Addressing Critical Needs—
A Shared Vision with Heart Teams

Jean-Luc Lemercier
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Edwards Lifesciences

TAVI’s rapid evolution has made it one of the most exciting developments in the treatment of valvular heart disease. As one of the leaders in this field, it is our duty to maintain the pace of innovation. While additional treatment options for patients remain important, so too do refinements that can meaningfully improve outcomes.

The Edwards SAPIEN 3 valve is a case in point. Recently approved for use in Europe, Edwards’ most advanced transcatheter valve reflects our strategy of using innovation to service continual enhancement in clinical outcomes. Its design has the potential to reduce paravalvular leak and vascular complications.

We look forward to working with you to bring the Edwards SAPIEN 3 valve to your clinical practice and patient care.

Clinical Trial Update

The Edwards SAPIEN 3 Valve
CE Mark Trial Overview
Study design, patients, early observations

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The SAPIEN 3 CE Mark Trial is a non-randomized, prospective, multicentre study designed to assess the safety and device success of the Edwards SAPIEN 3 valve and the Edwards Commander and Edwards Certitude delivery systems in patients with symptomatic, severe aortic stenosis who are indicated for surgical aortic valve replacement (SAVR). Initial enrollment consisted of 50 high-risk patients. The subsequent 100 patients enrolled could have an

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The SAPIEN 3 valve with the low-profile Edwards Commander and Edwards Certitude delivery systems incorporates features intended to facilitate accurate positioning and improve paravalvar sealing. We have reported our preliminary clinical experience with the SAPIEN 3 valve in two Canadian medical centers: St Paul’s Hospital in Vancouver and Hospital Laval in Quebec City and have now extended our analysis to 26 patients in a study led by Dr John Webb. Average patient age was 78.2±9.3 years, 88.5% were male and the average STS score was 6.1±3.6. Device size was 26 mm in 88.5% and 29 mm in 11.5% of patients. Valve positioning was accurate in all cases, with no moderate or severe paravalvar leaks. Mean aortic valve gradient decreased from 39.6±15.7 mmHg to 12.4±4.7 mmHg and mean aortic valve area increased from 0.67±0.16 cm² to 1.62±0.35 cm² (p<0.001). Major vascular complications occurred in 3.8%. There were no stroke events. Hospital discharge was a median of three days after the procedure.

Survival at 30 days was 96.2%, and 92.3% of survivors were in NYHA functional class I or II.

We concluded that early outcomes with the SAPIEN 3 valve were excellent with improved device positioning and reduced post-procedural regurgitation. Longer follow-up of a larger group of patients, as being evaluated in The PARTNER Trial and in Europe is needed to validate these findings.
Positive clinical experience

“Our experience with the SAPIEN 3 valve was quite positive for transfemoral and transapical implantation when starting the study early in 2013. None of our initial 15 patients who were included in the clinical trial in January and February 2013 have had any clinically relevant aortic incompetence (Figure 2).”

Thomas Walther, Jörg Kempfert, Helge Möllmann
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TAVI Team

The SAPIEN 3 Valve: Evolution or Revolution?

In just a few years, TAVI has become a well-accepted approach for patients with severe aortic stenosis who are at high risk or denied for surgery. Today the 30-day mortality rate in high-risk patients is close to 5%. However, some limitations remain, which are the last frontiers for extending indications to intermediate-risk patients. Two of the most critical needs are the risk of severe vascular complications with the femoral approach (about 10%) and significant paravalvular leak (8 to 20%).

The SAPIEN 3 valve is a very clear advance on previous designs which incorporates an inner and outer skirt made of polyethylene terephthalate (PET) that serves as a paravalvular sealing system and an active 3-dimensional coaxial positioning catheter that is compatible with a 14F expandable sheath for the 23 and 26 mm valves and 16F for the 29 mm valve.

