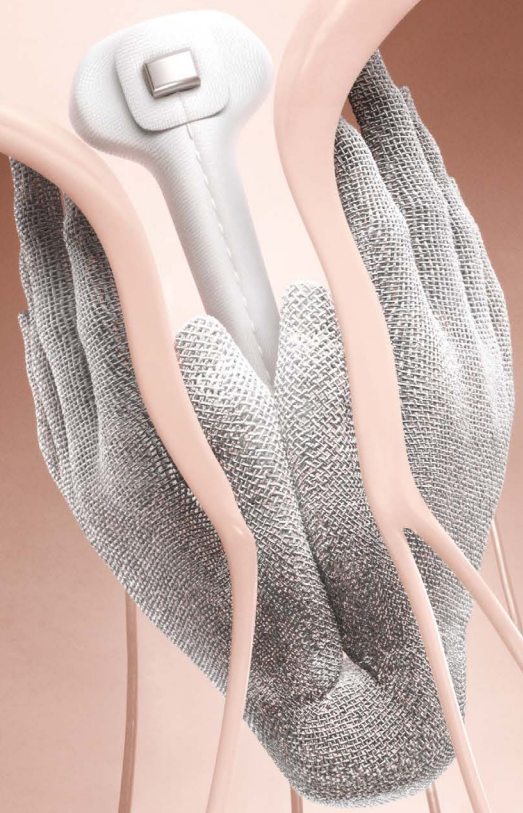
TMTT Today

Your source for innovations in Edwards' transcatheter mitral & tricuspid therapies

PASCAL Stabilizer Rail System: An addition to the PASCAL Platform

Providing stability, control and procedural confidence for all your PASCAL platform procedures



In your hands we can create amazing

Advances for treating TR

- The PASCAL Ace implant: All the benefits in a narrower device
- The Cardioband tricuspid system: Transcatheter annuloplasty for treating severe TR

Expanding real-world data with the PASCAL platform for treating MR and TR

Issue #5 – May 2021

Edwards

Dear Reader,

Dear Reader

Edwards Lifesciences aim to deliver cutting-edge technologies that assist in producing improved outcomes for your patients with valvular pathologies. We recognise the need to build confidence in emerging approaches and techniques, so we are constantly improving our products to optimise your procedures and bringing together clinical evidence to help you evaluate these approaches.

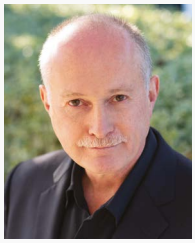
This issue of *Transcathetar Mitral and Tricuspid Therapies (TMTT) Today* introduces the PASCAL Stabilizer Rail System (SRS), which is designed to enhance your experience with the PASCAL platform. The PASCAL SRS uses a rail-based system and secure stabilizers to provide greater stability during PASCAL platform procedures, enabling greater control of catheter movements. For the first time, these procedures can be performed with single-handed catheter advancement, retraction and torquing. This capability should provide you with enhanced confidence when steering the PASCAL and PASCAL Ace implants, placing fine movement control in your hands to obtain predictable capture, positioning and release of implants. Read on to learn about early users' experience with the PASCAL SRS!

The true test of technologies is how they perform in the real world. In this issue, we bring you the latest real-world data from both mitral and tricuspid regurgitation (MR and TR) procedures using the PASCAL platform. These include outcomes from the first 2,100+ PASCAL procedures in MR alongside data from the PASCAL Ace implant for the treatment of MR and TR. Early experiences with the PASCAL Ace implant indicate similar reductions in regurgitation in patients with MR and TR as seen with the PASCAL implant. Finally, we bring you real-world data on the Cardioband tricuspid valve reconstruction system, which offers a safe and effective option for difficult-to-treat patients with severe TR and annular dilatation.

Rodolfo Estay, MSc, MBA

Vice President, Europe

Transcatheter Mitral and Tricuspid Therapies



Dr Ted Feldman, MD MSCAI FACC FESC

Vice President of Global Medical Affairs

Transcatheter Mitral and Tricuspid Therapies

Enjoy reading!

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Broad adoption of the PASCAL Platform: Real-world data in 2,100+ patients

Dr Sergio Berti,
Fondazione Toscana Monasterio, Massa, Italy

Dr Sergio Berti is an interventional cardiologist and Director of the Diagnostic and Interventional Cardiology Department at the Ospedale del Cuore Massa; Director of the Diagnostic and Interventional Cardiology Department, area della ricerca Pisa; and Director of the Area for Innovative Technologies in Cardiology at Fondazione CNR Toscana Monasterio in Italy. Dr Berti has been Principal Investigator in many clinical studies, including AHEAD, MiBAND, MiCLASP and RHEIA.

Real-world data provide the opportunity to assess the use and performance of the PASCAL platform in routine clinical practice, beyond the rigid protocols of clinical trials. A retrospective analysis of the first 1,200 PASCAL repair system procedures in MR previously demonstrated excellent efficacy in patients with severe MR, with 73% of patients achieving MR ≤1+ after the procedure and 97% achieving MR ≤2+.[1] Please read *TMTT Today #1* for more information.

TMTT Today Issue 1 QR code

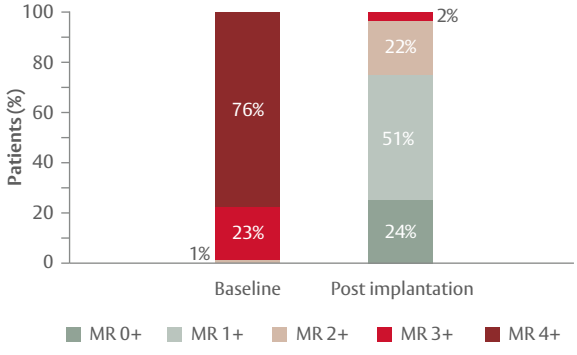
'Overall, procedural success was excellent, with 98% of patients having residual MR ≤2+ and 75% with MR ≤1+. These results are in line with the ones at our centre' Dr Sergio Berti

'The aetiology of patients in this dataset – 53% with FMR, 28% with DMR and 19% with mixed aetiology – is an accurate snapshot of the real world'
Dr Sergio Berti

Now, retrospective data from over 2,100 transcatheter mitral valve repair (TMVr) procedures analysed by Edwards Lifesciences confirm the PASCAL platform's excellent efficacy and safety profiles.[2] While 99% of patients had MR ≥3+ and 76% had MR 4+ at baseline, 98% achieved MR ≤2+ and 75% achieved MR ≤1+ following TMVr with the PASCAL platform (**Figure 1**).[2] Almost all patients (99.9%) were free of intraprocedural death or shift to surgery, and serious adverse events* were reported in less than 2% of patients.

* Defined as intraprocedural complications as per implanter/echo physician feedback to the onsite Edwards Clinical Specialist supporting the case.

