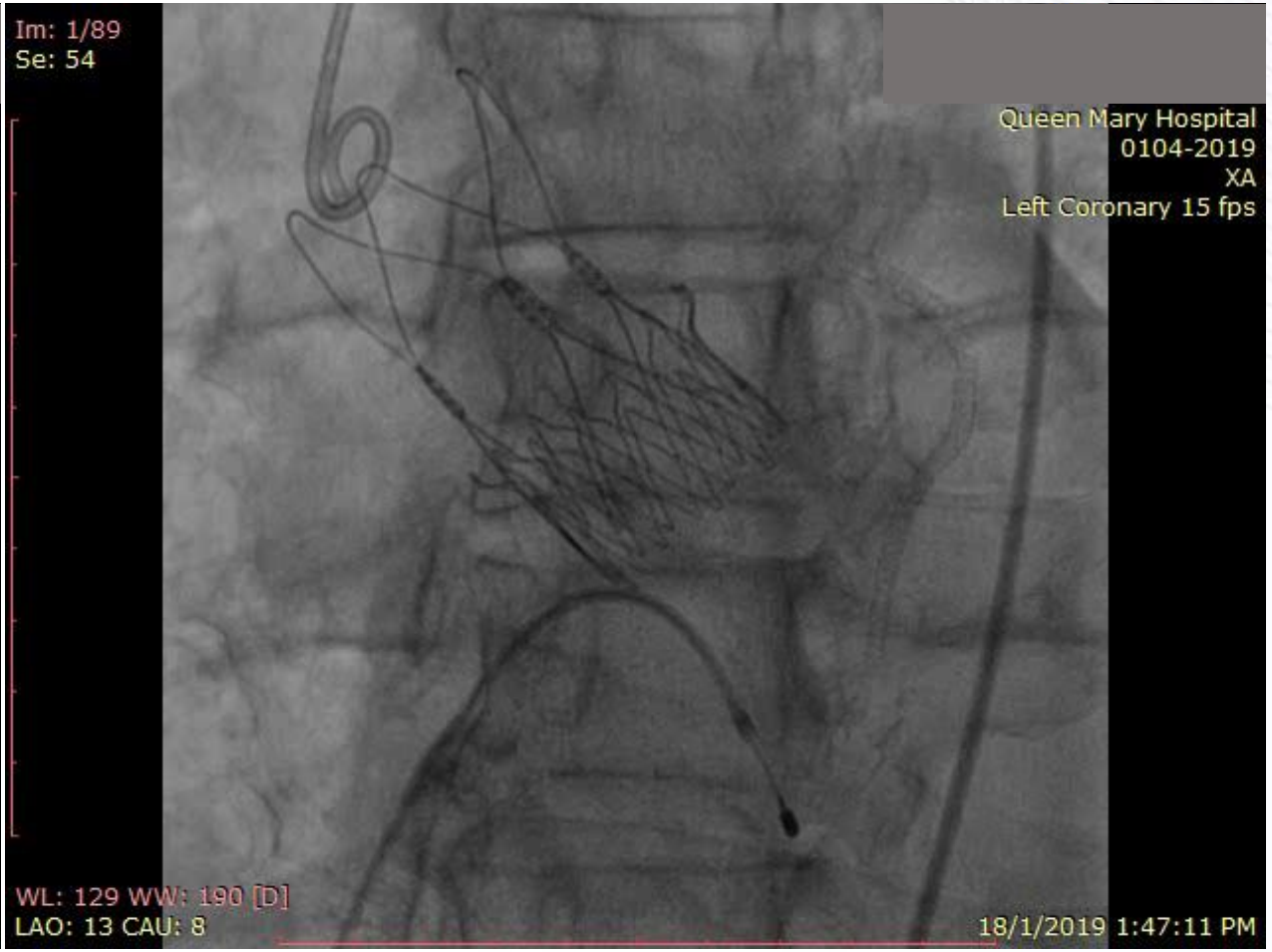


Perpendicular Plane

Perpendicular Plane




Im: 1/92
Se: 48
Queen Mary Hospital
0104-2019
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
LAO: 13 CAU: 8
18/1/2019 1:36:27 PM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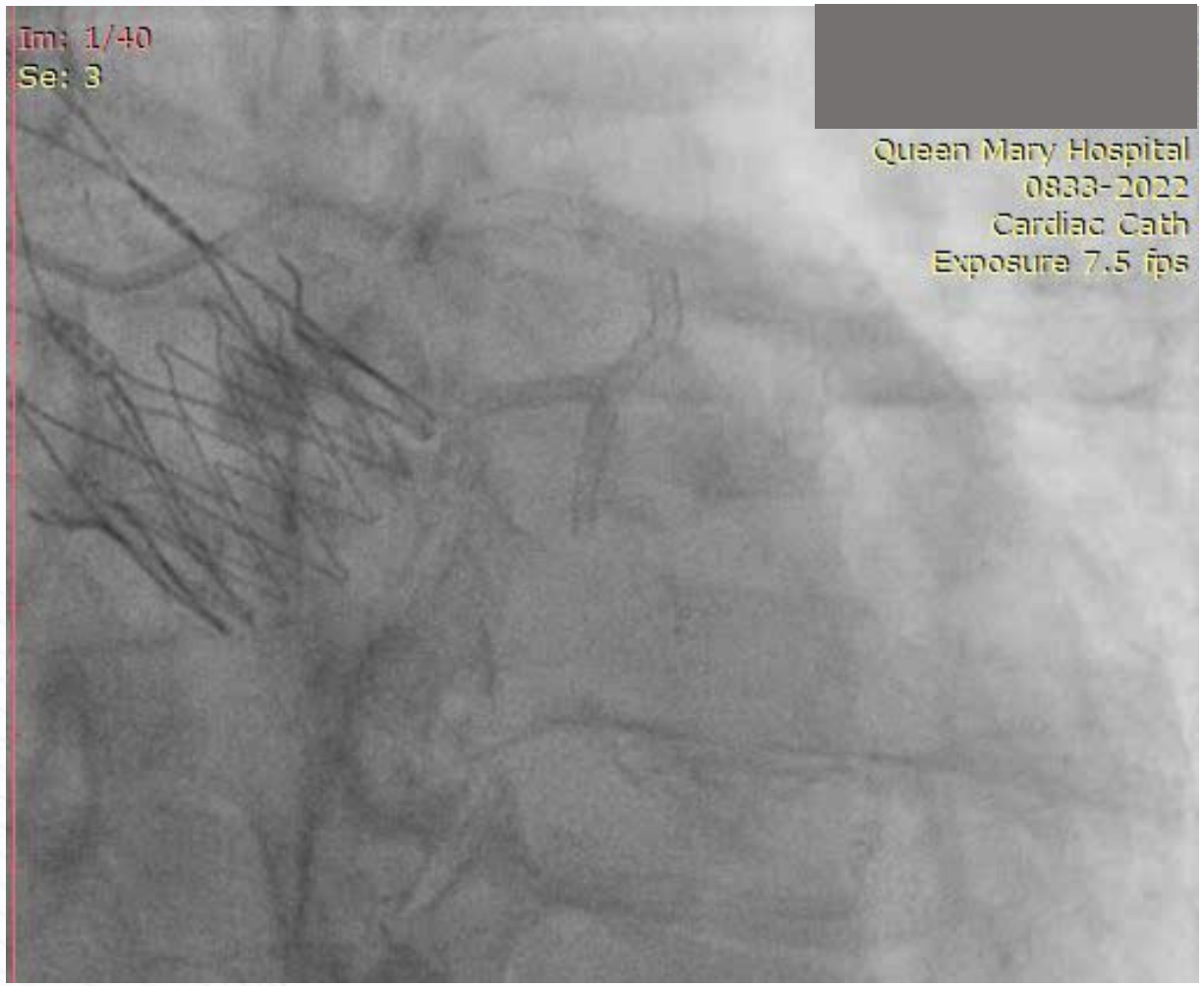
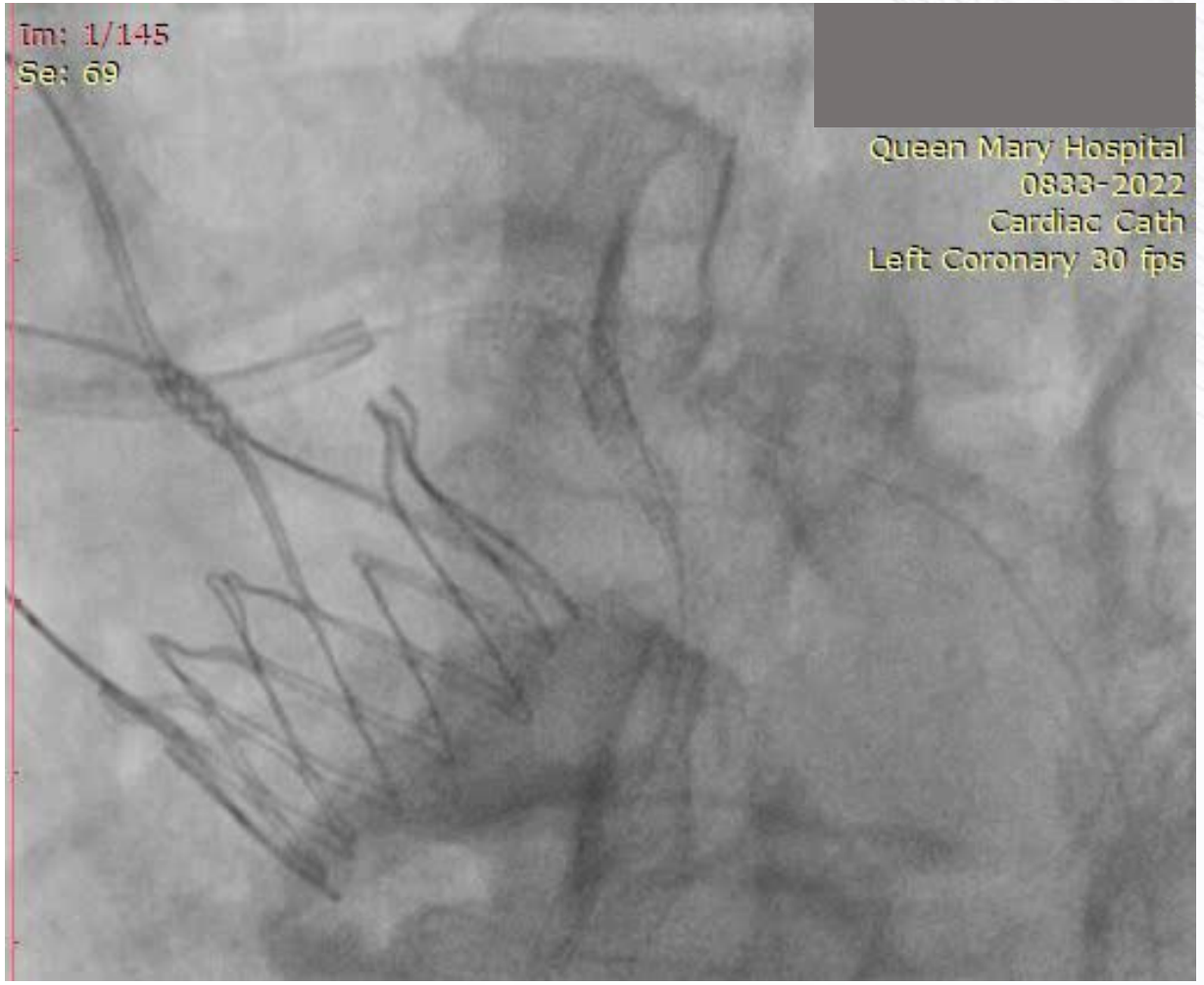
LAO: 13 CAU: 8
18/1/2019 1:47:11 PM


Im: 1/40
Se: 3
Queen Mary Hospital
0833-2022
Cardiac Cath
Exposure 7.5 fps


Im: 1/35
Se: 8
Queen Mary Hospital
0833-2022
Cardiac Cath
Exposure 7.5 fps


Im: 1/32
Se: 57
Queen Mary Hospital
0833-2022
Cardiac Cath
StentBoost LCA 30 fps


Im: 1/145
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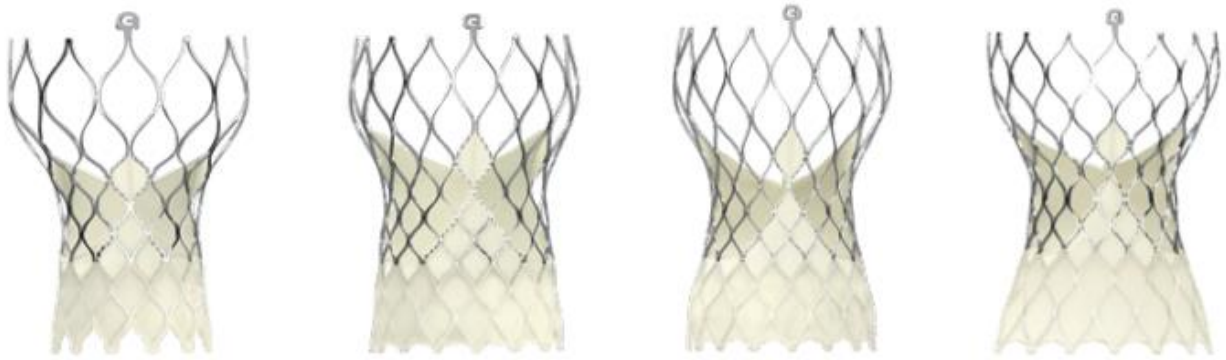
Queen Mary Hospital
0833-2022
Cardiac Cath
Left Coronary 30 fps

