Cohort 1 and the ongoing SOURCE Registry

I had the honour of presenting the 30-day results of the first cohort of patients within the SOURCE Registry at the recent EuroPCR meeting in Barcelona. The SOURCE Registry itself is a landmark piece of work achieved by the Edwards European Clinical Investigators and sets a new standard for the evaluation of the commercial experience of TAVI in a high-risk patient population. It is the first TAVI registry with consecutive patients, effectively eliminating study bias. The complete data set reflects the expansion of TAVI into real life, including the learning curve of many new centres. In order to preserve the integrity of the study data, each adverse event was individually reviewed by myself and Dr. Olaf Wendler, the study’s Principal Investigators.

COHORT 1 of the Source Registry consists of 1,038 consecutive patients undergoing TAVI in 32 centres from November 2007 to January 2009. Due to the remarkable effort by the clinical and research teams at each of the 32 sites, we were able to report 100% of procedural data and 98% of 30-day data.

The first important observation from the data is the difference in demographics between the transfemoral (TF) patients (n=463) and the transapical (TA) patients (n=575). The logistic EuroSCORE was significantly higher in the TA group (29.1% vs. 25.7% p<0.005), reflecting a much higher incidence of comorbidities including peripheral vascular disease, carotid artery disease, coronary artery disease, prior CABG, renal dysfunction and mitral valve disease. For this reason, the 30-day results of the TF and TA approaches cannot be directly compared, as the patient populations are different.

Acute procedural success was achieved in 93.8% of patients; this number was similar for TF and TA. Thirty-day survival was 93.7% and 89.7% in the TF and TA groups respectively, and compares extremely favourably when compared to the logistic EuroSCORE.

Conversion to open AVR occurred in 2.7% of the cases. Valve embolisation was unusual and occurred in only 0.3% of the cases. Similarly, the incidence of coronary obstruction was also low, occurring in only 0.6% of cases.

Key data and the 30-day major complication rates are shown in Tables 1 and 2. Overall 30-day mortality was 8.5%. The stroke rate was 2.4% and similar in TF and TA.

The pacemaker...
rate was 6.7%, which is similar to that reported with surgical AVR, but a low incidence in the TAVI arena. Major vascular complications occurred in 10.6% of the TF cases and 2.4% of the TA cases. Interestingly, 30-day mortality was no longer associated with major vascular complication rates in the TF group, suggesting that many lessons have been learned in dealing with this potentially lethal complication. The next challenge will be to get the same sort of improvement in the TA group, where access-related vascular complications remain a factor of poor prognosis, suggesting that this should be the next area of concentration for learning and proctoring. When this is addressed, there will be yet another improvement in the TA results.

The next important presentation of the SOURCE Registry data will be the one-year results. In previous registries, there has been an important increase in mortality between 30 days and one year, due to the compassionate use indication for the ‘sickest of sick’ patients in early procedures—most of whom died from non-cardiac causes. The one-year SOURCE data will allow us to see if patient selection has improved so that this can be avoided.

Finally, I believe the COHORT 1 patients from the SOURCE Registry will become a landmark group of patients who will provide a benchmark for the future. We are already collecting data for COHORT 2, which will consist of the patients undergoing TAVI from the same 32 centres in the 2nd year of commercialisation. The COHORT 1 patient group will continue to be followed over the next few years at regular intervals, and the follow-up will tell us about the robustness of the procedure and the prosthesis. It will also provide the baseline clinical outcomes against which all future patient groups and devices can be compared.

### TABLE 1: KEY DATA (≤ 30 DAYS)

<table>
<thead>
<tr>
<th></th>
<th>TRANSFEMORAL (n=463)</th>
<th>TRANSAPICAL (n=575)</th>
<th>TOTAL (n=1038)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute procedural success*</td>
<td>95.2%</td>
<td>92.7%</td>
<td>93.8%</td>
</tr>
<tr>
<td>30-day survival</td>
<td>434 (83.7%)</td>
<td>516 (89.7%)</td>
<td>950 (91.5%)</td>
</tr>
<tr>
<td>Logistic EuroSCORE§</td>
<td>25.7%</td>
<td>29.2%</td>
<td></td>
</tr>
</tbody>
</table>

* Defined as deployment of an Edwards SAPIEN device, retrieval of the delivery catheter, no conversion to conventional surgery and the patient leaving the interventional room alive.

