

# J-Valve Development, Design and Data

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**AP VALVES 2018, Seoul**



Centre for  
Heart Valve Innovation  
St. Paul's Hospital, Vancouver



**HEART CENTRE**  
AT ST. PAUL'S HOSPITAL

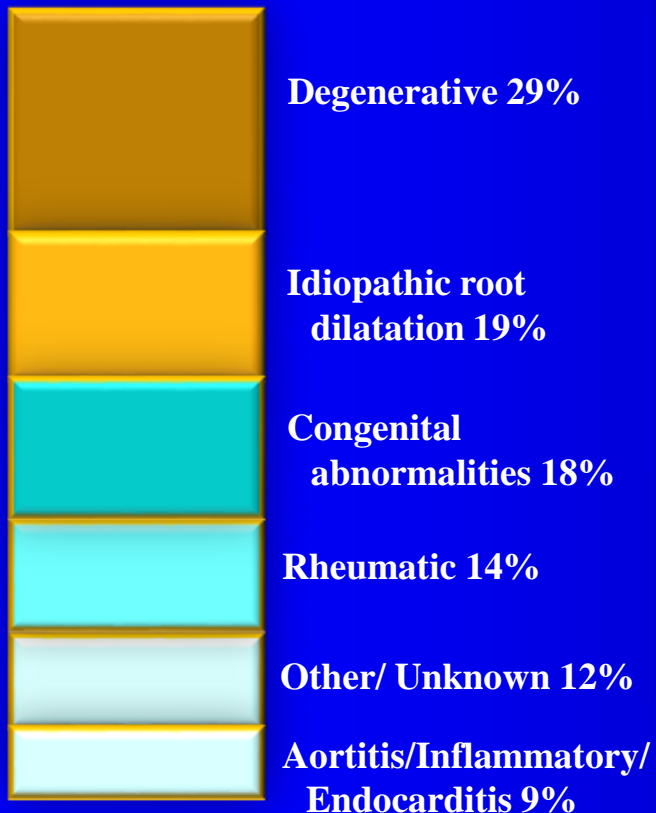
# Disclosure

## Consultant:

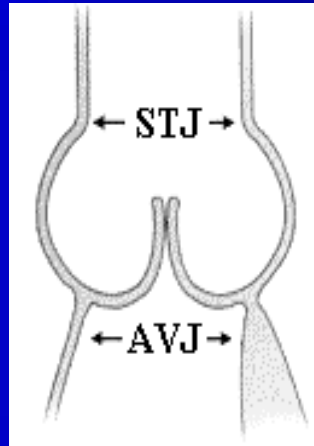
- **Edwards Lifesciences**
- **JC Medical Inc.**

# Aortic Regurgitation

## Etiologies



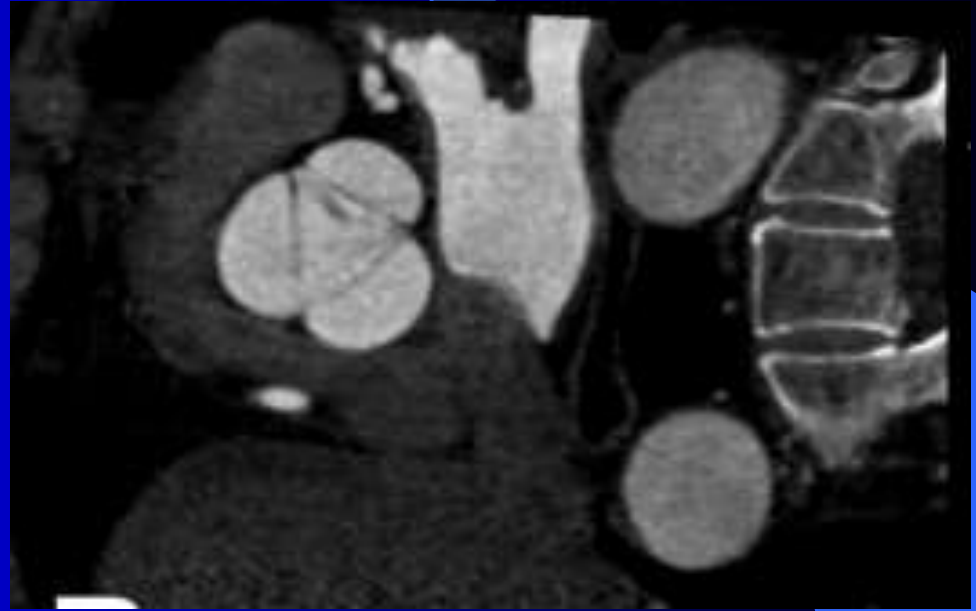
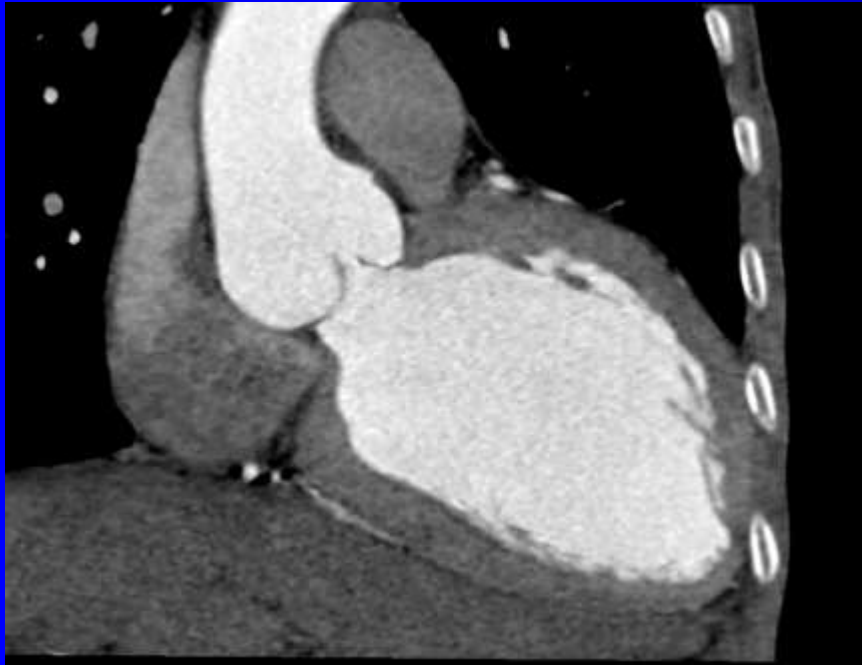
## Challenges in TAVI for AI



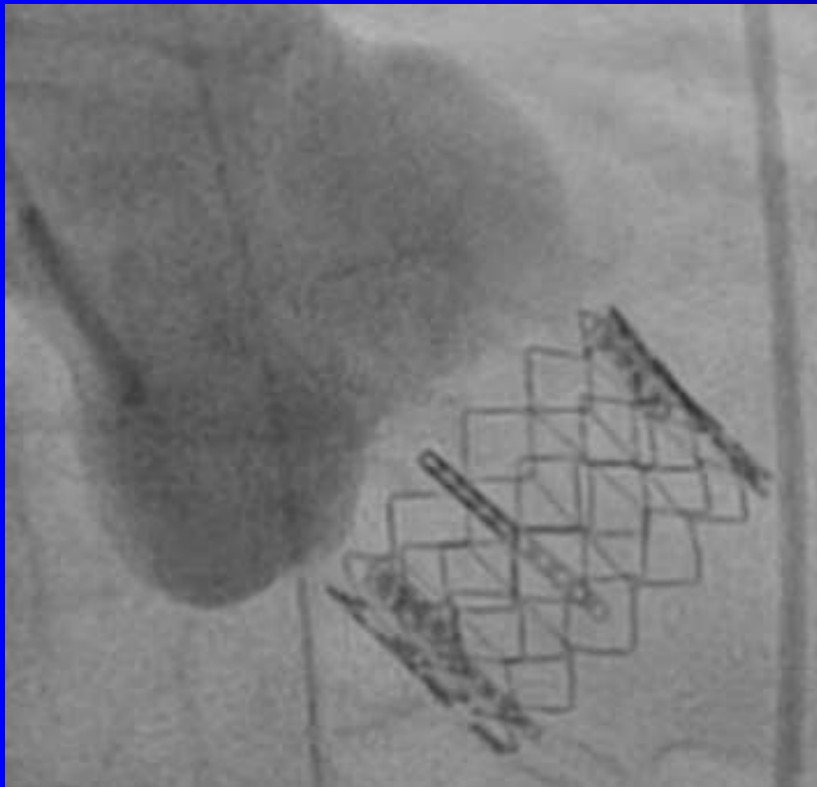
- Lack of calcification – fixation of valve
- Dilated annulus and aorta - Stabilization of dilating structure
- Destruction of cusps – fixation and PVL
- Multiple etiologies
- Sizing
- Aortic pathology – intimal tear/dissection

