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THE ISRAEL SOCIETY OF CARDIOTHORACIC SURGERY
האיגוד הקרדיולוגי בישראל
ISRAEL HEART SOCIETY

The 60th International Conference of the Israel Heart Society
in association with the Israel Society of Cardiothoracic Surgery
22-23 April 2013, ICC International Convention Center, Jerusalem

# CoreValve in a Degenerative Surgical Valve

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# Disclosure Statement of Financial Interest

I, Ran Kornowski, do not have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation. I serve occasionally as a certified TAVI proctor for Edwards Lifesciences and Medtronic-Corevalve.

# Background

- Surgical bioprosthetic valves tend to fail over time.
- Mode of failure could be aortic stenosis, aortic regurgitation, para-valvular leak or mix failure.
- Re-do SAVR is associated with augmented risk and often occurs at advanced age.
  - Jones J. M. et al.; J Thorac Cardiovasc Surg 2001;122:913-918
- TAVI offers a novel mode of treatment for aortic bioprosthetic valve failure instead of re-do SAVR.

# Mechanism of valve failure

AS

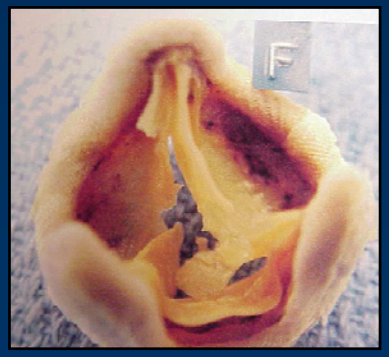
Pannus

Thrombus

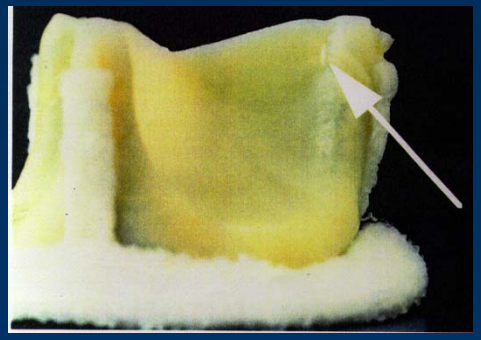
Calcification

AR

Wear& Tear (int.)



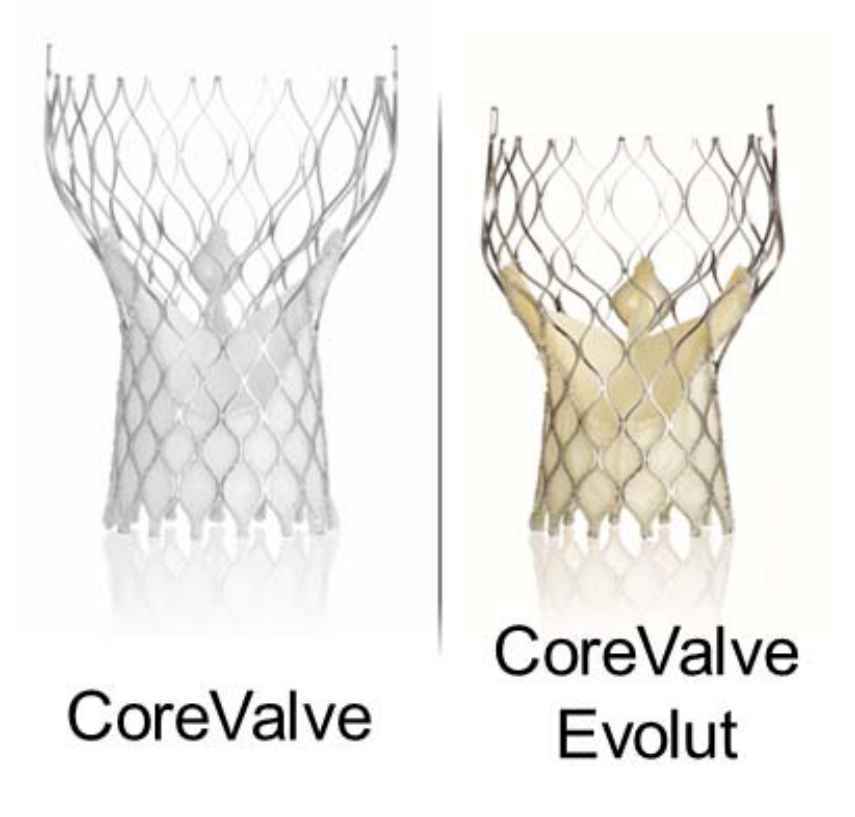

Wear& Tear (ext.)



Endocarditis

# CoreValve in a Degenerative Surgical Valves

## CoreValve \ CoreValve Evolut™ Design




**Principle features:**

- **Tailored height and shape**
- **Conformability and sealing**
- **Optimized radial force**
- **Coaptation** in non-circular anatomy
- **Supra-annular valve position**

