

How Evolut R Has Impacted My Practice?

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Physician Name

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Company/Relationship

Medtronic, CoreValve: C, SB, AB, OF
Direct Flow: C, SB, AB
Mitralign: AB, SB, E
Boston Scientific: C, SB, AB
Biosensors: E, SB, C, AB
Kona: AB, E
Abbott Vascular: AB
InSeal Medical: AB, E,
Valtech: E, SB,
Claret: SB
Keystone: AB
Shockwave: E, AB

Key

G – Grant and or Research Support E – Equity Interests S – Salary, AB – Advisory Board
C – Consulting fees, Honoraria R – Royalty Income I – Intellectual Property Rights
SB – Speaker's Bureau O – Ownership OF – Other Financial Benefits

Agenda

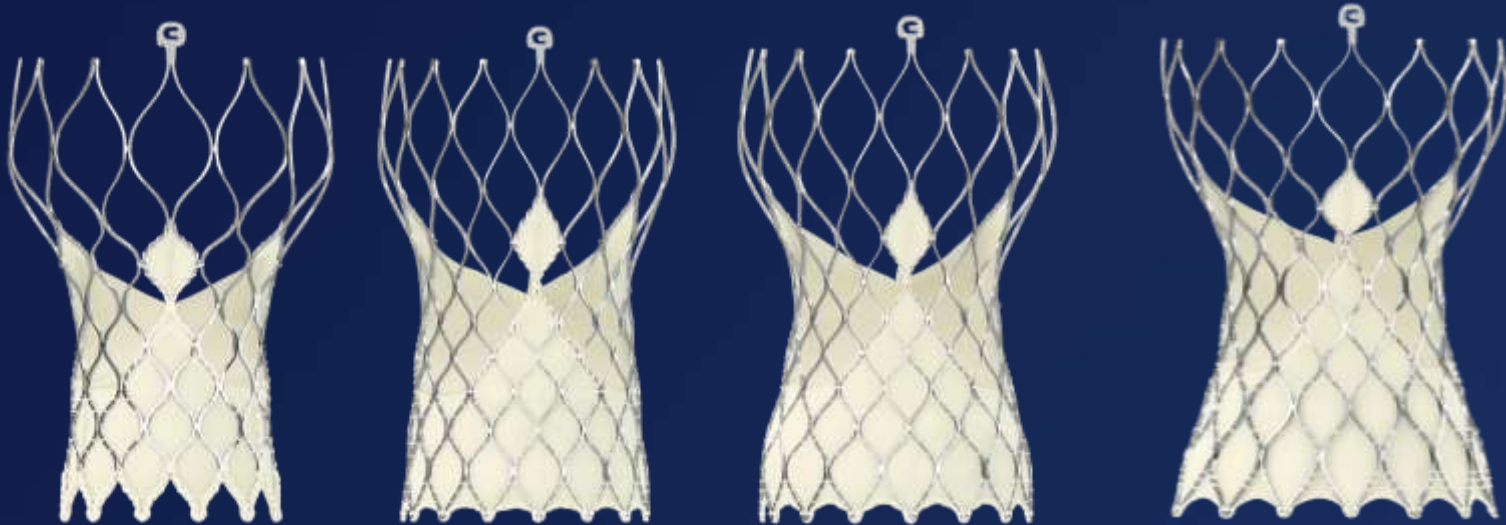
- ✓ Overview of the Evolut R system
- ✓ Recapturability and when it is important?
- ✓ impact of Evolut R on alternative access
- ✓ Evolut R in horizontal anatomy?
- ✓ Evolut R Evidence Summary: Does real world experience match the outcomes from the Evolut R clinical trials?

Evolut R: Self Expanding, Supra-Annular & Recapturable

Indicated Size Range

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

Evolut R 34 mm
Received IDA Approval



Evolut R 23 mm

Evolut R 26 mm

Evolut R 29 mm

Evolut R 34 mm

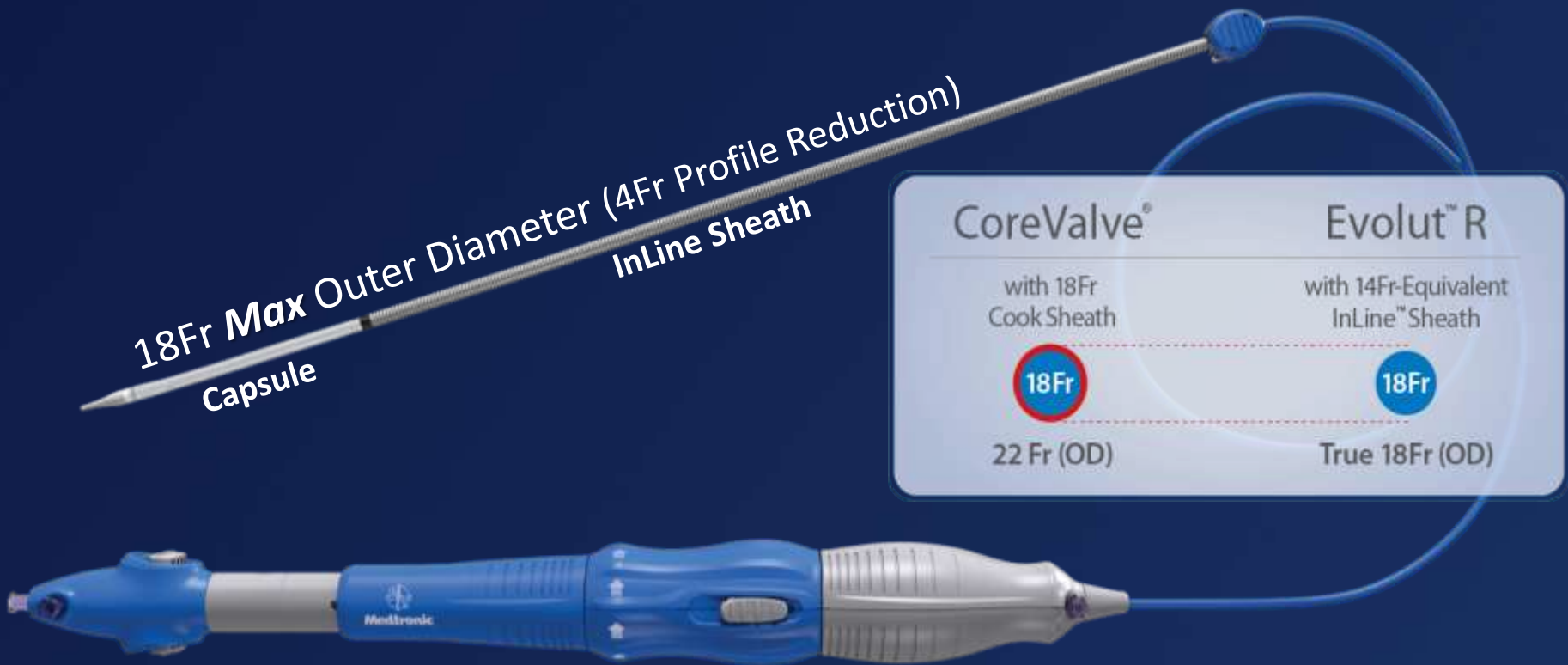
18 19 20 21 22 23 24 25 26 27 28 29 30

Patient Annulus Diameter Range (mm)

