

Review Article

Portico™ Transcatheter Heart Valve

APOSTOLOS TZIKAS^{1,2}, MICHAEL CHRISOHERIS², ANTONIOS HALAPAS²,
KONSTANTINOS SPARGIAS²

¹Interbalkan European Medical Centre, Thessaloniki, ²Hygeia Hospital, Athens, Greece

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Portico™ (St. Jude Medical Inc, St. Paul, MN, USA) is the first commercially available fully retrievable and repositionable bioprosthetic transcatheter heart valve (Figure 1).¹⁻³ The valve frame is made of nitinol, a nickel-titanium alloy. The valve leaflets are made of bovine pericardium and the distal part of the frame is covered by a cuff of porcine pericardium, which has Linx™ anticalcification treatment, similar to the classical surgical bio-prosthetic valves from St. Jude (i.e. Tri-recta™).⁴ Portico™ is self-expandable and functions at the level of the aortic annulus. Its leaflets are specially designed to coapt in circular and elliptical annulus configurations (Figure 2). For the moment, 2 sizes are available: 23 mm and 25 mm, for aortic annulus dimensions of 19-21 mm and 21-23 mm, respectively. A full size series with the addition of 27 mm and 29 mm valves for annuli of 23-25 mm and 25-27 mm, respectively, is expected to become available soon after CE mark studies are completed. At first inspection, the Portico™ valve looks like a CoreValve® (Medtronic Inc. St. Paul, MN, USA); however, its design has many special features that aim to reduce cardiac conduction abnormalities and paravalvular leaks and to increase the accuracy and safety of implantation.

Prevention of conduction abnormalities

The distal part of the valve, which is in

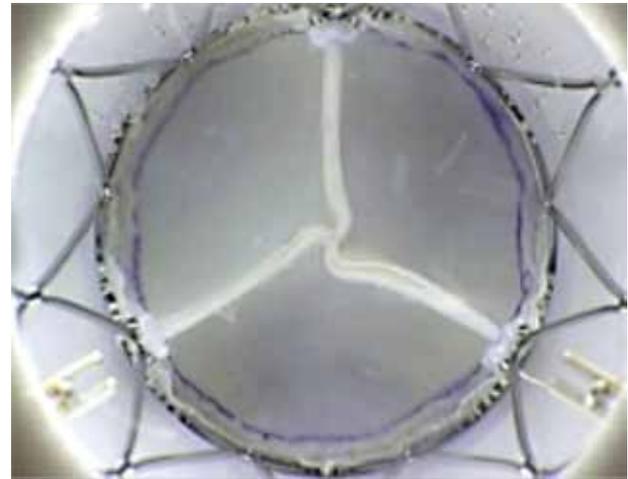
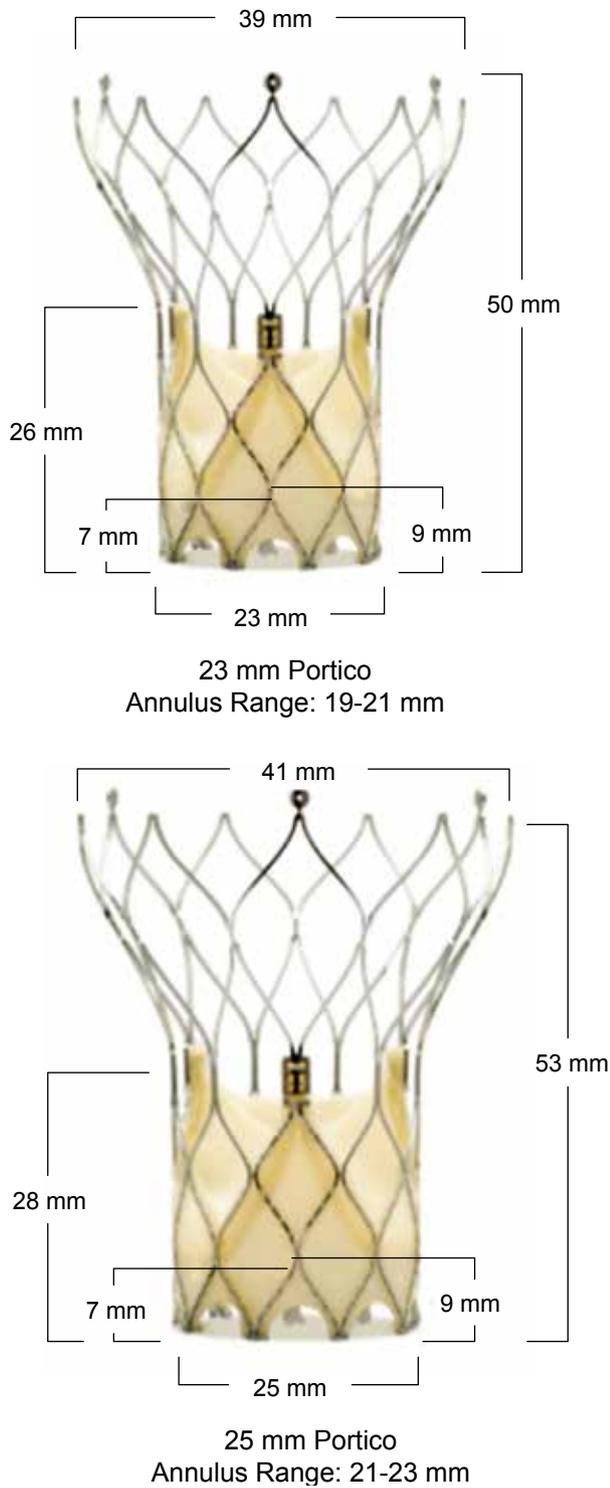
contact with the left ventricular outflow tract (LVOT), is straight (not flared) in order to decrease the potential implications of trauma in the area of the LVOT close to the interventricular septum and the His bundle beneath it (Figure 1). Moreover, the optimal depth of implantation of only 3-4 mm distally to the aortic annulus contributes to the further reduction of conduction disorders and subsequent need for permanent pacemaker implantation (Figure 3). Finally, the valve frame applies a stable radial force to the LVOT at different degrees of expansion (depending on the annulus size), which decreases local tissue trauma. All these design characteristics may explain the relatively low frequency (10.8%) of permanent pacemaker implantation in the first published clinical series.³

