

Searching for the Perfect Aortic Valve Mechanical Expanded Lotus Valve

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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

What is the PERFECT TAVI Device?

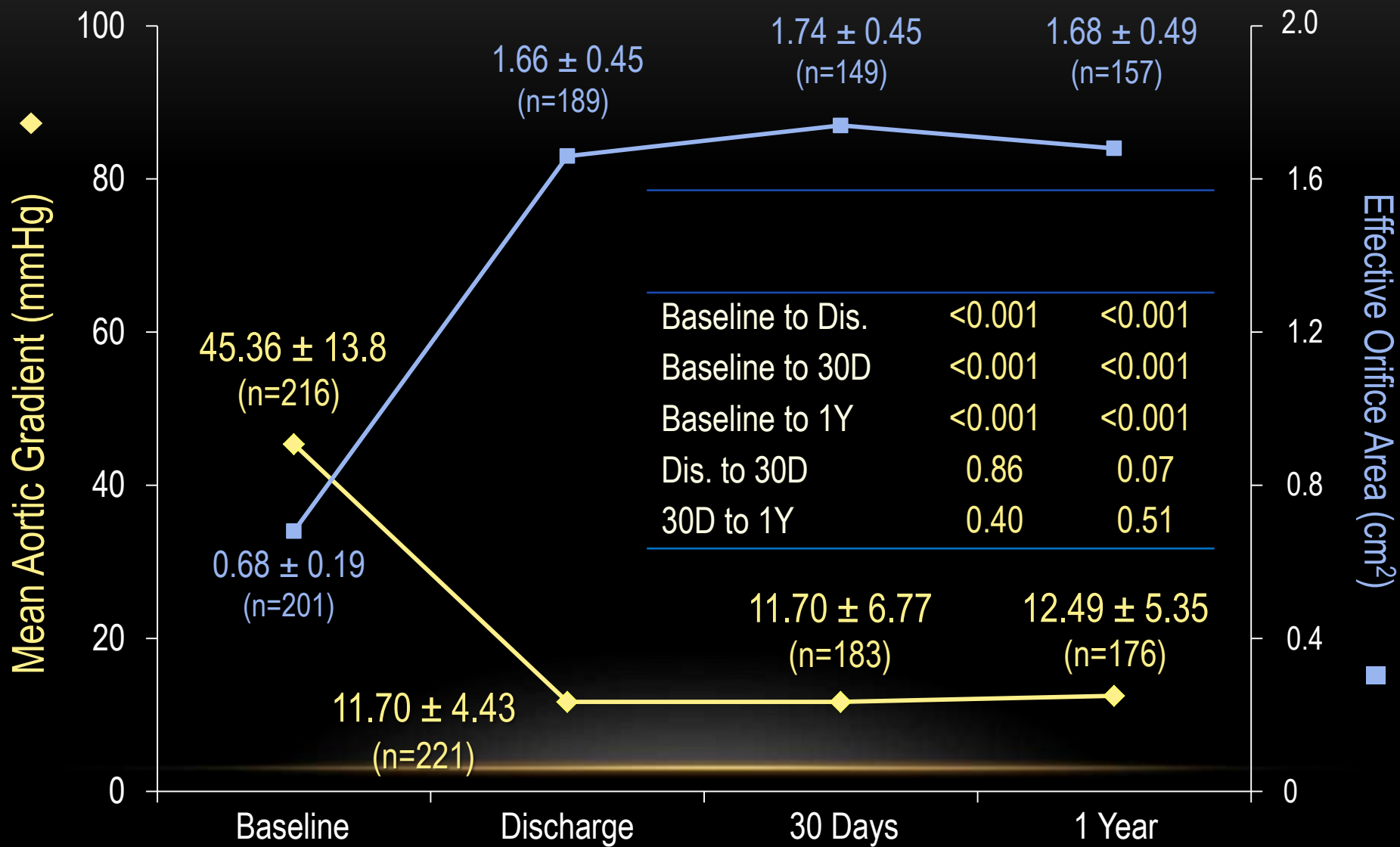
Checklist for the Perfect TAVI:

- Reduces Mean Aortic Valve Gradient <15 mm Hg
- Increases EOA
- Minimal Moderate and Severe PVL
- No Need for Rapid Pacing
- Repositionable and Retrievable
- Maintains Hemodynamic Stability Throughout Procedure
- Minimal Aortic Valve Malpositioning
- Long-term Durability
- Minimal Conduction Disturbances
- S&E in Intermediate / Low Risk Patients

HOW CLOSE IS THE CURRENT GENERATION OF
TAVI DEVICES TO PERFECTION?

REPRISE II with Extended Cohort (N=249; As Treated)

