

# Hidden Beauty of Evolut R

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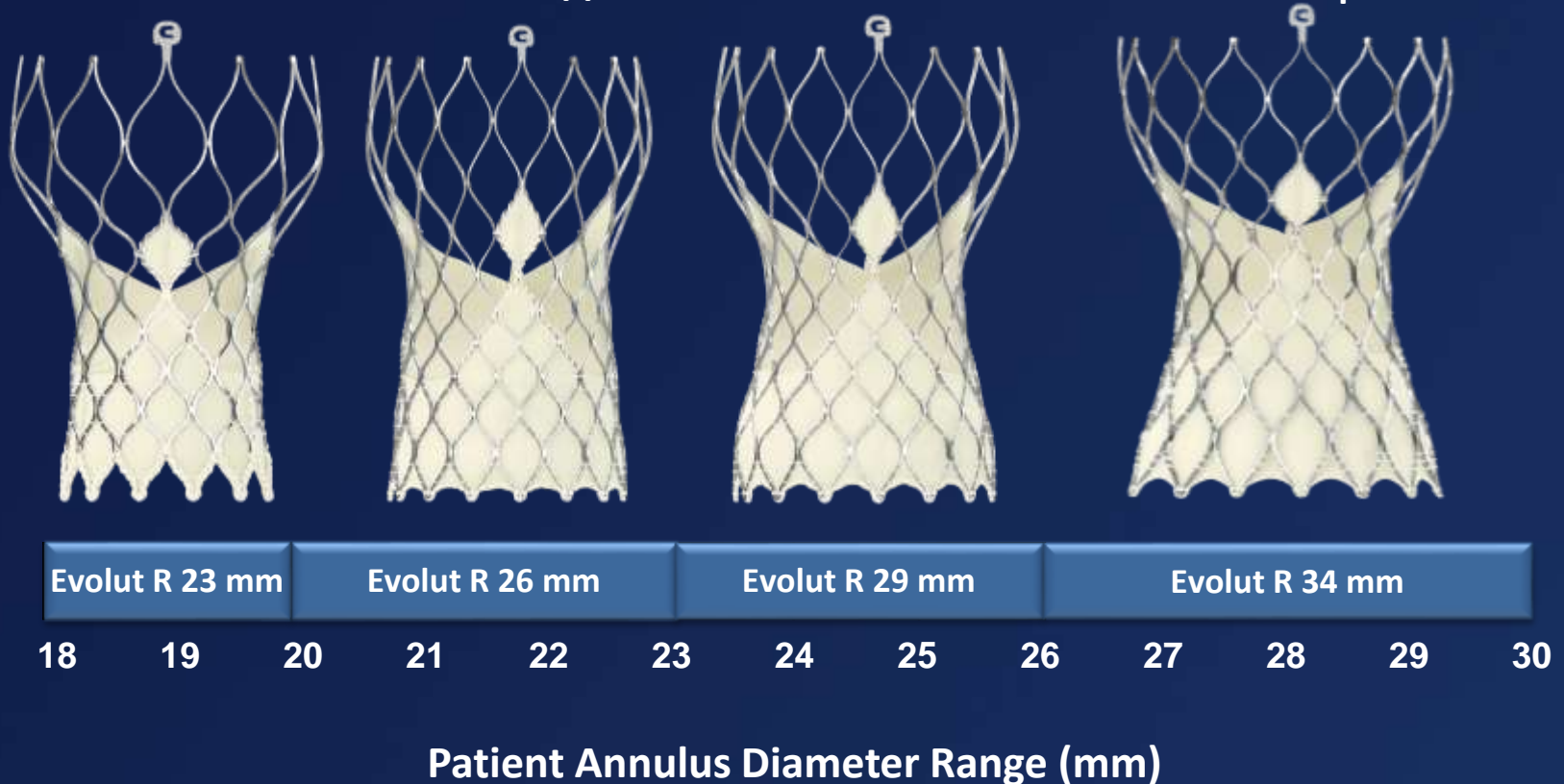


# Evolut R : broad coverage of size

Indicated Size Range

Evolut R 23, 26, 29 mm  
CE and FDA Approved

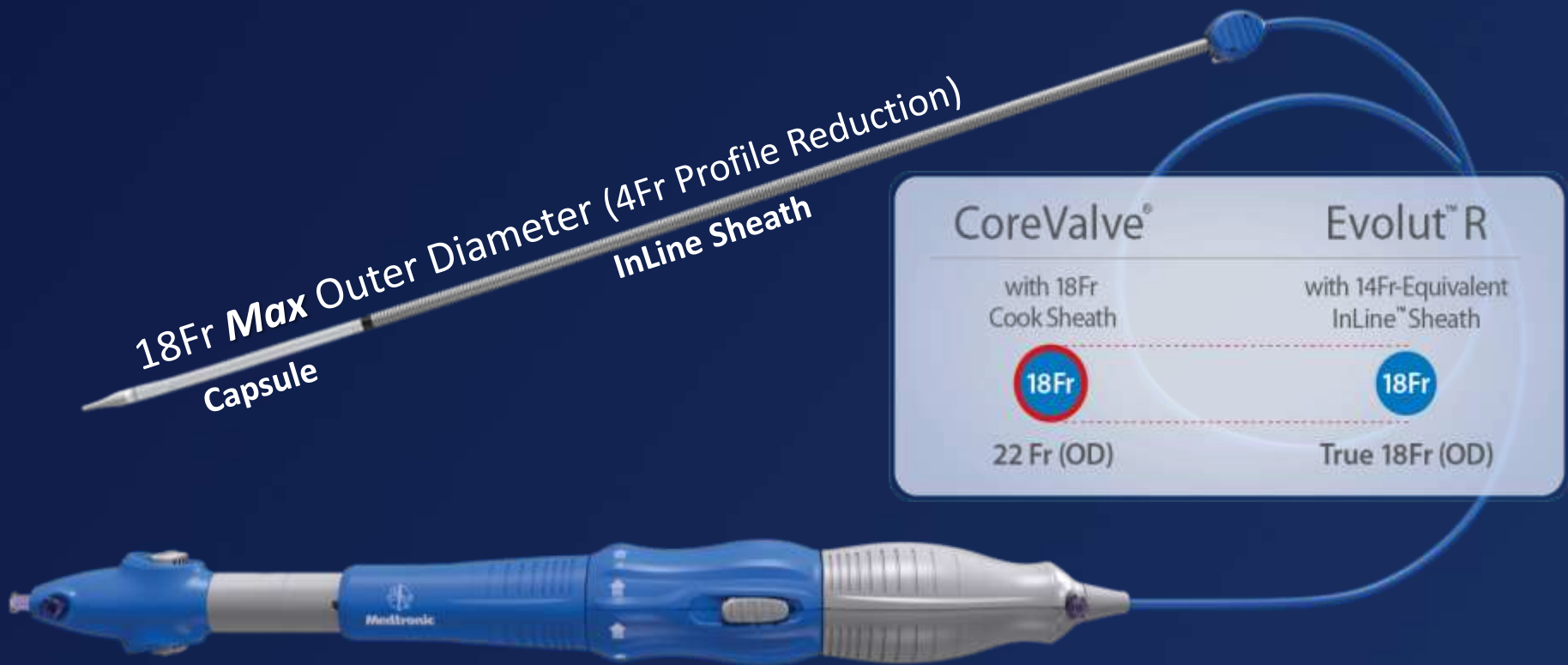
Evolut R 34 mm  
Under Development



# Evolut R : vascular-friendly

14 Fr-Equivalent System with InLine Sheath

Minimum artery diameter is 5.0 mm across all valve sizes



# Contemporary Delivery Systems

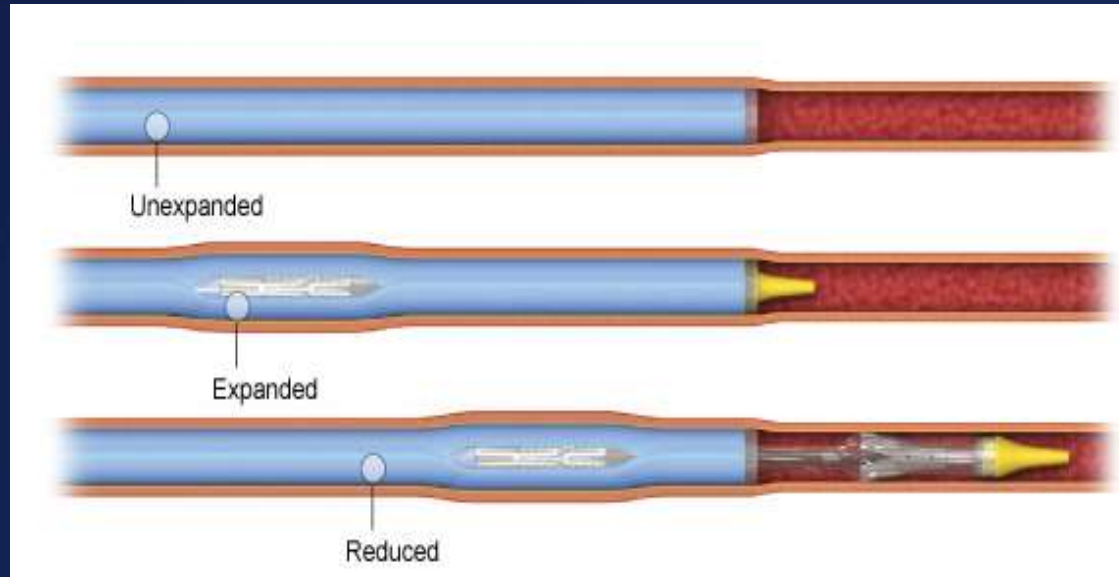
## Indicated Vessel Size

Evolut R has the potential to reach 17% more patients due to its low profile

	 SAPIEN 3		 Lotus	 Evolut R
Valve Size (mm)	20, 23, 26	29	23, 25, 27	23, 26, 29
Indicated Vessel Diameter (mm)	5.5	6.0	6.0	5.0