Prevention of paravalvular leaks

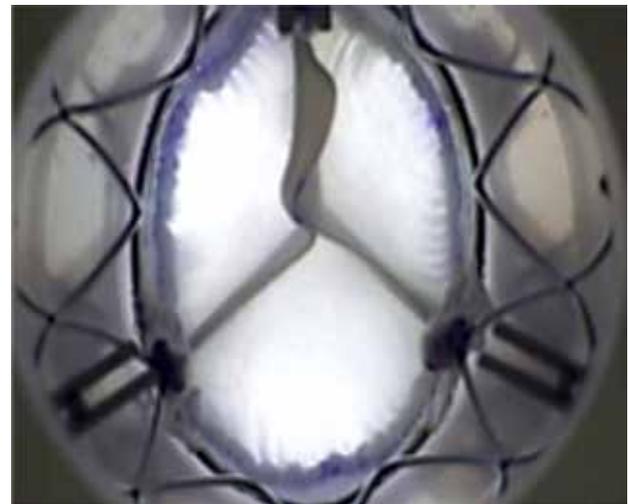
Portico has large cells with less metal and more tissue that can conform better around calcific nodules on the native valve leaflets, improving valve apposition and minimizing the risk of paravalvular leaks from the aorta to the left ventricle (Figure 1). In addition, the valve is fully retrievable and repositionable (up to 80-90% of deployment, see below) and allows a better control of the depth of implantation and implantation optimization in case of significant paravalvular leak.

Address:
Apostolos Tzikas

10 Asklepiou St.
57001 Thessaloniki,
Greece
aptzikas@yahoo.com



Circular Configuration



Elliptical Configuration

Figure 1. Portico transcatheter heart valves 23 mm and 25 mm. The valve frame has large cells in order to better accommodate the calcific nodules of the native aortic valve, to improve sealing, and to decrease the rate of paravalvular leaks. The distal part of the valve frame is not flared so as to avoid trauma on the His bundle in the left ventricular outflow tract, which has been associated with heart block and the need for permanent pacemaker implantation. Note: Pictures are not to scale.