Medtronic Evolut PRO/PRO+

Access Route Distribution

- Size of Device Used



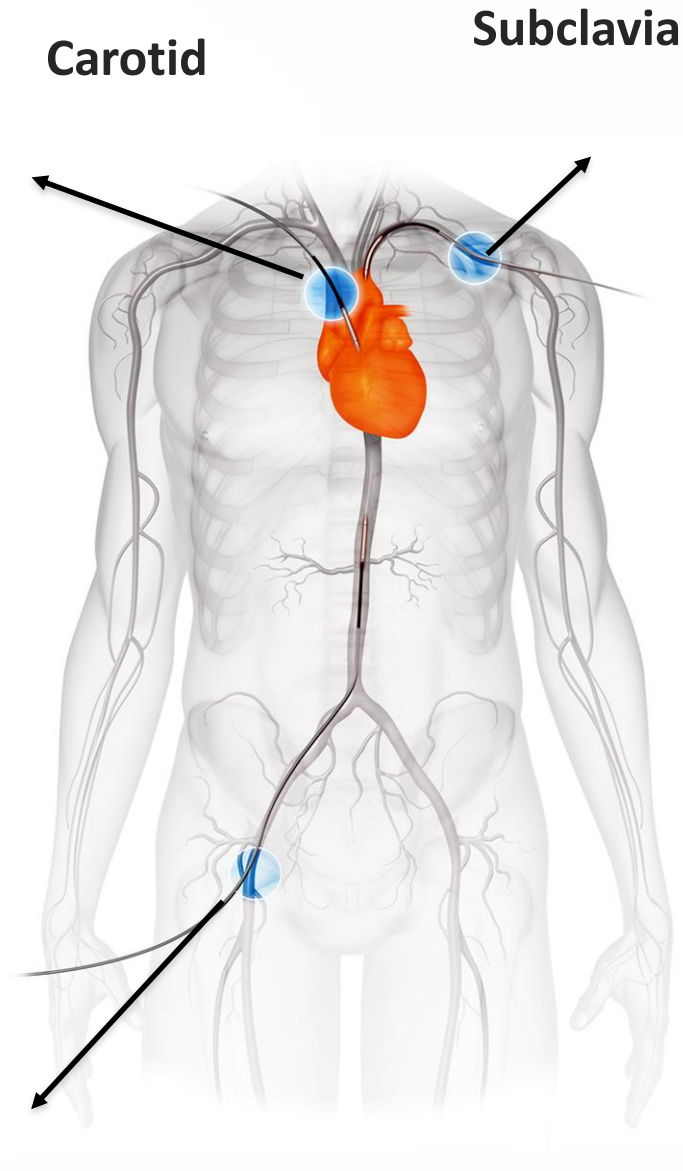
Valve Size Selection				
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter (A)	18–20 mm	20–23 mm	23–26 mm	26–30 mm
Annulus Perimeter*	56.5–62.8 mm	62.8–72.3 mm	72.3–81.7 mm	81.7–94.2 mm
Sinus of Valsalva Diameter (Mean) (B)	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean) (C)	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm

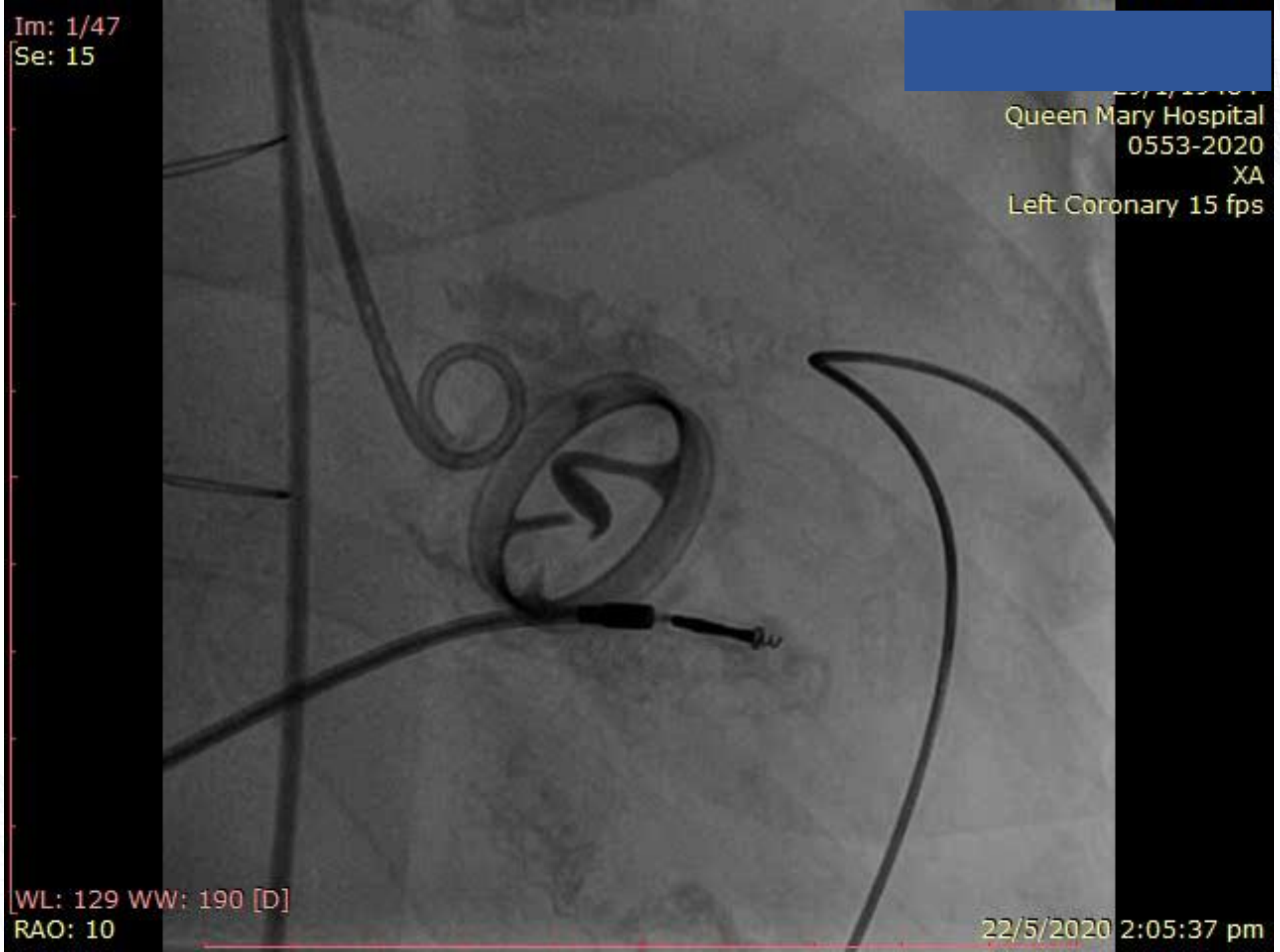
23 mm	26 mm	29 mm	34 mm
7.9%	37.9%	42.7%	11.4%