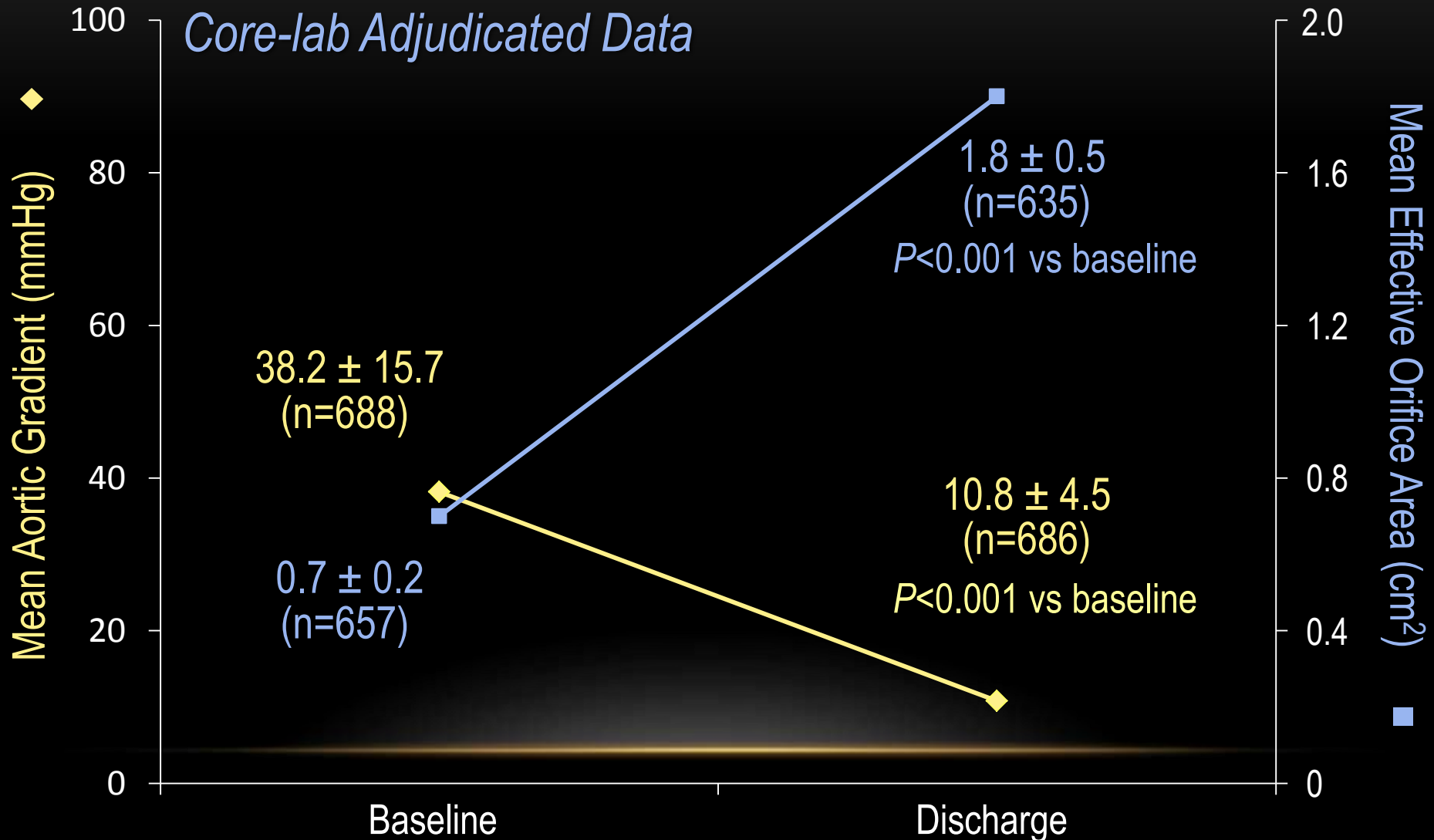
Mean Aortic Gradient & EOA



RESPOND 750-Patient Interim Analysis

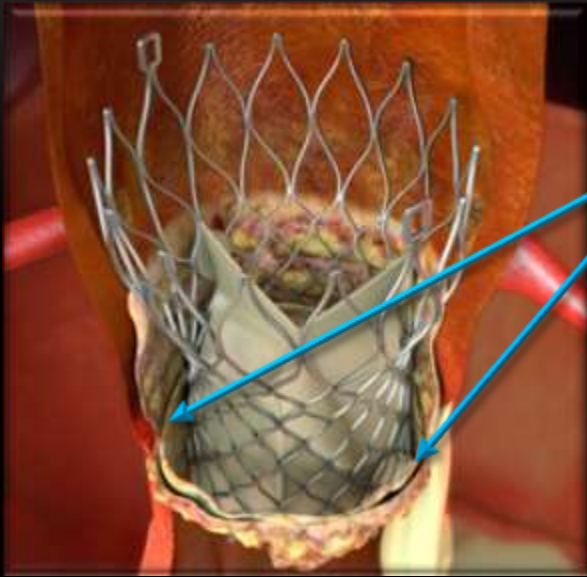
Mean Aortic Gradient & EOA

Core-lab Adjudicated Data



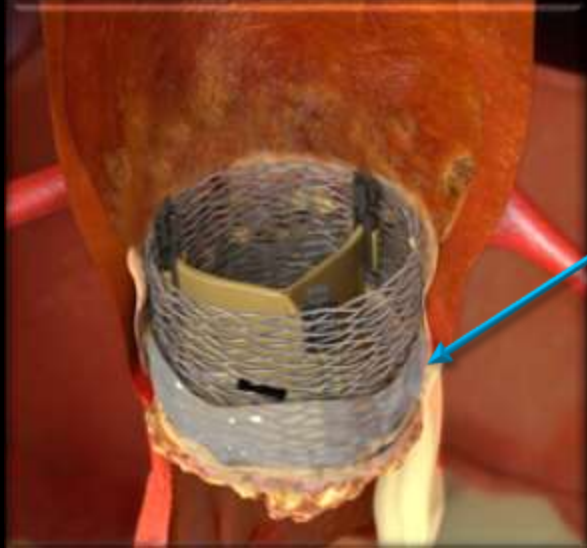
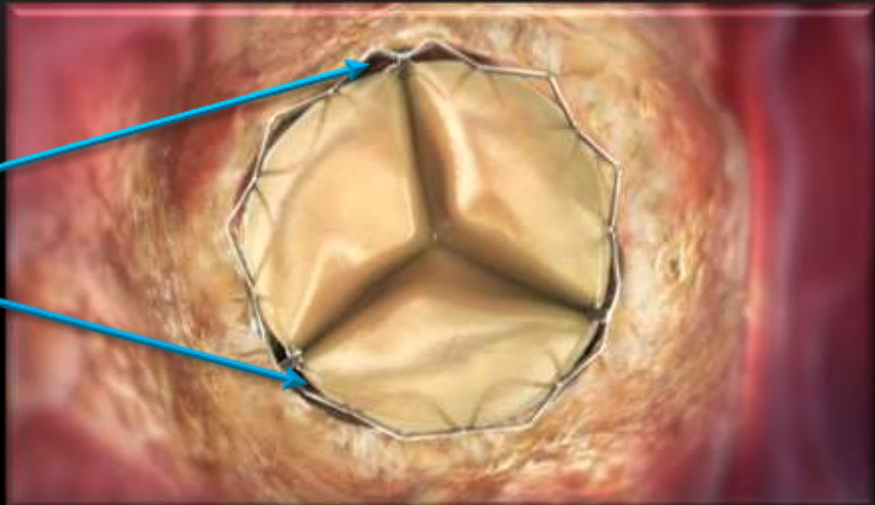
LOTUS VALVE SYSTEM DESIGN GOALS

MINIMIZE PARAVALVULAR LEAK (PVL)