Figure 1. Residual MR following 2,100+ TMVr procedures.[**2]**



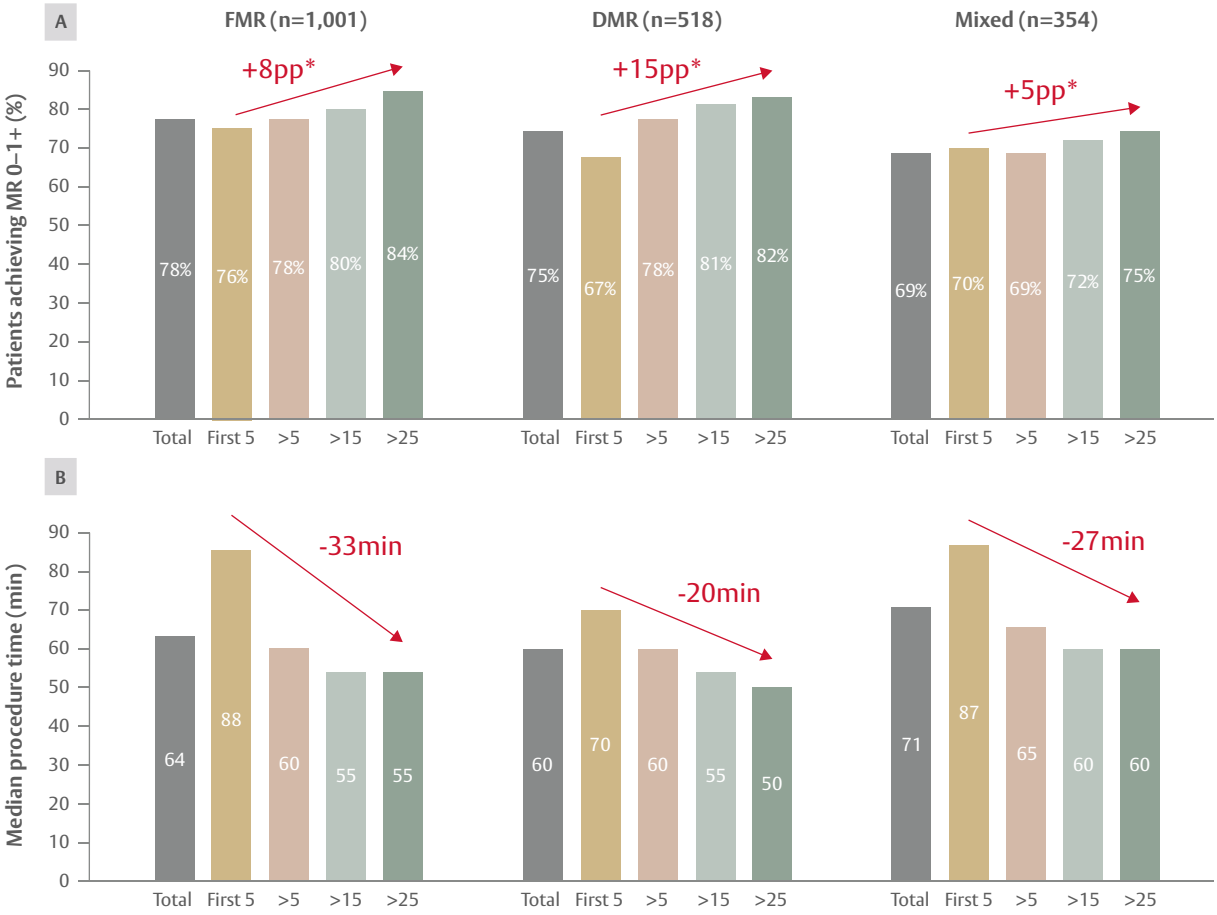
** As per implanter/echo physician acute assessment and reported to Edwards Lifesciences by onsite clinical specialist; non-aborted procedures only.

The patients had diverse MR aetiologies; 53% had functional MR (FMR), 28% had degenerative MR (DMR) and 19% had MR of mixed aetiology. Improvements in MR grade occurred irrespective of MR aetiology: 78% of patients with FMR, 75% with DMR and 69% with mixed MR achieved MR ≤1+ following TMVr using the PASCAL platform (**Figure 2**).[2] Improvements in MR grade were also independent of the implant used.[2]

Physicians using the PASCAL platform experienced a short learning curve (**Figure 2**), emphasising the procedure's ease of use. High rates of patients achieving MR ≤1+ were observed within the first few procedures and, after the first 15 cases, at least 80% of patients with FMR or DMR achieved MR ≤1+. Procedure times also fell rapidly, reaching 60 minutes or less after five cases and 55 minutes or less after 25 cases in patients with FMR or DMR. These data demonstrate how quickly physicians are able to gain confidence and achieve optimal outcomes with the PASCAL procedure.[2]

'The PASCAL platform is easy to use, even for less experienced operators. The reduction of procedural time to less than 60 minutes after only five cases underlines the relative ease in familiarising yourself with the PASCAL platform. Reducing procedure time is very important as it has a great impact on the optimisation of cath lab activity' Dr Sergio Berti

Figure 2. Real-world learning curve with the PASCAL platform by MR aetiology. (A) Patients achieving MR ≤1+, (B) Median procedure times.[2]



Non-aborted cases with aetiology information available
*pp – percentage points

Conclusion

The real-world data from the first 2,100+ PASCAL procedures in MR provide further evidence of the efficacy, safety, ease-of-use and wide adoption of the PASCAL platform in routine clinical practice. The design of the PASCAL platform, combining independent leaflet capture, atraumatic clasping and a flexible spring closure, allows users to position and reposition the PASCAL implant with confidence. The low rate of intraprocedural complications and rapid learning curve demonstrated by this experience should provide confidence for current and future users of the PASCAL platform that they can deliver life-changing outcomes for their patients from the outset, irrespective of MR aetiology.[2,3]

'PASCAL was safe for the treatment of MR, if we consider that 99.9% of patients were free from intraprocedural death or shift to surgery and less than 2% had intraprocedural serious adverse events' Dr Sergio Berti

'These data on over 2,000 unselected patients treated with the PASCAL platform in the real world, which included centres with low–intermediate experience, represent another piece of the puzzle in support of the widely adopted PASCAL platform in MR' Dr Sergio Berti

Reason #5

Capture optimization

One more reason to adopt the **PASCAL Repair System**

The PASCAL repair system is designed to allow repositioning of the PASCAL implant to reduce the level of regurgitation for your patient.[1,2]

Independent leaflet capture is even more powerful when combined with:[2,3]

- Atraumatic clasping, allowing the leaflet to be recaptured multiple times, as needed
- Spring based passive-closing system, providing a more assured method for leaflet capture than a mechanical clamp

1. Kitamura M, Fam NP, Braun D *et al.* 12-month outcomes of transcatheter tricuspid valve repair with the PASCAL system for severe tricuspid regurgitation. *Catheter Cardiovasc Interv.* 2021; doi:10.1002/ccd.29583.
2. Edwards Lifesciences. Data on file: PASCAL ACE Implant component design enhancement. 2020.
3. Hausleiter J. Latest evidence on TR treatment: the present (repair) and the future (repair + replacement). Presented at the PCR Valves e-Course, 2020.