# Lowest Delivery Profile

True 14Fr system with 5mm vessel indication



VS



# Lowest Delivery Profile

True 14Fr system with 5mm vessel indication

## Sheath size comparison (Evolut R vs Sapien3)



# Evolut R : risk of stroke

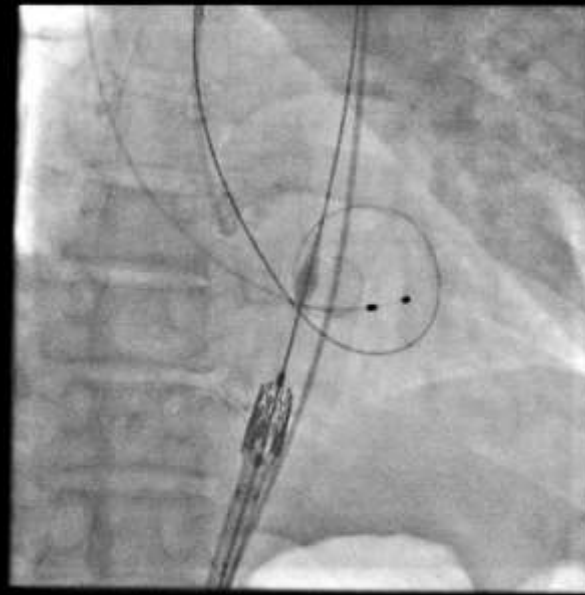
Flexibility Of The Catheter Enables Easy Navigation Through Vasculature and Across The Aortic Arch

Evolut R



slim &  
smooth

Sapien XT



bulky &  
friction

Lotus



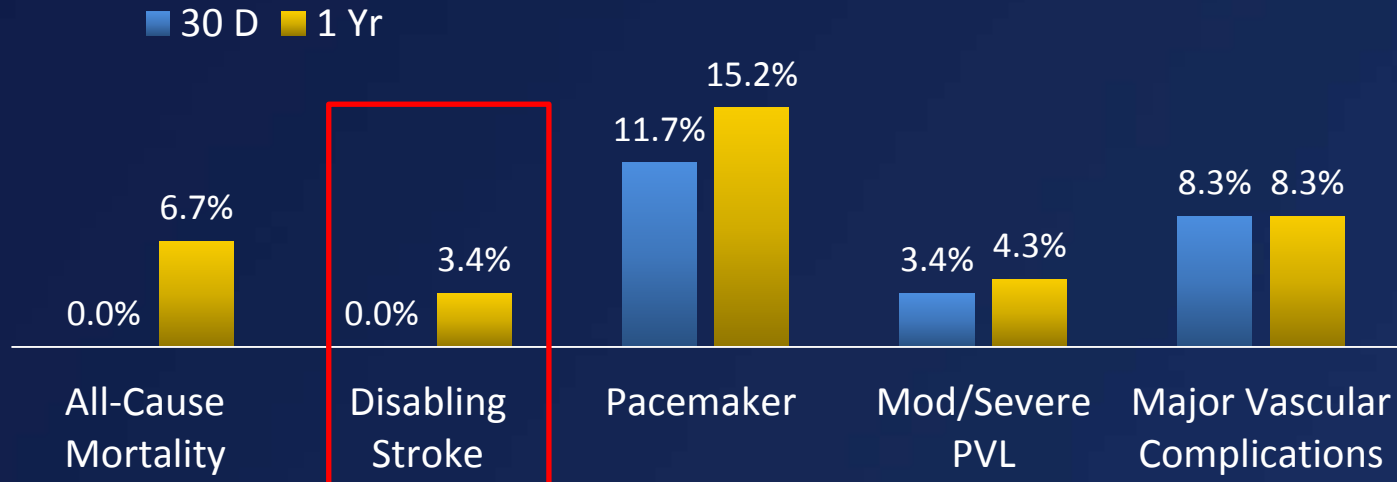
bulky &  
friction

# Evolut R Clinical Evidence : low risk of stroke

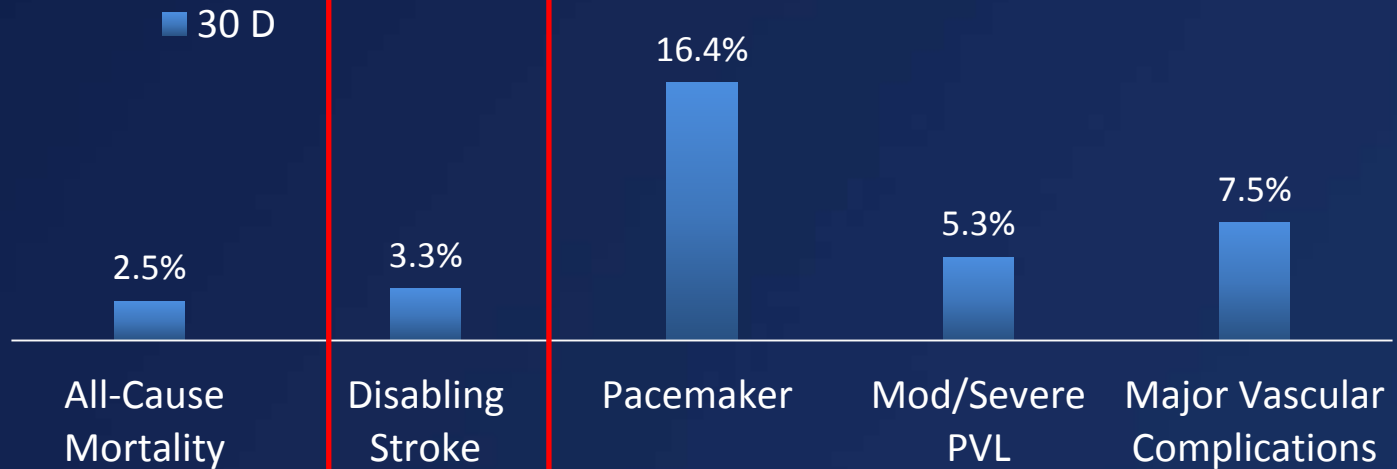
## Medtronic-Sponsored Studies



Evolut R CE Study  
N=60



Evolut R US Study  
N=241



<sup>1</sup>Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; <sup>2</sup>Manoharan, et al., presented at TCT 2015; <sup>3</sup>Williams, et al., presented at ACC 2016;



# Evolut R :

Wide Orifice Area With Supra-Annular Valve Design

Evolut R



Sapien 3



Lotus



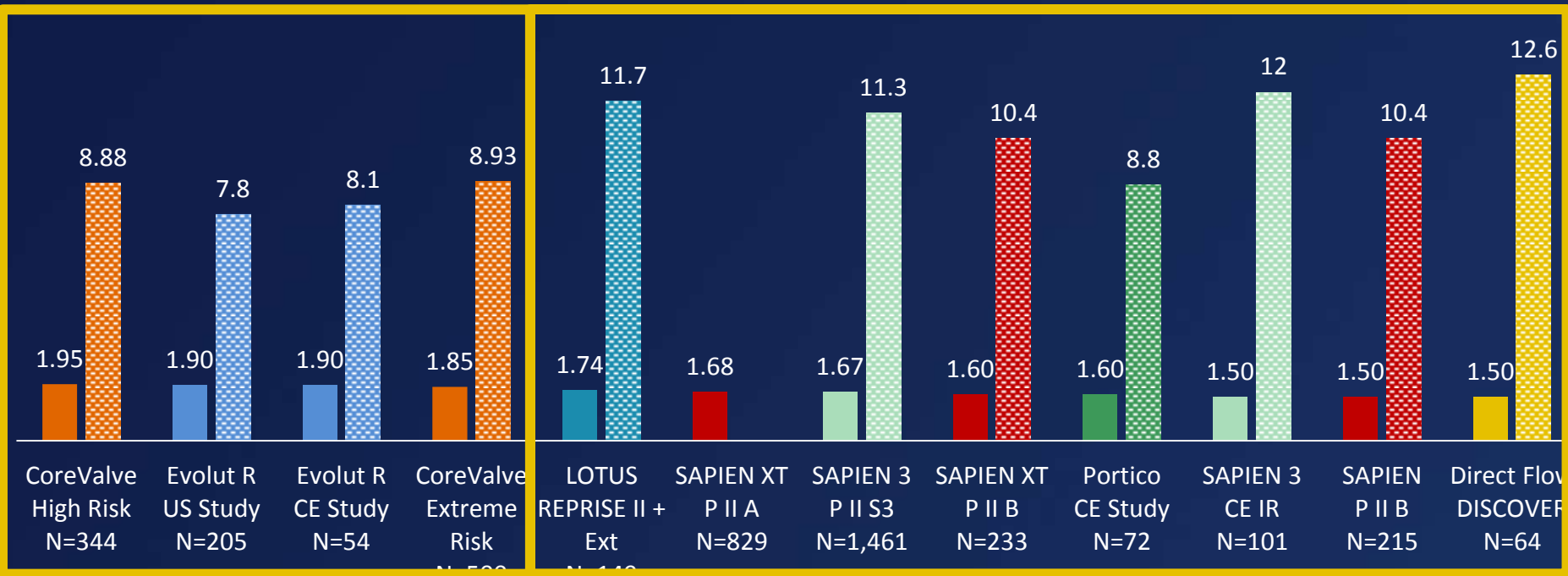
# Hemodynamics : best d/t wide orifice area

