

Masters' Video Live Session II: Case-Based Transcatheter Valve Therapeutics

Lotus Valve

Minimization of Paravalvular Leak
with a Repositionable Next Generation TAVR Device

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Disclosure Information

The following relationships exist:

Grant support: Abbott, BSC, Edwards, WL Gore

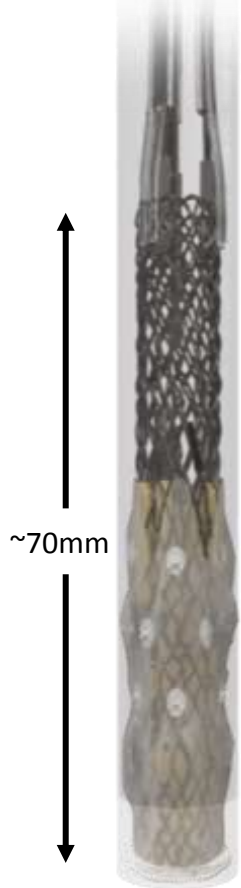
*Consultant: Abbott, BSC, Coherex, Edwards, JenaValve,
Diiachi Sankyo-Lilly, WL Gore*

*Off label use of products and investigational devices
will be discussed in this presentation*

Lotus Valve System

Controlled Mechanical Expansion

Valve elongated in catheter for delivery



Valve unsheathed into intermediate configuration



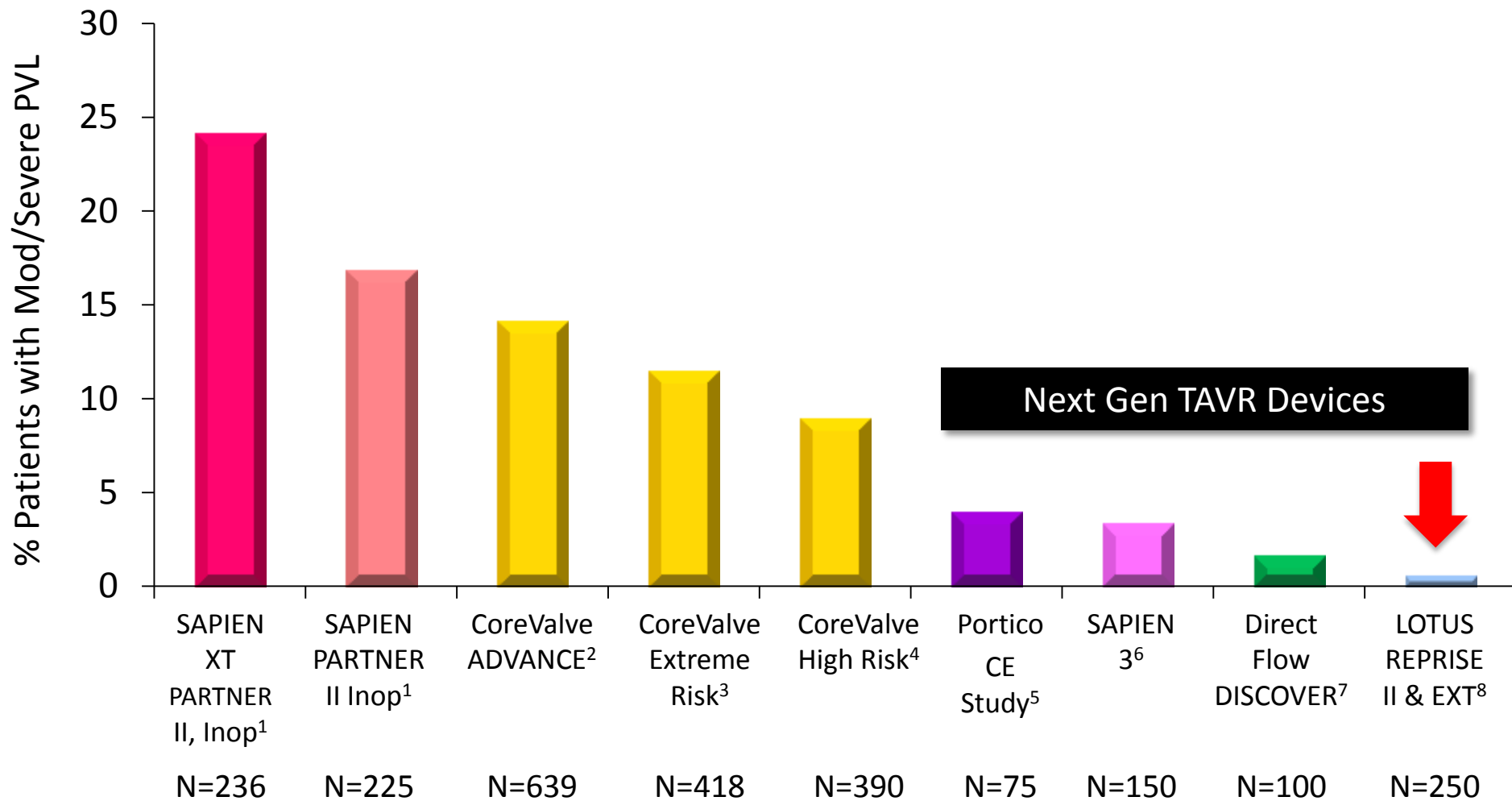
Valve expands radially as it shortens and locks into final configuration