Edwards

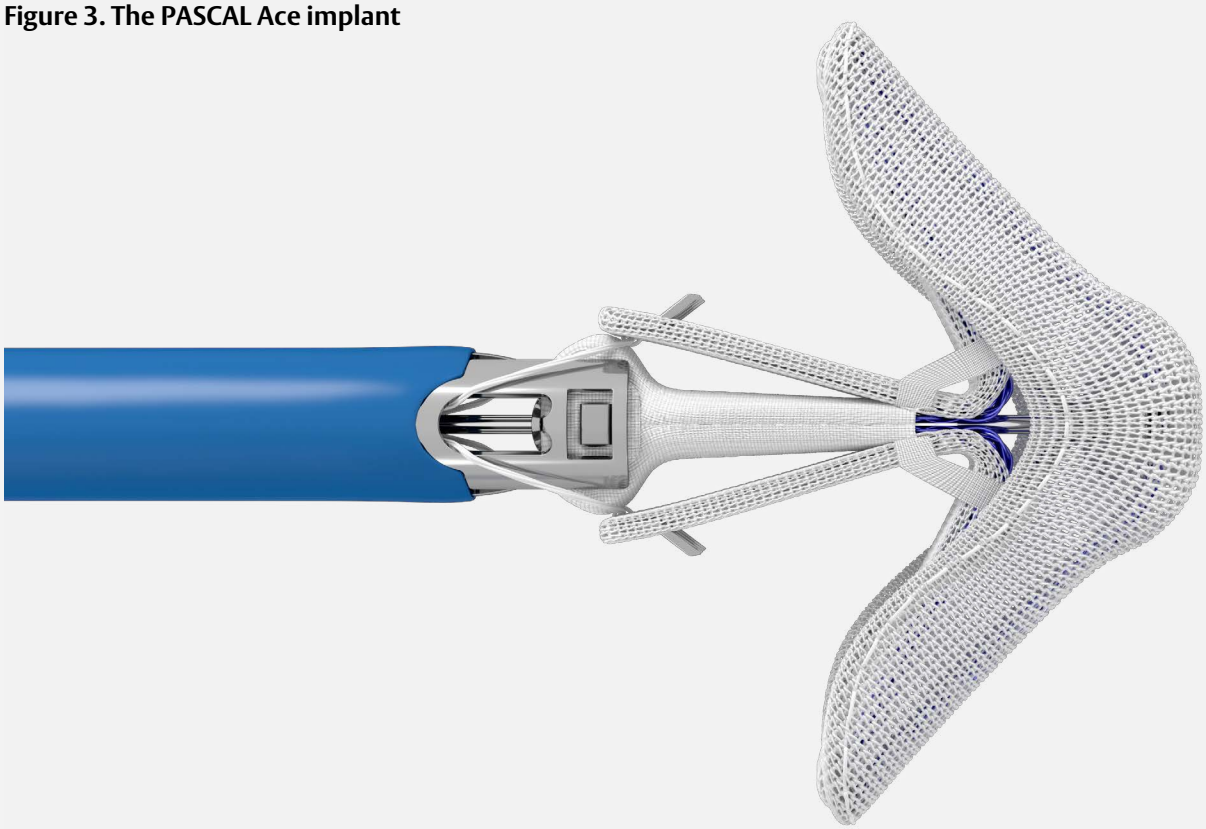
Early experience with the PASCAL Ace Implant System

Introduction

The PASCAL platform has demonstrated significant clinical benefits for patients with severe MR and TR. In the CLASP Study, impressive reductions in MR were observed, irrespective of MR aetiology, with 100% of patients having MR ≤2+ at 1 year post-procedure and 82% having MR ≤1+.[3]
A compassionate use study and a multicentre German study have reported similar benefits for patients with severe TR. In these studies, 79% and 83% of patients achieved TR grade ≤2+ at 30 days following the procedure, respectively.[4,5]

The PASCAL Ace implant shares all the key features of the PASCAL implant that are important for clinical success (**Figure 3**). In addition, its narrower profile makes navigation of the device easier and allows expansion to additional patient anatomies. Both devices offer independent clasping and a central spacer to bridge coaptation gaps with minimal leakage while minimising leaflet stress.[6] Physicians are now able to choose a PASCAL platform device that is best suited to an individual patient's anatomy and characteristics.[6]

Figure 3. The PASCAL Ace implant



PASCAL Ace Implant System in treating MR

Professor Holger Nef has experience using the PASCAL Ace implant system for TMVr.[7] Here, he presents early data from the Universitätsklinikum Giessen.

Professor Dr med. Holger Nef,
Universitätsklinikum Giessen, Germany

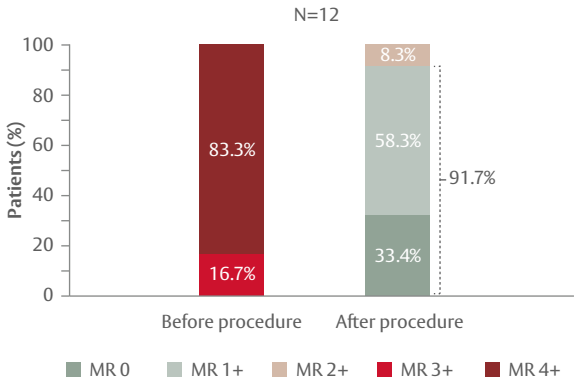
Professor Holger Nef is an interventional cardiologist and Associate Director at the University of Giessen, Germany. Professor Nef has been Investigator or Principal Investigator in a number of clinical trials, including BIOADAPTOR, MiCLASP, TriCLASP, EXPAND G4 and TRICI-HF.

In our single-centre, observational, early real-world experience, 12 patients with symptomatic, clinically significant MR (MR ≥3+) received the PASCAL Ace implant from August 2020. All patients had at least moderate-to-severe MR (2 had MR 3+ and 10 had MR 4+) prior to the procedure, despite optimal medical therapy (**Figure 4**).[7]

We had a 100% procedural success rate* with the PASCAL Ace implant in these patients. The median procedure time was short (38 minutes), and 1.18 devices were implanted on average per patient. The procedure also had an excellent safety profile, with no intraprocedural serious adverse events among the 12 patients.[7]

* Defined as successful device implantation with proper placement and positioning of the device, MR ≤2+, mean gradient <5 mmHg, and continued intended device safety and performance

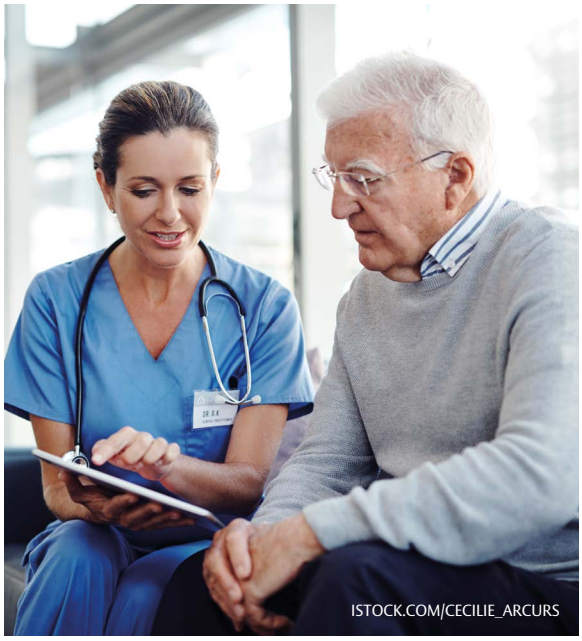
Figure 4. Change in MR grade following TMVr using the PASCAL Ace implant (N=12)[7]



Professor Nef, personal communication.[7]

'We had a high rate of procedural success (100% in 12 patients) with the PASCAL Ace implant – it was a safe procedure with no intraprocedural serious adverse events and 91.7% of patients achieving MR grade ≤1+. This shows the PASCAL Ace is a very successful device in a population with different anatomies' Professor Holger Nef

'Median procedure time [with the PASCAL Ace implant] was 38 minutes. The narrow profile of the PASCAL Ace implant reduces the risk of entanglement with the chordae, so there would be less need to regrasp the mitral leaflets to get a good result' Professor Holger Nef



'The PASCAL Ace implant is very easy to use – you have a short learning curve. After 5–10 procedures you can adapt very easily' Professor Holger Nef

At baseline, 100% of patients had MR ≥3+. Following the PASCAL Ace implant procedure, we observed a reduction in MR grade to MR ≤1+ in 91.7% of patients, and to MR ≤2+ in 100% of patients (**Figure 4**). The mean gradient among the 12 patients following the procedure was 3 mmHg.[7]

Our data add to the growing body of evidence highlighting the clinical benefits of the PASCAL platform in patients with severe MR.

