# Transseptal Mitral Valve in Valve Replacement (TMVR)

**JONG WOOK LEE , RT**

**Cardiovascular center, Seoul St. Mary's Hospital**
**The Catholic University of Korea**

신청기술 : 경피적 승모판막 재치환술

경피적 승모판막 재치환술(Transcatheter Mitral Valve-in-valve Replacement (Implantation))은 외과적으로 삽입된 생체 인공 승모판막의 협착 또는 기능부전이 있는 환자를 대상으로 경피적 접근을 통해 새로운 인공 승모판막을 삽입하여 환자의 판막기능을 대체하는 기술로, 의료법 제53조 및 신의료기술평가에 관한 규칙 제3조의 규정에 따라 '경피적 승모판막 재치환술(경피적 승모판막 Valve-in-valve 삽입)'이라는 기술명으로 2023년 2월 21일에 신의료기술평가 신청되었다.

동 기술은 2021년 10월 17일 '경피적 승모판막 Valve-in-Valve 삽입(Transcatheter Mitral Valve-in- Valve Implantation)'이라는 기술명으로 의료기기 허가-신의료기술평가 통합운영 신청되어 2022년 제6차 신의료기술평가위원회(2022.6.24.)에서 연구단계기술(기술분류 II-a)로 평가된 바 있다.

이후 동일 의료기회사에서 최종 변경허가 전 소위원회에서 검토되었던 사용목적(STS 위험 점수에 기초하여 30일에 수술예측사망률이 ≥ 8%인 경우와 STS 위험 계산기로 측정되지 않은 기타 임상 동반 질환이 있는 경우)으로 식품의약품안전처 의료기기 변경허가(2023.2.16.)를 득한 뒤 신의료기술평가를 재신청하였다.

평가결과

동 기술은 체계적 문헌고찰을 통해 기 평가 소위원회에서 선택되었던 총 17편(코호트연구 4편, 증례연구 13편)의 문헌에 근거하여 안전성과 유효성을 평가하였으며, 기 평가 이후 확인된 3편(증례연구 3편)을 추가 검토하였다.

안전성

동 기술의 안전성은 시술 관련 합병증과 보존한도로 평가하고자 하였으나, 보존한도에 대해 보고한 문헌은 없었다.

시술 관련 합병증(16편)은 사망을 비롯하여 좌심실 유출로 폐쇄, 혈관/출혈 합병증, 뇌졸중, 부정맥 등이 0 ~ 38.9%로 보고되었으며, 수술적 승모판막 재치환술과 비교한 연구(4편)에서는 중재군 0 ~ 12.2%, 비교군 0 ~ 22.2%로 치료법 간 유의한 차이가 없거나 중재군의 발생률이 유의하게 낮은 것으로 보고되었다. 기 평가 이후 확인된 증례연구 3편에서는 사망 0 ~ 6.7%, 그 외 합병증(출혈, 뇌졸중, 신장 손상 등) 0 ~ 41.9%로 보고되었다.

기 평가 소위원회는 관련 문헌에서 시술 관련 합병증이 수술적 승모판막 재치환술군과 비교 시 유의한 차이가 없거나 발생률이 더 낮고, 보존한도는 관련 문헌에서 보고되지 않았으나 Sathananthan 등(2020)에서 가속 수명시험결과로 SAPIEN 3 장비의 내구성이 25년으로 예측되어 안전성은 수용 가능하다는 의견이었다.

1. 외과적으로 삽입된 생체 인공 승모판막의 협착 또는 기능부전이 있는 환자
2. STS Score 8% 이상 (심장통합진료)

# FDA approved SAPIEN 3 for mitral ViV in 2017


## Edwards SAPIEN 3 Valve Receives FDA Approval For Aortic, Mitral Valve-In-Valve Procedures

**IRVINE, Calif., June 5, 2017** -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today announced it has received U.S. Food and Drug Administration (FDA) approval for aortic and mitral valve-in-valve procedures using the Edwards SAPIEN 3 transcatheter heart valve. The SAPIEN 3 valve is the first transcatheter heart valve approved in the U.S. for th aortic and mitral patients who are at high risk for a subsequent open-heart surgery to replace

HOME > 보건/산업 > 보건/정책

## '경피적 승모판막 재치환술' 등 신의료기술 인정

한국보건의료연구원, 23년 제3차 신의료기술 고시 개정사항 발표

이지혜 | admin@hkn24.com | 승인 2023.04.28 11:18

# Total 7 cases of TMVR (Valve-in-Valve)

- 18.10.19 F/83 – TMVR
- 19.09.11 M/80 – TMVR
- 20.12.16 F/77 - TMVR + TAVI
- 21.01.27 M/80 - TMVR
- 22.08.03 F/76 - TMVR + TAVI

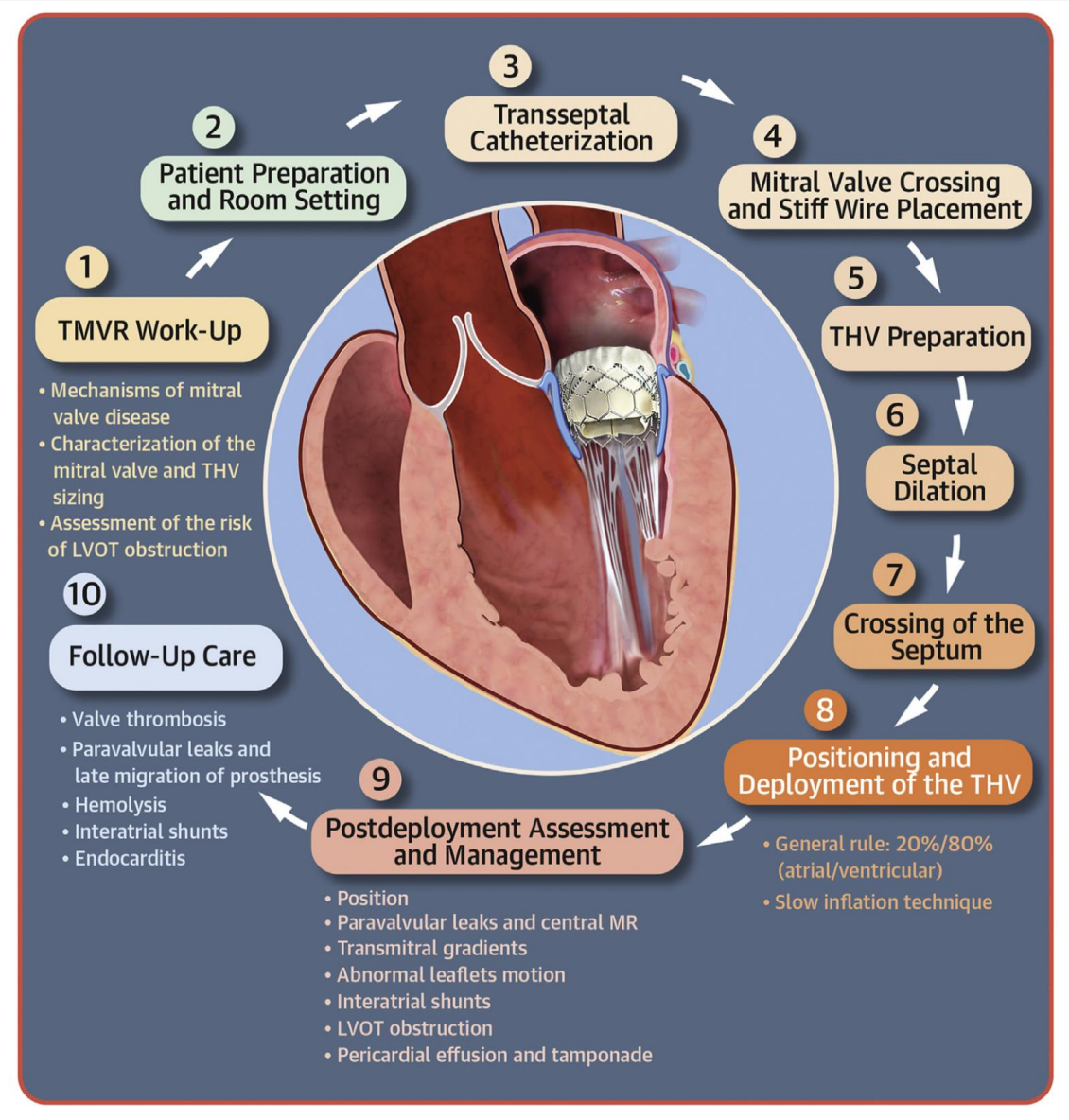
신의료기술인정 前
→전액비급여본인부담 or 의료지원사업팀

---

- 23.09.06 F/85 – TMVR
- 24.01.11 F/82 - TMVR

신의료기술인정 後

# Major Steps of Transseptal Transcatheter Mitral Valve Replacement








Urena, M. et al. J Am Coll Cardiol Intv. 2017;10(19):1905–19.

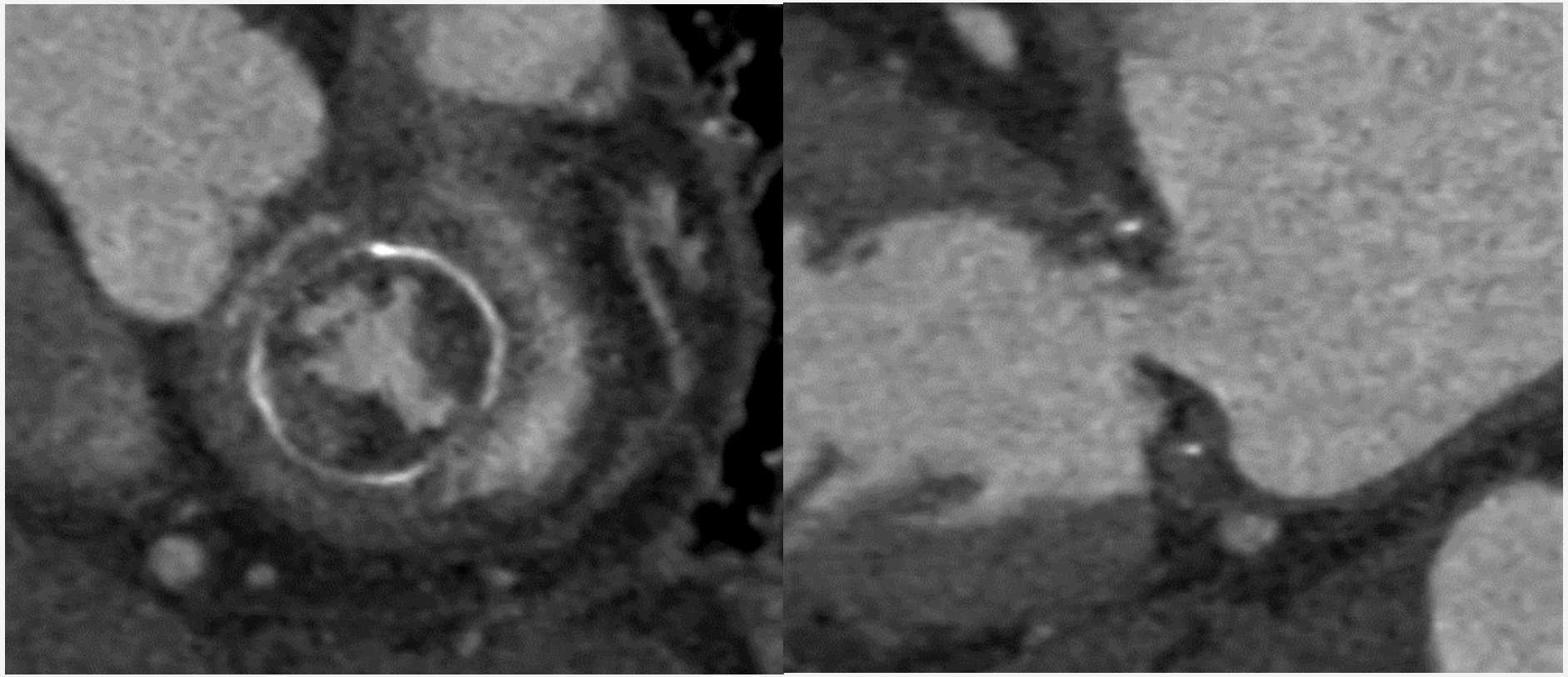
# 1st CASE (2018.10.19) - TMVR

- F/83 (140cm/53kg)
- Chief complaint
  - Dyspnea
- Medical history
  - Severe MS s/p MVR (’16.09 St.Jude Epic tissue valve, 27mm 의정부성모병원)
  - HTN (+), DM(-), Dyslipidemia(+)
  - Permanent AF, HF
  - Apixaban 2.5mg bid, amlodipine 5mg, bisoprolol 2.5mg, laisx 20mg, spironolactone 12.5mg, atorvastatin 10mg

# 1st CASE (2018.10.19) - TMVR

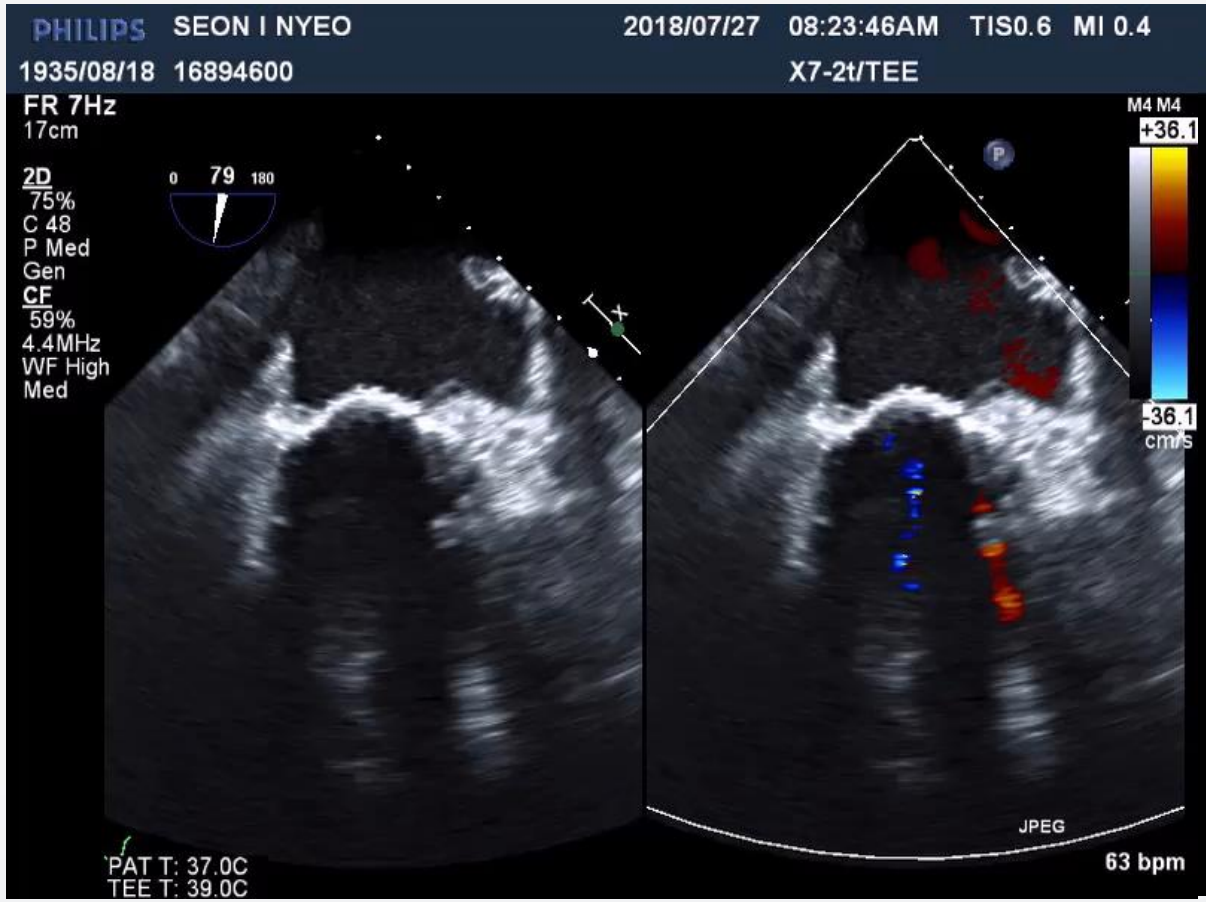
- 2016.09 Severe MS s/p MVR (Epic tissue valve, 27mm 의정부성모)
- 2016.10 TTE
  - EF 55%, s/p MVR : MVA(PHT=110)=2.0cm2,  MeanPG=2.3mmHg, MV calcification,  MR(tr)
- 2018.07 NYHA III-IV dyspnea, pul. edema 로 응급실 내원
- 2018.07 TTE
  - EF 59%, s/p MVR : **Severe MS** (MVA by PHT = 0.8cm2), no paravalvular leak (의정부성모)

# CT Cardiac pre-op valve (2018.07)



- MVR state with thick pannus formation around the valve ring
- Thickening of tissue valve leaflet

# Transesophageal Echocardiogram (TEE) (2018.07)

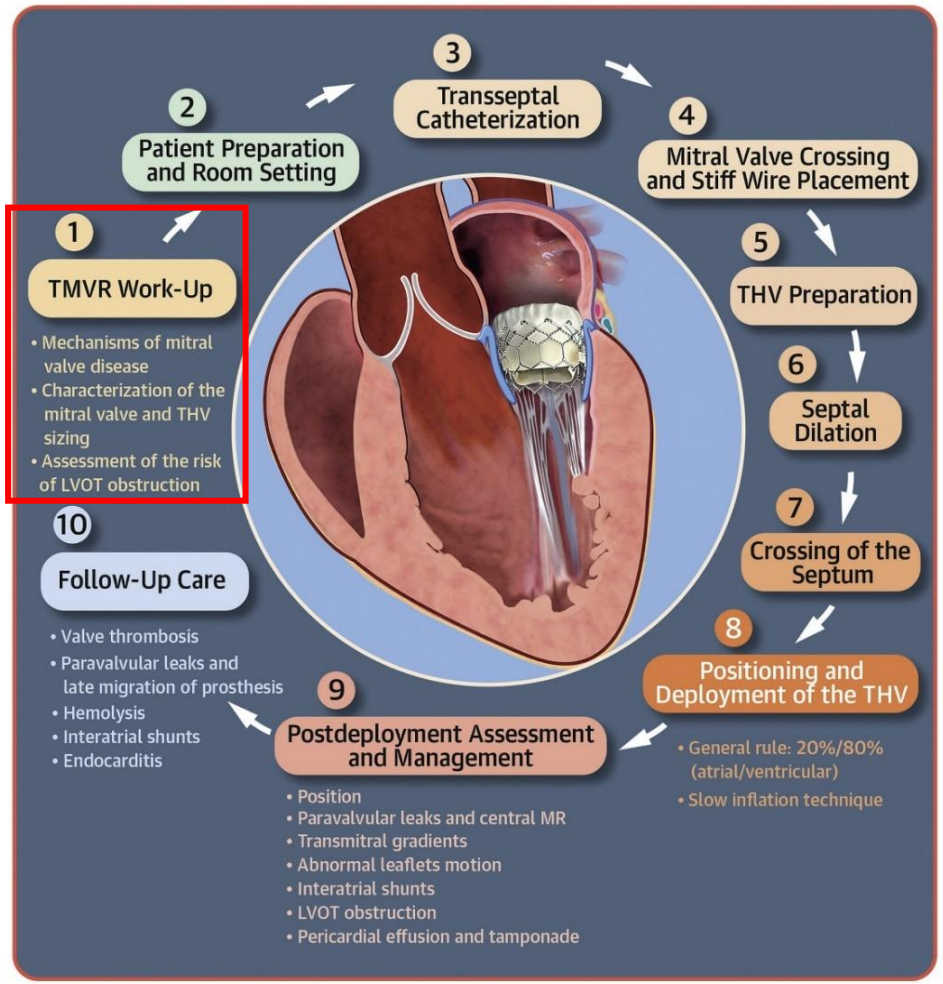




- STS Score : 17.6%

# Transcatheter Mitral Valve Replacement (TMVR)

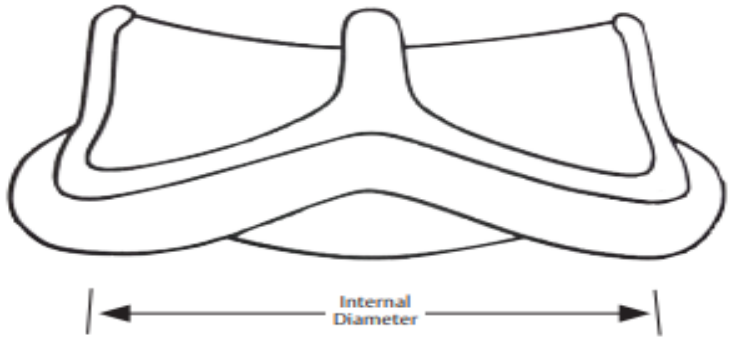
**CENTRAL ILLUSTRATION: Major Steps of Transseptal Transcatheter Mitral Valve Replacement**



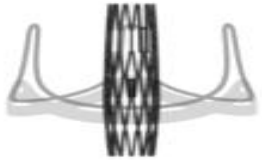
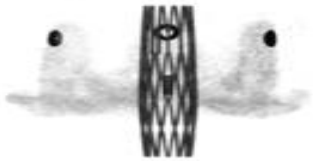

Urena, M. et al. J Am Coll Cardiol Intv. 2017;10(19):1905–19.

