From the simplest gesture to the latest technical innovation, the question of the learning curve—our ability to incorporate new skills and knowledge into our practice—is of paramount importance. When we hear of procedural success rates for the transfemoral (TF) and transapical (TA) approaches that are both now higher than 95%—and thus superior to previously published data—it underlines the fact that there is a dedicated and carefully planned adoption and training programme in place.

This sophisticated system is comprised of various offerings, including simulator-based training, case observation and on-site proctorship in each centre where transcatheter aortic valve implantation has been introduced. It is the result of a shared commitment—not only by dedicated specialists but also by Edwards Lifesciences—to an extensive, continuous and evolving effort.

Our goal of improving the “learning curve” is clearly complemented by the Edwards SOURCE Registry. Started in January 2008, this registry is aimed at documenting the clinical results of commercially implanted Edwards SAPIEN™ prostheses.

In January of this year, the group of interventional cardiologists and cardiac surgeons who serve as Proctors for Edwards’ European training programme met in Paris for the first “TAVI Proctors’ Meeting.” They shared their experiences, discussing the technical aspects of thousands of implantations, and also reflected on the inclusion criteria for patients and midterm post-operative results.

It has now been more than one year since the Edwards SAPIEN bioprosthesis became commercially available for TAVI using the RetroFlex and Ascendra delivery systems. With more than 2,500 Edwards SAPIEN valves already implanted in clinical studies in more...
Approaching new technologies and protocols requires an openness to dialogue as well as a commitment to respond to questions as they arise. In the year and a half since the Edwards SAPIEN valve received its CE mark—and with more than 2,500 valves now implanted in clinical studies worldwide—the primary question today is, "How advanced is our knowledge of transcatheter aortic valve implantation (TAVI) with the balloon-expandable Edwards SAPIEN prostesis?"

A simple and obvious question, perhaps, but with the amount of TAVI data increasing every month, it is critical that we carefully evaluate the results using our experience to place this pioneering technique into context. While this procedure is still relatively new and offers less abundant long-term data than surgery, we see a clear pattern of improvement in published studies and registries such as the PARTNER EU study or the SOURCE Registry.

THE TEAM APPROACH With careful training of multidisciplinary teams (including interventionalists, cardiologists, surgeons, anaesthesiologists, and imaging specialists), the success rate of the procedure is now consistently well over 90%. This can be attributed to both improved technical skills and our ever-increasing experience, which leads us to better patient selection. Valve function itself appears excellent, and careful procedural technique (as in any clinical setting) remains an important aspect, which we continue to monitor and address through our training as well as our research. All in all, the frequency of major complications has dramatically decreased and, with experience, the incidence of prosthetic embolism is becoming extremely rare. Severe aortic regurgitation is present in less than 5% of cases. The matrix of developments, including the positive evolution towards close, coordinated collaboration between interventionalists and surgeons, improved patient screening, and the use of a purely percutaneous approach in select patients, have all led to the aforementioned decrease in the incidence of major vascular complications. Midterm results over five years in Alain Cribier’s series (and up to two to three years in several other series) are extremely encouraging and have shown no signs of valve dysfunction. In addition, most surviving patients have seen dramatic improvements in their quality-of-life—which is, after all, of the greatest importance for this elderly population.

EXPANDED PATIENT SELECTION AND TREATMENT With TAVI as a viable option today, clinicians are referring many patients for treatment who would not have been referred for surgery in the past. This has been reported recently in several publications (as was the case in the Euro Heart Survey). If current trends at Bichat Hospital (Paris, France) hold true, then we will see that our team approach, linked to careful screening, will allow us to propose intervention for approximately two-thirds of those patients who were previously not referred for surgery. Half of these patients will receive TAVI (the TF or TA approach), while 15-20% will receive classic surgical aortic valve replacement, which remains the gold standard of care for many patients (these figures based on early experience at Bichat Hospital). The remaining one-third of these previously non-referred patients will be kept on medical therapy alone, either because their life expectancy is too short, or because they are too frail for any intervention. These numbers are not set in stone, and will most likely evolve with better knowledge of both the safety and long-term results of TAVI; nonetheless, they are extremely encouraging for our patients and their families.