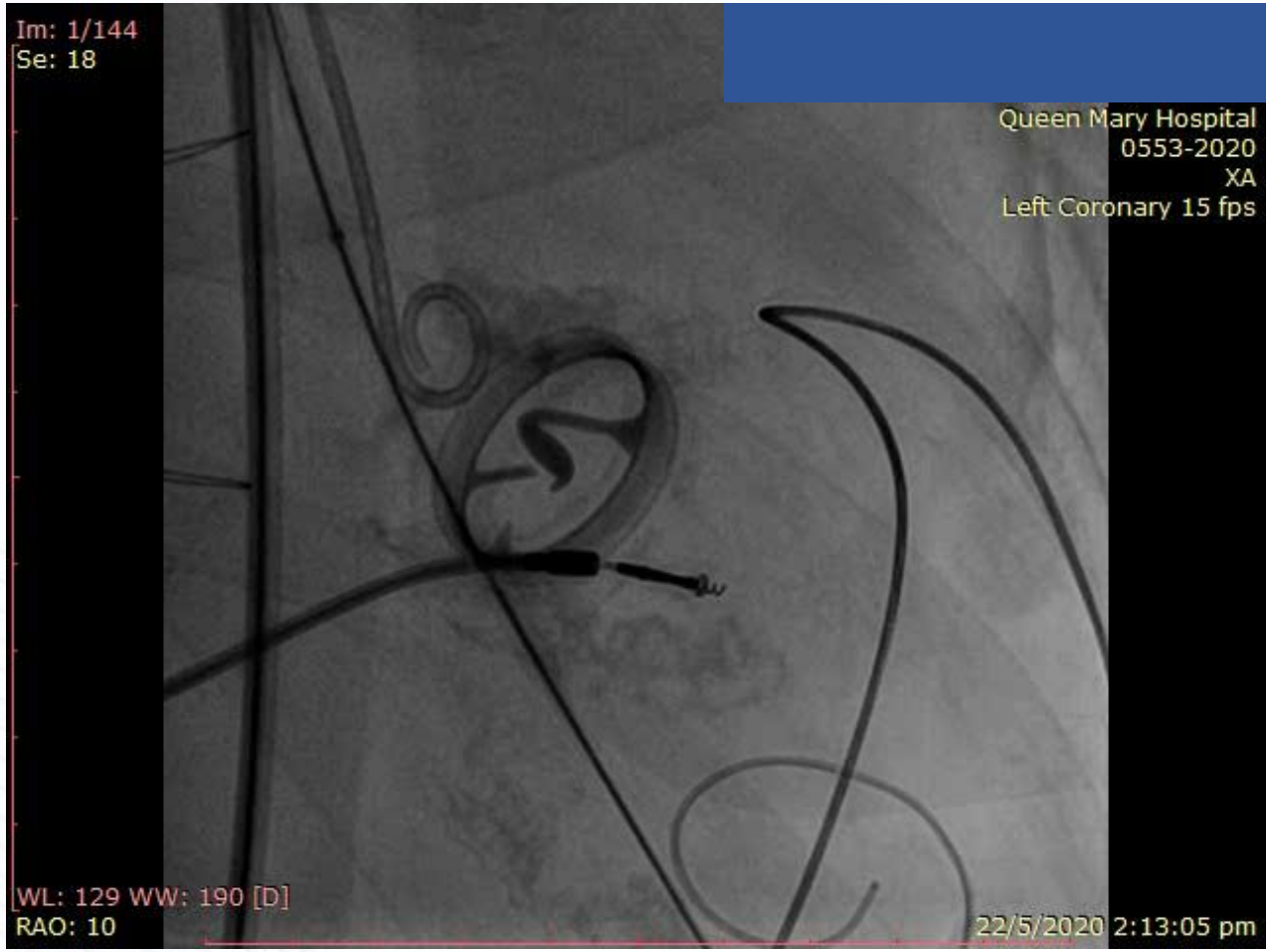
Medtronic Evolut PRO/PRO+

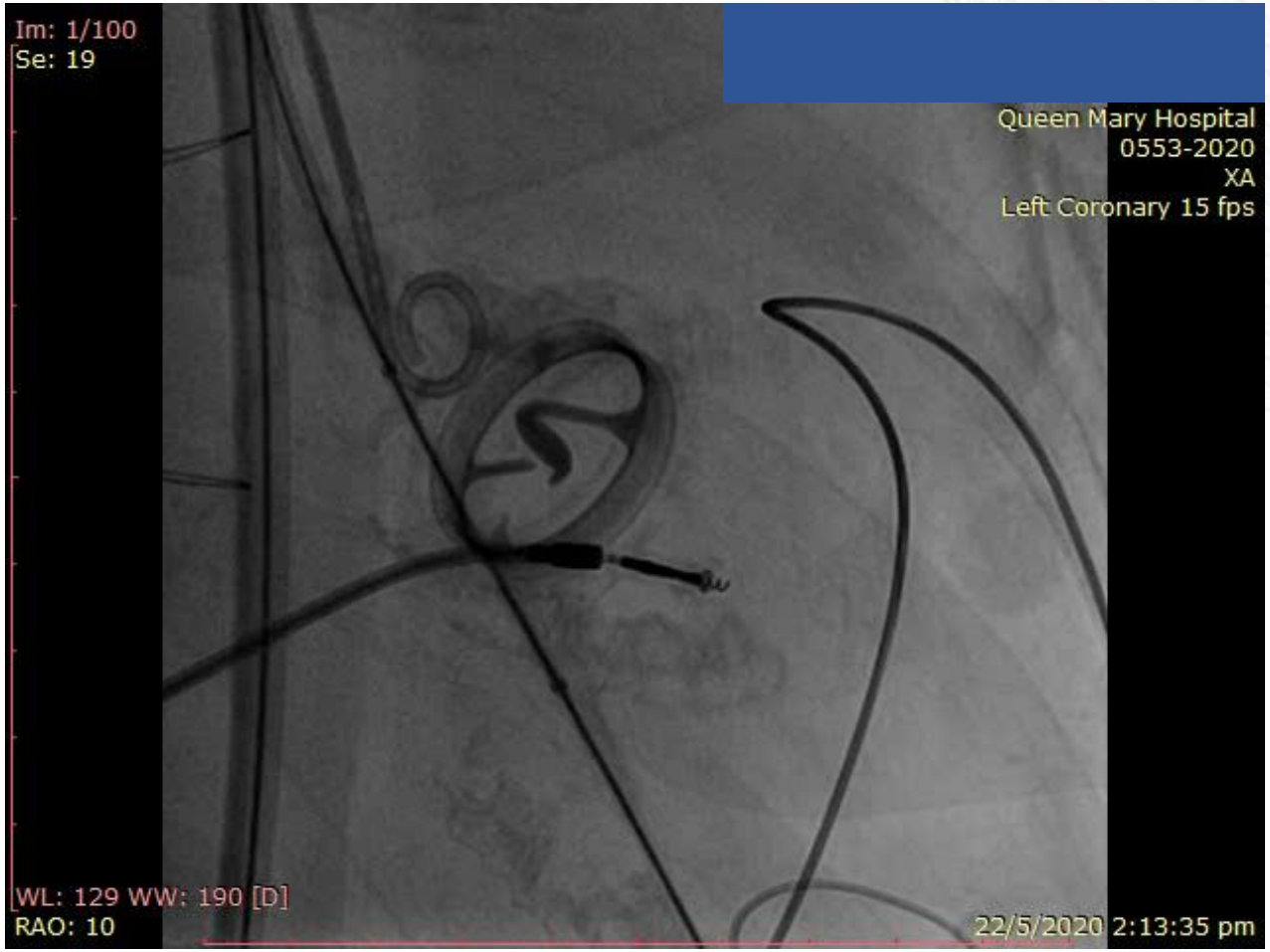
Access Route Distribution

CoreValve/Evolut R/PRO/+	
Transfemoral	95.1%
Subclavian	1.4%
Direct Aortic	3.3%
Trans-Carotid	0.2%
Others	0

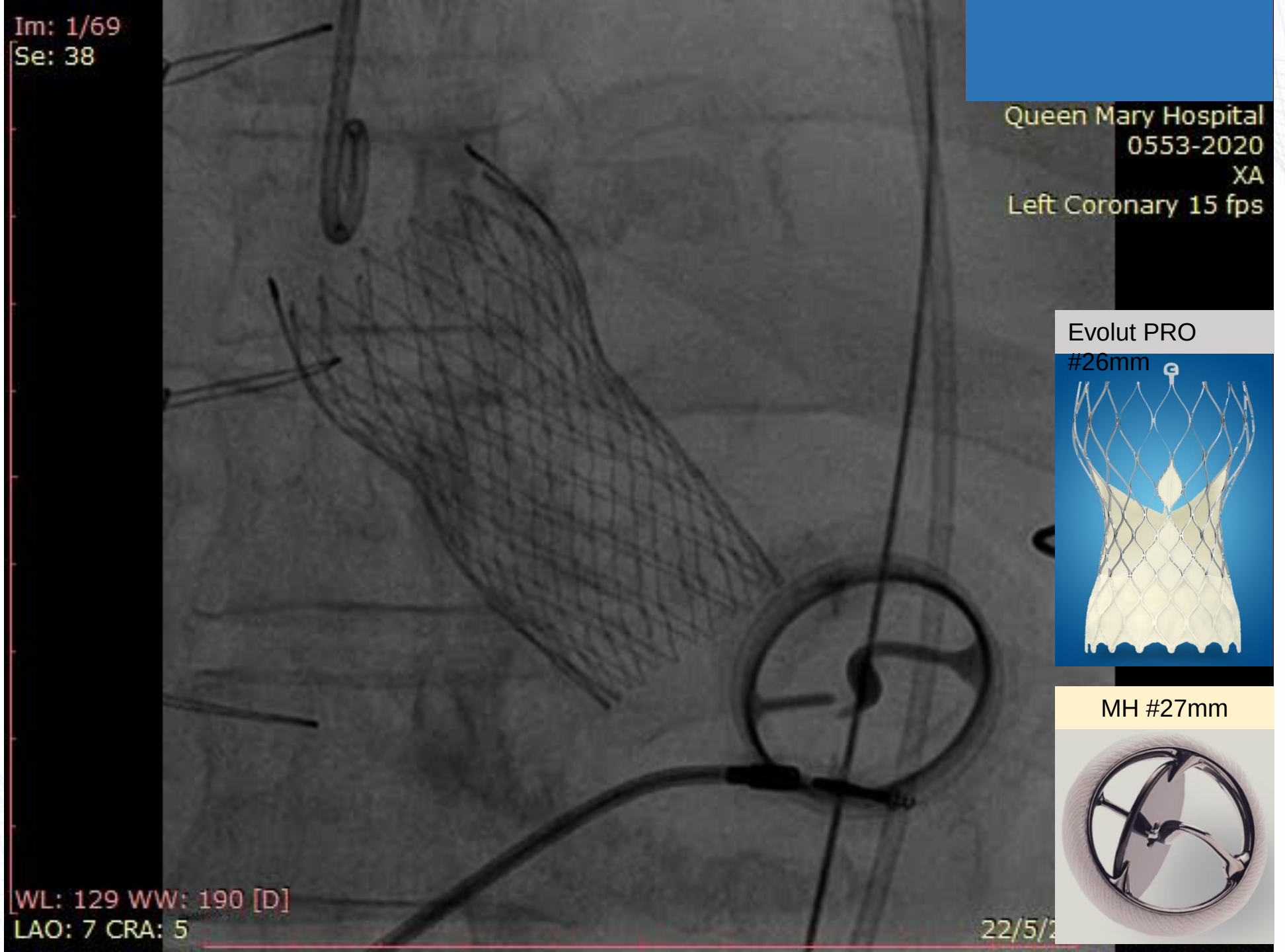



Im: 1/47
Se: 15
[redacted]
Queen Mary Hospital
0553-2020
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
RAO: 10
22/5/2020 2:05:37 pm


Im: 1/144
Se: 18
Queen Mary Hospital
0553-2020
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
RAO: 10
22/5/2020 2:13:05 pm

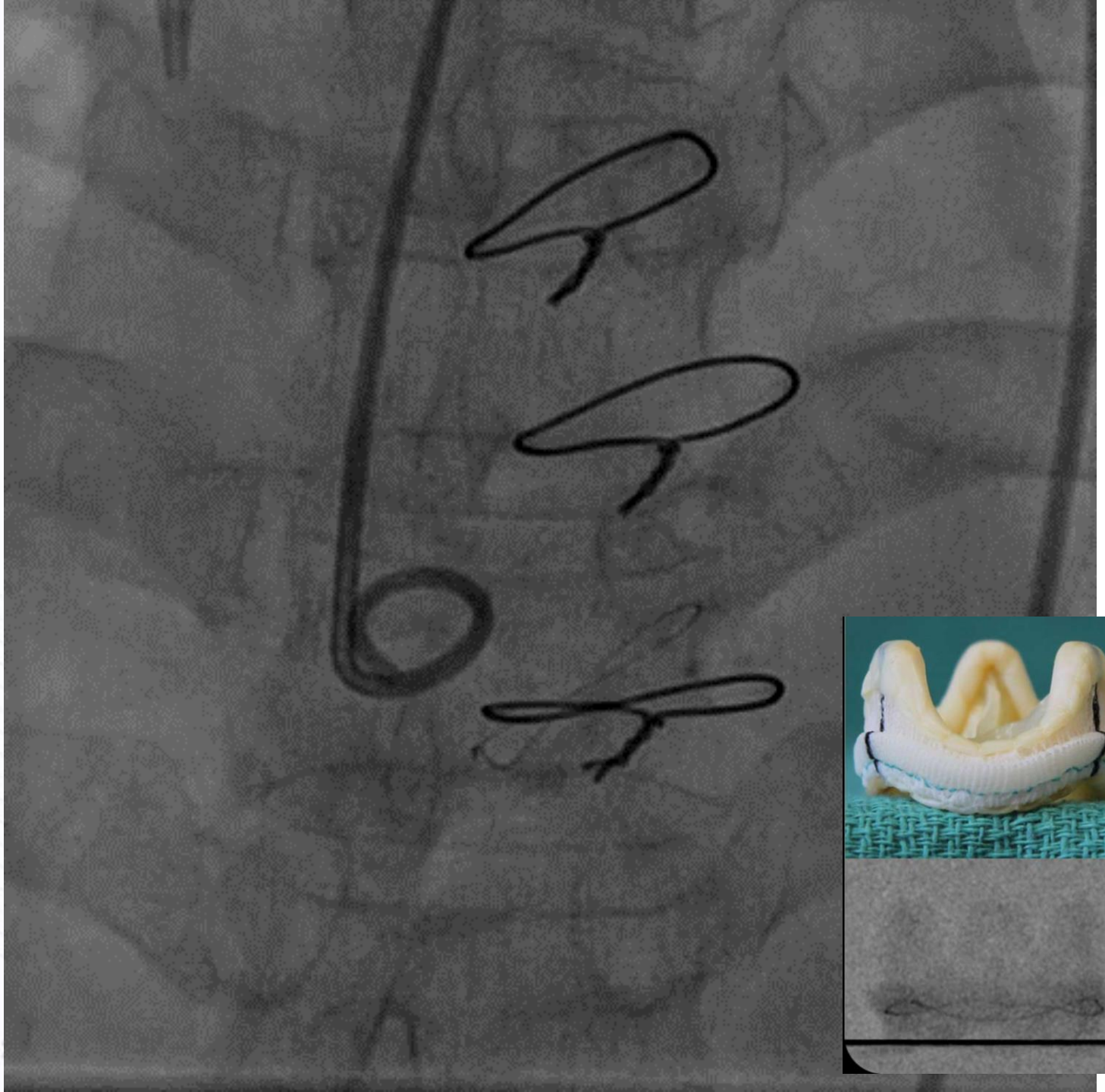

Im: 1/100
Se: 19
Queen Mary Hospital
0553-2020
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
RAO: 10
22/5/2020 2:13:35 pm


Im: 1/38
Se: 30
[redacted]
Queen Mary Hospital
0553-2020
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
LAO: 8 CAU: 9
22/5/2020 2:28:13 pm