**Can you use the same devices for AI and AS?**

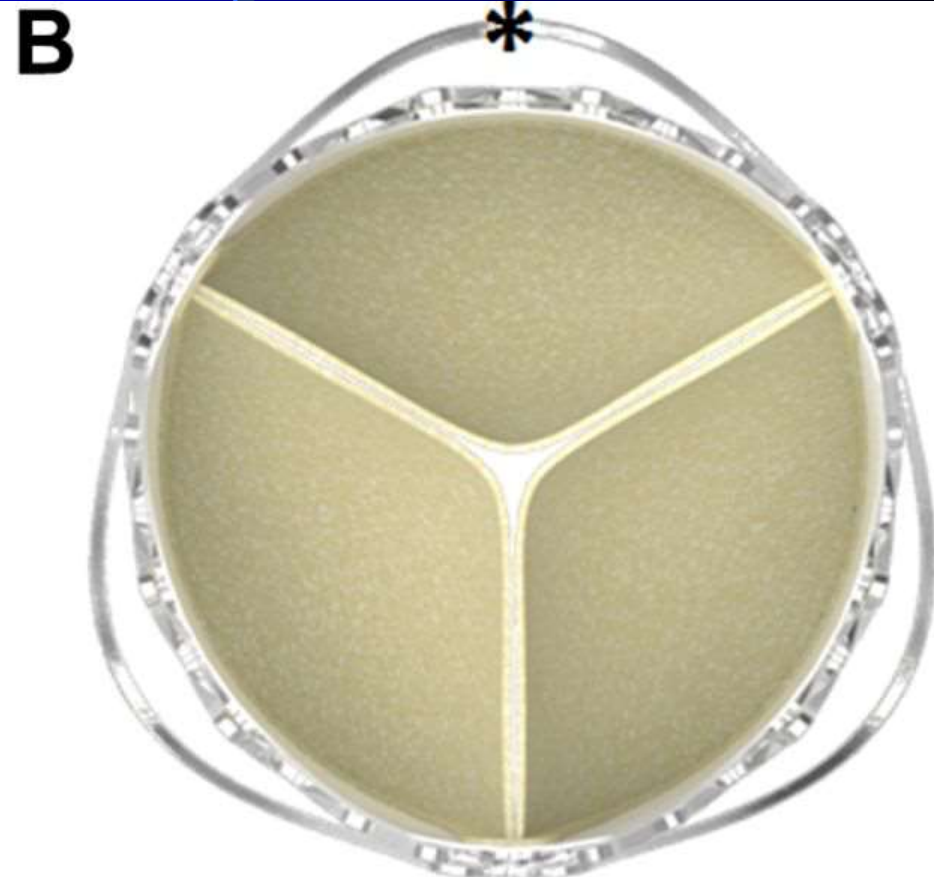
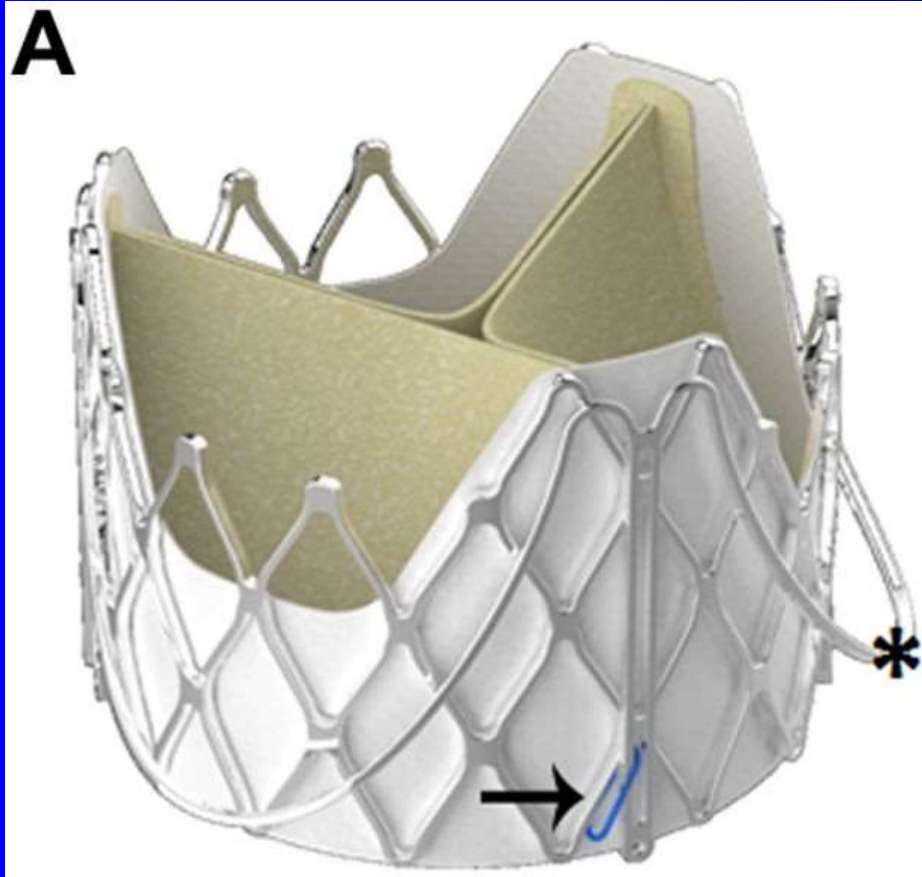
# Dilated aortic root is commonly seen in pure AI patients



# Problems with most THVs in non-calcified AI patients



# Design of J-Valve





# THVs with Clipping Device

**Jena Valve**

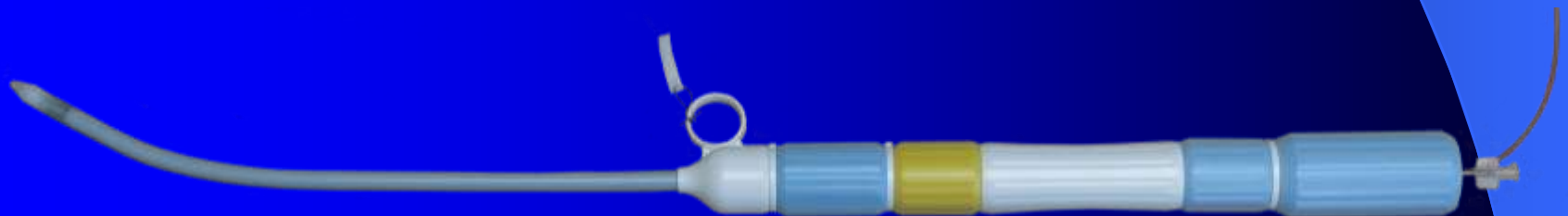
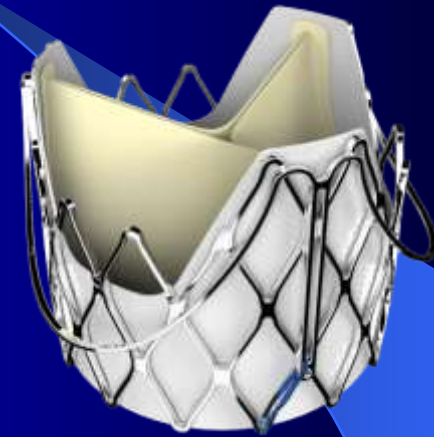
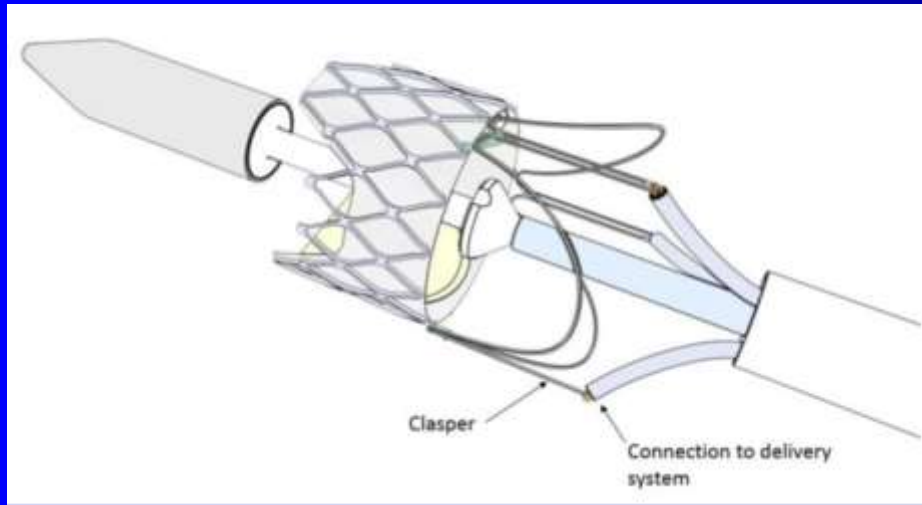