Without question, a very careful and stepwise training, along with the continued evolution and improvements in the system itself (which are now offered by the RetroFlex 3 delivery system), will further improve TAVI results. Finally, the findings from comprehensive registries, as well as that of randomised trials such as the US PARTNER IDE trial, will be crucial to our future knowledge of the TAVI technique and the improvement in our patient selection.

Valve positioning tips and tricks

PROFESSOR ALAIN CRIBIER, MD
Hôpital Charles Nicolle, University of Rouen
Rouen, France

The Edwards SAPIEN transcatheter heart valve (THV) was developed to be implanted across the aortic annulus in the subcoronary position. Ideally, its frame should not extend over the coronary ostia, nor should it extend below the onset of the transventricular septum and the mitral valve’s anterior leaflet. THV positioning before implantation is often based on fluoroscopic visualisation of calcification on the aortic valve leaflets. Post-implantation, valve positioning is generally confirmed by angiography and CT-Scan. Optimal positioning is critical in order to prevent valve embolisation and paravalvular leak. Adjunctive TEE may be helpful in cases of mild valvular calcification, and many centres routinely use it.

Before valve crossing and positioning, the fluoroscopic view that allows the aortic valve to be seen in a perpendicular plane (i.e. all three cusps seen in the same plane) must be determined. Slight LAO/cranial projection is most common, but other projections may be required depending on aorta/left ventricle angulation.

Transfemoral (TF) implantation with the RetroFlex I delivery system is usually associated with an antegrade shifting of the Edwards SAPIEN valve by 1 to 3 mm during balloon inflation—a phenomenon not observed in the transapical (TA) approach. Thus, initial THV positioning differs and is slightly lower with the TF RetroFlex I delivery system (3/4 of the frame below the level of valvular calcification) than with TA positioning (equator of the frame adjacent to valvular calcification). Little, if any, shifting is observed with the new RetroFlex 3 delivery system and the initial positioning is now similar in both TA and TF approaches. Finally, contrast testing above the aortic valve, as well as a test of rapid pacing, will be useful to ensure the final location and stability of the Edwards SAPIEN valve before delivery.
A high risk transapical procedure with a good outcome due to conscientious operative strategy

INTRODUCTION
“A particular challenge for centres starting a TAVI programme is the high risk profile of the patients. These patients face operative mortalities (as calculated by the logistic EuroSCORE), oftentimes greater than 20%. In this review we present just such a case, where Leen van Garss of Maastricht introduces us to a patient where ‘being prepared’ for any eventuality was not only a simple phrase, but also has allowed this patient to be alive today with NYHA II and an improved quality-of-life.”

OLAF WENDLER

COMMENTARY
The potential for left ventricular deterioration during the waiting time for the transcatheter aortic valve implantation (TAVI) procedure is, of course, one of the problems that TAVI centres may encounter. In the patient that we are presenting, severe impaired left ventricular function was the main risk factor for haemodynamic deterioration during the procedure. In these types of exceptionally high-risk patients, it is vital to prepare to go on bypass—and to consider placing arterial and venous cannulae in advance of the procedure.

PATIENT PROFILE
Shortness of breath with chest pain and a history of heart disease, our patient was becoming increasingly bedridden.

CLINICAL DATA
We considered this procedure to be high-risk, and prepared vascular access for extra-corporeal circulation (ECC) by inserting two 4 Fr sheaths in the left groin. Care was taken to ensure that neither sheath interfered with the access for the pigtail diagnostic catheter, which had been placed through the right femoral artery for this transapical (TA) procedure.

As feared, after rapid pacing associated with balloon valvuloplasty, the patient’s haemodynamics failed to recover sufficiently. CPR was started as we moved quickly to implant the Edwards SAPIEN valve.

The patient recovered adequately during the 30 minutes on ECC. The Edwards SAPIEN valve position was confirmed to be good and our patient was weaned successfully from inotropics and ECC.

Extubated after 15 hours without neurological dysfunction, the patient was kept in the ICU for an additional three days.

At ten-months follow-up, the patient was seen at our polyclinic, satisfied with his significantly improved quality of life.

His condition is now NYHA class II.

TAKE-HOME MESSAGE
An appropriate risk analysis of the individual circumstances for each patient considered for TAVI is recommended. Operators should be prepared with a pre-operative strategy individualised for each patient.

High-risk procedures can be performed even in the beginning of a centre’s experience—with on-site proctor support—if potential procedural difficulties are recognised and the centre is adequately prepared for the worst possible scenario. In fact, with adequate forethought and preparation, high-risk patients can be treated with extremely good results.