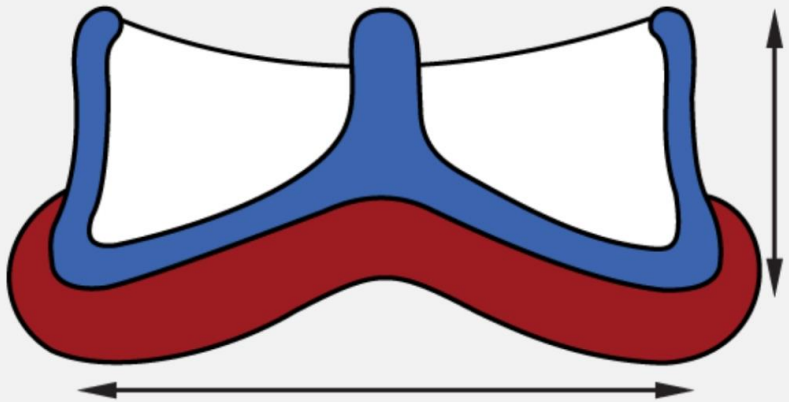


Evolut PRO #26mm

MH #27mm



Size: 19



Stent ID	Height	True ID
19	14	17

Fracturable

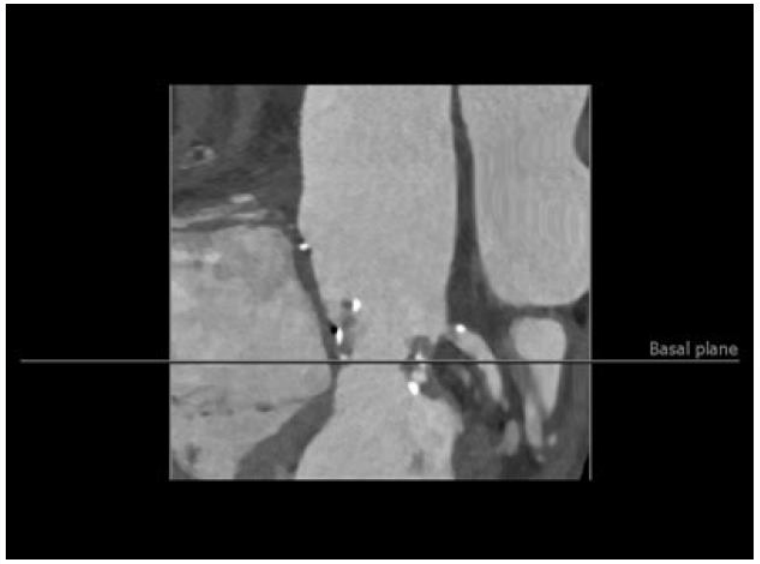
True Balloon Size: 20mm

After fracture
THV size needed may be larger

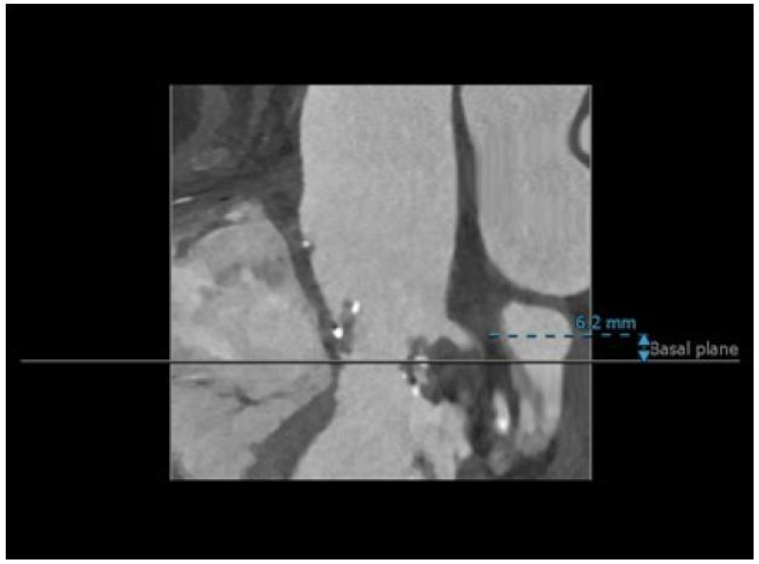
THV CURRENT

THV ARCHIVED

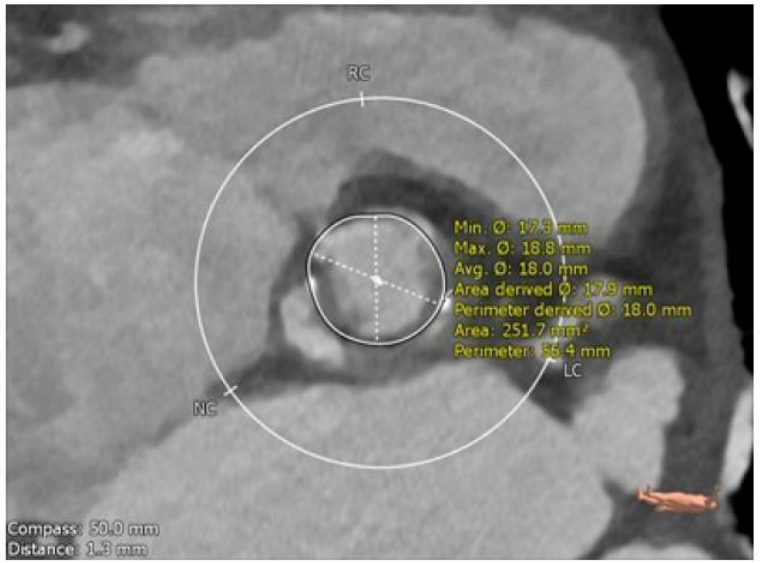
Stretched Vessel



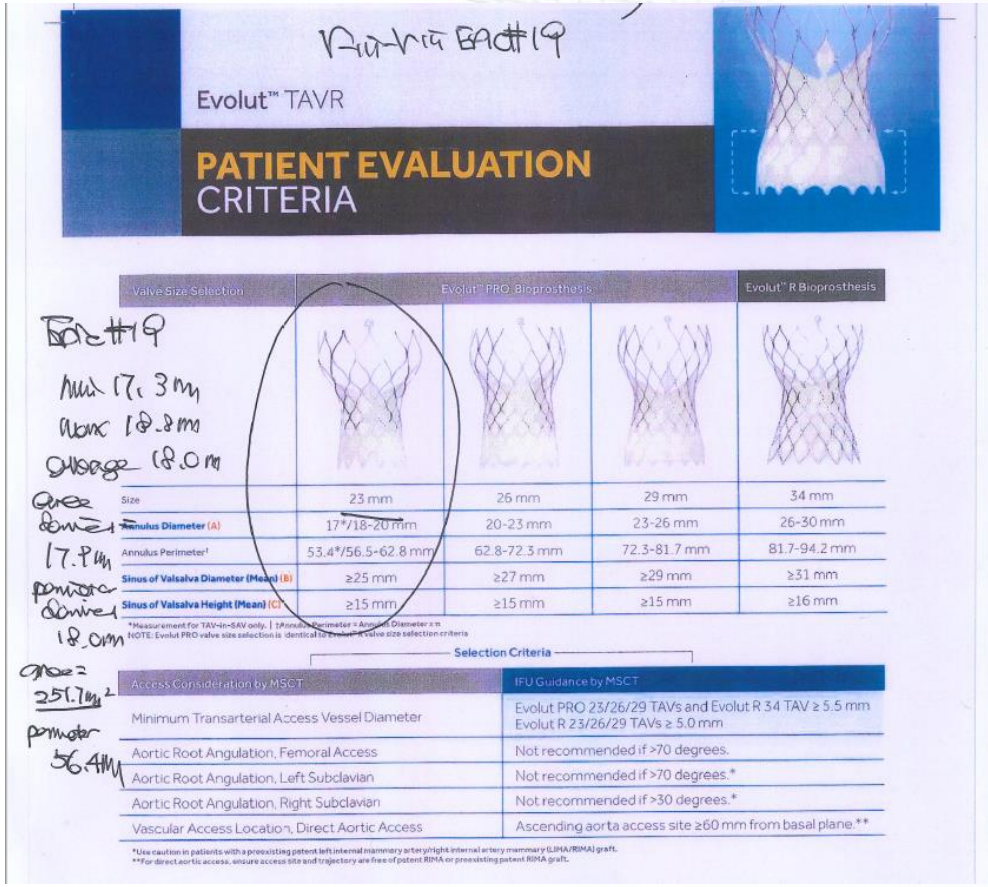
Stretched CMPR (Phase 35.0%)



Perpendicular Plane



Perpendicular Plane



Evolut™ TAVR

PATIENT EVALUATION CRITERIA

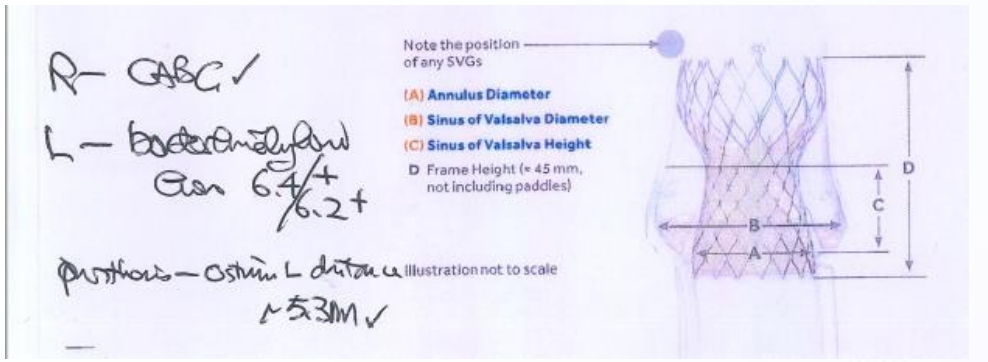
Valve Size Selection	Evolut™ PRO Bioprosthesis			Evolut™ R Bioprosthesis
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter (A)	17*/18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter†	53.4*/56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-94.2 mm
Sinus of Valsalva Diameter (Mean) (B)	≥25 mm	≥27 mm	≥29 mm	≥31 mm
Sinus of Valsalva Height (Mean) (C)	≥15 mm	≥15 mm	≥15 mm	≥16 mm

*Measurement for TAV-in-SAV only. | †Annulus Perimeter = Annulus Diameter × π
NOTE: Evolut PRO valve size selection is identical to Evolut R valve size selection criteria

Selection Criteria

Access Consideration by MSCT	IFU Guidance by MSCT
Minimum Transarterial Access Vessel Diameter	Evolut PRO 23/26/29 TAVs and Evolut R 34 TAV ≥ 5.5 mm Evolut R 23/26/29 TAVs ≥ 5.0 mm
Aortic Root Angulation, Femoral Access	Not recommended if >70 degrees.
Aortic Root Angulation, Left Subclavian	Not recommended if >70 degrees.*
Aortic Root Angulation, Right Subclavian	Not recommended if >30 degrees.*
Vascular Access Location, Direct Aortic Access	Ascending aorta access site ≥60 mm from basal plane.**

*Use caution in patients with a preexisting patent left internal mammary artery/right internal artery mammary (LIMA/RIMA) graft.
**For direct aortic access, ensure access site and trajectory are free of patent RIMA or preexisting patent RIMA graft.



Note the position of any SVGs

(A) Annulus Diameter
(B) Sinus of Valsalva Diameter
(C) Sinus of Valsalva Height
D Frame Height (≈ 45 mm, not including paddles)

Illustration not to scale

Edwards 20mm X 4cm Balloon

TAVR in Hong Kong – More TAVI Systems

TAVI Devices Used in Hong Kong

- Edwards SAPIEN 3
- Medtronic Evolut PRO+
- Boston Scientific ACURATE neo2

- Abbott NAVITOR
- Biosensor NVT ALLEGRA

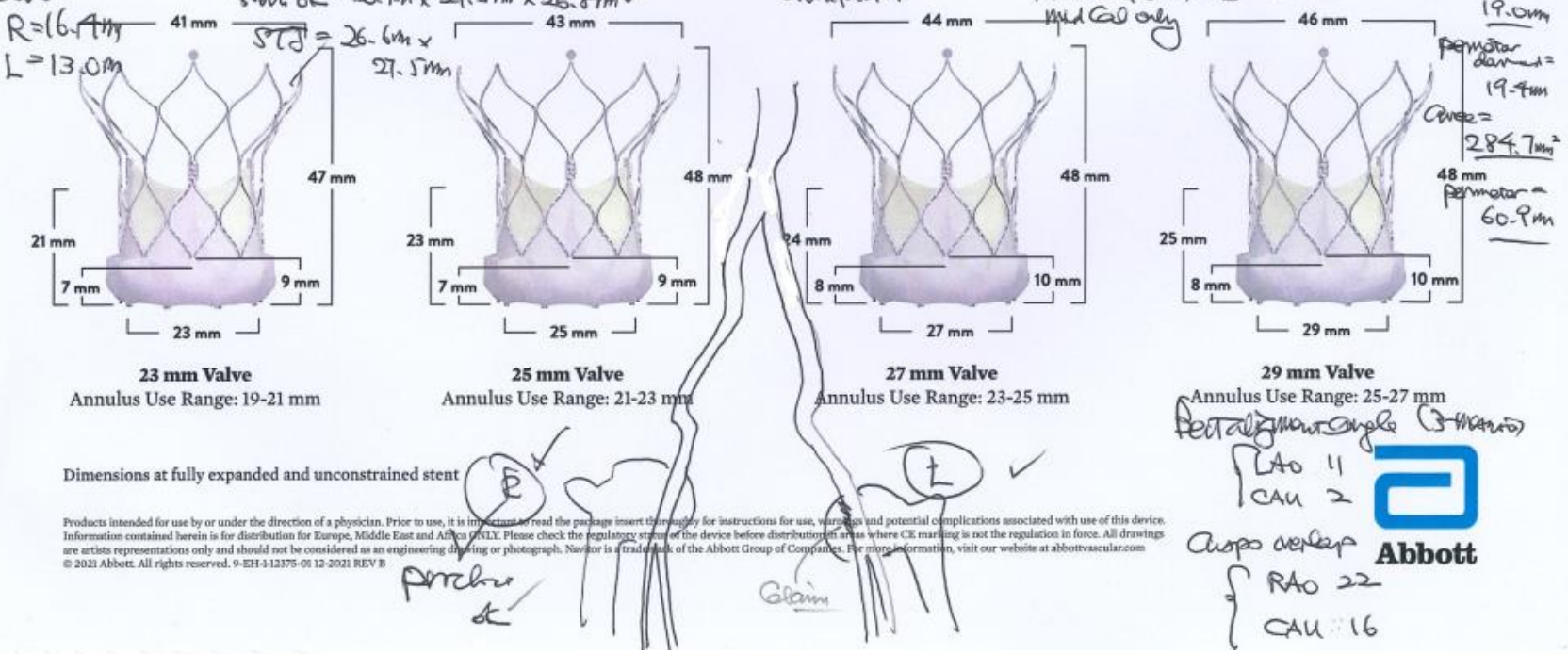
- JC Medical J Valve

Navitor

NAVITOR™ VALVE SIZING GUIDE

Navitor Valve Size	Annulus Use Range Diameter (mm)	Annulus Area (mm^2)*	Annulus Perimeter (mm)*	Ascending Aorta Diameter (mm)	Sinus of Valsalva Width (mm)	Minimum Vessel Diameter (mm)	Implant Target Depth Below Annulus (mm)
23 mm	19-21	277-346	60-66	26-36	≥ 25	≥ 5.0	3
25 mm	21-23	338-415	66-73	28-38	≥ 27	≥ 5.0	3
27 mm	23-25	405-491	72-79	30-40	≥ 29	≥ 5.5	3
29 mm	25-27	479-573	79-85	32-42	≥ 31	≥ 5.5	3

*Recommendation based on circular or elliptical geometry (≥ 0.73 ratio)