EnVeo R Delivery System

14 Fr-Equivalent System with InLine Sheath

Minimum artery diameter is 5.0 mm across all valve sizes

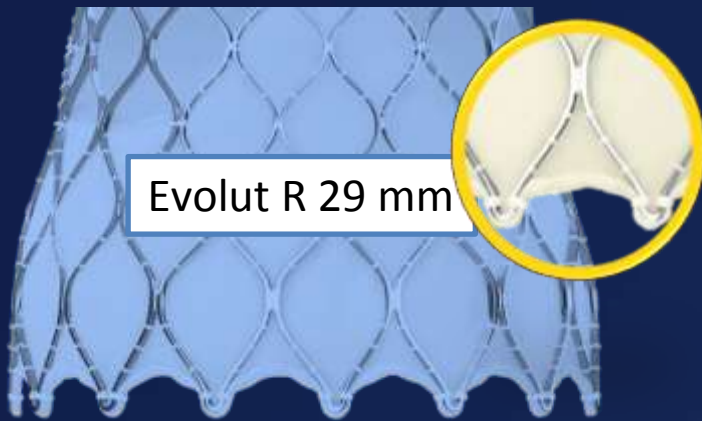
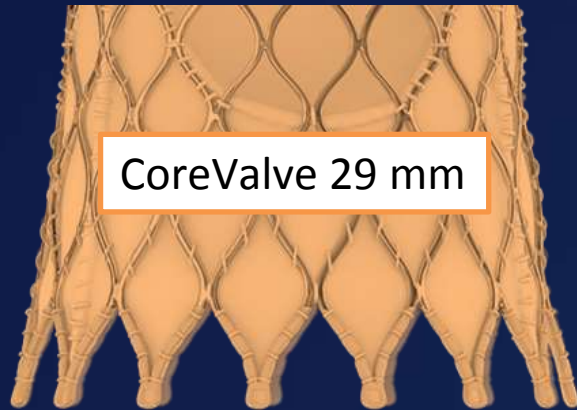


Evolut R

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

Recapture and Reposition

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

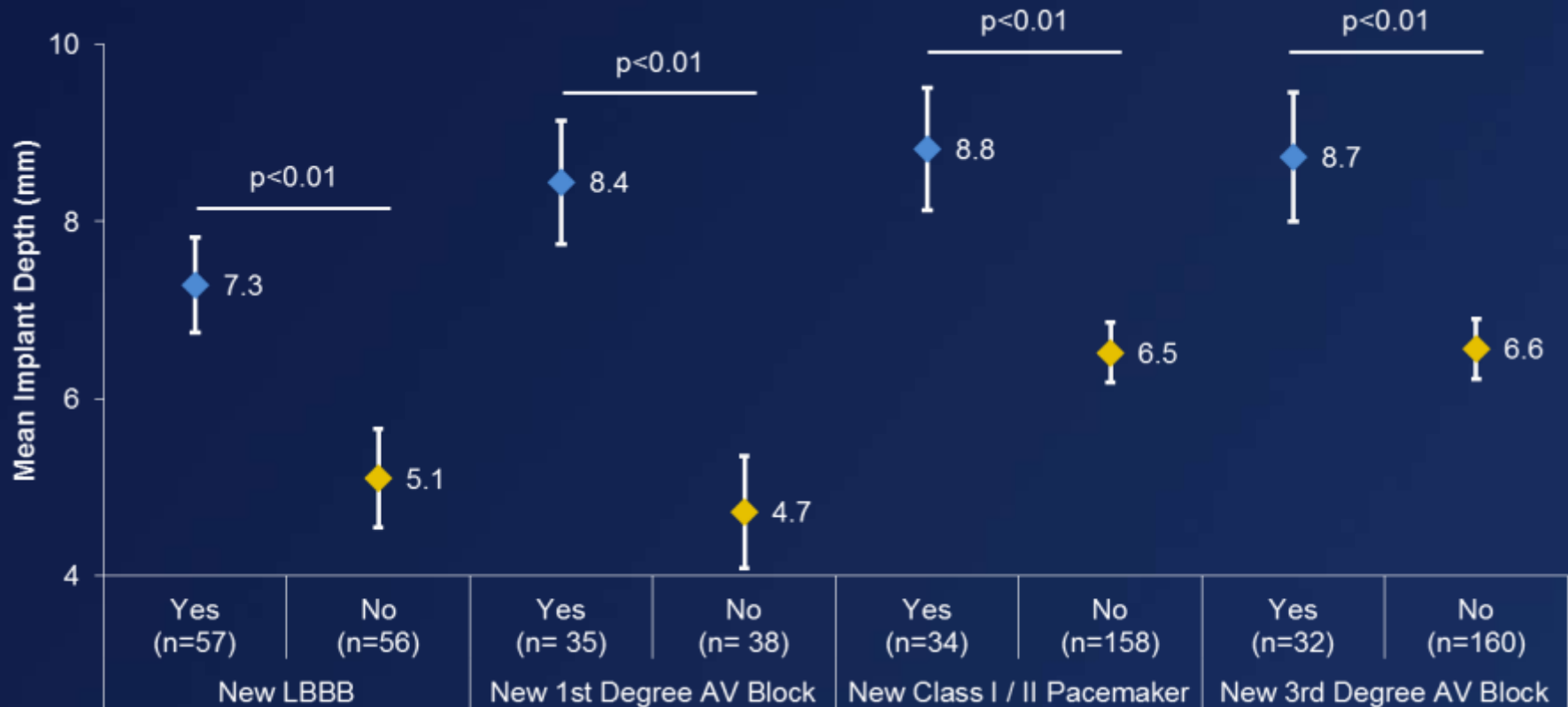


Recapturability and when it is important?

Recapturability Allows for Control of Accuracy,
critical for Evolut R Outcomes

Implant Depth

Key driver of conduction disturbances – which can be controlled



pooled t-test p values, standard error is shown as error bars

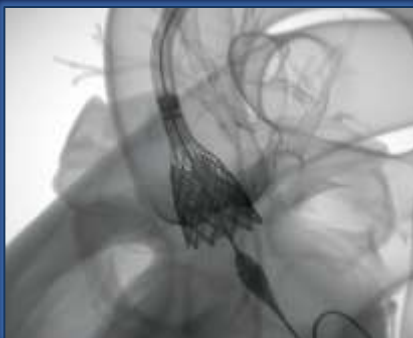
New pacemaker at 30 days, new conduction disturbance is defined as a conduction disturbance not present at baseline which developed within 30 days of TAVI

3rd Degree AV Block data from CEC adjudication, LBBB and 1st Degree AV Block from core lab adjudication

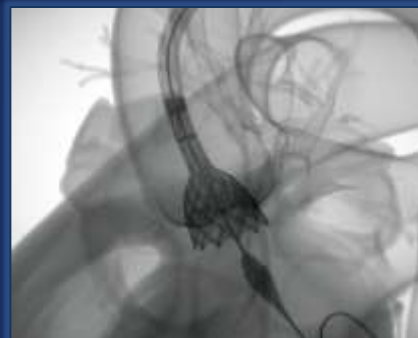
Implant depth defined as the distance from the lower edge of the non-coronary leaflet to the ventricular edge of the frame

Successfully used 22 times in 15 patients (25%):

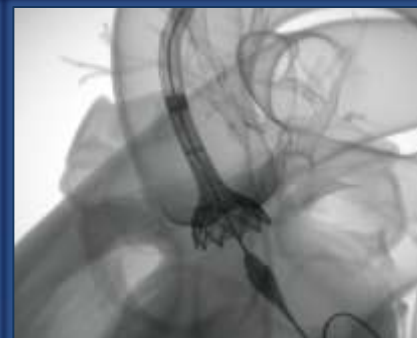
- 10 Partial resheaths among 7 patients
- 12 Full resheaths among 10 patients
- No full recaptures to retrieve
- Resulted in a final implant depth of LCS=6.3±4.1 mm, NCS=5.9±3.4 mm