The valve structure is still made of cobalt-chromium and the proximal struts are larger, with the angle between the struts modified to improve the profile while maintaining the same radial strength. The crimped and deployed valve is 3-4 mm higher than the SAPIEN XT valve, which results in a larger landing zone. The delivery system is very intuitive. The nose-cone-tipped inner balloon catheter on which the valve is crimped has radiopaque valve alignment markers defining the valve position and the working length of the balloon. A central radiopaque marker aids valve positioning at the annulus level. The outer deflectable flex catheter is attached to the handle, which incorporates a wheel for extra flex of the catheter tip to gain coaxiality with the annulus. An indicator shows the degree of tip flexion. Final positioning at the annulus level is obtained by rotating the fine alignment wheel which allows for millimetric movement of the SAPIEN 3 valve.

We were able to include nine patients (mean age 87.9±6.1 years, Logarithmic Euroscore 29.9±17.6) in the SAPIEN 3 CE Mark Trial; valve implantation using slow initial inflation was successful in 100% of cases. The outcomes from these patients will be presented, along with the entire study data, at EuroPCR 2014. Our preliminary experience is more than promising and hints at the SAPIEN 3 valve being a true revolution in the TAVI world. The SAPIEN 3 valve with its low-profile, ultra-low 14F eSheath and 18F Edwards Certitude Sheath can be positioned in both planes of the annulus and in a larger landing zone. This makes implantation more intuitive, which may dramatically reduce the risk of vascular complications and paravalvular leak.

Significant advantage for all patients

“When I saw this valve for the first time, I was a bit surprised but, after looking at it more carefully, I realized it is quite a clever concept — especially the new technique to diminish or really alleviate the risk for paravalvular leakage. We have had a very good experience in our first 22 patients. We had good screening with CT and echo pre-operatively and good sizing, and we really did not see any relevant paravalvular leak in any of the patients treated so far: this translates into a very significant advantage for all patients. Until now, PV leakage has been one of the major drawbacks. If we can stop that and if we have a device that allows us to implant it safely without risk of PV leakage (or with only minimal PV leakage), then this is a major step forward.”

Thomas Walther
Kerckhoff Heart Center, Cardiac Surgery Clinic, Bad Nauheim, Germany

SAPIEN 3 Valve
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Experience in 34 Consecutive Patients — an Interview with Dr. Achim Büttner on Behalf of the TAVI Heart Team

In February and March 2014, the SAPIEN 3 Transcatheter Heart Valve (THV) was implanted in 34 consecutive TAVI patients at our centre. All had symptomatic severe aortic stenosis and were treated via femoral vascular access.

Patient characteristics:
- Mean age was 83.8±5.0 years
- Multidetector computed tomography (MDCT) estimated aortic annular area 45.7±5.9 mm²
- Area derived annular diameter 24.0±1.5 mm
- Doppler-echo mean pressure gradient 46±15 mmHg
- Calculated aortic valve area 0.8±0.2 cm²
- Mean age was 83.8±5.0 years
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5 patients received a 23 mm valve, 22 patients received a 26 mm valve and 7 patients received a 29 mm valve. Valve implantation using slow initial inflation was successful in all 34 cases. No balloon pre-dilatation was performed in the last 23 cases and we had no difficulties in crossing the native valve or fine-positioning the THV. Paravalvular leakage (PVL) was less than mild in all cases (no PVL in 65%, trace in 35%). No post-dilatations were performed.

There were no major vascular complications (focal femoral artery stent implantation in two patients). The post-transcatheter aortic valve replacement MDCT showed consistently symmetrical and circular valves and the Doppler-echo mean pressure gradient at discharge was 9.8±2.9 mmHg.

Conclusion: The SAPIEN 3 valve and delivery system could facilitate fully percutaneous implantation in a broader range of patients with the potential to provide more accurate positioning and less paravalvular regurgitation.

Was the implant procedure faster or more efficient than previously? If so, in what way?