**J-Valve**



# J-Valve™

JC Medical Technology



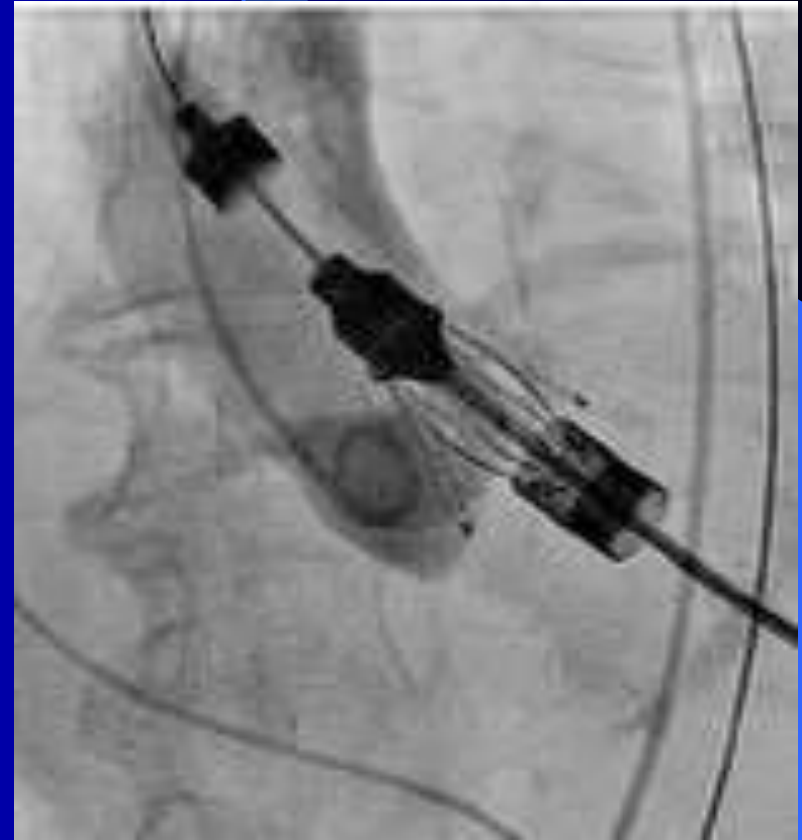
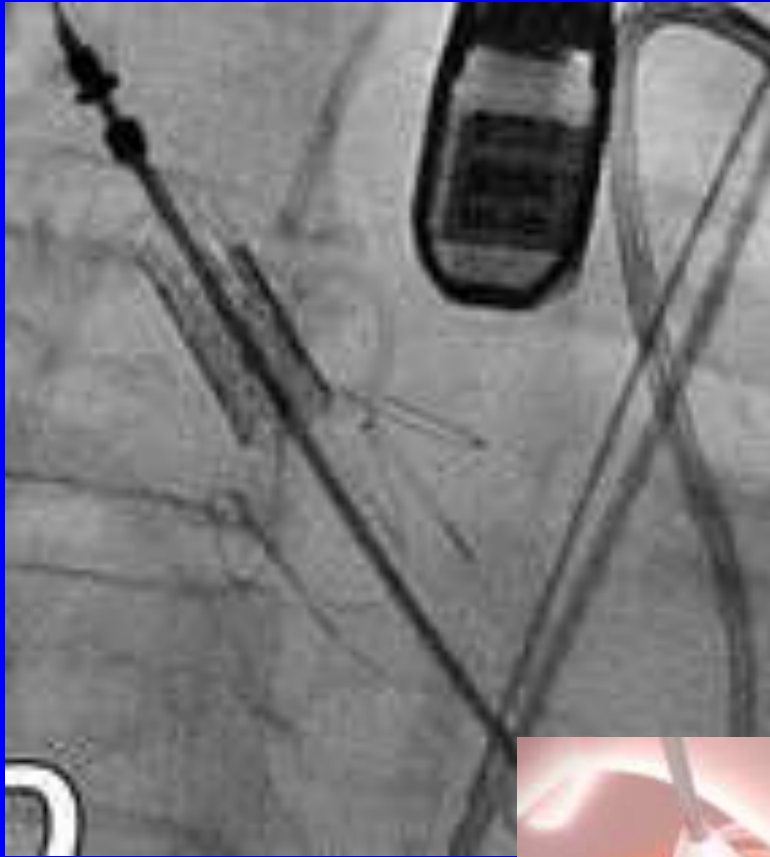
**Designed for both AS and AI**



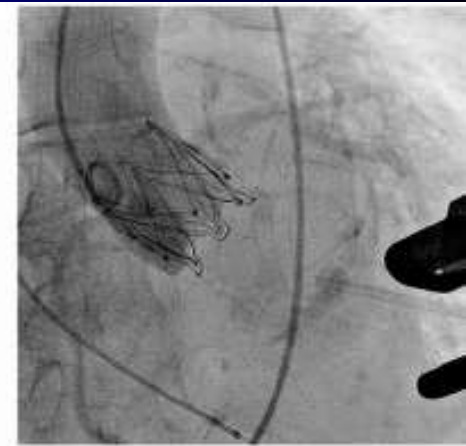
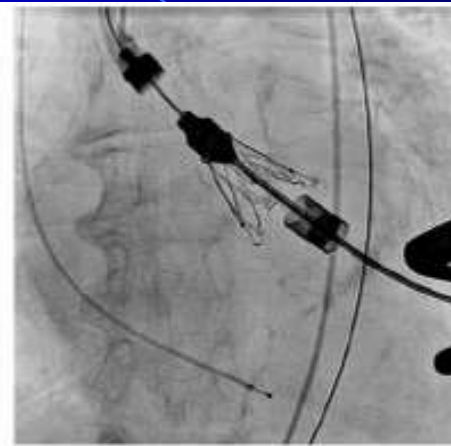
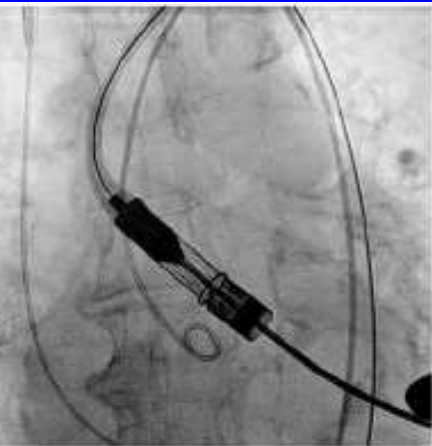
# JenaValve vs J-Valve