## EOA (cm<sup>2</sup>) and Mean Gradient (mm Hg) at 30 Days

- CoreValve and Evolut R consistently provide the largest EOA and lowest mean gradient
- This may offer a particular advantage to patients that are already symptomatic with a low gradient—achieving the lowest possible gradient after TAVR may lead to better symptom relief
- The FDA has recently removed labeling contraindicating TAVR in these patients

### CoreValve and Evolut R

### Competing Valves



<sup>1</sup>Adams, et al., *N Engl J Med* 2014; 370: 1790-8; <sup>2</sup>Williams, et al., presented at ACC 2016; <sup>3</sup>Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; <sup>4</sup>Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; <sup>5</sup>Meredith, et al., presented at PCR London Valves 2014; <sup>6</sup>Leon, et al., *N Engl J Med* 2016 Apr 2 [E-pub ahead of print]; <sup>7</sup>Kodali, et al., *Eur Heart J* 2016; doi:10.1093/eurheartj/ehw112; <sup>8</sup>Webb, et al. *J Am Coll Cardiol Interv* 2015; 8: 1797-806; <sup>9</sup>Manoharan, et al., et al. presented at TCT 2014; <sup>10</sup>Vahanian, et al., presented at EuroPCR 2015; <sup>11</sup>Webb, et al. *J Am Coll Cardiol Interv* 2015; 8: 1797-806; <sup>12</sup>Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8

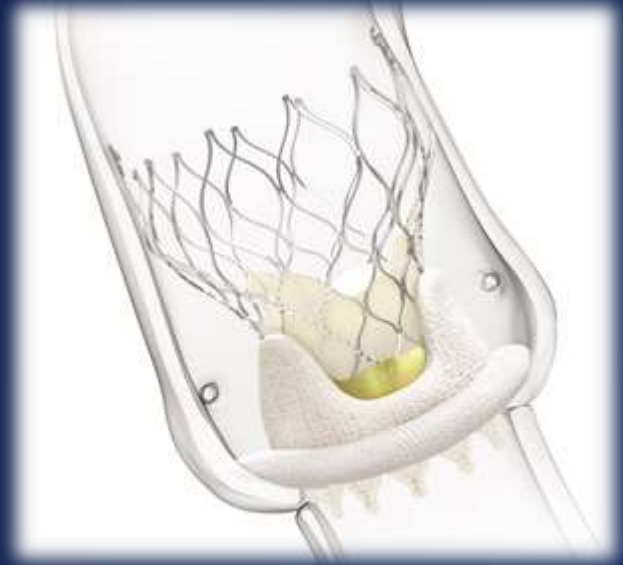
# Valve-in-Valve

## Supra-Annular Design Maximizes Forward Flow

Surgical bioprostheses often fail due to stenosis, which reduces the effective orifice area. It can be difficult to “gain back” this space with TAV in SAV, especially in small annuli.

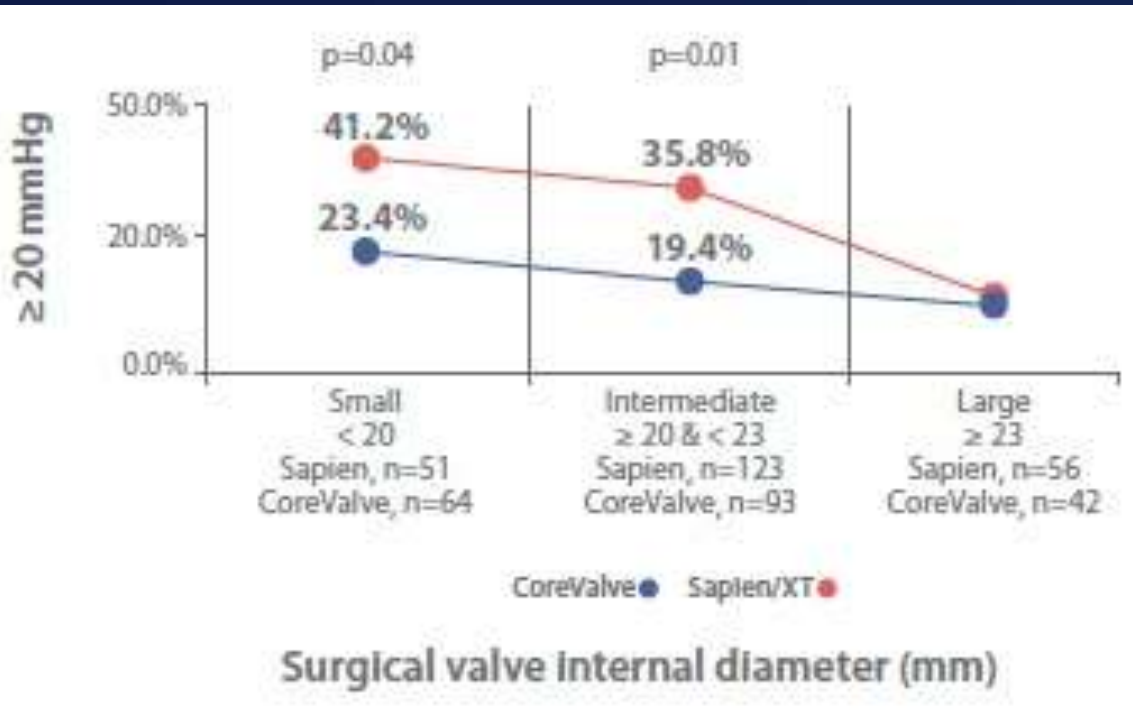
Advantages of a self-expanding valve:

- Supra-annular leaflets optimize forward flow and maximize the potential effective orifice area
- The 23 mm CoreValve is indicated to treat failed surgical valves with a 17 mm internal diameter