The design of the Edwards Commander delivery system is a step forward and makes the procedure less traumatic and faster to do. The reduced profile of the valve and the added distal flex of the delivery system seems to reduce the risk of vascular complications and easing positioning of the THV in the native aortic valve. Our initial experience showed that implantation of the SAPIEN 3 THV is feasible without balloon pre-dilatation.

Case 1: 86-year-old patient, transapical SAPIEN 3 valve implantation

This 86-year-old patient presented with progressive dyspnoea due to severe aortic stenosis. Echocardiography showed an aortic orifice area of 0.8 cm² with a gradient of 86/41 mmHg. Because of significant co-morbidities (previous pacemaker implantation for AV-block, pulmonary emphysema and an abdominal aortic aneurysm), we selected a transapical approach using the Edwards Certitude delivery system. As in all our TAVI patients, we performed a planning CT that was reconstructed prior to the procedure using a dedicated software program. From the CT we calculated a perimeter-derived aortic annulus diameter of 24.6 mm and an area-derived diameter of 24 mm. The reconstructed CT-image (Figure 5) shows a tricuspid aortic valve with heavy calcification distributed in a symmetric pattern across all three leaflets.

The overall goal of aortic valve replacement is to restore left ventricular function and physiologic blood flow through the aortic annulus and at the same time to protect from new risks or complications related to the intervention. During the recently finished SAPIEN 3 valve CE Mark Trial, our team at the University Heart Center Hamburg had the chance to treat 21 patients suffering from severe aortic stenosis with the new SAPIEN 3 valve. Here we would like to present two representative cases and share some of our insights.

The Hamburg Experience

Patrick Diemert and Hendrik Treede
Institutional Cardiovascular and Thoracic Surgery, University Heart Center Hamburg, Hamburg, Germany

The current SAPIEN 3 valve allows for significant downsizing from earlier TA delivery systems, which means that both the intercostal access and the sutures of the cardiac apex can be kept very small in the sense of a truly minimally invasive approach. We routinely perform TA implantations of the SAPIEN XT valve without pre-dilatation with good results. So far, we followed the Instructions for Use and the clinical trial protocol of the SAPIEN 3 valve study demand pre-dilatation for both TA and TF delivery, but in our opinion, the pre-dilatation step can be omitted for most cases. However, more data will be needed on this aspect of the SAPIEN 3 valve. We introduced the 26 mm SAPIEN 3 valve and positioned the middle marker at the insertion point of the leaflets, which in our experience is the optimal starting point for deployment of the SAPIEN 3 valve (Figure 5).

The balloon was slowly inflated over a period of 4 seconds; during balloon inflation we gave a bolus of contrast. The “slow-deployment technique” allows for correction of the positioning height during expansion, which in our case was not needed. In spite of the heavy calcification, we achieved excellent stent expansion and a very good functional result.

On transoesophageal echo and aortic angiography we could not detect any paravalvular leakage, and the gradient post-implantation was 84/44 mmHg with a calculated aortic orifice area of 2.2 cm². The patient was extubated right after the procedure and showed no postoperative pain and an uneventful postoperative course.

Do you feel this valve offers more benefits than previous SAPIEN valve families? More than other commercial valves? If yes, explain the benefits.

Compared to the previous SAPIEN family of valves, a wider range of annular diameters up to 29.5 mm can be treated with the SAPIEN 3 THV. For borderline annular diameters, a smaller THV size can be considered due to the effect of the outer skirt in reducing paravalvular leakage. This could reduce the risk for annular ruptures where there is severe calcification or a small aortic root.

A stunning realization was the efficacy of the outer skirt in substantially reducing paravalvular regurgitation.

Do you plan to use this valve in more patients? If yes, what type of patients – i.e., inoperable, severe aortic stenosis, others?