- Valve deployed via controlled mechanical expansion
- No rapid pacing during deployment
- Valve functions early enabling controlled deployment
- **Ability to assess valve in final configuration before release**
 - Reposition to optimize outcomes
 - Change valve size if needed

1 Month Moderate & Severe PVL

Echo Core Lab Adjudicated Clinical Trials



¹North Shore, ²Linke A, PCR 2014. ³Popma J, JACC 2014; 63(19): 1972-81, ⁴Adams D, N Engl J Med 2014; 370: 1790-98
⁵Manoharan, et al. TCT 2014. ⁶Webb J, EuroPCR 2014. ⁷Schofer, JACC 2013. ⁸Meredith I, London Valves 2014

Lotus Valve System Overview

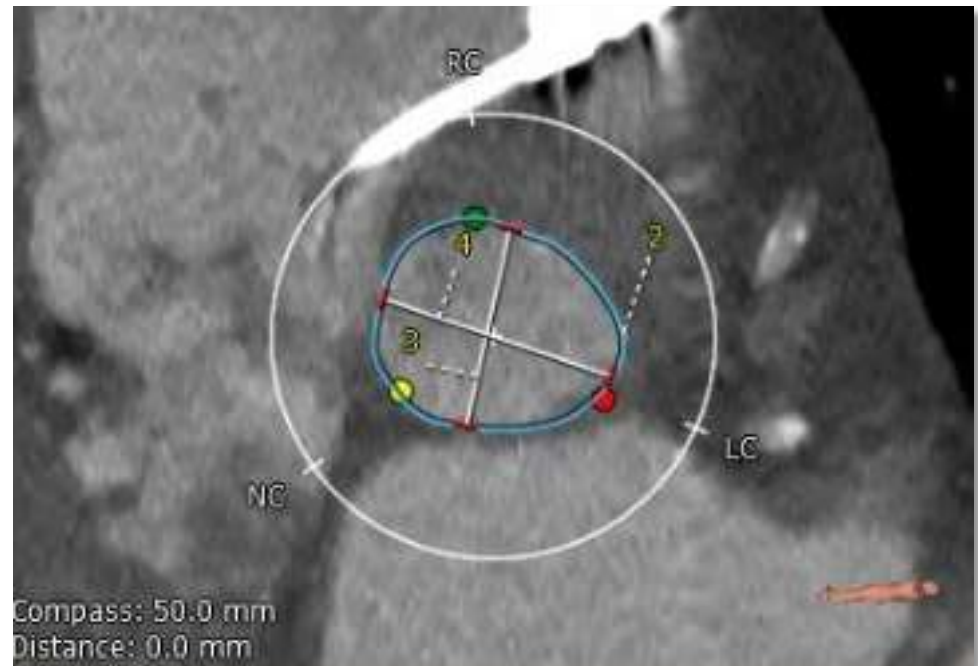


Unsheathing and resheathing the valve



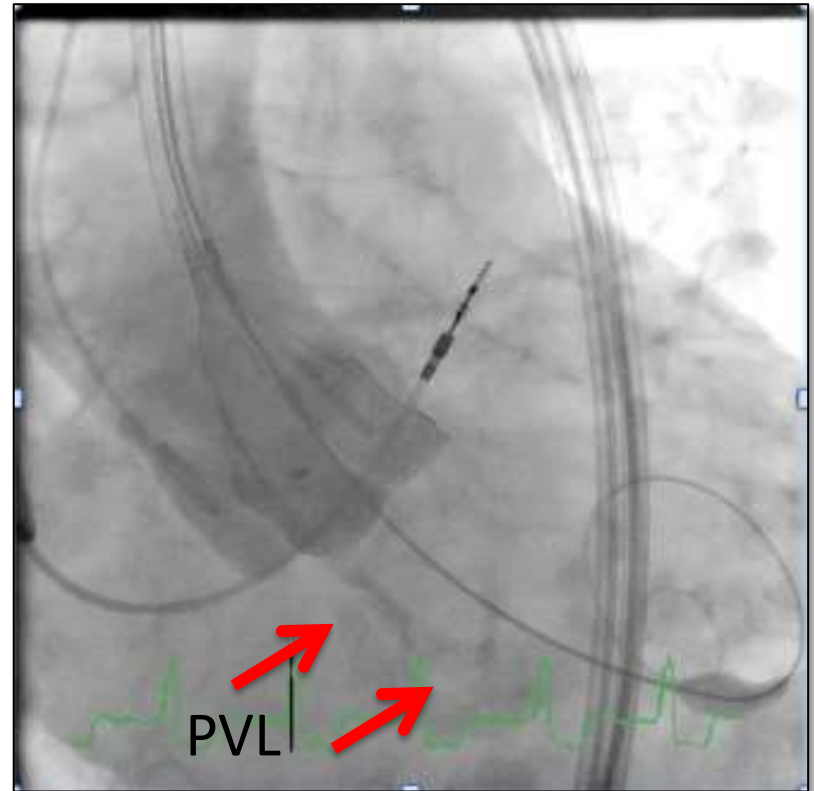
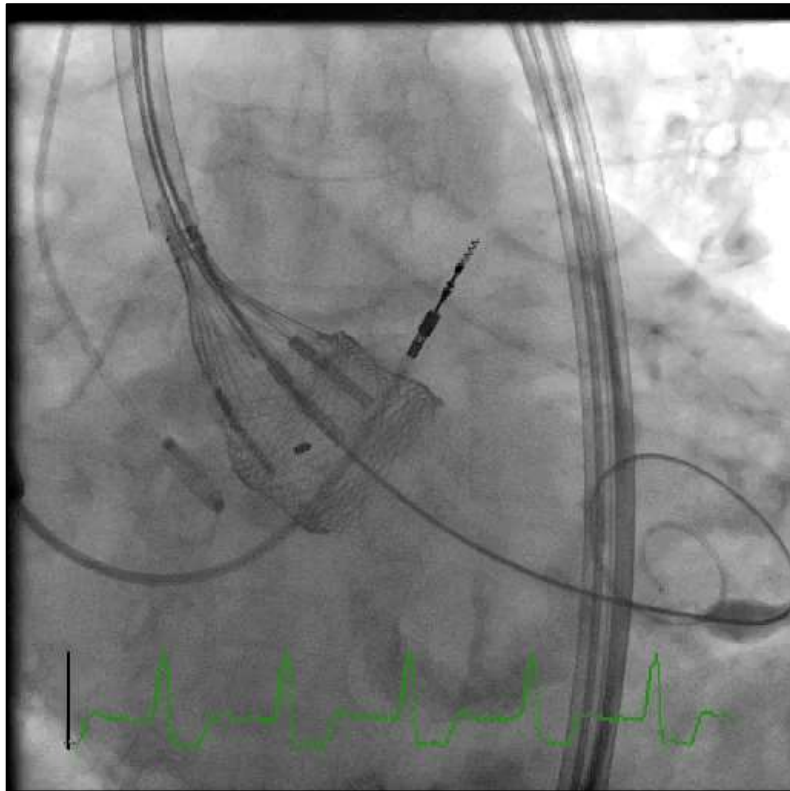
REPRISE III Case Example

- 93F
- STS 13.2%
- LVEF >75%
- AVA 0.51cm²
- Vmax 4.07m/sec
- Annulus 25mm
- LVOT 24mm
- Moderate leaflet calcium