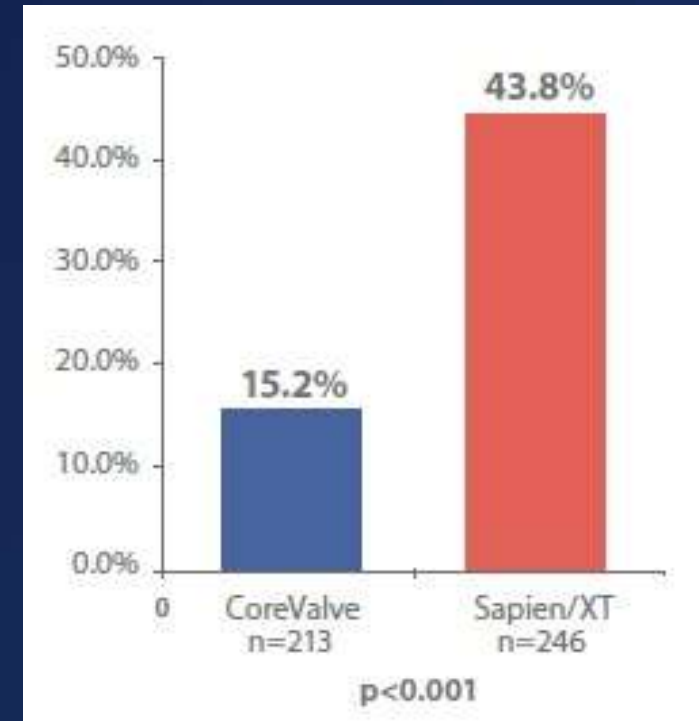


# Systems indicated for Valve-in-Valve

Evolut R shows superior hemodynamics in Valve-in Valve



**Lowest  
Post-Procedure Gradients**



**Low Rate  
of Prosthesis Mismatch**

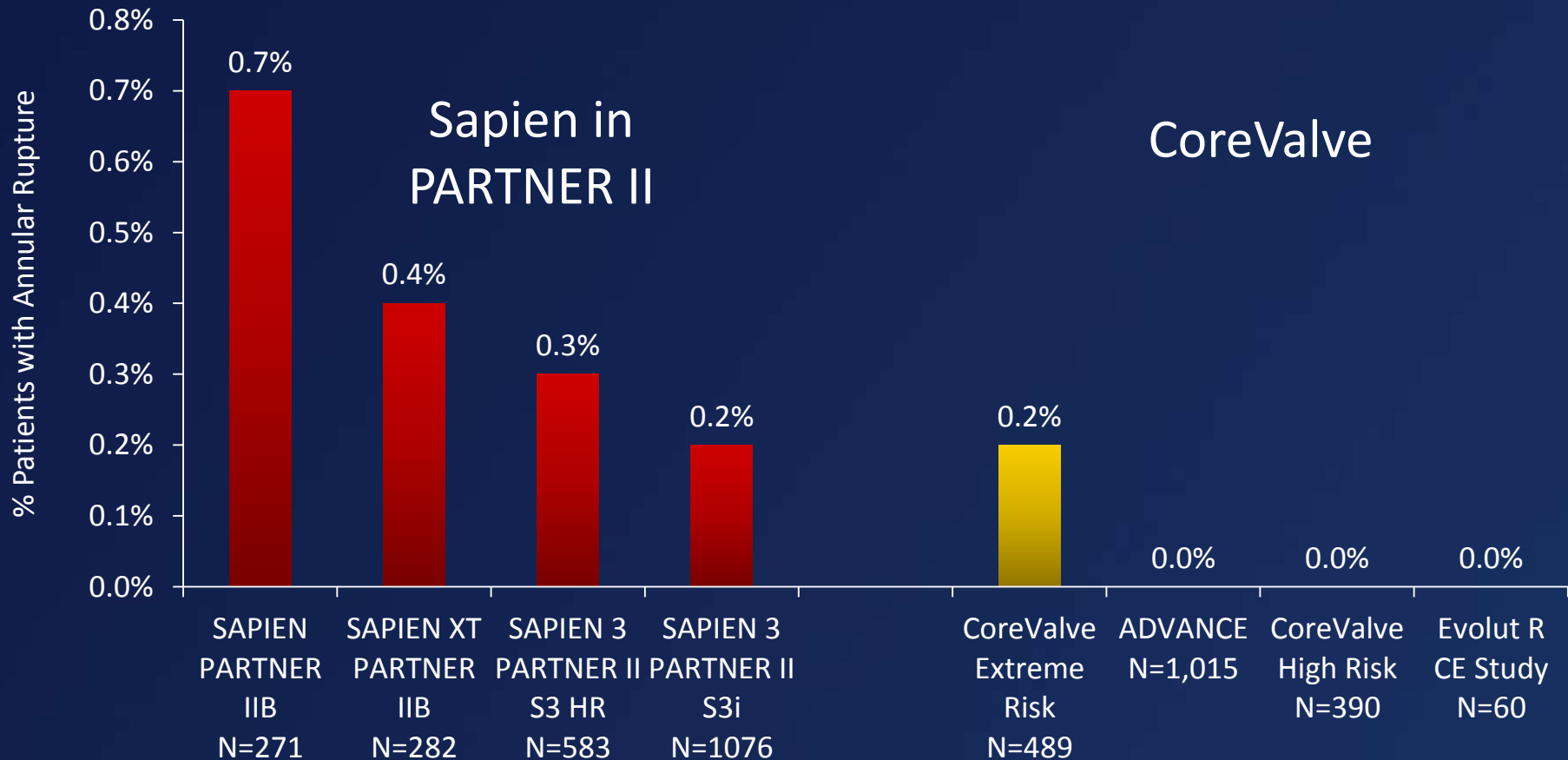
# Catastrophic Failures Are Less Frequent with Self-Expanding Valves

*Annular Ruptures*

# Annular Rupture is Rare but Catastrophic

Carries a ~50% mortality rate

Annular rupture is mainly associated with **the inflation of a balloon**, either during valve deployment or pre- or post-dilation



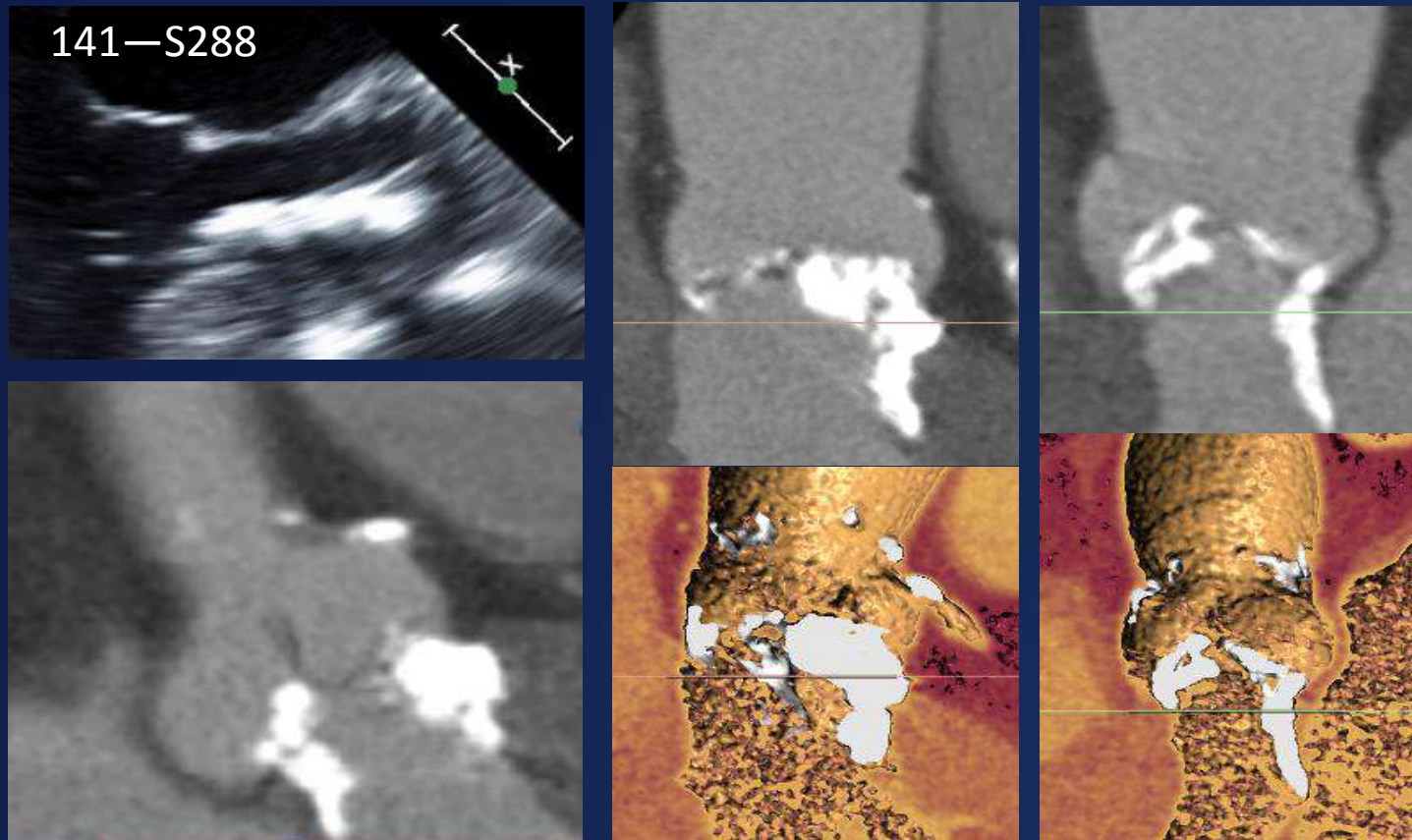
<sup>1</sup>Leon, et al. presented at ACC 2013; <sup>2</sup>Kodali, et al., presented at ACC 2015; <sup>3</sup>Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; <sup>4</sup>Linke, et al., *Eur Heart J* 2014; 35: 2672-84; <sup>5</sup>Adams, et al., *N Engl J Med* 2014; 370: 1790-8; <sup>6</sup>Meredith, et al. presented at EuroPCR 2015

# Patients with Moderate or Severe LVOT Calcification

Safety of the slow and steady deployment in difficult anatomy

Advantages of a self-expanding valve :

- Conformable frame doesn't force annular remodeling upon deployment
- Slow, steady deployment may help to prevent disruption of fragile tissue



