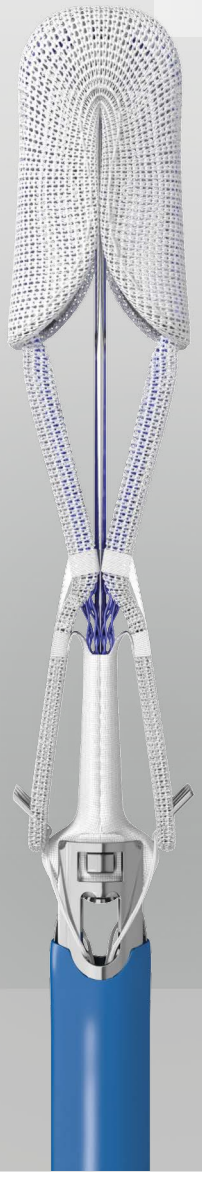
TMTT Today

Your update on Edwards' Mitral & Tricuspid innovations

The PASCAL Platform
A complete solution for transcatheter mitral and tricuspid valve repair

Discover how the PASCAL platform can optimise valve repairs for you and your patients ...



The latest data in transcatheter mitral leaflet repair

CLASP Study outcomes at 1 year focusing on degenerative and functional MR patients

The new PASCAL Ace Implant System

The power of the PASCAL Repair System and PASCAL Ace Implant System combination

The PASCAL Platform: impressive outcomes in mitral valve repair and a new solution for the tricuspid valve repair challenge

Atrial pressure monitoring during mitral and tricuspid procedures

How atrial pressure monitoring provides procedural guidance and a proxy for outcomes

The value of atrial pressure monitoring during tricuspid valve repair using the PASCAL Delivery System

Issue #3 – December 2020

Edwards

Dear Reader,

This third issue of the *TMTT Today* series for 2020 will update you on Edwards' Transcatheter Mitral and Tricuspid Therapies currently in use across Europe.

The first article in this issue, presented by Professor Lüdike, reviews data from the **CLASP** study – an important trial evaluating the efficacy and safety of the PASCAL repair system in mitral leaflet repair. See how the reduction in mitral regurgitation (MR) using the PASCAL repair system is achieved irrespective of MR aetiology.

Next, we are excited to introduce the **PASCAL Ace implant system**, the latest innovative addition to the PASCAL repair system. The PASCAL Ace implant complements the PASCAL platform, providing the same key features and benefits of PASCAL therapy but with a narrower profile, which has the potential to expand the range of patients who may be treated. Professor Rudolph, Dr Friedrichs and Professor Hausleiter present case studies highlighting the use of the PASCAL Ace implant for mitral and tricuspid valve repair.

Finally, we introduce the option of **atrial pressure (AP) monitoring**. Physicians now have the option to measure atrial pressures through the PASCAL steerable catheter with a commercially available pressure monitor, which ensures the pressure signal comes from the atrium. The feature can aid clinical decision-making during transcatheter mitral and tricuspid valve repair procedures by providing both procedural guidance and a proxy for outcomes. Dr Markovic describes a case study illustrating its use in treating patients with tricuspid regurgitation.

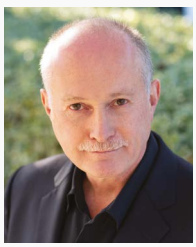
As in previous issues, our contributors all provide their own top tips on how to make the most of these valuable tools for mitral and tricuspid valve repair.

We hope you have enjoyed reading this series of TMTT newsletters for 2020, and that the information provided has given insight and opportunities to improve your procedures and optimise outcomes for patients with mitral and tricuspid regurgitation.

Enjoy reading!