# JenaValve vs J-Valve



# Implantation of JenaValve



a

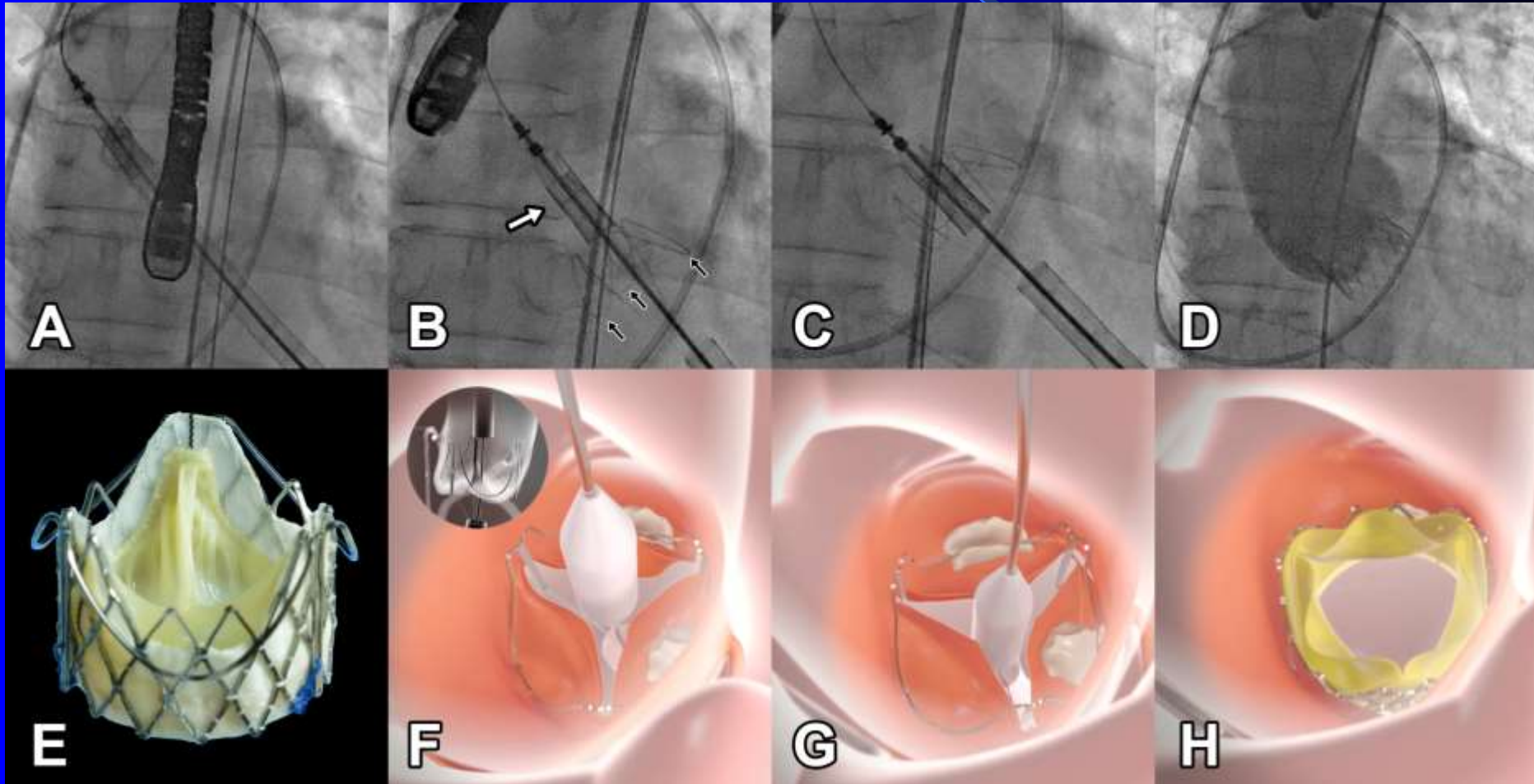
b

c

d



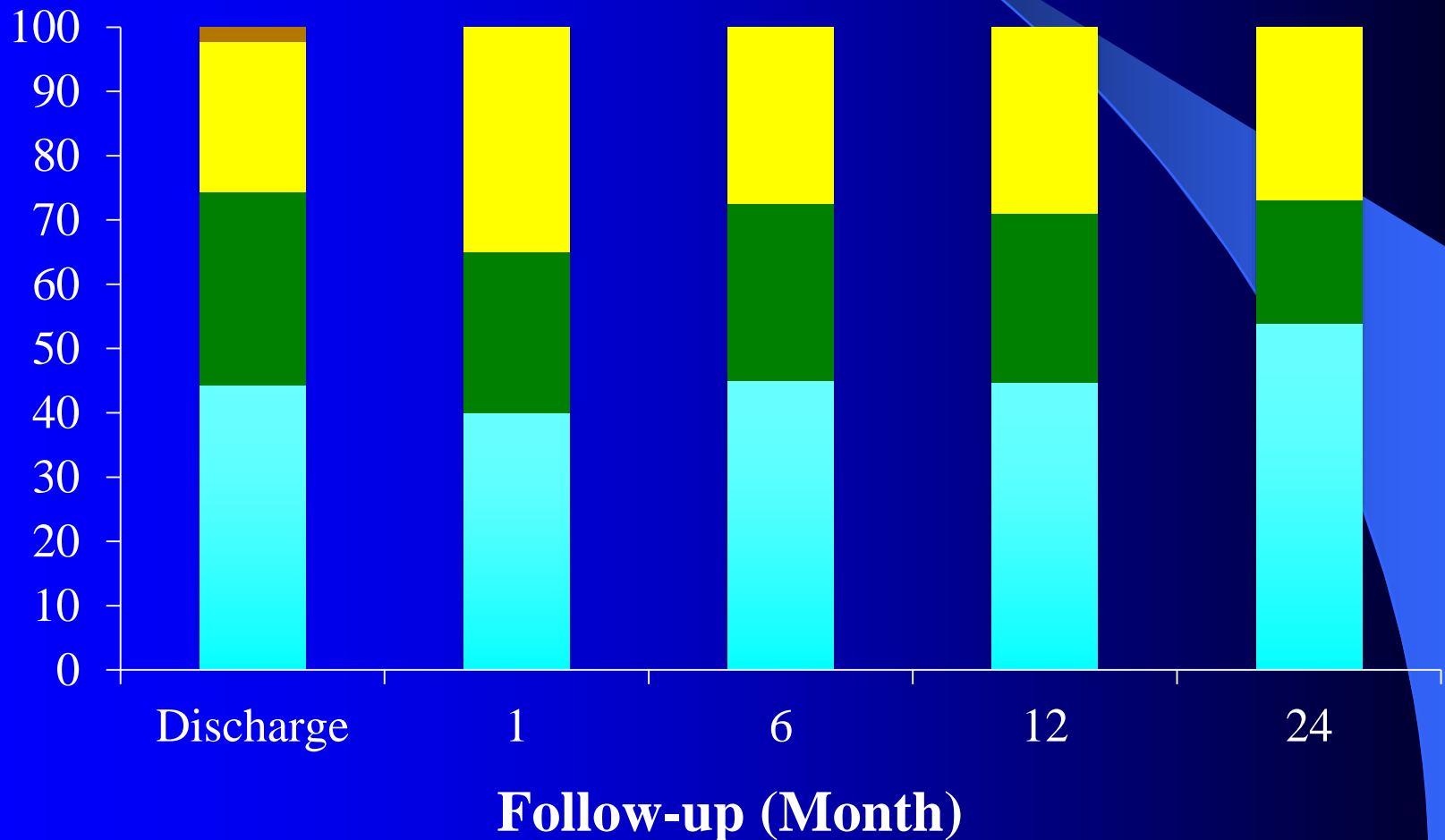
# Implantation of J-Valve



# Chinese Clinical Trial 2 Year Outcome

## Paravascular Leak

■ None ■ Trivial ■ Mild ■ Moderate ■ Severe



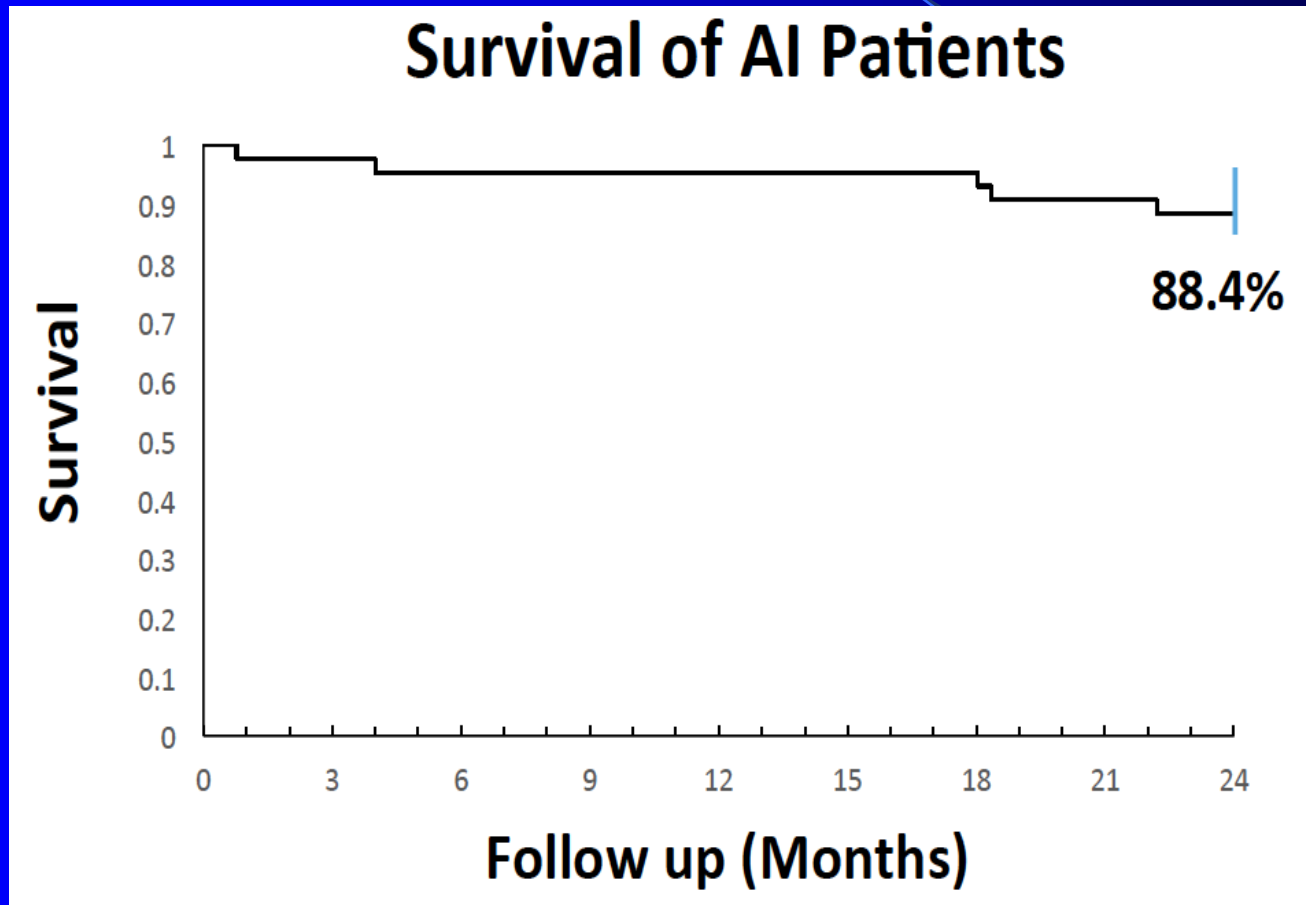
# Chinese Clinical Trial 2 Year Outcome

|  |             |
|--|-------------|
| <b>30-day all cause mortality</b>                      | <b>2.5%</b> |
| <b>CVA</b>   | <b>0.0%</b> |
| <b>2-year accumulated III° AVB</b>                     | <b>4.7%</b> |
| <b>Paravalvular leak &gt;mild at 30 days and 2 yrs</b> | <b>0.0%</b> |