Figure 2. Leaflet coaptation in circular and oval anatomies. Portico is designed for leaflet coaptation in circular and elliptical annulus configurations.

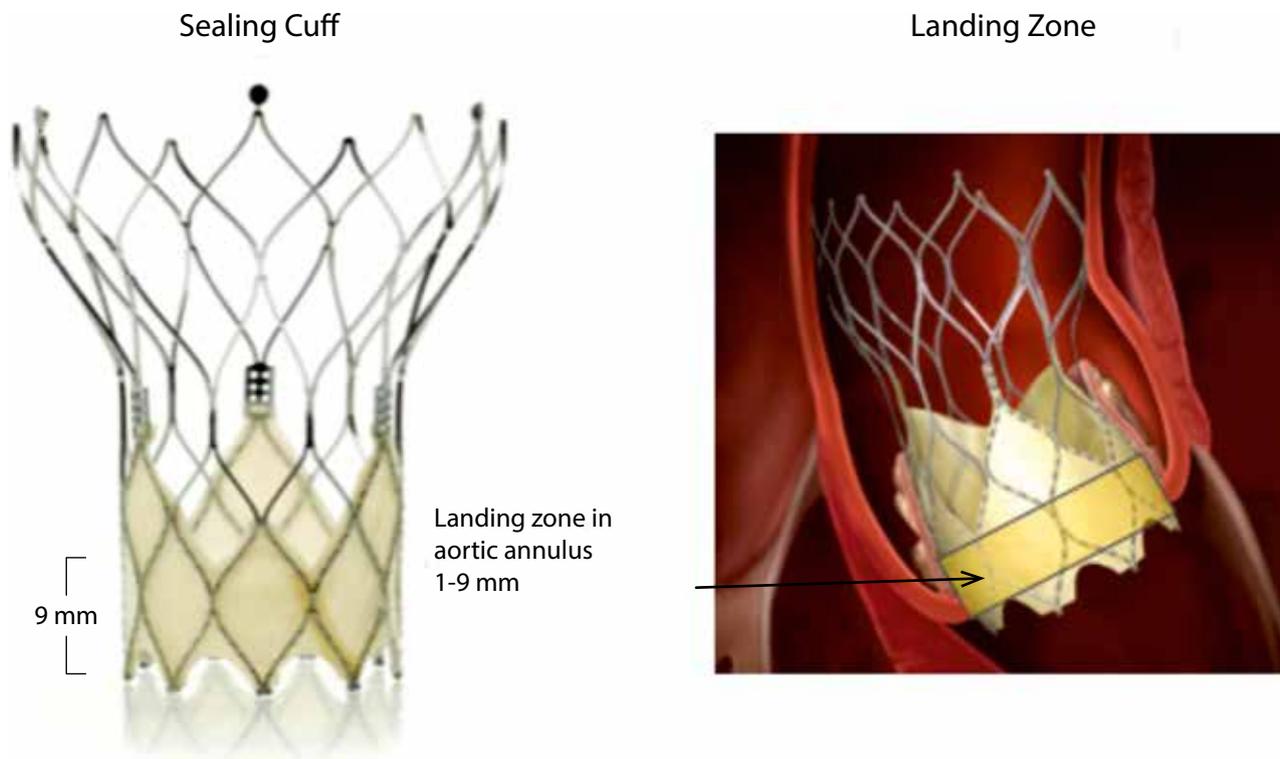


Figure 3. Depth of implantation in relation to the aortic annulus. The optimal depth of implantation is only 3-4 mm distally to the aortic annulus in a range between 1-9 mm. At this depth of implantation, the risk of damaging the His bundle is significantly lower.