# Sizing & Positioning in VIV

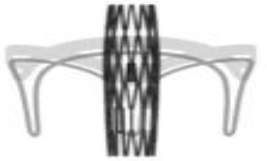
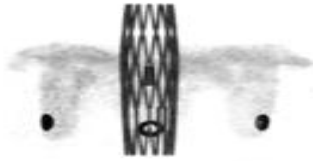
| Surgical Valve True ID* | SAPIEN 3 Transcatheter Heart Valve Size |
|---|---|
| 16.5-19 mm | **20 mm** |
| 18.5-22 mm | **23 mm** |
| 22-25 mm | **26 mm** |
| 25-28.5 mm | **29 mm** |




## Aortic Positioning

| Surgical Valve Features | SAPIEN 3 Valve Positioning Considerations |
|---|---|
| Visible stent frame  | Align the base of the **central marker 3-5 mm above the base** of the surgical valve stent frame  |
| Visible outflow markers only  | Align the outflow of the **crimped SAPIEN 3 valve 2 mm above** the surgical valve outflow markers  |
| No visible radiopaque markers  | Align the **base of the central marker** with the annular plane  |
| Final SAPIEN 3 valve implant depth should be targeted **no more than 20% (ventricular)** for optimal valve function | |

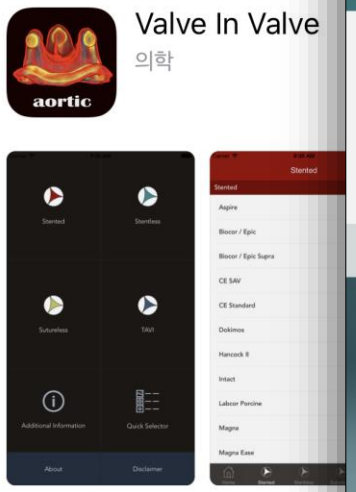
## Mitral Positioning

| Surgical Valve Features | SAPIEN 3 Valve Positioning Considerations |
|---|---|
| Visible stent frame  | Align the base of the **central marker 3-5 mm below the base** (towards ventricle) of the surgical valve stent frame  |
| Visible outflow markers only  | Align the outflow of the **crimped SAPIEN 3 valve 2 mm below** (towards ventricle) the surgical valve outflow markers  |
| No visible radiopaque markers  | Align the **base of the central marker** with the annular plane  |
| Final SAPIEN 3 valve implant depth should be targeted **no more than 20% (atrial)** for optimal valve function | |

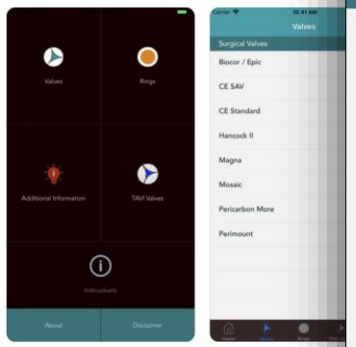
6:25

Valve in valve

Valve In Valve
의학



Valve In Valve (M
의학



투데이 게임 앱

6:50

Valves Biocor / E

Biocor / Epic

St. Jude Medical
Porcine leaflets
Leaflets sutured 'inside' the ste
Fluoroscopic Marker – Sewing r

*Double tap image for f*

*Image scrolls ho*

Sizes

25 27

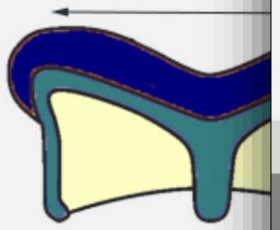
Home Valves Rings

6:50

Biocor / Epic Valve Siz

Biocor / Epic, 27

Stent ID: 2



True ID

THV Selecto

Home Valves Rings

6:50

Back S3 Ideal Placement

Biocor / Epic

Central marker on S3 placed few mm ventricular to the sewing ring marker

*Double tap image for fullscreen*

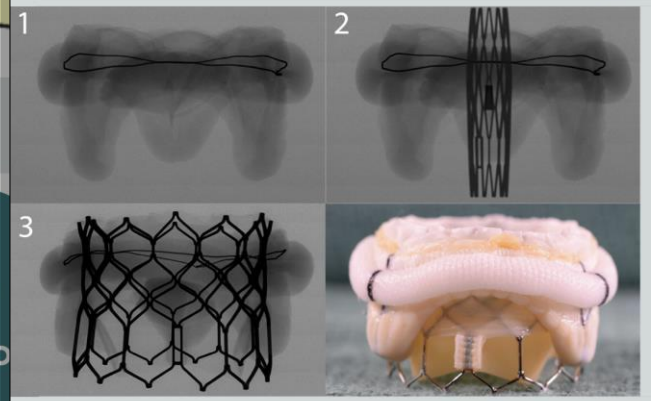


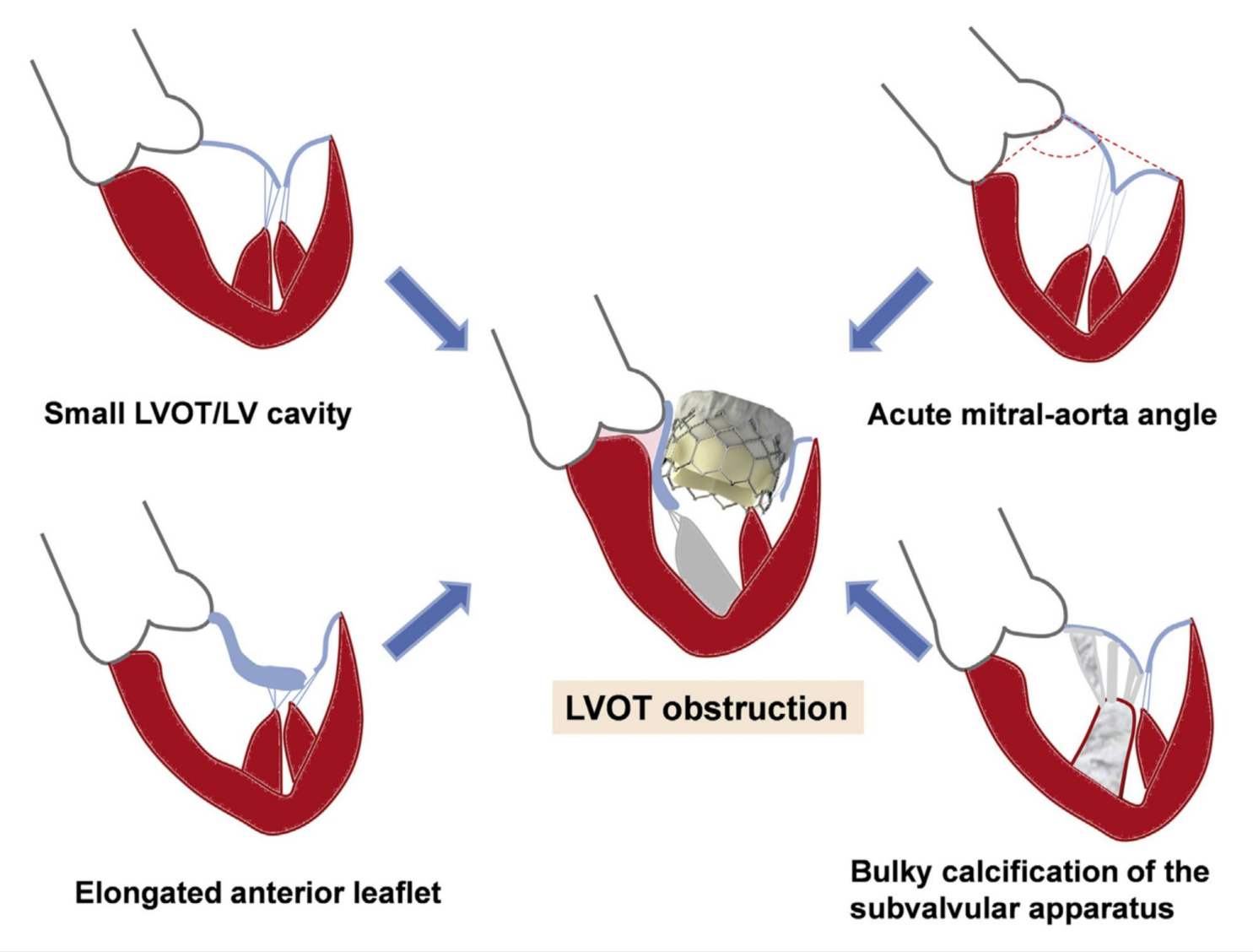

*Image scrolls horizontally*

Video Guidance

Play Video

Home Valves Rings TAVI Valves Information

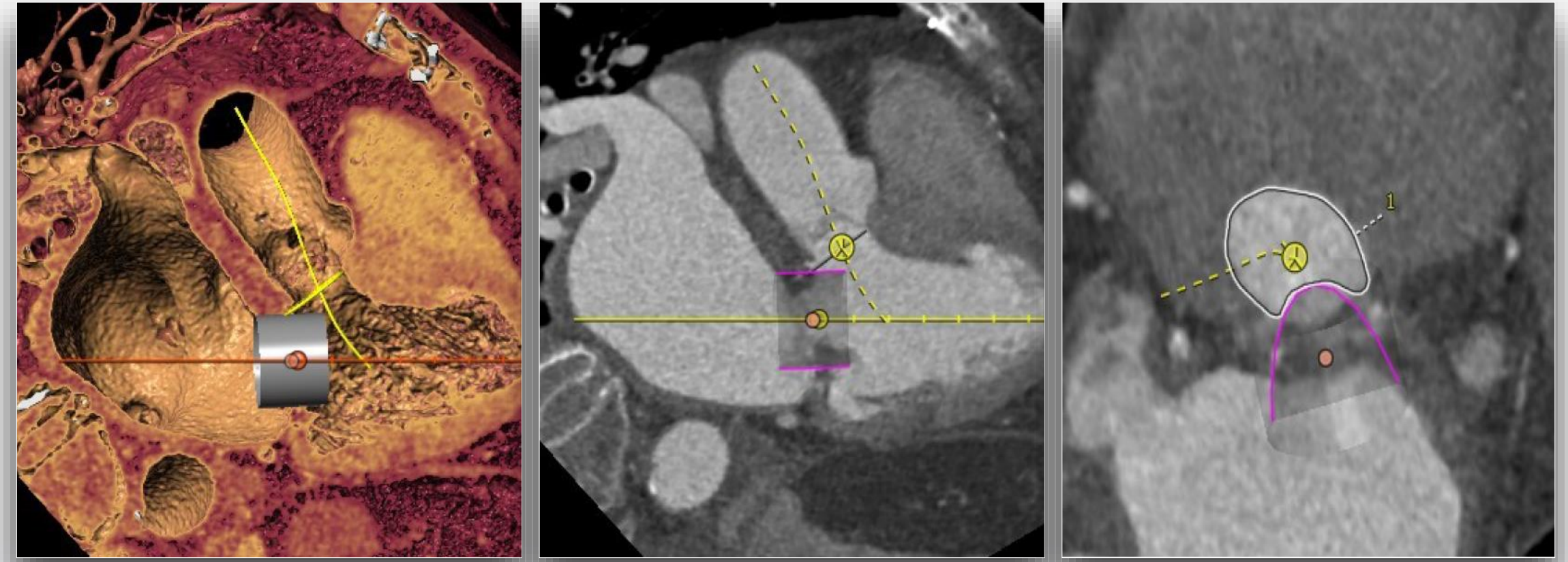
# TMVR Work-Up ; LVOT obstruction






Urena, M. et al. J Am Coll Cardiol Intv. 2017;10(19):1905–19.

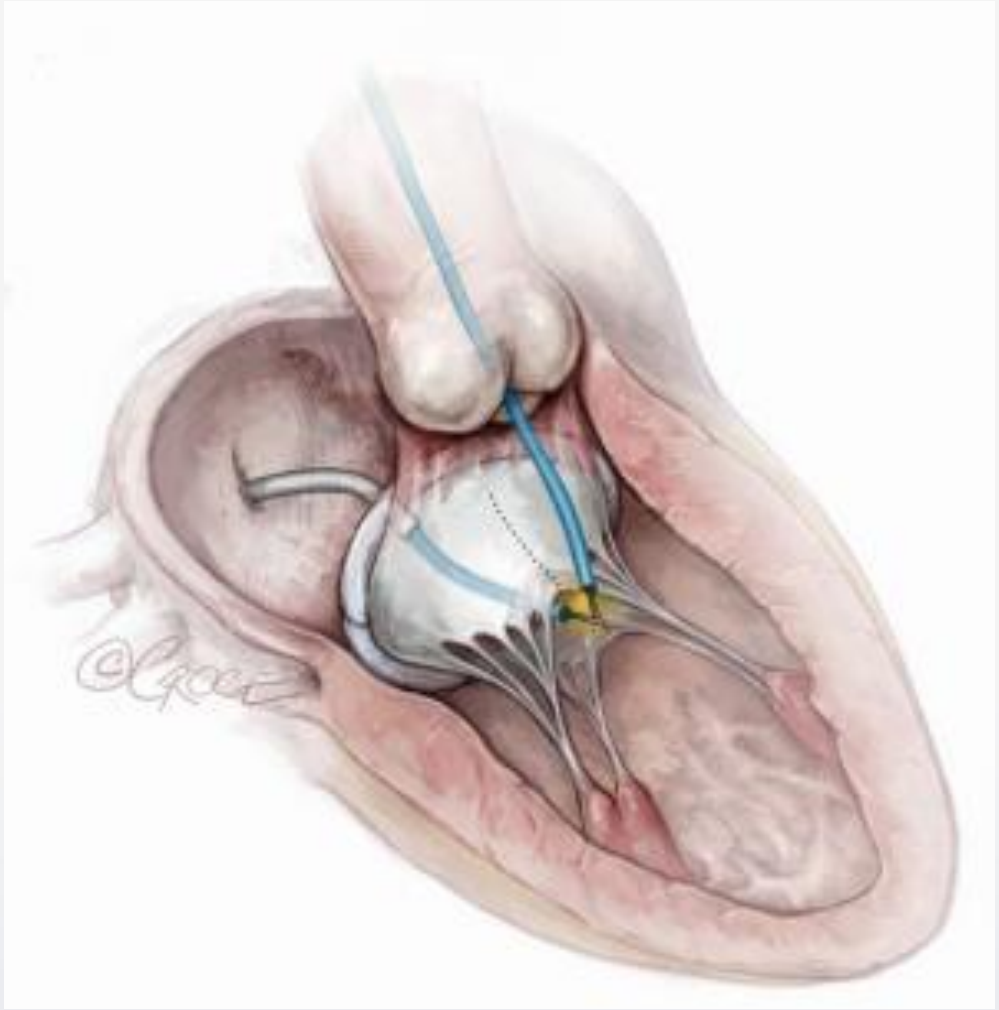
# TMVR Work-Up ; LVOT obstruction



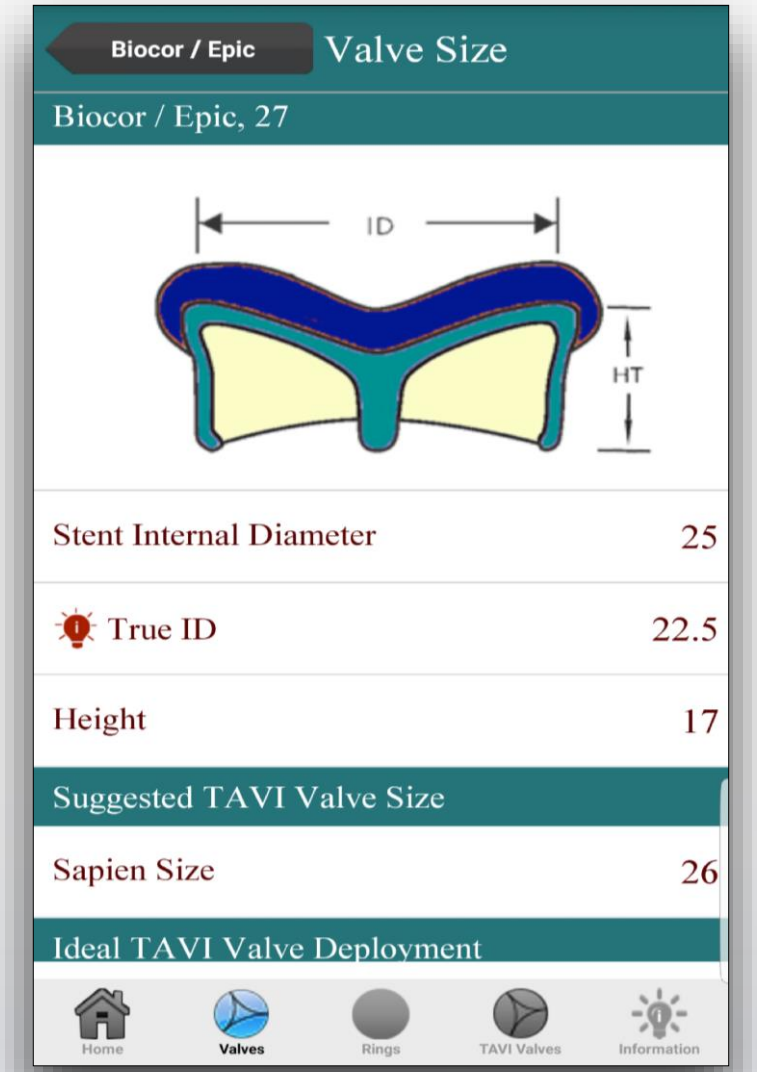

Geometric obstruction predicted by neoLVOT area <200 mm²

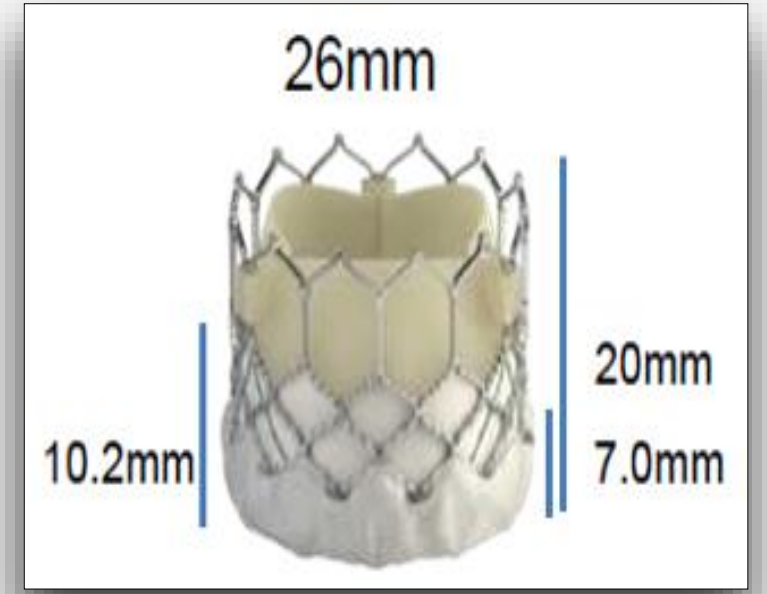
# In cases anticipating LVOT obstruction, then LAMPOON

Laceration of the Anterior Mitral leaflet to Prevent Outflow ObtructioN (LAMPOON)