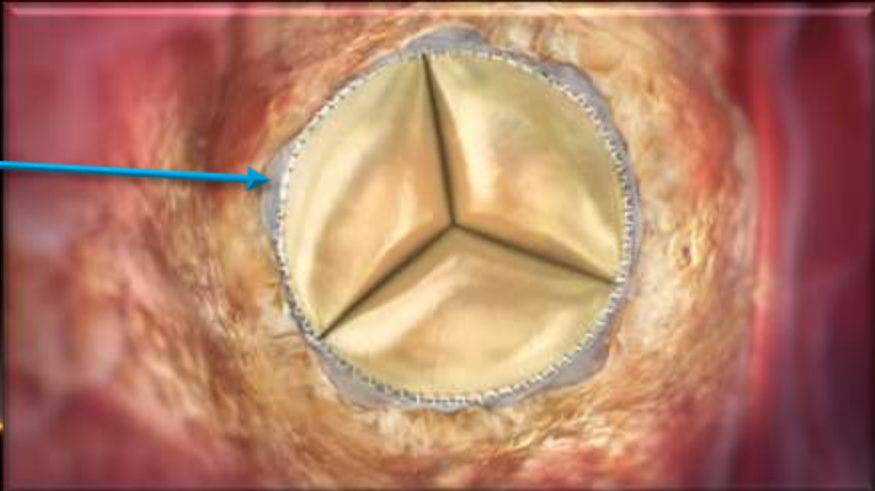


Non-circular
Annulus
+
Irregular
Calcification

PVL



Lotus Valve
Adaptive seal
to mitigate PVL



Repositioning with the Lotus Valve

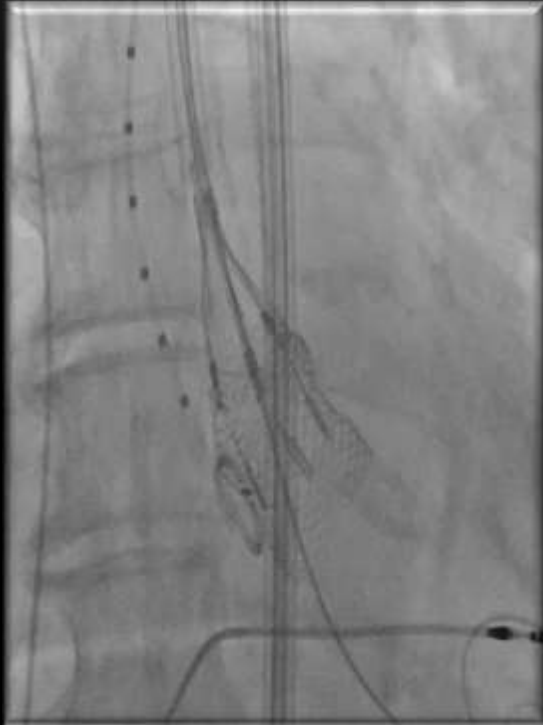
The Lotus Valve is resheathed prior to repositioning



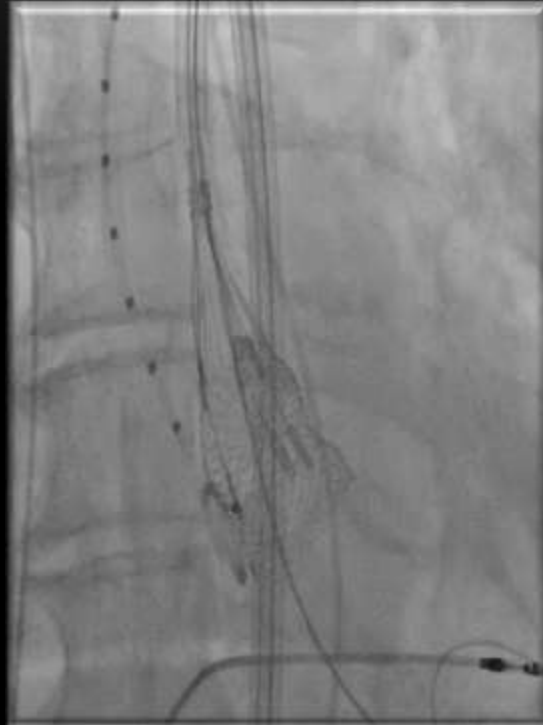
Lotus Valve Before Repositioning

Lotus Case Example

25mm Lotus Valve repositioning to eliminate PVL



Moderate PVL initially
despite placement at
intended position



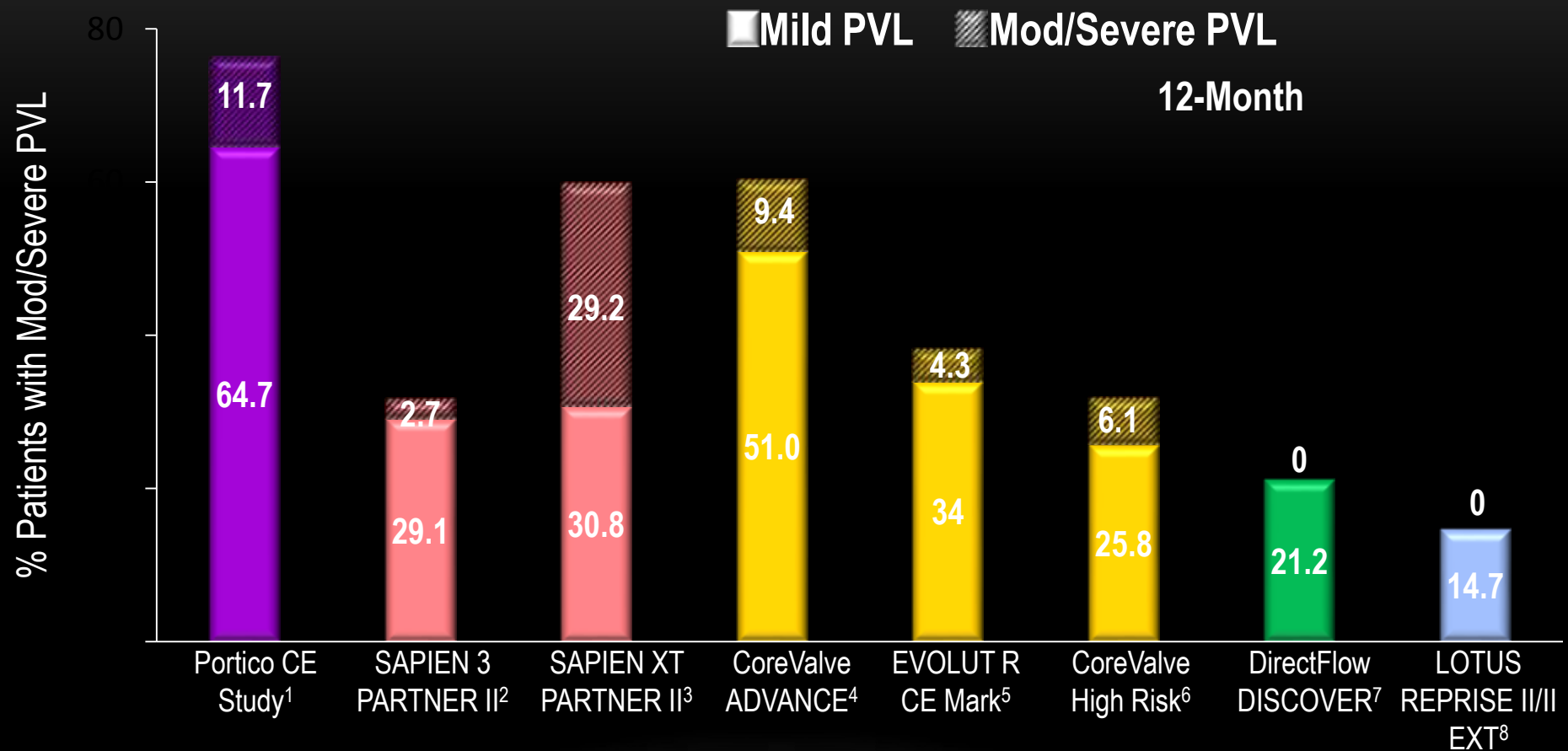
Repositioning
Still mild PVL due to
heavily calcified LVOT