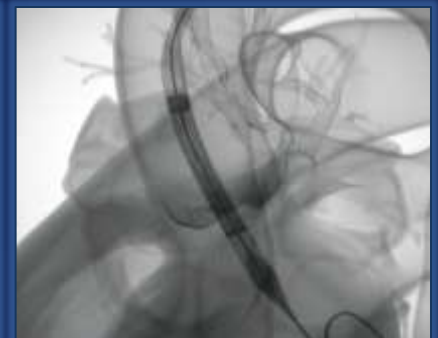
Valve too deep



Recapture begins



Partially recaptured



Valve fully captured

Recapturability

Use it to control position and improve patient outcomes

Mean Implant Depth

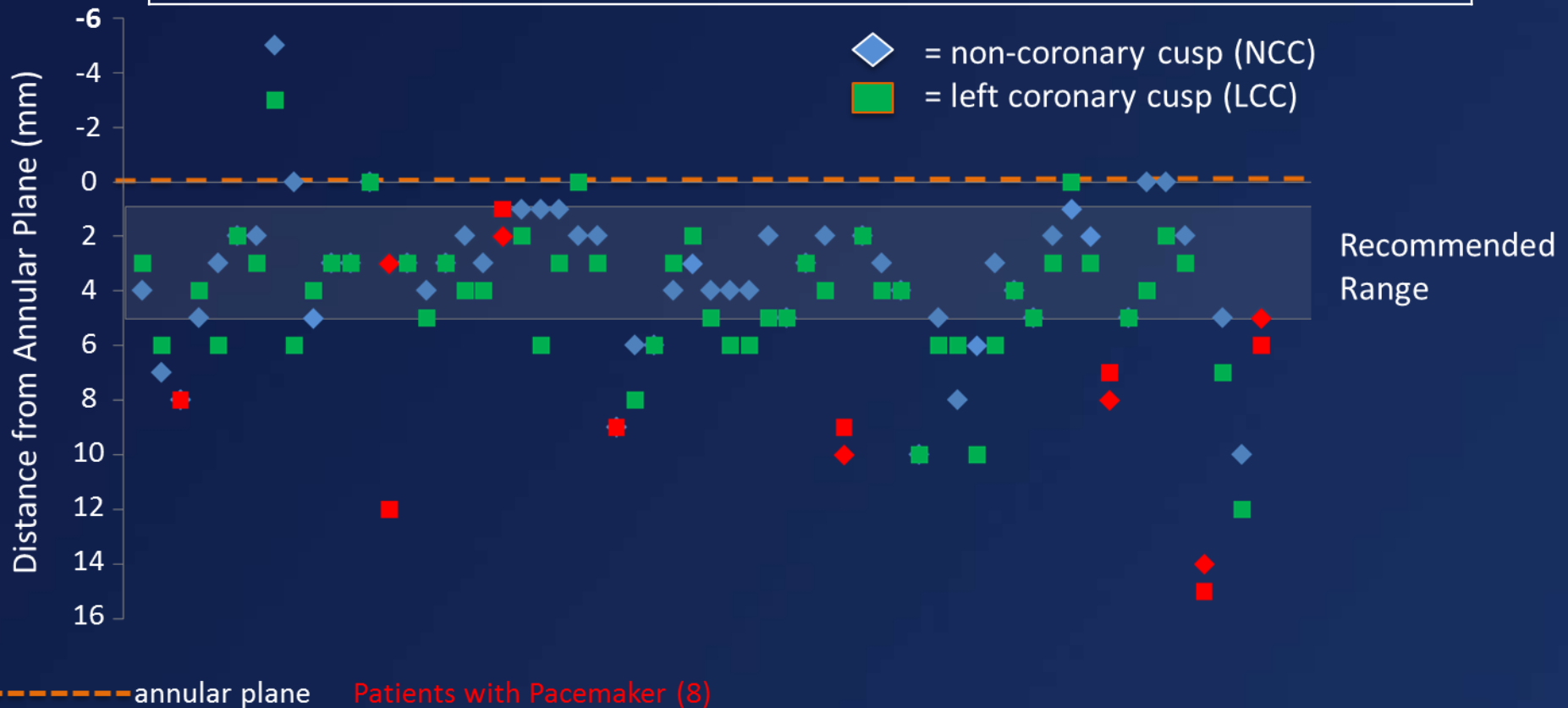
Patients with a pacemaker

- 8.1 ± 3.5 mm (non-coronary cusp)

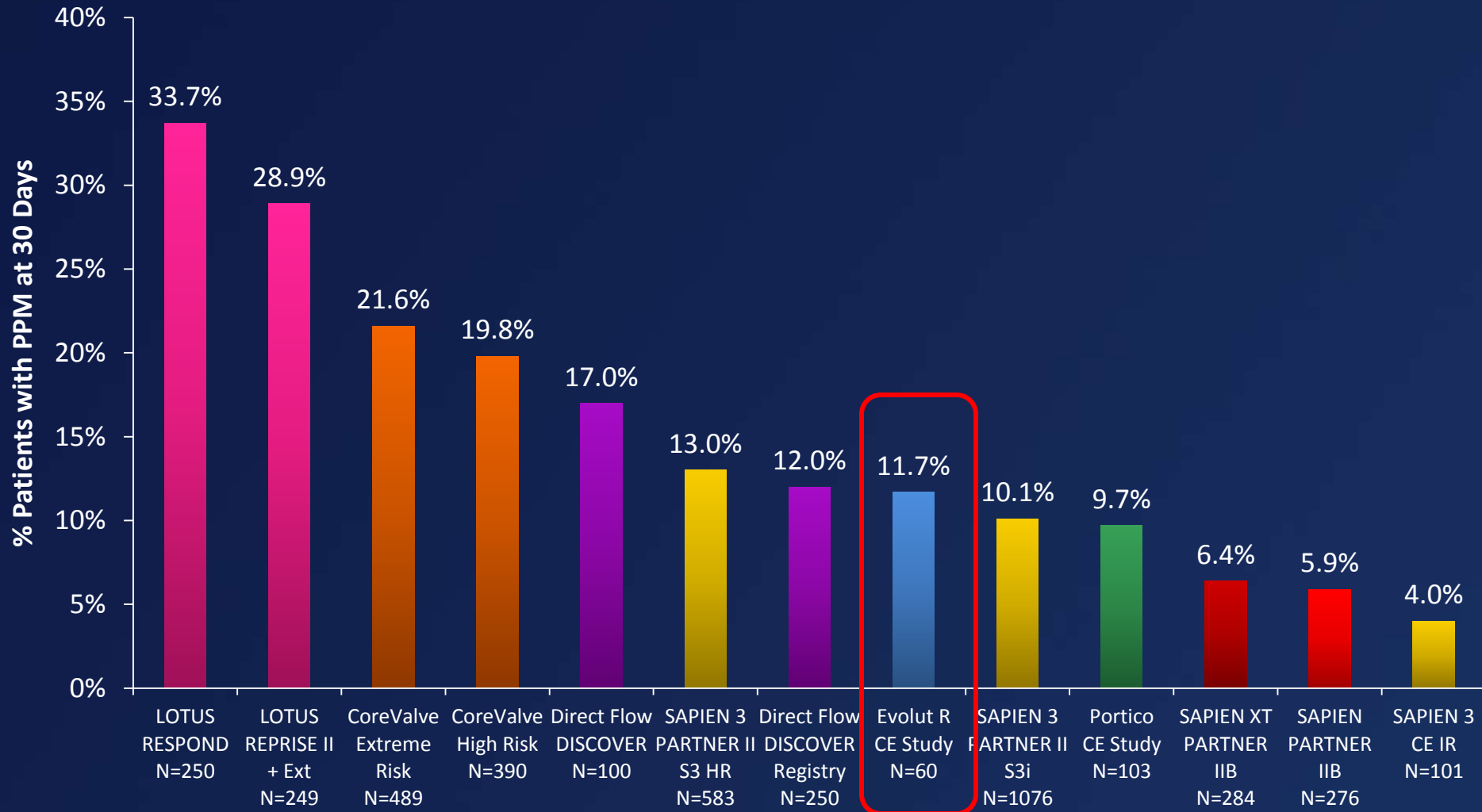
Patients with NO pacemaker

- 3.3 ± 2.5 mm (non-coronary cusp)