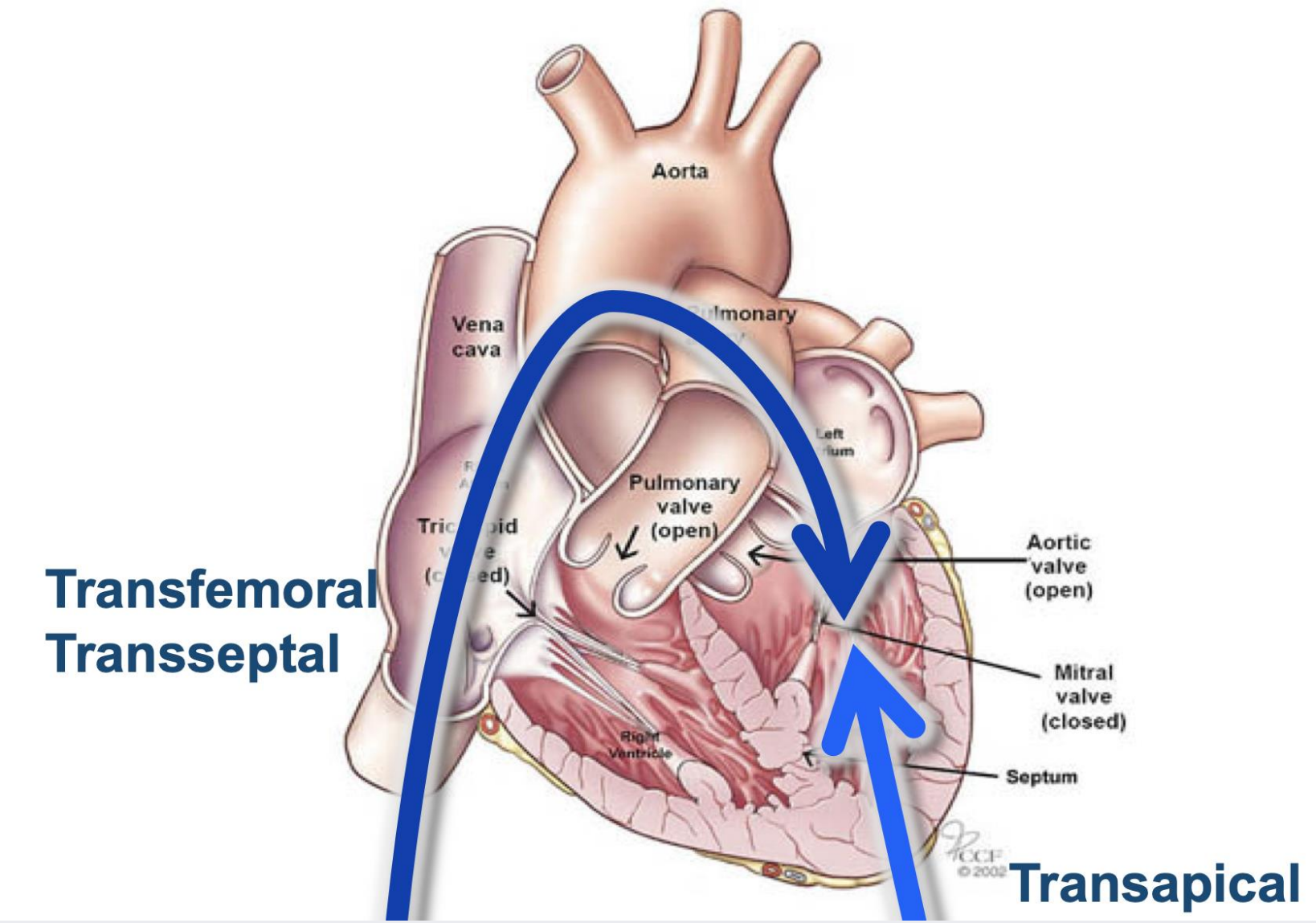
# TMVR Work-Up ; Size selection



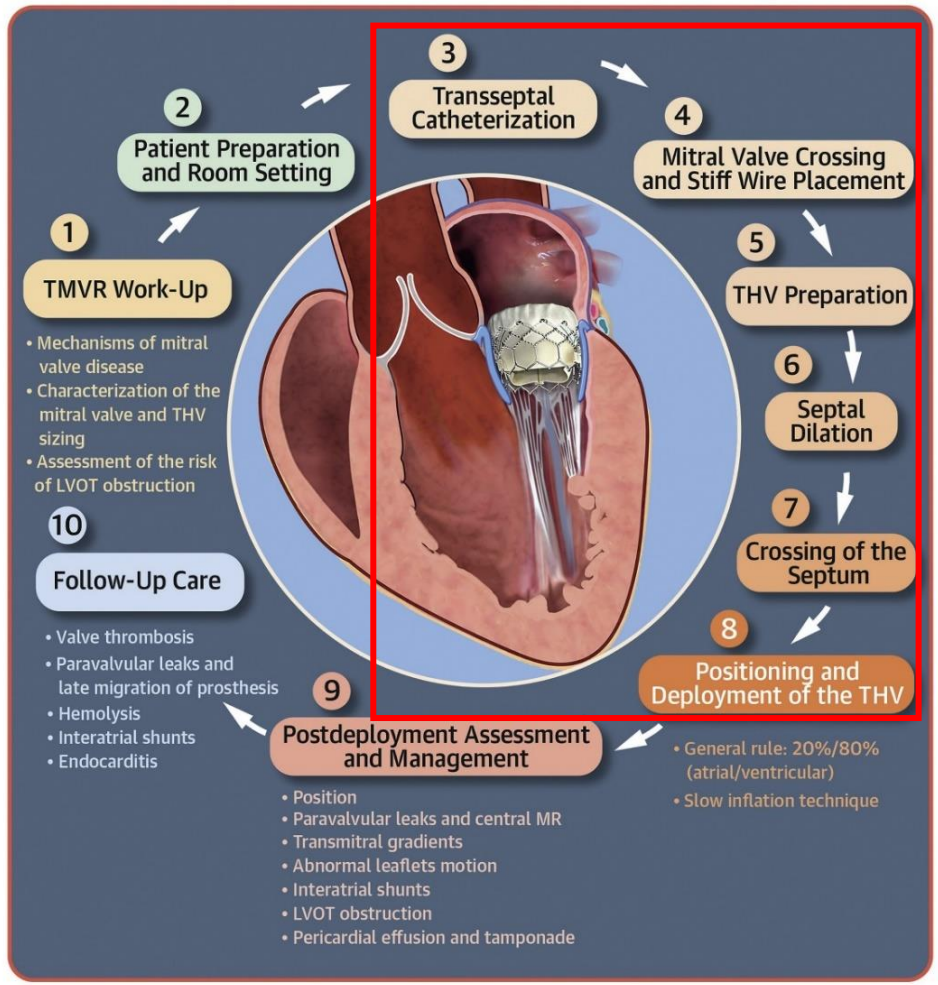

**Mitral sugical valve EPIC 27mm -> Sapien 3 26mm**

# The Challenge: Accessing The Mitral Valve



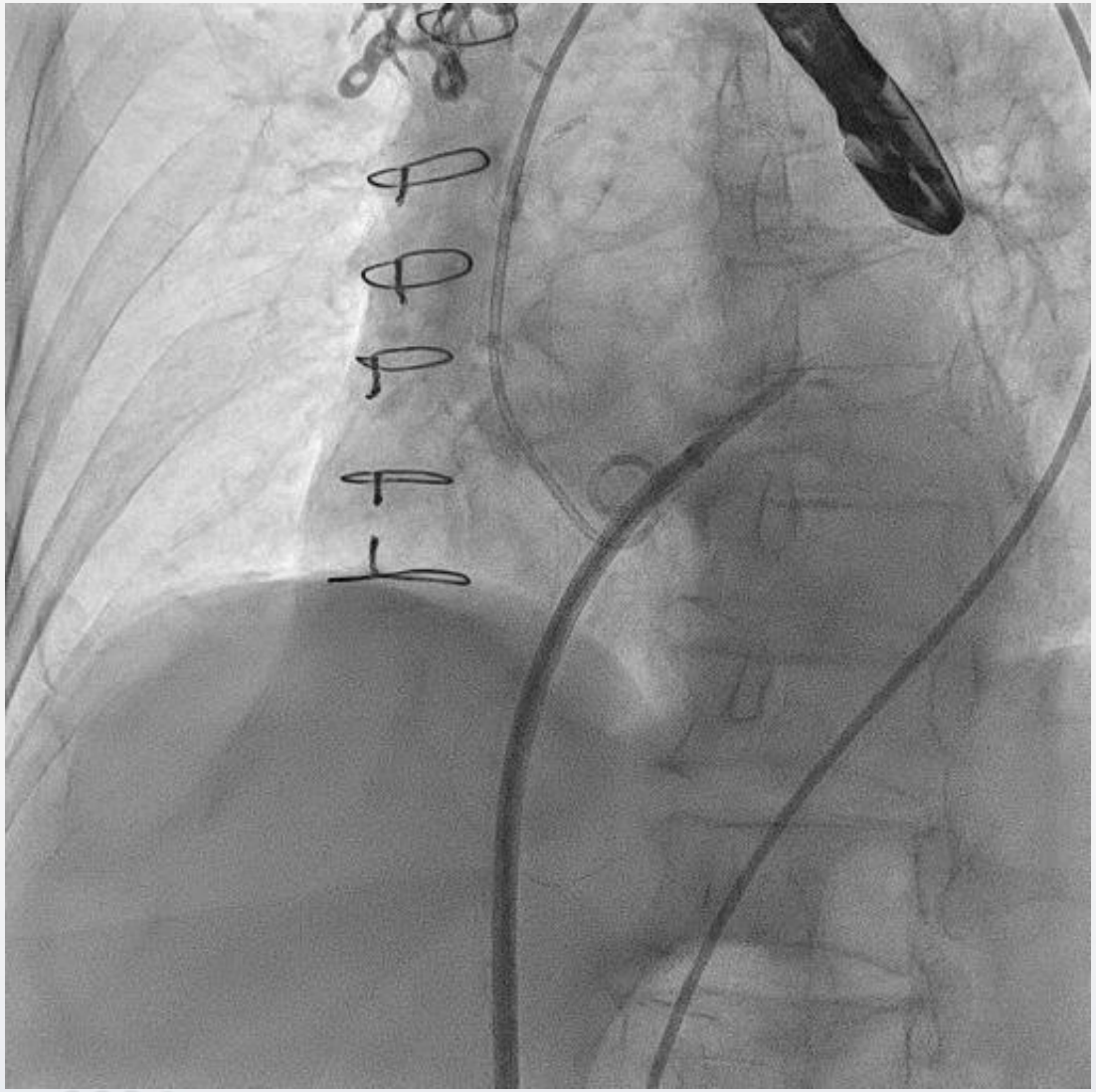
# Transcatheter Mitral Valve Replacement (TMVR)

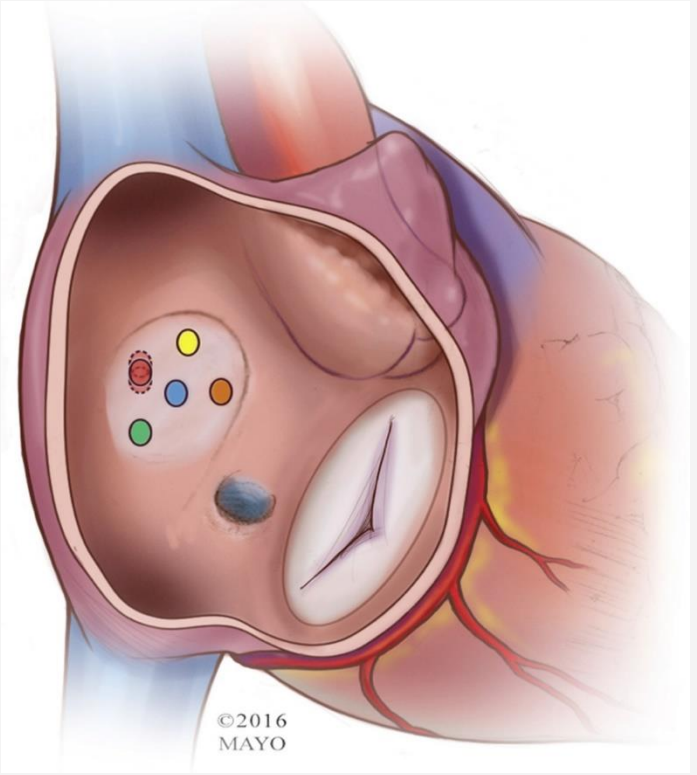
**CENTRAL ILLUSTRATION: Major Steps of Transseptal Transcatheter Mitral Valve Replacement**




Urena, M. et al. J Am Coll Cardiol Intv. 2017;10(19):1905–19.

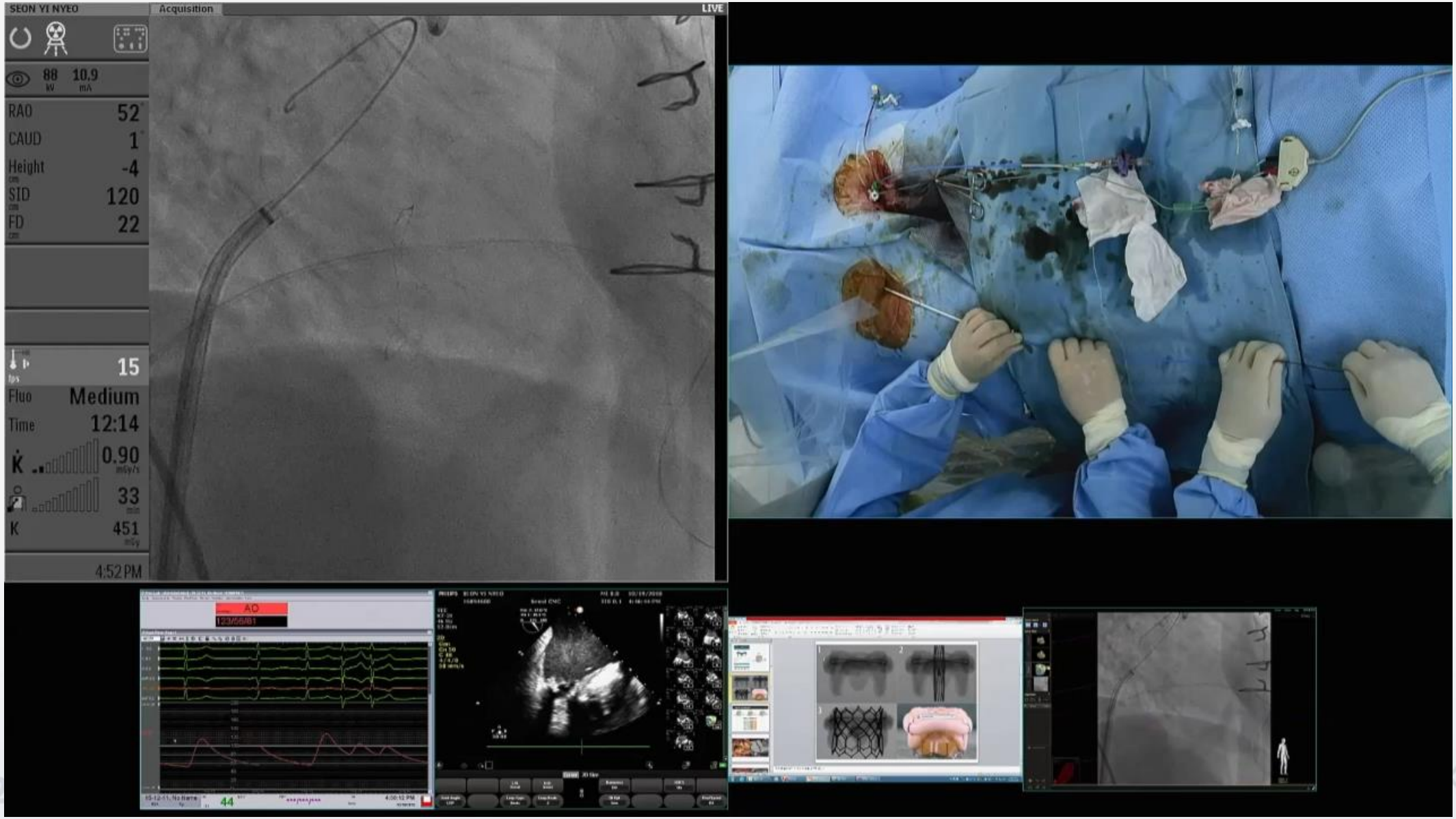
# Septal puncture



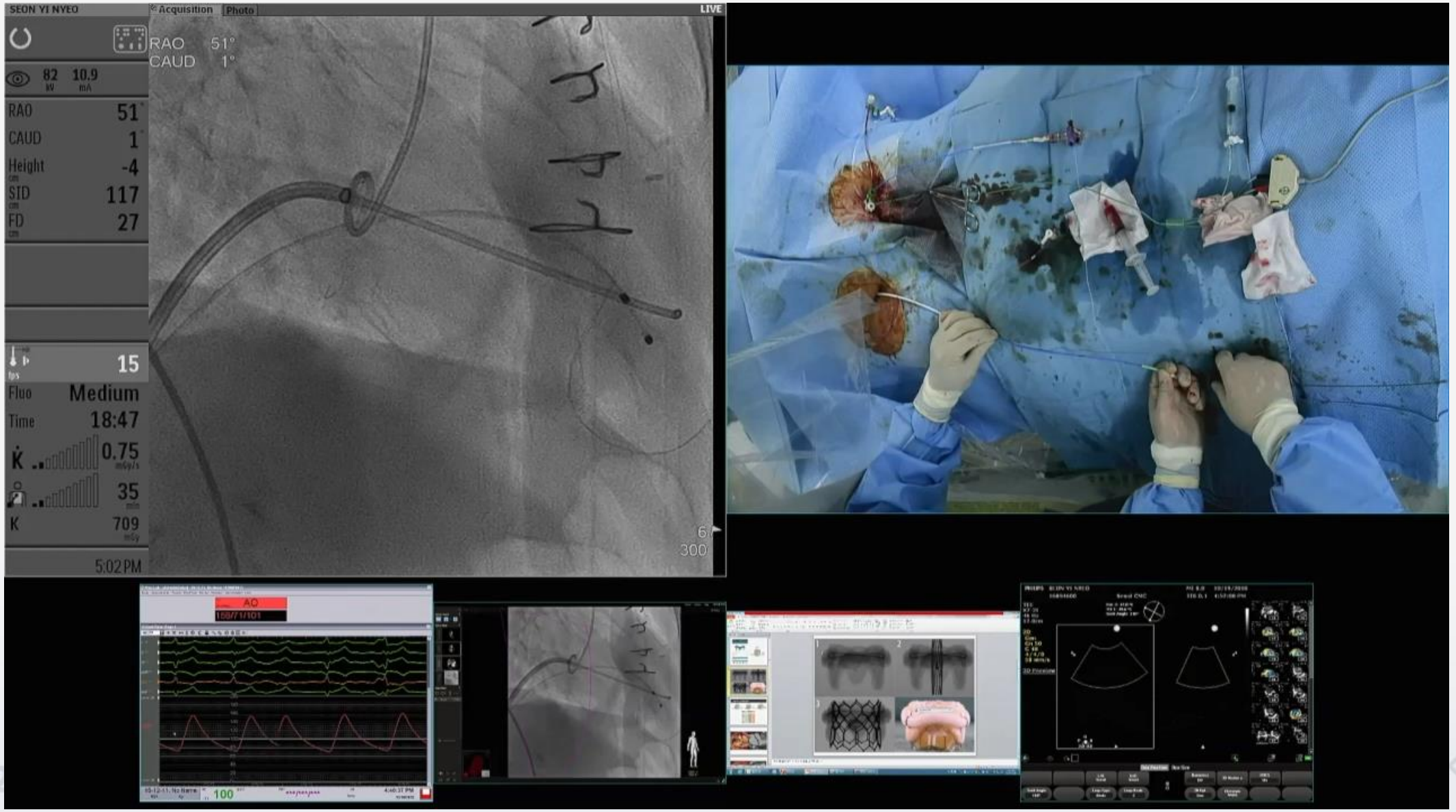



- **Red:** MitraClip, paravalvular leak closure (a higher crossing site is recommended for medial leaks, and a lower crossing site is recommended for lateral leaks; dashed red circles).
- **Yellow:** transseptal patent foramen ovale closure.
- **Blue:** percutaneous left ventricular assist device placement, hemodynamic studies.
- **Green:** left atrial appendage closure.
- **Orange:** pulmonary vein interventions.