Final repositioning
No PVL

12-Month Moderate & Severe PVL

TAVI Clinical Trials



STS Score:	NA	8.6	10.3	5.3	7.0	7.3	9.7	6.5
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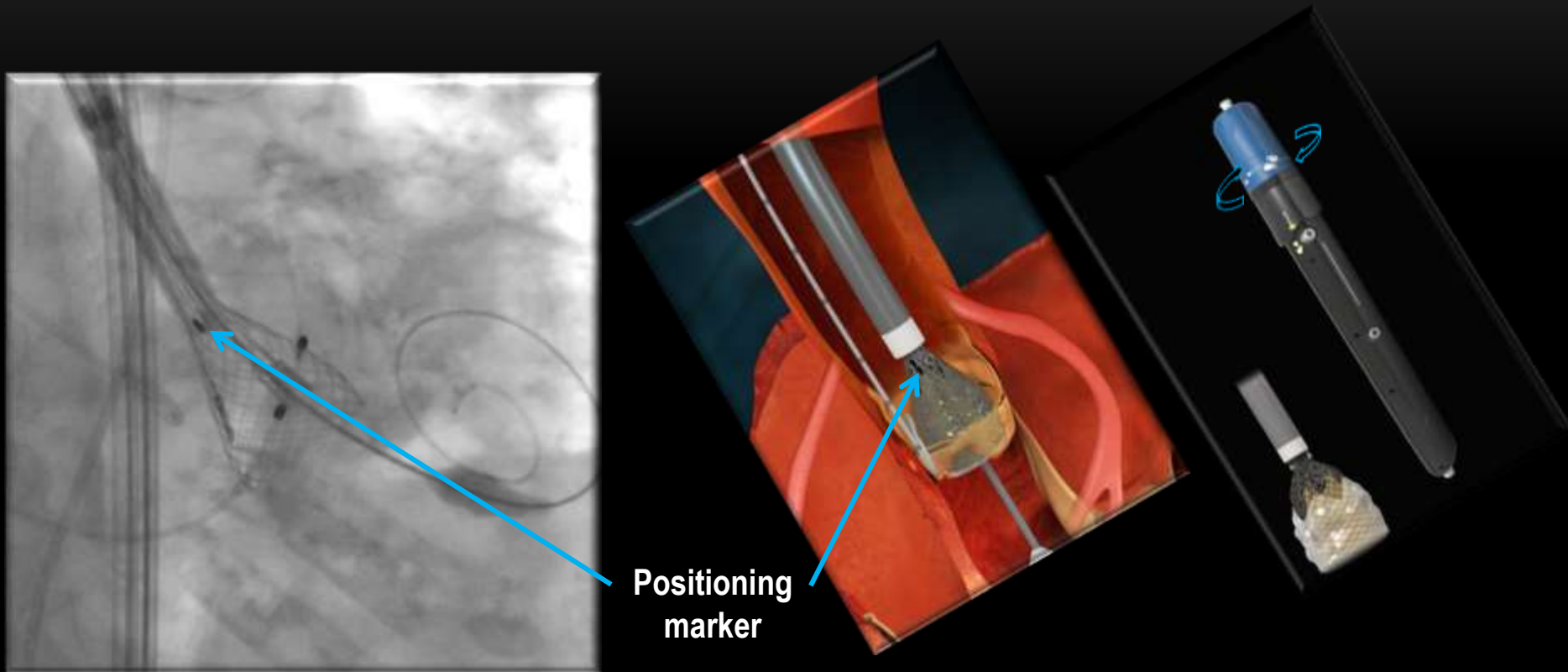
N:	34	364	284	996	47	390	66	163
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Results from different studies are not directly comparable. Information provided for educational purpose only.

¹Leon M, ACC 2013. ²Hermann, TCT 2015. ³Leon, NEJM 2010. ⁴Linke A, PCR 2014. ⁵Smith, NEJM 2011. ⁶Manoharan, TCT 2015. ⁷Popma J, JACC 2014. ⁸Ian Meredith, PCR LV 2015.

Lotus Valve Deployment: Unsheathing

Early function enables hemodynamic stability



Central radiopaque positioning marker guides placement. The Lotus Valve is functioning when 1/2 of the valve is unsheathed. Rapid pacing is not required.

Early function enables hemodynamic stability

Fluoro top view of Lotus Valve

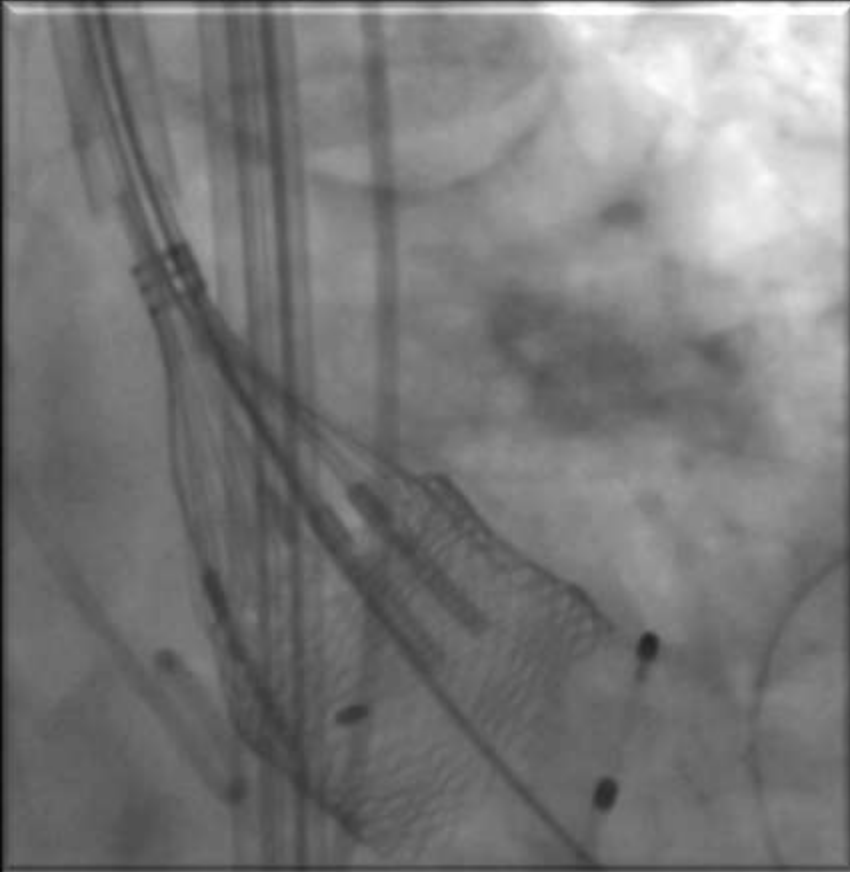
Boroscopic LVOT view of Lotus Valve



Lotus Valve Deployment in Benchtop Flow Model

Lotus Valve Deployment: Locking

Controlled, Accurate, and Predictable Positioning



Valve may be assessed in final locked position

Valve is locked but still FULLY repositionable & retrievable

REPRISE II WITH EXTENDED COHORT (N=250)