'I love the Nitinol design [of the PASCAL Ace implant]. It allows passive closure, which is gentle on the leaflets. Also, the central spacer allows leaflets to fit comfortably into the device, and the possibility to elongate allows you to navigate through the dense chordae' Professor Holger Nef

PASCAL Ace Implant System in treating TR

Professor Philip Raake started using the PASCAL platform at the Universitätsklinikum Heidelberg in 2019, and currently performs both TMVr and TTVr (transcatheter tricuspid valve repair) procedures using it. Here, he describes his experiences with the PASCAL Ace implant system in TTVr and offers advice for new operators.

Professor Dr med. Philip Raake,
Klinik für Kardiologie, Universitätsklinikum Heidelberg, Germany

Professor Philip Raake is Head of the Cardiac Catheter Laboratory of Internal Medicine III at Universitätsklinikum Heidelberg. Professor Raake is or has been Investigator or Principal Investigator in the CLASP IID/IIF, TriCLASP, EXPAND G4 and RESHAPE-HF2 clinical trials.

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We use the PASCAL Ace implant for all our PASCAL TTVr procedures. TTVr has distinct challenges compared with TMVr and several features of the PASCAL Ace implant make it a suitable choice in this setting. First, it can be elongated in case of subvalvular navigation challenges, presenting a narrow profile that can be navigated through the dense chordae network of the tricuspid valve to reach its optimal landing zones without getting entangled. Second, the clasps of the PASCAL Ace implant are close to the shaft, so there are no features onto which the chords may become attached. Third, the PASCAL Ace implant's flexibility reassures operators that leaflet stress is minimised during capture optimisation and after implant release: its passive closing mechanism enables acute implant flexing, reducing risks of leaflet tearing. Fourth, the implant allows for independent leaflet grasping, which is crucial for the treatment of TR. In my experience, approximately 95% of TR cases require independent leaflet grasping, making the PASCAL Ace implant an ideal choice. Finally, the design of the PASCAL Ace implant, with its narrow profile and central spacer, helps to minimise shadowing and facilitates echocardiographic visualisation of leaflets during procedures.[6]

An important factor when performing TTVr is appropriate patient selection. While patients suitable for the procedure are symptomatic, it is important that they are in an early stage of disease without a completely dilated right side of the heart.

When using the PASCAL Ace implant for TTVr, operators need to learn how to steer the implant to the valve to obtain the best results. The anterior or posterior leaflet should be clasped before moving to the septal leaflet. This minimises the tension needed to adjust the implant's position within the valve. Depending on leaflet pathology, we usually start by deploying one PASCAL Ace implant in the anteroseptal commissure. If this is not sufficient in reducing TR, we implant another device in the anteroseptal or posteroseptal commissure according to the individual valve pathology.

'We use the PASCAL Ace implant for all of our PASCAL TTVr procedures'
Professor Philip Raake

Due to the inherent challenges associated with imaging the tricuspid valve when performing TTVr, it is important to collaborate with an experienced interventional echocardiographer. The standard procedure is to perform leaflet capture in the mid/deep oesophageal view, with a dedicated clasping view (biplane right ventricle inflow/outflow with reversed four-chamber view), and to check correct leaflet insertion using a transgastric view. Operators should take their time to ensure leaflets are in the correct position during clasping. If positioning is uncertain, our approach is to optimise echocardiography and obtain better images.

When clasping leaflets, it is important that leaflet tissue is captured down to the spacer. By moving the implant slightly, we can see if the leaflet is fully laid down on the implant. Once a favourable position is achieved, we can confidently bring down the clasp, clasping the leaflets and typically obtaining a good correction of TR. We aim for a mean gradient below 3 mmHg, which we have found easy to achieve. We usually find that the TR improvement is maintained or even improved once the PASCAL Ace implant is released from the catheter.

'For TR, PASCAL Ace is really essential as you have a much denser chordae network – the narrow PASCAL Ace implant can get between the chords [to reach its optimal landing zones]'
Professor Philip Raake

In approximately one third of our patients with TR, implantable cardioverter defibrillator or pacemaker leads are present in the tricuspid valve. We can still use the PASCAL Ace implant in these patients provided we are confident that the leads are not causing TR by impairing proper leaflet coaptation. If TR is caused by the lead, surgery and correction of the lead is indicated to resolve TR.

We have now performed dozens of TTVr procedures using the PASCAL Ace implant. In these procedures, we have observed high procedural success rates, good reductions in TR and an improvement in symptoms with the implant. We also observed a rapid improvement in procedural times and felt comfortable after only eight cases, which demonstrates the short learning curve we found with the PASCAL Ace implant. I would recommend using the PASCAL Ace implant to colleagues performing TTVr.

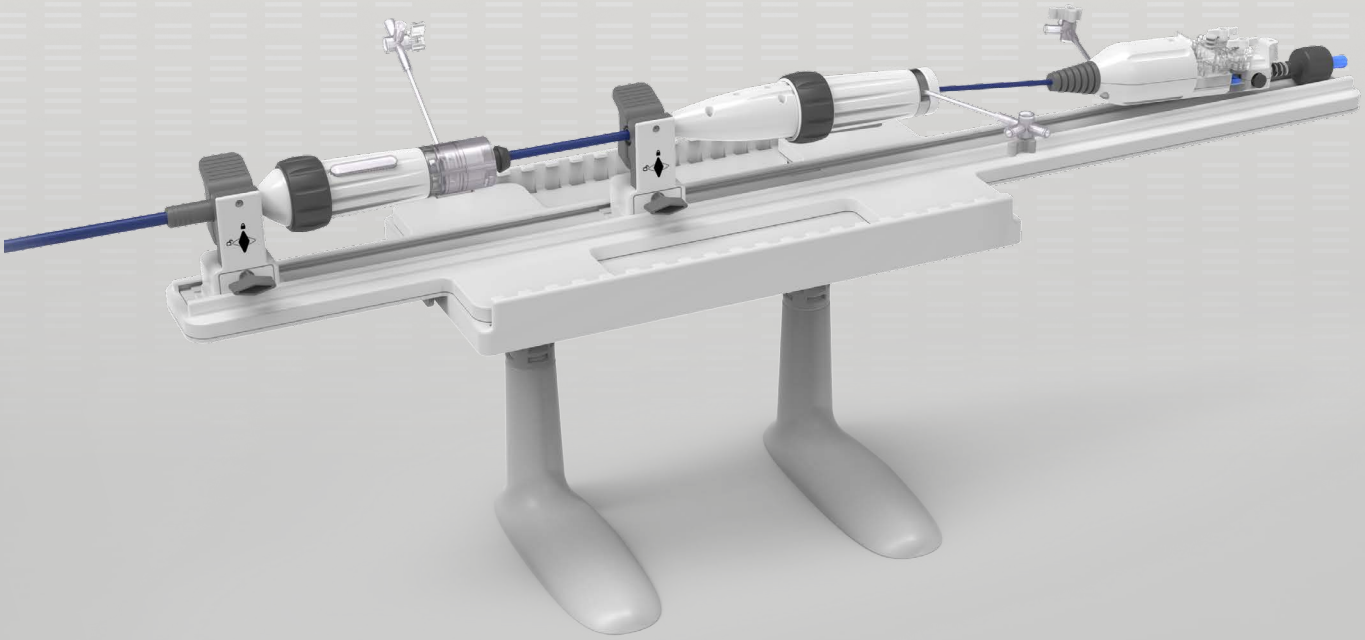
'We typically find that the TR improvement is maintained or even improved once the PASCAL Ace implant is released from the catheter'
Professor Philip Raake

Conclusion

The PASCAL platform is a differentiated set of implants, comprising the PASCAL implant and the PASCAL Ace implant. Like the PASCAL implant, the PASCAL Ace implant is designed to offer physicians a safe and effective solution for the treatment of patients with MR and TR, while providing a narrower implant profile. This has particular benefits for TR as it facilitates navigation through the dense chordae of the tricuspid valve. Implant elongation also contributes to chordal safety, allowing the PASCAL Ace implant to be confidently and safely extracted or repositioned if entanglement occurs.[6,8] Early experiences suggest impressive reductions in MR and TR with the PASCAL Ace implant, mirroring outcomes already reported with the PASCAL implant. This treatment approach will be further evaluated in prospective randomised trials, including CLASP II TR.