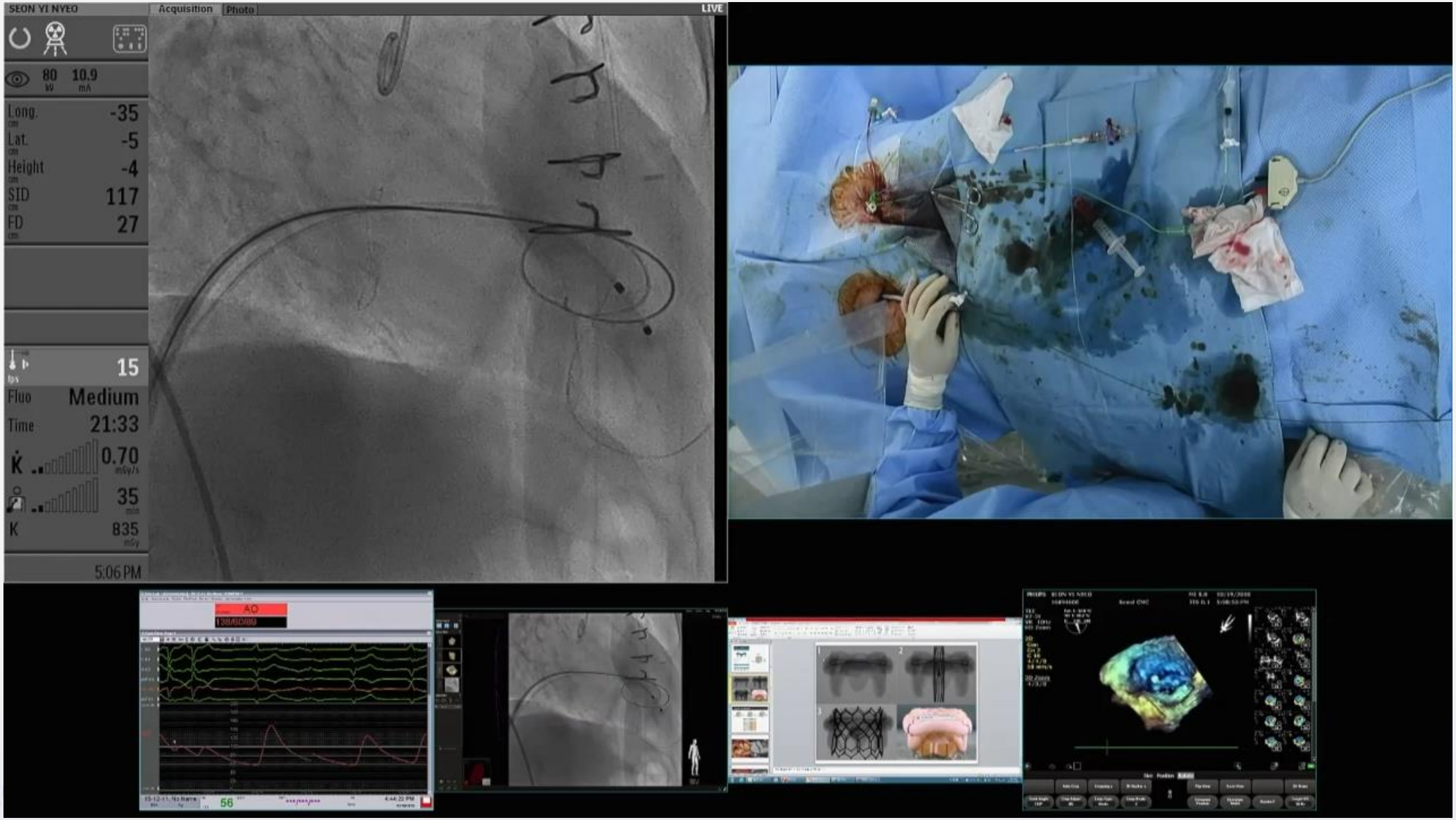
# Wire crossing



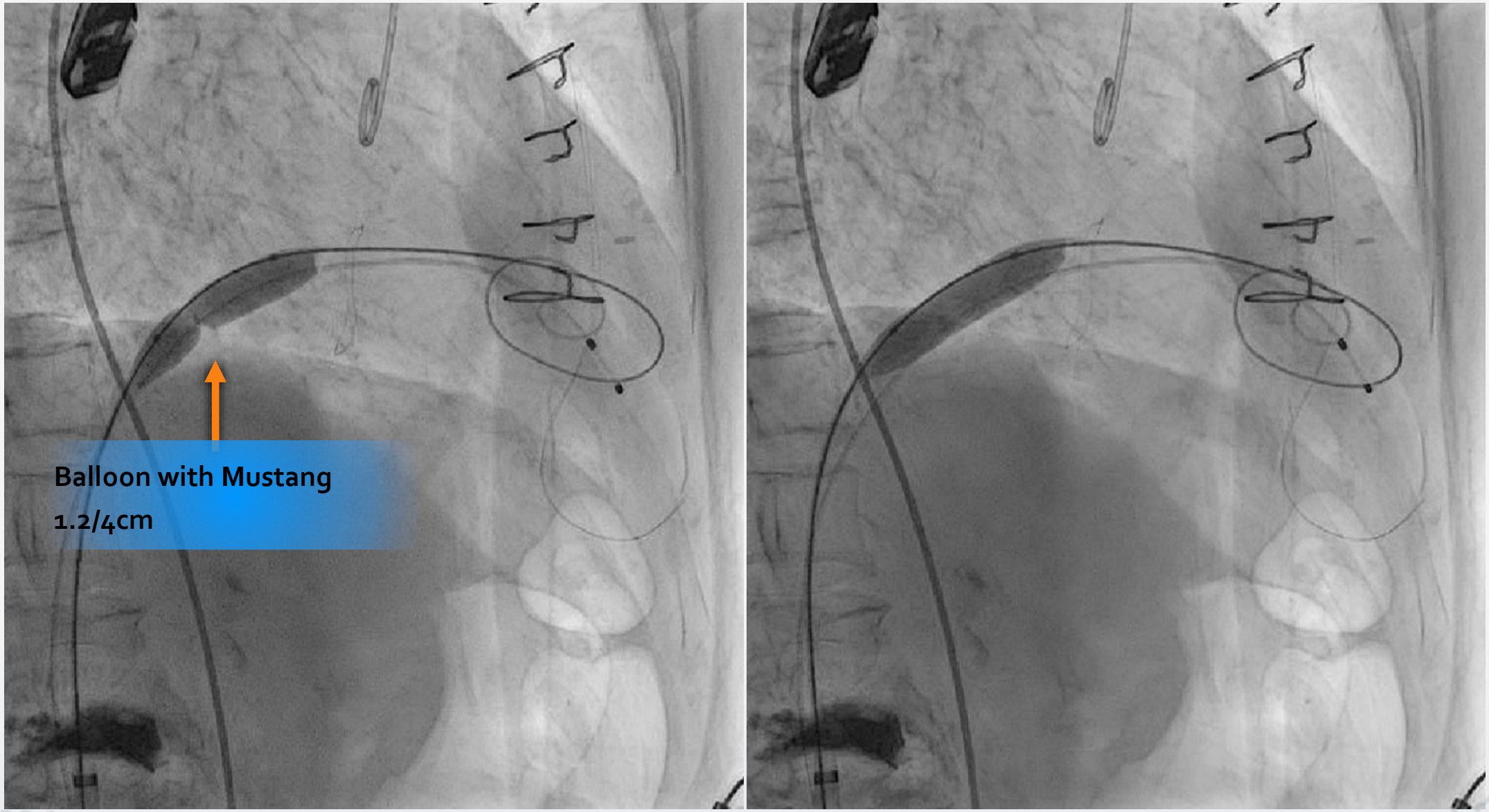
# Safari wire placement



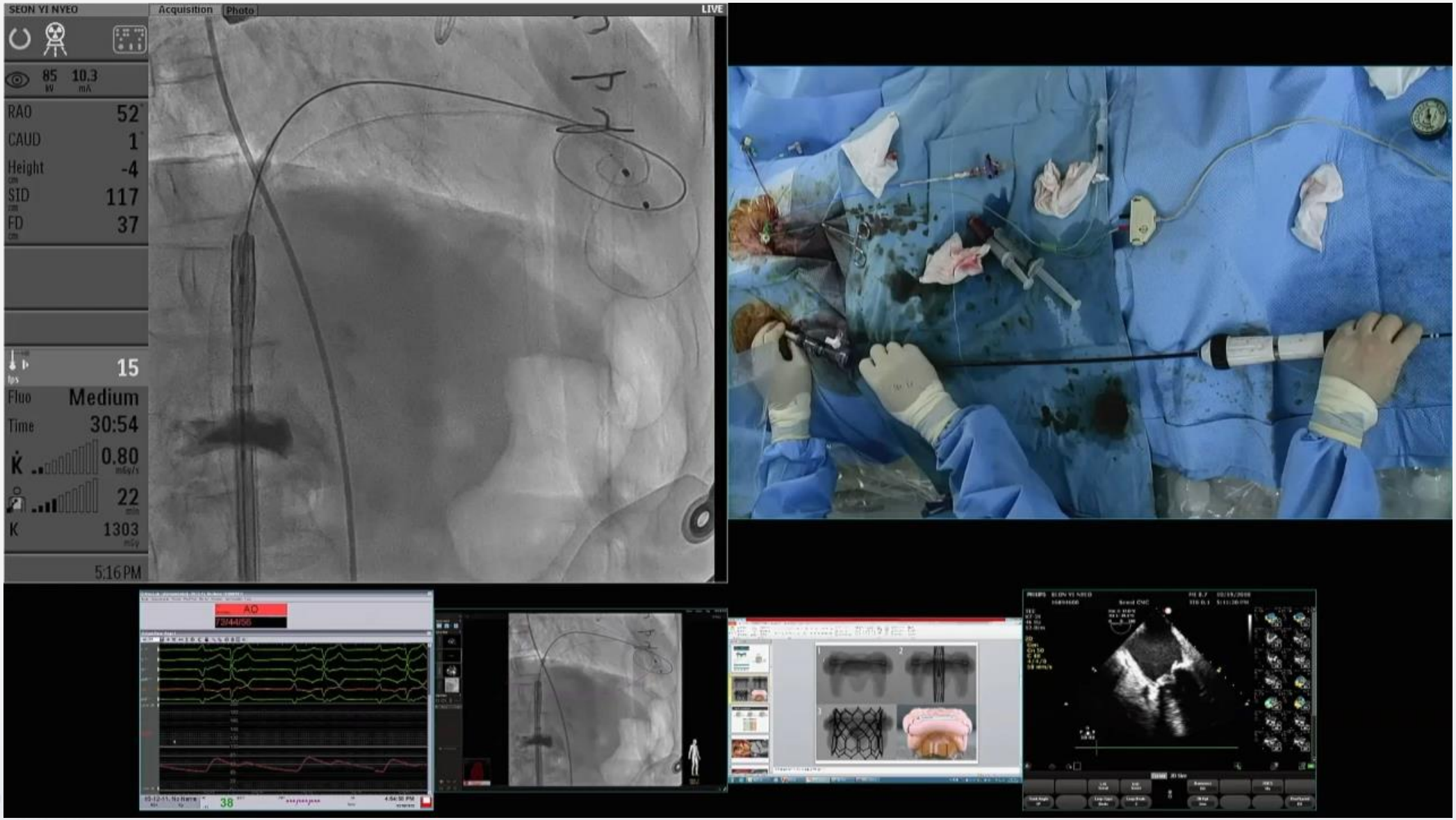
# E-sheath change



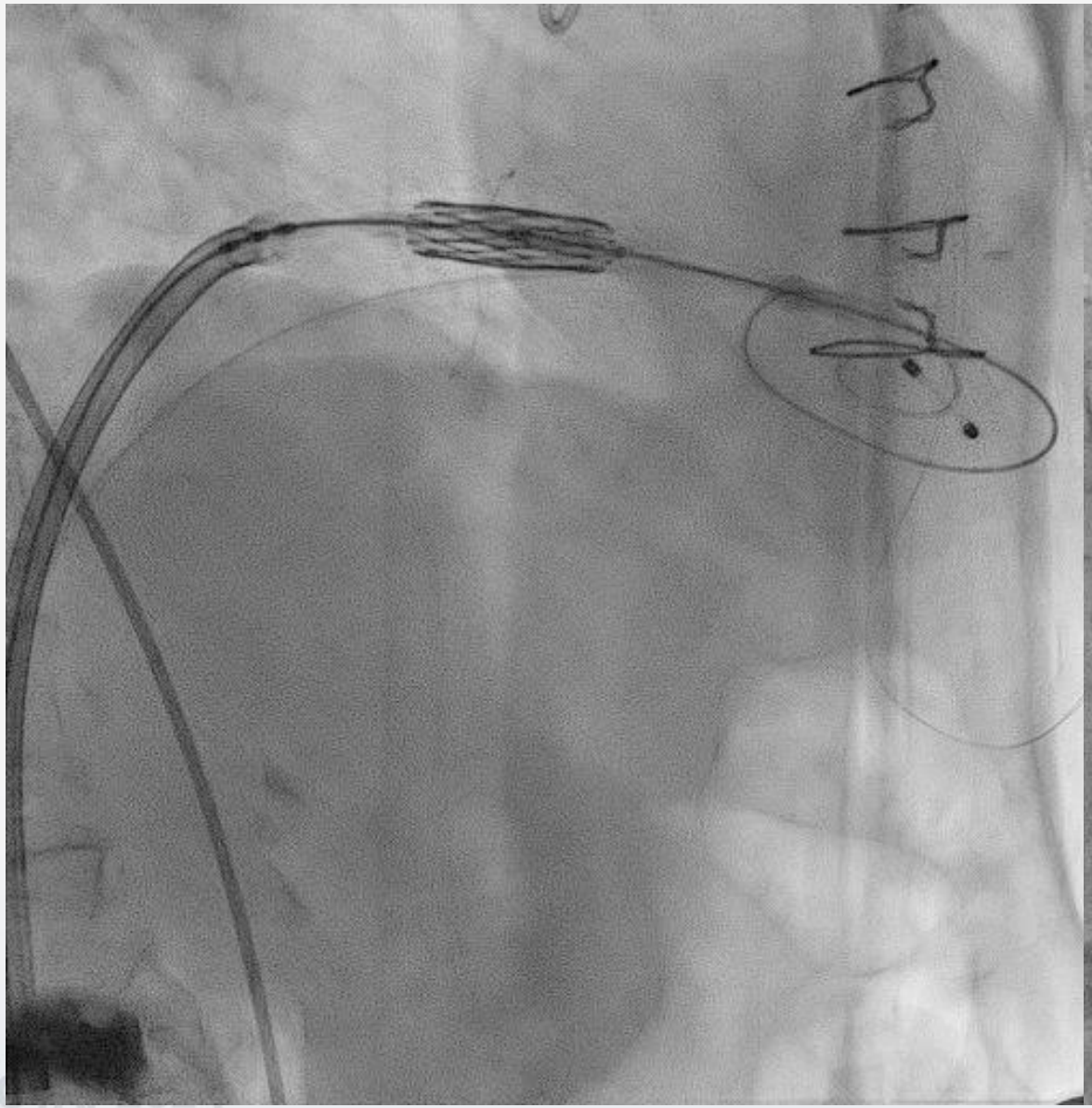
# Ballooning of septal puncture site



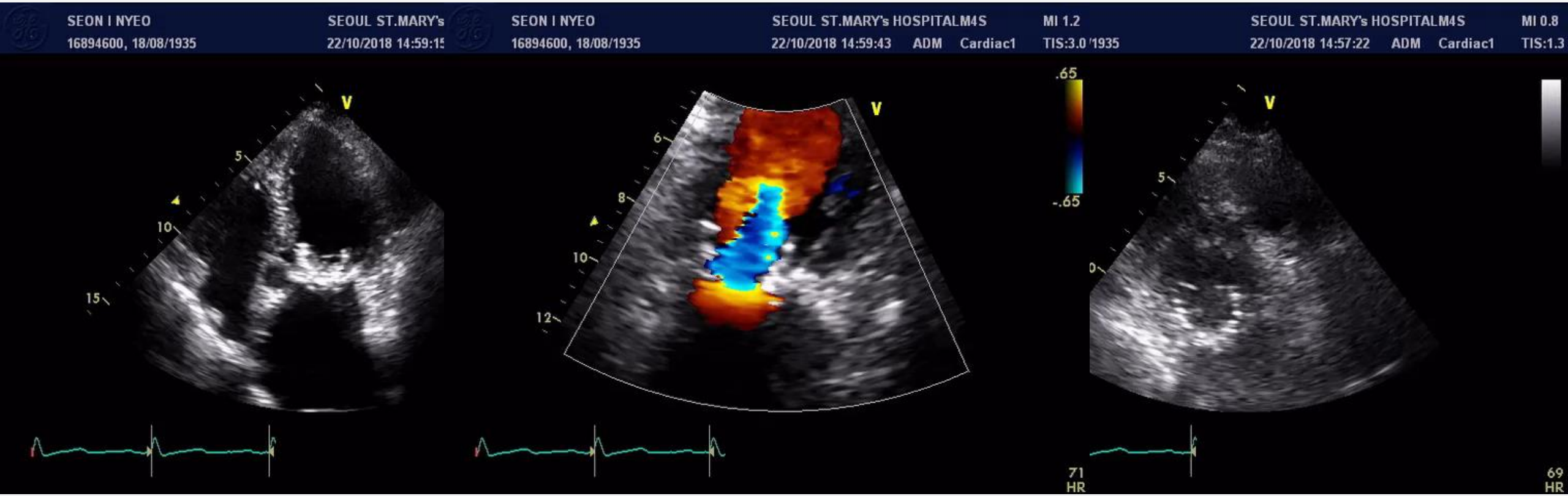
# Crossing Septum & Mitral Valve



# Sapien3 (26mm) implantation & Final



# Transthroacic Echocardiogram (post TTE) (2018.10)

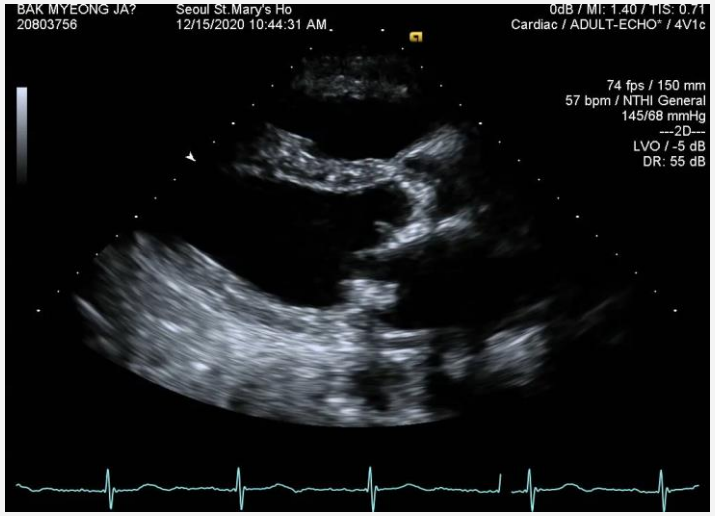


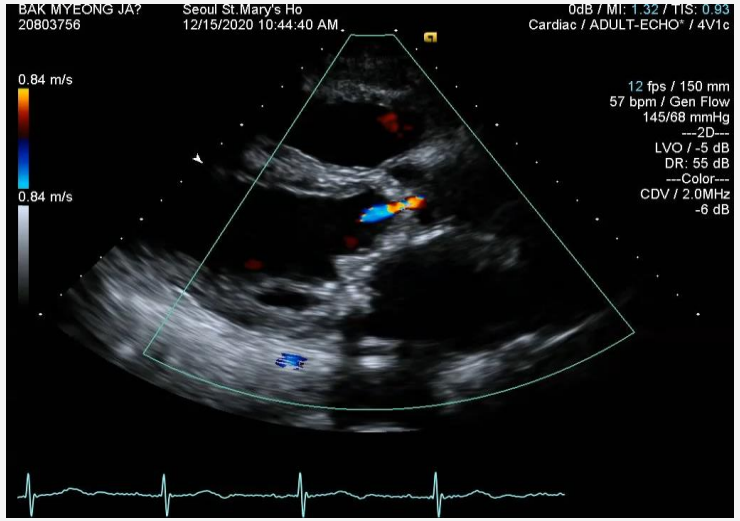

MVA = 0.8 -> 2.0 cm2 by PHT
Vmax=1.7 m/s, PGmean=4.8 mmHg, PHT=109.9 ms

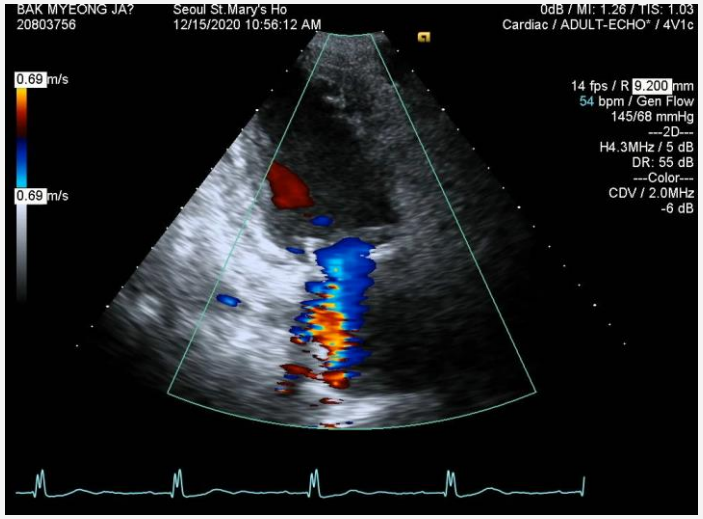
# 2nd CASE (2020.12.16) – TMVR + TAVI

- F/77 (160cm/52kg)
- Chief complaint
  - Dyspnea
- Medical history
  - **Severe MS s/p MVR** (’11.01 tissue valve Epic 29mm) & LA volume reduction & MAZE
  - HTN (+), DM(-), Dyslipidemia(-)
  - s/p PCI on RCA (‘06 여의도성모병원)
  - PAF with tachy-brady syndrome
  - Warfarin 3mg, Valsartan 40mg, Lasix 20mg, amiodarone 100mg

# Transthroacic Echocardiogram (TTE) (2020.10)



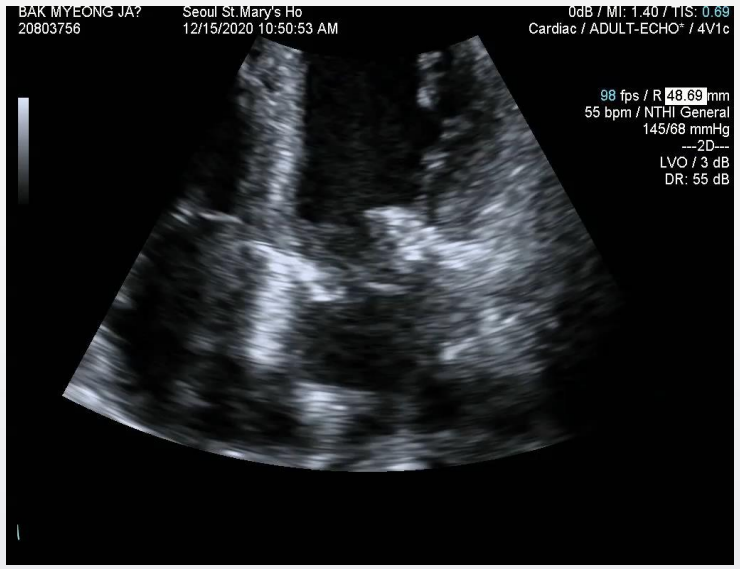



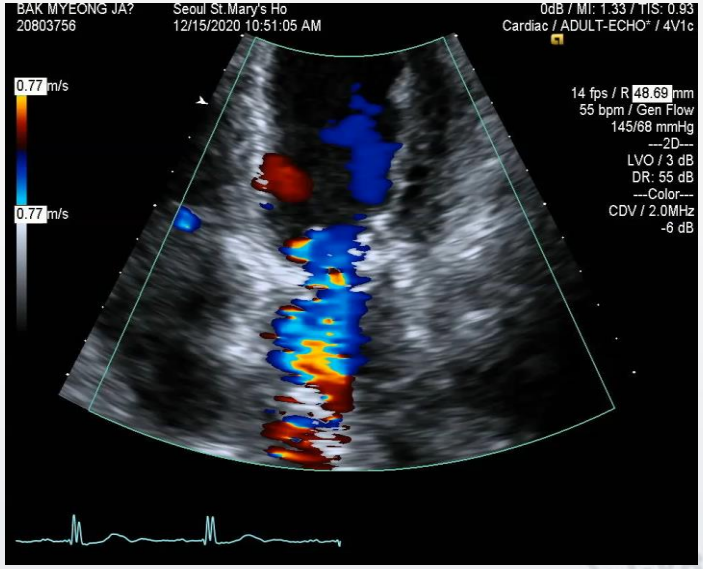




- Severe MR due to bio-MVR dysfunction (prolapsed bioleaflet)
- Severe AS and mild AR, rheumato-degenerative

  (AV Vmax : 4.0m/s, Mean PG : 36.7, AVA : 0.96)