DEVICE PERFORMANCE

Successful access, delivery, deployment & system retrieval	98.8%*
Successful valve repositioning, if attempted (n=85)	100.0%
Partial valve resheathing (n)	71
Full valve resheathing (n)	14
Successful valve retrieval, if attempted (n=13)	92.3%*
Aortic valve malpositioning	0.0%
Valve migration	0.0%
Valve embolization	0.0%
Ectopic valve deployment	0.0%
TAV-in-TAV deployment	0.0%

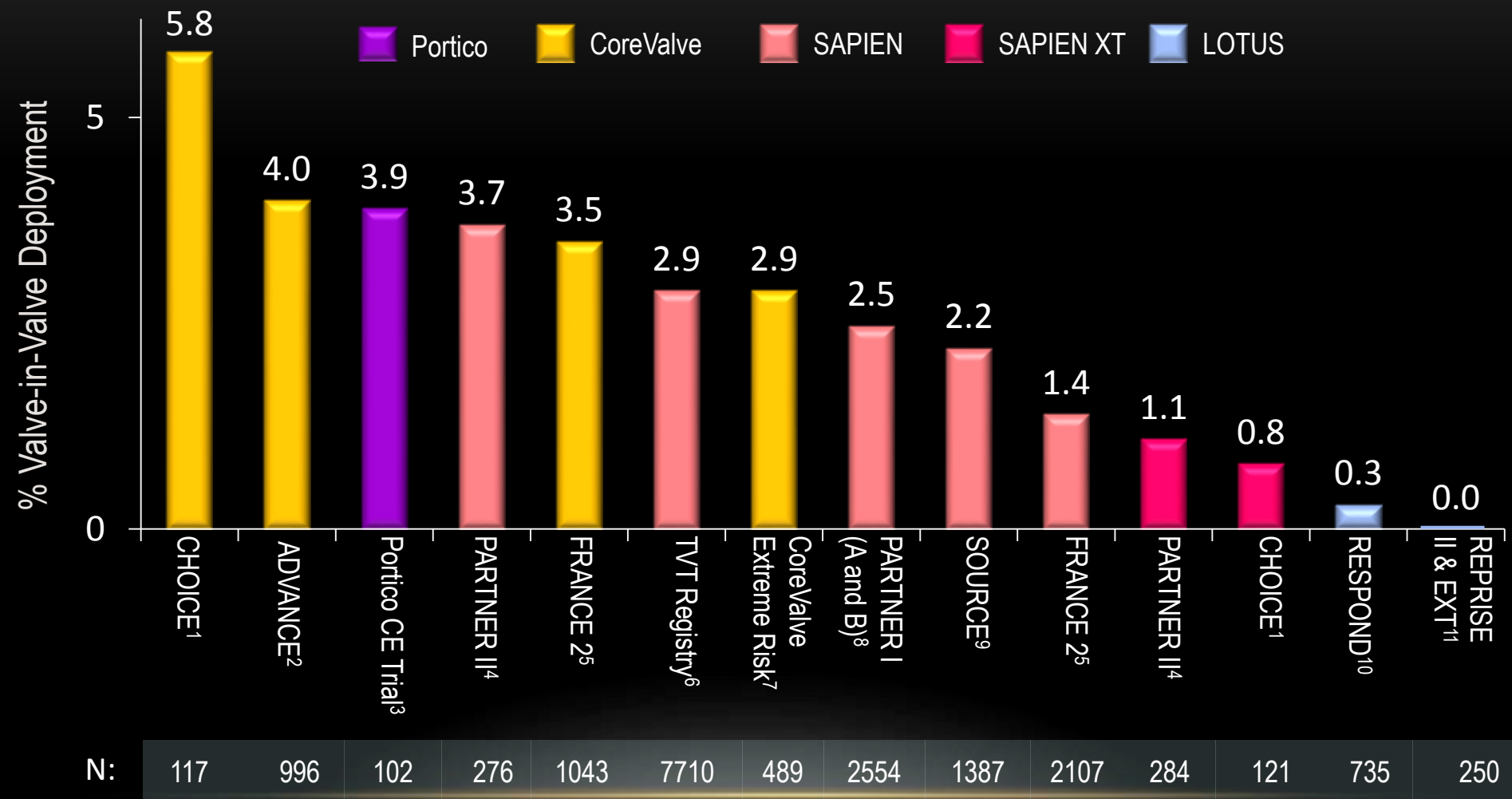
*2 intraprocedural complications occurred prior to valve deployment; 1 retrieval with incomplete retraction into delivery catheter but successfully removed. Lotus valve implanted 42 days afterwards in this patient.

RESPOND SAFETY ENDPOINTS – PERIPROCEDURAL

750-PATIENT INTERIM ANALYSIS (AS-TREATED POPULATION)

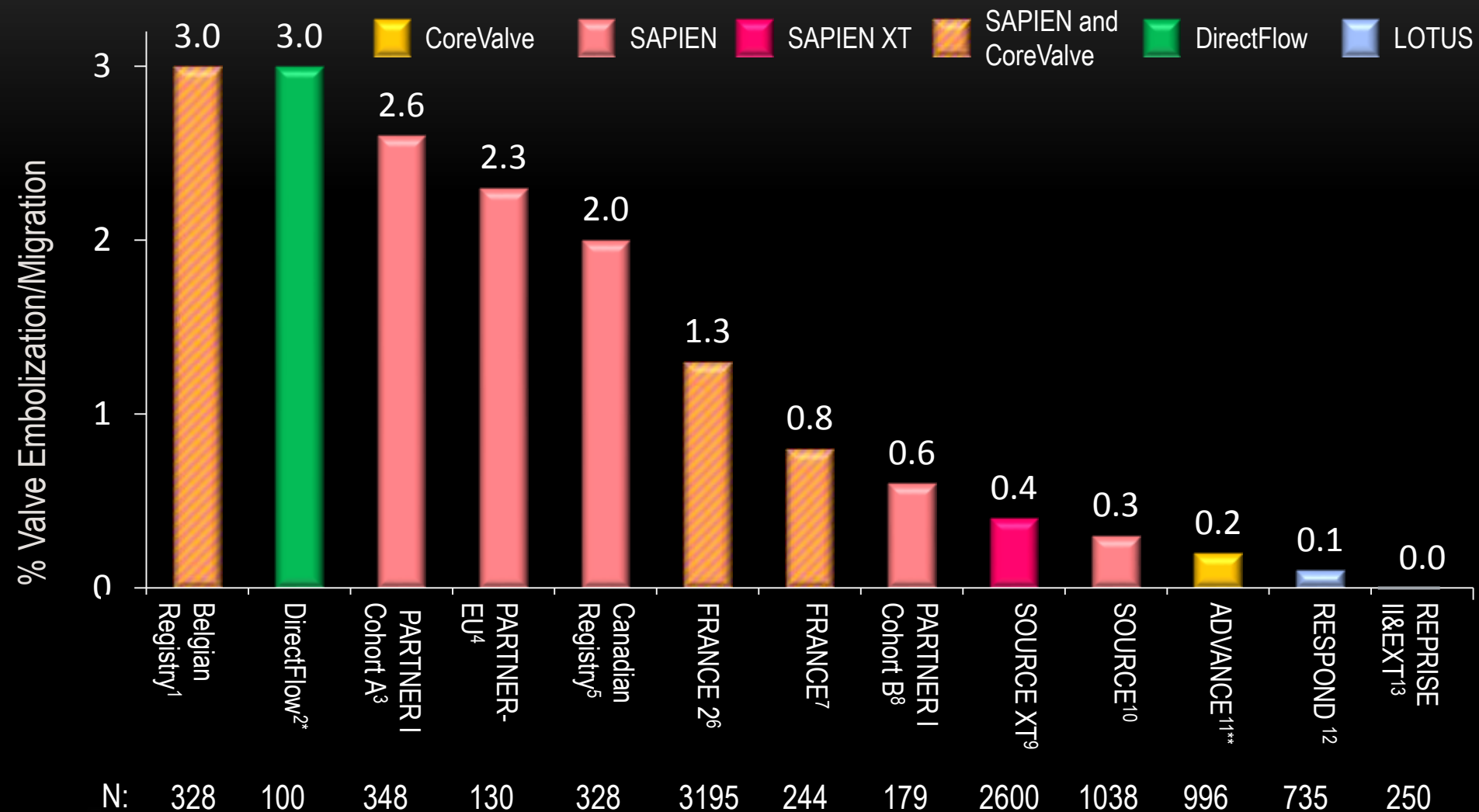
Coronary obstruction	0.1% (1/735)
Cardiac tamponade	0.7% (5/735)
Valve migration	0% (0/735)
Valve embolization	0.1% (1/735)
Ectopic valve deployment	0.1% (1/735)
TAV-in-TAV deployment	0.3% (2/735)