Difference (P<0.001)

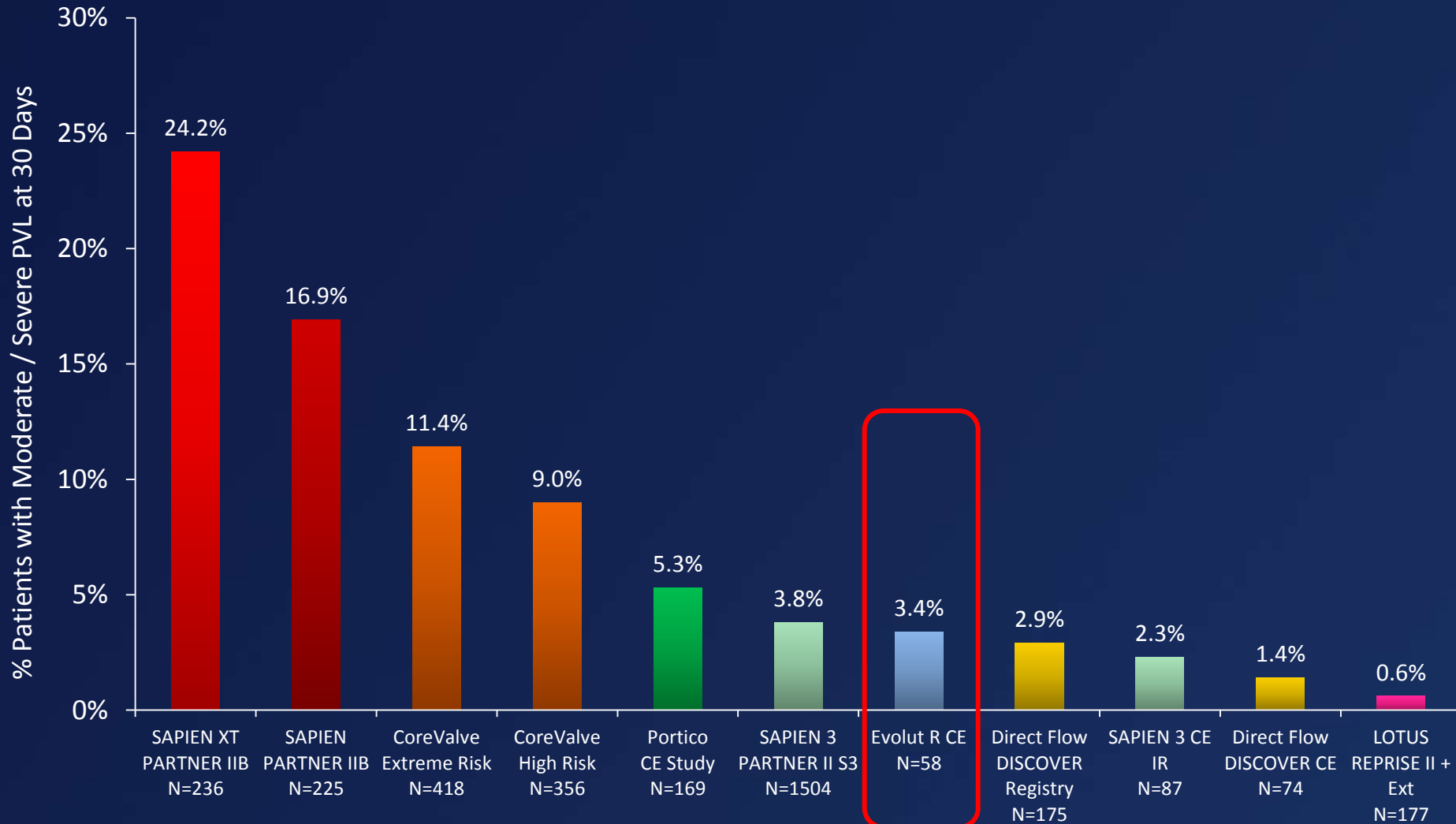


30 Day Permanent Pacemaker Rate



¹Van Mieghem, et al., presented at EuroPCR 2015; ²Meredith, et al., presented at PCR London Valves 2014; ³Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ⁴Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ⁵Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ⁶Kodali, et al., presented at ACC 2015; ⁷Naber, et al., presented at EuroPCR 2015; ⁸Meredith, et al., presented at ACC 2015; ⁹Kodali, et al., presented at ACC 2015; ¹⁰Manoharan, et al., et. al. presented at TCT 2014; ¹¹Leon, et. al. presented at ACC 2013; ¹²Vahanian, et al., presented at EuroPCR 2015

30 Day Moderate and Severe PVL



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

Recapturability and when it is important?

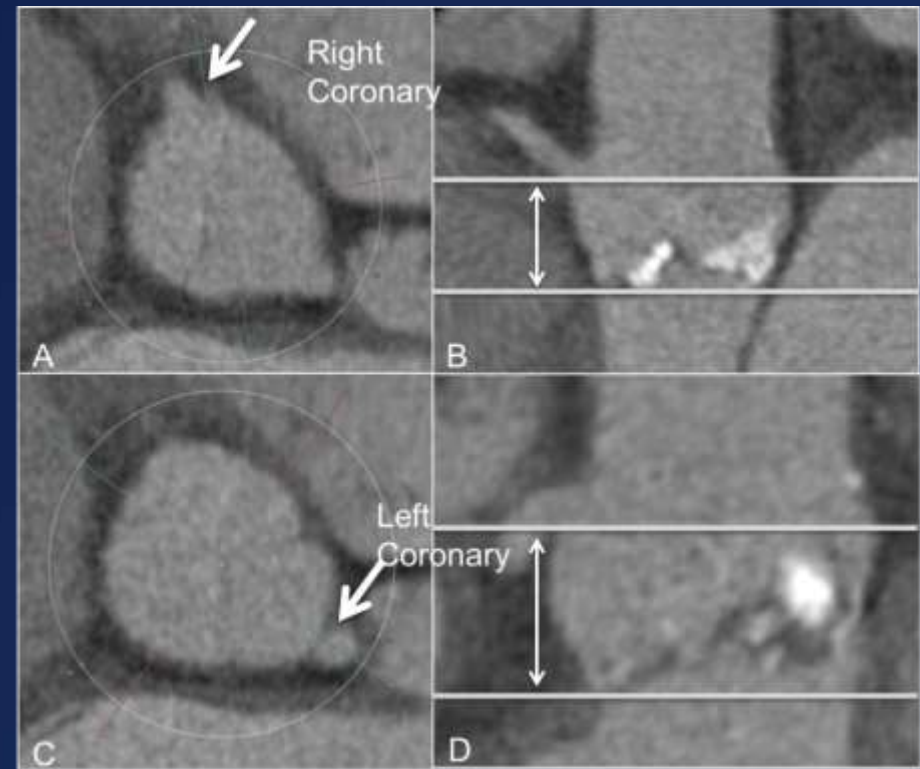
Patients At High Risk For Coronary Obstruction

Patients at High Risk for Coronary Obstruction

Coronary obstruction following TAVR is mainly due to the displacement of the calcified native cusp over the coronary ostia

