

# Leveraging Evidence – e communication – faster and broader access

EDWARDS TRANSCATHETER HEART VALVE PROGRAM

## THE SOURCE XT POST-APPROVAL STUDY & SUBANALYSES

Edwards Lifesciences would like to thank all participating Heart Teams for their outstanding dedication to the rigorous SOURCE XT post-approval study.

2700 consecutively enrolled patients in 90 centres from 17 countries

Transcatheter data at one year (N = 1065)

- 88% survival in patients receiving the SAPIEN XT Transcatheter Heart Valve
- 99% none/trace or mild paravalvular leak
- 90% NYHA Class III


[Click here for SOURCE XT Registry Clinical Testimonials](#)

"The SOURCE A SOURCE XT studies have transformed the accepted quality of post-CE Mark release-based registries. The rigor with which the data were collected and adjudicated for the SOURCE XT Registry has raised the bar against industry analyses and helped us to guide appropriate patient selection for TAVI."

Martin Thomas and Clif Alexander, King's Health Partners, London

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PRELIMINARY CLINICAL EXPERIENCE USING THE SAPIEN 3 DEVICE

Danny Dvir, Josep Rodas-Cabau, David A. Wood, Henrique Ribeiro, Marco Barbanti, Robert De Larochelliers, John Tan, Eric Dumont, Melanie Freeman, Daniel Doyle, John G. Webb.  
Vancouver, British Columbia, and Quebec City, Quebec, Canada

### Background

- The SAPIEN 3 transcatheter heart valve with the low profile Compressor Transcatheter and Cordiside Transcatheter Delivery Systems (Edwards Lifesciences, CA) incorporates features intended to facilitate accurate positioning and improve paravalvular sealing.
- We review the initial clinical experience with this device.

### Objectives

The aim of this study was to demonstrate the first-in-human feasibility and short-term clinical outcomes with a new balloon-expandable transcatheter heart valve (THV).

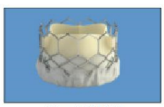


Figure 1. SAPIEN 3

### Methods and Results

- SAPIEN 3 valves were implanted in 26 patients (age 79.2±5.3 years, 84.6% male, STS score 8.1±3.6).
- Device size was 26mm in 88.5%, 28mm in 11.5%.
- Valve positioning was accurate in all cases, with no moderate or severe paravalvular leaks.
- Mean aortic valve gradient decreased from 39.8 ± 15.7mmHg to 15.4 ± 4.4mmHg and mean aortic valve area increased from 0.67 ± 0.16cm<sup>2</sup> to 1.82 ± 0.35cm<sup>2</sup> (p<0.001).
- Major vascular complications occurred in 3.8%, major life-threatening bleeding rate in 7.7%, and there were no stroke events.
- Hospital discharge was a median of 3 days after the procedure.
- Survival at 30 days was 98.2% with 92.3% of survivors in NYHA functional class I or II.

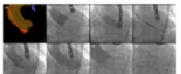


Figure 3. SAPIEN 3 Implantation Sequence

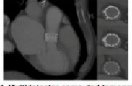


Figure 4. Multisection computed tomography showed consistently symmetric and circular THVs.

### Conclusions

Early outcomes with the SAPIEN 3 THV were excellent with improved device positioning and reduced post-procedural repositioning. Longer follow-up of a larger group of patients is needed to validate these findings.




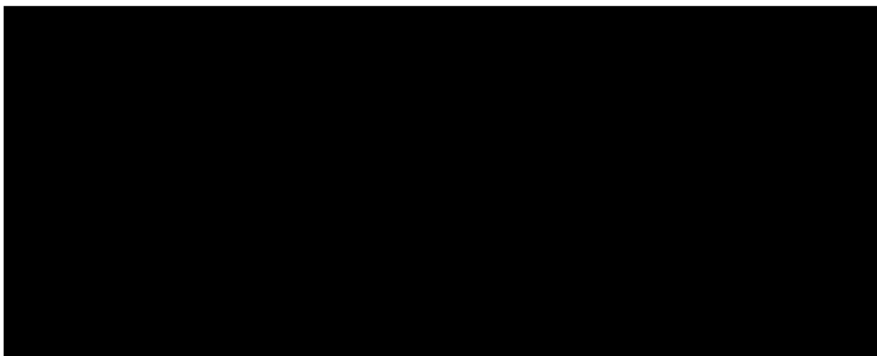
Figure 2. Alignment of the THV is achieved by rotating the fine adjustment wheel at the back of the handle (white arrows on black wheel).



## Edwards Lifesciences

28<sup>th</sup> November, 2013

[“Link to SOURCE XT Post-Approval Study Clinical Testimonial!”](#)



EDWARDS TRANSCATHETER HEART

### THE SOURCE XT POST-APPROVAL STUDY & SUBANALYSIS

Edwards Lifesciences would like to thank the investigators for their outstanding dedication to the rigorous conduct of the SOURCE XT Post-Approval Study.

