

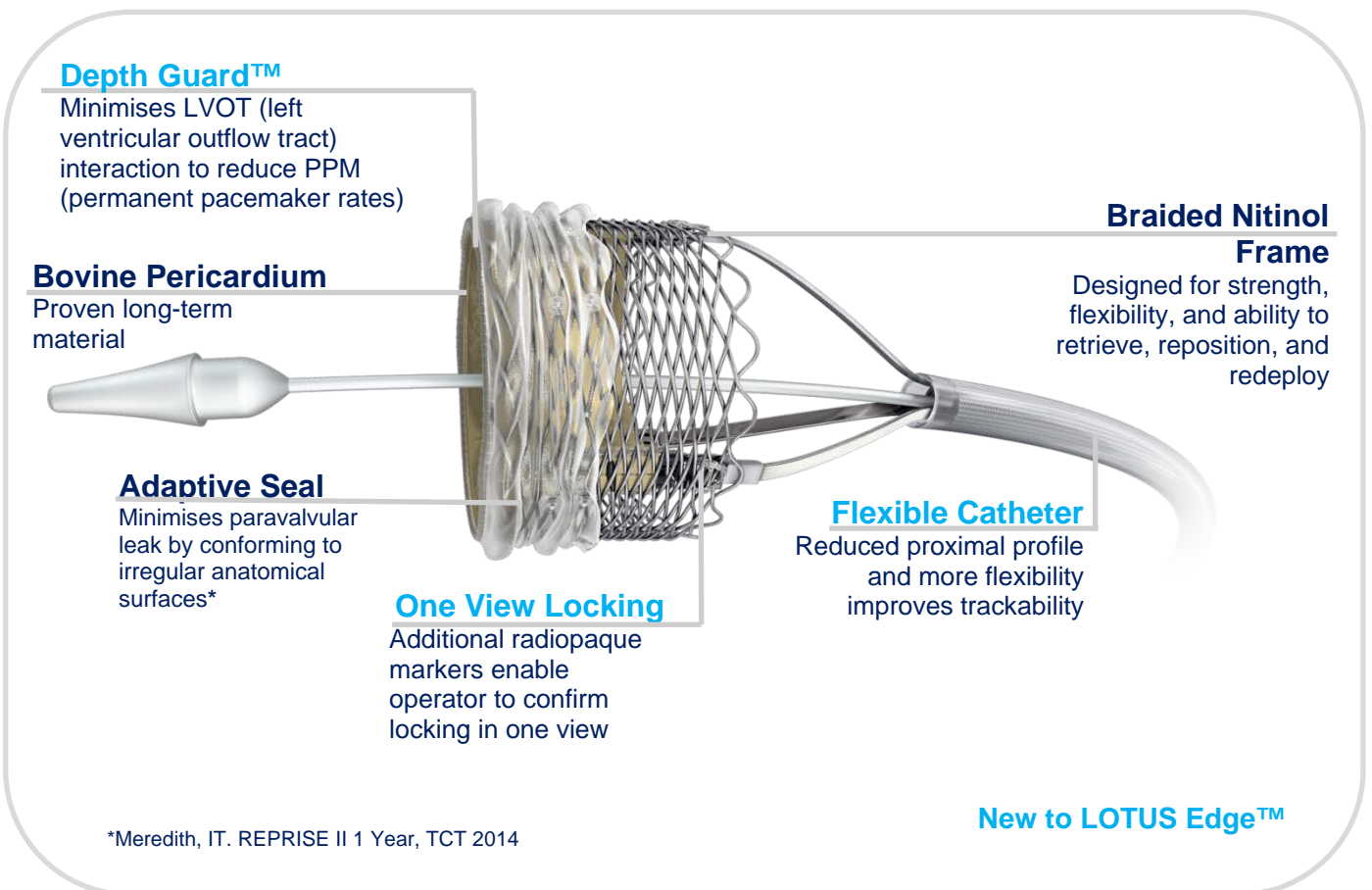
The LOTUS Edge™ Valve System - Factsheet

The LOTUS Edge™ Valve System is a differentiated next generation transcatheter aortic valve implantation (TAVI) device that helps **simplify the implant procedure as result of its new delivery and deployment system**.

LOTUS Edge builds on the previous generation Lotus™ Valve System and it is designed for precise placement. It can also be completely repositionable, prior to release, even after full deployment.

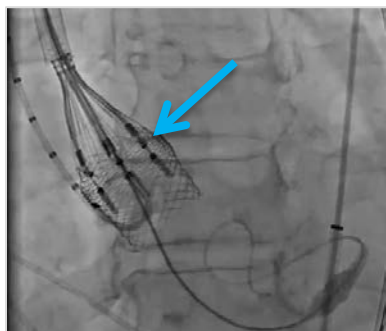
The Adaptive Seal™ enables it to **minimise paravalvular leak (PVL), a known predictor of mortality**^{1,2,3,4,5} by conforming to the anatomy to create a tight seal.