WHY BEING PREPARED COUNTS

L VAN GARSS, MD
J MAESEN, MD
V VAN OMMEN, MD
on behalf of the TAVI team at Academic Hospital Maastricht, The Netherlands

HISTORY SNAPSHOT
- An 80-year-old man suffering from:
  - symptomatic severe aortic valve stenosis (AVA 0.7 cm²) with a logistic EuroSCORE of 90.86%
  - STS mortality risk score of 28.3%
  - admitted for transapical aortic valve implantation
- Medical history consisted of:
  - CABG, nephrectomy, hypercholesterolaemia, hypertension
  - significant asymptomatic stenosis of the left carotid artery. A proximal stenosis in the coronary venous graft was stented pre-operatively
  - Over the last weeks his condition had deteriorated severely, presenting in NYHA class IV
  - LVEF was 26%, with severe mitral valve regurgitation and pulmonary hypertension (65-70 mmHg)
  - Renal function was poor: Creatinine of 242 umol/L (2.73 mg/dl)
  - Increasingly bedridden as a result of experiencing shortness of breath with chest pain and a history of heart disease
  - Inotropics were started before the operation

Dr. Leen van Garss poses with her post-operative patient.
HISTORY SNAPSHOT

83 year-old man
• Prostate cancer (favourable prognosis)
• Pacemaker
• Lives in the south of France (Orange)
• Very active person until October 2008, at which time he became very symptomatic with disabling exertion angina and dyspnea
• PCI performed for 3-vessel CAD (bare metal stents implanted in the LAD and LCX)
• February 2009: again very symptomatic—permanent dyspnea (class IV NYHA), orthopnea; diagnosis: severe AS with LV dysfunction and pulmonary hypertension
• Referred to Bichat for TAVI
• In spite of his condition, the patient travelled by train from Orange to Paris by himself—a distance of over 600 km!

An active older patient with a complex problem

INTRODUCTION

This TF patient, ‘Charles M,’ demonstrates two important teaching points:

1: IT IS POSSIBLE TO COMBINE percutaneous coronary intervention (PCI) and transcatheter aortic valve intervention (TAVI) in the same procedure.

This approach was chosen in this case because the patient presented with class IV congestive heart failure (due to severe aortic stenosis), which occurred in the context of an acute coronary syndrome (with troponin elevation due to sub-occlusive in-stent restenosis of the LAD). We thought that both the coronary and valvular diseases needed to be treated immediately and simultaneously.

2: EXTREME INSTABILITY OF SEVERAL BAV BALLOONS—despite adequate capture during pacing—led us to do multiple pacing runs.

Finally, BAV with the NuMed Nucleus™ balloon was successfully achieved. However, the need to do multiple BAVs left us anxious about the behaviour of the balloon during delivery of the Edwards SAPIEN valve. After careful analysis of the distribution of calcification, the prosthesis was delivered at the right place with an optimal result.

TAKE-HOME MESSAGES

If clinically indicated, combined PCI + TAVI can be performed.

Despite adequate pacing, severe instability of standard BAV balloons can occur, precluding effective aortic predilatation. Multiple pacing periods can lead to haemodynamic deterioration. The use of more stable balloons can be useful, without precluding the safety of prosthesis delivery.

PATIENT PROFILE

‘Charles M’ is an active man, well into his 80s, whose overall health deteriorated in just a few months, requiring intervention. Though faced with multiple comorbidities, including a treatable prostate cancer, he remains upbeat and optimistic. His morale is excellent, as is his desire to live life to its fullest potential.

CLINICAL DATA

Upon admission: pulmonary oedema, chest pain evolving since at least 24 hours, troponin 8.

TTE: severe AS, mean gradient 50 mmHg, LVEF 40% with antero-apical akinesia, SPAP 70 mmHg.

Annulus diameter 24 mm.

Favourable, immediate improvement with diuretics and anti-thrombotics.

Coronary angiogram: sub-occlusive in-stent restenosis on the LAD, no proximal restenosis on the LCX.

Large and mildly calcified femoro-iliac arteries on angiogram.

Decision to combine first PCI on the LAD, then TF AVI during the same procedure.