# Catastrophic Failures Are Less Frequent with Self-Expanding Valves

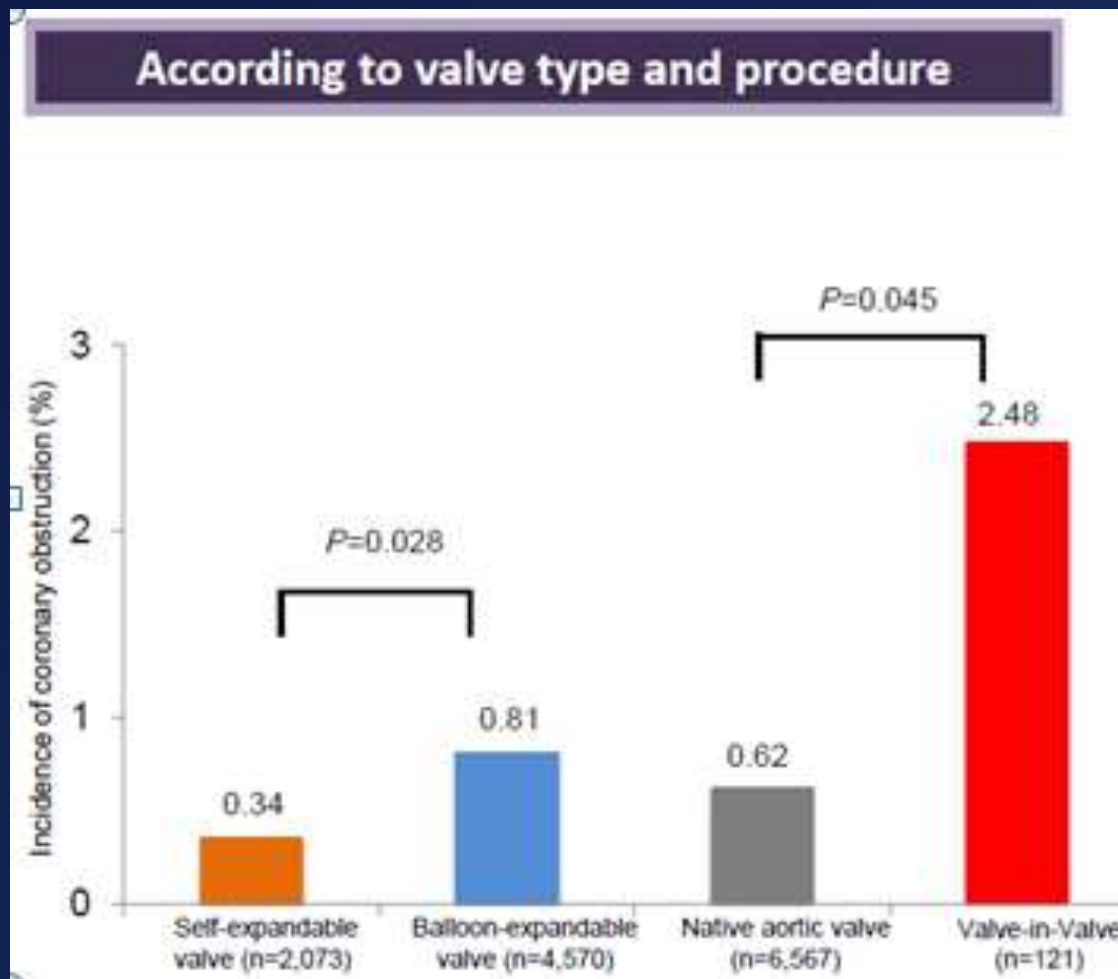
*Coronary Occlusions*



# Coronary Occlusions are Rare but often Catastrophic

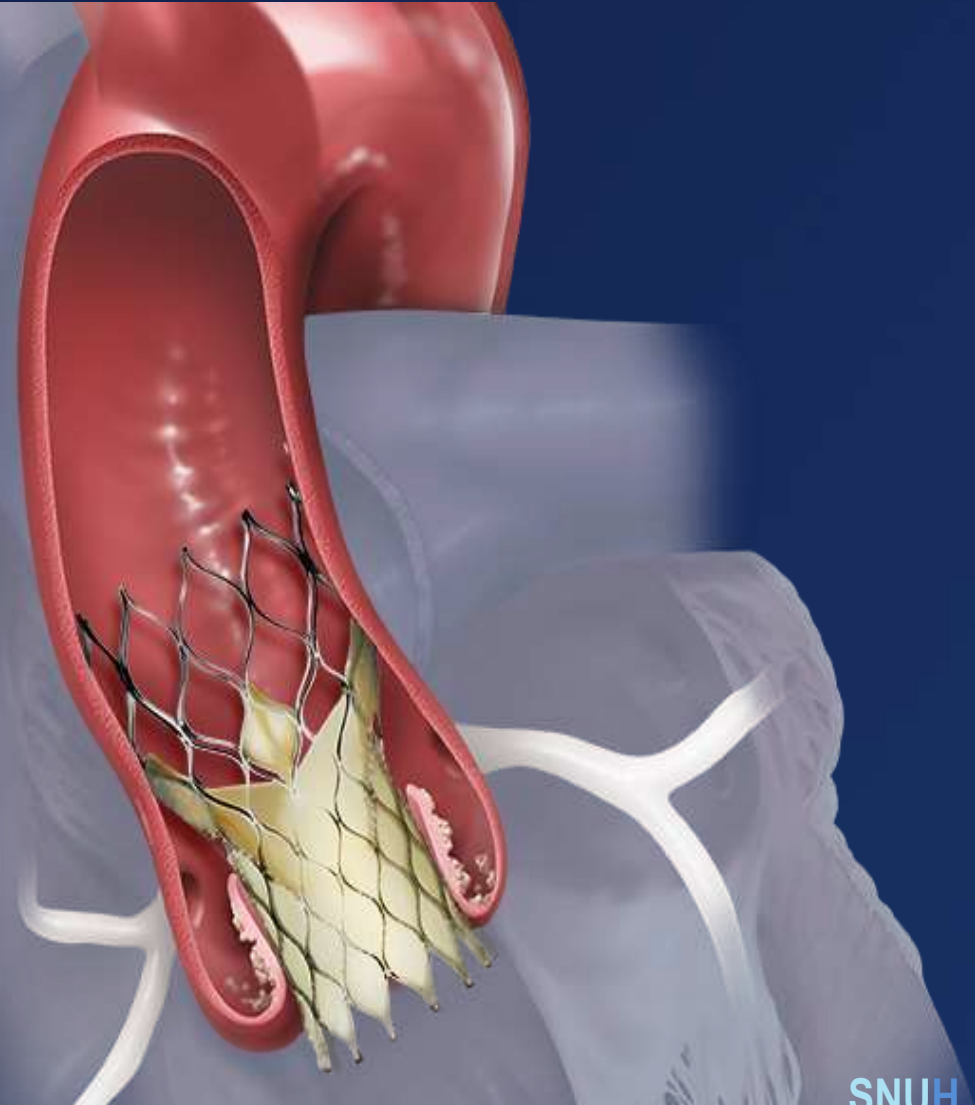
Lead to >40% in-hospital mortality

Significantly more common with balloon expandable than self expandable valves  
(0.81% vs. 0.34%,  $p=0.028$ )<sup>1,2</sup>