23 mm Valve
Annulus Use Range: 19-21 mm

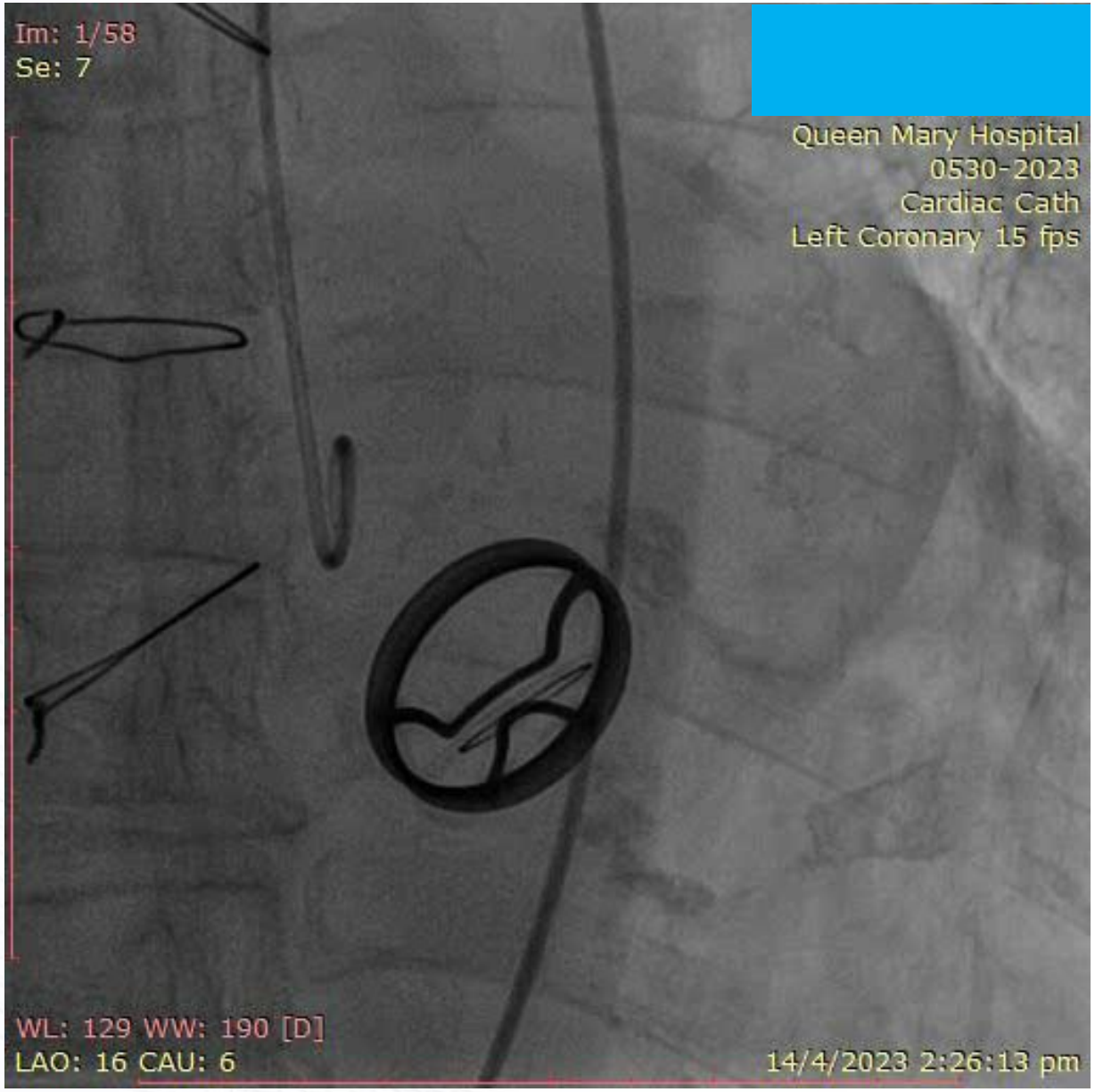
25 mm Valve
Annulus Use Range: 21-23 mm

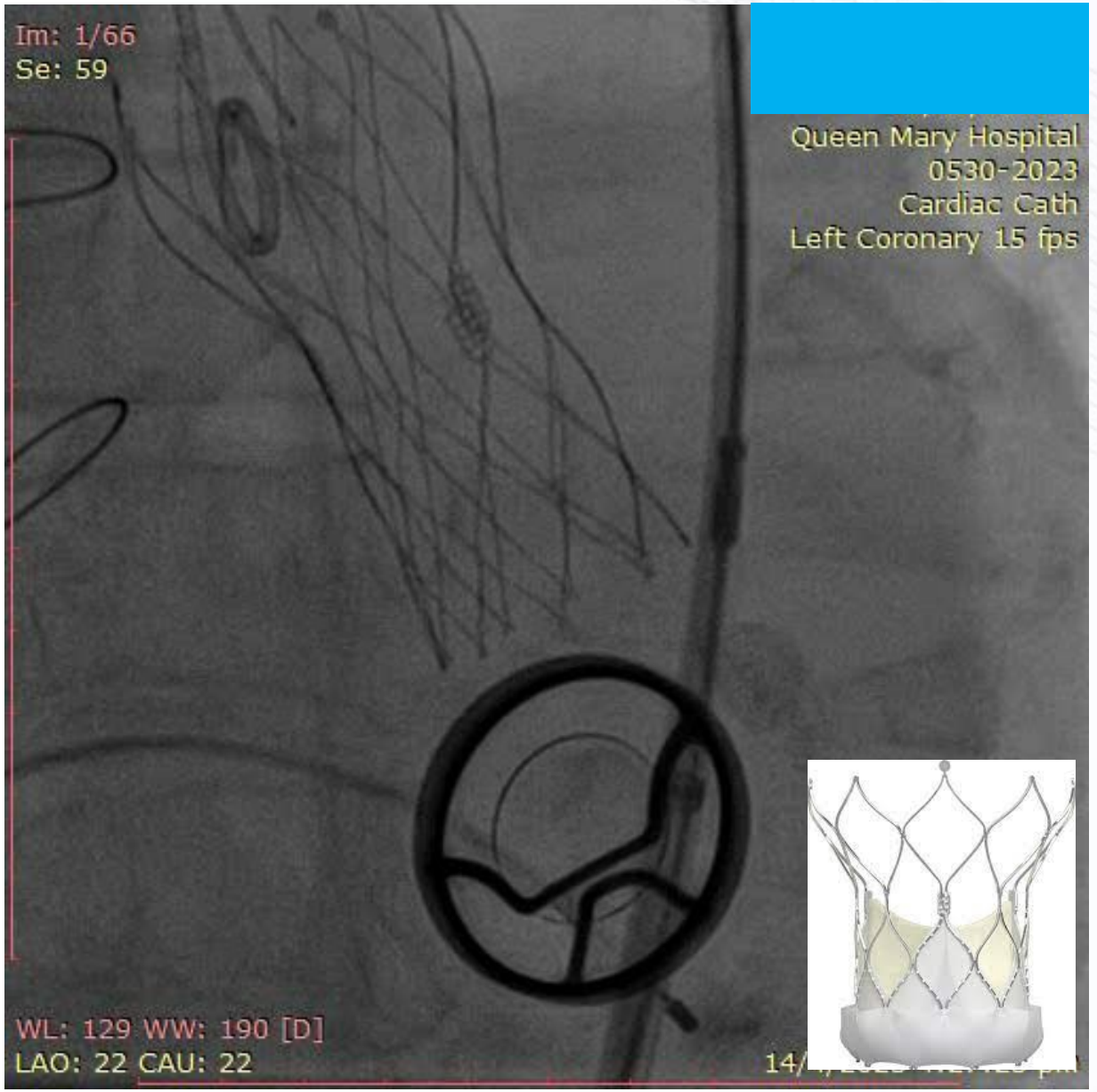
27 mm Valve
Annulus Use Range: 23-25 mm

29 mm Valve
Annulus Use Range: 25-27 mm

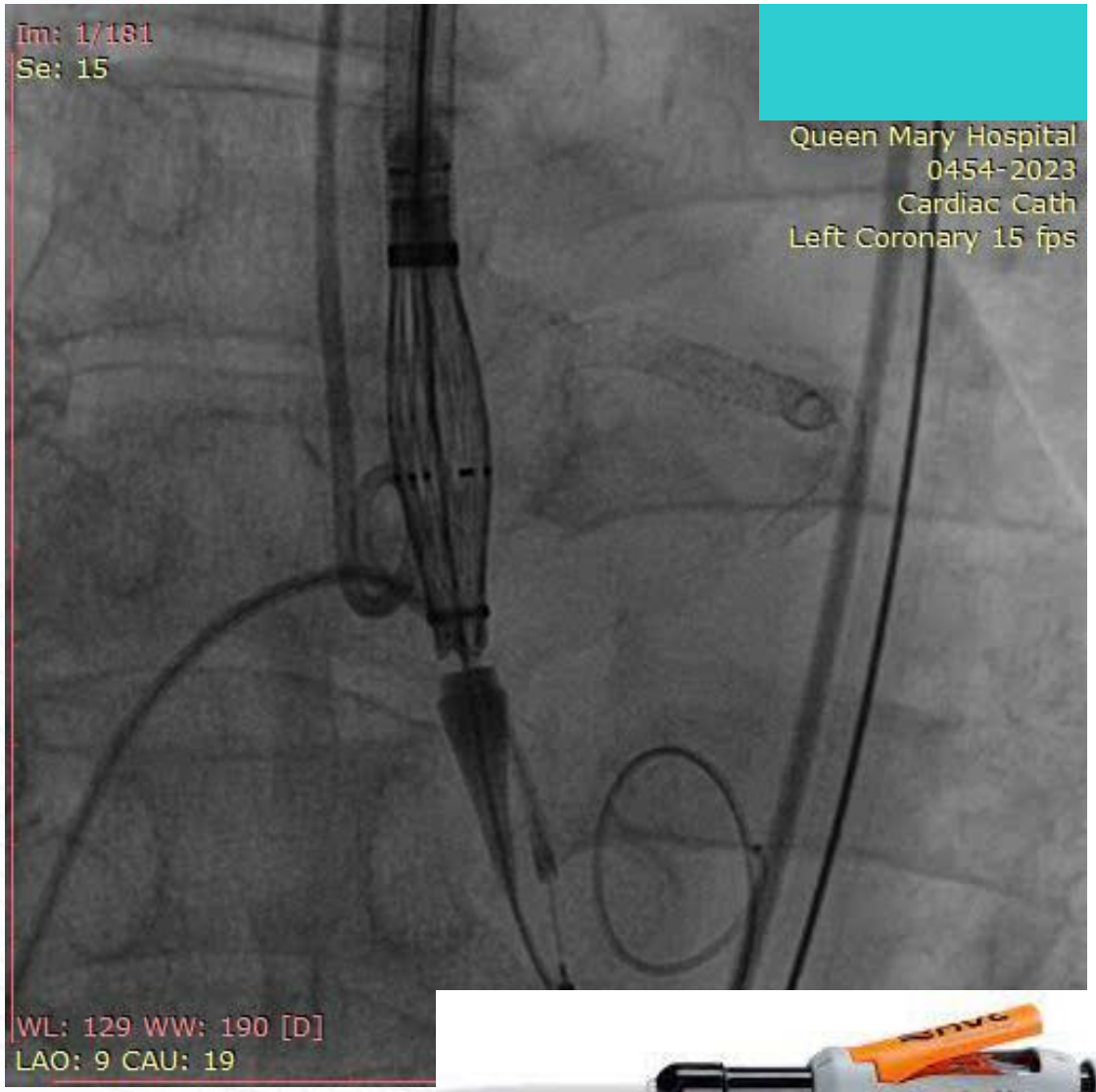
Dimensions at fully expanded and unconstrained stent