PASCAL Stabilizer Rail System

First experience with the PASCAL Stabilizer Rail System



Professor Dr med. Peter Lüdike,
Universitätsklinikum Essen, Germany

Professor Peter Lüdike is Head of Heart Failure and Intensive Care Medicine at Universitätsklinikum Essen and has run the programme for minimally invasive catheter therapy for mitral and tricuspid valve defects since 2017. His vision is for the Essen University Medical Center to become an international reference centre in the field of cardiac insufficiency.

Dr med. Leonhard-Moritz Schneider
Universitätsklinikum Ulm, Germany

Dr Leonhard-Moritz Schneider is a specialist physician at Universitätsklinikum Ulm with a focus on echocardiography and interventional valve repair. Dr Schneider has participated in over 500 mitral or tricuspid valve procedures and has been an Investigator in a number of clinical trials, including CLASP IID/IIF, TRiCLASP, TRiBAND, EXPAND G4, bRIGHT, HighLife, MATTERHORN, ASCEND and REPLICATE.

As part of its continuous drive toward improved TMVr and TTVr procedures, Edwards Lifesciences has developed the PASCAL Stabilizer Rail System (SRS) to enhance the experience with the PASCAL platform (Figure 5; Figure 6). The intuitive design of the PASCAL SRS provides greater stability during PASCAL procedures, enabling controlled, single-handed catheter advancement, retraction and torquing when manoeuvring and positioning the PASCAL and PASCAL Ace implants.[9]

Dr Leonhard-Moritz Schneider

The SRS system allows you to have more stability when moving the steerable catheter.

We can do the whole management of catheters alone now. The movements are clearer and we feel much more comfortable.

Professor Peter Lüdike

With the PASCAL SRS, it is easy to lock and unlock the catheter with a simple hand movement and manoeuvre the system without applying a lot of force. It is a real improvement of the whole system.

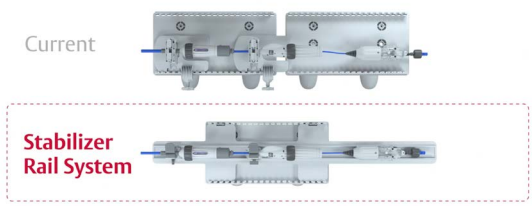
The individual parts of the system interlock very smoothly and there are no unexpected steps or movements.

See *the PASCAL SRS in action**

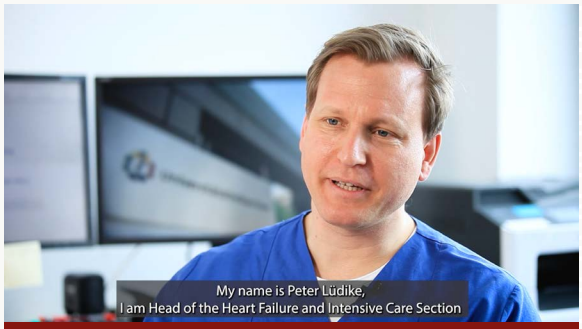
Early users of the PASCAL SRS, Professor Peter Lüdike and Dr Leonhard-Moritz Schneider, describe the system as intuitive to use and easy to handle. Here, they share insights from their experiences with the system.

The PASCAL SRS employs a rail-based system with a single table and secure stabilizers that axially align catheters, thereby reducing unintended movements. The individual components of the PASCAL SRS interlock smoothly. Multiple stabilizers enable the user to advance, retract and torque catheters with control. This allows stable, incremental movements and fine adjustments to be made single-handedly, reducing the need for a second operator. We found the catheters easy to lock and unlock using a simple, **single-handed** movement. Furthermore, the stepless rail mechanism allows for precise manoeuvring without the need to apply significant force to the system.[9]

With a simplified process and ease-of-use enhancements helping to reduce unintended catheter movements, we expect the PASCAL SRS to improve procedural confidence.



See how the PASCAL SRS facilitates TMVr and TTVr*



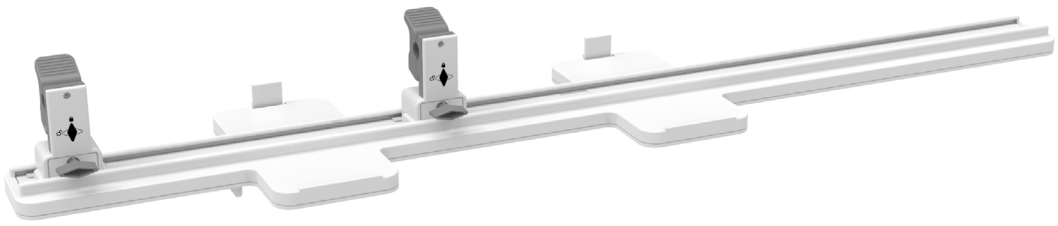
Hear Professor Peter Lüdike discuss the benefits of using the PASCAL SRS*

*For multimedia access see here: **http://bit.ly/TMTTToday**

Figure 5. PASCAL SRS

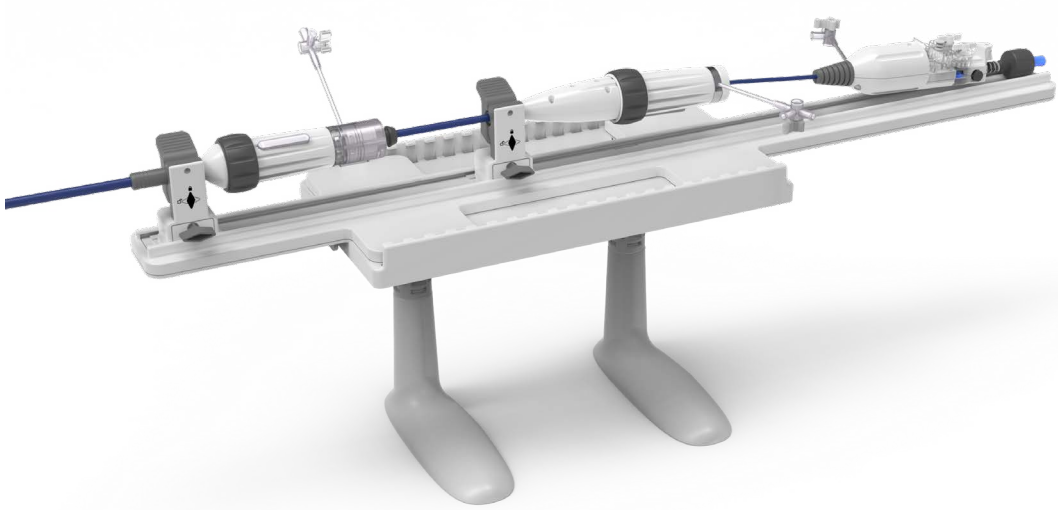
Increased stability

A rail-based system with multiple stabilizers to advance, retract, and torque catheters