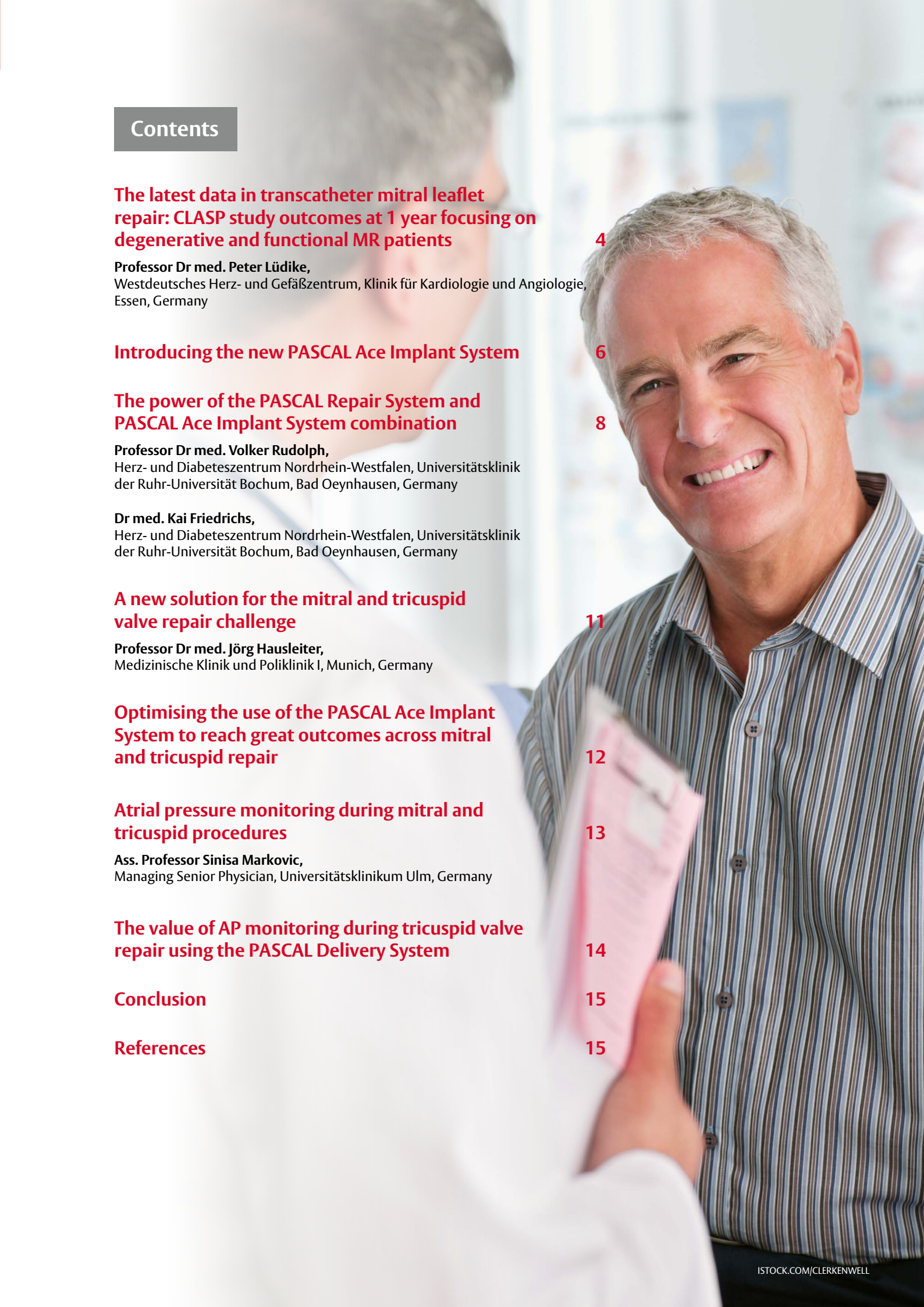
Sincerely,

Rodolfo Estay, MSc, MBA
Vice President, Europe
Transcatheter Mitral and Tricuspid Therapies (TMTT)



Ted Feldman, MD, MSCAI, FACC, FESC
Vice President of Global Medical Affairs
Transcatheter Mitral & Tricuspid Therapies (TMTT)

Contents



ISTOCK.COM/CLERKENWELL

The latest data in transcatheter mitral leaflet repair: CLASP study outcomes at 1 year focusing on degenerative and functional MR patients

Professor Dr med. Peter Lüdike,
Westdeutsches Herz- und Gefäßzentrum, Klinik für Kardiologie und Angiologie, Essen, Germany

Professor Lüdike is Senior Physician of the Heart Failure and Intensive Care section in the Department of Cardiology and Vascular Medicine at the West German Heart and Vascular Center, University Hospital Essen. He achieved Venia legendi for internal medicine in 2018 and was appointed as full Professor for heart failure in 2020. His research interests include intensive care medicine, emergency medicine, heart failure, mitral valve disease and the role of macrophage migration inhibitory factor in the development of ischaemic heart disease.