In our initial series (N=34 consecutive TAVI patients), the SAPIEN 3 valve was suitable for all anatomies and implantation was successful via femoral access in all patients. The reduced profile is likely to encourage access via the transfemoral route and reduce the need for transapical interventions. The favorable hemodynamics of the SAPIEN 3 valve with minimal pressure gradient and substantially reduced transvalvular regurgitation appears to improve outcomes. However, this has to be proven in prospective trials and registries before TAVI indications can be expanded to younger and healthier patients. A THV with a large inner diameter would enable opportunities for future valve-in-valve implantations which could be especially important in younger patients.

Deployment Tips and Tricks

Holger Schröfel
Heart Team Karlsruhe, Cardiac Surgery Clinic Karlsruhe, Germany

The TAVI Team in Karlsruhe has implanted more than 1,600 transcatheter valves since April 2008. In the summer of 2013 we had the opportunity to test the newly developed SAPIEN 3 valve as part of the CE Mark Trial. The most obvious changes you will notice are the new stent geometry and the innovative outer skirt which is designed to dramatically reduce PV leaks. The implantation starts, as usual, with the positioning of the valve in the perpendicular oriented aortic root. For this, the new valve positioning marker (in the middle of the balloon) is very useful. The SAPIEN 3 valve should be positioned with the centre marker at the insertion point of the leaflets (Figure 3). The biggest difference in implanting the SAPIEN 3 valve is the new stent design: the stent clearly shortens during deployment (personal observations 15-25%) and mainly during the last quarter of the implantation procedure (Figure 4). The experienced TAVI interventionalist can easily get used to the new implantation characteristics, and excellent implantation results can be achieved quickly and reliably.
Case 2: 81-year-old patient, transfemoral SAPIEN 3 valve implantation

This 81-year-old lady was admitted to our hospital with a history of syncope and exertional angina. Angiography ruled out coronary artery disease, but echocardiography revealed high grade aortic stenosis with a gradient of 91/43 mmHg and an effective orifice area of 0.7 cm². Our patient had a history of allergic asthma that was intermittently treated with steroids; otherwise the medical history was without significance. However, because the patient appeared frail with reduced grip-strength and mobility, the Heart Team selected transfemoral (TF) TAVI rather than surgical aortic valve replacement.

Computed tomography showed a tricuspid aortic valve with eccentric calcification (Figure 6). The aortic annulus diameter was 20 mm on TOE and 21 mm by CT (perimeter-derived effective annulus diameter). The aorta, iliac and femoral vessels did not show any significant calcification, but the diameters of the common femoral arteries were quite narrow with only 0.6 cm on the left side and 0.7 cm on the right side. We decided on a 23 mm SAPIEN 3 valve using the 14F expandable Edwards Commander delivery system. With this significantly downsized delivery system, transfemoral access did not present a problem in spite of the narrow femoral arteries.

This was one of our first cases with the SAPIEN 3 valve, and we were very mindful of the asymmetric foreshortening of the stent during valve deployment. It is quite essential for the implantor to be aware that the lower stent part of the SAPIEN 3 valve will show a higher degree of foreshortening compared to the upper half of the stent. During our first SAPIEN 3 valve cases we quickly learned that you can have very predictable results with the SAPIEN 3 valve if you follow three important rules:

1. Start with the middle positioning marker at the insertion point of the leaflets.
2. Use nominal volume for deployment.
3. Perform a very slow inflation with a bolus of contrast to correct for implantation height, if necessary.

In our case, we had an excellent result without the need for post-dilatation and without paravalvular leakage despite the eccentric calcification (see Figure 6). The transvalvular gradient was 9/4 mmHg, and the calculated aortic orifice area was 1.9 cm². The patient was extubated on the OR table immediately after the procedure and showed an uneventful postoperative course. The SAPIEN 3 valves allow for predictable and precise placement which is key to shorter procedures and, more importantly, to fewer maneuvers and manipulations within the native valve. This is important as the number of maneuvers has been associated with stroke.