§ The logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) is a method of calculating predicted operative mortality for patients undergoing cardiac surgery.

### TABLE 2: MAJOR COMPLICATIONS (≤ 30 DAYS)

<table>
<thead>
<tr>
<th></th>
<th>TRANSFEMORAL (n=463)</th>
<th>TRANSAPICAL (n=575)</th>
<th>TOTAL (n=1038)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>29 (6.3%)</td>
<td>59 (10.3%)</td>
<td>88 (8.5%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>11 (2.4%)</td>
<td>16 (2.8%)</td>
<td>27 (2.5%)</td>
</tr>
<tr>
<td>Renal failure requiring dialysis</td>
<td>6 (1.3%)</td>
<td>41 (7.1%)</td>
<td>47 (4.3%)</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>31 (6.7%)</td>
<td>42 (7.3%)</td>
<td>73 (7.0%)</td>
</tr>
<tr>
<td>Major Vascular complications</td>
<td>49 (10.6%)</td>
<td>14 (2.4%)</td>
<td>63 (7.0%)</td>
</tr>
</tbody>
</table>
Into the Heart of the Matter: The integration of transcatheter valve implantation in the larger history of valve replacement

WILFRIED WISSEER, MD
Associate Professor of Surgery, Medical University Vienna, Vienna, Austria

Biological aortic valve prostheses, as well as surgical techniques, have experienced continuous improvements over the last five decades. Valve design enhancements, along with specialised manufacturing and the use of anticalcification treatment incorporated into tissue processing, have led to improved valve durability with increasingly diminished structural valve deterioration. It is against this backdrop that the dramatic and initial conceptual innovation for TAVI took place, and a new procedure was added to our surgical armamentarium as an option for treating aortic valve stenosis. It was only then that high-risk patients, who otherwise would have been refused for open-heart surgery, could be treated.

With the advent of this technology, our surgical profession has experienced a paradigm shift toward minimally invasive techniques, which now allows us to ‘touch’ our target area – the heart – in a very different way than previous approaches. It is now necessary to learn and integrate catheter skills into surgical practice; this has resulted in broadening and challenging our field. Furthermore, with the crucial collaboration between surgeons, cardiologists, anaesthetists, nurses and technicians during these procedures, TAVI truly represents a team approach, which has established pathways for medical improvements for our profession and our patients. In addition, it has inspired a lively and positive dialogue among participating specialists.

Today, as a result of this dialogue and evolving procedural techniques, a large internationally-structured training program has been established under the guidance of Edwards Lifesciences and Physician Proctors during which necessary skills can be introduced and team organisation optimised. The elements critical for enabling a new centre to succeed range from an interdisciplinary team spirit and specific task assignments and team line-ups, to the architecture of the clinical space itself. These can be acquired through guidance, discipline and strong partnership.

Today, as dedicated TAVI specialists, we can be proud of what we have accomplished. Together, through continuous improvement and pedagogy, TAVI procedures have been successfully implemented in new centres – safely and with reproducible results. The process of learning, communicating and dialogueuing that we have put into place, has greatly improved our perception of TAVI itself, and helped facilitate the “learning curve”. As Proctors, we regularly meet to share experiences and disseminate learnings. The next Proctors’ meeting will focus on the continued refinement and definition of proctoring guidelines.

For the present, it is important to remember that at the onset of AS symptoms, AVR surgery remains the gold standard of care for many patients and they should be referred for treatment early. The advent of TAVI has, in fact, increased the number of patients receiving surgery, since the awareness created by the new procedure has increased the number of referrals, many of whom are surgical candidates. The primary concern for us as physicians is to offer the best option of care to our patients on an individualised, specialised basis. It is therefore not simply a question of which therapeutic concept is best—as conventional surgical valve replacement, minimally invasive procedures and transapical and transfemoral TAVI each has its place. Rather, it is a question of which patient-tailored treatment will be the best in terms of minimising risk in comparison to long-term survival and quality of life.

Thus far, TAVI has proven to be an encouraging, adjunctive treatment option and has clearly become one of our available choices for high risk patients who have few or no other treatment options. Today, TAVI has an important role to play for some of our patients, and it is a role that we are seeing evolve with each passing day.