Over the past few years, the field of transcatheter mitral and tricuspid repair has witnessed a significant increase in published clinical evidence. This article focuses on MR outcomes from the PASCAL CLASP study.

Study design

The **CLASP study** is an ongoing single-arm, multicentre prospective study evaluating the safety and clinical outcomes of the PASCAL repair system.[1] Among other endpoints, the CLASP study evaluated clinical success rates 30 days after the procedure, which was defined as procedural success with evidence of MR reduction to grade ≤2+ and no major adverse events at 30 days, and at 1-year follow-up.[1]

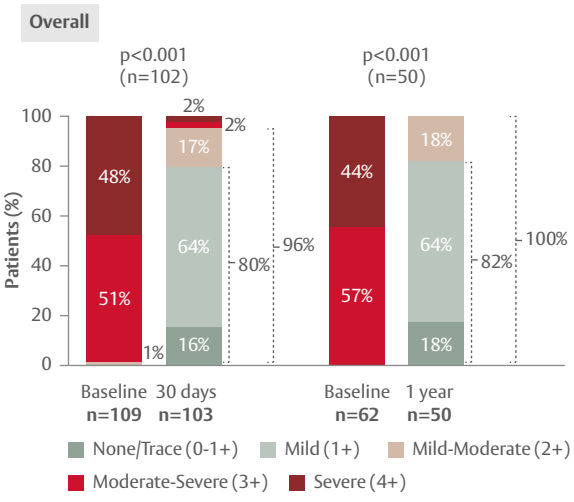
To be included in the study, patients had to have severe MR (grade ≥3+), according to echocardiography and inclusion criteria.[1] An independent echo core laboratory (ECL) ensured all participants had MR grade ≥3+ prior to enrolment through echocardiography assessment.[1] Of the first 62 participants reported, 100% had grade 3+ or grade 4+ MR at baseline (Table 1), which was either degenerative, functional or mixed aetiology (36%, 56% and 8%, respectively). These participants all had New York Heart Association (NYHA) functional class ≥II (52% with class III or IV).[1]

'PASCAL is our standard device of choice in patients... it is highly effective and has the same inclusion and exclusion criteria as other technologies.' Professor Peter Lüdike

Table 1. ECL-adjudicated MR severity at baseline in the CLASP Study

MR Severity at baseline	Patients (%)
	CLASP (n=62)
1+	0
2+	0
3+	58
4+	42

Figure 1. The CLASP Study: MR severity at baseline and after 30 days and 1 year, all aetiologies[2]
©2020 Elsevier, reproduced with permission



Results

MR outcomes at 30 days and 1 year

CLASP Study early data reported on 62 patients treated with the PASCAL repair system. Here we update on 1-year outcomes for these 62 patients and 30-day outcomes for 109 patients treated between June 2017 and September 2019. Among patients whose implantation was successful (n=104/109), most experienced a significant reduction in MR severity: **after 30 days, 96% of these patients had mild/moderate MR (grade ≤2+) and 80% had mild MR to none (grade ≤1+; p<0.001 vs baseline; Figure 1)**.[2] The 30-day results were similar regardless of MR aetiology: MR grades ≤2+ and ≤1+, respectively, were achieved in 96% and 77% among the functional MR subset and 97% and 86% among the degenerative MR subset (Figure 2).[2] **At 1 year, 100% of patients with successful implantations had mild/moderate MR (grade ≤2+) and 82% had mild MR (grade ≤1+; p<0.001 vs baseline; Figure 1)**.[2] Once again, the 1-year results were similar regardless of MR aetiology: MR grades ≤2+ and ≤1+, respectively, were achieved in 100% and 79% among the functional MR subset and 100% and 86% among the degenerative MR subset (Figure 2).[2]