In summary: With the new SAPIEN 3 valve we have consistently achieved good implantation results with a remarkably low rate of paravalvular leakage. The downsizing of both TA and TF delivery systems is a significant advantage. There are some important changes in the implantation technique compared to the SAPIEN XT valve that implanters need to be aware of, especially in regard to the need for fewer maneuvers, the future potential of deploying valve without prior BAV and predictable deployment. However, if these steps are properly applied, the SAPIEN 3 valve implantation is very straightforward and reliable.

“The low 18F profile of the Edwards Certitude delivery system allows for much easier delivery, as well as greatly improved flexibility for ease of coaxial positioning of the SAPIEN 3 valve across the annulus. The delivery system also incorporates an integrated pusher and easier-to-use handle design. The SAPIEN 3 valve and the Edwards Certitude delivery system have facilitated our Heart Team procedures by enabling shorter procedure times and easier closure.”

Holger Schröfel
TAVI Team Karlsruhe, Cardiac Surgery Clinic Karlsruhe, Germany
TAVI talk Quotable

Fewer vascular complications

“The Commander delivery system has a central fluoroscopic marker that sits under the center of the crimped SAPIEN 3 valve. There are three other important features of the SAPIEN 3 valve which should be remembered. The height of the SAPIEN 3 valve provides a large 'landing zone' and the height varies depending on the valve size. The second feature is the cell size at the top of the valve which allows easy access to the coronary arteries, if needed. The final feature is the shortening of the valve during deployment. This occurs two thirds of the way up from the ventricular side of the device and happens ‘late’ during balloon inflation and in a very predictable fashion. From prior studies, we know that one of the biggest concerns in TAVI has been the rate of vascular complications. With the significant reduction in sheath sizes, it is expected that vascular complications will also diminish significantly, and we look forward to new data and sub-analyses that will enable us to have further comparisons with earlier generation valves and delivery systems.”

Martyn Thomas on behalf of the Heart Team
Clinical Director, Guy’s and St Thomas’ Hospital, London, UK

Imaging with SAPIEN 3 Valve: Overall Imaging Considerations

Philipp Kahler
For the West German Heart Center Essen TAVI team

Fewer than 10 years after its introduction, TAVI has become the new standard of treatment for inoperable patients with severe symptomatic aortic stenosis and a viable alternative for high-risk but operable patients. This breakthrough technology continues to evolve rapidly. One of the most important current development objectives is procedural safety, specifically including the reduction of access site complications and paravalvular regurgitation, both of which have been associated with increased mortality. As TAVI has evolved, so has the visualization of the cardiac and vascular anatomy during pre-interventional patient screening, peri-interventional imaging guidance and post-procedural evaluation of the implanted valve. Various imaging modalities such as transthoracic (TT) and transoesophageal 2D and 3D echocardiography (TOE), X-ray-fluoroscopy and angiography as well as multi-detector computer tomography (MDCT) are now being employed for the various aspects of TAVI imaging.

Adequate patient selection is the primary key for a predictable procedure with an optimal outcome and a minimized complication rate. Pre-interventional imaging is used to confirm the diagnosis of severe aortic stenosis and to precisely assess the aortic valve pathology including calcium distribution, the dimensions of the left-ventricular outflow tract, the aortic annulus, the aortic root and the distances from the coronary arteries to the annular plane. It also enables assessment of tortuosity, calcification and diameter of the peripheral access vessels (Figure 7). In addition, coronary artery status, left ventricular function and concomitant valvular heart disease need to be assessed.

- TT and TOE evaluate the diagnosis of severe aortic stenosis as well as left-ventricular function and the presence of concomitant valvular heart disease.
- Coronary angiography determines coronary artery status.
- Real-time 3D TOE and MDCT improve accuracy of single-plane measurements such as the aortic annulus, i.e. the mid-oesophageal long-axis view. These technologies take into account the non-circularity of the annulus by measuring mean diameter, annular perimeter and area (Figure 8).
- MDCT sizing has been studied intensively over recent years, and it has already been evaluated prospectively for the SAPIEN XT valve, demonstrating that a controlled oversizing of around 10% of the annular area leads to a significant reduction of relevant paravalvular leaks without increasing complications such as annular rupture. In addition to annular sizing, MDCT also allows the determination of the distance from the coronary arteries to the annulus and evaluation of the access vasculature. While angiography of the iliac and femoral arteries should also be performed during invasive coronary angiography, MDCT with 3D reconstruction completes the picture, giving relevant information on the degree and distribution of calcium which would otherwise have to be evaluated by intravascular ultrasound (Figure 7).