A large multicenter registry of 6,688 patients demonstrated that particular anatomic features increased the risk of coronary obstruction¹:

- Left Coronary Artery height < 12 mm
- Sinus of Valsalva diameter < 30 mm

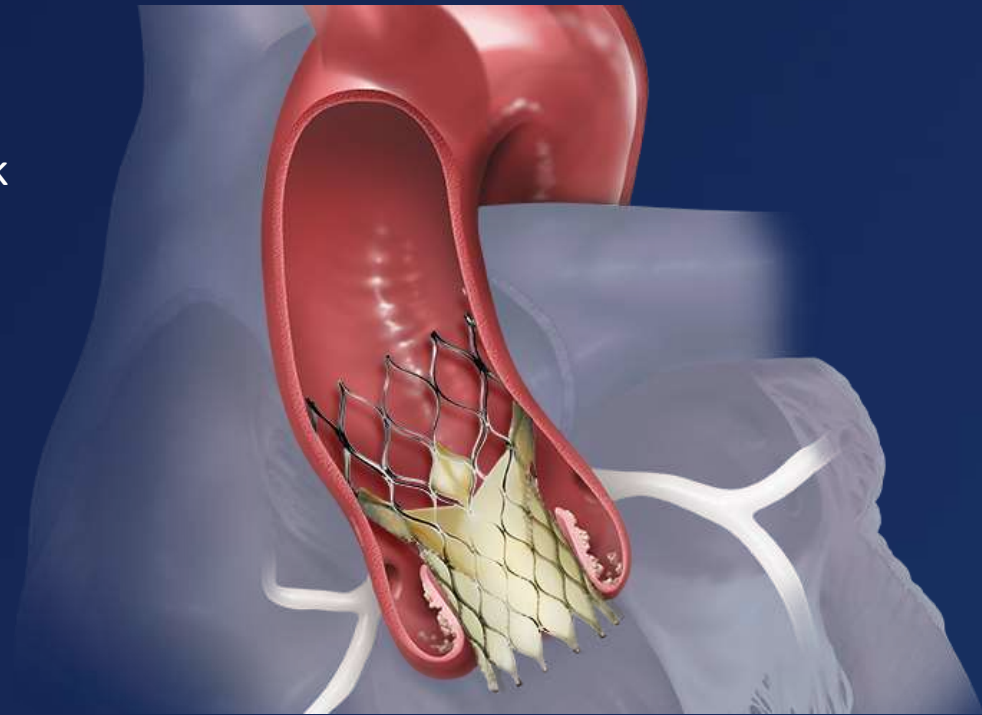


Patients at High Risk for Coronary Obstruction

Evolut R Can Be Completely Recaptured and Repositioned in Emergency Situation

Medtronic recommends implantation in patients with coronary ostia height ≥ 14 mm, however the self-expanding valve may still be a better choice in patients at high risk for 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



Recapturability and when it is important?

Patients With Stented Left Main and Valve in Valve
Patients

Patients With Stented Left Main and Valve-In-Valve Patients

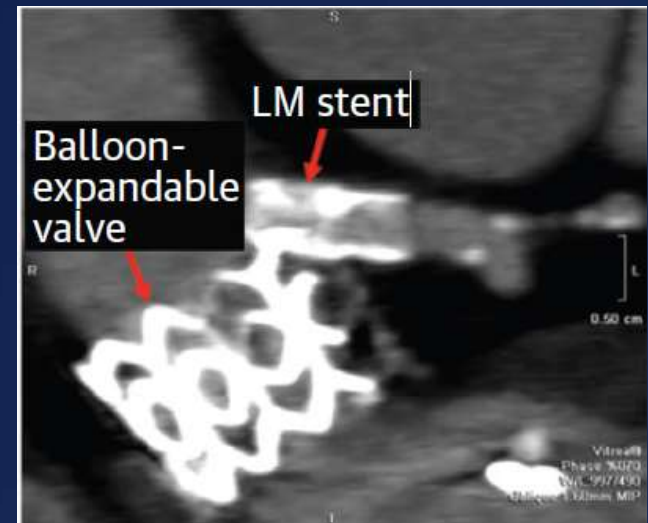
Implantation of a TAV could result in impingement or other physical interaction with stents pre-existing in the left main¹.

Advantages of Evolut R valve:

- Tapered shape of the frame diminishes the risk of interaction
- Evolut R can be recaptured and repositioned if a physical interaction between the devices occurs

Positioning Accuracy is key to achieving optimal outcome in Valve-in-valve patients while avoiding coronary occlusion.

- Evolut R can be recaptured and repositioned for accurate placement



Impact of Evolut R On Alternative Access

More Patients with Small Vasculature Can Safely
Be Treated Transfemorally

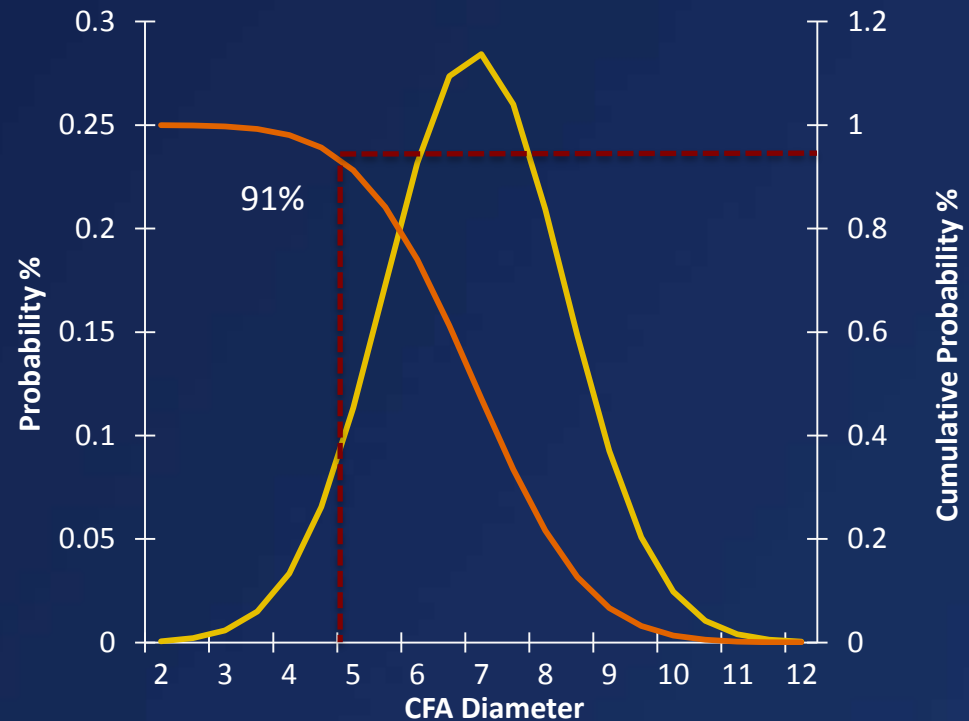
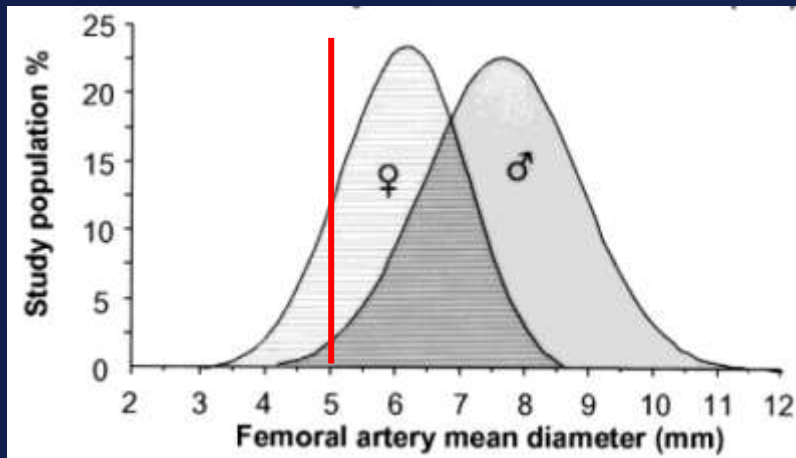
Minimal Femoral Artery Diameter

How Many Patients Can We Treat Transfemorally?