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Next page: Insights into the use of contrast angiography during valvuloplasty... TAVItalk TF case reports.

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INTRODUCTION

This case illustrates the role of contrast angiography during balloon valvuloplasty in detecting the risk of coronary ostia occlusion during the Edwards SAPIEN valve implantation. Despite the absence of stenosis in the coronary angiogram, the rise of the native calcified leaflet can reduce the diameter of the coronary ostium resulting in a dramatic fall in coronary flow. In this case, a strategy using coronary protection allowed the safe deployment of the Edwards SAPIEN valve, ensuring the patency of the jeopardised left main.

PATIENT PROFILE

Mrs. C.C. is a 79-year-old woman and a long-term victim of chronic pulmonary disease and obesity. Recently, her cardiologist discovered another cause of dyspnea: a severe aortic stenosis with impaired left ventricular function.

CLINICAL DATA

Baseline angiography of the ascending aorta showed a calcified native valve, but also heavy calcification at the ostium of the left coronary artery (Fig. 1a & 1b, page 3).

Contrast angiography during balloon valvuloplasty showed a significant reduction of the diameter of the ostium of the left main (Fig. 2), probably due to the rise of the native leaflet into the left sinus of valsalva.

Selective injection of the left coronary artery showed, again, the absence of stenosis and the absence of fall in blood pressure (Fig. 3).

At this moment, we considered three strategies:

1) Cancelling the case because of the very high risk of left coronary artery closure after valve insertion;
2) Protecting the left main by inserting a 0.014” wire during the Edwards SAPIEN valve deployment, with bail-out stenting after valve implantation, if needed;
3) Preventive stenting of the left main.

Because we considered this patient’s anatomy to be at very high risk for left main occlusion, we decided to implant a stent at the ostium of the left main prior to implantation of the Edwards SAPIEN valve (Fig. 4).

A balloon valvuloplasty was repeated, and contrast angiography showed the patency and normal diameter of the left main during balloon inflation (Fig. 5).

It was not until this moment that we considered the left main to be protected and that the Edwards SAPIEN valve was implanted with a good result.

A selective injection of the left coronary artery was repeated showing a patent and large left main (Fig. 6).

TAKE-HOME MESSAGES

Contrast angiography during balloon valvuloplasty plays a key role in detecting the potential risk of coronary ostia occlusion during TAVI.

In spite of the absence of significant stenoses, the rise of the native leaflet during the inflation of the balloon can compromise coronary ostium patency.

Strategies exist and should be discussed and considered before Edwards SAPIEN valve implantation to prevent abrupt closure of coronary arteries, which is always a dramatic situation.

Preventive, or bail-out, coronary stenting allows for Edwards SAPIEN valve implantation and maintained patency of the potentially jeopardised coronary ostium.
Technical complexity in a case with a pseudo-bicuspid aortic valve

INTRODUCTION

The case of this patient demonstrates the potential to perform TAVI in patients with pseudo-bicuspid valve with heavy calcification (Fig. 1). The deployment of the valve was difficult due to the height and asymmetry of the calcium deposits, however, with attention to detail during deployment an excellent position was obtained (Fig. 2a, 2b). Please note that bicuspid valves are contraindicated for TAVI. In this case, the valve was so distorted that it ‘behaved’ like a bicuspid valve, but, anatomically, it was still tricuspid. For this patient, no alternative approaches were deemed appropriate and, based on our team’s collective clinical assessment, he was declined for surgery.

The patient had heavily calcified, tortuous external iliac arteries necessitating a transapical approach. The images demonstrate the prosthesis position appearing low. However, it is perfectly placed without any aortic regurgitation.

PATIENT PROFILE

This 86-year-old retired engineer presented with worsening severe shortness of breath and chest pain on exercise. He was limited to 200 yards on level ground and with occasional episodes of shortness of breath while laying flat, waking him up at night.