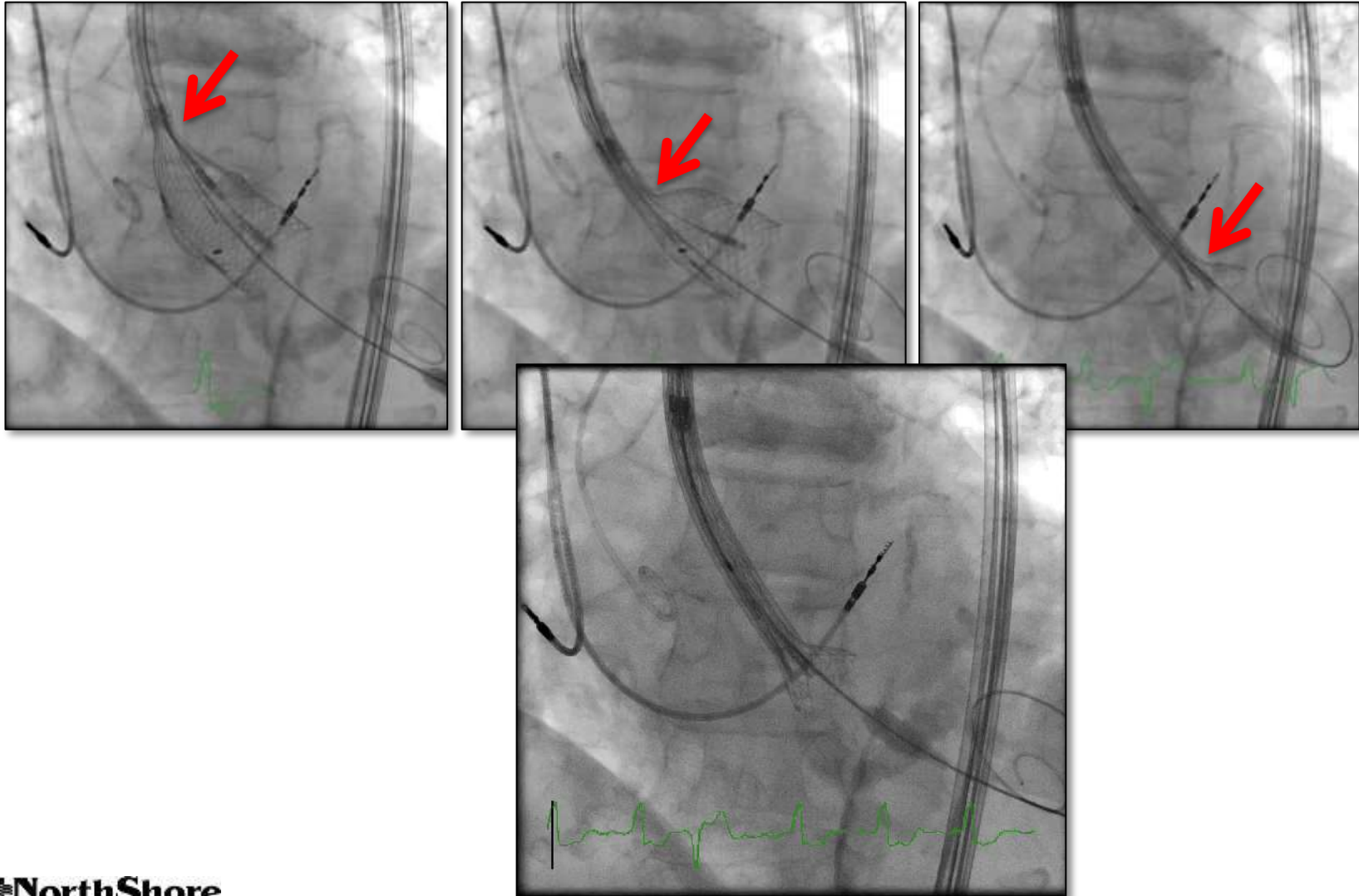
Area derived \emptyset	25.6 mm
Perimeter derived \emptyset	25.9 mm
Area	514.4 mm ²
Perimeter	81.5 mm
Diameter	22.8 mm
Diameter	27.1 mm