  LVEF : 67%
- MR Vena Contracta 0.78cm
- MR PISA 6.22**cm²**



# 2nd CASE (2020.12.16) – TMVR + TAVI

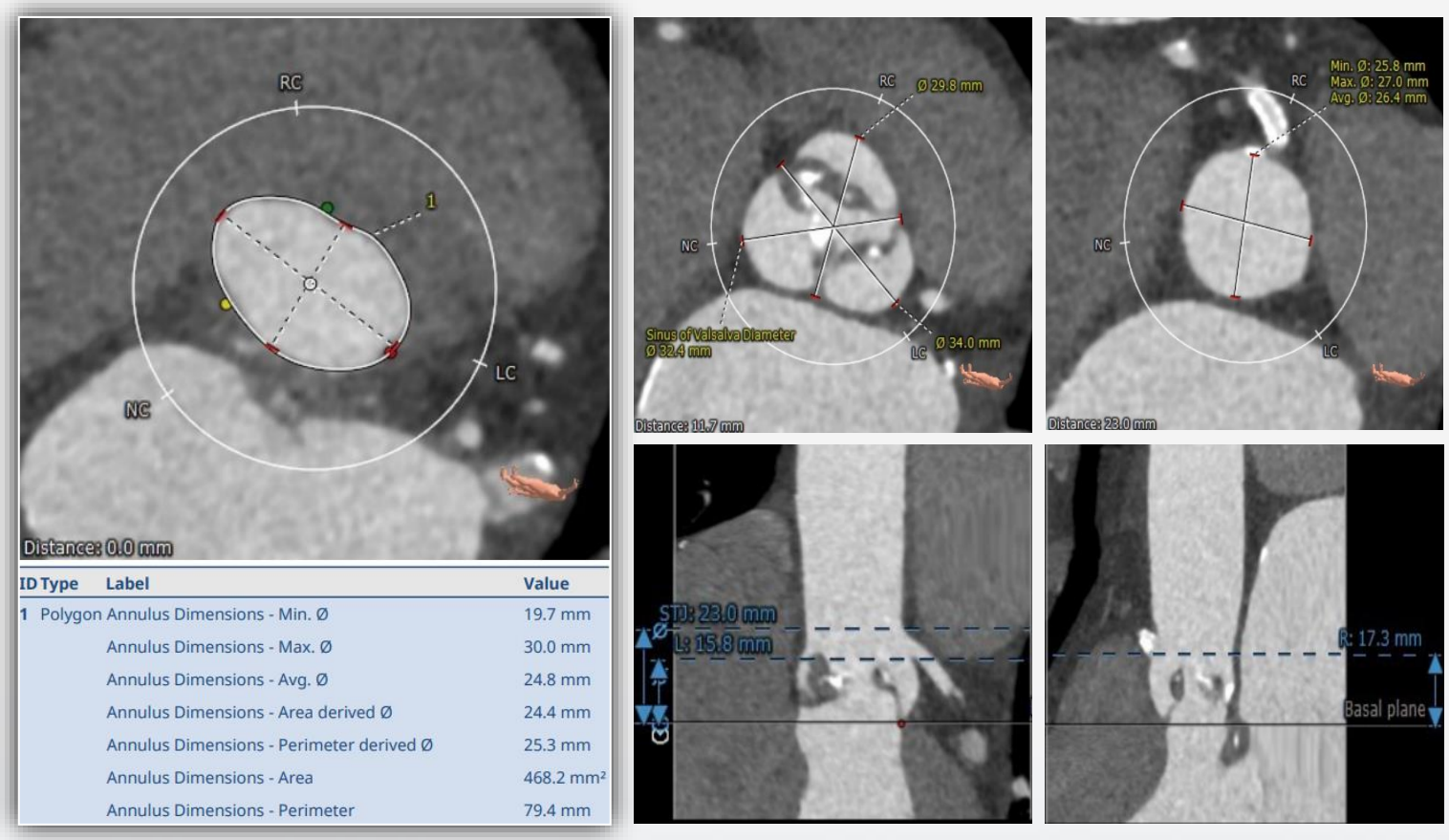
- AVR & Re-do MVR

→ STS score: 9.8%

→ TAVI & TMVR

- Simultaneous TAVI and TMVR  1st case in Korea

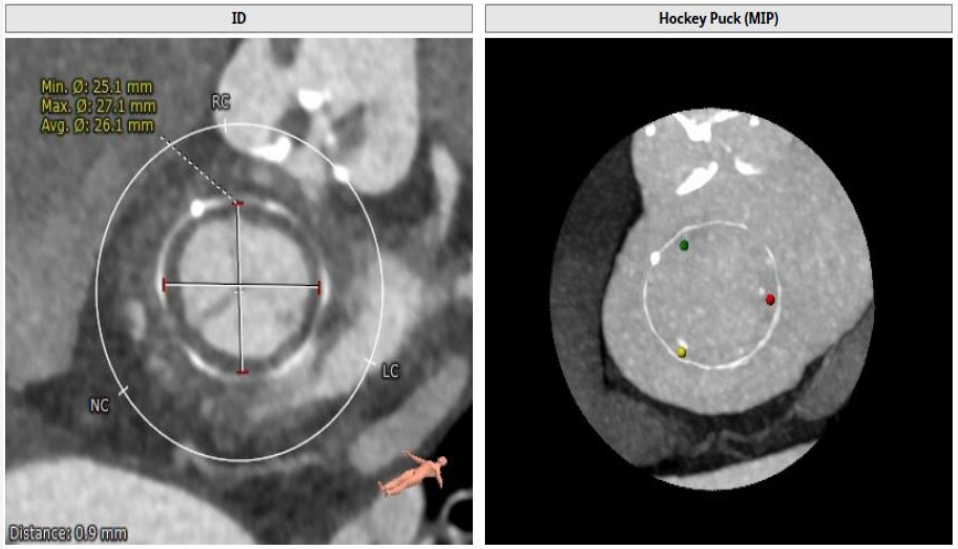
# TAVR & TMVR w/u – TAVI valve size measure




| ID | Type | Label | Value |
|---|---|---|---|
| 1 | Polygon | Annulus Dimensions - Min. Ø | 19.7 mm |
| | | Annulus Dimensions - Max. Ø | 30.0 mm |
| | | Annulus Dimensions - Avg. Ø | 24.8 mm |
| | | Annulus Dimensions - Area derived Ø | 24.4 mm |
| | | Annulus Dimensions - Perimeter derived Ø | 25.3 mm |
| | | Annulus Dimensions - Area | 468.2 mm² |
| | | Annulus Dimensions - Perimeter | 79.4 mm |

→ Sapien 26mm

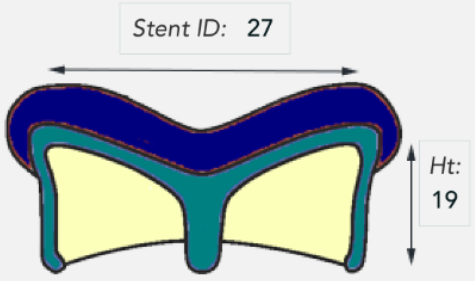
# TAVR & TMVR w/u – TMVR CT evaluation


Min. diameter : 25.1mm
Max diameter : 27.1mm
Area 542.1 mm2
Perimeter 82.9 mm

# TAVR & TMVR w/u – Valve sizing

Biocor / Epic, 29




True ID 25

THV Selector

TAVI Valve Choices For:
Biocor / Epic, 29

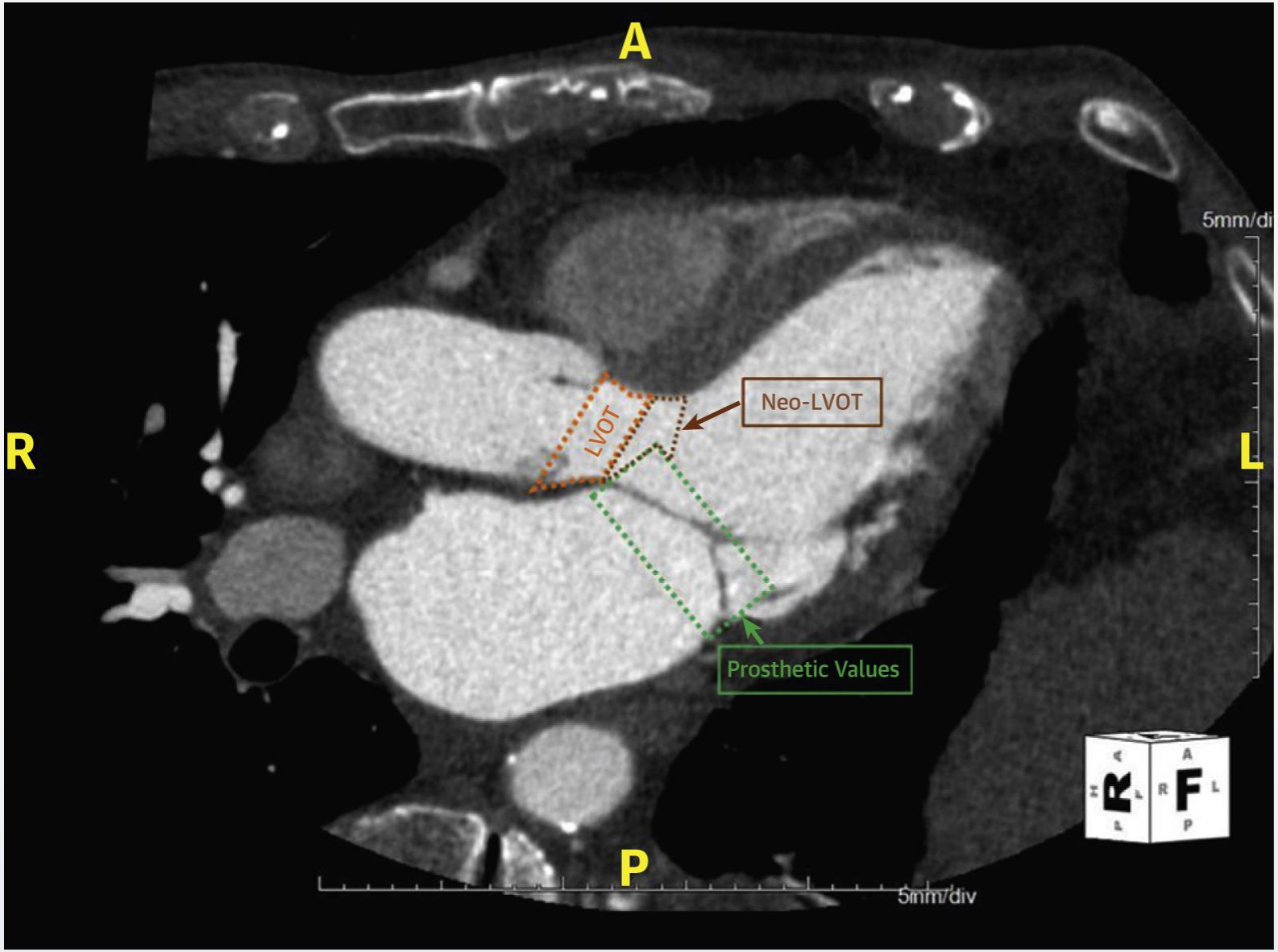
Borderline Sizes

*Sapien XT*
26/29

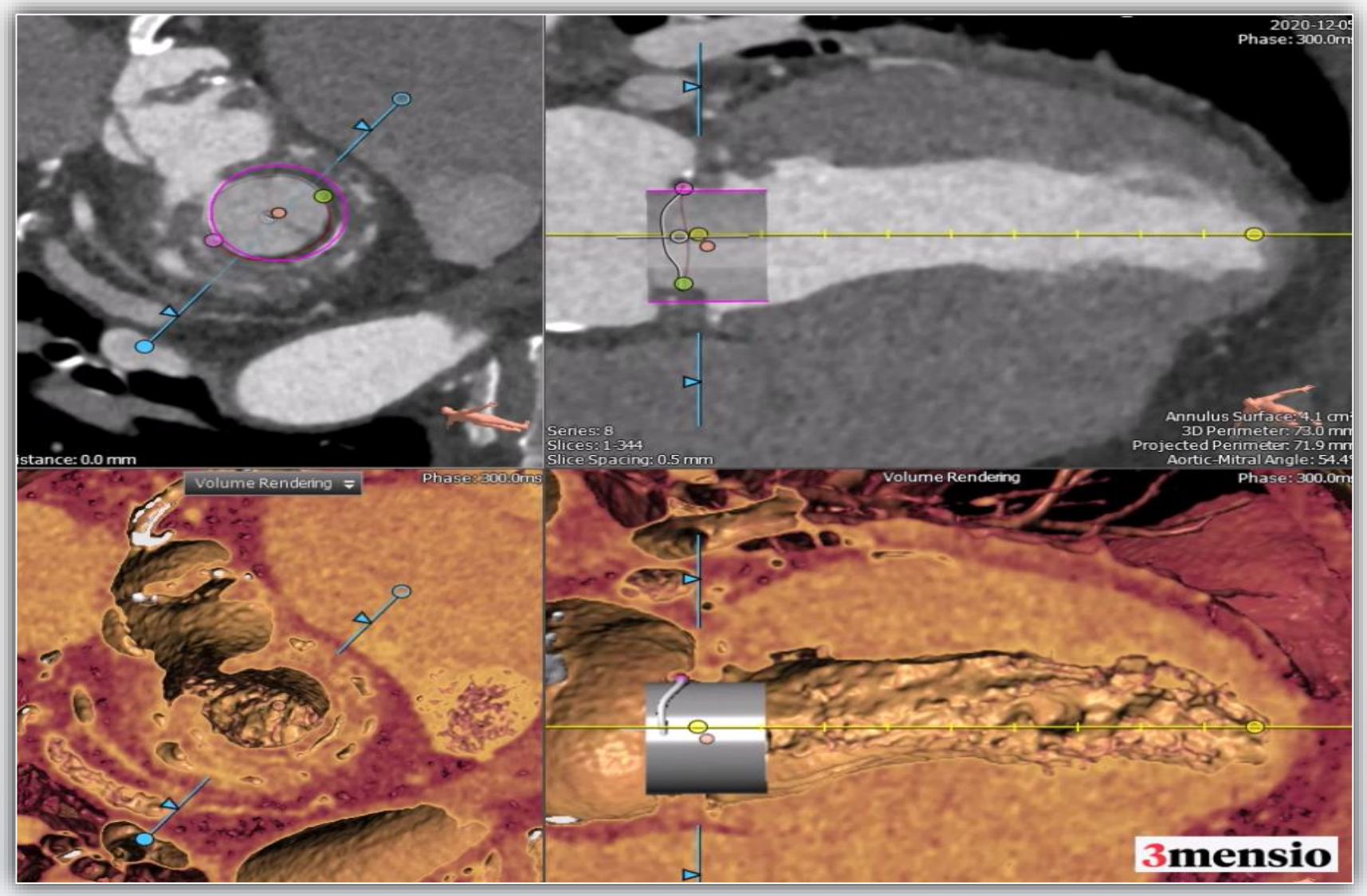
*Lotus*
27

*S3*
26/29*

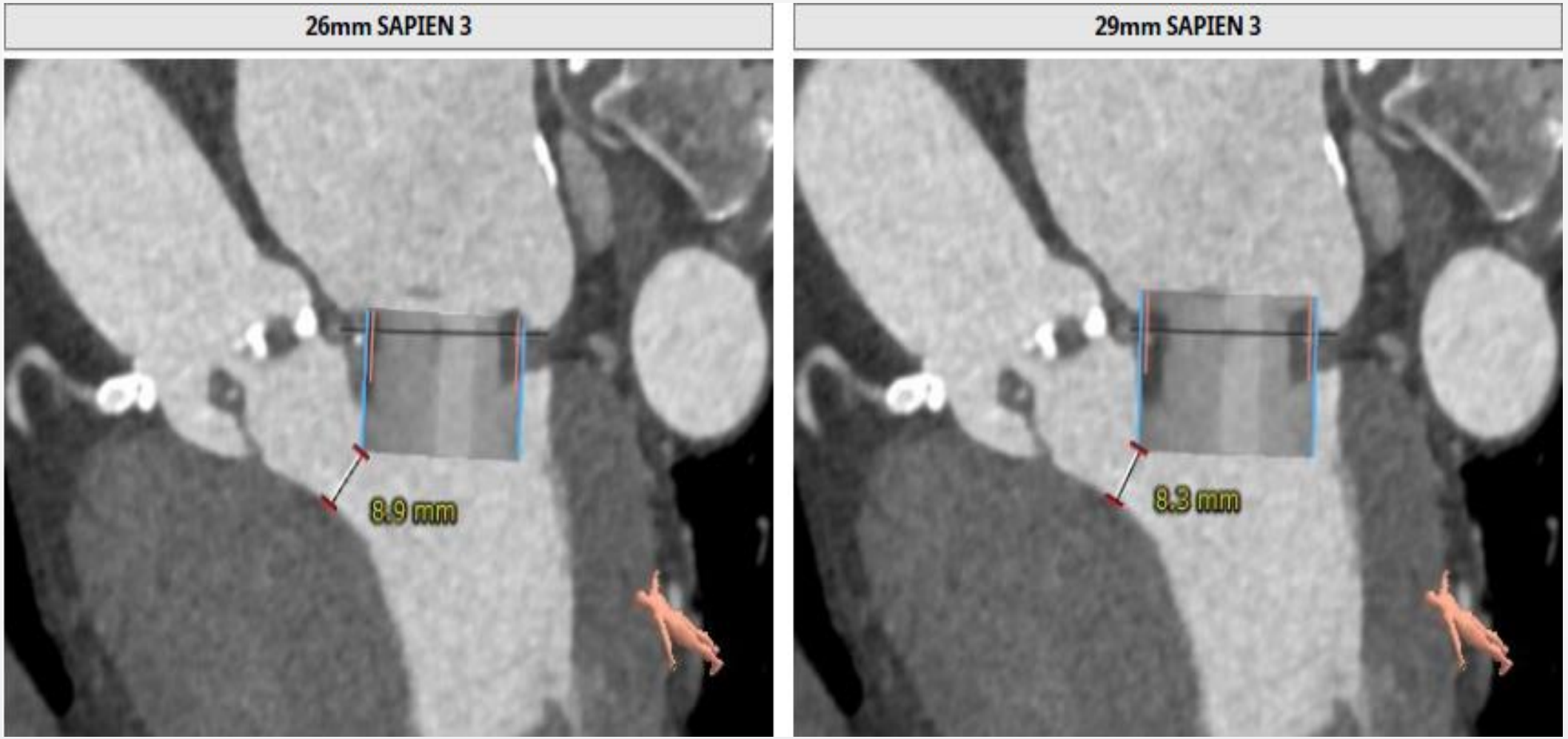
# TAVR & TMVR w/u – Neo-LVOT



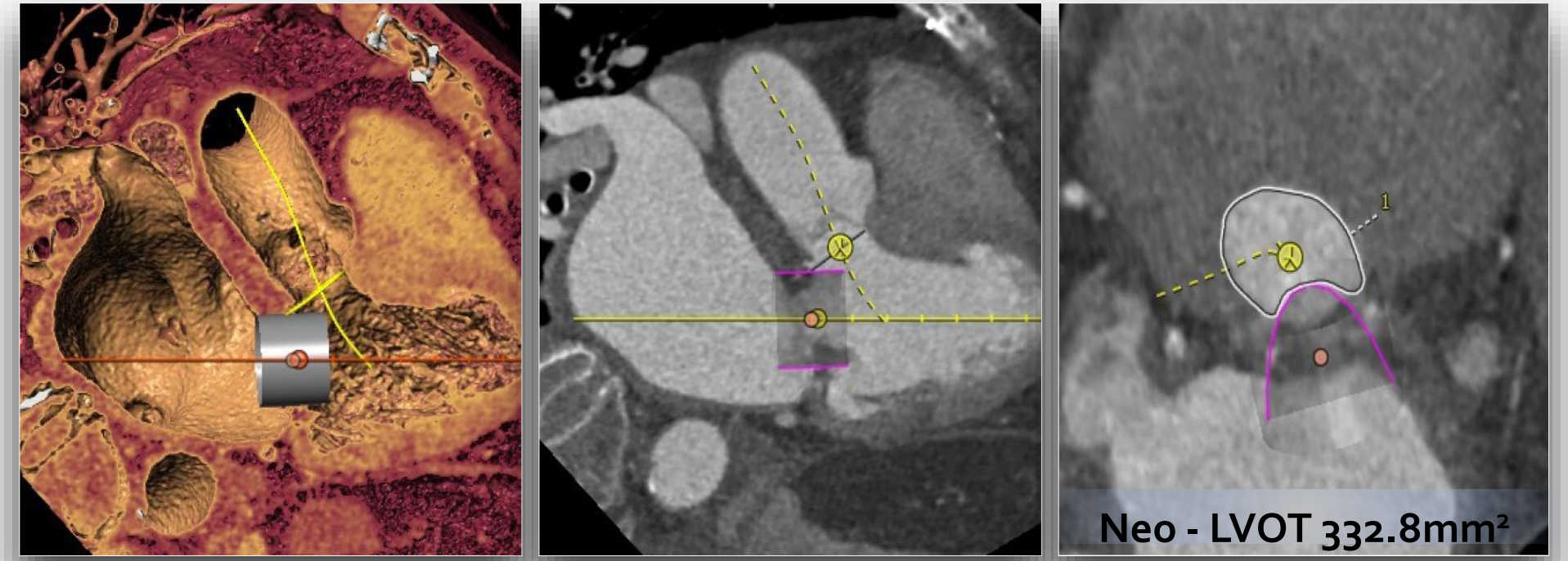
# TAVR & TMVR w/u – Virtual Valve simulation