**In the CoreValve Evolut™:**

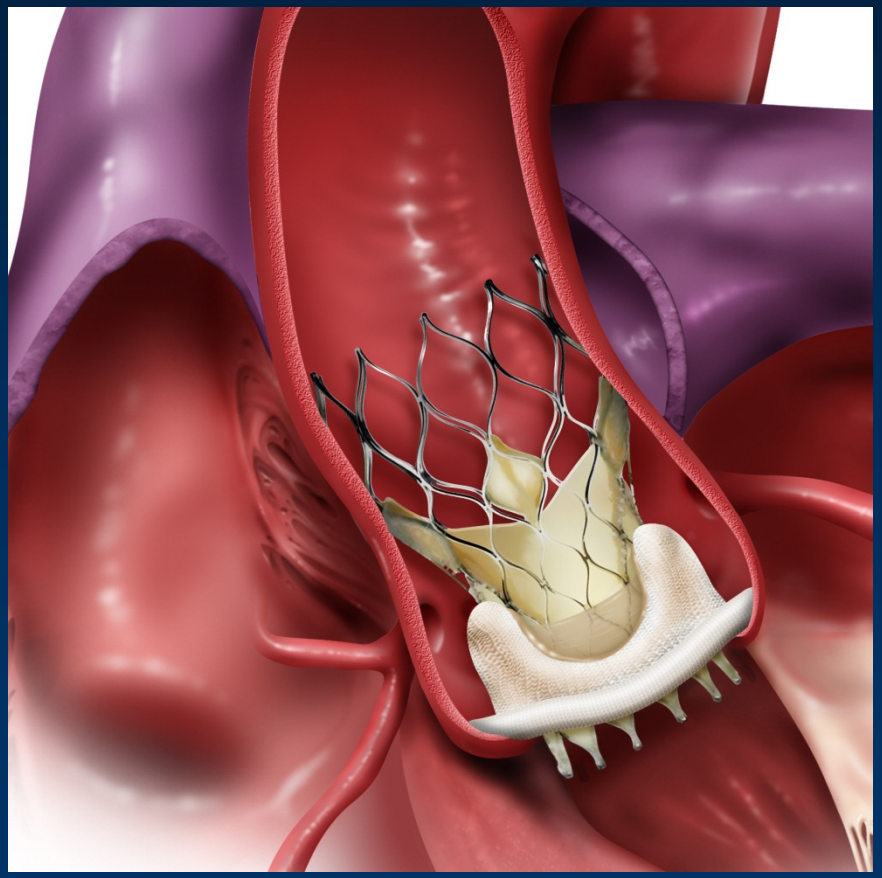
**AOA® Anti-Mineralization Treatment:**

- Reduce both early and late valvular calcification

# CoreValve in a Degenerative Surgical Valve

## Supra-Annular Design

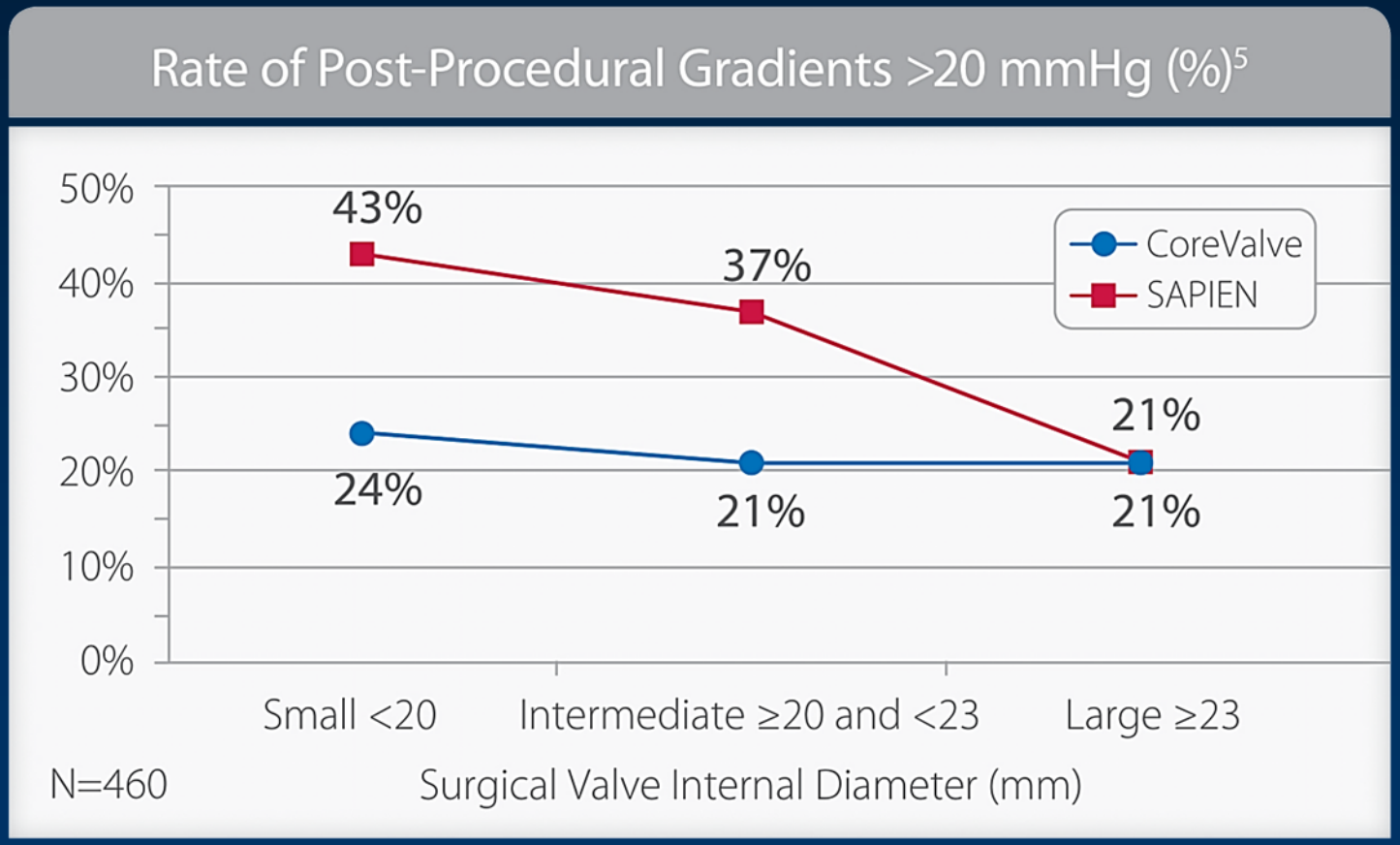
- The supra-annular design enables blood flow as the leaflets are positioned *above* the surgically implanted valve; reducing dependence on the inner dimension of the surgical bioprosthesis.



# CoreValve in a Degenerative Surgical Valve

## Hemodynamic Performance

- CoreValve demonstrates lower post-procedural gradients following Valve-in-Valve procedures.




Dvir et al., TCT. Miami, Fl. Oct 2012

# Stented versus Stentless Valves

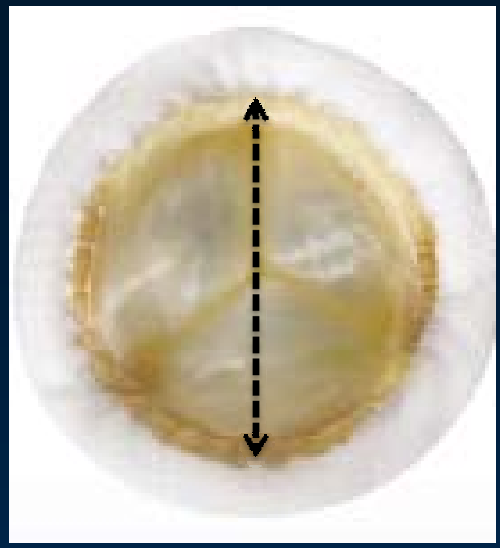
Important Consideration

Stented SAV

Stentless SAV

# VIV Inside Diameter Importance

= valve inside diameter



## Valve-in-Valve Sizing Guide

A = Valve Height
B = Valve Orifice Diameter

### Stented Bioprostheses

| | Valve Size | 19 mm | 21 mm | 23 mm | 25 mm | 27 mm | 29 mm | 31 mm |
|---|---|---|---|---|---|---|---|---|
| Medtronic Mosaic[xi] | Diameter | 17.5 | 18.5 | 20.5 | 22.5 | 24 | 26 | |
| | Height | 13.5 | 15 | 16 | 17.5 | 18.5 | 20 | |
| Medtronic Hancock® II[ii] | Diameter | | 18.5 | 20.5 | 22.5 | 24 | 26 | |
| | Height | | 15 | 16 | 17.5 | 18.5 | 20 | |
| Medtronic Hancock Modified Orifice (M.O.) 250[iii] | Diameter | 16 | 18 | 20 | 21.8 | | | |
| | Height | 17 | 18.5 | 19.5 | 21.25 | | | |
| Medtronic Hancock Porcine Standard[iv] | Diameter | | | 20 | 21.8 | 22.3 | 24.1 | 26 |
| | Height | | | 17.25 | 18.75 | 20 | 21.25 | 22.75 |
| Edwards Perimount 2700[vi] | Diameter | 18 | 20 | 22 | 24 | 26 | 28 | |
| | Height | 13 | 14 | 15 | 16 | 17 | 18 | |
| Edwards Perimount 2800[vii] | Diameter | 18 | 20 | 22 | 24 | 26 | 28 | |
| | Height | 14 | 15 | 16 | 17 | 18 | 19 | |
| Edwards Perimount Magna 3000[viii] | Diameter | 18 | 20 | 22 | 24 | 26 | 28 | |
| | Height | 14 | 15 | 16 | 17 | 18 | 19 | |
| Edwards Perimount Magna Ease 3300[ix] | Diameter | 18 | 20 | 22 | 24 | 26 | 28 | |
| | Height | 13 | 14 | 15 | 16 | 17 | 18 | |
| Edwards Porcine Bioprosthesis 2625[xv] | Diameter | 17 | 19 | 21 | 23 | 25 | 27 | 29 |
| | Height | 15 | 16 | 16 | 18 | 18 | 19 | 19 |
| Edwards S.A.V.[xii] | Diameter | 17 | 19 | 21 | 23 | 25 | 27 | |
| | Height | 14 | 15 | 16 | 17 | 17 | 18 | |

| | Valve Size | 19 mm | 21 mm | 23 mm | 25 mm | 27 mm | 29 mm | 31 mm |
|---|---|---|---|---|---|---|---|---|
| Sorin Mitroflow LX[x] | Diameter | 15.4 | 17.3 | 19 | 21 | 22.9 | | |
| | Height | 11 | 13 | 14 | 15 | 16 | | |
| Sorin Mitroflow 12[xi] | Diameter | 15.4 | 17.3 | 19 | 21 | 22.9 | 24.7 | |
| | Height | 11 | 13 | 14 | 15 | 16 | 16.4 | |
| St. Jude Medical Biocor[xi] | Diameter | | 19 | 21 | 23 | 25 | 27 | |
| | Height | | 14 | 15 | 16 | 17 | 19 | |
| St. Jude Medical Biocor Supra[xi] | Diameter | | 19 | 21 | 23 | | | |
| | Height | | 14 | 15 | 16 | | | |
| St. Jude Medical Epic[x] | Diameter | | 19 | 21 | 23 | 25 | 27 | |
| | Height | | 14 | 15 | 16 | 17 | 19 | |
| St. Jude Medical Epic Supra[x] | Diameter | | 19 | 21 | 23 | 25 | 27 | |
| | Height | | 14 | 15 | 16 | 17 | 19 | |
| St. Jude Medical Trifecta[x] | Diameter | | 17 | 19 | 21 | 23 | 25 | |
| | Height | | 15 | 16 | 17 | 18 | 19 | |

### Stentless Bioprostheses

| | Valve Size | 19 mm | 21 mm | 23 mm | 25 mm | 27 mm | 29 mm | 31 mm |
|---|---|---|---|---|---|---|---|---|
| Medtronic Freestyle[xiii] | Diameter | 16 | 18 | 20 | 21.5 | 23.5 | 26 | |
| | Height | 30 | 32 | 32 | 34 | 34 | 39 | |
| Medtronic 3f[xiii] | Diameter | 17 | 19.6 | 22.6 | 23.7 | 25.8 | 27.6 | |
| | Height | 23 | 25 | 27 | 29 | 31 | 32 | |

| Valve Size | Aortic Annulus Diameter | Ascending Aorta Diameter | Perimeter Ranges |
|---|---|---|---|
| Corresponding Medtronic CoreValve | | | |
| 23 mm | 18 mm - 20 mm | ≤ 34 mm | 56 mm - 62.8 mm |
| 26 mm | 20 mm - 23 mm | ≤ 40 mm | 62.8 mm - 72.3 mm |
| 29 mm | 23 mm - 27 mm | ≤ 43 mm | 72.3 mm - 84.8 mm |
| 31 mm | 26 mm - 29 mm | ≤ 43 mm | 81.6 mm - 91.1 mm |