25mm LOTUS Valve

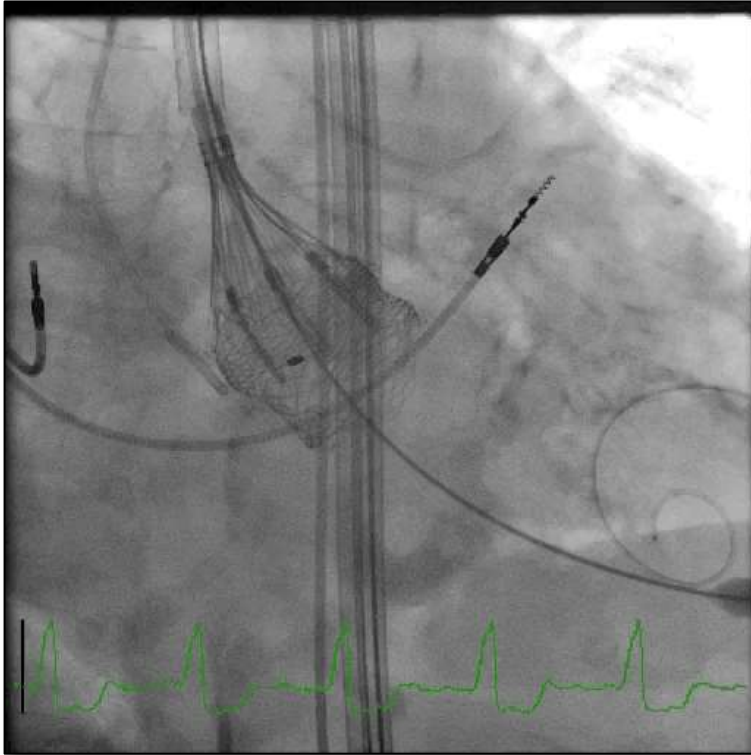


Fully deployed and locked
Not yet released

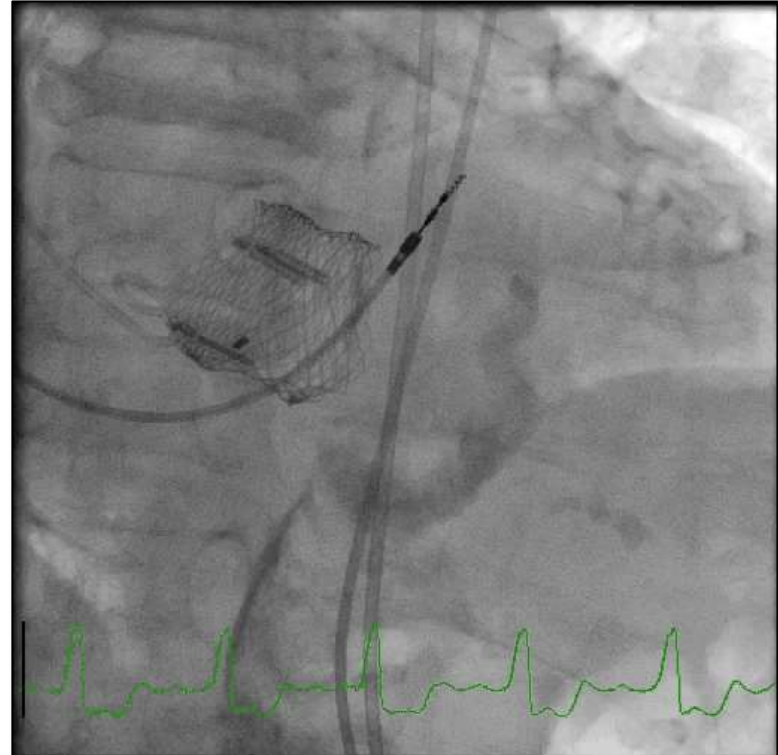