Common Femoral Artery was measured by angiography in 200 patients

	All (n=200)	Women (n=79)	Men (n=121)
Mean Lumen Diameter (mm)	6.9 ± 1.4	5.1 ± 1.1	6.3 ± 1.2

- ~74% of patients have CFA ≥6 mm
- ~91% of patients have CFA ≥5 mm



EnVeo R Delivery System

14 Fr-Equivalent System with InLine Sheath

Minimum artery diameter is 5.0 mm across all valve sizes



Contemporary Delivery Systems

Indicated Vessel Size

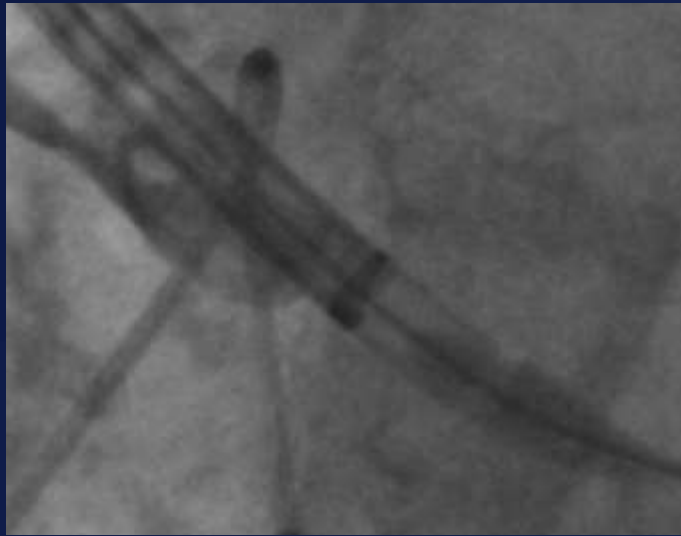
Evolut R has the potential to reach 17% more patients due to its low profile

	 SAPIEN XT			 SAPIEN 3		 Lotus	 CoreValve	 Evolut R
Valve Size (mm)	20, 23	26	29	20, 23, 26	29	23, 25, 27	23, 26, 29, 31	23, 26, 29
Indicated Vessel Diameter (mm)	6.0	6.5	7.0	5.5	6.0	6.0	6.0	5.0

Evolut R In Horizontal Anatomy

Self-Centering Can Help Evolut R Achieve Optimal Outcome In More Horizontal Anatomy, But Need To Pay Attention To Orientation

Hat Marker Orientation Can Be Used to Achieve Self-Centering Even In More Horizontal Anatomy



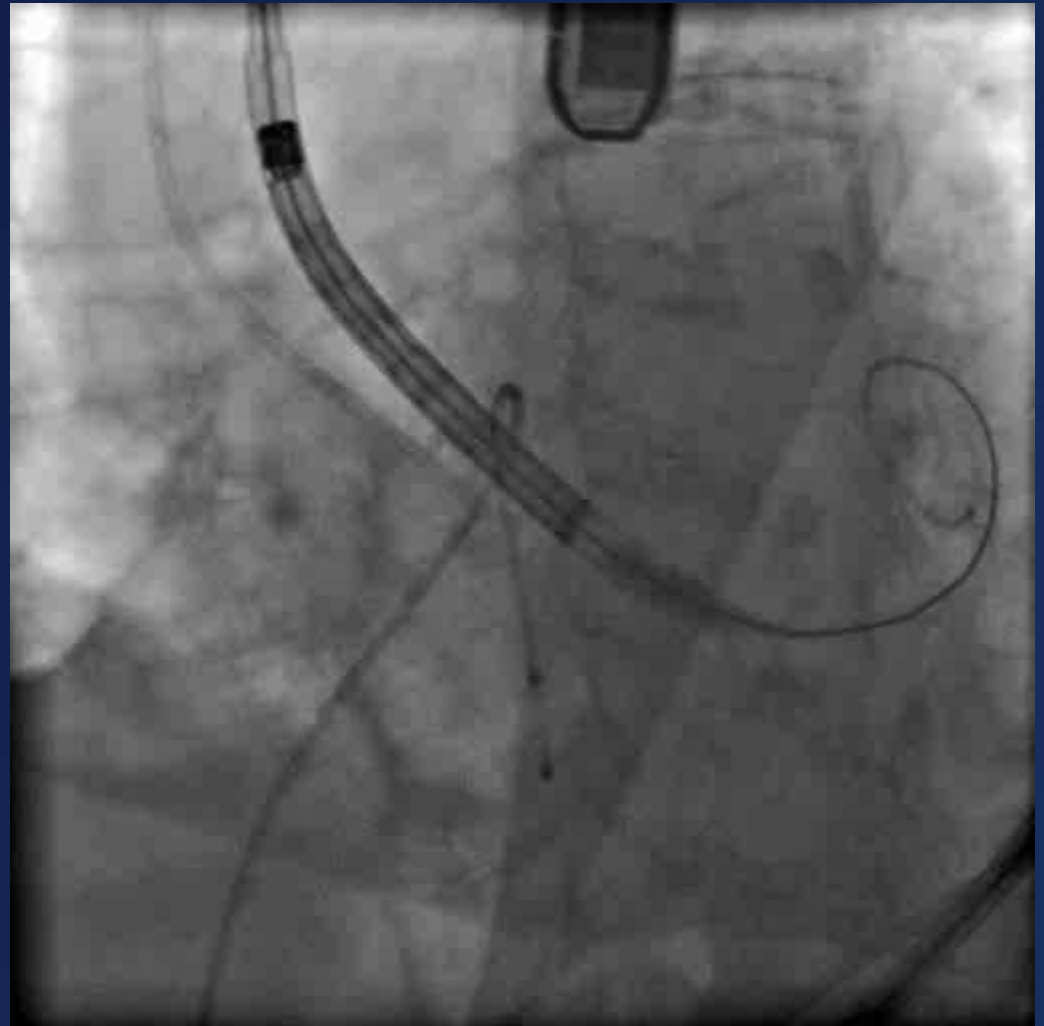
- Initial Hat Marker Position:



- DCS Alignment:



- Result:
 - Optimal alignment for self-centering



Evolut R Evidence Summary:
Does Real World Experience Match The
Outcomes From The Evolut R Clinical Trials?