Uneventful outcome at day 4.
Everybody’s grandmother

DOMINIQUE HIMBERT, MD
on behalf of the TAVI team at
Hôpital Bichat, Paris, France

INTRODUCTION

The case of ‘Suzanne F’ illustrates the potential pitfall of being misled by calcification when it mimics the plane of the annulus which may, in fact, be situated below the calcification.

Instead of calcification, the level of the pigtail, as well as angiogram and TEE monitoring, are the appropriate indicators for the optimal place to deliver the prosthesis. The images portray the prosthesis as appearing to be placed much too low with regard to the calcification.

However, it is perfectly positioned as is demonstrated in the final angio (as confirmed by TEE), with no AR.

PATIENT PROFILE

‘Suzanne F’, an 83-year-old diabetic woman, has close and vibrant ties to her family who are an integral part of her everyday life. Just prior to the procedure, she complained of pain in her left leg and shortness of breath, which caused increased anxiety and excessive sweating.

HISTORY SNAPSHOT

83-year-old woman
• Hypertension
• Hypercholesterolaemia
• Diabetes mellitus
• COPD
• Severe peripheral artery disease with multiple stenting
• Recent ischaemic event in the left leg
• No other comorbidity which would preclude quality of life or life expectancy
• Very close familial environment
• Admitted for pulmonary oedema related to AS

CLINICAL DATA

TTE: AVA=0.78 cm² (0.5 cm²/m²).
FVEF=30%; mean gradient=30 mmHg.
SPAP=50 mmHg.
Annulus diameter=20 mmHg.
Porcelain aorta.
No severe stenosis on coronary angiogram.
EuroSCORE=50%.
Decision of TA -AVI.
Uneventful outcome at day four.

TAKE-HOME MESSAGES

Thorough pre- and peri-procedural analysis of the initial aorta with angiography, echo and CT scan are mandatory to avoid misplacement of the prosthetic valve, as the pattern of aortic calcification can mimic the annulus. The placement of the prosthesis should always be guided by consistent findings from pigtail position, supra-aortic angiogram and TEE monitoring.

Fig. 1: Fluoroscopy of the ascending aorta, showing calcification mimicking the annulus, but situated above its plane, delineated by the position of the pigtail catheter.

Fig. 2: Angiogram of the ascending aorta, showing the pigtail catheter on the aortic root in the Valsalva sinus.

Fig. 3: After implantation, the prosthesis seems too low with regards to the calcification.

Fig. 4: On angiogram, the position of the prosthesis is perfect, as confirmed by transesophageal echocardiography.
The RetroFlex 3 delivery system is the next step in the evolution of the Edwards transfemoral approach to TAVI. The articulating shaft of the RetroFlex 3 delivery system allows for controlled navigation through the aortic arch, guiding the Edwards SAPIEN THV to the native calcified valve. The RetroFlex 3’s tapered tip allows for atraumatic native valve crossing.

The RetroFlex 3 delivery system is used with the balloon-expandable, stainless steel-framed Edwards SAPIEN transcatheter heart valve. The SAPIEN valve provides consistent radial strength, ensures both immediate and long-term concentric shape retention—essential for long-term durability, as well as both acute and chronic haemodynamic optimisation.

Each Edwards SAPIEN valve is the result of a careful production process incorporating bovine pericardial tissue leaflets that have undergone a proprietary anti-calcification treatment process. Each SAPIEN valve leaflet is individually matched for thickness and deflection to ensure optimal coaptation.

---

**Ask our engineers**

**Q** What is the difference between the RetroFlex I, II and 3 delivery systems?

**A** All three RetroFlex delivery systems feature:

- The Edwards SAPIEN transcatheter balloon-expandable heart valve, and
- Delivery System Articulation

RetroFlex I was the first TAVI delivery system in the world to offer an articulation feature, which was created to minimise delivery system friction in the aorta. This first-generation system did not feature a tapered tip for native valve crossing.

RetroFlex II maintains the Edwards feature of delivery system articulation, while, for the first time, adding a tapered tip to enhance native valve crossability.

RetroFlex 3 integrates the best of all of Edwards previous designs by providing an articulating delivery system to facilitate navigation through the aortic arch, a tapered distal end to enhance crossing of the native calcified valve, as well as an easy-to-use handle.