CLINICAL DATA

TTE: AVA = 0.5cm²; LVEF = 45%; peak gradient = 110mmHg; mean gradient = 80mmHg; SPAP = 31mmHg; Aortic root = 3.6cm, ascending aorta = 4.1cm; Mild aortic regurgitation; LVED = 5.2cm; Moderate left ventricular hypertrophy; No severe stenoses on coronary angiography; FEV1 = 2.17 litres; FEV/FVC(%) 85.6; TLCO = 6.75; Logistic EuroSCORE = 30.71%; Uneventful outcome discharged at day 7.

TAKE-HOME MESSAGES

Catheter-based aortic valve implantation is an emerging and evolving treatment option. Increasingly more complex cases with challenging anatomical lesions can now be attempted. Surgery remains the standard of care and should be the first therapeutic option. As a result of our TAVI programme, our actual number of AVR surgeries has gone up due to increased referrals. As this catheter-based technology becomes more widely available, no patients with aortic stenosis should be denied the opportunity to be assessed by a specialist unit.

HISTORY SNAPSHOT

86-year-old man
- Hypertension
- Diabetes mellitus
- Recurrent transient ischaemic attacks (minor bilateral carotid disease)
- Macular degeneration
- Resolving left pleural effusion
- Bilateral renal tumours (curative chemotherapy 2004)
- No other comorbidities which would preclude quality of life

CASE REPORT

Transapical

Fig. 1: Echocardiogram demonstrating a pseudo-bicuspid aortic valve. The arrowhead marks the taut leading calcified raphe. An annular ring of calcification is visible around the valve orifice.

Fig. 2a: Fluoroscopy of the ascending aorta, showing height of calcification (top arrows). Aortic annulus is visible (bottom arrow). Undeployed valve in situ.

Fig. 2b: After implantation, the position of the prosthesis is perfect. The origin and filling of the left main stem (LMS) coronary artery is visible.

Europe/September 2009
A state-of-the-art heart valve bioprosthesis should be designed to provide both immediate and sustained long-term haemodynamic performance, as well as structural integrity. The valve should also be easy to deliver and not impinge on surrounding cardiac anatomy. Therefore, the primary considerations for effective valve design are: 1) durability, 2) haemodynamics, and 3) ease of use. Tissue treatment and material selection have a significant influence on durability. This issue will focus on the Carpentier-Edwards ThermaFix tissue treatment process and its influence on valve durability.

**What is the Carpentier-Edwards ThermaFix tissue treatment process?**

The ThermaFix tissue treatment process is the third generation of anti-calcification technology developed by Edwards Lifesciences. Valve leaflets that have been cut from bovine pericardial tissue, and also matched for thickness and elasticity, are placed in sterile containers with a gluteraldehyde solution and incubated for a total of six days. These leaflets are then treated with ThermaFix, a combination of a heat treatment and chemical process, which effectively reduces 98% of calcium binding sites in the tissue.

**How does the ThermaFix tissue treatment mitigate calcification?**

Following glutaraldehyde fixation of pericardial tissue, two major binding sites for calcium (residual/unstable molecules and phospholipids) remain on each leaflet. Either of these can attract calcium molecules over time and can lead to tissue calcification, one of the primary causes for tissue valve deterioration. Edwards SAPIEN valve leaflets undergo a heat treatment which removes unstable gluteraldehyde molecules, followed by a chemical treatment designed to remove phospholipids. Treating the leaflets with the multi-step anti-calcification process is intended to enhance the Edwards valves' long-term performance1 (see below).

**How efficient is the ThermaFix tissue treatment process?**

In vitro and in vivo studies were performed, analysing calcification, chemical, histological and biomechanical qualities in order to assess the safety and efficacy of this tissue treatment.

While no changes were found in functional valve performance, animal studies showed there was up to 81% reduction in calcium uptake over controls1. (See below.)

The ThermaFix tissue treatment builds upon the Edwards XenoLogiX treatment process used for more than 20 years in Carpentier-Edwards surgical valves. Clinical follow-up in 267 surgical patients with treated valves demonstrated that 92% of those age 60 or older did not experience valve deterioration at 20 years2.

Today, both Edwards pericardial surgical valves and the Edwards SAPIEN transcatheter valves are treated with ThermaFix tissue treatment with the goal of continuing to demonstrate increased valve durability for patients.

The ThermaFix tissue treatment process reduces potential calcium-binding sites

Untreated leaflet tissue — in the body.