VALVE-IN-VALVE DEPLOYMENTS TAVI CLINICAL TRIALS AND REGISTRIES



¹ Abdel-Wahab, JAMA 2014. ² Linke, et al. EHJ, March 2014. ³ Makkar, Presented at TVT 2014. ⁴ Leon, et al. TCTMD online. ⁵ Van Belle, et al. *Circulation* 2014. ⁶ Mack, et al. JAMA 2013. ⁷ Reardon, et al. *J Thor and Cardiovasc Surgery* 2014. ⁸ Makkar, et al. JACC 2013. ⁹ Thomas, et al. *Circulation* 2011. ¹⁰ Van Mieghem, ACC 2016. ¹¹ Meredith, PCR LV 2014.

VALVE EMBOLIZATION / MIGRATION TAVI CLINICAL TRIALS AND REGISTRIES

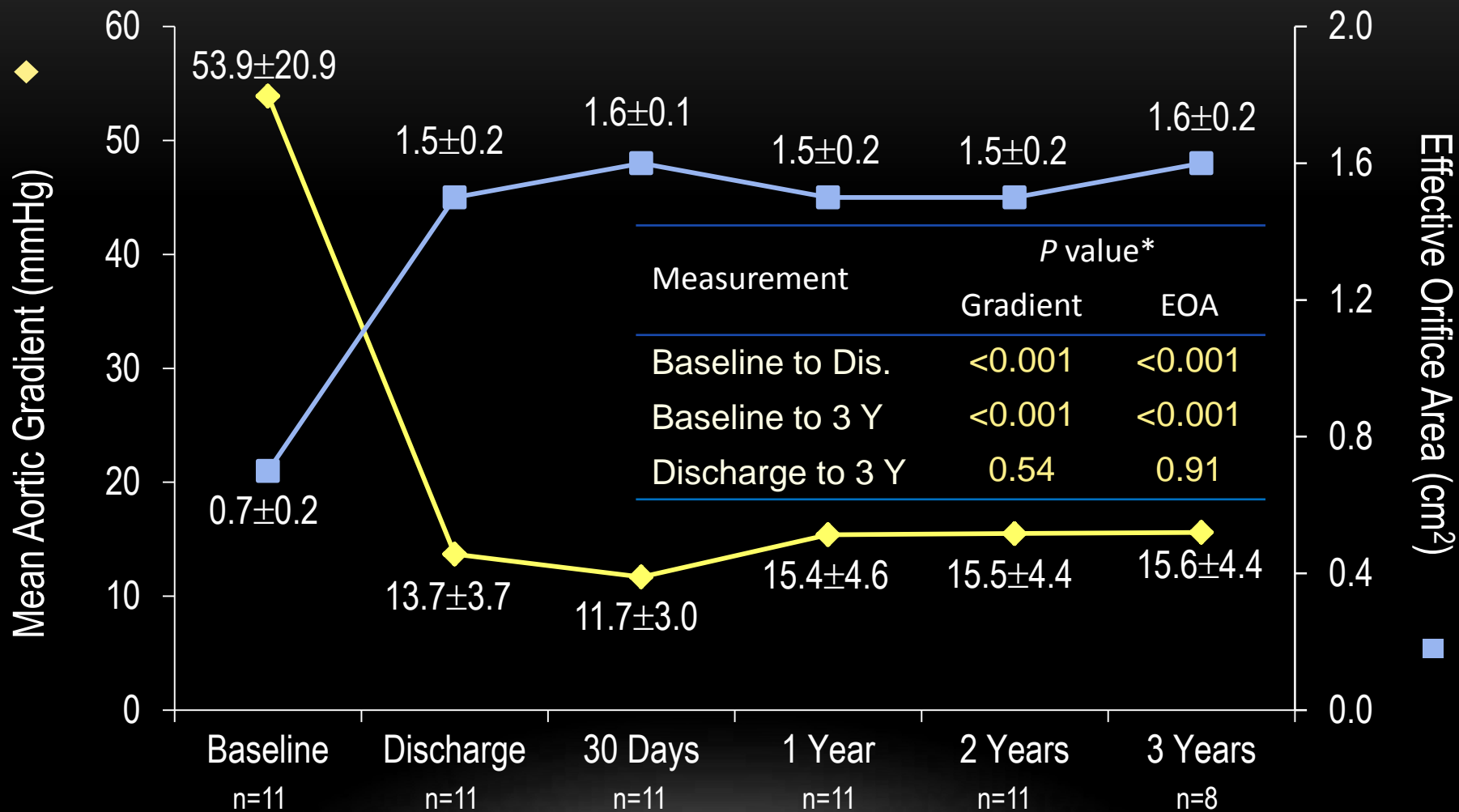


¹Bosmans, et al. *ICTS* 2011, ²Schofer, et al. *JACC* 2014., ³Smith, et al. *NEJM* 2011., ⁴Lefevre, et al. *Eur Heart J* 2011., ⁵Rodes-Cabau, et al. *J Am Coll Cardiol* 2010., ⁶Gilard, et al. *N Engl J Med.* 2012., ⁷Eltchaninoff, et al. *Eur Heart J.* 2011., ⁸Leon, et al. *N Engl J Med.* 2010., ⁹Wendler O, et al. *Eur J Cardio-Thoracic Surg* 2013. ¹⁰Thomas, et al. *Circulation* 2011., ¹¹Linke, et al. *EHHJ*, March 2014., ¹²Van Mieghem, *ACC* 2016.