Intuitive design

Secure stabilizers to allow for stable, incremental movements and fine adjustments



Simplified process

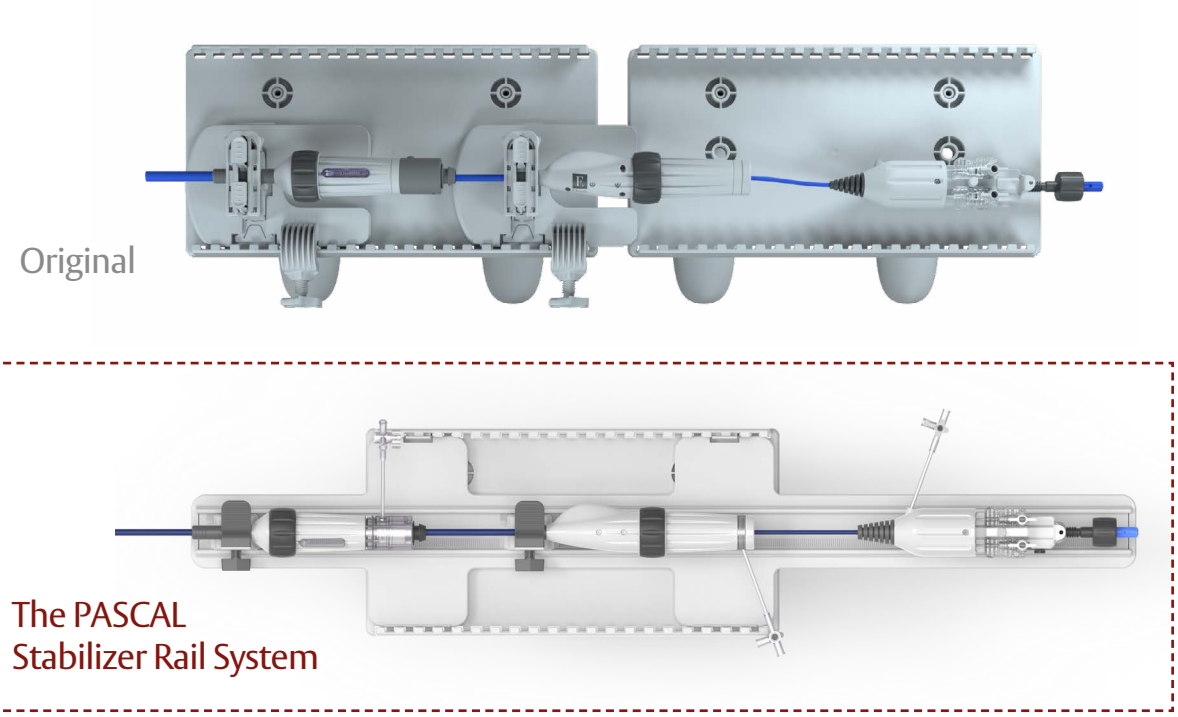
Ease-of-use enhancements help reduce unintended catheter movements throughout the procedure

The Stabilizer Rail System is designed to enhance your experience with the PASCAL platform

The PASCAL SRS is a valuable addition to the PASCAL platform. By aligning elements involved in the mechanical locking and unlocking of the guide sheath, and eliminating variability when manoeuvring the catheters, users can adopt a systematic and predictable approach to their procedural flow.

We anticipate a short learning curve with the PASCAL SRS based on its intuitive design and ease of handling, and would recommend the system to colleagues already using the PASCAL platform.

Figure 6. Evolution of the PASCAL SRS



Professor Peter Lüdike

We are all very convinced [by the PASCAL SRS]. It is intuitive to use and easy to handle. When there is a difficult anatomy, it is nice to have more stability.

I plan to use the PASCAL SRS for all my PASCAL platform procedures.

Dr Leonhard-Moritz Schneider

I congratulate Edwards for introducing the PASCAL SRS. It makes the whole procedure easier and more comfortable.

Everyone in our centre loves it. Now that the PASCAL SRS is available, we plan to use it for all [PASCAL platform] procedures.

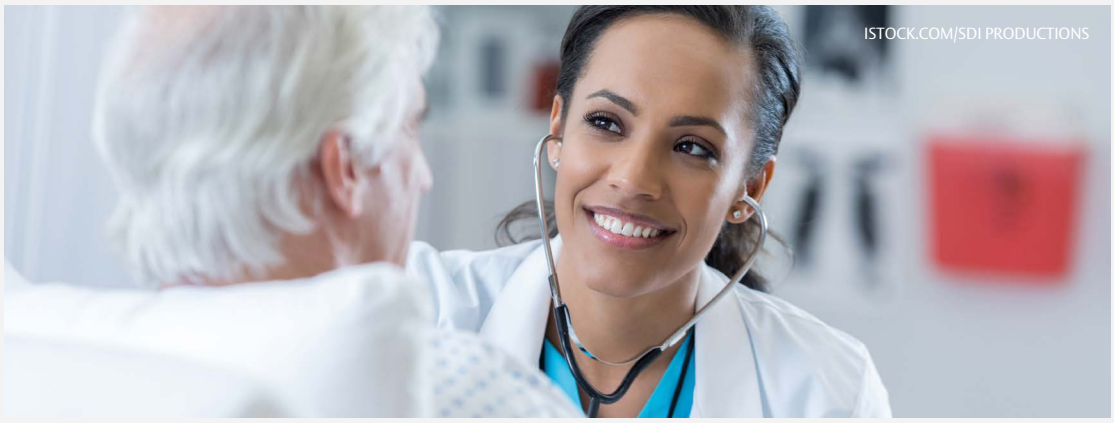
PASCAL SRS

Expert experiences in TR

Dr med. Christian Besler,
Herzzentrum Leipzig, Germany

Dr Christian Besler is an interventional cardiologist and Senior Physician at the Heart Center Leipzig. He has been actively involved in the clinical implementation and scientific advancement of tricuspid interventions, contributing as an Investigator to the CLASP IID/IIF and HERACLES-HFpEF clinical studies.

In Leipzig, we have performed numerous mitral and tricuspid interventions with the PASCAL platform and more recently have been able to test the performance of the PASCAL SRS in both mitral and tricuspid repair.



In the tricuspid valve, successful interventions require a very precise and careful approach as even small movements can cause injury to the leaflets or subvalvular apparatus. Furthermore, the implant needs to be positioned precisely to achieve optimal TR reduction. Both the stability and the manoeuvrability offered by the PASCAL SRS address these important issues in transcatheter tricuspid interventions. The guide and steerable catheter are now easily fixed within the PASCAL SRS with a flick of the wrist. The screw used to lock the position of the guide and steerable catheter in the previous version of the stabilizer has been replaced by a flip switch, making the operator`s life much easier. Both catheters can now be moved on the rail very gently and easily, which improves steering and alignment of the PASCAL and PASCAL Ace implants above or below the tricuspid valve. The simplified and gentle manoeuvring of the implants along the anteroseptal and posteroseptal commissures then allows for more precise positioning of the implants in the grasping area.