# Chinese Clinical Trial 2 Year Outcome

## Survival

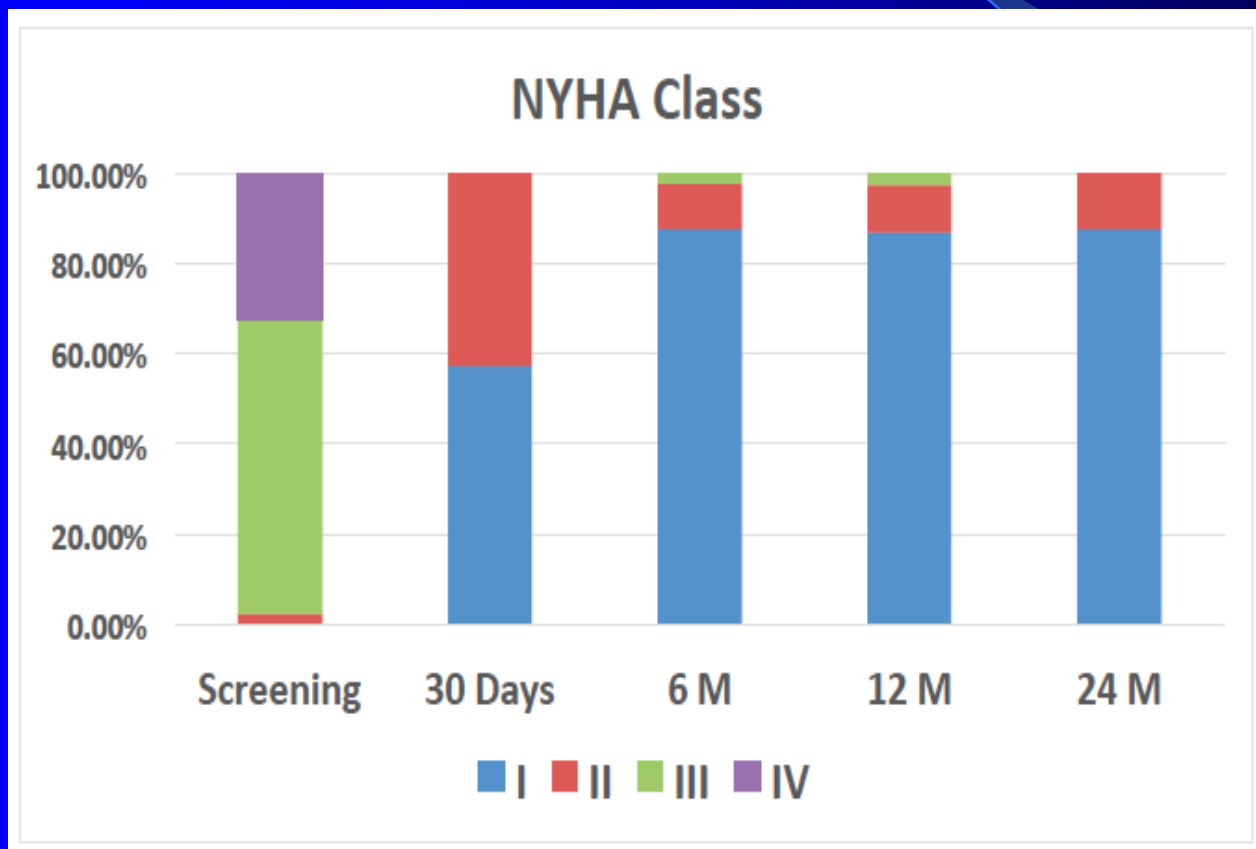


**Mean Follow-up:  $24.9 \pm 2.6$  months**

# Chinese Clinical Trial 2 Year Outcome

## NYHA Class

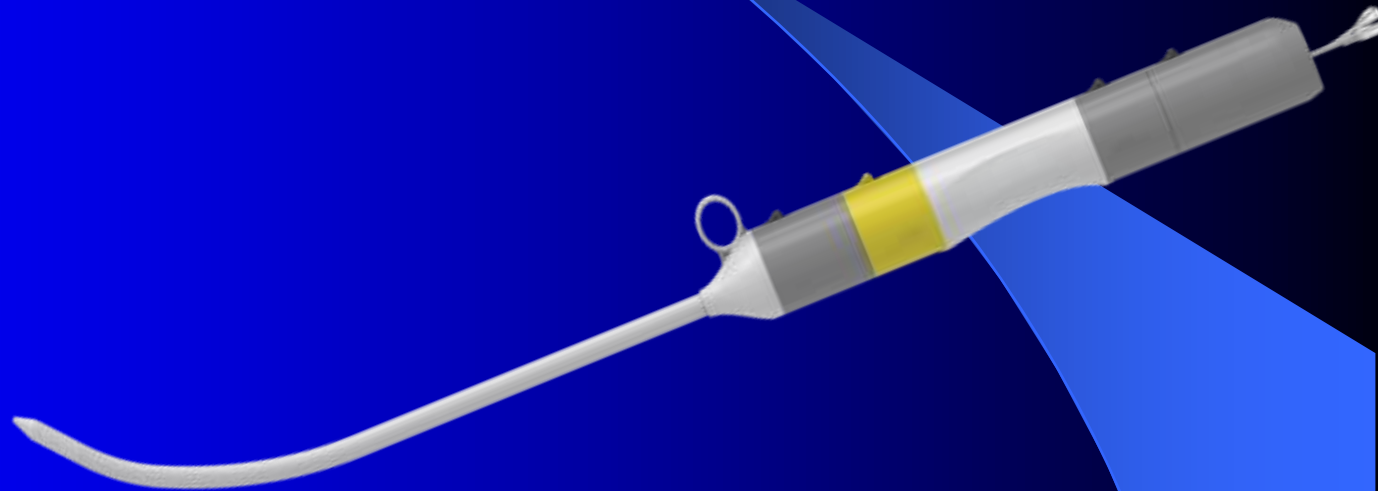
AI Patients



Mean Follow-up:  $24.9 \pm 2.6$  months

# J-Valve<sup>®</sup>

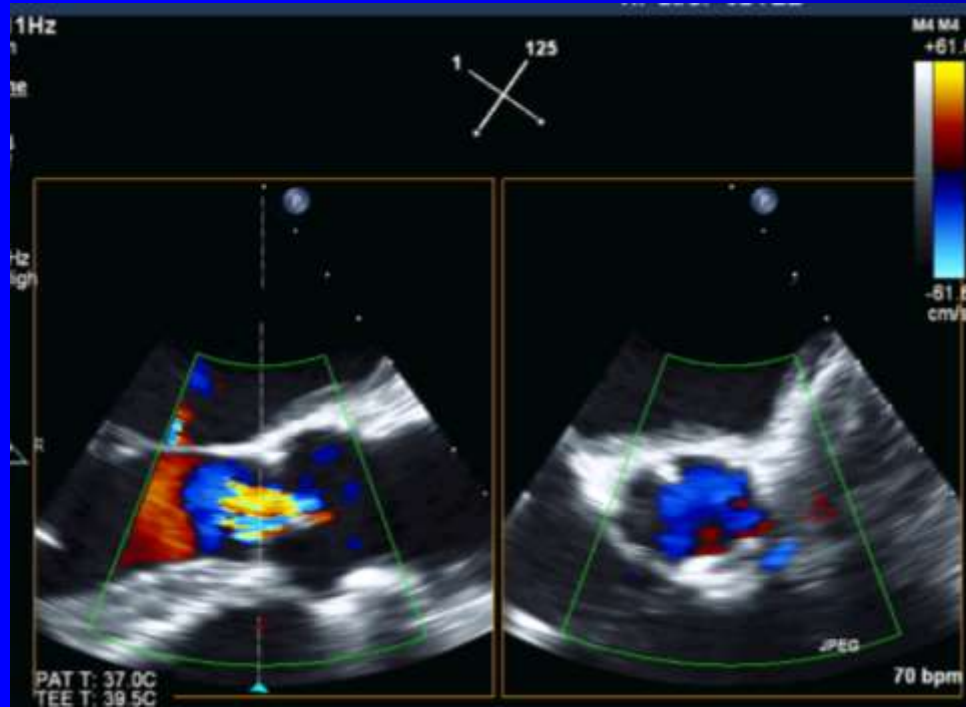
Approved by CFDA in Apr. 2017



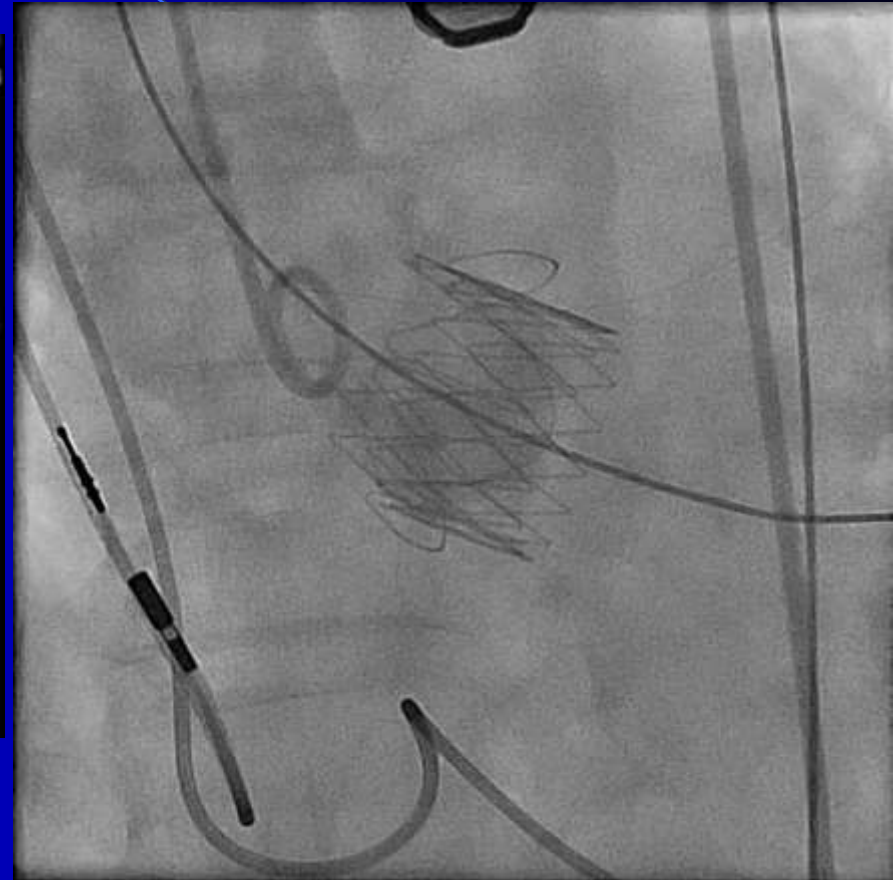
# J-Valve for **native** non-calcified AI