The Portico™ delivery system

Portico™ is compatible with an 18 F sheath. For the moment, only a femoral delivery system is available (Figure 4a, 4b), whereas alternative access versions are expected soon (trans-subclavian, transaortic, trans-apical). Valve loading is simple and fast, as there is no need to immerse and wash the device in cold saline. Loading takes 1-2 minutes in total, which is very important in case there is a need for urgent implantation. Clockwise rotation of the wheel on the manifold pushes the valve towards the LVOT, so the operator needs to correct by pulling the delivery sheath a few millimeters backwards in order to maintain an implantation depth of approximately 4 mm. In case optimal implantation depth is not achieved, or if the valve is mistakenly pulled above the annulus level, counter-clockwise rotation of the wheel can bring the valve back into the delivery system and the whole process can be repeated immediately without removing the system from the aorta (Figure 4b). Retrieval (resheathing) of the valve is possible until 80-90% of deployment and can be done within a few seconds. When the valve is fully released, retrieval is no longer possible. This simple retrieval feature can be very important in

cases of hemodynamic instability, when the operator has to react quickly in order to avoid potential cardiac arrest. Moreover, valve retrieval during implantation (up to 90%) facilitates deployment accuracy and lowers the risk of conduction abnormalities and paravalvular leaks (see above). Finally, the Portico™ delivery system is considered ideal for new operators, because it minimizes the risk of potential errors during the learning curve for transcatheter aortic valve implantation.

Stable hemodynamics during the whole procedure

One of the main advantages of Portico™ is related to the fact that its leaflets are stitched into the lower part of the frame and are designed to function at the level of the aortic annulus (Figure 4a). The valve starts to function immediately after its distal part is open. Therefore, the patient remains hemodynamically stable throughout the whole implantation process. Rapid pacing is not needed (like the Edwards valve) and left ventricular stress is avoided, since the ventricle does not eject against a closed valve (the so-called “parachute effect” seen with CoreValve®). Thus, many operators consider Portico™ the ideal choice for patients with a low ejection fraction and borderline hemodynamics.

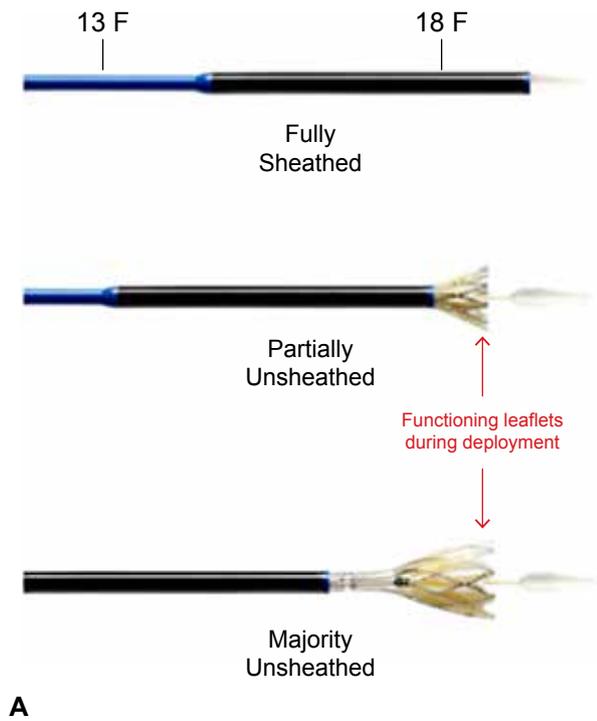
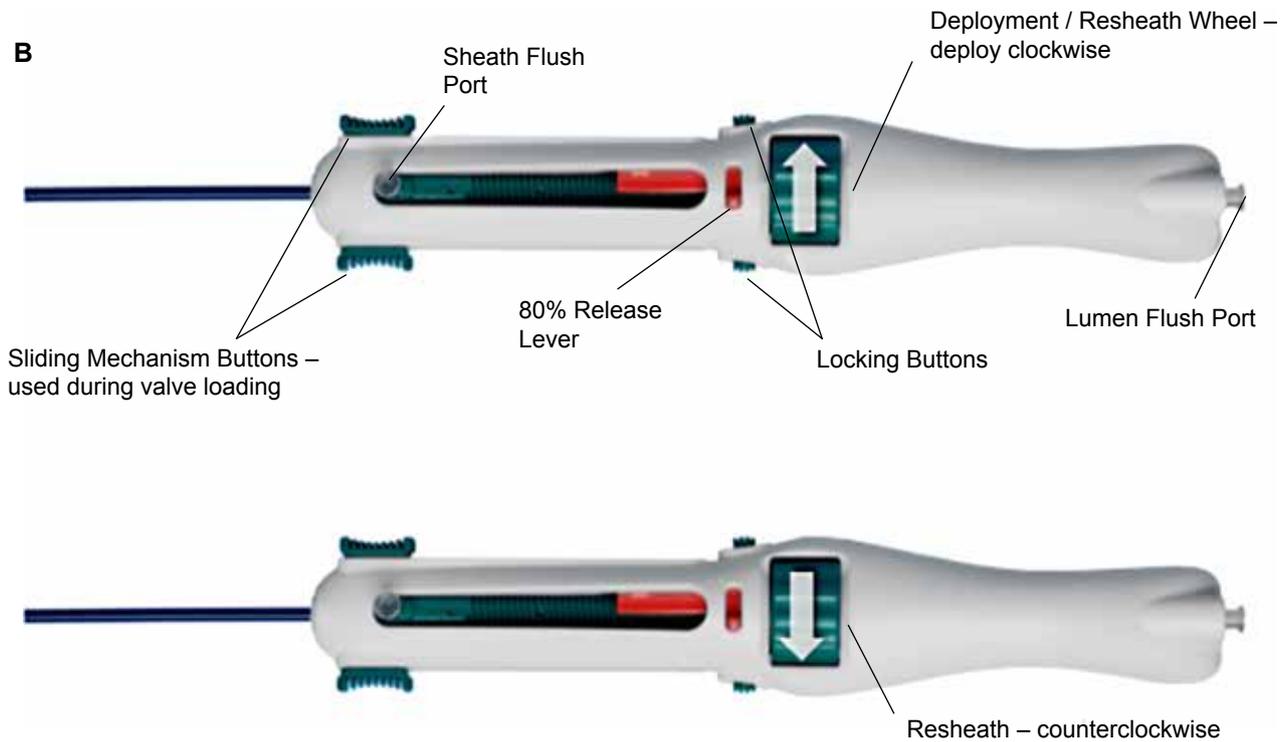