# TAVR & TMVR w/u – 26mm or 29mm



# TAVR & TMVR w/u – Mesure of Neo LVOT




Geometric obstruction predicted by neoLVOT area <200 mm²

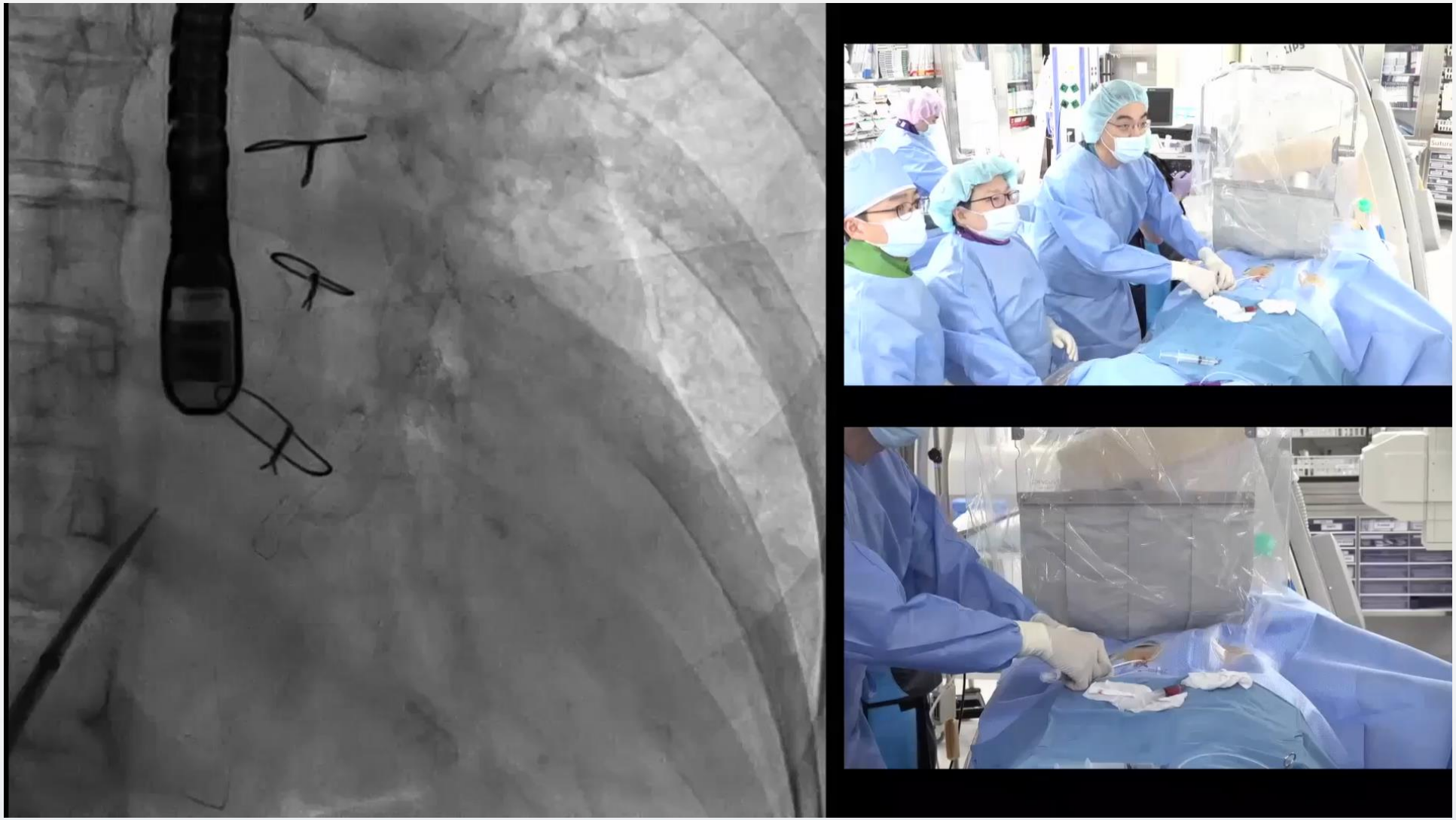
# Simultaneous TAVI & TMVR

1st case reported in 2017

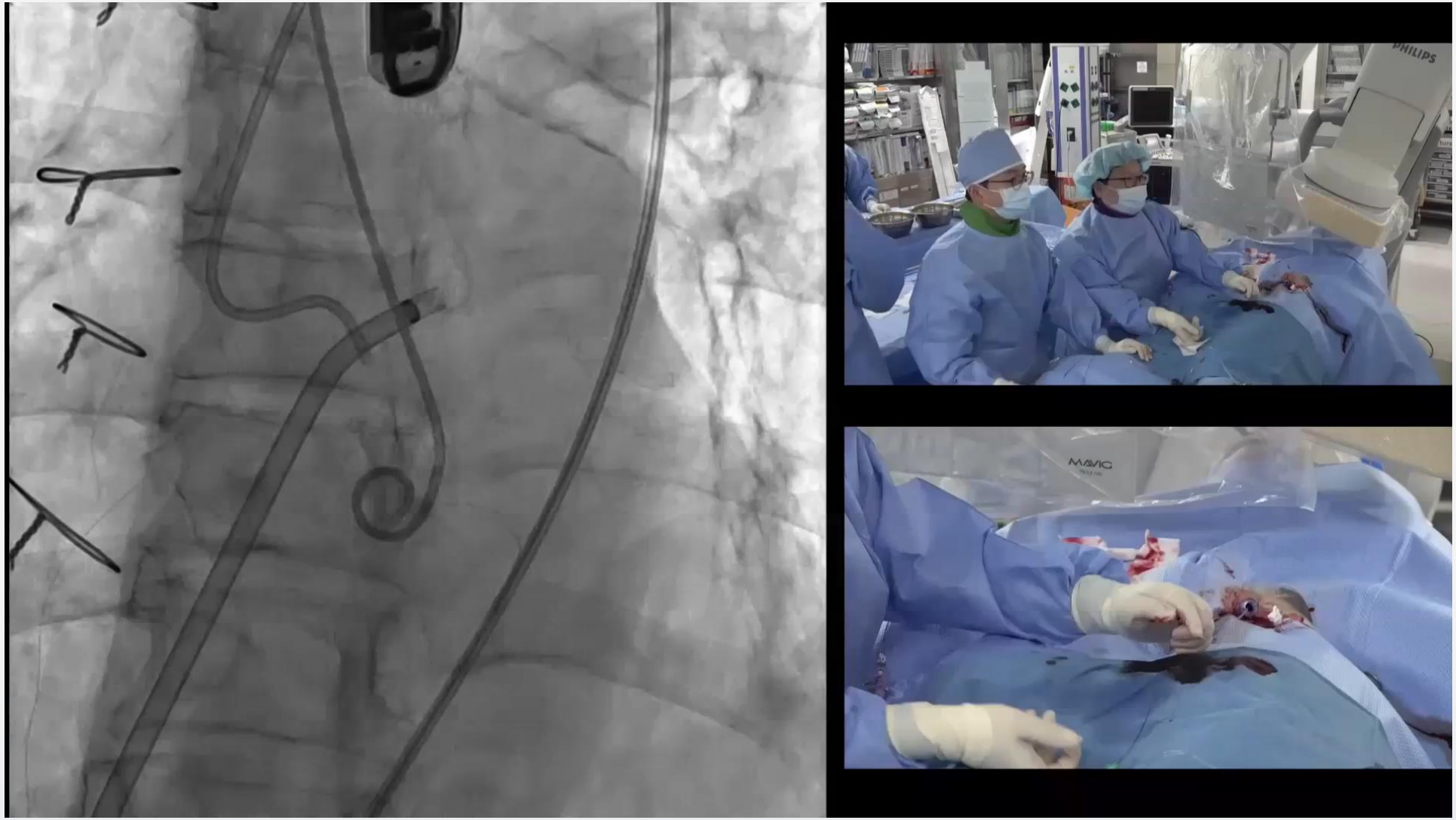
TAVI first? Or TMVR first?

- If a double-valve transcatheter replacement is indicated ; Regarding the best order, usually the aortic valve is performed first.
- The rationale for this strategy is that, since the aortic and mitral annuli are contiguous, bridged by the aorto-mitral fibrous curtain, some degree of obstruction for the new aortic valve deployment can happen if the mitral is treated first