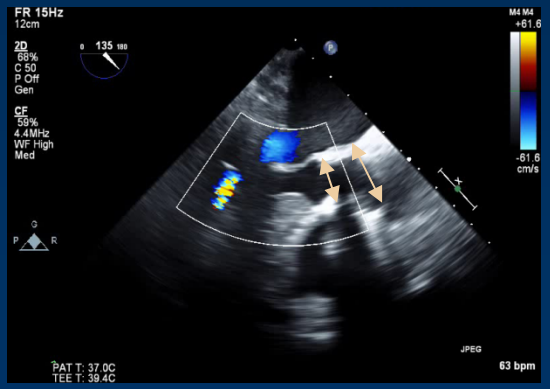
It is very important to recognize the angiographic “signature” of each valve

# Determine Annulus Diameter of SAV

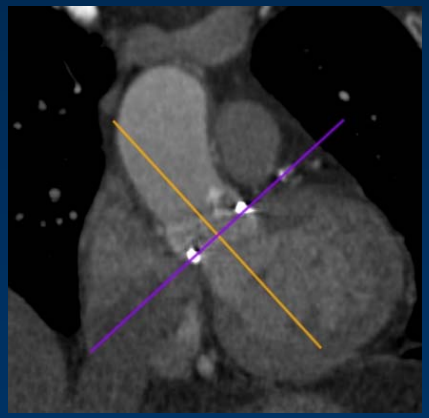
***Echo (also TEE) and Computed tomography (CT) are required.***

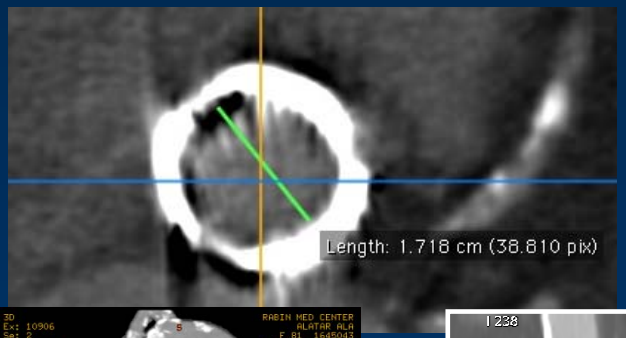
- Inside diameter of SAV inflow (at the annulus)
- Distance between coronary ostia take off and the valve
- R/O additional cardiac pathologies (thrombus, vegetation etc.)

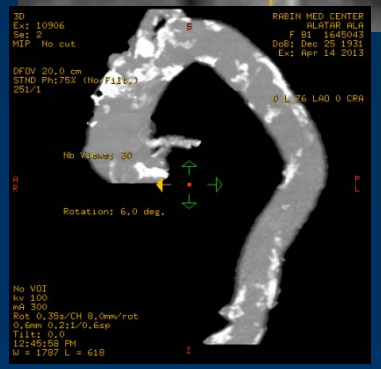
Echo measurement of the annulus and aortic root and assessment of additional cardiac structures.




Comprehensive CT evaluation: Access and the aortic root & bioprosthesis.

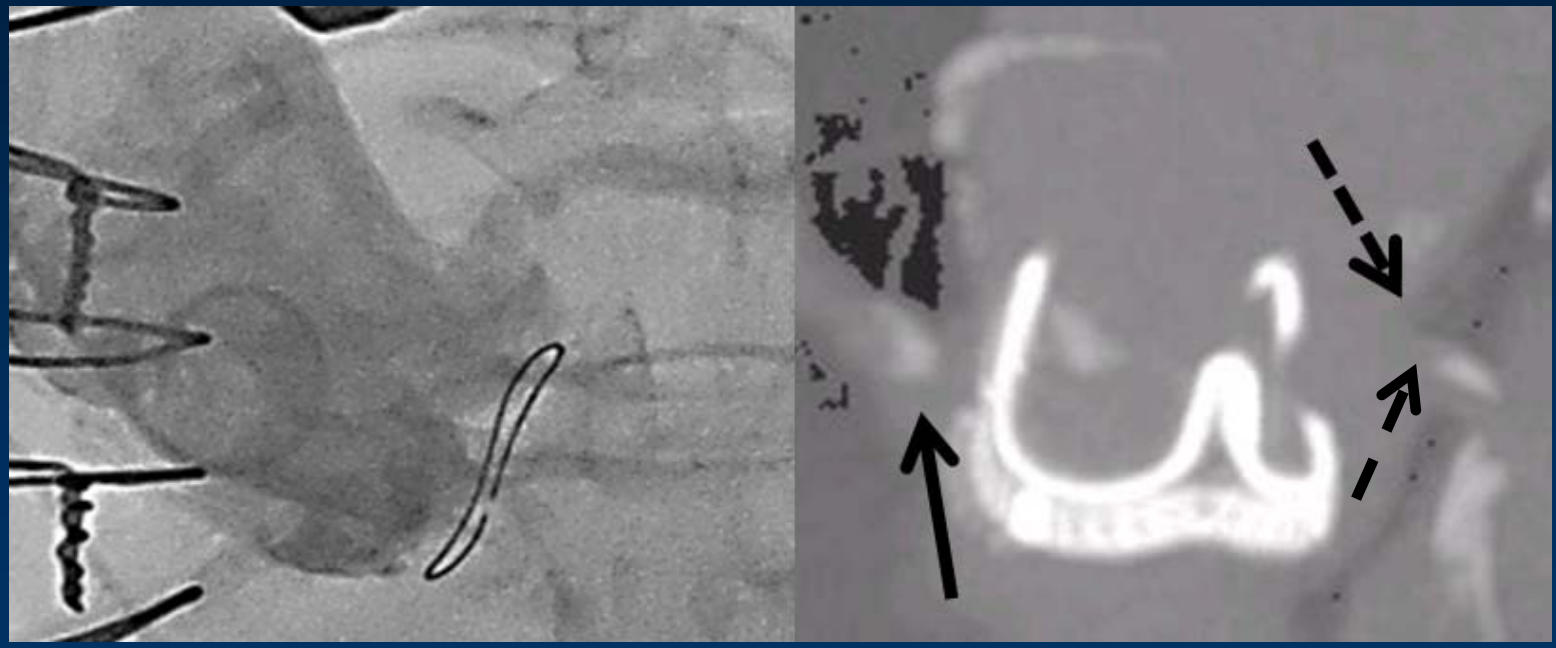





# Determine Valve to Coronary Distance

**Assess the risk for coronary obstruction**



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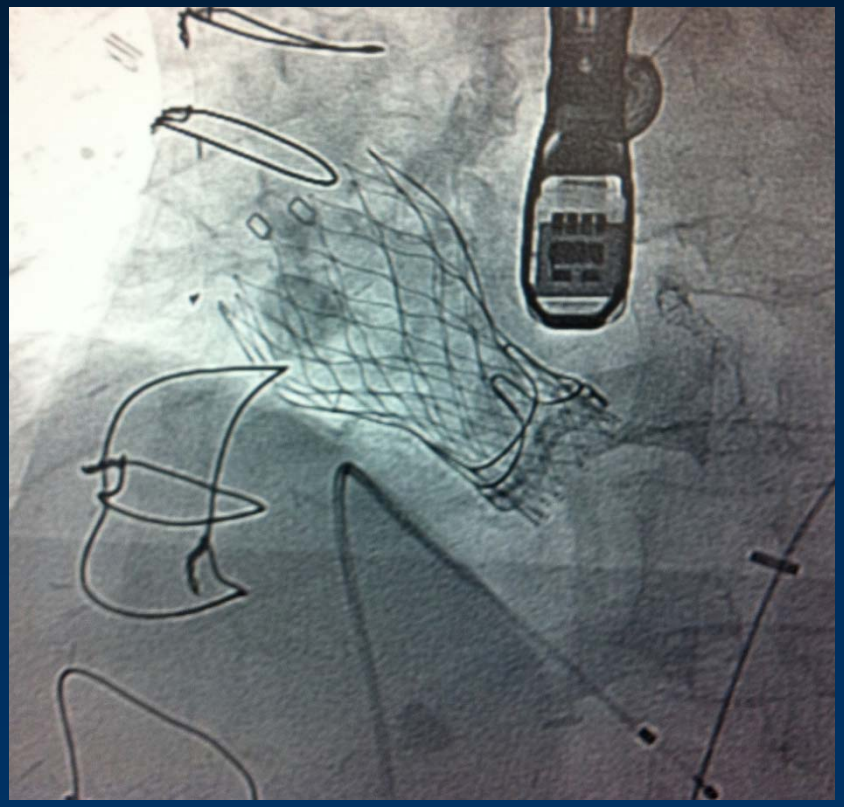
# Valve in Valve – Case Examples

# Patient 1 (D.I)

Age: 81
Gender: Female

First valve:
1998

Valve type:
CE Primount –
stented 19mm



TAVI - V in V

April 2013

CV Evolut™ 23mm

Access: Femoral

Pre: Severe AS
(67\42 mmHg)

AR grade post: 0\1

Post gradient:

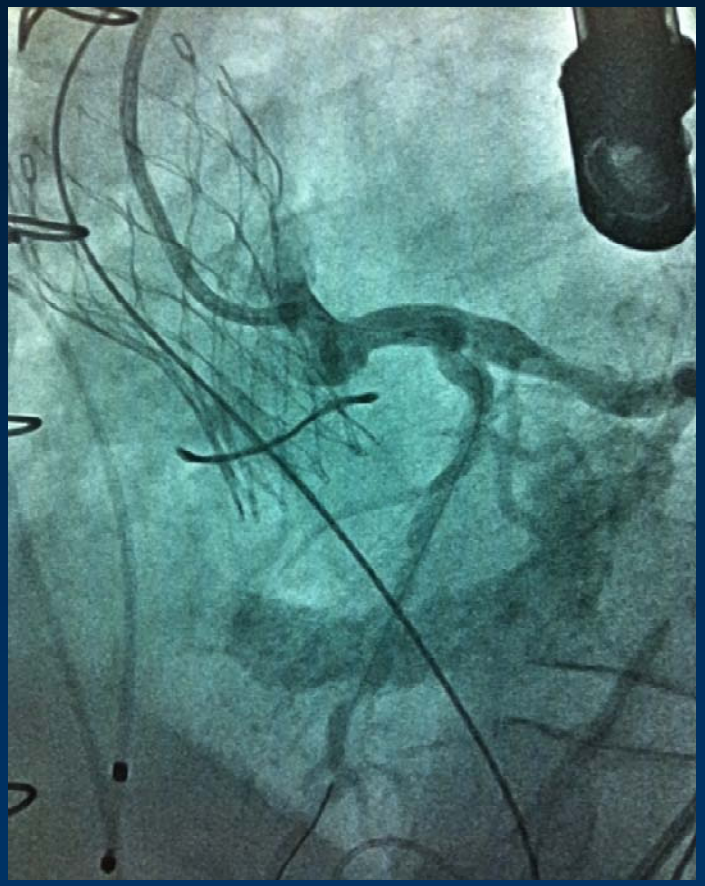
(21\13 mmHg)

# Patient 2 (S.A)

Age: 82
Gender: Male

First valve:
2003

Valve type:
Mitroflow –
stented 19mm



TAVI - V in V

December 2012

CV Evolut™ 23mm

Access: Femoral

Pre: AR +AS

AR grade post: 0

Post gradient:

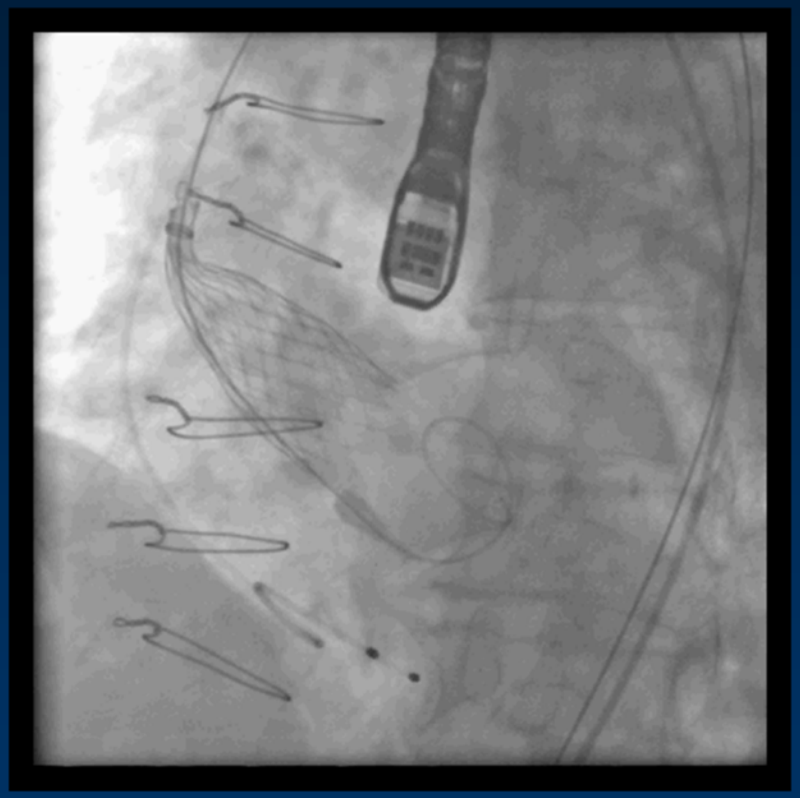
(18\9 mmHg)

# Patient 3 (S.A)

Age: 86
Gender: male

First valve:
1996

Valve type:
Toronto -
stentless



TAVI - V in V

March 2012

CoreValve, 26mm

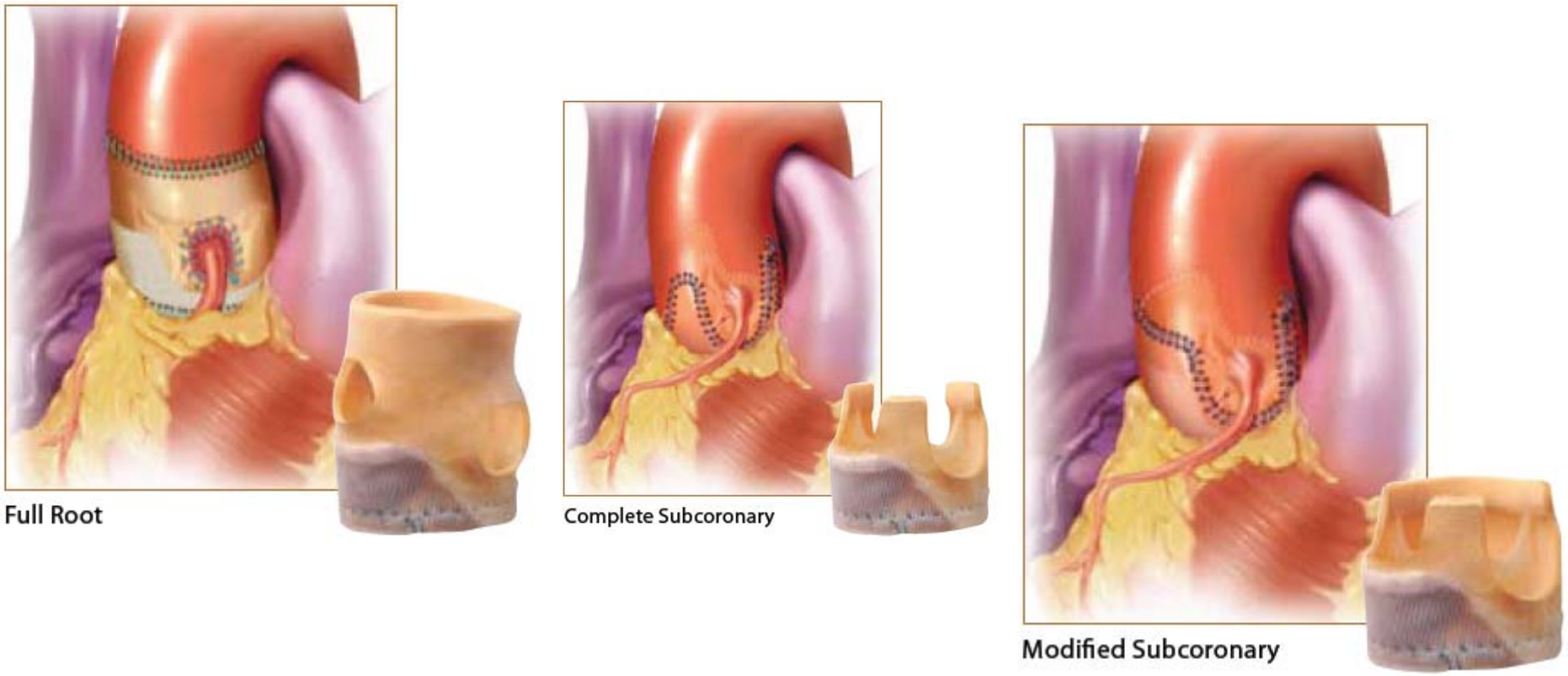
Access: Femoral

AR grade pre: 4

AR grade post: 1

# Stentless VIV Implants

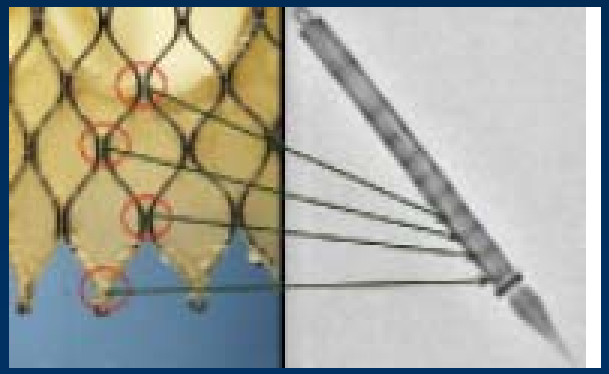
Typical Implant Techniques for Homografts and Stentless Bioprostheses