# J-Valve for native non-calcified AI

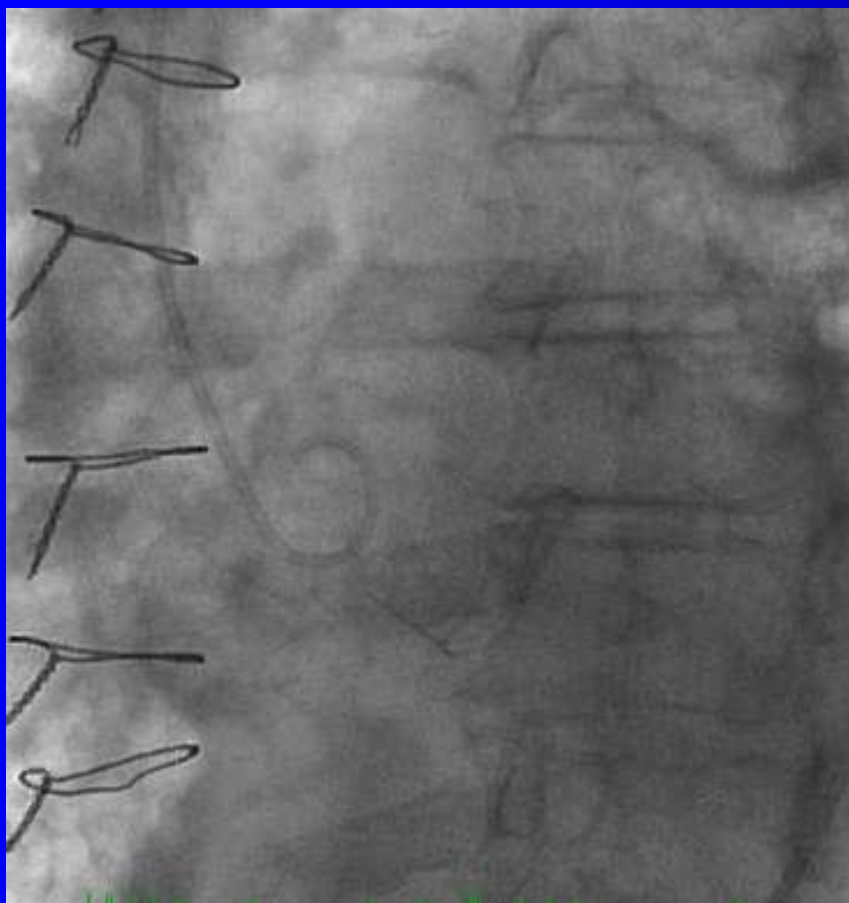


**Pure aortic regurgitation**

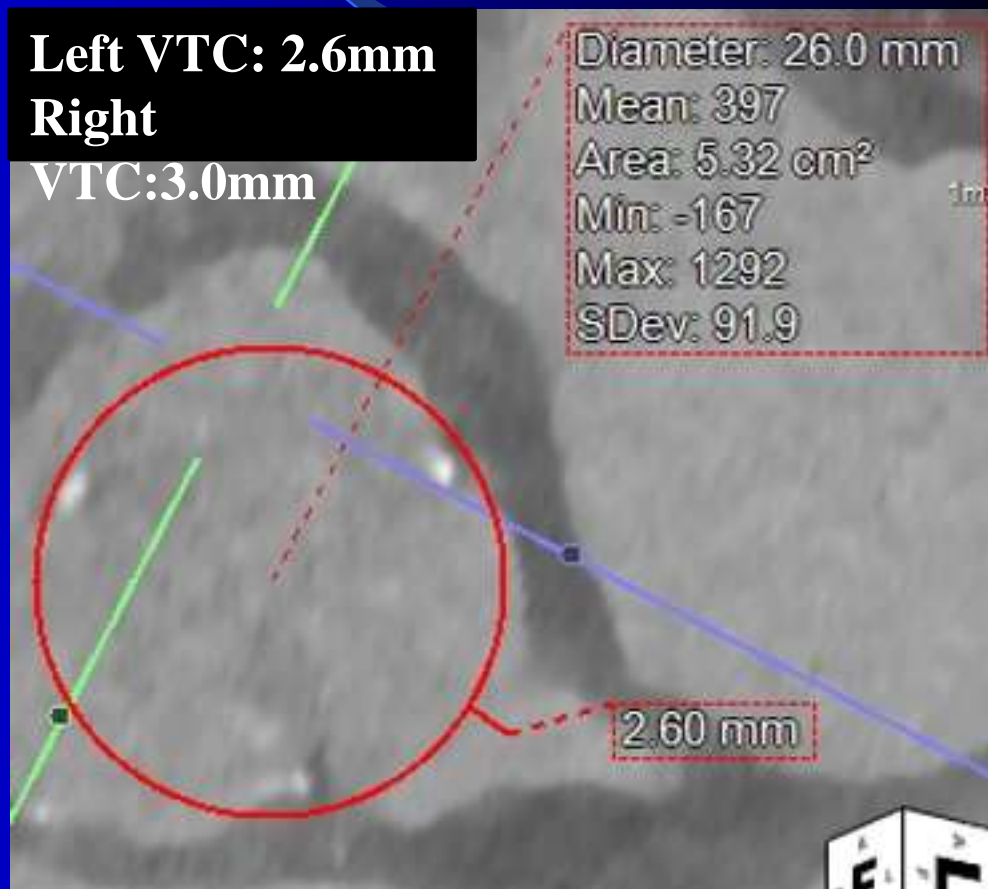


**Post implantation of J-valve**

# J-Valve for failed aortic bioprosthesis with risk of LM obstruction

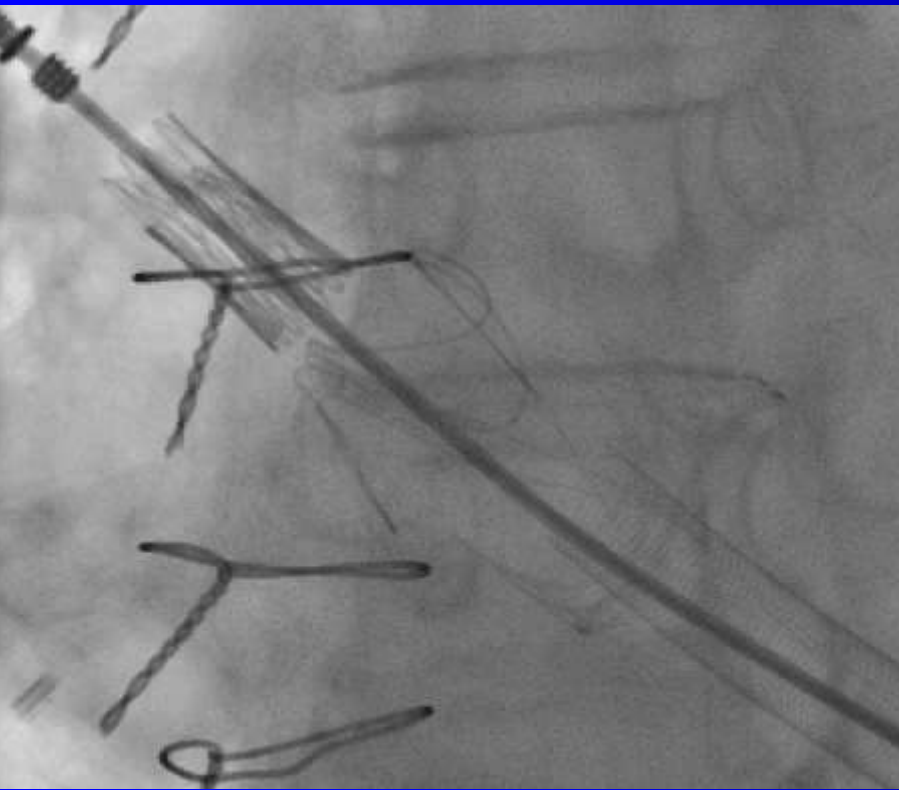


Left VTC: 2.6mm  
Right  
VTC:3.0mm

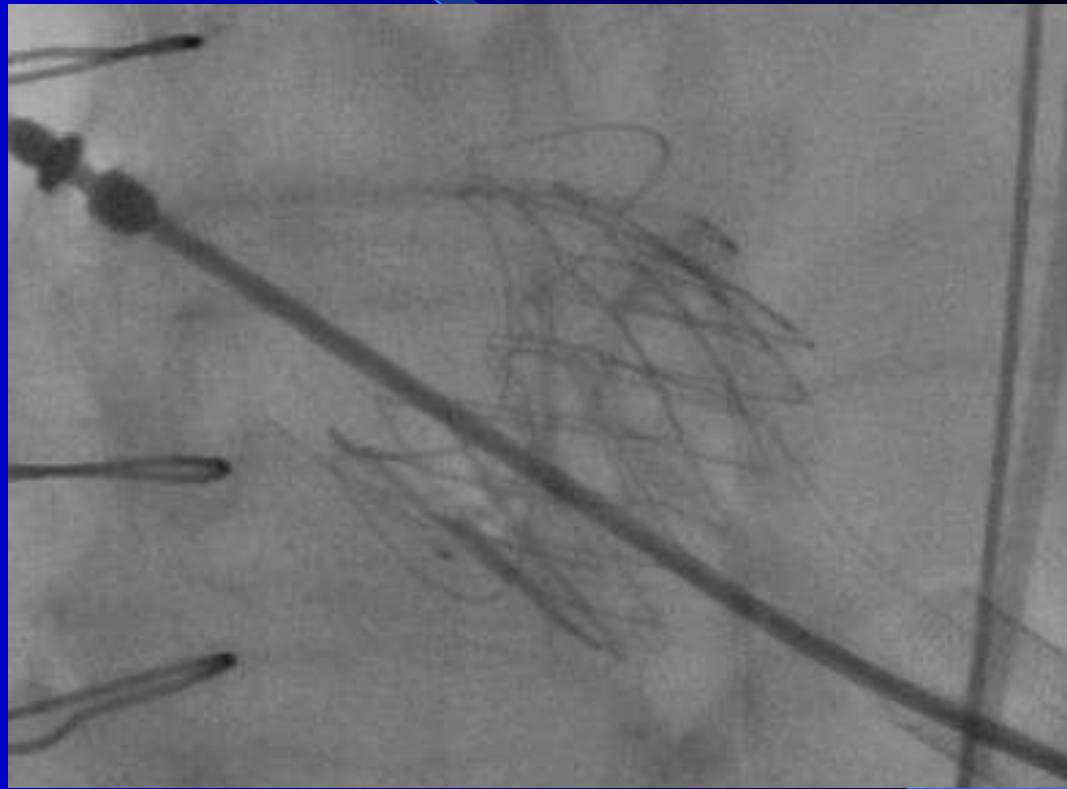




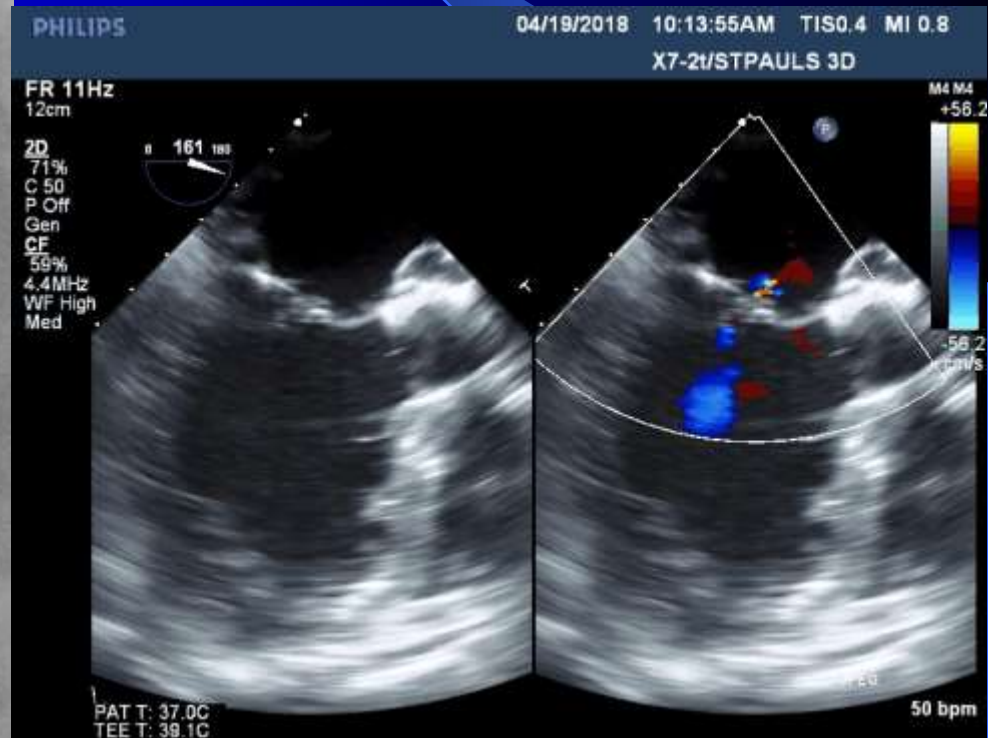