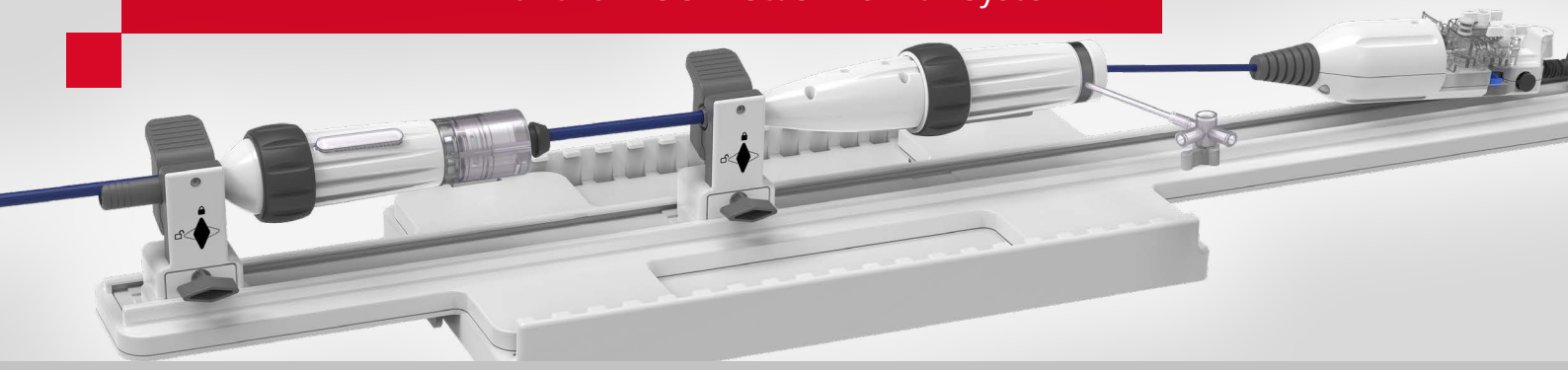
Based on our early experience, the PASCAL SRS is a major technical refinement of the PASCAL platform. It not only improves the ease-of-use and stability of the system, but also the steering of the implant along the commissures. We believe the PASCAL SRS will be of benefit to both the operator and the patient as it may impact on procedural safety and feasibility.

Conclusion

The PASCAL SRS has been developed to enhance operator experience and procedural confidence with the PASCAL platform by providing greater stability, thereby enabling controlled catheter manipulation when manoeuvring and positioning the PASCAL and PASCAL Ace implants.[9] Early users have already expressed appreciation and enthusiasm at the unique and intuitive design of the PASCAL SRS, seeing the added value of allowing single-handed, stable, incremental movements and fine adjustments to be made to guiding catheters during procedures.

Reason #8 Enhanced stability

with the PASCAL Stabilizer Rail System



One more reason to adopt the **PASCAL Repair System**

We are dedicated to optimize mitral and tricuspid repair therapy partnering with our users. This has led to the development of the PASCAL Stabilizer Rail System, which provides enhanced stability and enables controlled catheter movement.[1]

The PASCAL Stabilizer Rail System brings:[1]

- **Increased stability** – A rail-based system with multiple stabilizers to advance, retract, and torque catheters
- **Intuitive design** – Secure stabilizers to allow for stable, incremental movements and fine adjustments
- **Simplified process** – Ease-of-use enhancements help reduce unintended catheter movements

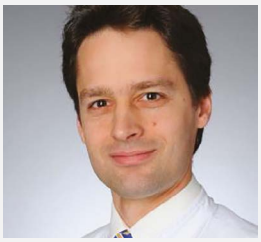
1. Edwards Lifesciences. Introducing the new PASCAL Stabilizer Rail System. 2021.

Edwards

Real-world data with the Edwards Cardioband Tricuspid Valve Reconstruction System

Professor Dr med. Roman Pfister,
Herzzentrum der Universität zu Köln, Germany

Professor Roman Pfister is Deputy Head of the Department of Internal Medicine III at the Herzzentrum der Universität zu Köln and leads the Heart Failure and Transplantation Programme and the Interventional AV-Valve Treatment Programme.



Dr med. Maria Isabel Körber,
Herzzentrum der Universität zu Köln, Germany

Dr Maria Isabel Körber is an attending physician and clinical research fellow at the Herzzentrum der Universität zu Köln. Her focus is on interventional valve therapy and interventional echocardiography.

The Edwards Cardioband tricuspid valve reconstruction system was the first commercially available transcatheter therapy for the treatment of tricuspid heart valve disease, receiving its CE mark in 2018. It remains the only transcatheter annuloplasty solution available.[10] The Cardioband tricuspid system restores the valve to a more functional state and facilitates leaflet coaptation by reducing the annulus.[11,12] The Cardioband tricuspid system can be positioned precisely to conform to an individual patient's anatomy, and allows for real-time adjustment and confirmation of procedural results. Here, Professor Roman Pfister and Dr Maria Isabel Körber present results from the first 60 patients treated with the Cardioband tricuspid system and describe how it fits into the armamentarium of tricuspid therapies.

TR is associated with high perioperative risk and poor patient outcomes. Treatment options for these patients are limited.[13] We typically see patients late in the development of their disease, sometimes more than 10 years after they have developed moderate or severe TR. Over 90% of our patients have annular dilatation, so annuloplasty is an intuitive approach to treatment. However, as most patients are not candidates for surgery, the challenge is to provide a treatment that is highly effective but minimally invasive. The Cardioband tricuspid system satisfies these requirements and offers this fragile patient population a safe and effective treatment option.[13]

'More than 90% of TR cases are caused by annular dilatation. An annuloplasty approach is very adequate and intuitive' Dr Maria Körber

We have performed a real-world, multicentre analysis of procedural and clinical outcomes from the first 60 patients treated with the Cardioband tricuspid system. The patients were treated at one of four German high-volume centres (Cologne, Göttingen, Erlangen and Bad Oeynhausen) between October 2018 and February 2020. Of the 60 patients, 48% presented with severe TR, 30% had massive TR and 22% had torrential TR.[13]

The technical success rate with the Cardioband tricuspid system was very high (97%). Procedural success, defined as technical success with at least a one-grade improvement in TR, was achieved in 88% of patients (**Table 1**).[13]

'With the Cardioband tricuspid system, we achieved a technical success rate of 97% and a procedural success rate of 88%' Dr Maria Körber

Impressive reductions in TR were demonstrated with the Cardioband tricuspid system. TR severity was significantly reduced between baseline and discharge, and this improvement was maintained at 30-day follow-up (**Figure 7**). Most patients (88%) demonstrated at least a one-grade improvement in TR and over half had at least two grades of TR reduction.[13] We also observed a significant reduction in annular dilatation following implantation of the Cardioband tricuspid system. There was a significant reduction in both the biplane vena contracta diameter and in the end-diastolic septolateral diameter of the tricuspid annulus after implantation and cinching. Most importantly, these outcomes were accompanied by a significant improvement in function, with over 80% of patients in NYHA Class I or II at 30-day follow-up (**Figure 7**).