¹³Meredith, *PCR LV* 2014. *Includes valve embolization and need for surgery. **Only includes valve embolization

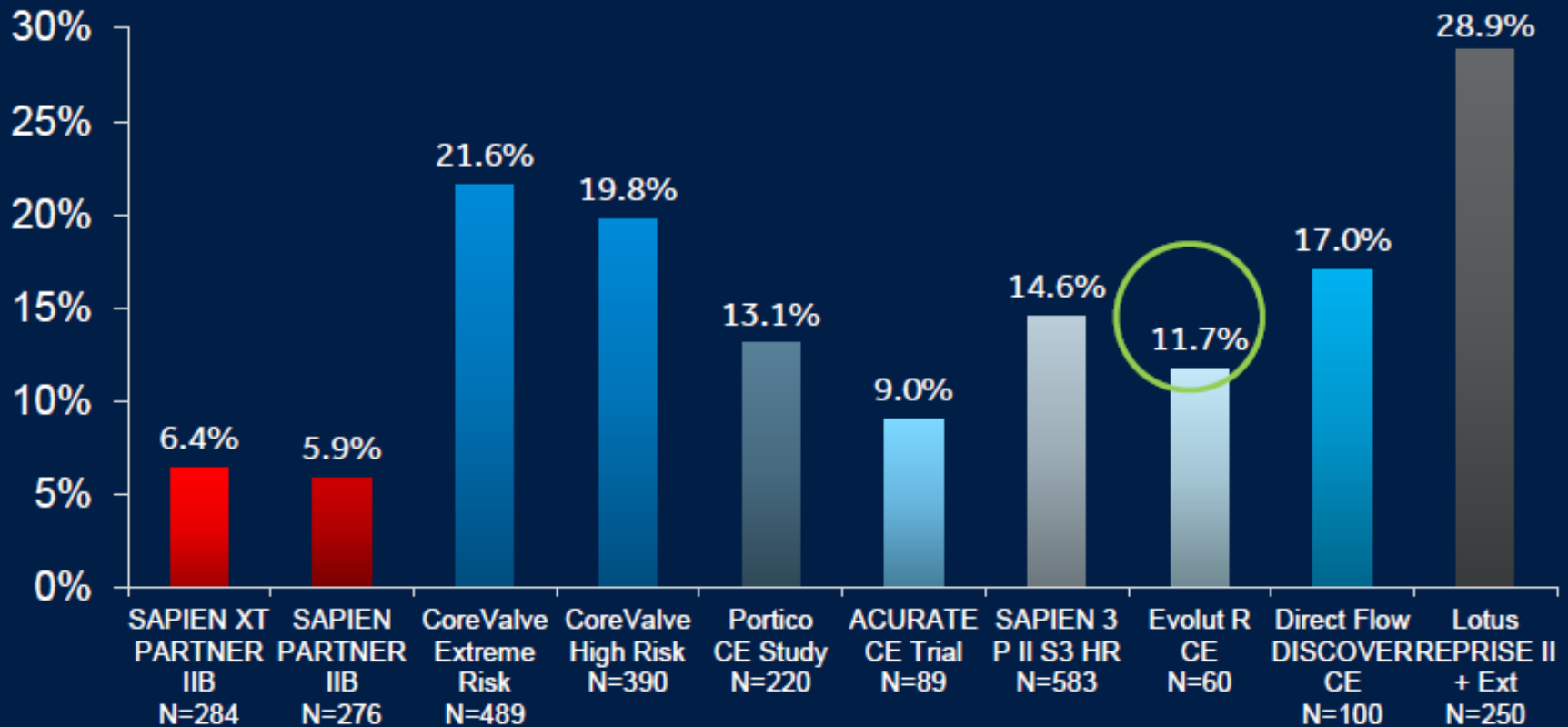
REPRISE I – VALVE HEMODYNAMICS TO 3 YEARS

MEAN AORTIC VALVE GRADIENT & EFFECTIVE ORIFICE BY PATIENT



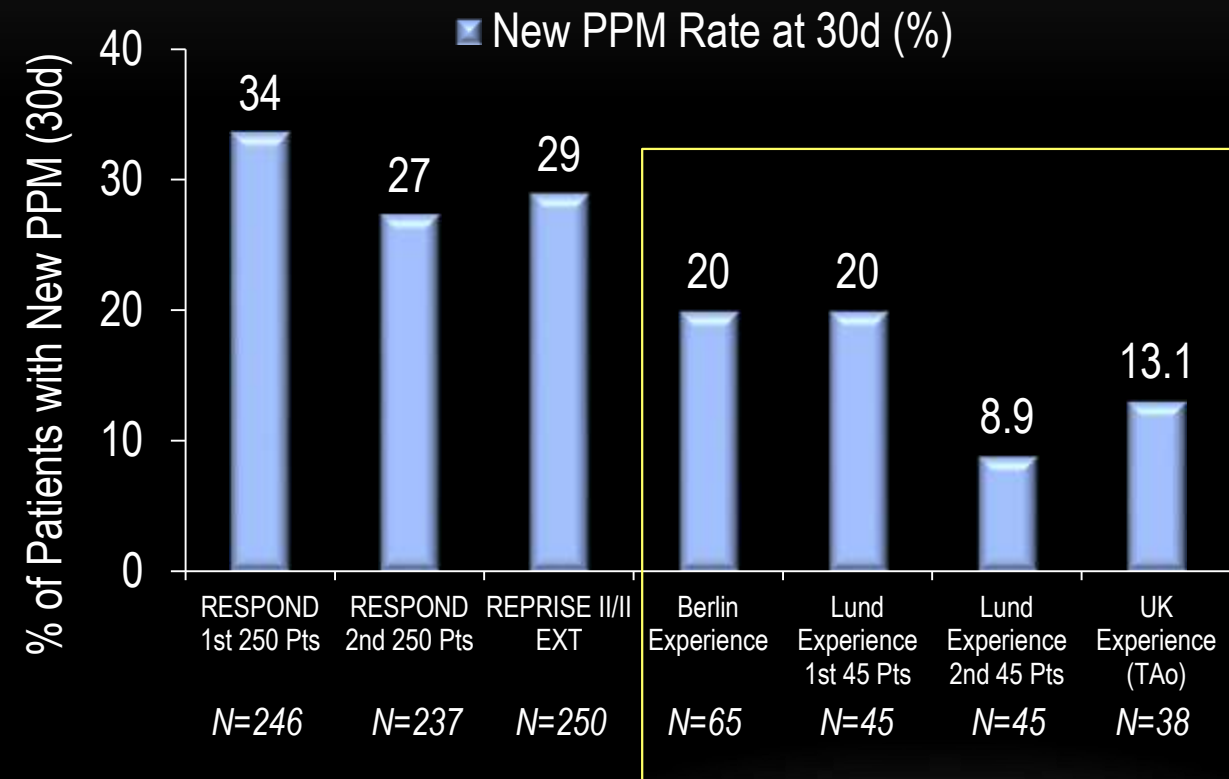
PPM RATES IN PERSPECTIVE

PERMANENT PACEMAKERS PACEMAKER RATE AT 30 DAYS



HOW MAY TECHNIQUE/PROTOCOL IMPACT PPM RATE?