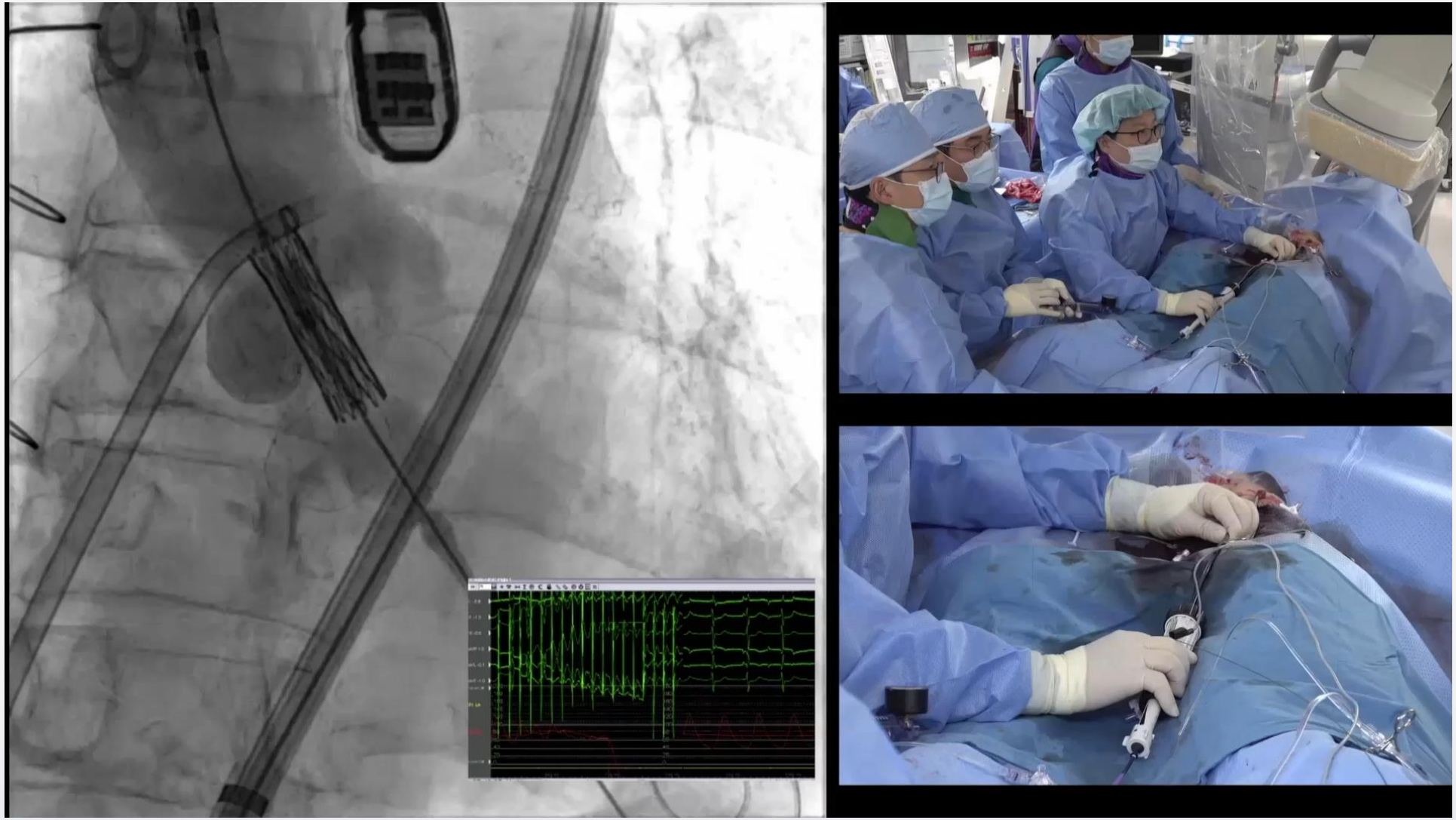
# Septal puncture



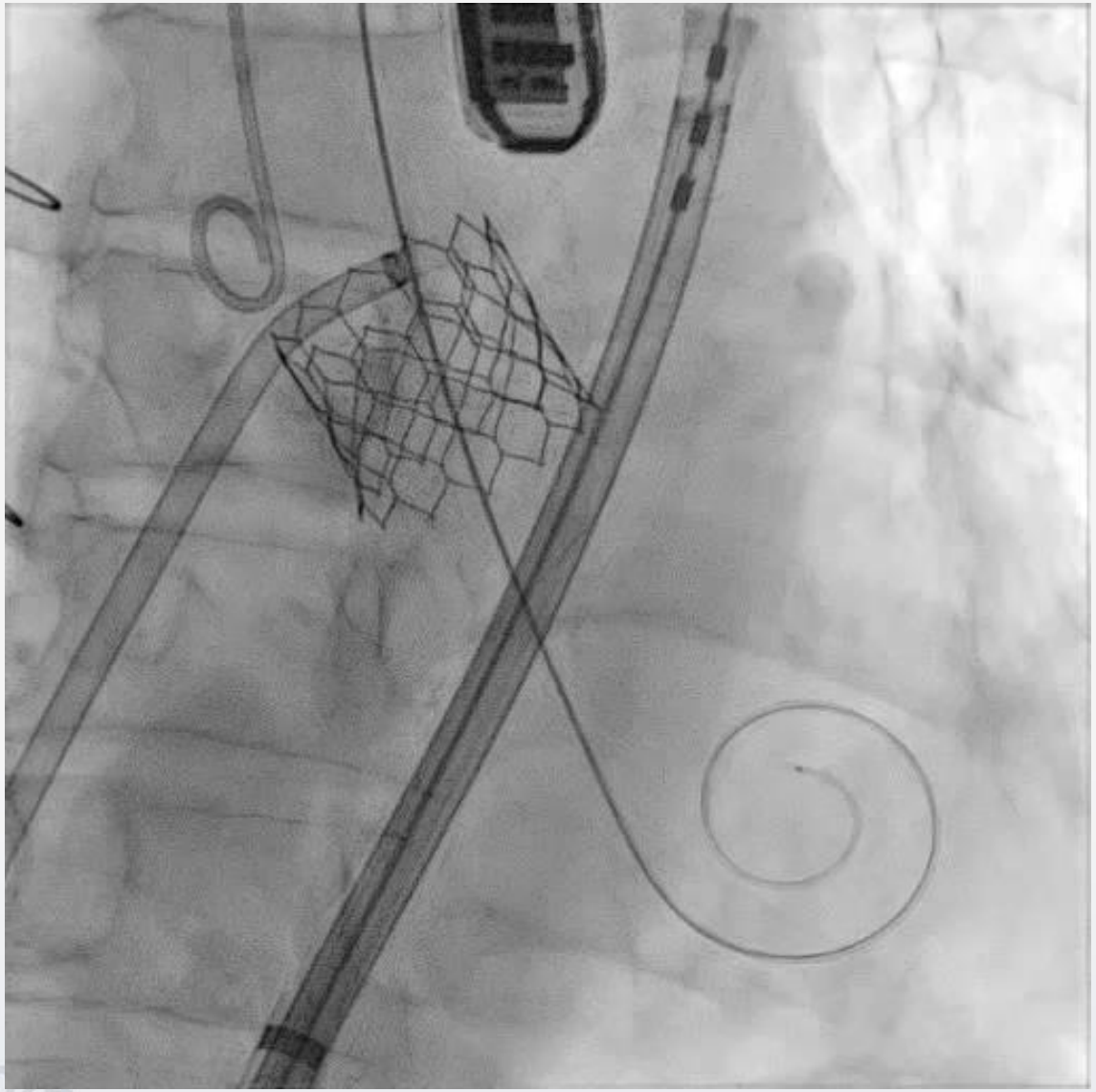
# Aortic Wire Crossing

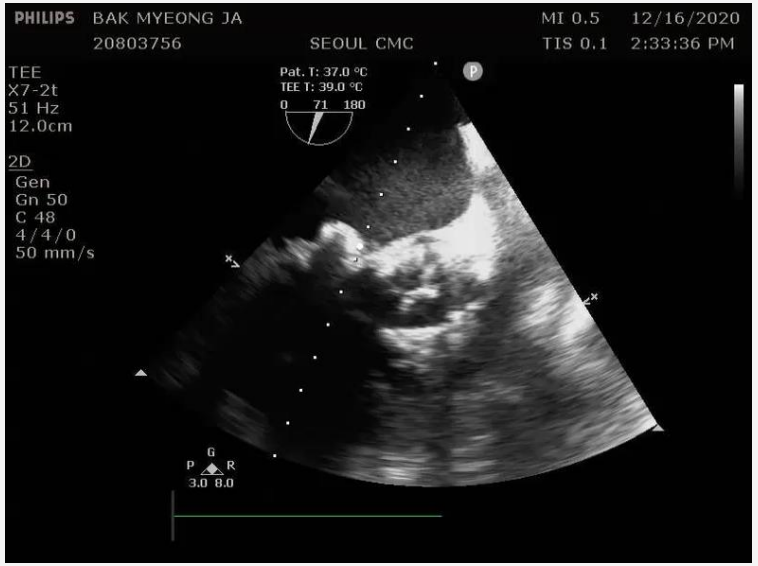


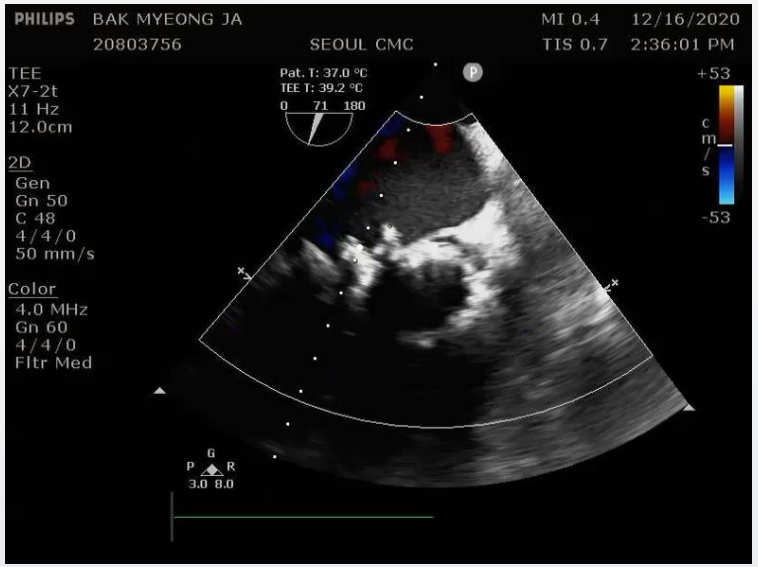
# TAVI Valve implantation



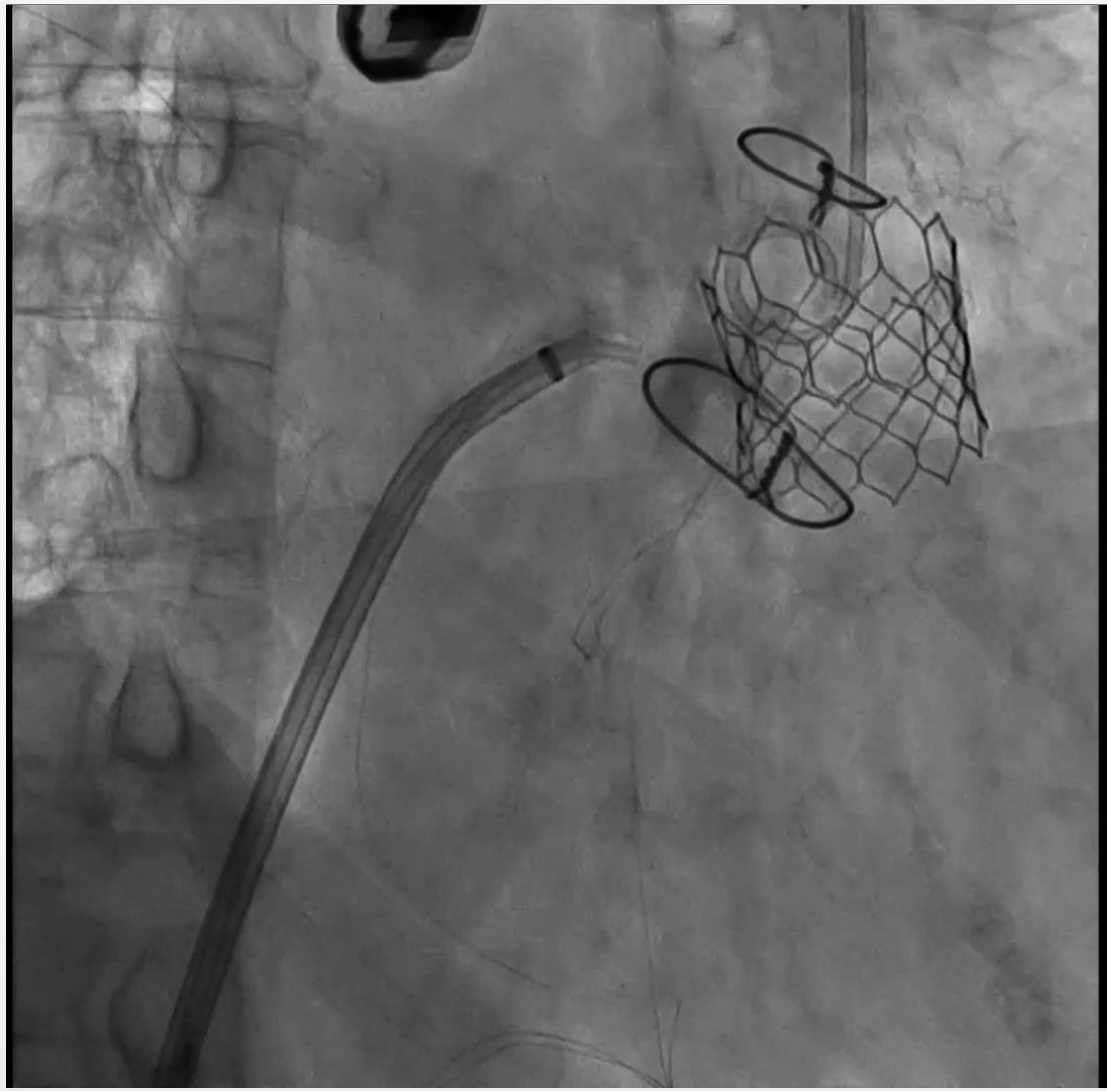
# Post TAVI Aortography & TEE





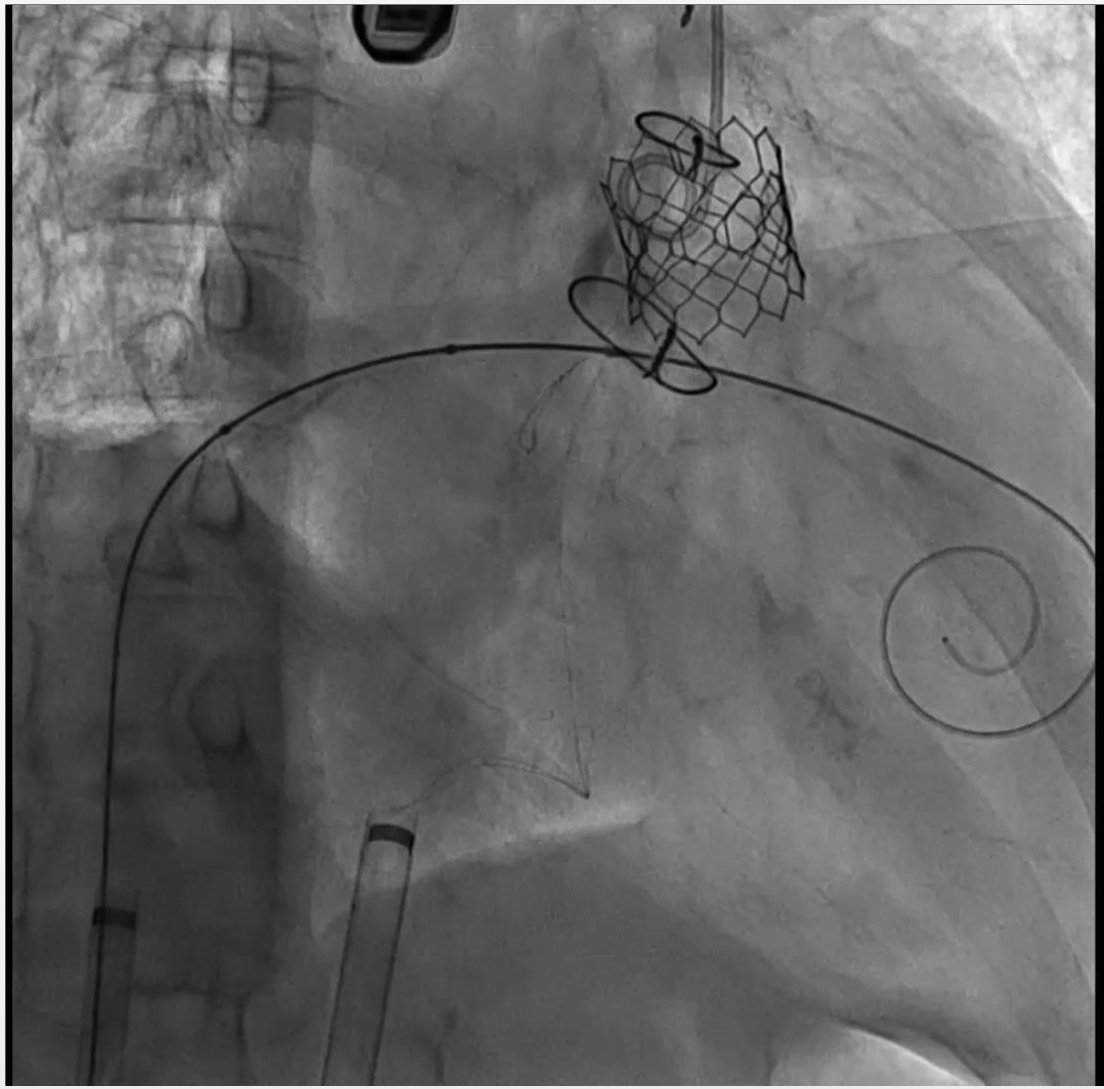



# Wire Crossing

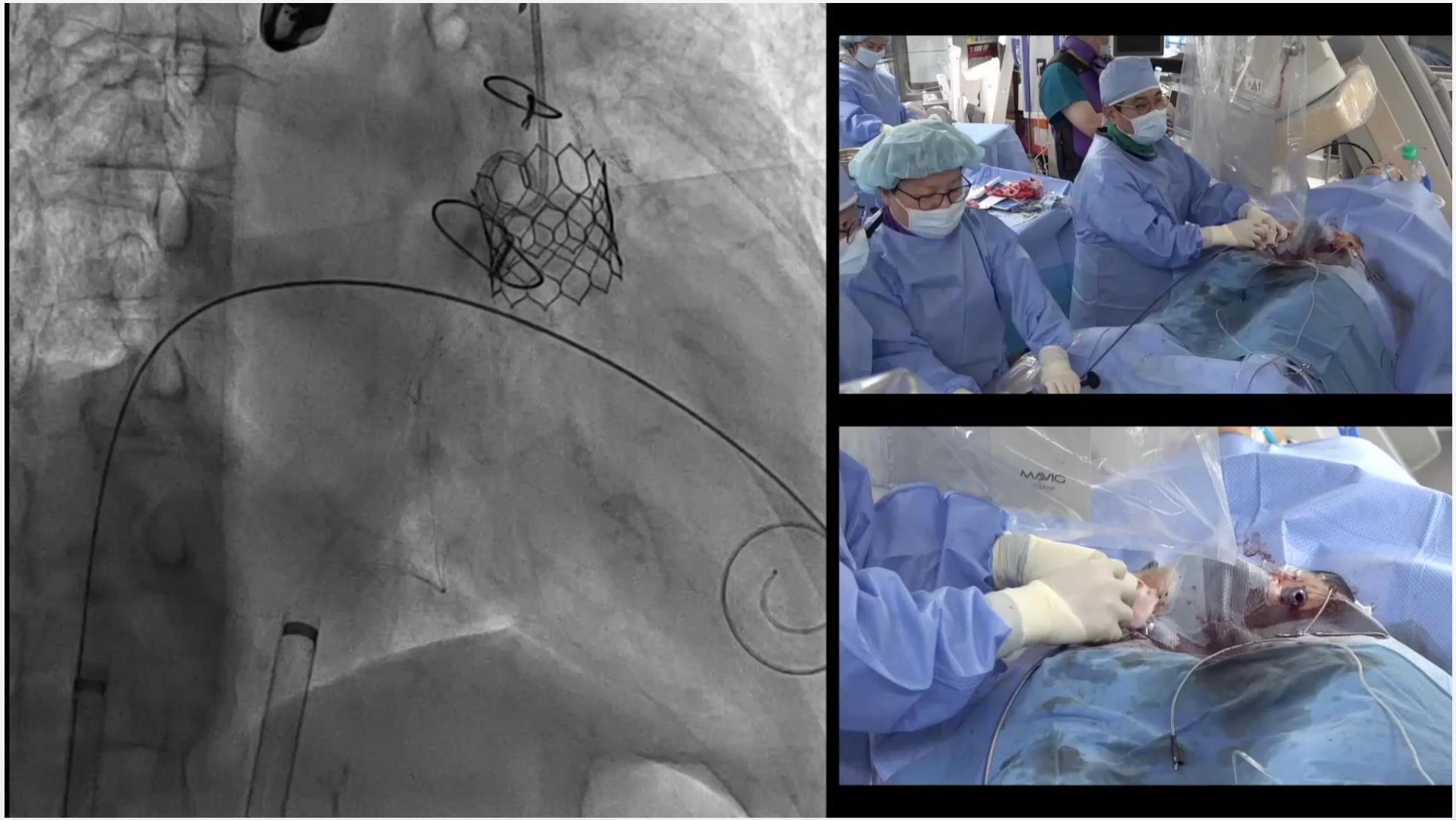


# TMVR sheath insertion

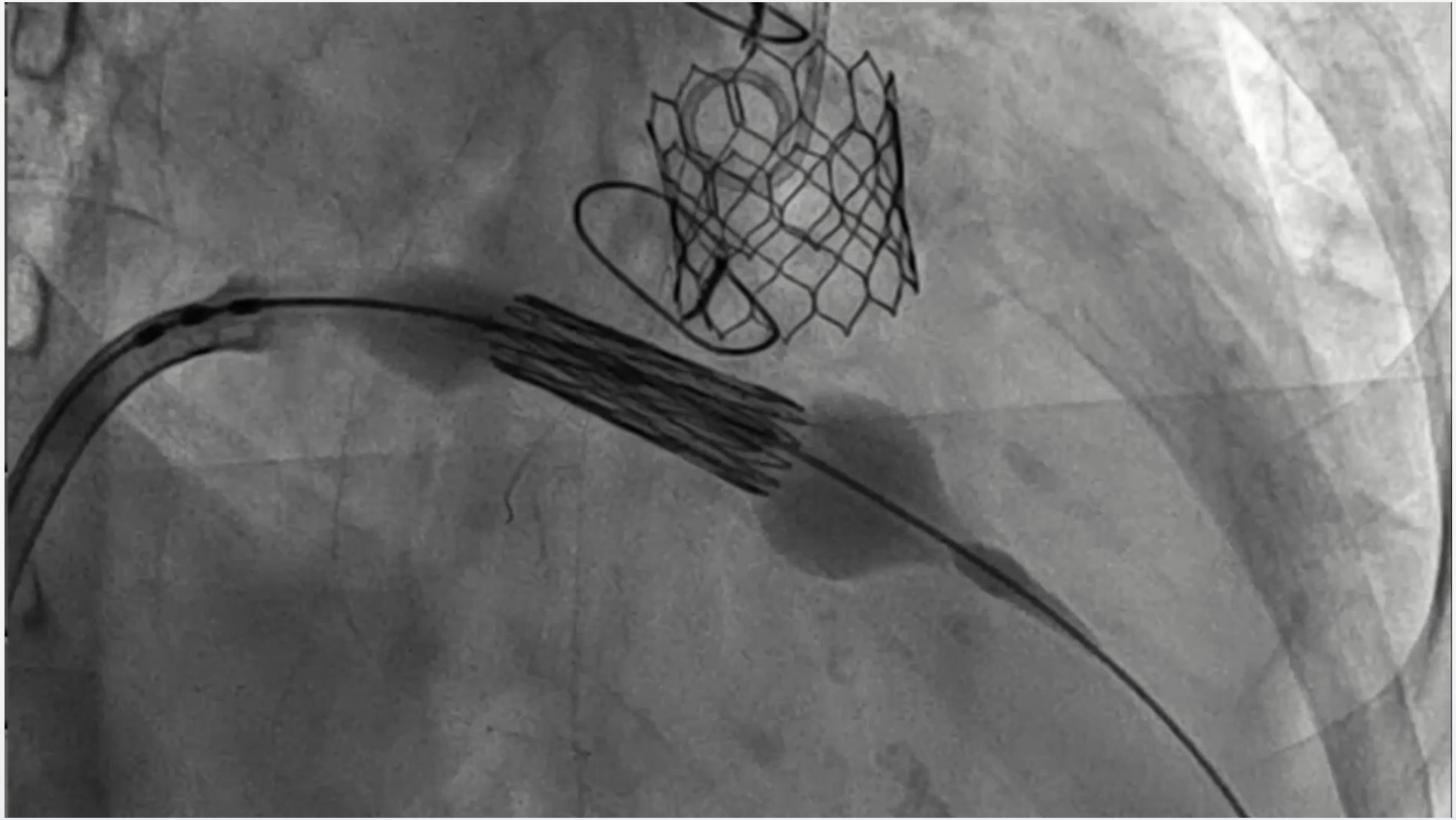
# Septal ballooning



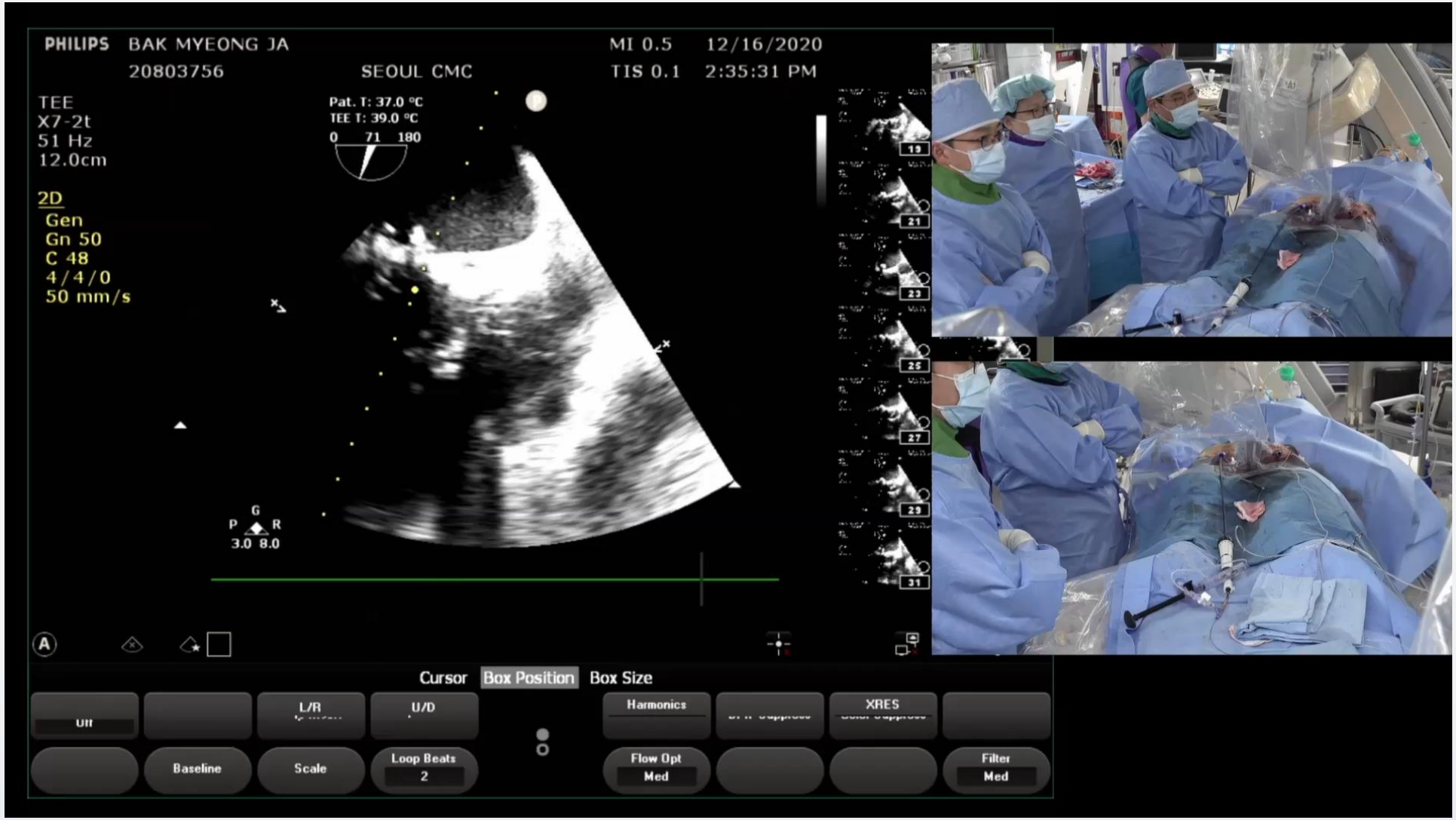
# TMVR Valve Insertion

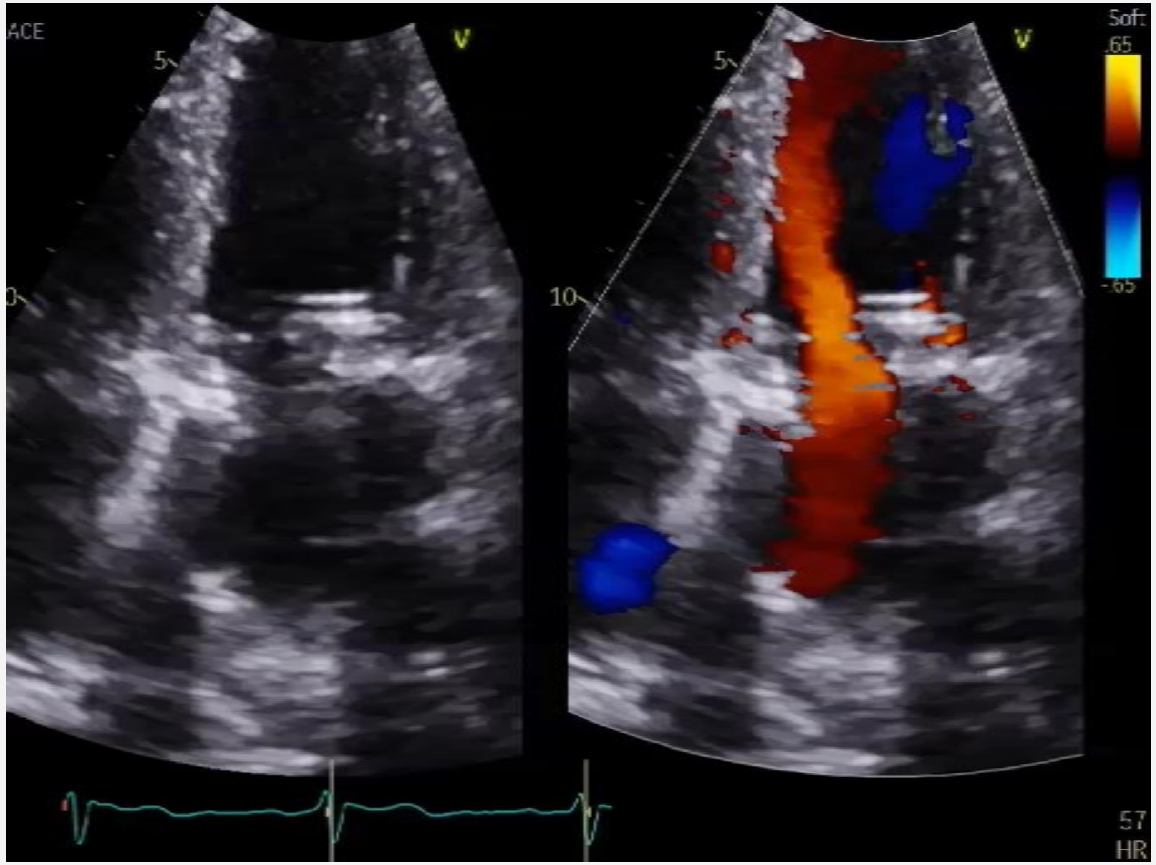


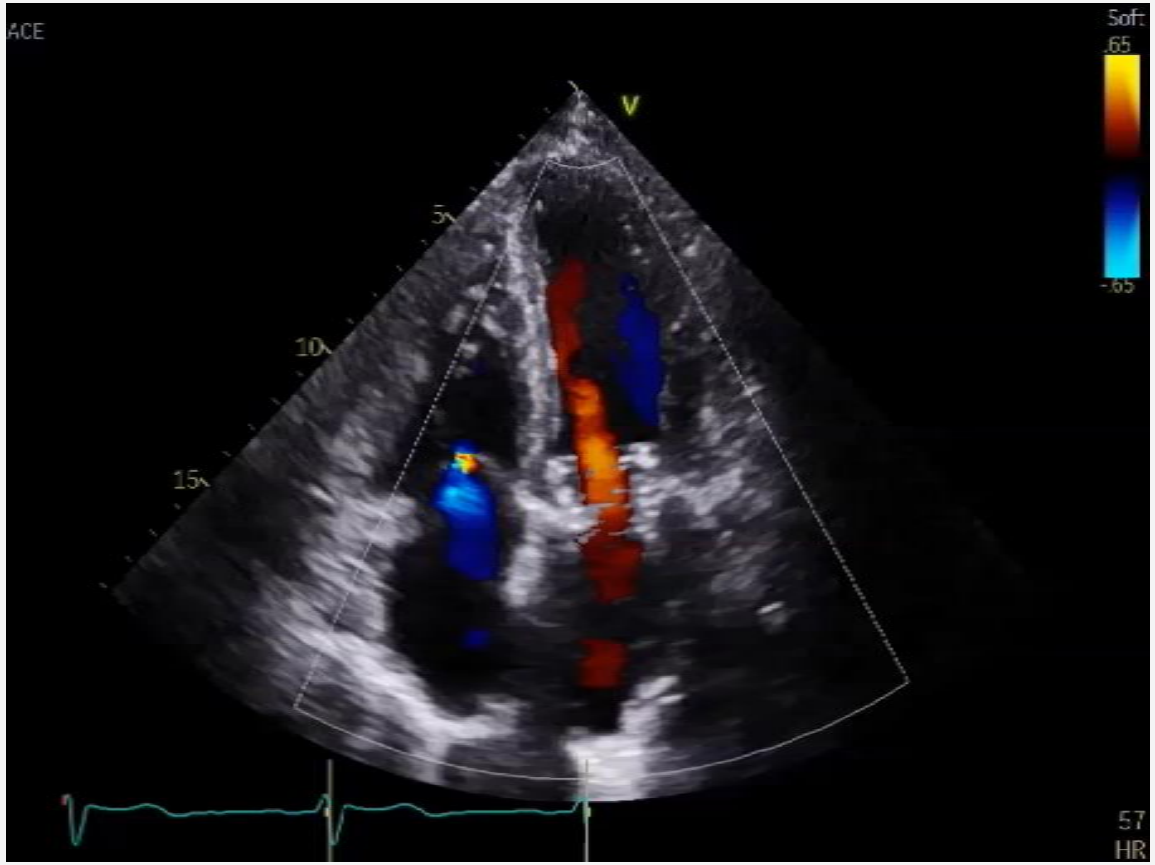
# Valve in Valve



# Post-procedure Realtime TEE



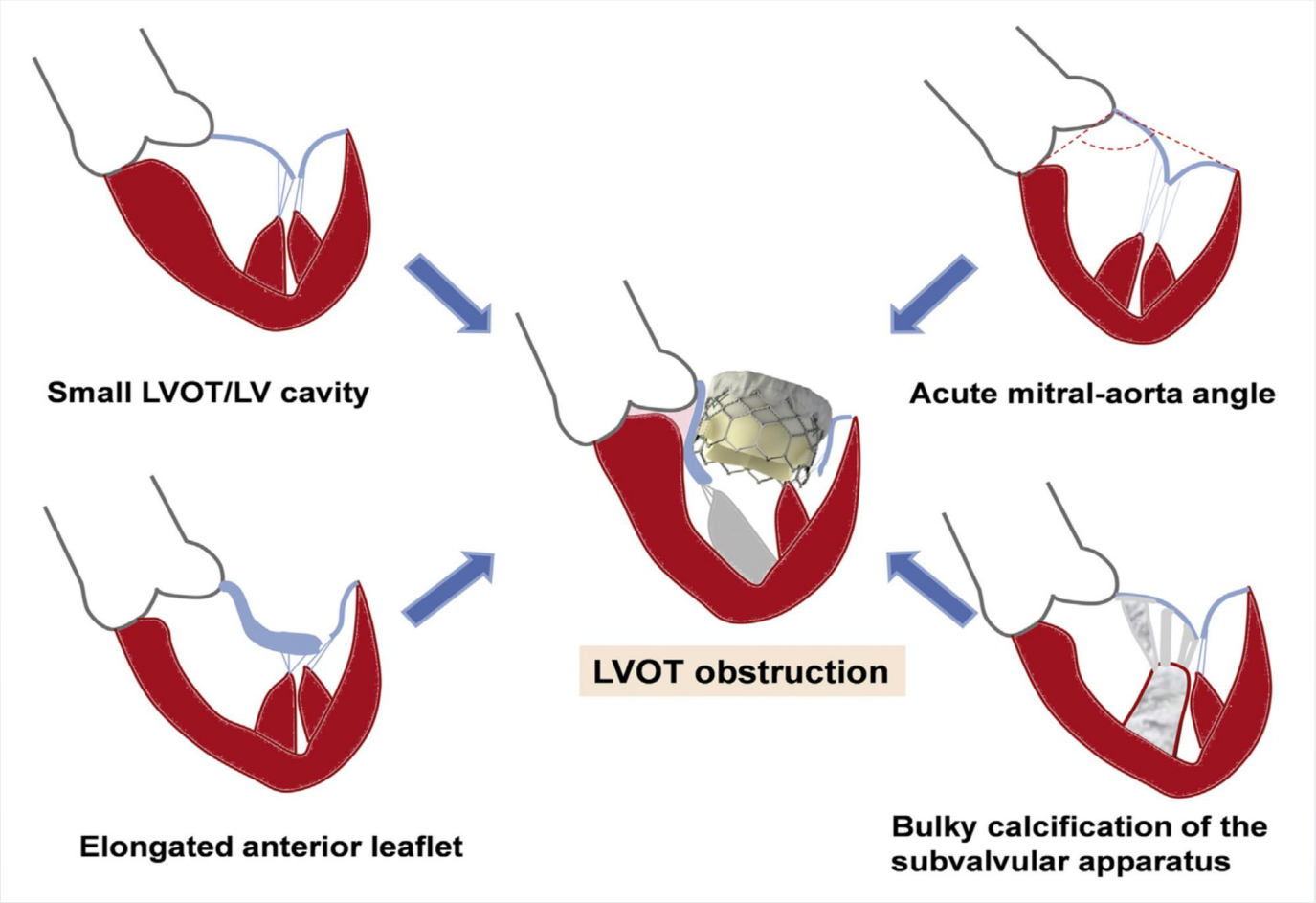



- AV Vmax=4.0-> 2.3m/s, meanPG=36.7-> 11.4mmHg
- MR severity: Severe-> Trivial
- RVSP=64-> 56mmHg
- RV base=44.8-> 40.6mm

# Summary 1

- TMVR Work-up to prevent complications (LVOT obstruction , Etc…)

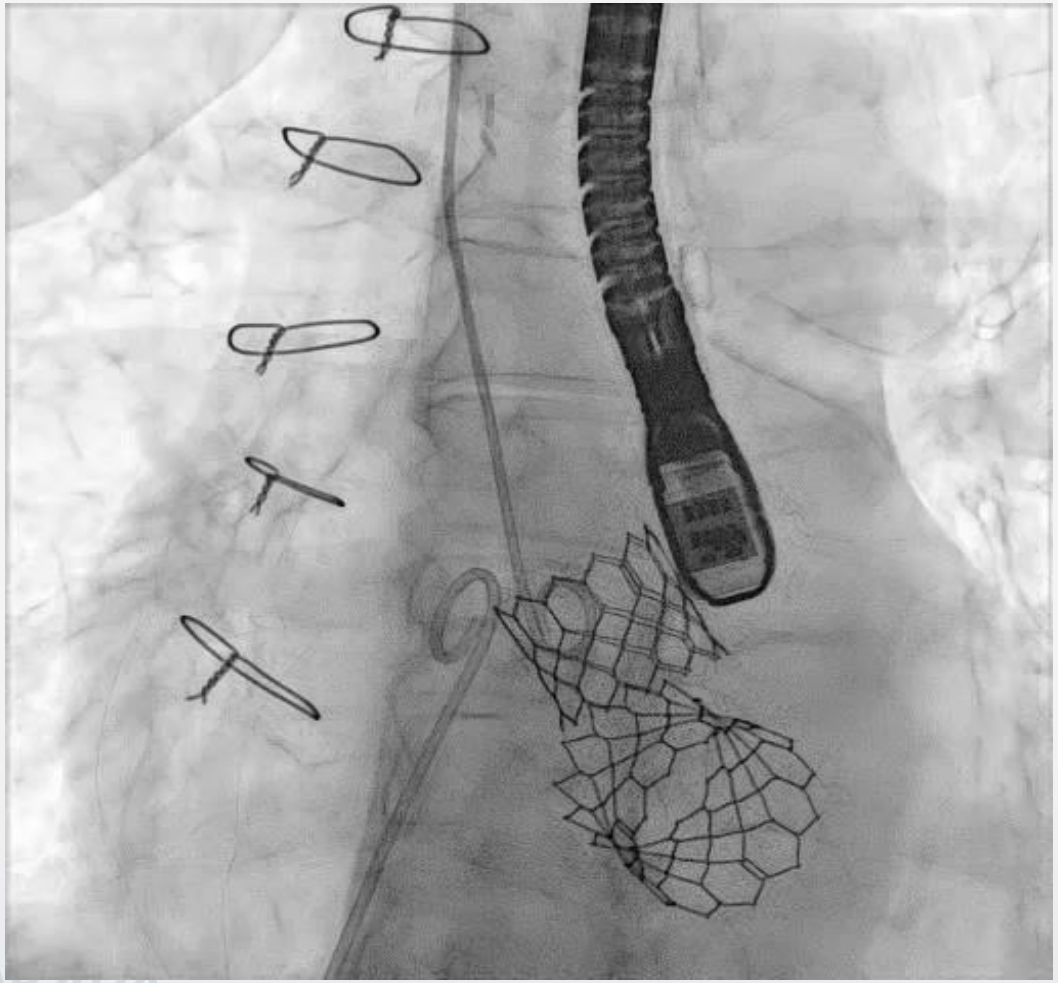


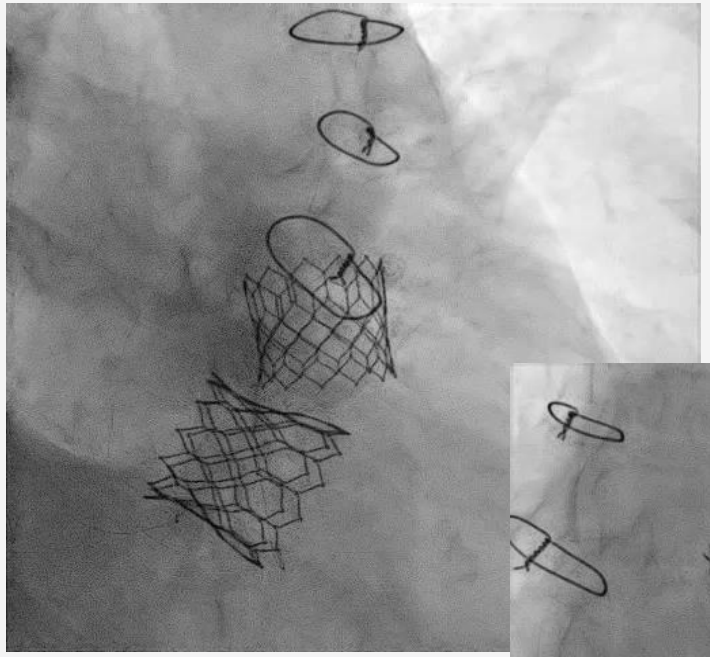


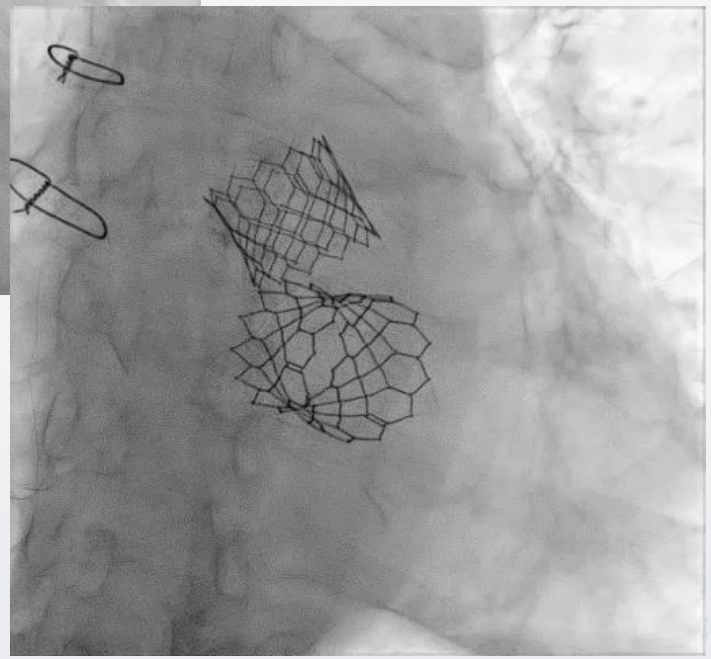

Urena, M. et al. J Am Coll Cardiol Intv. 2017;10(19):1905–19.

# Summary 2

- In double valve intervention, aortic valve 1st is usually recommended







# TAVI with TMVR (Evolut + Sapien)

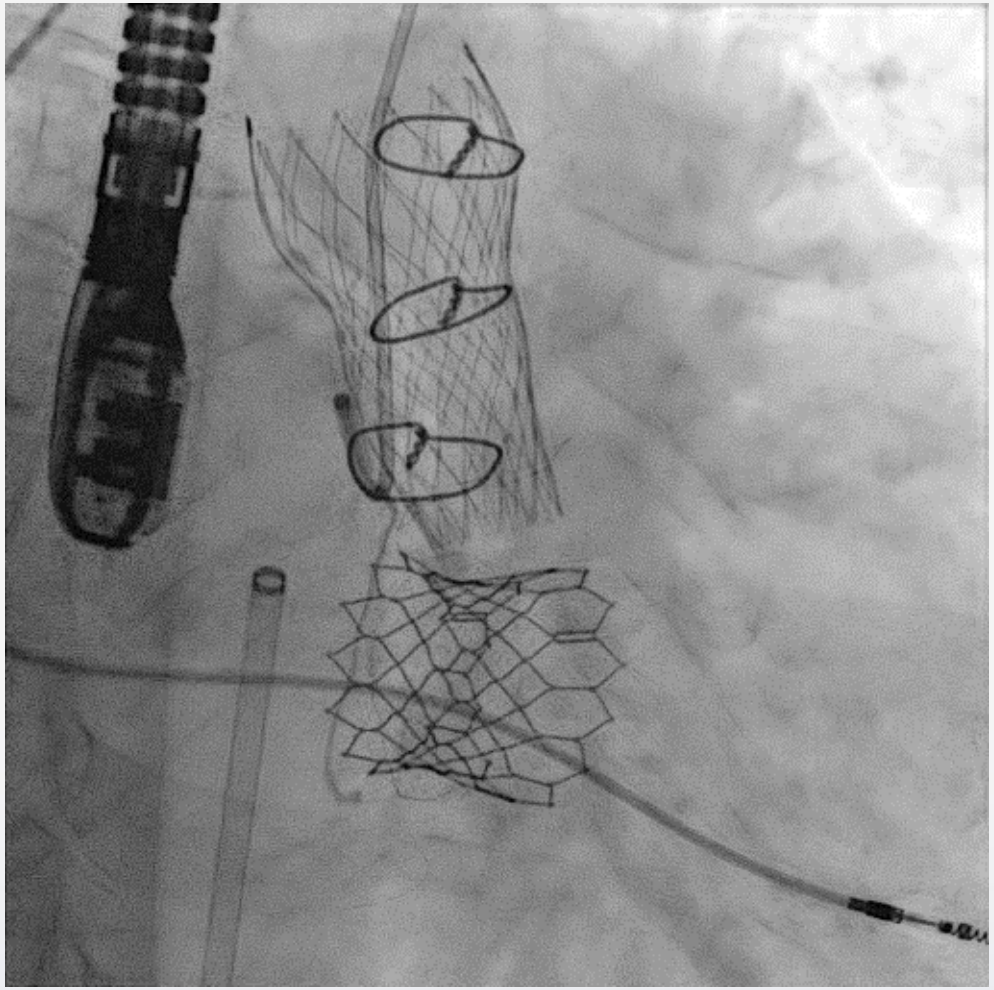
## Severe MS & Severe AS

## AV Vmax= 4m/s

## STS score 19.953%

**TAVI：** SVR Epic 19mm -> Evolut PRO 26mm

**TMVR：** MVR Epic 27mm -> Spien3 26mm



# TMVR 재료대 및 수기료

| 종류 | 처방코드 | 처방명▲ | 총용량 | 수량 | 횟수 | 일수 | 용법/검체 |
|---|---|---|---|---|---|---|---|
| 신규 | 추가 | Y08050222 | [선] Swartz Transseptal Guiding Introducer All Size (At | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y08050051 | [선] Transseptal Needle BRK Series All Size (ST.Jude | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y08060151 | [선] Safari Guidewire All Size (Lake Region Medical) | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y08060091 | [선] Amplatz Extra Stiff Guide Wire 200Cm이상,All Size ( | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y08040655 | [선] Mustang Balloon Dilatation Catheter,PTA&담도 All : | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y08040005 | [선] Performa Catheter All Size (Merit Medical) | 1 | 1 | 1 | 1 | CP*145*6Fr, #7509-23 |
| 신규 | 추가 | Y08040005 | [선] Performa Catheter All Size (Merit Medical) | 1 | 1 | 1 | 1 | JR*4.0*6Fr, 7503-B1 |
| 신규 | 추가 | Y08040721 | [선] Rubicon TM Support Catheter All Size (Boston Sc | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y12000075 | [선] 중재적 방사선 시술팩 수입: ㈜앤티아이 (정액재료대) | 1 | 1 | 1 | 1 | - |
| 신규 | 추가 | Y08050724 | [선] Radifocus Introducer II All Size,4Fr~8Fr/7Cm,10Cm | 1 | 1 | 1 | 1 | 5Fr, 7Cm, A type, RS*A50G07S |