Table 1. Procedural outcomes following TTVr using the Cardioband tricuspid system.[13]

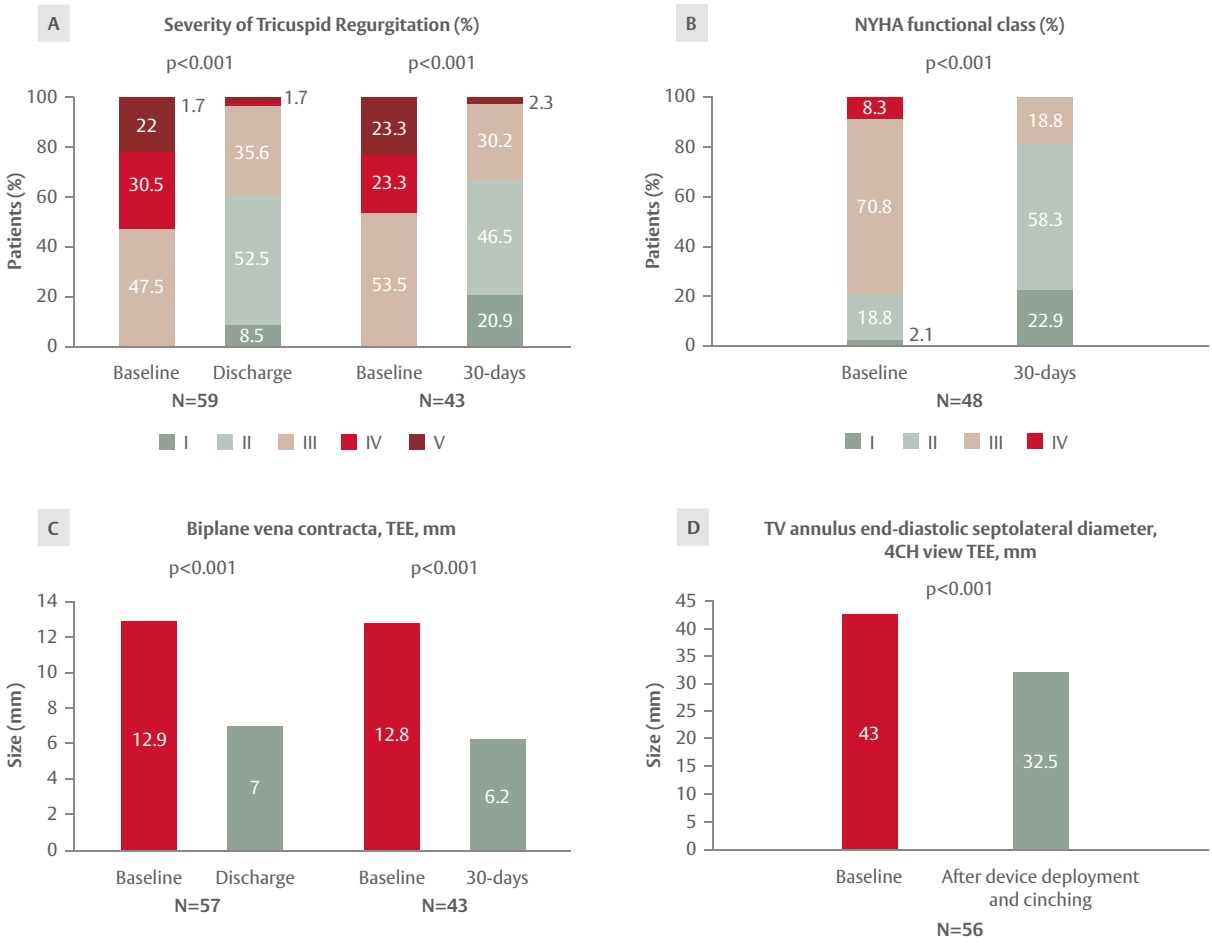
Procedural outcomes	N=60
Length of stay in hospital, days	13.5 ± 13.2
Procedure time, min	248 ± 77
Contrast-medium volume, ml	147 ± 85
Number of anchors	16 ± 1
Implant size	
C (89–96 mm)	2
D (97–104 mm)	3
E (105–112 mm)	15
F (113–120 mm)	40
Technical success rate*, %	96.7
Procedural success rate§, %	88.3

* Successful delivery, deployment and positioning of device, absence of procedural mortality and freedom from emergency surgery related to the device

§ Technical success* and TR reduction ≥1 grade

Data from Table 1 were presented by Dr Körber at PCR Valves e-Course 2020.[13] Reproduced with permission

Figure 7. Efficacy outcomes following TTVr using the Cardioband tricuspid system. (A) TR severity; (B) NYHA class; (C) Vena contracta diameter; (D) End-diastolic septolateral diameter [13]



TEE, transesophageal echocardiography

Data presented by Dr Körber at PCR Valves e-Course 2020.[13] Reproduced with permissionn

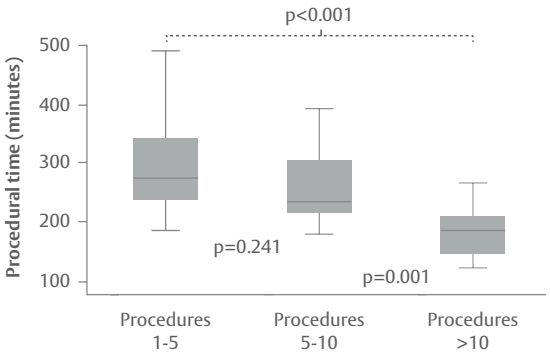
The Cardioband tricuspid system demonstrated a good safety profile with only four patients (6.7%) reaching the primary safety endpoint,* despite the highly morbid patient population. The most frequent complications were bleeding, acute renal failure and haemodynamically relevant arrhythmia, each occurring in 12% of patients. Right coronary artery perforation occurred in three patients. Notably, 12 patients had temporary deformation of the right coronary artery, but this was typically benign and tended to resolve within a few days of the procedure.[13]

* Death, myocardial infarction, need for urgent cardiothoracic surgery or stroke

'The Cardioband tricuspid system significantly reduced TR grade, NYHA functional class, the coaptation gap, annular diameter, and the diameter of the vena contracta' Dr Maria Körber

We experienced a short learning curve with the Cardioband tricuspid system. While average procedure time was 248 minutes, new operators were typically able to perform the procedure in less than 200 minutes following only 10 procedures (**Figure 8**).[13] The efficacy and safety of the Cardioband tricuspid system were also observed at an early stage of the learning curve. For learning how to use the Cardioband tricuspid system, our main tip is to visualise and memorise each manoeuvring step used to guide the system along the annulus from the aorta to the coronary sinus.

Figure 8. Improvement in procedure times during the learning curve with the Cardioband tricuspid system[13]



Data presented by Dr Körber at PCR Valves e-Course 2020. Reproduced with permission

'We experienced a short learning curve with the Cardioband tricuspid system. As operators gained more experience, procedural times reduced significantly'
Dr Maria Körber

Conclusion

This real-world study suggests that the Cardioband tricuspid system is safe and feasible for the treatment of severe TR, even early in the learning curve, and offers physicians an effective option in this difficult-to-treat and highly morbid patient population.[13] These data are consistent with 2-year outcomes from the TRI-REPAIR study, which demonstrated sustained annular reduction and reduced TR severity in patients with severe TR, and 30-day outcomes from the US Early Feasibility study, which showed high procedural feasibility with no 30-day mortality.[12,14] The real-world study therefore adds to a growing body of evidence supporting use of the Cardioband tricuspid system as a treatment for severe TR.

Conclusion

Edwards Lifesciences remains committed to providing innovative, safe and effective solutions for the treatment of patients with MR and TR. The PASCAL platform has become an important tool for MR and TR, driven initially by the success of the PASCAL implant. Now, early experiences with the narrower PASCAL Ace implant in both MR and TR reinforce the efficacy, safety, ease-of-use and flexibility of the PASCAL platform in routine clinical practice. To facilitate PASCAL platform procedures, the PASCAL SRS allows operators to perform controlled movement and positioning of the PASCAL and PASCAL Ace implants. PASCAL SRS has already gained encouraging feedback from expert users of the PASCAL platform. Finally, the Cardioband tricuspid system offers a safe and effective approach for patients with severe TR and annular dilatation, who have a poor prognosis and are typically not indicated for surgery.

Together, these developments provide physicians with a wide portfolio of interventional technologies and treatment solutions to benefit patients with even the most severe cases of MR and TR, and almost any valvular anatomy.

Ask your questions...

We can be reached at TMTT-Today@edwards.com to answer your questions about the PASCAL platform

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