# Evolut R allows for precise placement and repositioning in patients at high risk for coronary obstruction

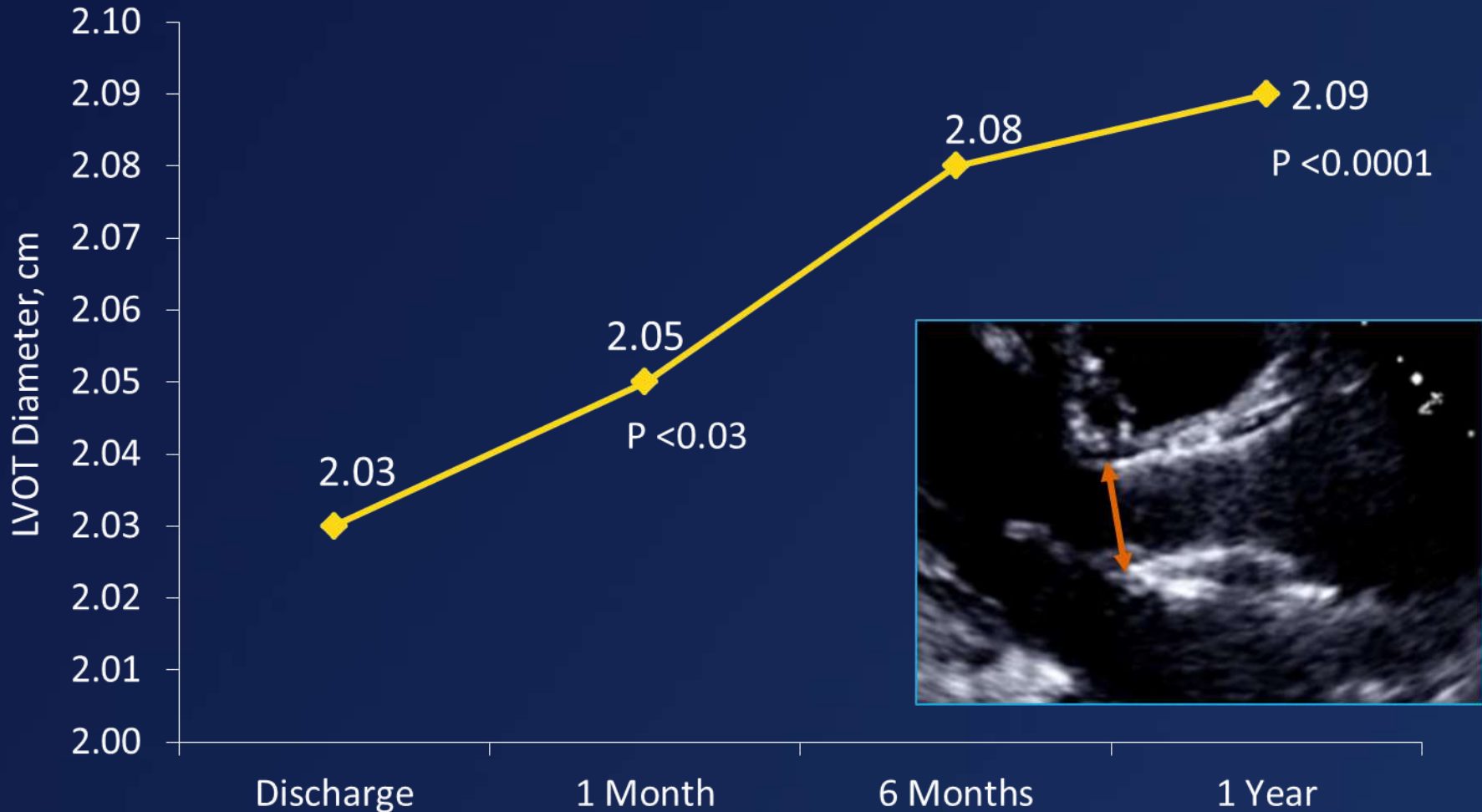
- Tapered shape of the frame diminishes the risk
- If needed, coronary access can be achieved through the struts of the frame
- Evolut R can be completely recaptured in an emergency situation



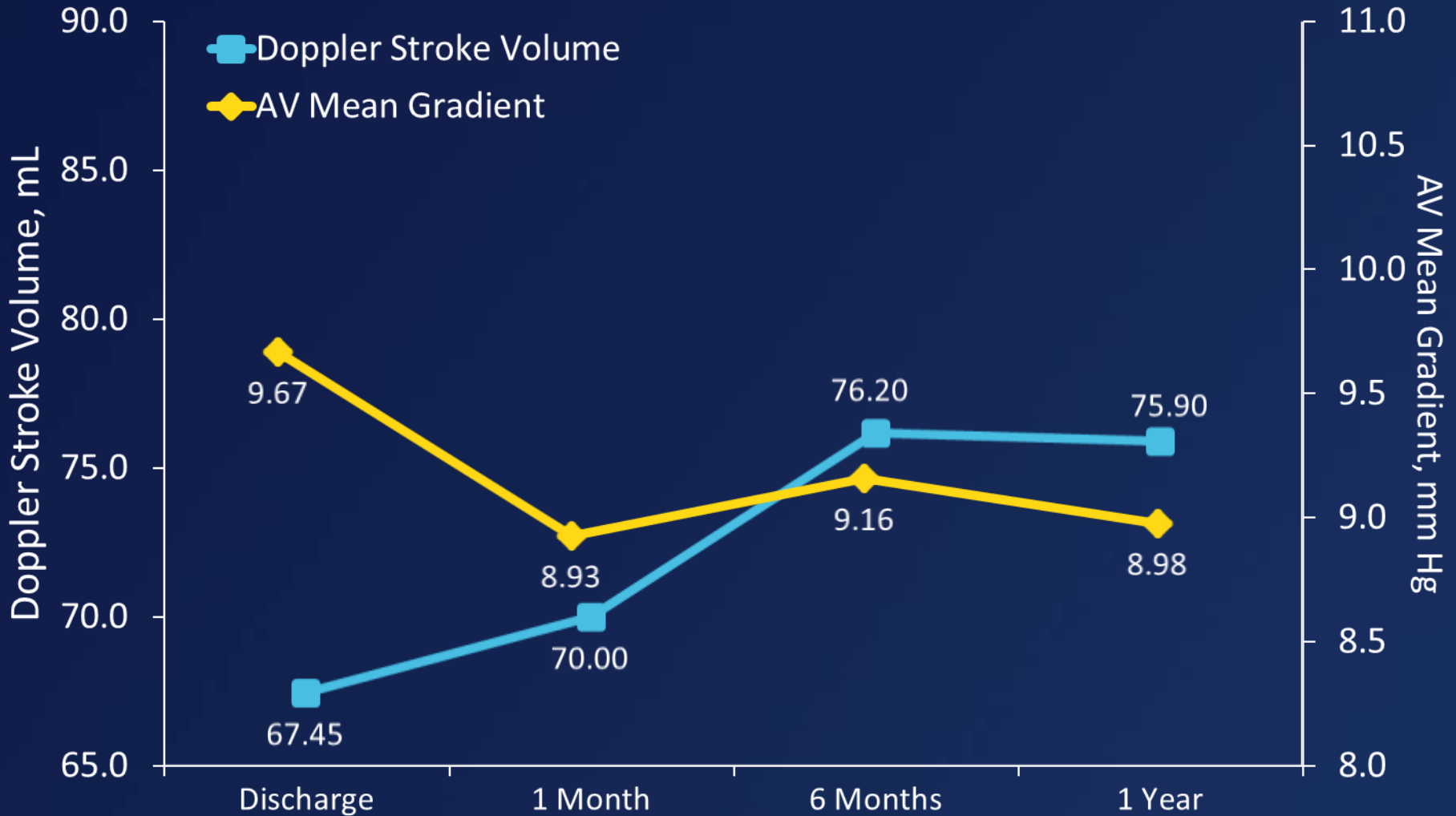
Continued Outward Expansion Promotes Improved Hemodynamics and Biological Sealing

# Evidence of Continued Outward Expansion

## LVOT Diameter Outer to Outer Edge



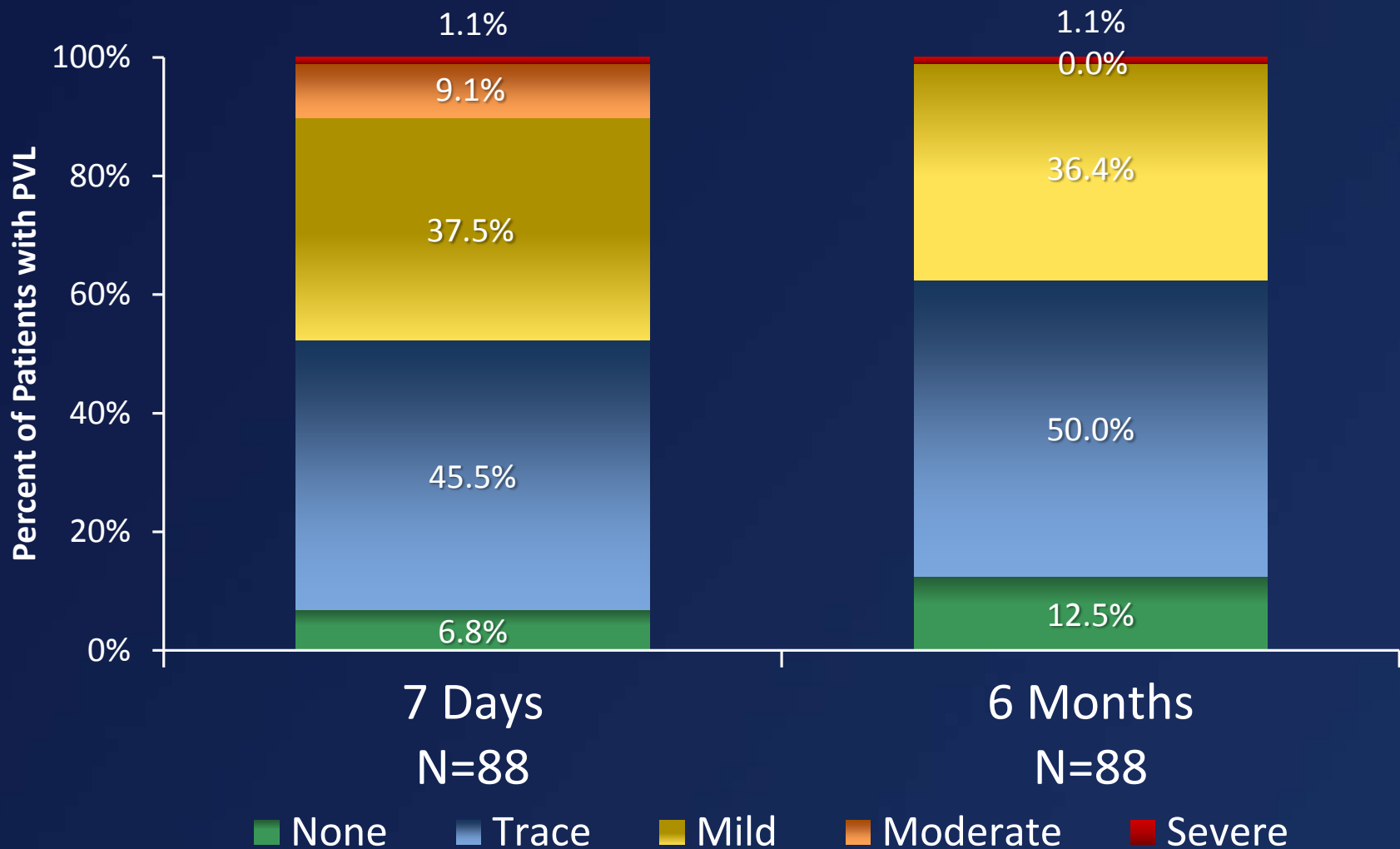
# Continued Outward Expansion Leads to Reduction in AV Gradient