**2706** consecutively enrolled patients in the SOURCE XT Post-Approval Study.

Transfemoral data at one year (N = 1685)

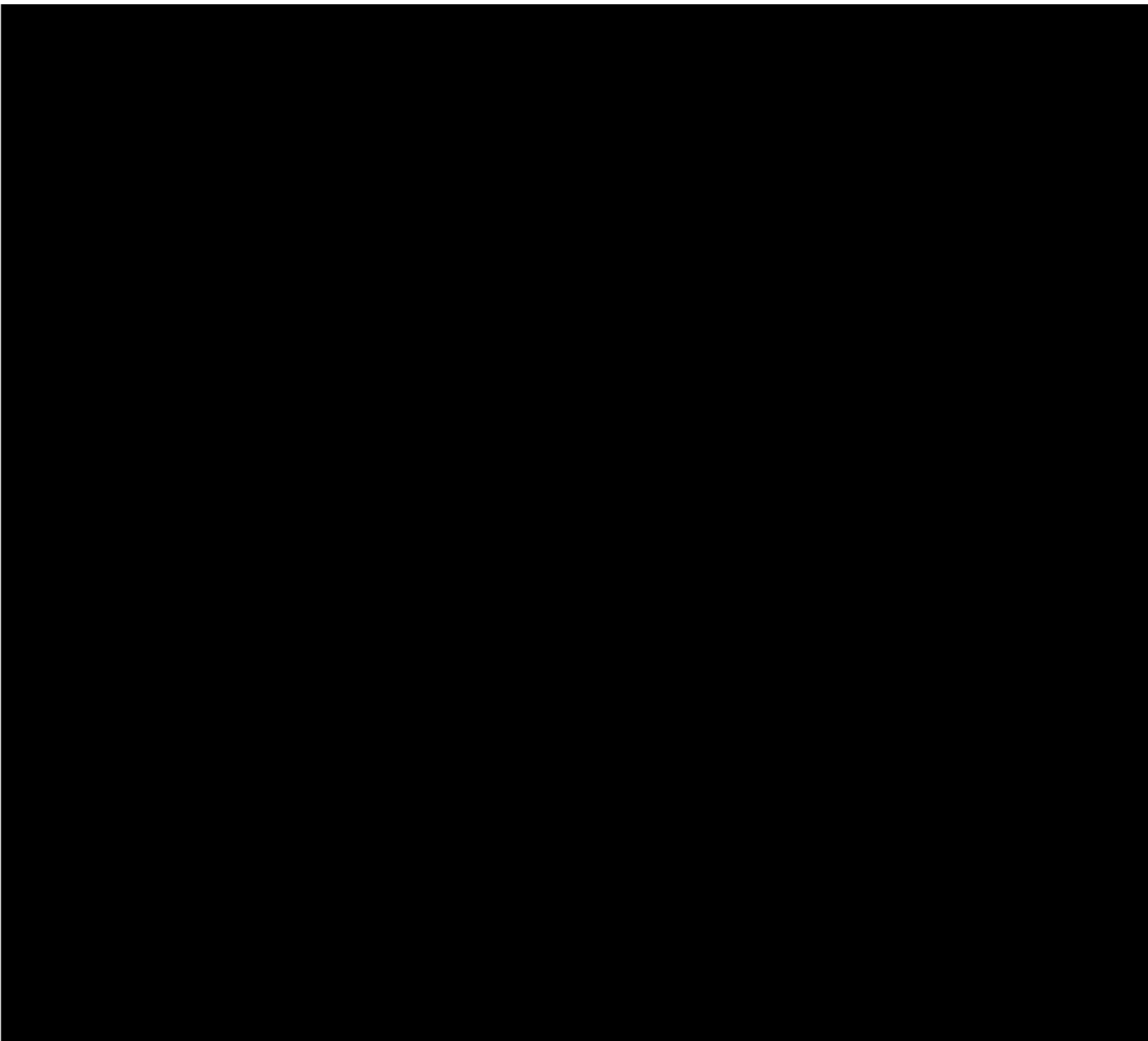
- **85%** survival in patients receiving the SAPIEN XT Transcatheter Heart Valve
- **93%** none/trace or mild paravalvular leakage
- **90%** NYHA Class VII

“The SOURCE & SOURCE XT studies have transformed transcatheter aortic valve replacement into a standard of care for aortic stenosis. The rigour with which the SOURCE XT Registry has meant that very important insights have been gained to guide appropriate patient selection for TAVI.”

*Martyn Thomas and colleagues*

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# Leveraging Evidence –

*J Am Coll Cardiol.* 2013;62(18\_S1):B219-B219

## Transfemoral transcatheter aortic valve implantation with the edwards the medtronic corevalve device

E.M. Wiegerinck et al. Academical Medical Center, University of Amsterdam  
Amsterdam, Netherlands

**THY Literature Update**  
Edition 6 - December 2013

**Background** Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure for the treatment of aortic stenosis. The Edwards SAPIEN 3 transcatheter aortic valve (TAV) is a new generation of transcatheter aortic valves designed for transfemoral access.

**Key Learning Points**

- The Edwards SAPIEN 3 TAV is a new generation of transcatheter aortic valves designed for transfemoral access.
- The Edwards SAPIEN 3 TAV is a new generation of transcatheter aortic valves designed for transfemoral access.

**Abstract**

**Background** Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure for the treatment of aortic stenosis. The Edwards SAPIEN 3 transcatheter aortic valve (TAV) is a new generation of transcatheter aortic valves designed for transfemoral access.

**Methods** The Edwards SAPIEN 3 TAV is a new generation of transcatheter aortic valves designed for transfemoral access.

**Results** The Edwards SAPIEN 3 TAV is a new generation of transcatheter aortic valves designed for transfemoral access.

**Conclusions** The Edwards SAPIEN 3 TAV is a new generation of transcatheter aortic valves designed for transfemoral access.

**For information only**

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# Using the Edwards Market Leaders to Leverage our Evidence **in 201**

Jean-Paul Herzog | Marketing THV - EMEAC