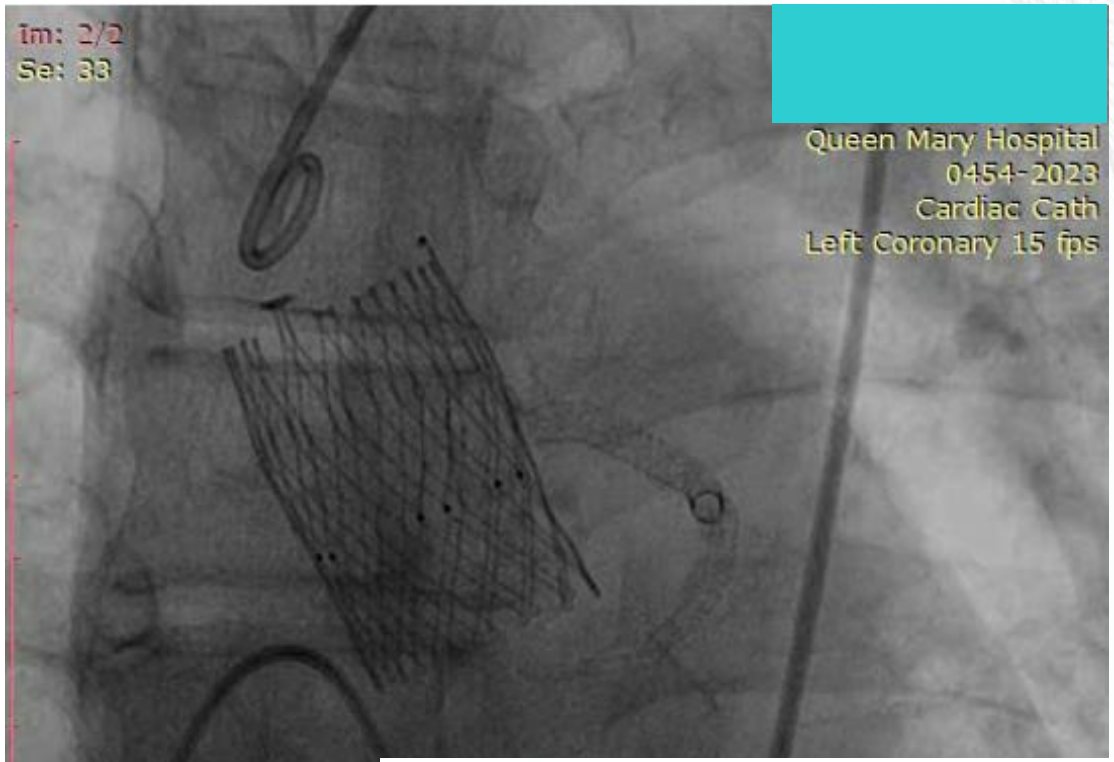
Abbott

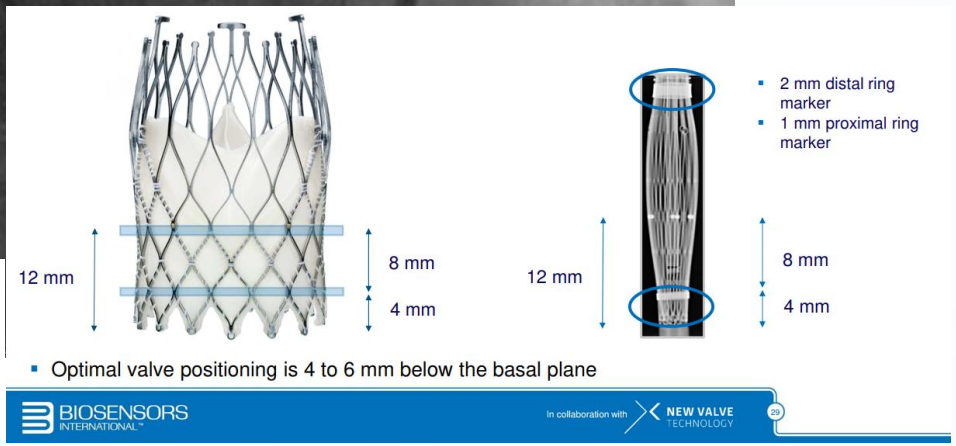

Im: 1/58
Se: 7
Queen Mary Hospital
0530-2023
Cardiac Cath
Left Coronary 15 fps
WL: 129 WW: 190 [D]
LAO: 16 CAU: 6
14/4/2023 2:26:13 pm


Im: 1/66
Se: 59
Queen Mary Hospital
0530-2023
Cardiac Cath
Left Coronary 15 fps
WL: 129 WW: 190 [D]
LAO: 22 CAU: 22

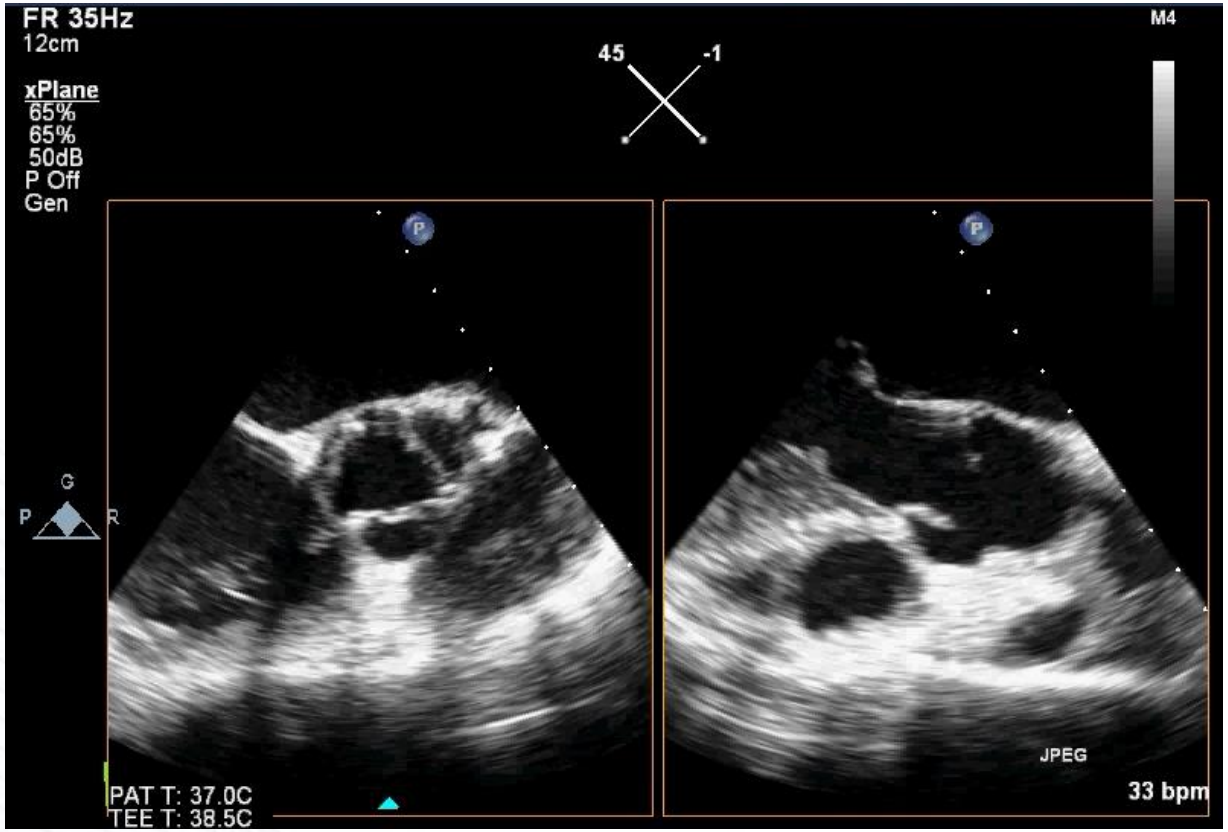
Allegra

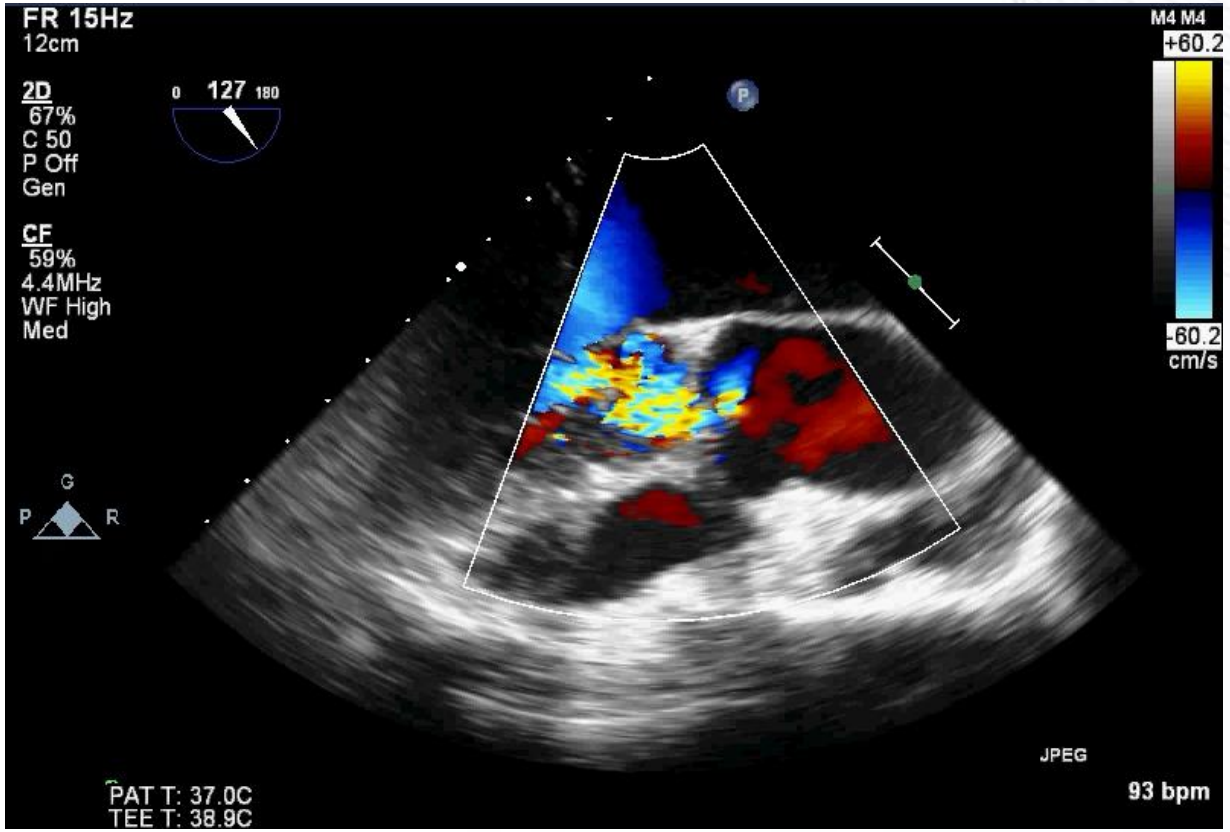

Im: 1/181
Se: 15
Queen Mary Hospital
0454-2023
Cardiac Cath
Left Coronary 15 fps
WL: 129 WW: 190 [D]
LAO: 9 CAU: 19


Im: 2/2
Se: 33
Queen Mary Hospital
0454-2023
Cardiac Cath
Left Coronary 15 fps

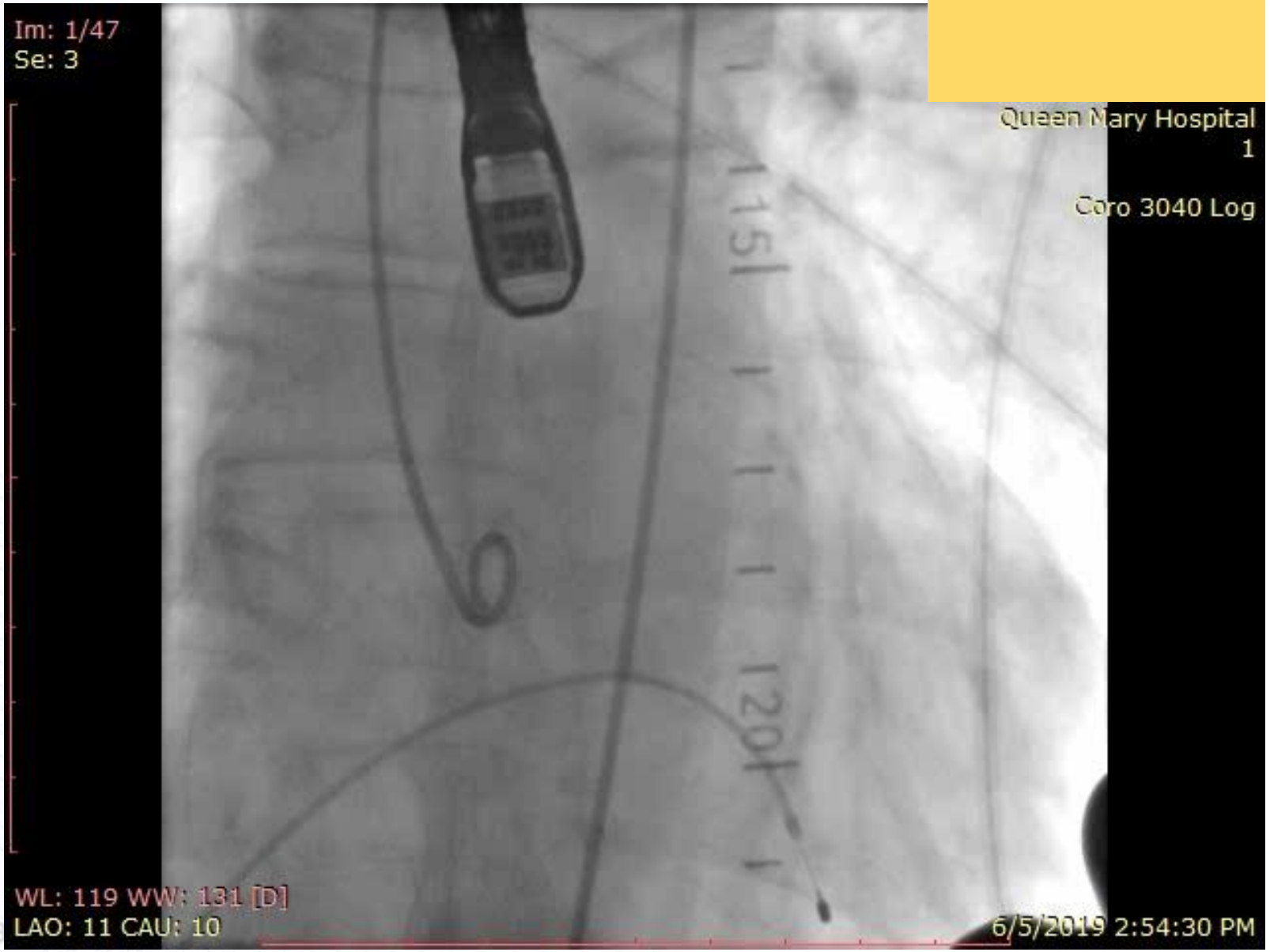

12 mm
8 mm
4 mm
12 mm
8 mm
4 mm
2 mm distal ring marker
1 mm proximal ring marker
Optimal valve positioning is 4 to 6 mm below the basal plane
BIOSENSORS INTERNATIONAL
In collaboration with
NEW VALVE TECHNOLOGY