# Continued Outward Expansion

## Leads to Regression of PVL with Time | ADVANCE II Study

Paired data show >mild PVL decreased significantly from day 7 to 6 months (p=0.005†)

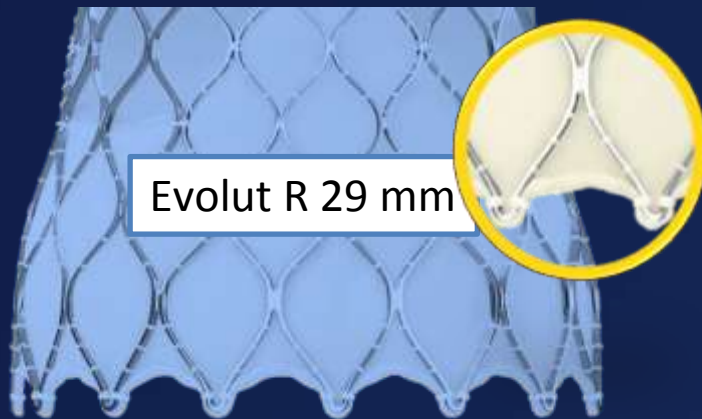
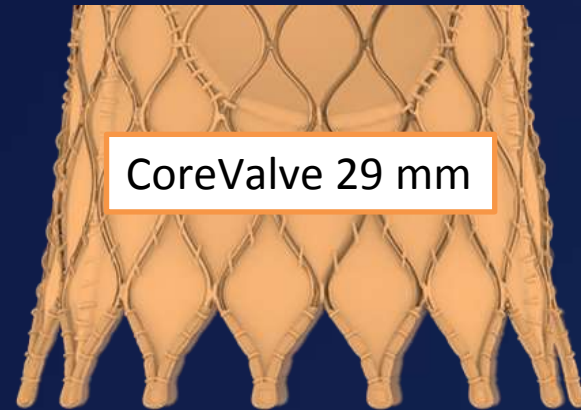


†McNemar's test on paired data

# Evolut R : Enhanced Sealing

## Enhanced Sealing with a More Conformable Frame \*

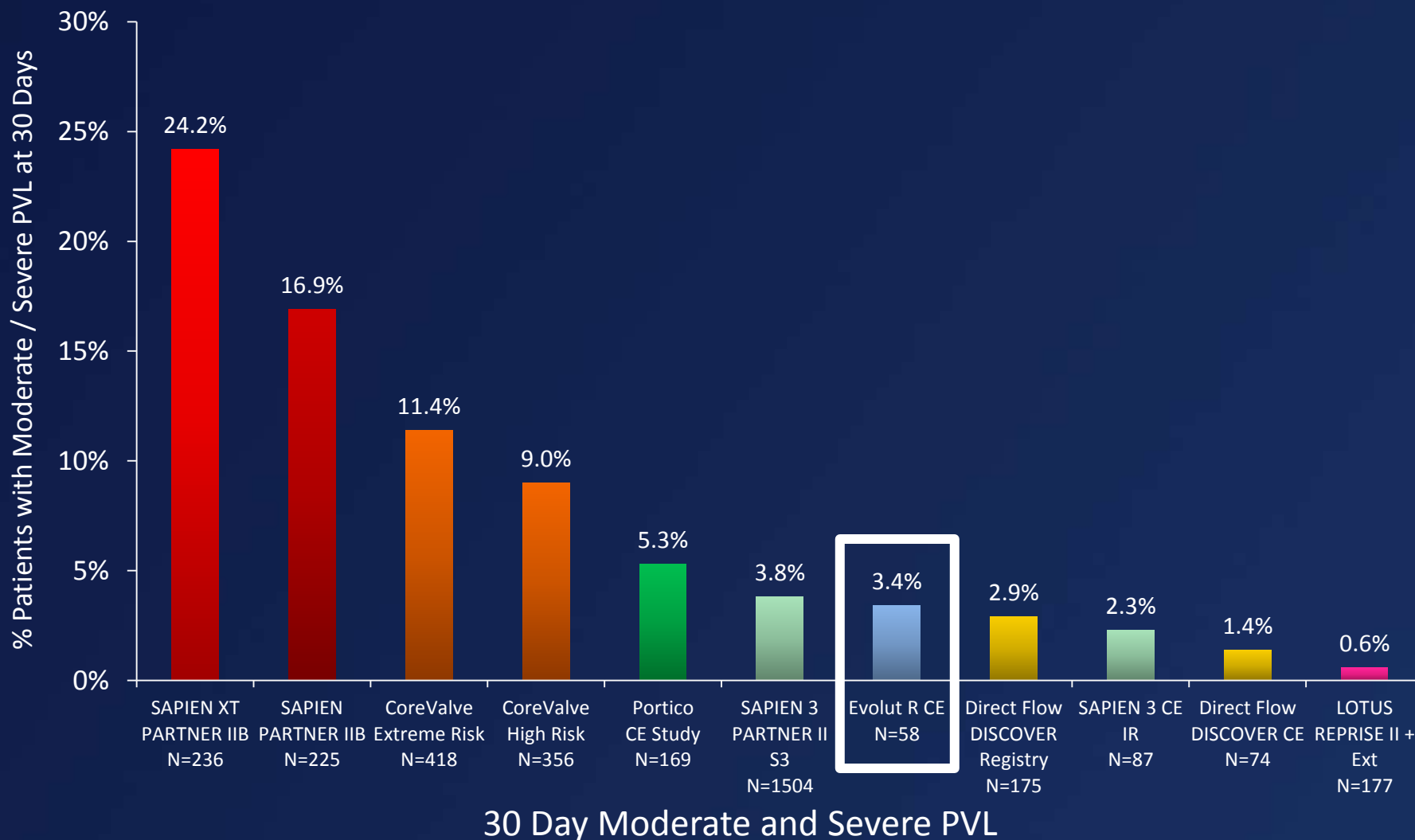
1. Increased Oversizing
2. More Consistent Radial Force
3. Extended Sealing Skirt



Note: images may not be to exact scale and are for illustration purposes only.

\*CoreValve Evolut R 26 and 29 mm only

# Evolut R Has Comparable PVL Performance Without The Tradeoffs



<sup>1</sup>Leon, et. al. presented at ACC 2013; <sup>2</sup>Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; <sup>3</sup>Adams, et al., *N Engl J Med* 2014; 370: 1790-8; <sup>4</sup>Linke, et. al. presented at PCR London Valves 2015; <sup>5</sup>Kodali, et al., presented at ACC 2015; <sup>6</sup>Meredith, et al., presented at ACC 2015; <sup>7</sup>Naber, et al., presented at EuroPCR 2015; <sup>8</sup>Vahanian, et al., presented at EuroPCR 2015; <sup>9</sup>Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; <sup>10</sup>Meredith, et al., presented at PCR London Valves 2014



## Evolut R: Final Thoughts

The Evolut R offers the specific advantages:

- ✓ Wide ranges of annulus sizes
- ✓ Vascular friendly
- ✓ Re-capturability
- ✓ Widest effective orifice area
- ✓ Supra-annular valve design – VIV (TAV-in-SAV)
- ✓ Low rates of annular rupture and coronary occlusions
- ✓ Evidence of superiority to SAVR in terms of survival (US pivotal trial)