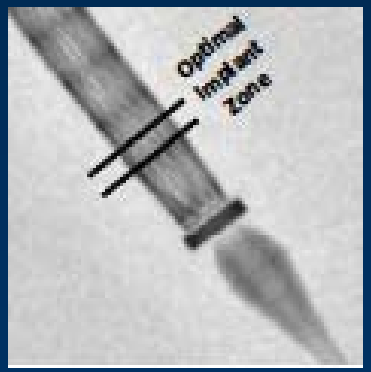


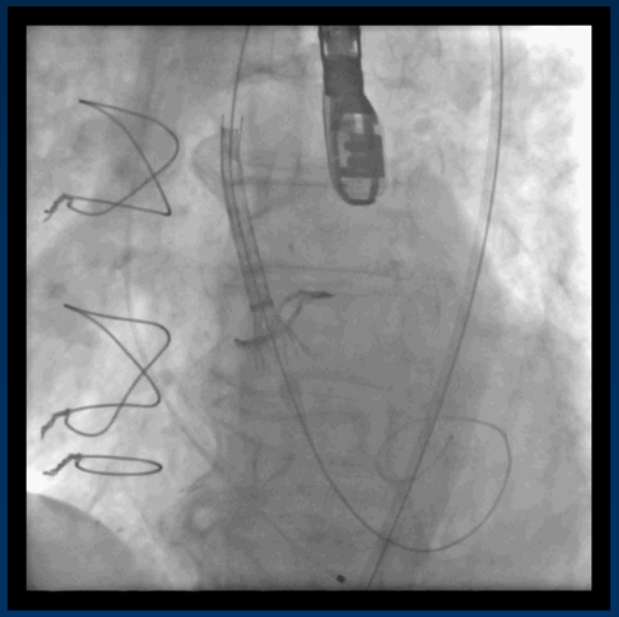

Stentless bioprostheses and homografts lack radiopaque structures and calcification is typically less than with native valves. This challenges visualization of the level of the annulus.

# Deployment Depth

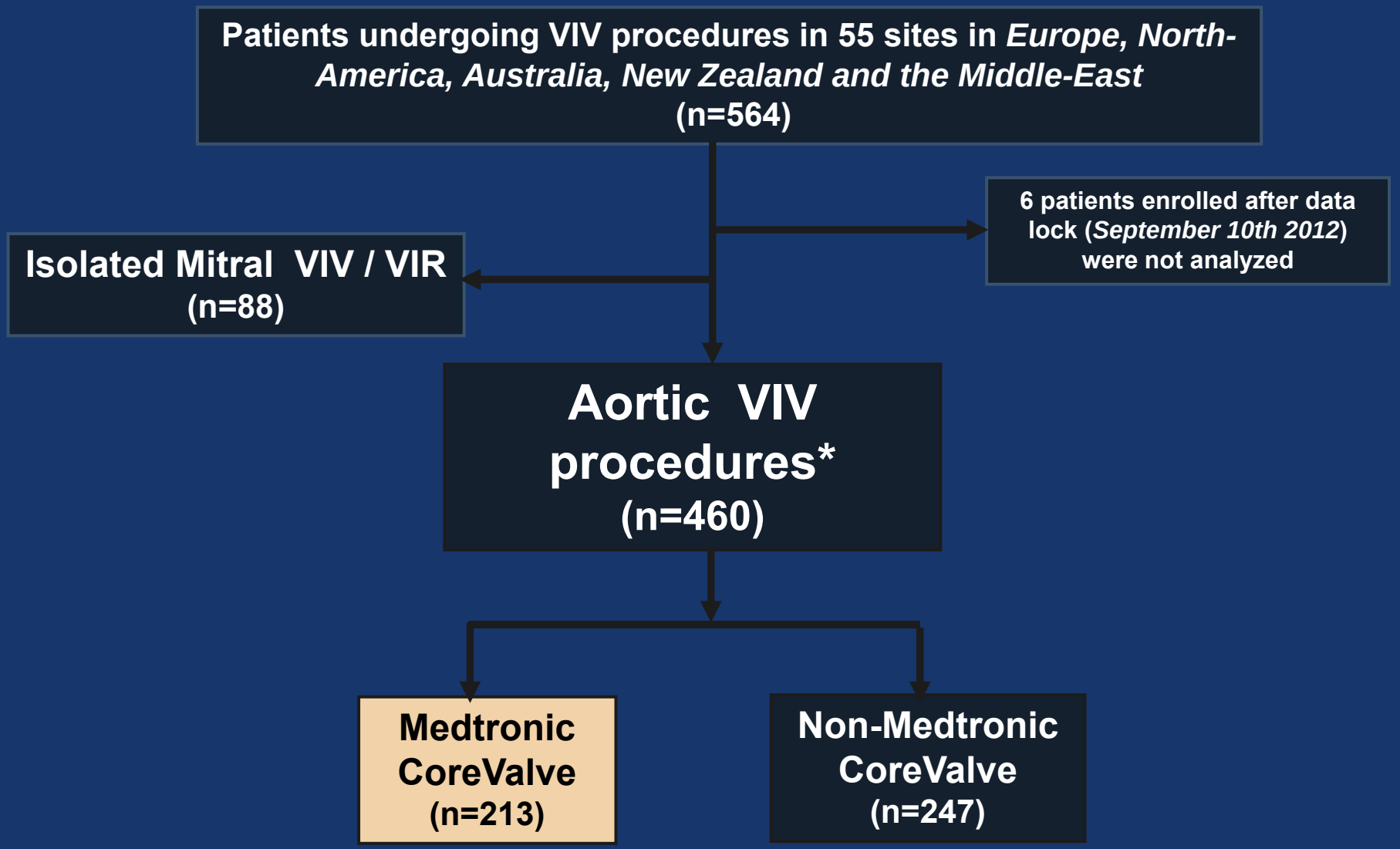
- Within the aortic annulus (approximately 4 mm to 6 mm below the annulus)





# Global Valve in Valve Registry




* Including 3 combined aortic VIV and mitral VIV procedures

# Baseline Demographics at Time of VIV

| | *CoreValve* *n=213* |
|---|---|
| Age (yrs) | 77.6 ± 10.0 |
| Gender (% male) | 53.1% |
| LogEuroSCORE | 31.1 ± 16.8 |
| STS score (%) | 12.8 ± 10.6 |
| Diabetes Mellitus | 31.1% |
| Peripheral Vascular Disease | 17.9% |
| Chronic Renal Failure | 38.0% |
| Previous stroke | 12.2% |
| NYHA III/IV | 93.9% |

# Baseline Valve Parameters

| Mechanism of failure | |
|---|---|
| Regurgitation | 36.6% |
| Stenosis | 35.2% |
| Combined | 28.2% |

| | *CoreValve* *n=213* |
|---|---|
| Stented | 71.4% |
| Stentless | 28.6% |
| **Label Size** | |
| ≤21 mm | 36.2% |
| 22-26 mm | 54.5% |
| ≥27 mm | 5.2% |
| Unknown | 4.2% |

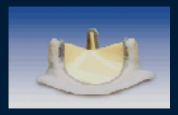
# Bioprosthetic Valves Types

## Carpentier-Edwards


Magna


Theon


CE SAV


Perimount

## Medtronic


Hancock II


Mosaic


Freestyle Stentless

## Sorin Biomedica


Pericarbon


Pericardon Freedom

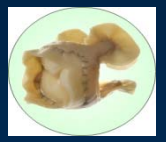

Freedom


Soprano

## Sorin-Carbomedics


Mitroflow

## Shelhigh


NR 2000 Semistented


NR 900 A Tricuspid valve

## St Jude Medical


Toronto SPV Stentless


Biocor


Epic


Trifecta

## Vascutek


Aspire stented


Elan stentless

## Ionescu Shiley

## Labcor laboratories


Dokimos


Maxime


Imperiii stentless

## Gamina


Cryolife 0'Brien stentless


TLPB-A-Supra


Kiros

# Valve in Valve Procedures

| | *CoreValve* *n=213* |
|---|---|
| **Device size** | |
| 23mm | 3 (1.4%) |
| 26mm | 173 (81.2%) |
| 29mm | 34 (16.0%) |
| 31mm | 3 (1.4%) |
| **Access** | |
| femoral artery | 197 (92.5%) |
| axillary artery | 12 (5.6%) |
| apical | 0 |
| direct-aortic | 4 (1.9%) |
| **TEE** | 45.1% |
| **General anesthesia** | 55.4% |

# Valve in Valve Procedures

| | *CoreValve* *n=213* |
|---|---|
| Pre implantation valvuloplasty | 19.2% |
| Initial device malposition | 16.0% |
| Attempted Valve retrieval | 9.0% |
| 2nd device implanted | 4.8% |
| Post implantation valvuloplasty | 7.5% |
| Need for an emergent surgery | 2.5% |
| Clinically-evident Coronary obstruction | 3.0% |

# Post procedure Echocardiography

| | *CoreValve* *n=213* |
|---|---|
| AV area ($cm^2$) | 1.58 ± 0.41 |
| AV max gradients (mmHg) | 26.2 ± 12.1 |
| AV mean gradients (mmHg) | 14.1 ± 7.3 |
| AR (≥2) | 8.0% |
| LVEF (%) | 51.2 ± 12.2 |