Evolut R Clinical Evidence

3 Bodies of Work

Evolut R CE Study^{1,2}



N = 60
Oct 2013 – July 2014
STS: $7.0 \pm 3.7\%$
Age: 82.8 ± 6.1 years
Female: 66.7%
Diabetes: 26.7%
COPD: 43.3%
PVD: 16.7%
Follow-up through 1 yr

Evolut R US Study³



N = 241
Sept 2014 – July 2015
STS: $7.4 \pm 3.4\%$
Age: 83.3 ± 7.2 years
Female: 68.5%
Diabetes: 32.4%
COPD: 54.0%
PVD: 34.9%
Follow-up through 30 d

TVT Registry⁴



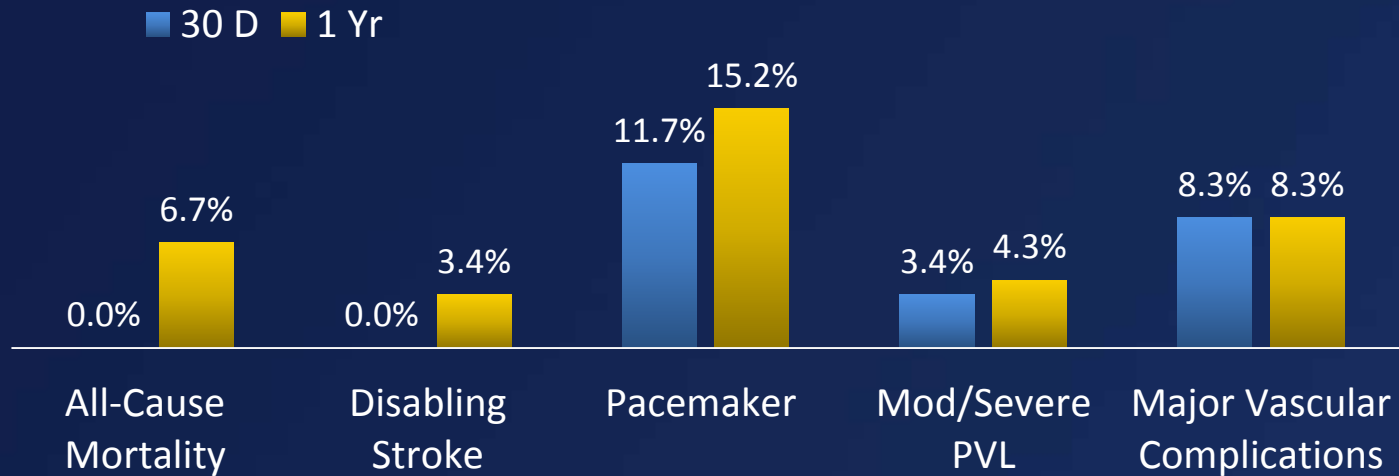
N = 771
July 2015 – Dec 2015
STS: $8.0 \pm 4.8\%$
Age: 81.2 ± 8.1 years
Female: 63.7%
Diabetes: 37.2%
COPD: 45.2%
PVD: 31.8%
Follow-up through 30 d

Evolut R Clinical Evidence

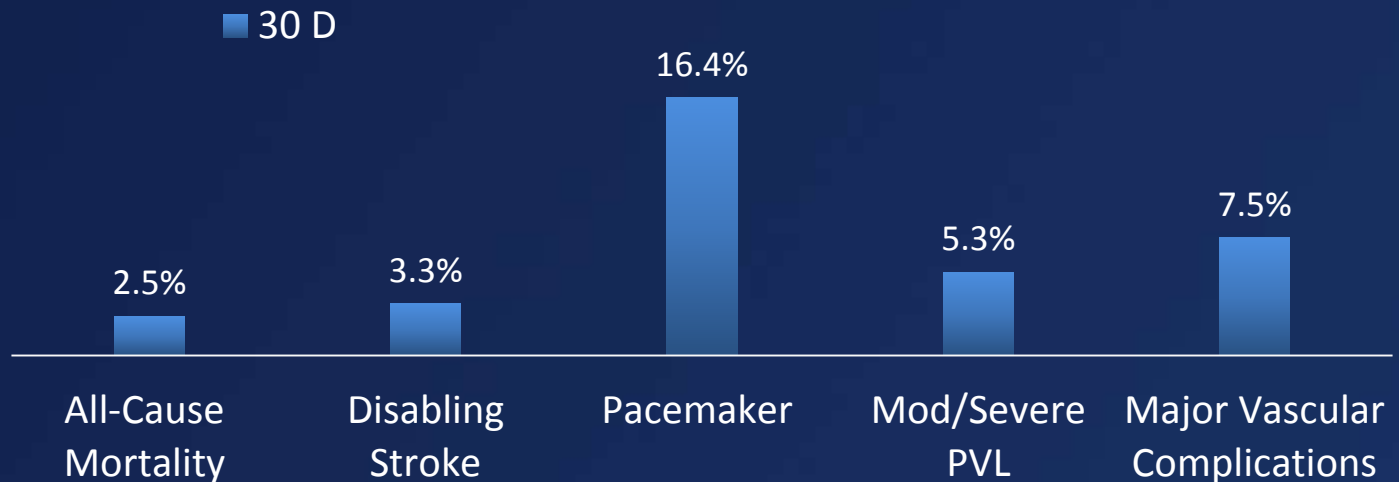
Medtronic-Sponsored Studies



Evolut R CE Study
N=60



Evolut R US Study
N=241



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

Evolut R Clinical Evidence

Medtronic-Sponsored Studies

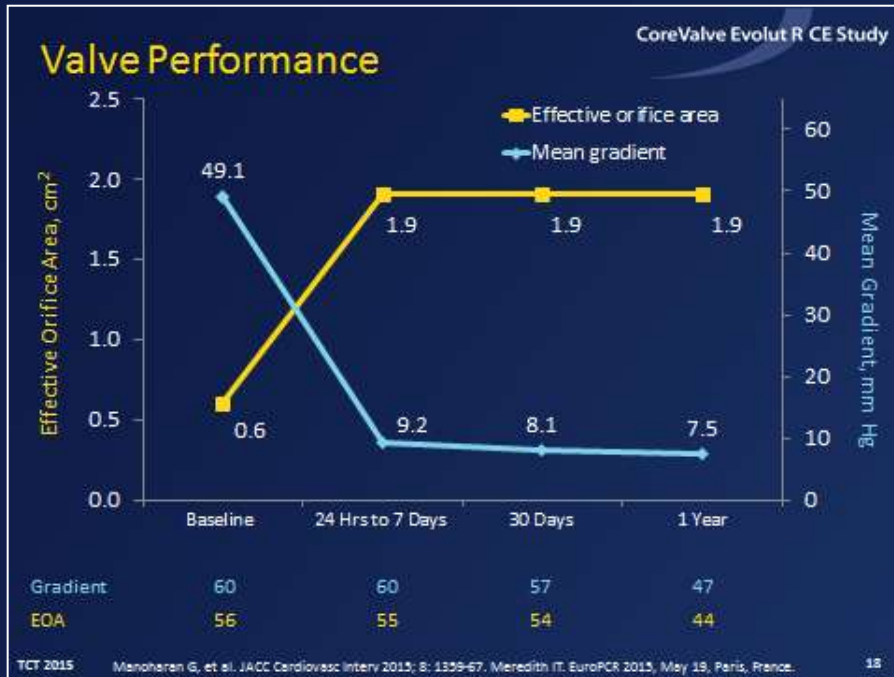
Forward-flow hemodynamics were exceptional in both studies