**Q** Does the RetroFlex 3 delivery system cross the native valve more easily than the RetroFlex I delivery system?

**A** The tapered distal end & pleated balloon of the RetroFlex 3 were designed to provide a smooth transition from the guidewire to the crimped Edwards SAPIEN valve. It is expected this will allow for smooth crossing of native, calcified aortic valves.

**Q** Is the RetroFlex 3 delivery system smaller than the RetroFlex I delivery system?

**A** The current RetroFlex 3 delivery system has the same profile as the RetroFlex I and II delivery systems. However, the RetroFlex 3 delivery system features improved ease-of-use, improved crossability, and has been shown to cross more easily through sheaths.

**Q** What are the advantages of the Edwards SAPIEN transcatheter heart valve?

**A** The Edwards SAPIEN transcatheter heart valve was designed for accurate placement. Its discrete, non-interfering valve height and consistent radial frame strength are designed to allow for concentric valve deployment—features important for long-term valve durability and haemodynamic improvement.
Henning R. Andersen wins Hartmann Prize

Dr. Henning R. Andersen of the Department of Cardiology, Skejby Hospital, University of Aarhus, in Aarhus, Denmark has just been awarded the Danish Hartmann Prize. Given annually, Dr. Andersen was chosen for this year’s prize for his work in pacemaker treatment, primary PCI and transcatheter heart valves (THV). Andersen is a pioneer in the evolution of transcatheter heart valves, and is responsible for the clinical development of THV at Skejby Hospital. His work includes, among others, the Cribier-Edwards™ THV 23mm; Edwards SAPIEN THV 23mm, 26mm. Progress continues to be made in transcatheter heart valve design. Left to right: Andersen hand-made transcatheter aortic valve; Cribier-Edwards™ THV 23mm; Edwards SAPIEN THV 23mm, 26mm.

First generation procedures in ‘older generation’ patients

EULOGIO GARCIA, MD
Instituto Cardiovascular, Hospital Clinico San Carlos
Madrid, Spain

I have seen disasters with a previous technology that did not implement proper training and proctoring. The importance of appropriate case selection cannot be underestimated. The procedure is not difficult, but it has to be precisely and properly done. It is thanks to the dedicated role of Clinical Specialists and Proctors that this procedure has evolved to where it is today—an approach with an extremely high procedural success (>95%). For these very high-risk patients, TAVI has been more warmly and quickly adopted by the medical community than we could have initially anticipated. Care still needs to be taken to ensure there is enough case volume in a centre to maintain learning. Most ICs have experience in PCI, which is more forgiving—with valves, the high-risk patient profiles and structural anatomy require more precision. We must always remember that just because a procedure needs to be ‘precise’ does not necessarily mean that it needs to be ‘difficult.’ You must think the procedure through to the end and predict the consequences, thereby focusing on obtaining a good result. Greater confidence comes with each procedure and, over time, physicians realise that the valve is nearly always in the correct place.

Wendler: The learning curve

(continued from page 1)

than 100 centres in over 20 countries, careful evaluation of clinical results becomes crucial. In light of these high success rates, the Proctors were consistent in their views of valve positioning techniques and deployment. Our future focus, however, needs to be on midterm results, particularly in patients who—despite a successful implantation—do not completely benefit from the procedure due to their other comorbidities. The consensus was that a detailed analysis of first-year mortality after implantation would help clarify which patients could benefit most from this new technique. The SOURCE Registry database is crucial—not just for the Edwards SAPIEN TAVI programme, but also to help us understand how these new techniques can be successfully implemented, how patients can be properly chosen, and how the programme itself impacts midterm and ultimate outcomes. With Edwards Lifesciences’ support and resources, the SOURCE Registry can produce an outstanding clinical dataset—one truly reflecting commercial experience. We must not rest upon our past learning or achievements, but instead continue to build on our results, using our experience to lead us ever onwards toward the future.

FOR USE OUTSIDE THE UNITED STATES ONLY. NOT INTENDED FOR GENERAL DISTRIBUTION.
Note TAVI Bene

UPCOMING MEETINGS AND LINKS

TAVI at EuroPCR
TAVI is a featured topic at EuroPCR (Barcelona, 19–22 May), with a focus on live and taped cases, practical case reviews, tips and tricks and clinical results. New data from the Edwards SOURCE Registry and PARTNER EU clinical trial will be presented directly following the TAVI Forum on Wednesday (Aortic Registry Update 19:00-20:00, Room 4). Edwards will also hold a symposium on Thursday, 21st May, from 12:00–13:30 on what clinicians have learned during the past decade of experience in TAVI procedures. In addition, simulator training will be available in the training village throughout the week. Sign-up is required, as space is limited. Professor Alain Cribier will be at the training village to provide an overview of the training programmes in Rouen and Leipzig. A proctor, members of our clinical specialist team and SIMSUITE will also be at each training session.