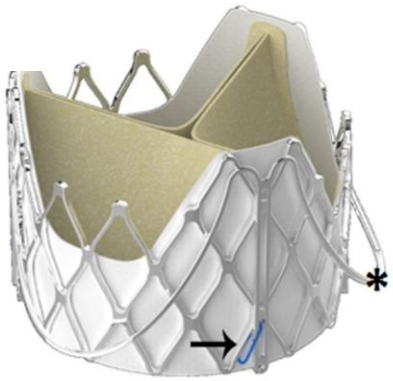
TAVI in Pure AR





J Valve TA





Suture

Clasper


Im: 1/51
Se: 17
1
Coro 3040 Log
WL: 119 WW: 120 [D]
LAO: 9 CAU: 7
6/5/2019 3:17:19 PM

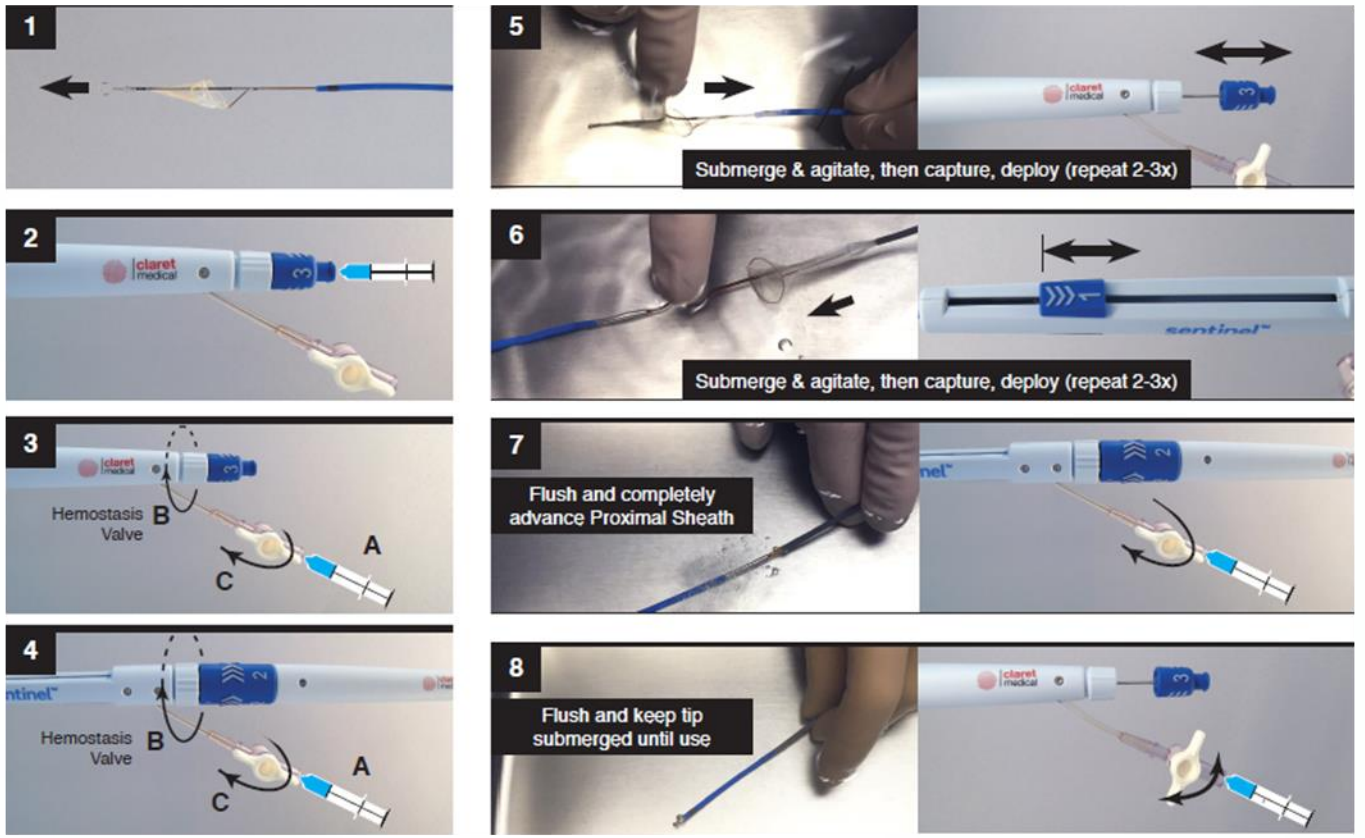

Im: 1/59
Se: 24
1
Coro 3040 Log
WL: 119 WW: 124 [D]
LAO: 9 CAU: 7
6/5/2019 3:22:32 PM

TAVR in Hong Kong – Cerebral Embolic Protection

CEP in TAVI

- Sentinel Embolic Protection

SENTINEL™ CPS– Device Preparation

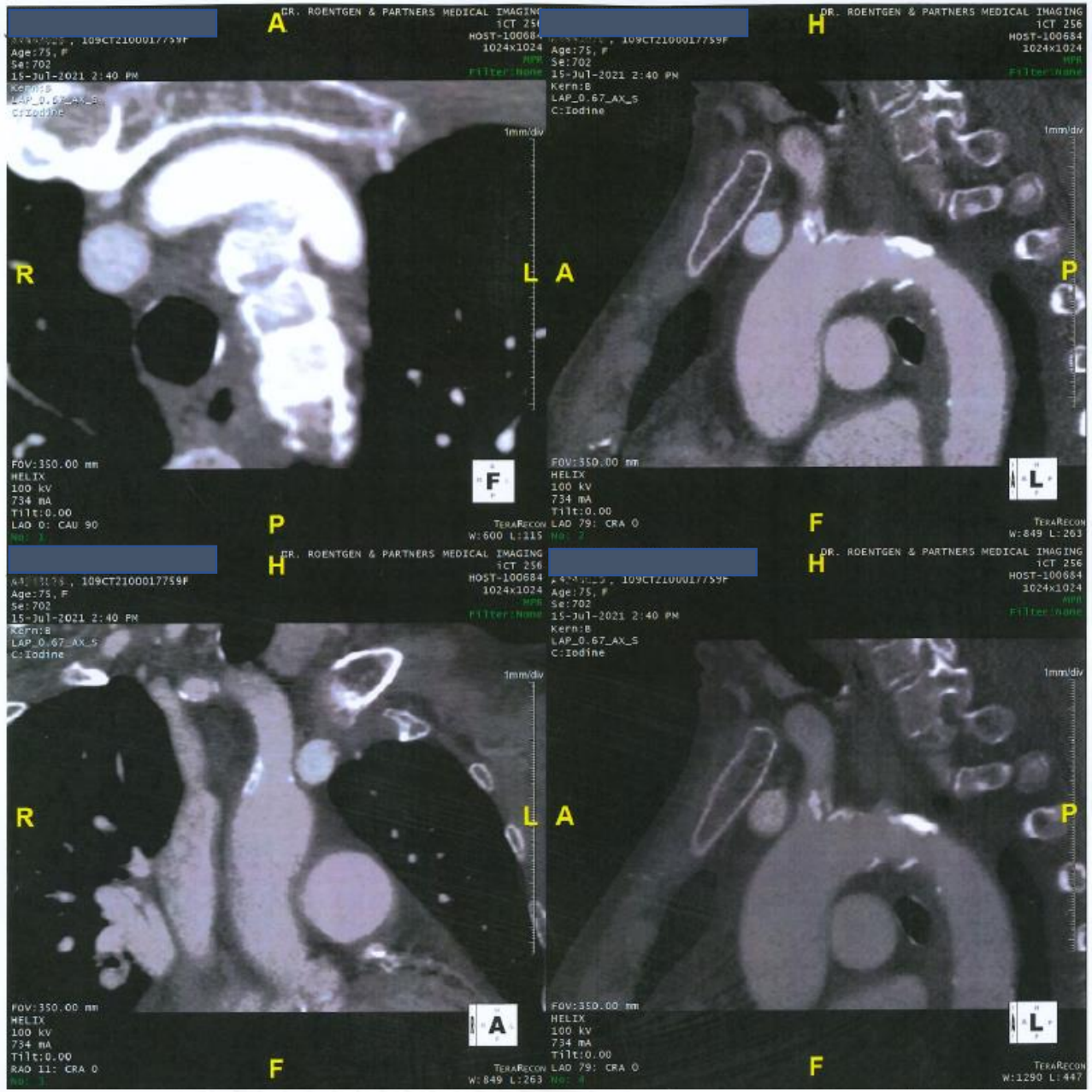


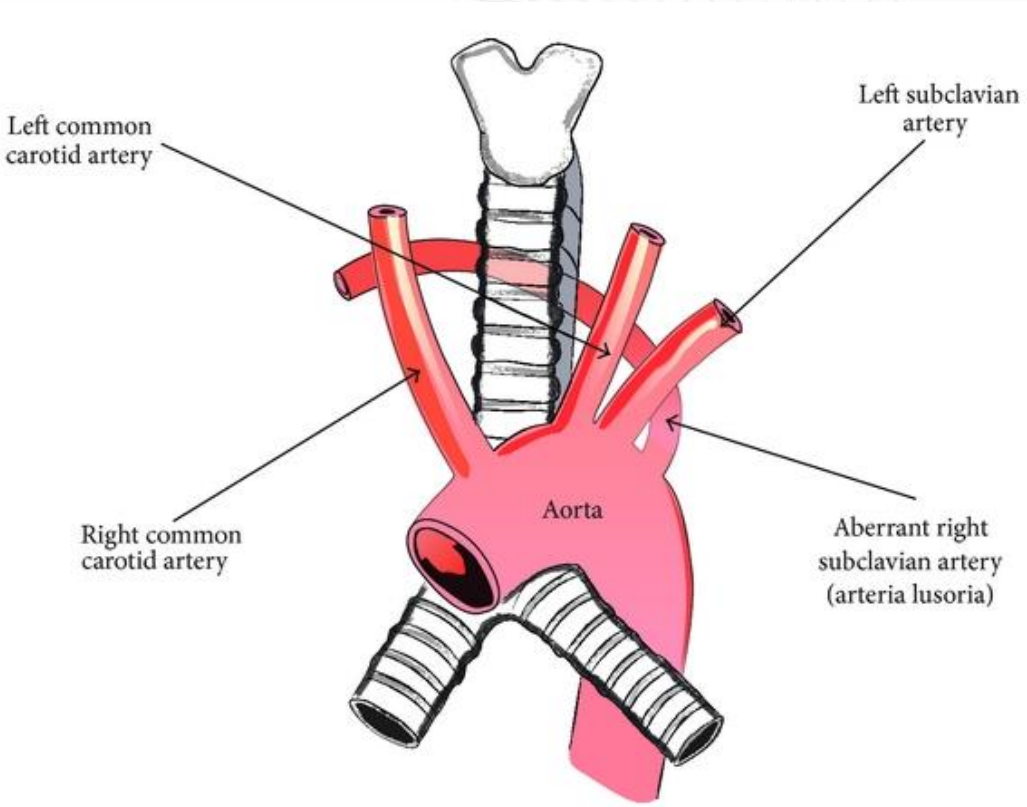
Be gentle when sheathing the Distal filter during prep