Tissue phospholipids and unstable gluteraldehyde molecules are major calcium binding sites, which can lead to tissue calcification.

ThermaFix process Step 1: Unstable gluteraldehyde molecule removal — in the lab.

Proprietary thermal treatment removes unstable gluteraldehyde molecules.

ThermaFix process Step 2: Phospholipid removal — in the lab.

Patented chemical treatment removes 98% of tissue phospholipids.

Treated leaflet tissue — in the body.

The ThermaFix tissue treatment process has removed most of the two major calcium binding sites.

Animal test results show up to 81% reduction in calcium uptake over gluteraldehyde controls.

<table>
<thead>
<tr>
<th>Animal Test Study</th>
<th>Reduction in Calcium Uptake</th>
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</thead>
<tbody>
<tr>
<td>Rat Subcutaneous Implant Study, 120 Days</td>
<td>81% reduction</td>
</tr>
<tr>
<td>Rabbit Intramuscular Implant Study, 28 Days</td>
<td>65% reduction</td>
</tr>
<tr>
<td>Sheep Heart Valve Implant Study, (n=6)</td>
<td>75% reduction</td>
</tr>
</tbody>
</table>

No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.

References:
1. Data on file at Edwards Lifesciences
2. Clinical communiqué 20 yr results AR002835

The Edwards Transcatheter Heart Valve Newsletter
FOR USE OUTSIDE THE UNITED STATES ONLY. NOT INTENDED FOR GENERAL DISTRIBUTION.
Edwards Lifesciences celebrates opening of new European Headquarters and Training Centre

On June 26, 2009, Edwards Lifesciences opened its new regional headquarters and physician training centre in Nyon, Switzerland. The facility will serve Edwards’ growing operations in Europe, the Middle East and Africa from a more central location, and features a state-of-the-art training facility where physicians and Edwards’ personnel can educate their peers on new technologies and techniques. The facility includes two hands-on simulators, a heart valve wet lab and an auditorium for viewing live case transmissions. More than 700 people are employed in Europe, with over 120 based in Switzerland. Edwards employs more than 6,200 worldwide, and the company’s global headquarters is located in Irvine, California, USA.

PATIENT SCREENING CRITICAL TO SUCCESS

The role of TEE and MSCT

IASSEN MICHEV, MD
Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy and the Interventional Cardiology Unit, EMO-GVM Centro Cuore Columbus, Milan, Italy

Screening candidates for percutaneous aortic valve procedures involves a complex decision making process that includes a multidisciplinary team evaluation. The key to success is careful patient selection and evaluation, in order to plan the most appropriate procedural strategy and avoid complications. TAVI is one of the most exciting new developments in the treatment of valvular disease. Many lives have been saved; many patients are enjoying a better quality of life thanks to TAVI. We have been lucky to be a part of this new venture. Now, the progress and expansion of TAVI relies on our clinical, investigational and educational diligence and discipline, working together as a team.

Based upon our experience in Milan, where more than 200 patients have been screened in the outpatient clinic, and more than 100 patients have been treated during the past 18 months, only high-risk surgical patients (logistic EuroSCORE >20%, or STS ≥10%), or those with porcelain aorta, previous cardiac surgery, liver cirrhosis or marked patient frailty are assessed for TAVI.

The severity of the aortic stenosis initially should be assessed by clinical examination and then by TTE, which can also provide some information regarding the annular diameter. However, further anatomical evaluation will usually be required, as TTE is inaccurate in patients with poor quality of images (in COPD), and may provide inaccurate information in subjects with an ovoid aortic annulus.

Whilst TEE has a role, in our practice multislice computed tomography (MSCT) is now establishing itself as the gold standard and as the next step for the non-invasive evaluation of TAVI patients. It enables accurate assessment of the peripheral access routes, aortic anatomy and annular dimensions within one test and also provides a rudimentary assessment regarding the extent of coronary artery disease.

Seeing with my hands

GILLIAN LONGANO, CATH LAB SISTER
Sunninghill Hospital, Johannesburg, South Africa

After two days of training and case observations, most important for me was ‘seeing with my hands.’ Our 20 participants, from four major hospitals in South Africa—some keen, some curious, a couple of nonbelievers—talked at the end of taking the new technique home, beginning a new phase of our two specialties working closely together with a renewed spirit of cooperation.
Note TAVI Bene

UPCOMING MEETINGS AND LINKS

TAVI at ESC, TCT and EACTS
TAVI will be featured prominently in upcoming ESC, TCT and EACTS congresses. See below for key events!