# Aortic Valve in Valve Procedures
# 30-day clinical results

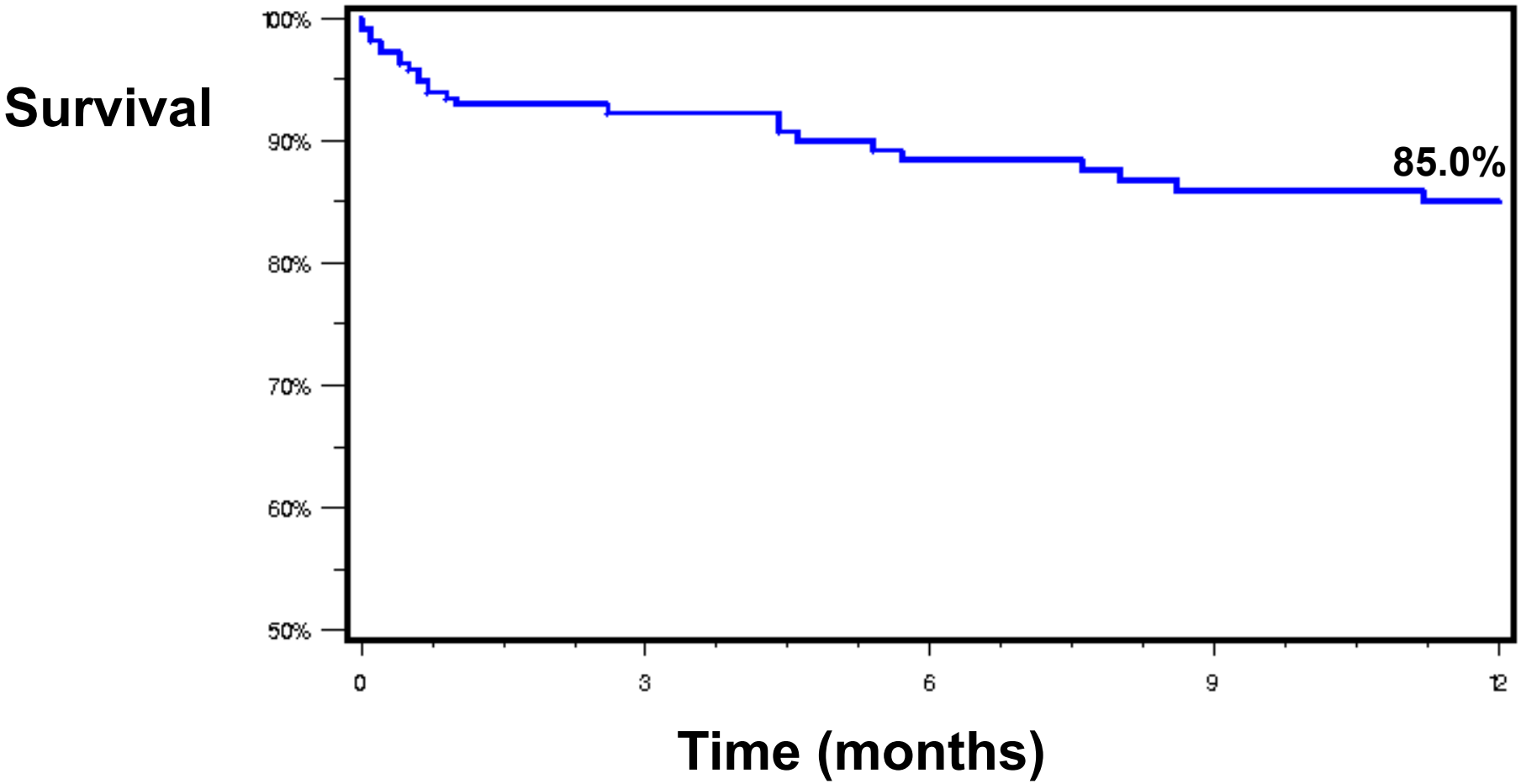
| | *CoreValve* *n=213* |
|---|---|
| All cause death | 7.2% |
| Cardiovascular death | 5.8% |
| Major stroke | 0.9% |
| Major vascular complication | 8.5% |
| Major / life threatening bleeding | 4.9% |
| Acute kidney injury (VARC>=2) | 5.0% |
| Permanent pacemaker implantation | 12.3% |

# Valve in Valve Procedures
# 30-day clinical results

**85.5% had NYHA class I /II 30 days after Corevalve VIV procedure!**

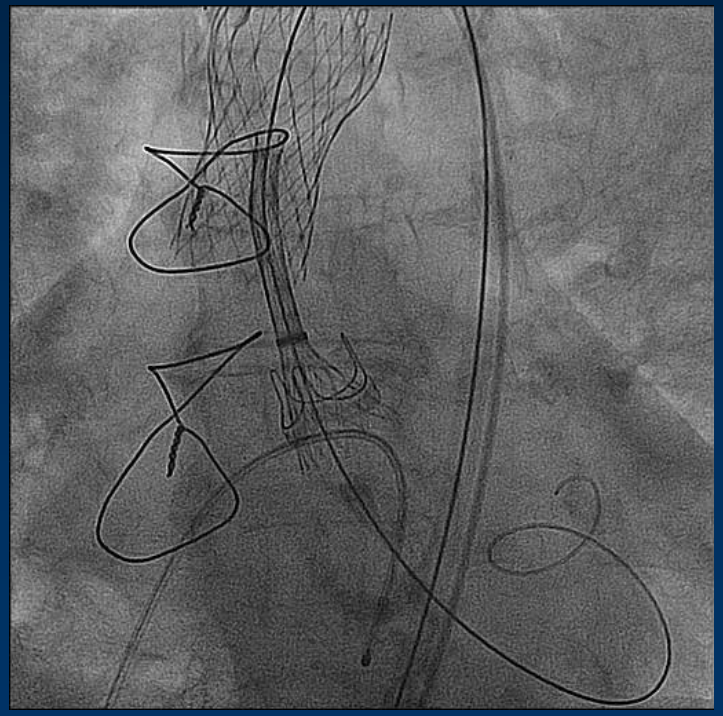
| | *Stenosis* *n=168* |
|---|---|
| NYHA I | 43.7% |
| NYHA II | 41.8% |
| NYHA III | 6.6% |
| NYHA IV | 0.9% |
| Death | 7.2% |

# 1-year Survival Curve of patients who underwent VIV procedures Using Medtronic CoreValve



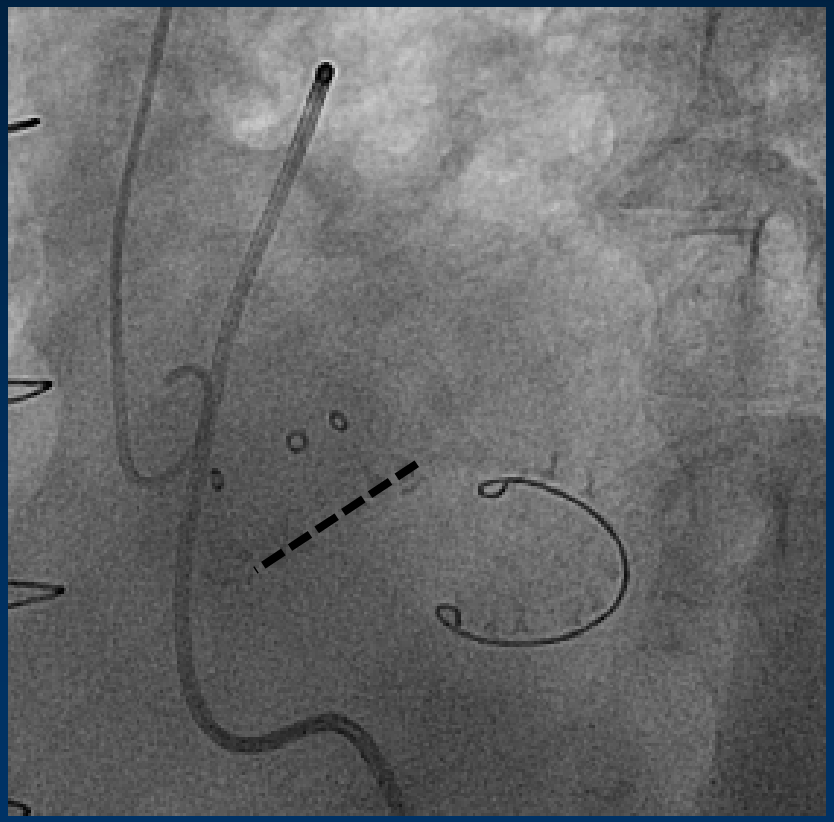
# Safety & Efficacy Concern 1: Device Malpositioning