Edwards Lifesciences TAVI Symposium
Thursday, 21st May, Room 3, 12:00–13:30

TRANSCATHETER AORTIC VALVE IMPLANTATION: WHAT HAVE WE LEARNED FROM THE PAST?
Chairperson Alec Vahanian, Co-chairperson Thomas Walther

INTRODUCTION AND OBJECTIVES
Alec Vahanian, Paris

VALVE DESIGN IS CRITICAL TO SUSTAINING DURABLE PERFORMANCE
Robert Klautz, Leiden

OPTIMAL PATIENT SELECTION IS IMPORTANT
Martyn Thomas, London

PROCEDURE EVOLUTION CONTINUES TO IMPROVE CLINICAL RESULTS
John Webb, Vancouver

PROCEDURE MANAGEMENT AND TEAMWORK ARE KEY
Martin Leon, New York City

PANEL DISCUSSION
TAKE-HOME MESSAGE
Thomas Walther, Leipzig

REFERENCES:
1. Clinical data on file, Edwards Lifesciences
3. Bench-test data on file, Edwards Lifesciences

2009 International Meetings

<table>
<thead>
<tr>
<th>Month</th>
<th>Dates</th>
<th>Conference</th>
<th>Location</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUNE</td>
<td>25-26</td>
<td>TVT</td>
<td>Seattle</td>
<td><a href="http://www.tvtconference.com">www.tvtconference.com</a></td>
</tr>
<tr>
<td>JUNE</td>
<td>27-30</td>
<td>SHV</td>
<td>Berlin</td>
<td><a href="http://www.shv.org">www.shv.org</a></td>
</tr>
<tr>
<td>JULY</td>
<td>9-11</td>
<td>CSI</td>
<td>Frankfurt</td>
<td><a href="http://www.csi-congress.org">www.csi-congress.org</a></td>
</tr>
<tr>
<td>AUG/SEPT</td>
<td>29-2</td>
<td>ESC</td>
<td>Barcelona</td>
<td><a href="http://www.escardio.org">www.escardio.org</a></td>
</tr>
<tr>
<td>SEPT</td>
<td>21-25</td>
<td>TCT</td>
<td>San Francisco</td>
<td><a href="http://www.escardio.org">www.escardio.org</a></td>
</tr>
<tr>
<td>OCT</td>
<td>14-16</td>
<td>TEAM</td>
<td>Madrid</td>
<td><a href="http://www.teamgrupo.es">www.teamgrupo.es</a></td>
</tr>
<tr>
<td>OCT</td>
<td>17-21</td>
<td>EACTS</td>
<td>Vienna</td>
<td><a href="http://www.eacts.org">www.eacts.org</a></td>
</tr>
<tr>
<td>DEC</td>
<td>6-8</td>
<td>ICI</td>
<td>Tel Aviv</td>
<td><a href="http://www.congress.co.il">www.congress.co.il</a></td>
</tr>
<tr>
<td>DEC</td>
<td>9-12</td>
<td>EUROECHO</td>
<td>Madrid</td>
<td><a href="http://www.escardio.org">www.escardio.org</a></td>
</tr>
</tbody>
</table>

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.

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.
The company’s global brands include Carpentier-Edwards, Cosgrove-Edwards, Fogarty, PERIMOUNT Magna, Edwards SAPIEN, Ascendra, RetroFlex, and Swan-Ganz.
The Edwards SAPIEN™ valve used with two different delivery systems obtained CE marking in 2007. Limited by Federal (USA) law to investigational use.
Edwards Lifesciences, S.A.
Chemin du Glapin 6, 1162 Saint-Prex, Switzerland.
Tel: +41 21 823 4300.
Additional company information can be found at http://www.edwards.com.

The Edwards Transcatheter Heart Valve Newsletter
FOR USE OUTSIDE THE UNITED STATES ONLY. NOT INTENDED FOR GENERAL DISTRIBUTION.