ESC Barcelona August 29-Sept 2
Monday, August 31
AORTIC VALVE REPLACEMENT 2009: Plenary session
8:30-10:00 Berlin Room (Zone 3)
Chairmen: C. Otto, R. Dion
Speakers: S. Rahimtoola, A.J.J.C. Bogers, A. Vahanian, T. Walther

Tuesday, Sept 1
FOCUS IMAGING INTERVENTION: Assessment of Aortic Stenosis, Live from Barcelona
11:00-12:30 London Room (Zone 3)
Chairwomen: C.Otto, P . Tornos
(supported by an unrestricted grant from Edwards Lifesciences)

SATELLITE SYMPOSIUM: TAVI—A new treatment modality for high risk aortic stenosis patients
14:00-15:30 Ankara Room (Zone 1)
Chairmen: J. Bax, A. Vahanian
Speakers: J. Bax, H. Baumgartner, O. Wendler, A. Cribier, D. Himbert, A. Vahanian
(supported by an unrestricted grant from Edwards Lifesciences)

TAVI at ESC, TCT and EACTS
TAVI will be featured prominently in upcoming ESC, TCT and EACTS congresses. See below for key events!

TCT San Francisco Sept 21-25
Sign up at the Edwards booth for hands-on simulator training!
Monday-Tuesday, Sept 21–22
THE VALVULAR DISEASE SUMMIT: Medical, Surgical, and Percutaneous Approaches
Part I: Overview and Aortic Valve Therapies
Part II: Mitral and Right Heart Valve Therapies
Monday evening:
TRANSCATHETER VALVE THERAPIES: Current and future implications for clinical practice
Reception: 19:00, Programme: 20:00-22:00
Hilton San Francisco Continental Ballrooms 1-5
(supported by an unrestricted grant from Edwards Lifesciences)

Wednesday-Friday, Sept 23–25
Many TAVI talks/cases in TCT programme

EACTS Vienna Oct 17-21
Monday, Oct 15 12:30-14:30
TAVI SYMPOSIUM: Redefining the frontiers of Valvular Disease Management
(supported by an unrestricted grant from Edwards Lifesciences)

CURRENT INDICATIONS:
Patients with symptomatic aortic stenosis, aortic valve area <0.8 cm² requiring aortic valve replacement who have high risk for operative mortality, or are “non-operable”, as determined by one of the following risk assessments: Logistic EuroSCORE >20% or STS Score >10.
To be performed via transfemoral or transapical access without cardiopulmonary bypass.

Upcoming International Meetings

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<tr>
<td>SEPT</td>
<td>TCT SAN FRANCISCO</td>
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<td>LONDON VALVE LIVE</td>
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<td>STS FT. LAUDERDALE</td>
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<tr>
<td>FEB</td>
<td>JIM ROME</td>
<td>TCT Conference 2009</td>
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</tbody>
</table>

COMPANY AND PRODUCT INFORMATION:
Edwards Lifesciences is the global leader in the science of heart valves and haemodynamic monitoring, with more than five decades of experience in partnering with clinicians to develop life-saving innovations. Headquartered in Irvine, CA, USA, Edwards treats advanced cardiovascular disease with its market-leading heart valve therapies, and critical care and vascular technologies, which are sold in approximately 100 countries.

Edwards and RetroFlex3 are trademarks of Edwards Lifesciences Corporation. Edwards Lifesciences, the stylized Edwards logo, Carpentier-Edwards, Edwards SAPIEN, Ascendra, PERIMOUNT Magna and ThermaFix are trademarks of Edwards Lifesciences Corporation and are registered in the United States Patent and Trademark Office.

The Edwards SAPIEN™ valve used with two different delivery systems obtained CE marking in 2007. Limited by Federal (USA) law to investigational use.

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Tel: +41 22 787 4362.

Additional company information can be found at http://www.edwards.com

Edwards SAPIEN THV RetroFlex 3 Transfemoral (TF) delivery system Ascendra Transapical (TA) delivery system