**CoreValve device retrieval: 9.0%**
**2nd THV device implanted: 4.8%**



# Safety & Efficacy Concern 2: Difficult positioning

**Difficult positioning in s Mosaic valve:**
**No fluoro markers at the sewing ring**

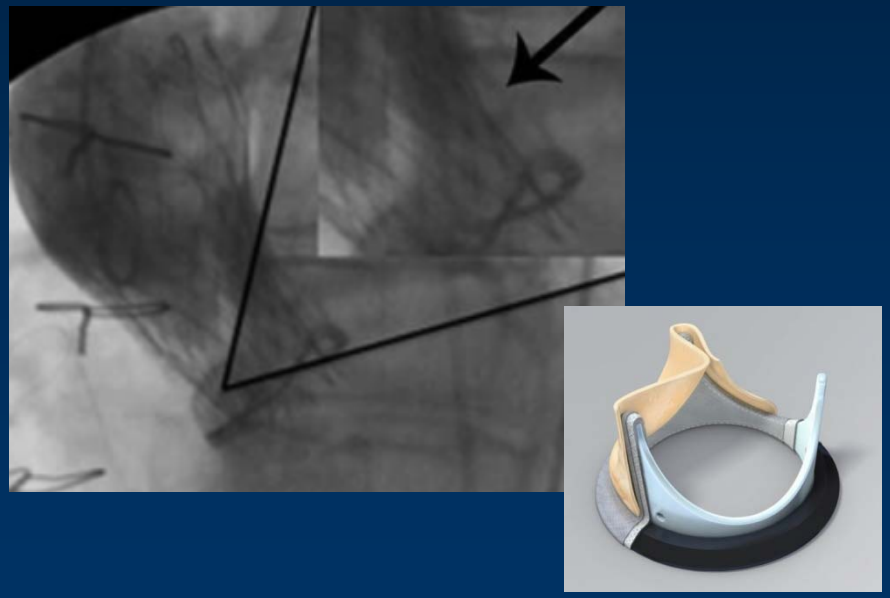


**Difficult positioning in a regurgitant stentless valve:**
**No fluoro markers, no calcification**

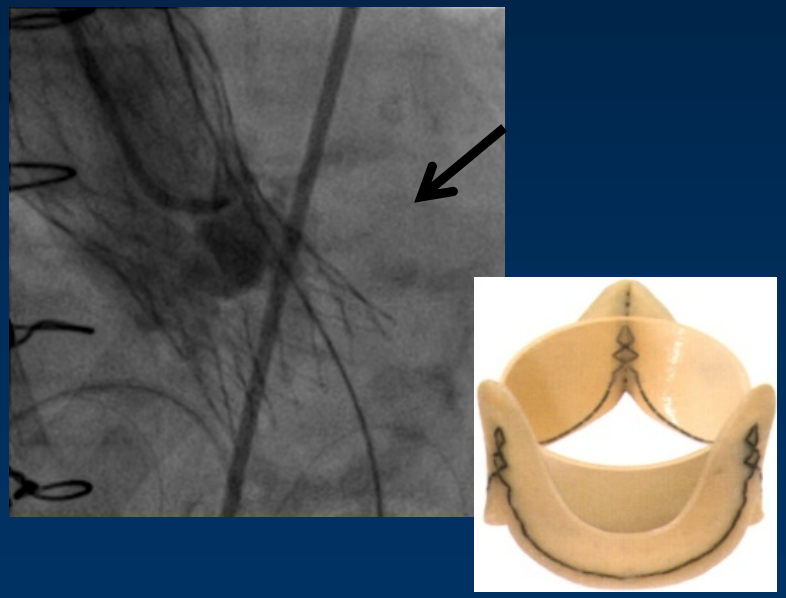
# Safety & Efficacy Concern 3: Coronary Obstruction

| | *Stenosis* | *Regurgitation* | *P* |
|---|---|---|---|
| **Coronary Obstruction*** | **3.9%** | **0.8%** | **0.02** |

**Immediate LM obstruction post VIV**



**Mitroflow**

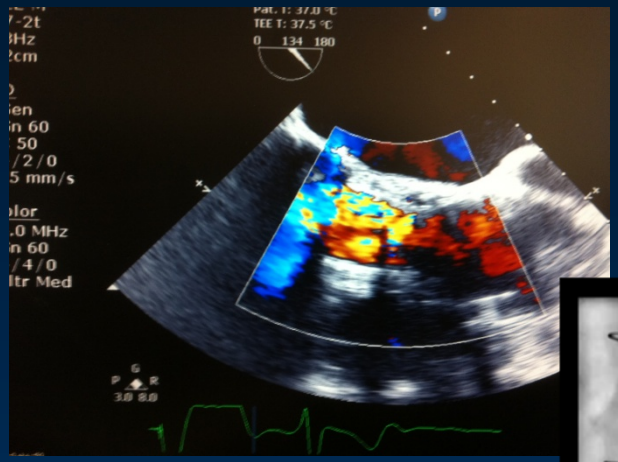


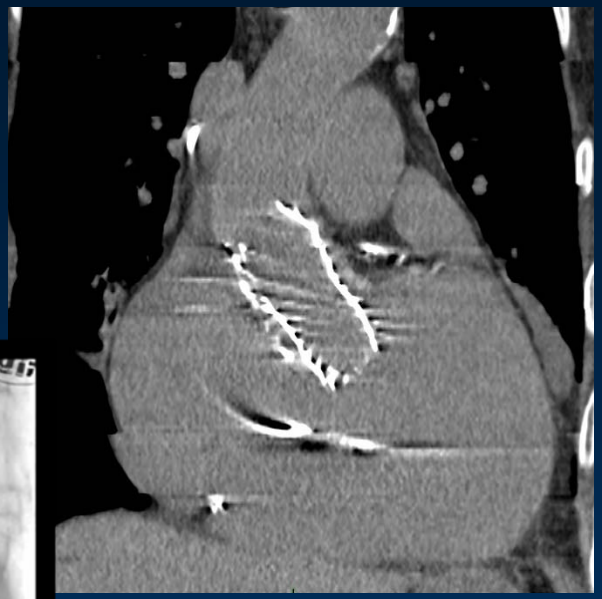
**Sorin Freedom**

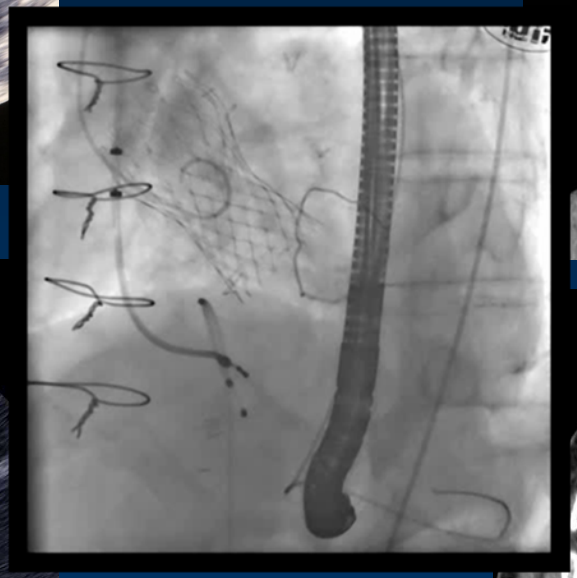
* Overall quote in the global registry included all VIV procedures (CV & ES)

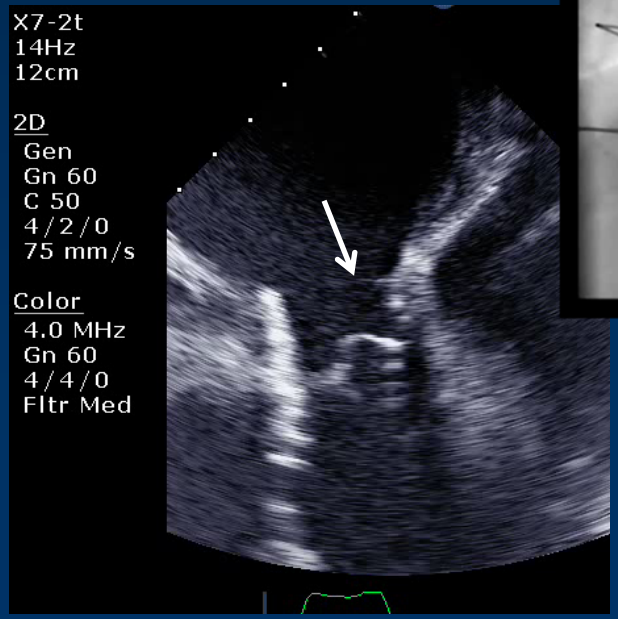
# Safety & Efficacy Concern 4: Durability?