Evolut R CE Study
N=60



Evolut R US Study
N=241

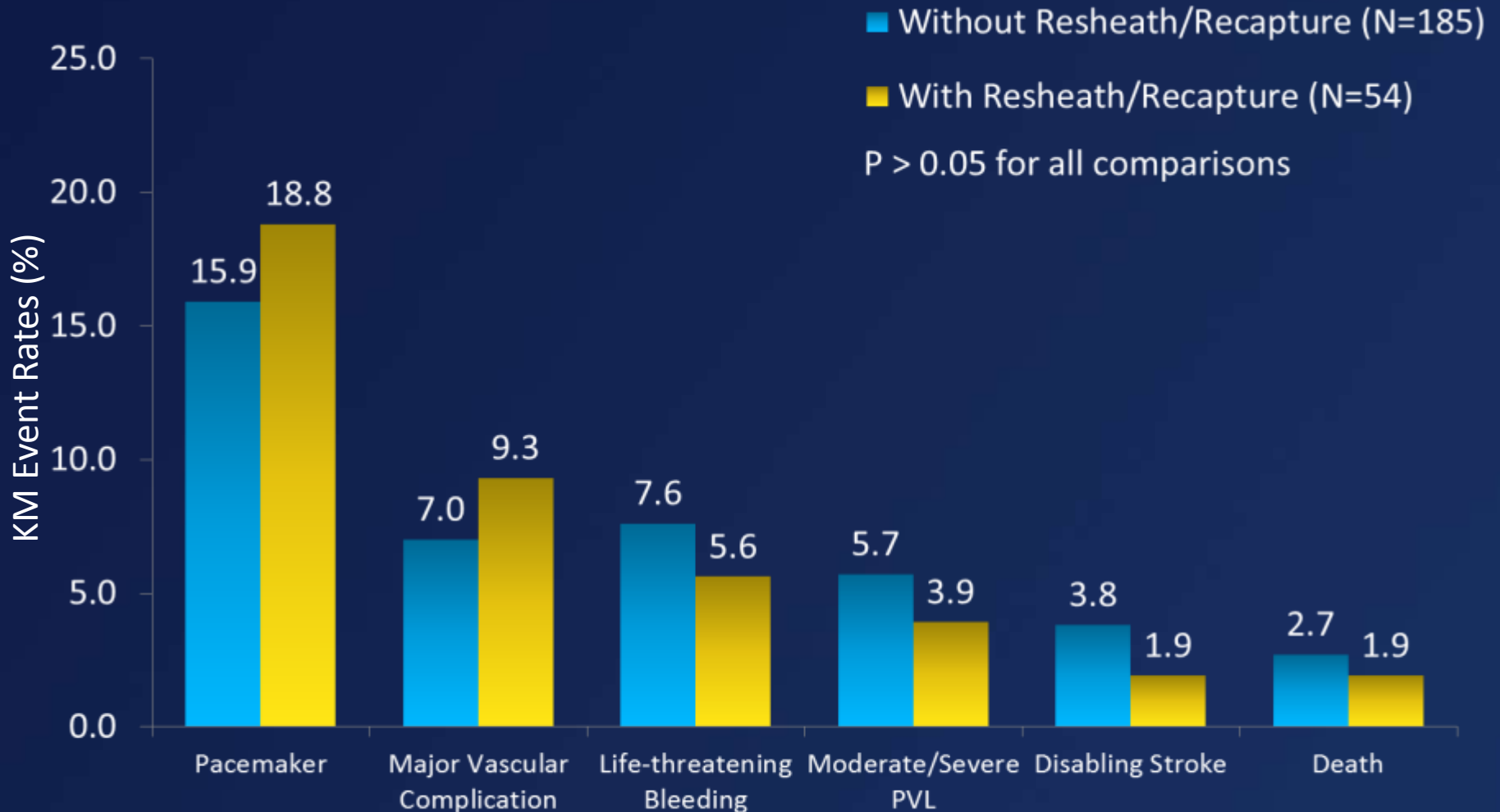


Outcomes at 30 Days by Resheath / Recapture



Evolut R US Study

Use of the resheath / recapture feature was safe and effective



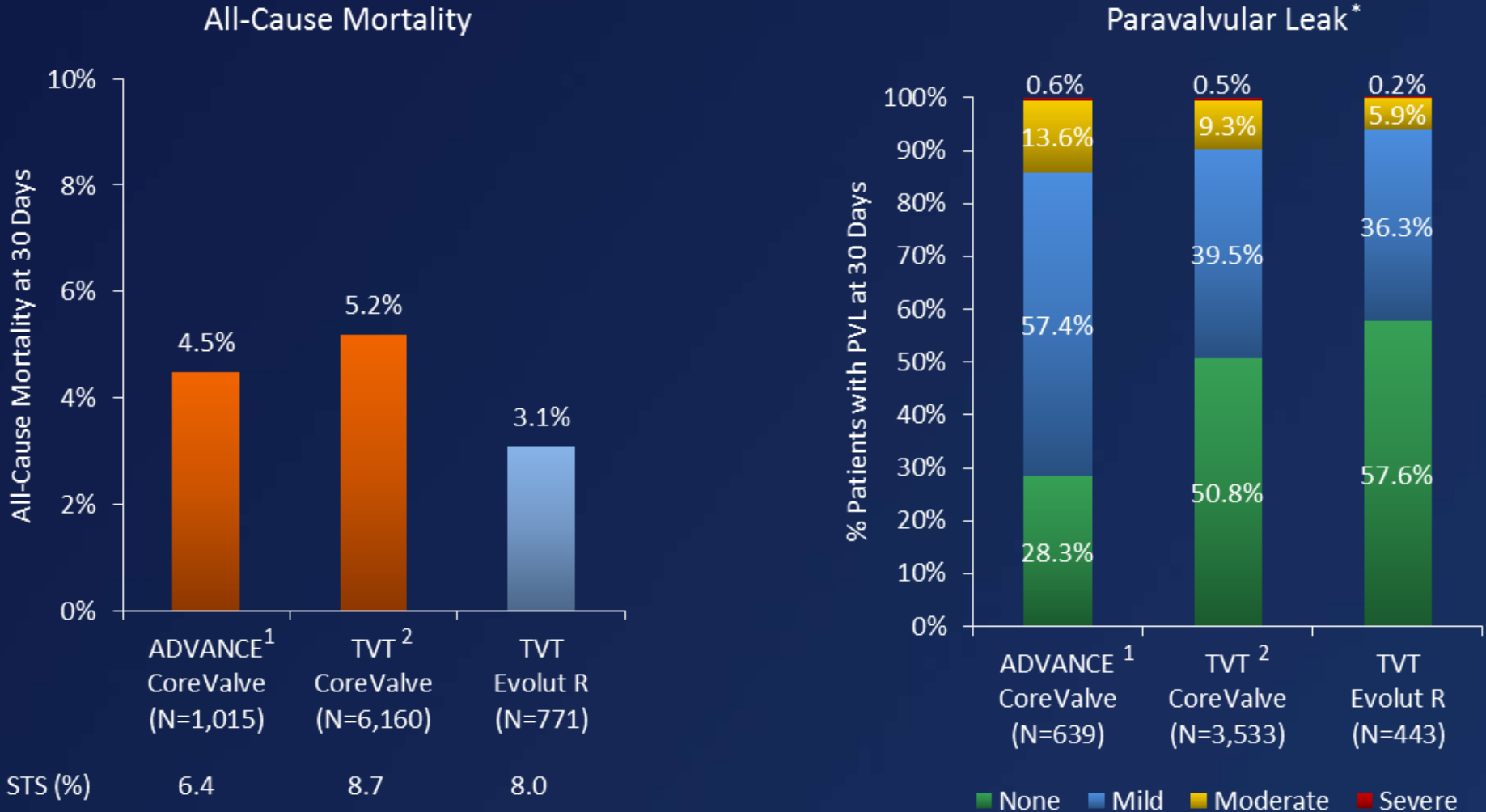
¹Williams, et al., presented at ACC 2016;

Evolut R Clinical Evidence



Commercial Experience in the TVT Registry

The first data on 771 patients show excellent outcomes in commercial practice



¹Linke, et al., *Eur Heart J* 2014; 35:2672-84; ²Popma, et al., presented at TCT 2015

*All data is site-reported

Summary

- Evolut R is built on the foundational self-expanding CoreValve platform, with a reduced delivery profile and the ability to recapture and reposition the valve.
- Data is now available on over 1,000 patients treated with this system.
- In both the clinical trial and commercial settings, Evolut R brings:
 - Low 30-day all-cause mortality
 - Reduced paravalvular leak and permanent pacemaker rate
 - Exceptional forward-flow hemodynamic