![Figure 7. Pre-interventional assessment of the peripheral vasculature using MDCT with 3D reconstruction (A), with post-processing by dedicated imaging software (3mensio Medical Imaging BV, Netherlands) (B, D) and evaluation of a plaque in the right common femoral artery using intravascular ultrasound during coronary and iliofemoral angiography (C)](image)

![Figure 8. Evaluation of the aortic valve anatomy and assessment of annular dimensions using 2D (A) as well as 3D (C, D) transoesophageal echocardiography and MDCT (B).](image)

![Figure 9. Post-procedural evaluation of the result using 2D transoesophageal echocardiography (A), fluoroscopy/angiography (B) and real-time 3D transoesophageal color Doppler echocardiography with post-processing (C, D).](image)
The cross-sectional areas of the SAPIEN 3 valve introducer sheaths have been reduced, allowing an access vessel diameter of 5.9 mm for the 29, 23 and 26 mm valves and 6 mm for the 29 mm valve that accommodates the 14 and 16 French sheaths, favoring transfemoral access. With a thorough vascular assessment and concomitant profile reduction, it is expected that vascular access site complications will decrease.

A major procedural challenge during TAVI is to achieve an exact valve positioning across the native annulus; correct deployment is of utmost importance for procedural success and patient outcome. While extremely rare, coronary artery embolization or valve dislocation into the ascending aorta due to a “too high” implantation could lead to acute, potentially life-threatening complications, as could ventricular embolization when the implanted “too deep.” Even a less severe malpositioning could be associated with an increased rate of complications such as paravalvular leaks or pacemaker dependence. Therefore, exact imaging guidance is needed to ensure accurate deployment. While TOE should routinely be used as an adjunct imaging modality in procedures under general anaesthesia, X-ray fluoroscopy with angiography remains the preferred imaging modality for implantations under conscious sedation, a practice that hampers TOE monitoring. C-arm CT with automatic aorta segmentation and valve landmark detection has been developed to simplify this procedure for the X-ray operator by facilitating selection of the implantation angulation with all three cusps aligned and by guiding valve positioning, as well as deployment utilizing a 3D overlay with the fluoroscopic images.

It is essential to understand that changes in the frame geometry mean that the valve leaflets short and long axes vary between SAPIEN XT and SAPIEN 3 valve platforms. The small geometry, height and outer polyethylene terephthalate (PET) skirt would require alteration to the sizing schema used for the SAPIEN XT valve platform. The small increase in height requires that the implanting physician be aware of both the height of the sino-tubular junction (STJ) as well as its diameter, with caution needed in the setting of a low STJ and the valve diameter is greater than the STJ diameter. Initial experience in Canada and Europe has confirmed the efficacy of the outer skirt in PAR reduction and may allow for less oversizing (or even modest annular undersizing) in patients with appropriate anatomy. The new SAPIEN 3 valve sizing algorithm is meant to take advantage of these engineering improvements and currently allows the optimal sealing zone to extend from approximately -5% to +20% when using the recommended balloon fill volumes, thereby eliminating the need for more extreme oversizing or changes in balloon volumes. These details need to be further verified through clinical data.