Recapture 25mm LOTUS



27mm LOTUS



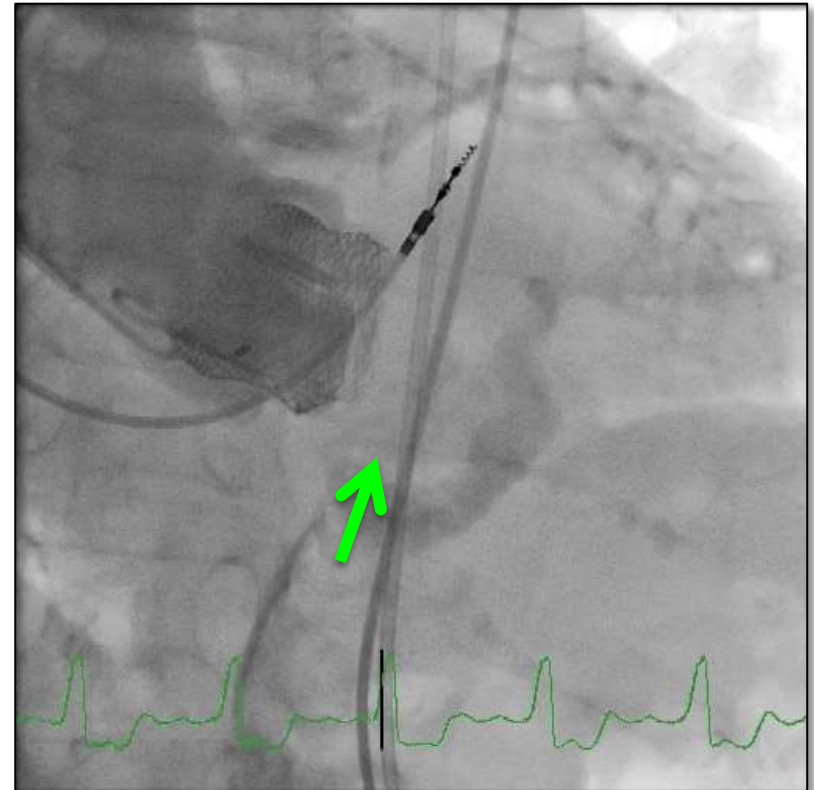
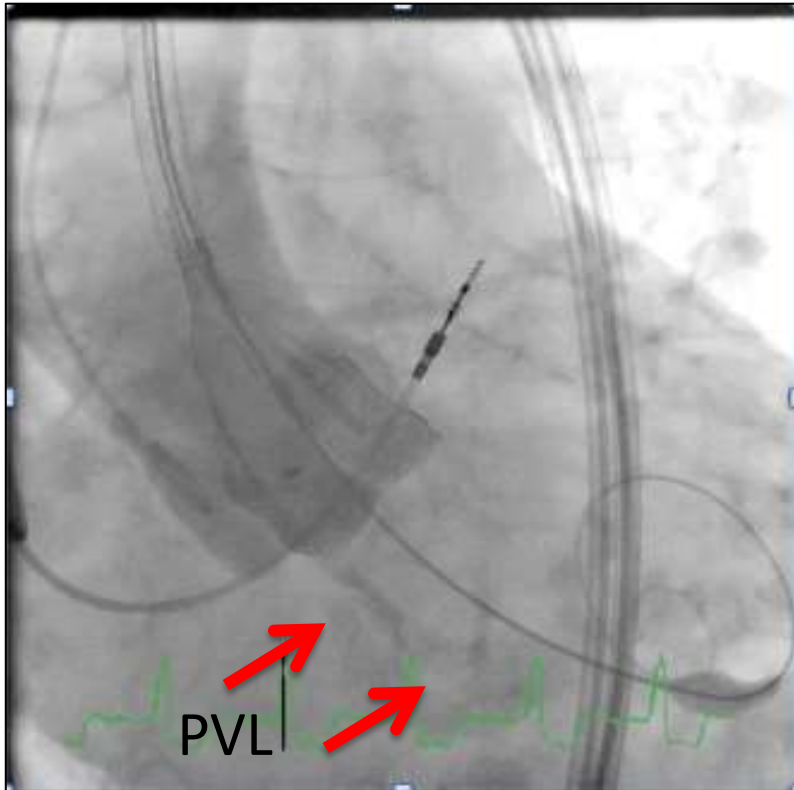
Before release