| 신규 | 추가 | Y08050724 | [선] Radifocus Introducer II All Size,4Fr~8Fr/7Cm,10Cm | 1 | 1 | 1 | 1 | 7Fr, 10Cm, R type, RS*R70K10I |
| 신규 | 추가 | Y08060011 | [선] Radifocus Guide Wire 200Cm이상,All Size (Terumc | 1 | 1 | 1 | 1 | 035*260*3*A(stiff), RF*PA35263 |
| 신규 | 추가 | Y08060011 | [선] Radifocus Guide Wire 200Cm이상,All Size (Terumc | 1 | 1 | 1 | 1 | 032*260*3*S, RF*GS32263M |

**수가목록** 엑셀저

| No | ± 그룹코드 | 수가코드 | 보험EDI코드 | 분류번호 | 처방명 | 보험 | | 일반 | 한글명 |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 급여구분 | 단가합 | 일반단가합 | |
| 1 | | JMC0014 | SSSSSS | 신의료기술 | 경피적 승모판막 재치환술 | 일반 | | 45,000,000 | [신의료] 경피적 승모판막 재치환술 |

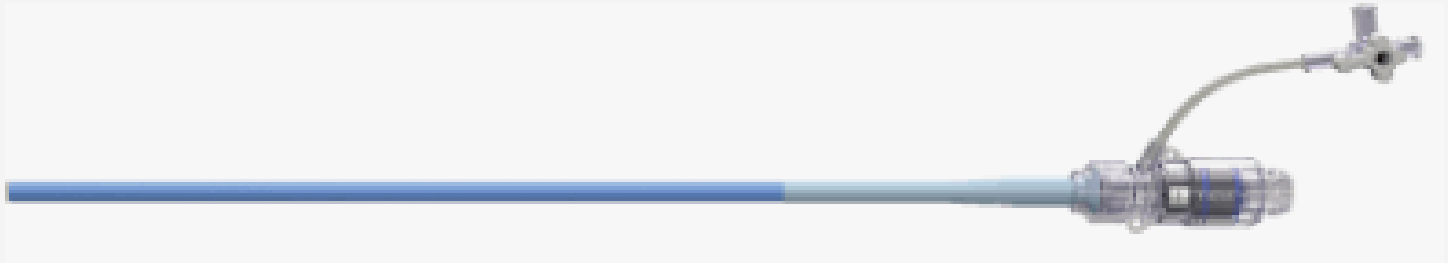
# TMVR 재료대 및 수기료

수가목록

엑셀저

| No | ± 그룹코드 | 수가코드 | 보험EDI코드 | 분류번호 | 처방명 | 보험 | | 일반 | 한글명 |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 급여구분 | 단가합 | 일반단가합 | |
| 1 | | JMC0014 | SSSSSS | 신의료기술 | 경피적 승모판막 재치환술 | 일반 | | 45,000,000 | [신의료] 경피적 승모판막 재치환술 |

+



# TMVR 재료대 및 수기료

## 23.09.06 F/85 – TMVR

| No | 적용일자 | 종료일자 | 주/부 | 보험유형 | 보조유형 | 희귀결핵 | 상한제차등구분 |
|---|---|---|---|---|---|---|---|
| 1 | 2023-09-03 | 2023-09-12 | 주유형 | 의료급여1종 | 정상 | N | 808 |

**진료비 합계**

| | | | | | |
|---|---|---|---|---|---|
| • 총진료비 | 1,529,781 | | • 급여총액/상한초과 | 1,463,941 | 0 |
| • 비급여보험/본인 | 0 | 65,840 | • 급여보험/급여본인 | 1,463,941 | 0 |
| • 선택보험/본인 | 0 | 0 | • 수혈/희귀결핵 | 0 | 0 |
| • 감면/미수액 | 0 | 0 | • 본인총액/수납액 | 65,840 | 0 |

**진료비 합계**

| | | | | | |
|---|---|---|---|---|---|
| • 총진료비 | 55,013,928 | | • 급여총액/상한초과 | 8,749,097 | 0 |
| • 비급여보험/본인 | 0 | 46,264,831 | • 급여보험/급여본인 | 8,273,546 | 475,551 |
| • 선택보험/본인 | 0 | 0 | • 수혈/희귀결핵 | 0 | 0 |
| • 감면/미수액 | 0 | 38,369,720 | • 본인총액/수납액 | 46,740,382 | 46,740,380 |

## 23.09.06 F/85 – TMVR

| No | 적용일자 | 종료일자 | 주/부 | 보험유형 | 보조유형 | 희귀결핵 | 상한제차등구분 |
|---|---|---|---|---|---|---|---|
| 1 | 2024-01-03 | 2024-01-13 | 주유형 | 건강보험 | 정상 | N | 808 |

**진료비 합계**

| | | | | | |
|---|---|---|---|---|---|
| • 총진료비 | 2,087,317 | | • 급여총액/상한초과 | 2,055,492 | 0 |
| • 비급여보험/본인 | 0 | 31,825 | • 급여보험/급여본인 | 1,640,337 | 415,155 |
| • 선택보험/본인 | 0 | 0 | • 수혈/희귀결핵 | 0 | 0 |
| • 감면/미수액 | 0 | 0 | • 본인총액/수납액 | 446,980 | 0 |

**진료비 합계**

| | | | | | |
|---|---|---|---|---|---|
| • 총진료비 | 54,918,920 | | • 급여총액/상한초과 | 8,748,339 | 0 |
| • 비급여보험/본인 | 0 | 46,170,581 | • 급여보험/급여본인 | 6,538,050 | 2,210,289 |
| • 선택보험/본인 | 0 | 0 | • 수혈/희귀결핵 | 0 | 0 |
| • 감면/미수액 | 0 | 0 | • 본인총액/수납액 | 48,380,870 | 48,380,870 |

# conclusion

- TMVR (Mitral Valve-in-Valve) is a reasonable alternative for patients with high surgical risk.
  - TMVR in VIV can be done safely with balloon expandable valve
  - Relatively safe procedure with careful approach & experienced aorta, mitral interventionist

# Thank You for Your Attention