Figure 4. The Portico delivery system. A. Special delivery system design. The frame's elastic features and low profile allow full retrieval in situ, up to 80-90% of implantation. The leaflets are placed at the distal part of the valve so they start functioning immediately after the valve comes out of the system. B. The manifold of the delivery system is simple and easy to use: clockwise and counterclockwise rotation of the special wheel (white arrow) is applied for valve deployment and retrieval, respectively. The 80% Release Lever is unlocked in the last phase, just before valve release.



Clinical studies

Portico™ is a new generation valve with a few hundred implants worldwide, so currently only a limited amount of clinical studies are available. The results of two small^{1,2} and one larger³ non-randomized study were encouraging. In the Portico™ CE Trial,³ 23 mm and 25 mm valves were implanted in 102 patients (51 of each size) and the patients were followed for 1 year. The average patient age was 84.1 ± 4.8 years. The STS Score was 6.0 ± 3.3 and the logistic EuroSCORE was 16.6 ± 7.6 . The valve was retrieved during the procedure in 23.8% of patients and retrieval was successful in 100%. The average depth of implantation was 6.5 ± 5.0 mm. Thirty-day and one-year mortality were 2.9% and 7.9%, respectively (cardiovascular mortality was 2.9% and 4.9%). Minor and major stroke occurred in 1% and 2.9% of patients at 30 days. The rate of permanent pacemaker implantation at 30 days and at 1 year was only 9.8% and 10.8% respectively, which is considered very low for a self-expanding valve. Mean pressure gradient decreased from 45.8 mmHg to 8.7 mmHg and the decrease was followed by significant clinical improvement. Finally, the rate of more than mild paravalvular aortic insufficiency was 3% and 0% at 30 days and at 6 months, respectively. Of course, these initial positive results need to be confirmed by larger, randomized studies, like the one started in the USA comparing Portico™ to Edwards and CoreValve®.⁵

Conclusions

Portico™ is a new-generation transcatheter heart valve manufactured by St. Jude Medical, which is specially designed to improve the clinical results of transcatheter aortic valve implantation, mainly by reducing the rate of permanent pacemaker implantation and paravalvular leaks. The valve is fully retrievable and repositionable, and is ideal for patients with a high risk for hemodynamic instability during the procedure. It is user-friendly and it has shown favorable results in the first clinical studies.

Disclosure

Apostolos Tzikas is a consultant for St Jude Medical.

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