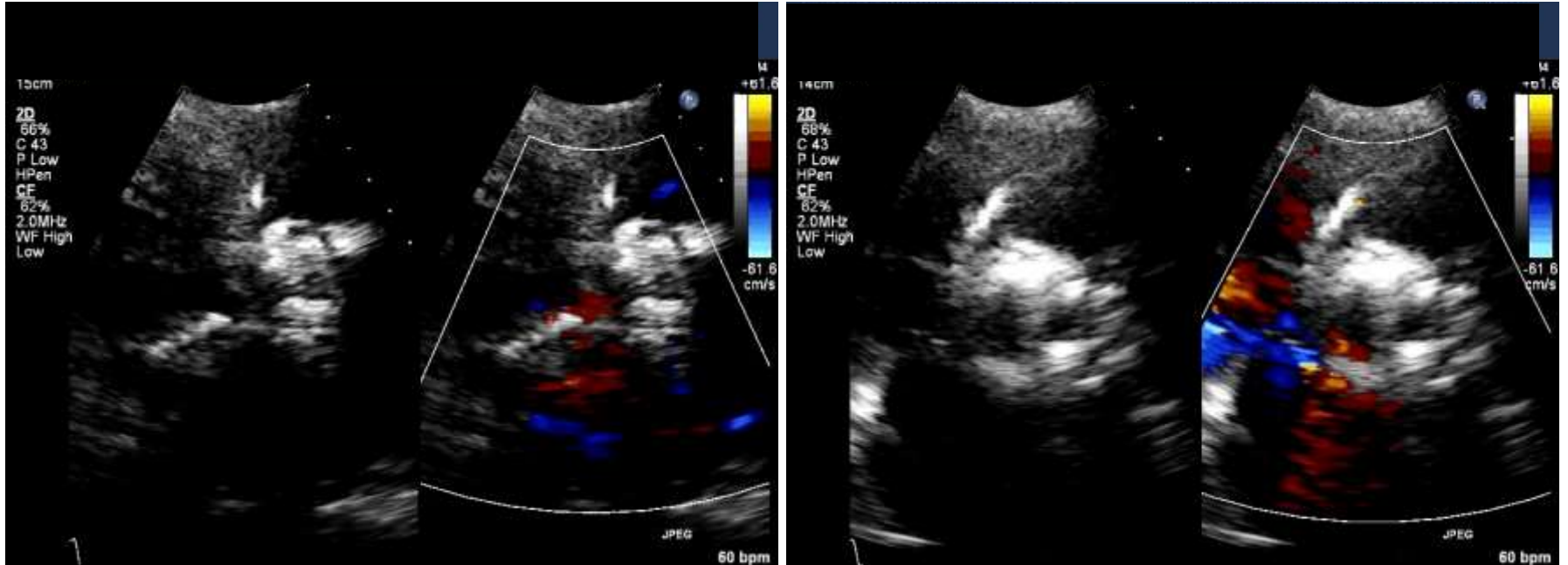
After release

LOTUS

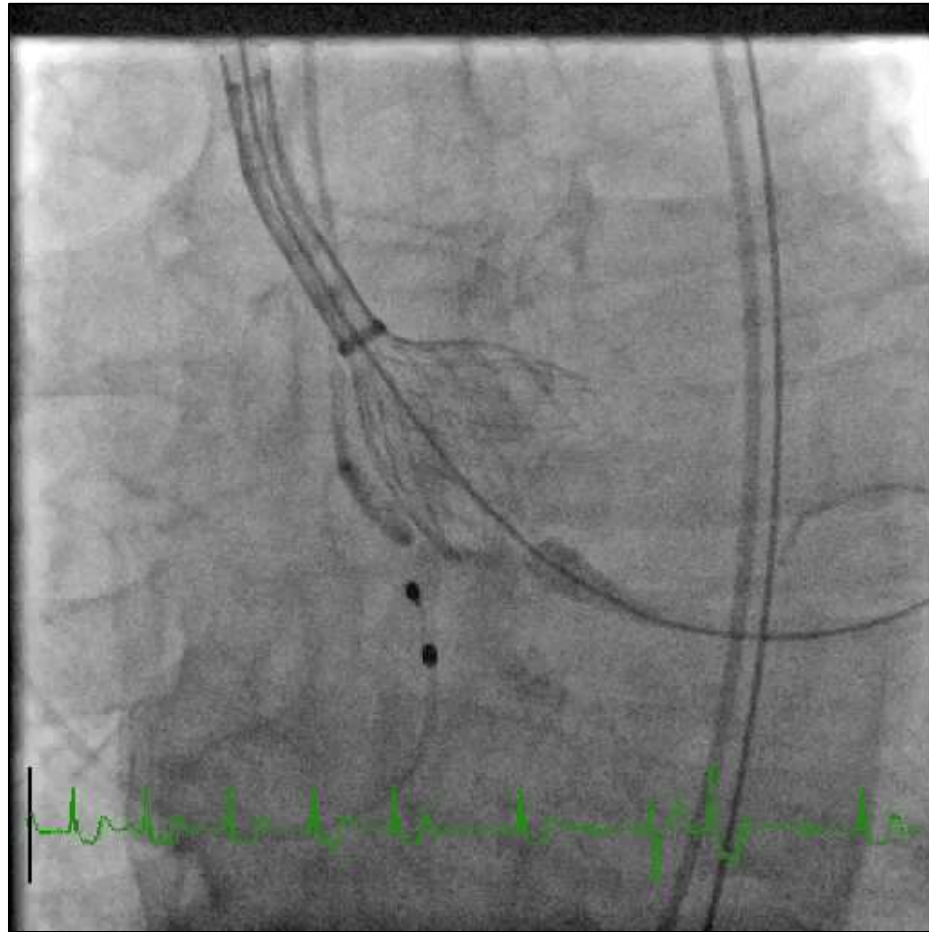
25mm vs 27mm



Final TTE 27mm LOTUS

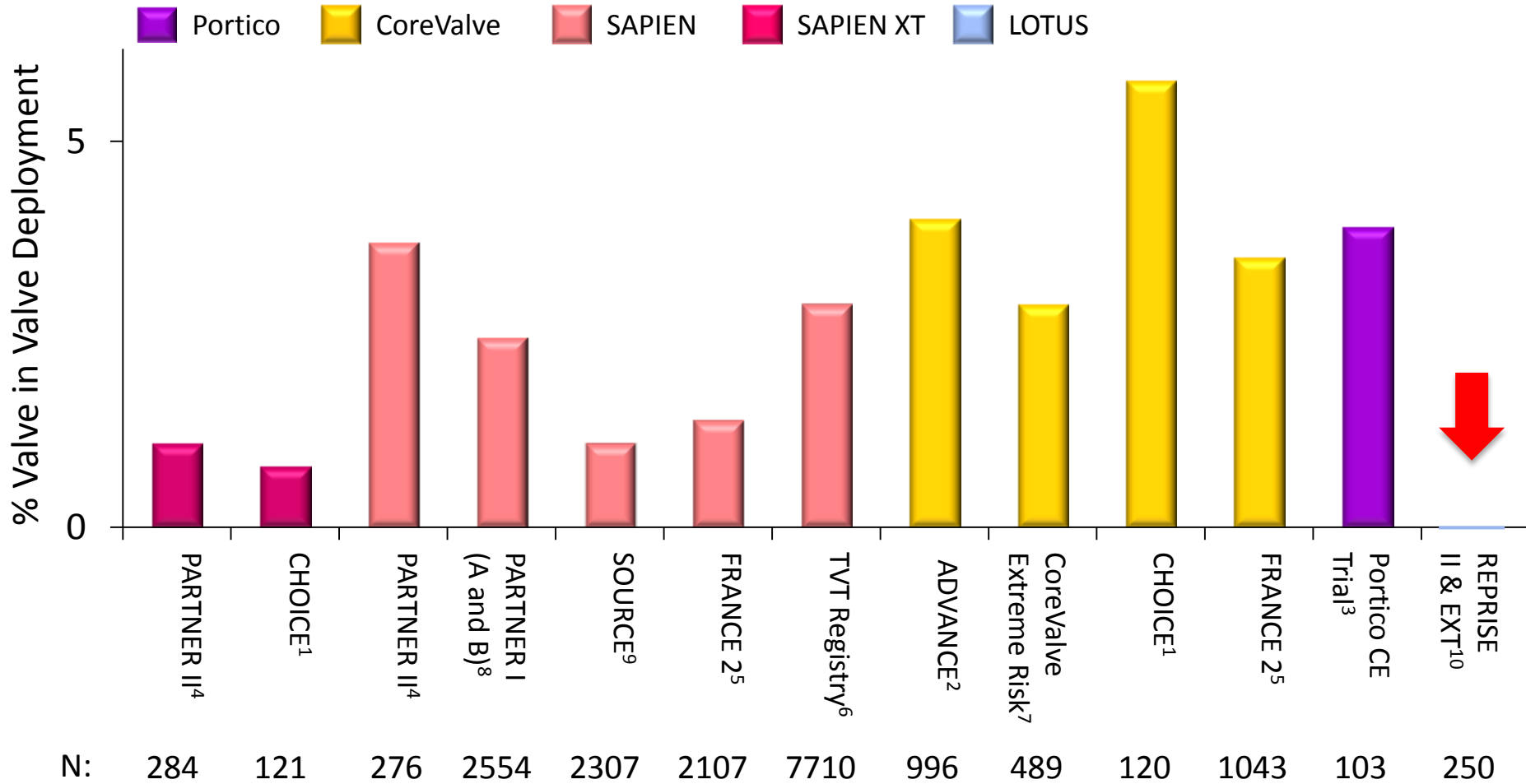


Pop-Out



Valve in Valve Deployments

TAVR Clinical Trials and Registries



Results from different studies not directly comparable. Information provided for educational purpose only.

¹ Abdel-Wahab, JAMA 2014., ² Linke, et al. EuroPCR 2014., ³ Manoharan, Presented at TCT 2014. ⁴ Leon, et al., ACC 2013. ⁵ Gilard, et al. *NEJM* 2012. ⁶ Mack, et al. JAMA 2013.

⁷ Beardon, et al. *J Thor and Cardiovasc Surgery* 2014. ⁸ Makkar, et al. JACC 2013., ⁹ Thomas, et al. TCT 2012. ¹⁰ Ian Meredith, London Valves 2014.