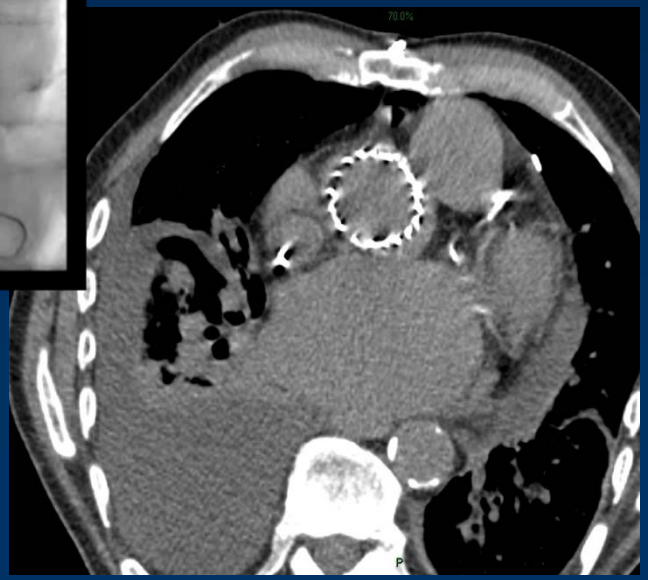
Severe AR 3 yrs following TAVI within failed stentless valve and one year after suspected endocarditis



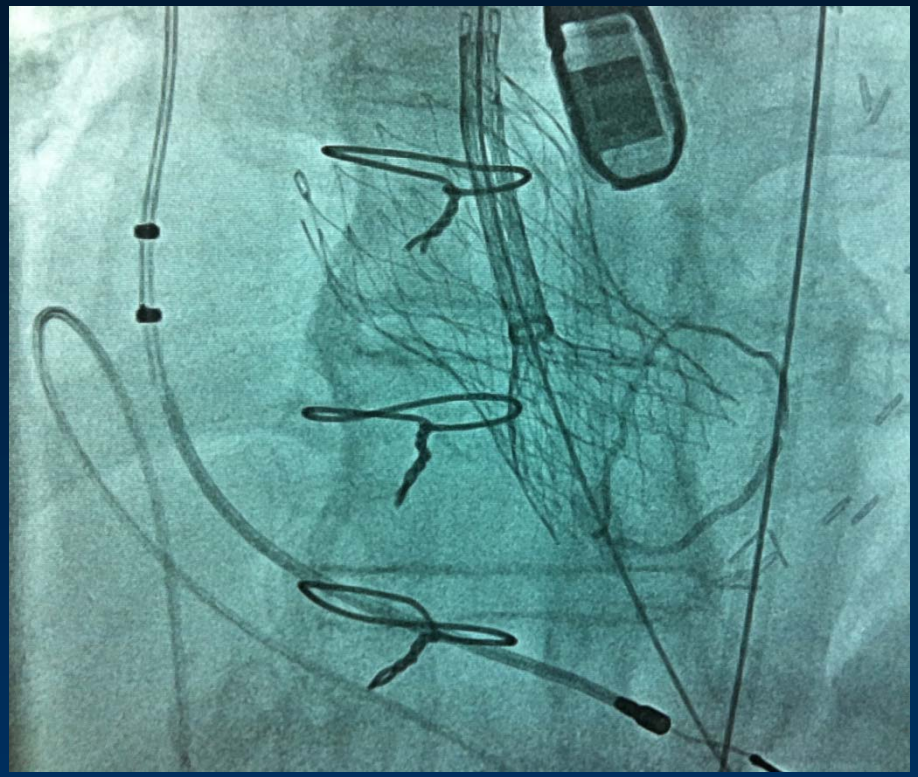




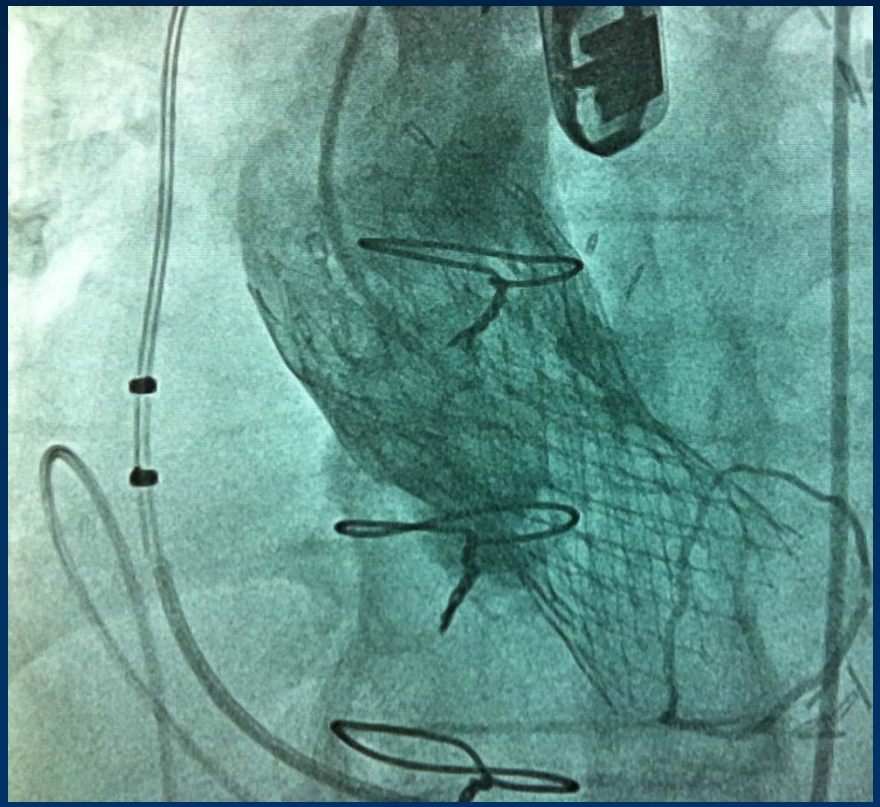


# Re-do Valve in Valve TAVI 3 years post VIV procedure



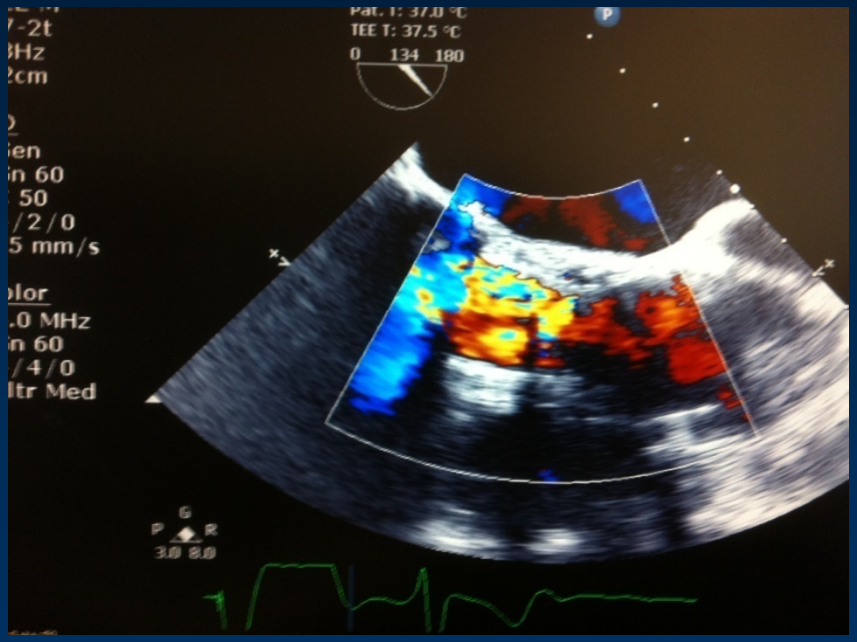
CoreValve 29 mm within previously implanted CoreValve 29 mm (3 yrs ago) for VIV indication (within 25 mm Toronto SPV)



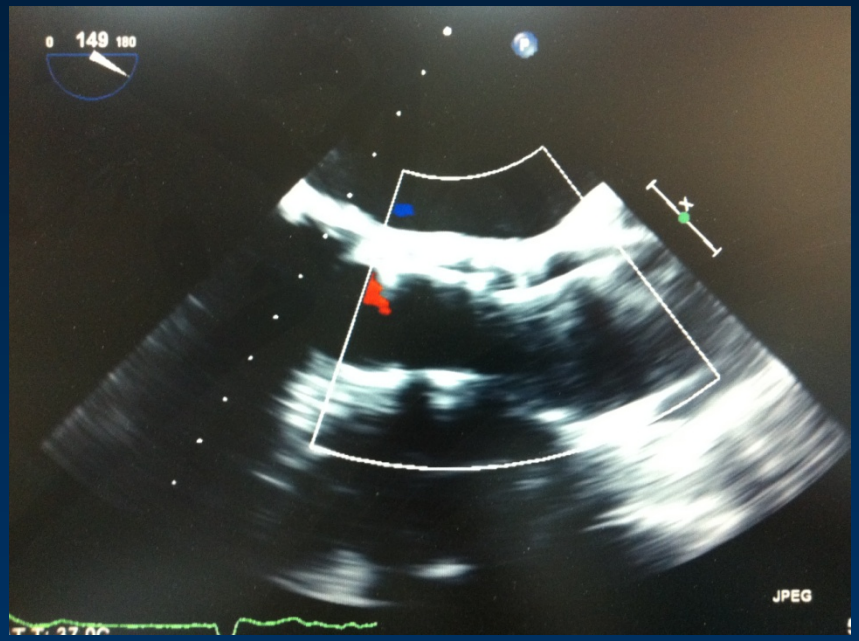
RMC VIV case #22 (4.2013)

# Re-do Valve in Valve 3 years post VIV procedure

Pre VIV-IV




Post VIV-IV



# Conclusions

- The VIV procedure using the Medtronic *CoreValve* device is feasible but technically challenging.
- Clinically, the technique is extremely effective in most patients, with 1-year results comparable with other TAVR cohorts.
- Residual valve gradients are low and relatively unaffected by valve sizes, probably due to supra-annular functional positioning.
- *The CoreValve Evolut* 23mm is a very useful add for VIV that should expand the treatment options for failed aortic bioprostetic valves

# THANK YOU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