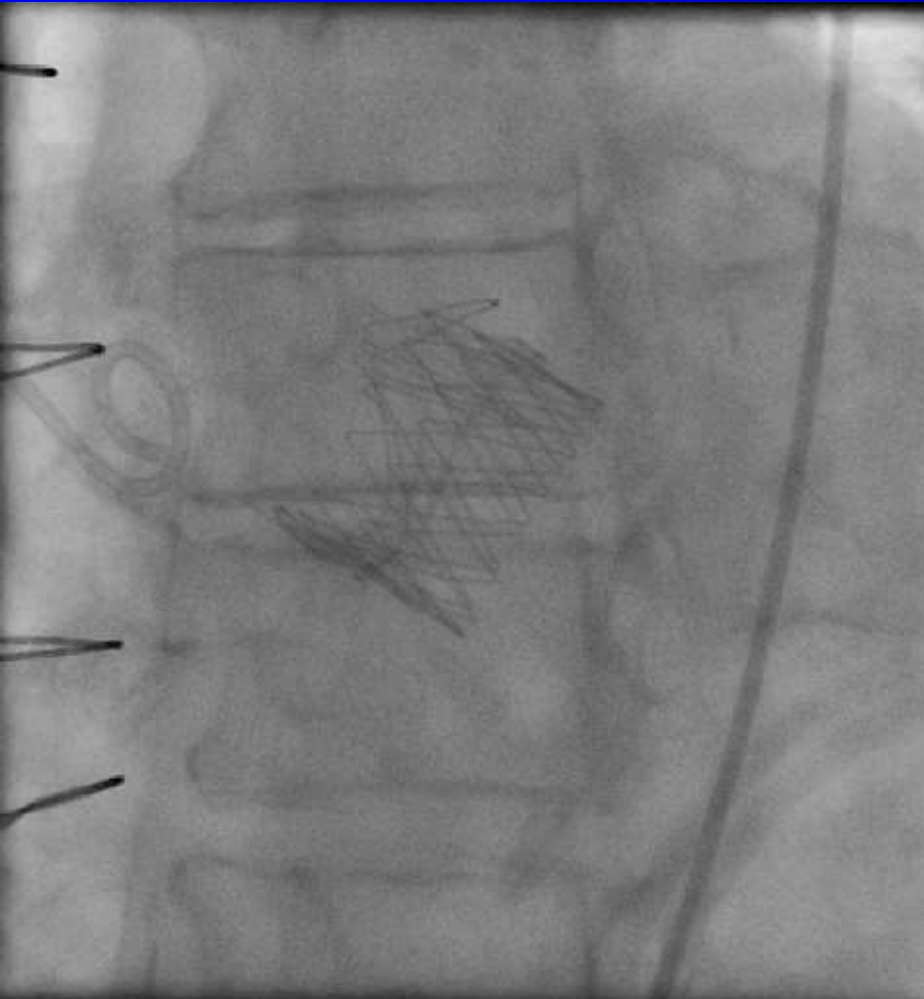
# J-Valve for failed aortic bioprosthesis with risk of LM obstruction



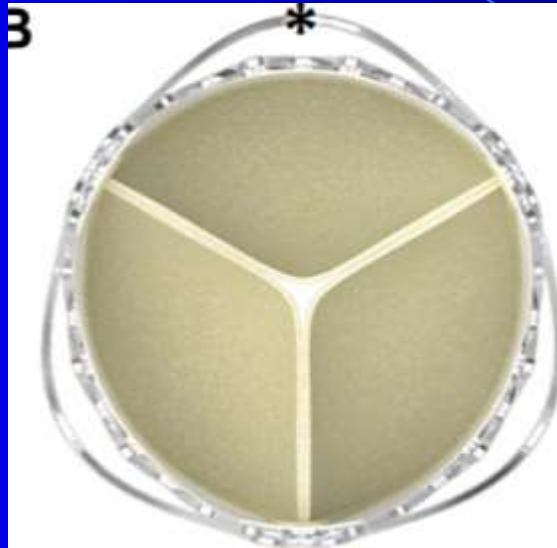
# J-Valve for failed aortic bioprosthesis with risk of LM obstruction



# J-Valve for failed aortic bioprosthesis with risk of LM obstruction



# J-Valve Vasper TF System



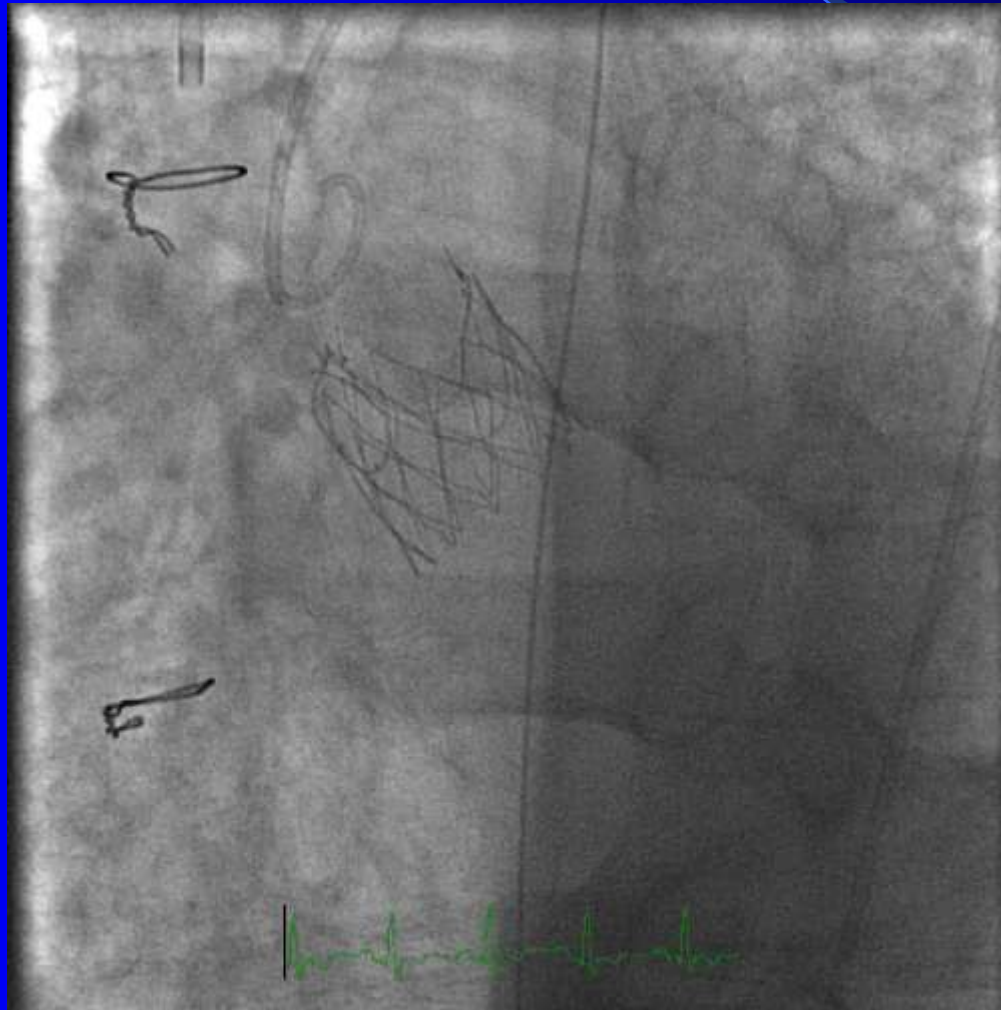
18 Fr.

# J-Valve Vasper TF System



# J-Valve Vasper TF System

FIH TF J-Valve implantation for pure AI





# Conclusion

**J-Valve is designed for both AS and AI patients.**

**Excellent 30 days and 2-year outcomes with J-Valve were demonstrated in pure AI patients**

**TAVI with J-Valve system is a viable alternative therapy for high-risk patients with non-calcified, pure AI.**

**J-Valve reduces the risk of coronary obstruction.**

**J-Valve could be implanted trasapically and transvascularly**

THANKS!