RECENT EXPERIENCE FROM THREE CENTERS WITH THE LOTUS VALVE

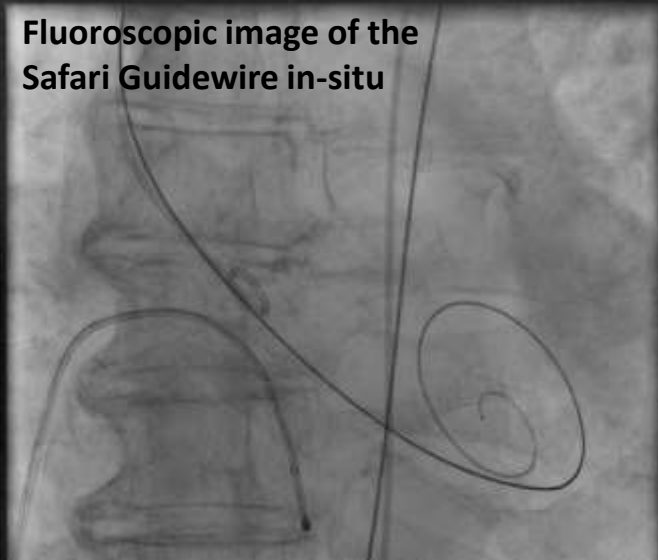


Possible contributors to reduction in PPM rate :

- Reduced valve interaction in LVOT during deployment
- Valve Sizing (5-10% of annular area)
- Normal Implant depth (4-6mm)
- Use of alternate access (TAo)

SAFARI²™ GUIDEWIRE DESIGN GOALS

Fluoroscopic image of the Safari Guidewire in-situ



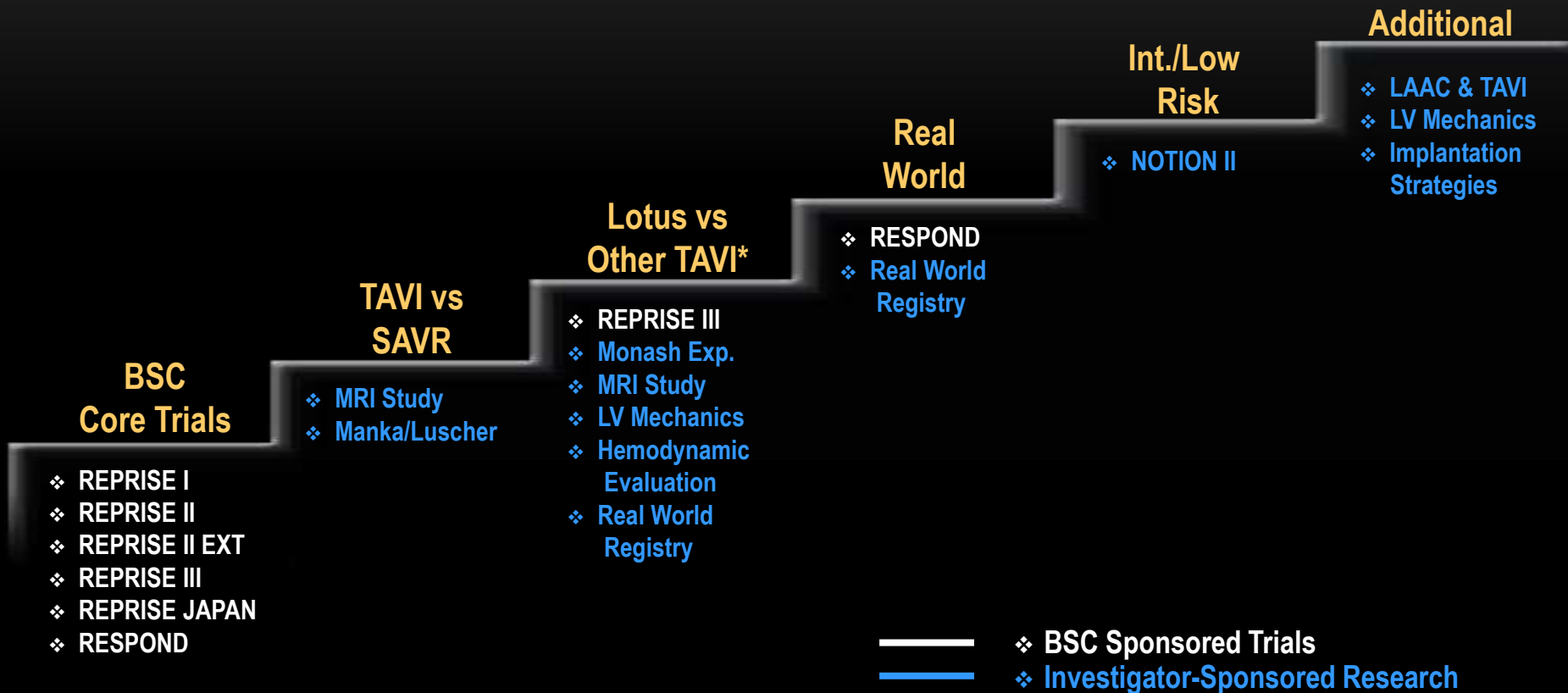
Graphic of Safari Guidewire positioned in the left ventricle



- Enhanced wire predictability, with superior shape retention
- Streamlined device delivery through optimized rail support
- Widest guidewire choice with three curve sizes

LOTUS CLINICAL TRIALS

ONGOING AND UPCOMING TRIALS



*Other TAVI includes: CoreValve, Evolut-R, S3, and SAPIEN XT

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Conclusion: No current generation valve meets all criteria

The search for perfection continues...

Lotus Valve	SAPIEN XT /S3	CoreValve /EVOLUT R	<u>Checklist for the Perfect TAVI:</u>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Reduce Mean Aortic Valve Gradient <15 mm Hg
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Increase EOA
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Minimal Moderate and Severe PVL
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	No Need for Rapid Pacing
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Repositionable and Retrievable
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Maintain Hemodynamic Stability Throughout Procedure
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Minimal Aortic Valve Malpositioning
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Long-term Durability
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Low Conduction Disturbances
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	S&E in Intermediate / Low Risk Patients

THANK YOU FOR YOUR KIND ATTENTION !