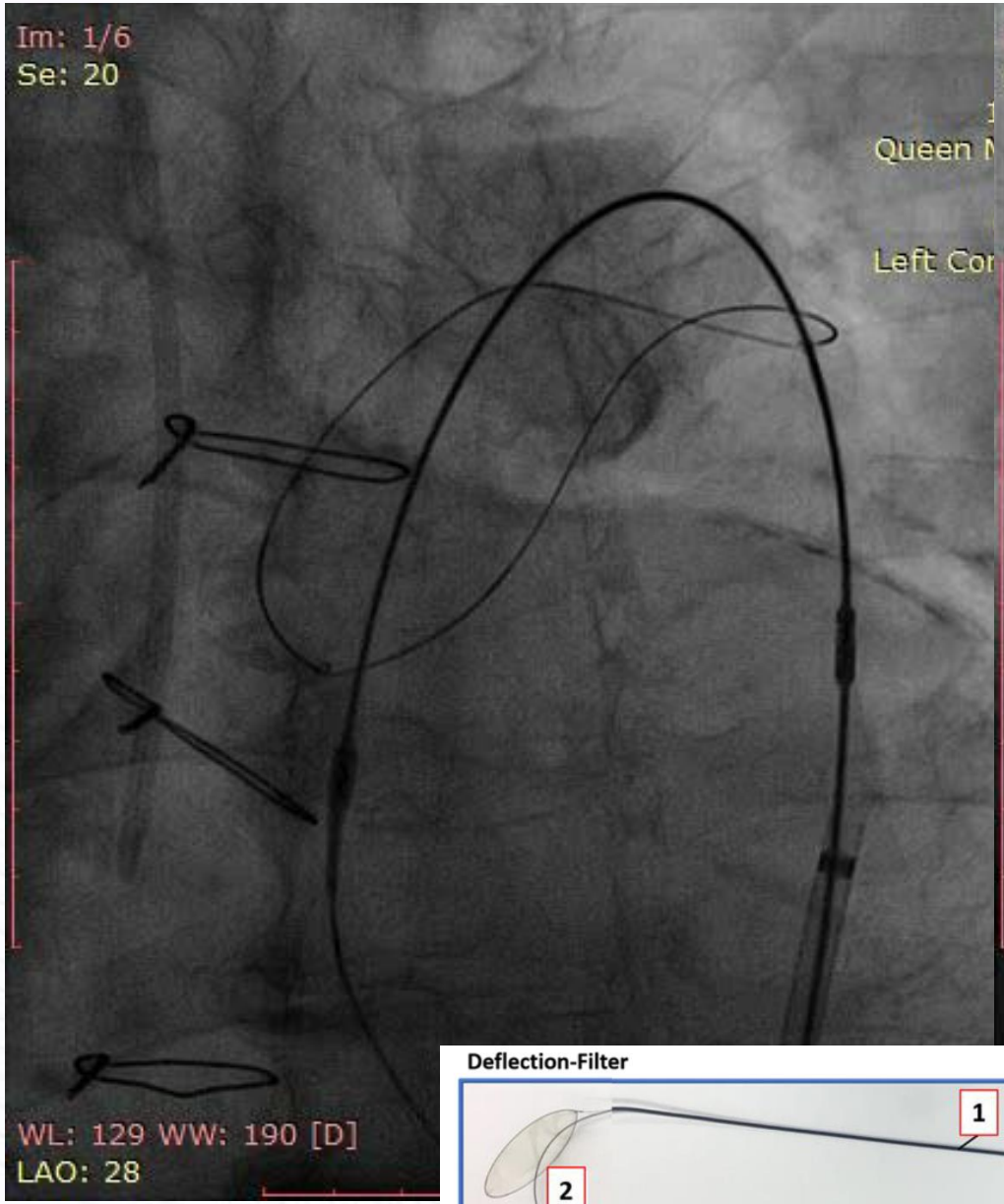
Do not use a SENTINEL system that has not been properly flushed

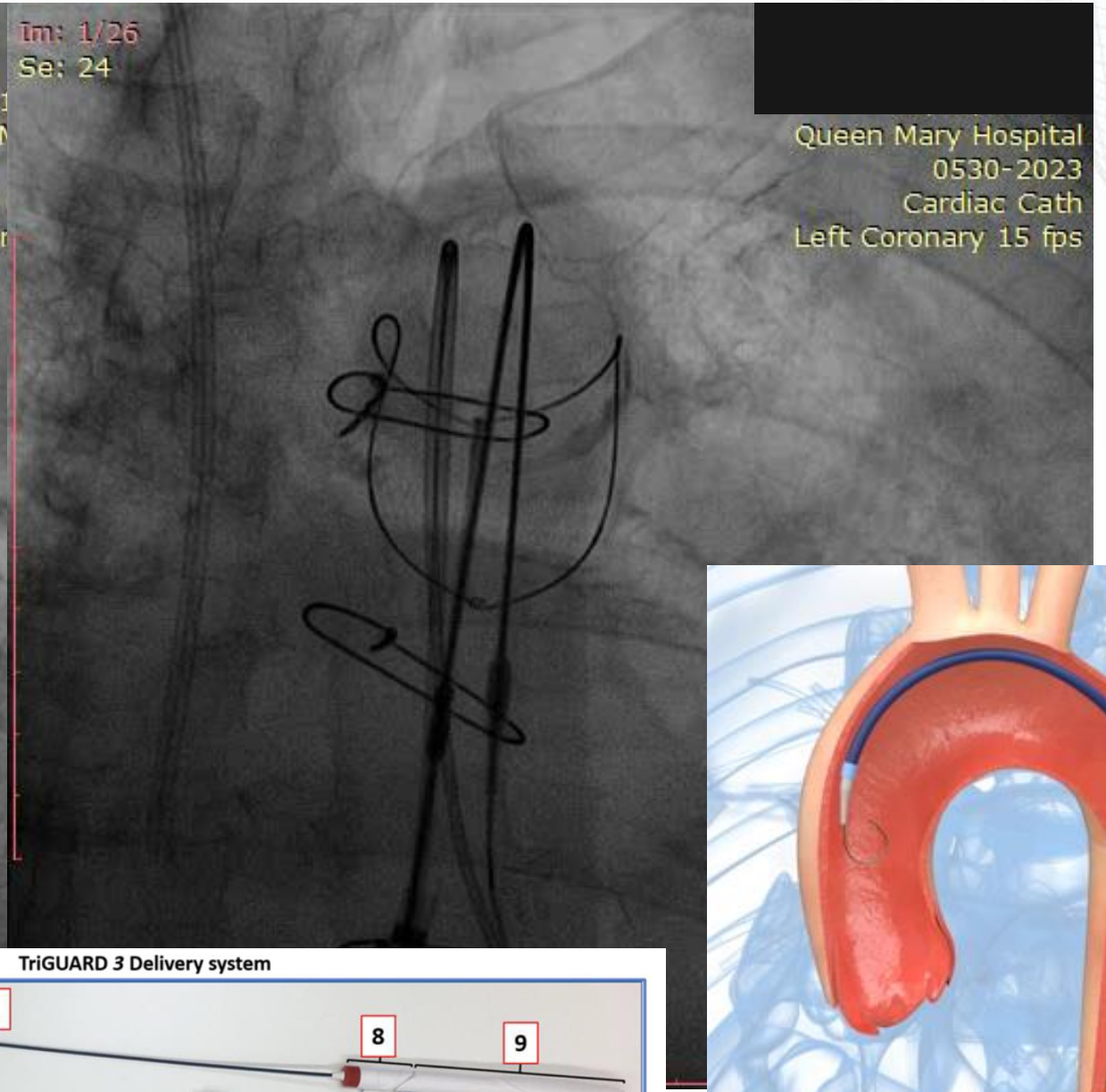
---

Failure to prepare and properly flush the device before use may introduce air and result in patient injury


DR. ROENTGEN & PARTNERS MEDICAL IMAGING
Age:75, F
Se:702
15-Jul-2021 2:40 PM
Kern:B
LAP_0.67_AX_S
C:Iodine
FOV:350.00 mm
HELIX
100 kV
734 mA
Tilt:0.00
LAO 0: CAU 90
LAO 79: CRA 0
RAO 11: CRA 0
TeraRecon
R
L
A
P
F
H

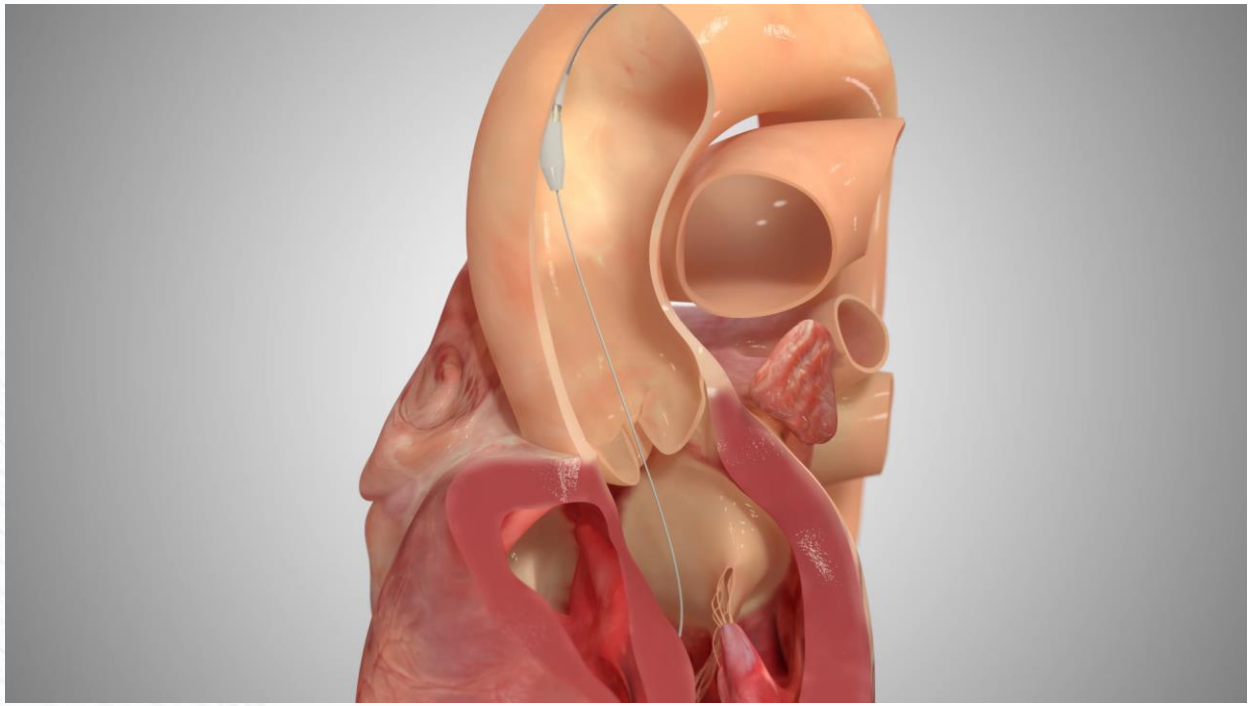

Left common carotid artery
Left subclavian artery
Aorta
Right common carotid artery
Aberrant right subclavian artery (arteria lusoria)


Im: 1/6
Se: 20
WL: 129 WW: 190 [D]
LAO: 28

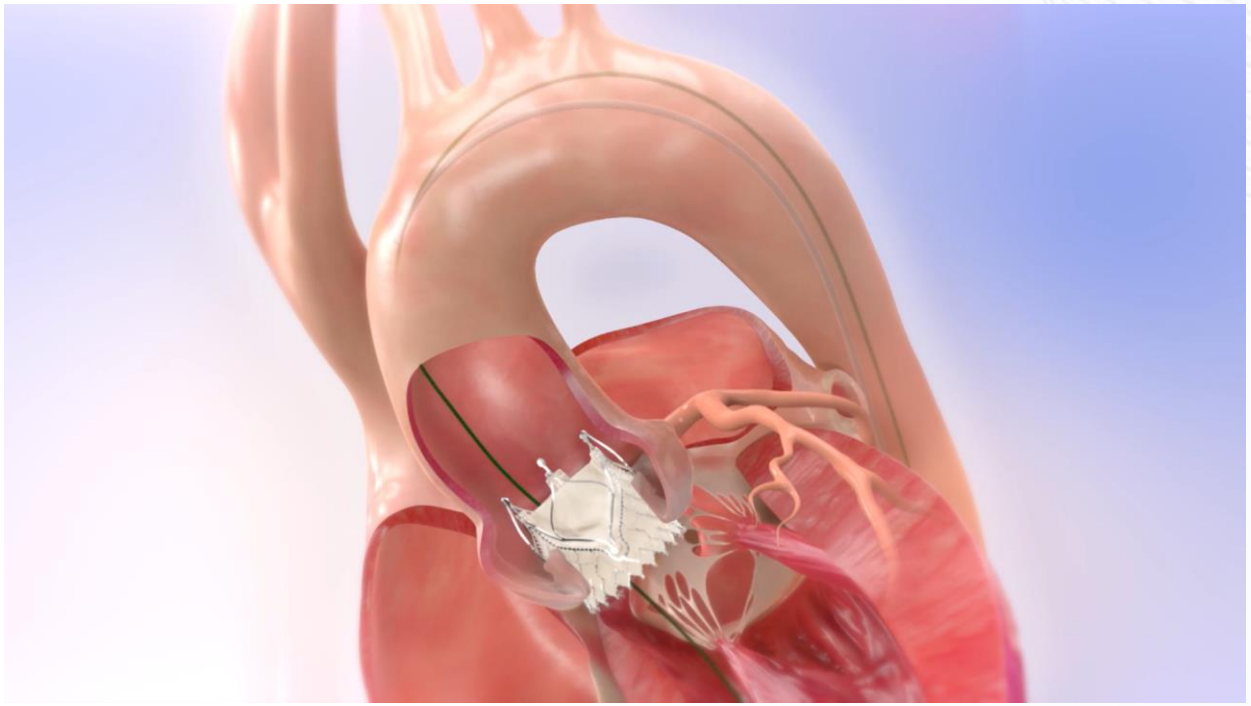

Im: 1/26
Se: 24
Queen Mary Hospital
0530-2023
Cardiac Cath
Left Coronary 15 fps


Deflection-Filter
TriGUARD 3 Delivery system
1
2
3
4
5
6
7
8
9

Other Systems



TF J Valve



TF JenaValve