Figure 10. Double oblique transverse reconstructions of the basal ring/annulus on MDCT in an 84-year-old male with severe aortic stenosis. Routine measurements performed on MDCT include the short and long axis (B) as well as the perimeter/circumference (C) and the annular area (D). (continued from page 17)
Engineers’ Corner — Designing the Future of TAVI

Tim Geiser
Edwards Lifesciences Senior Director, THV Research & Development

Since the release of the Edwards SAPIEN XT valve in 2010, Edwards’ team of Research & Development engineers has continued to advance the technology behind its transcatheter heart valves. Utilizing clinical feedback and cutting edge technical advancements in materials and design, the R&D Team has created its latest balloon-expandable valve offering: the Edwards SAPIEN 3 Transcatheter Heart Valve with two new low-profile delivery systems. The original SAPIEN valve received the CE mark in 2007, followed by the SAPIEN XT valve in 2010. This next generation SAPIEN 3 valve received the CE mark on January 27, 2014.

As an R&D team, we were challenged to develop a valve that was significantly lower in profile, that could eliminate PVL, or at least reduce it to very rare occurrence, that would not compromise on conduction disturbances, and still maintain the radial strength needed for circularity and optimal leaflet coaptation.

The SAPIEN 3 valve features inner and outer skirts made from PET. The outer skirt was added in order to minimize gaps between the stent wall and the native annulus. This was accomplished while maintaining the same proven pericardial leaflet thickness used in previous SAPIEN and SAPIEN XT valves. The team was also able to substantially reduce the crimp profile in both TF and TA delivery systems.

As with all Edwards heart valves (surgical and transcatheter), the valve design is subjected to rigorous testing, including accelerated wear testing to 200 million cycles for nominal and for irregular shape configurations (over, under and oval-shaped expansion), as required by both FDA and ISO testing standards.

Predictable Valve Deployment
The Edwards SAPIEN 3 valves are delivered transfemorally, transapically and via the transaortic approach. The SAPIEN 3 valve frame is designed for reliable circular deployment with the nominal diameter necessary for proper leaflet coaptation, as well as proper haemodynamics and valve durability.

Proven Leaflet Design and Tissue Processes
Edwards’ valves share many features that are core to Edwards’ long history of surgical tissue valve design. The leaflets are made of bovine pericardial tissue, which has clinically proven long-term durability. Circularity at the annulus allows for uniform leaflet coaptation, as well as proper haemodynamics and valve durability.

Simplifying the TAVI Procedure

"The new ultra-low 14F delivery profile with the Edwards Commander delivery system and the 18F profile of the Edwards Certitude delivery system enable easier and shorter procedures with reduced vascular complications. The SAPIEN 3 valve helps best achieve the principles of aortic valve replacement by enabling a predictable procedure and low rate of complications while maintaining optimal haemodynamics and durability. The minimal deployment maneuvers required, as well as the potential for reducing pre-implant BAVs, are huge benefits brought about by the reduced profile of both delivery systems and they have even further shortened procedure times."

Daniel Wendt and Philipp Kahler
Heart Valve Center, Tesla TAVI Team

"Passage of this valve has minimal resistance, highlighting the change to 14F, a major advantage. The easy flexibility of the catheter across the aortic arch as well as more distally helps cross and achieve coaptability in the annulus. The fine tune adjustment wheel allows for very precise mm by mm placement, which we never had before."

Marie Claude Morice
Institut Cardiovasculaire Paris Sud (ICPS) at the Jacques Cartier Hospital, Massy, France

*No clinical data are available with which to evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients.
Faster recovery times and shorter hospital stays

“The SAPIEN 3 valve is really terrific. Using the 14F Edwards Commander Delivery System, it is like going back to the very first BAVs. It greatly simplifies the procedure over early days with larger sheath sizes. The SAPIEN 3 valve is small and easy to position, with no PV leak in our experience. There is no need to take extra time for contrast media or general anaesthesia that can increase procedure risk. Conscious sedation is important to our patients, and the reduced profiles enable both faster recovery times and shorter hospital stays. It will be interesting to follow the profiles of future patients as we obtain new data from this greatly enhanced valve generation.”

Hélène Eltchaninoff
Chief of Interventional Cardiology
Charles Nicolle University Hospital, Rouen, France

References

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