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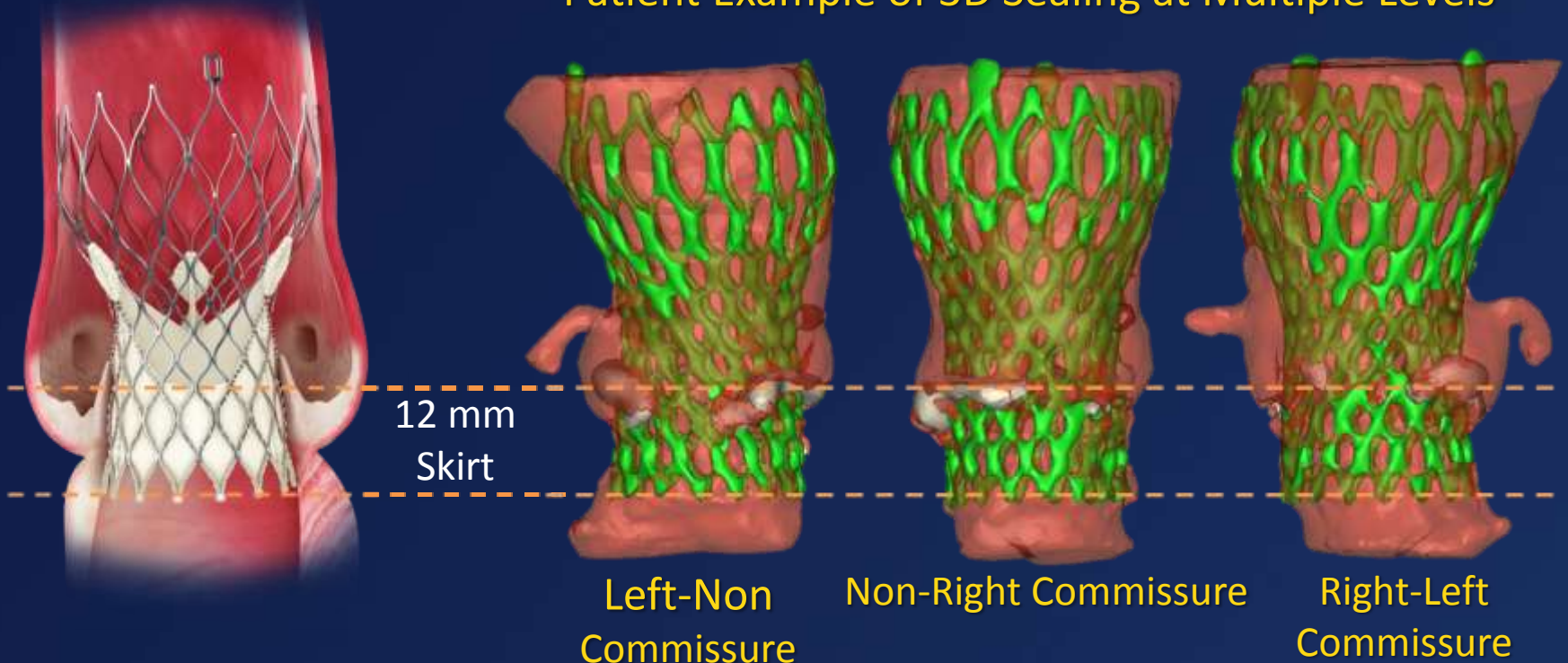


# Continued Outward Expansion

## Promotes Biological Sealing

With the CoreValve System, sealing can occur along the 12mm sealing skirt—in the aortic root, annulus, and LVOT—including above and below calcification

### Patient Example of 3D Sealing at Multiple Levels

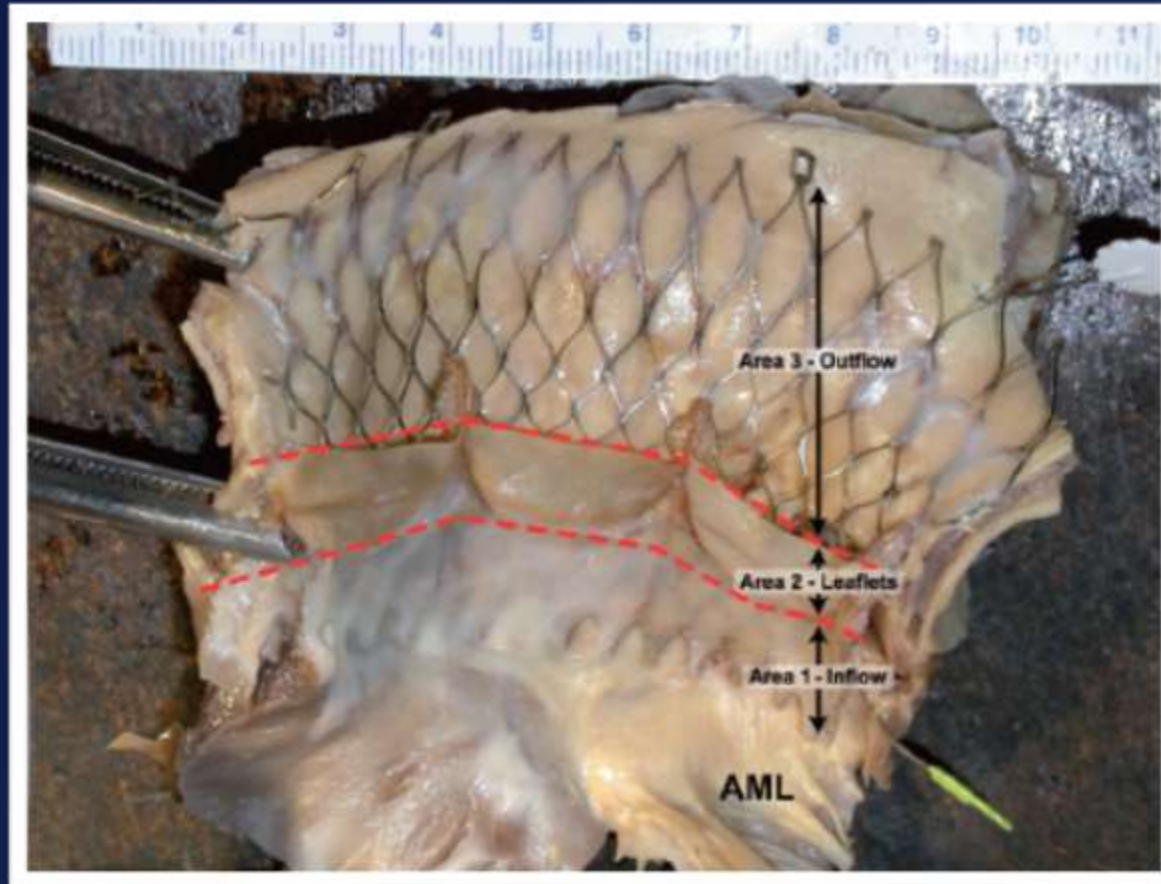


CT Images Courtesy of Dr. Piazza and Prof. Lange, German Heart Center Munich Germany

Bright green = CoreValve in contact with tissue  
Red = blood volume  
White = calcification

# Continued Outward Expansion

## Promotes Biological Sealing



Area 1 shows the location of the skirt, which demonstrates good healing and sealing of the CoreValve inflow.

# Evolut R Unsurpassed Hemodynamics With Supra-Annular Valve Design

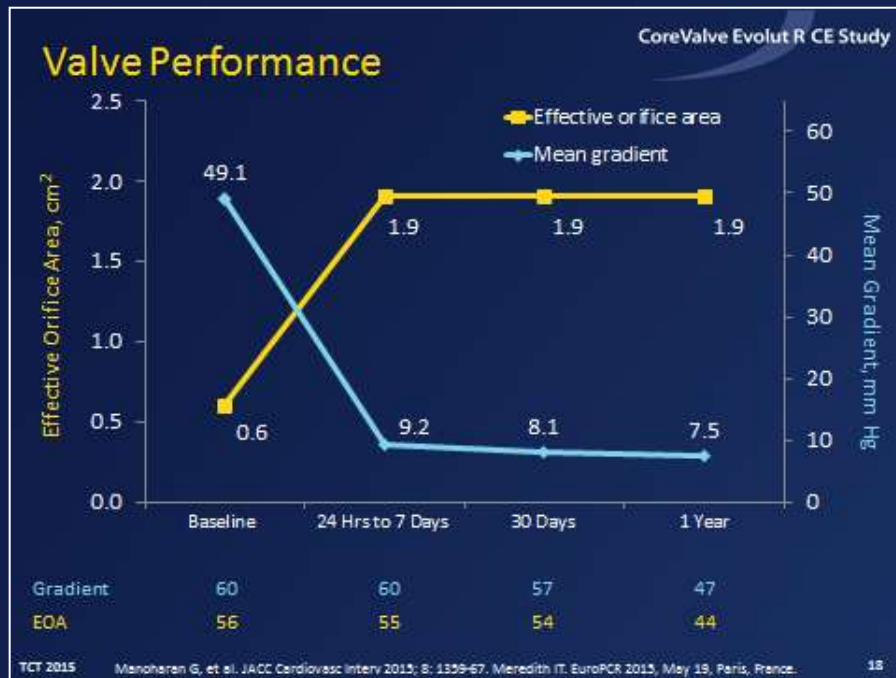
Forward-flow hemodynamics were exceptional in both studies



Evolut R CE Study  
N=60



Evolut R US Study  
N=241



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## Provides the Ability to Recapture and Reposition

EnVeo R DCS provides option to recapture and reposition up to three times before reaching the 'Point of No Recapture'\*



Tactile Indicator  
~ 2/3 Deployment



Just Prior to Point of No Recapture  
~ 80% Deployment\*

\* Up to 80% deployment