LOTUS Edge is available in three sizes - 23mm, 25mm and 27mm. 21mm and 29mm sizes are anticipated in early 2017.



Simplified delivery and deployment

Compared to the previous generation Lotus Valve System, the LOTUS Edge Valve System is easier to deliver, with a more flexible and trackable catheter.



One View Locking

The Depth Guard™ Deployment Technology and additional radiopaque markers make **deployment simpler**. The markers enable the implanting clinician to confirm the locking of the valve in one view (i.e. – (the valve is locked in place and is ready for release, thus **minimising use of contrast dye and radiation and overall reducing the procedure time**).

The Depth Guard Technology is designed to **minimise the depth of the valve implant**, and therefore reduce interaction with the left ventricular outflow tract (LVOT). This reduced contact with the LVOT is designed to **reduce permanent pacemaker (PPM) rates**.

The clinical programme and existing data

The Lotus™ Valve System is currently being evaluated in the **REPRISE (REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve SystEm)** clinical trial programme and a post-market, real-world study called **RESPOND**.^a

REPRISE I, REPRISE II and Extension trials have been completed and included a total of **261 patients** with severe aortic stenosis who received a Lotus™ Valve System.^b To further add to the body of existing clinical data, REPRISE III^c IDE trial started in 2014 and is currently enrolling.

The **latest data from the REPRISE I and REPRISE II** clinical trials¹ were presented at the TCT conference in 2015 and they confirmed safety and performance out to one year, with:

- more than 86 percent of patients showing no paravalvular leak (PVL) and no patients demonstrating moderate or severe PVL.
- Mortality at 1 year was a low 10.9 percent.

^a The RESPOND Registry is a prospective, open label, single arm, multi-center, observational post market study. It will collect data on clinical outcomes and device performance in 1,000 patients implanted at 50 centers around the world.

Clinical follow-up is at discharge, 30 days, 12 months and annually through five years. It features a primary endpoint of all-cause mortality compared to a performance goal, plus secondary endpoints using Valve Academic Research Consortium (VARC) guidelines and definitions.

^b 11 patients were enrolled in REPRISE I, 120 patients taking part in REPRISE II as well as 130 additional patients that have been enrolled in the REPRISE II extended cohort at 16 sites in Australia and Europe.

^c REPRISE III is a pivotal IDE (Investigational Device Exemption) trial. An IDE trial allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval application (PMA) or a Premarket Notification submission to the Food and Drug Administration (FDA). REPRISE III will randomise Lotus versus another valve (CoreValve® TAVR System) in 1,000 patients.

One-year outcomes from REPRISE II with extended cohort (n=250) were presented at PCR London Valves 2015.⁶

Highlights include:

- consistent and sustained hemodynamic performance with a low all-cause mortality of 11.6%
- accurate positioning, with 0.0% TAV-in-TAV, ectopic placement, valve migration or embolisation, and
- no moderate or severe PVL, as adjudicated by a core lab.

The latest results from the RESPOND Study from the full trial population of more than 1,000 patients were presented at EuroPCR 2016. The data show excellent device performance, a strong safety profile and extremely low rates of PVL.

Highlights from the RESPOND Study include:

- all-cause mortality at 30 days post-procedure was 2.2% in the as-treated population
- disabling stroke at 30 days post-procedure occurred in 2.2% of patients
- permanent pacemaker (PPM) implantation rate at 30 days was 30%
- correct positioning of one valve in proper location was 99.7%
- major vascular complications observed in only 2.1% of patients
- Less PVL than reported with competitive valve: no/trivial PVL in 91.9% of patients and mild PVL in 7.7% of patients at hospital discharge; moderate PVL was only 0.3% and there was no severe PVL; PVL with Lotus similar to rates seen with surgical valve replacement.

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References

¹ Kodali SK et al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012; 366:1685, <http://www.nejm.org/doi/full/10.1056/NEJMoa1200384> (Accessed: September 8, 2016).

² Tamburino C et al. Valvular Heart Disease. Circ 2011; 123:299, <http://circ.ahajournals.org/content/123/3/299.full> (Accessed: September 8, 2016).

³ Abdel-Wahab M et al. Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve implantation registry. Heart 2011; 97:899, <http://www.ncbi.nlm.nih.gov/pubmed/21398694> (Accessed: September 8, 2016).

⁴ Data from the FRANCE 2 registry presented by Prof Eric Van Belle at the ESC Congress 2013 in Amsterdam, Netherlands.

⁵ PARTNER I Trial – moderate & severe PVL.

⁶ Meredith. REPRISE II EXT. PCR LV 2015.