'In our PASCAL repair system cohort, we have more than 85% of cases where the MR is 0 or 1+.' Professor Peter Lüdike

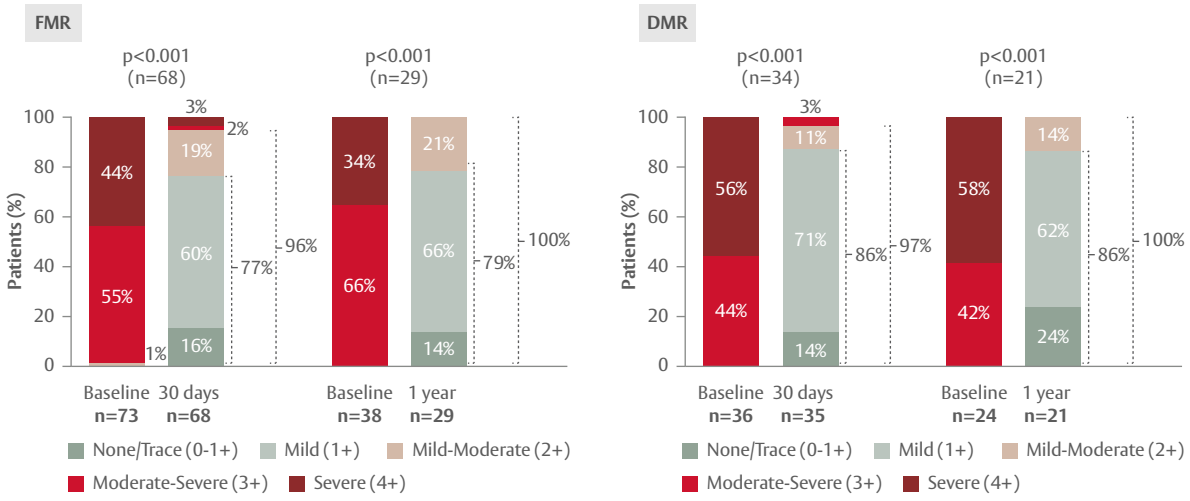
Conclusion

The CLASP study, evaluating MR severity outcomes with the PASCAL repair system, showed promising outcomes for transcatheter leaflet repair in patients, irrespective of their MR aetiology. After successful implantation of the PASCAL implant, MR was significantly reduced from baseline at 30 days and 1 year, irrespective of MR aetiology. All patients with MR of degenerative, functional or mixed aetiology achieved mild/moderate MR at 1 year and most had mild MR (grade ≤1+). These data highlight the impressive long-term efficacy of the PASCAL repair system in the treatment of MR.[2]

'We know that the population of patients with severe MR and especially tricuspid regurgitation (TR) is undertreated. This large population needs minimal invasive strategies because most of them are at prohibitive risk for surgery, and a lot of surgical procedures are not evidence based.' Professor Peter Lüdike

Don't miss the results from the CLASP IID Trial at the PCR London Valves e-course in November

Figure 2. The CLASP Study: MR severity after 30 days and 1 year, by MR aetiology[2] ©2020 Elsevier, reproduced with permission



Introducing the new PASCAL Ace Implant System

The PASCAL Ace implant, the latest innovative addition to the PASCAL platform, gives another transcatheter device option for mitral and tricuspid leaflet repair.[3,4] Designed with the same safety in mind as the PASCAL repair system, the PASCAL Ace implant system provides the same optimised leaflet capture and enhanced coaptation as the PASCAL repair system but with a narrower profile for confident subvalvular navigation in challenging patient anatomies (Figure 3).[3-6]

'Our experience with the PASCAL Ace implant is very positive. After the first cases, our impression is that it allows even more precise steering of the device, which enables its usability in challenging anatomies.'
Professor Volker Rudolph and Dr Kai Friedrichs

Figure 3. PASCAL implant (left) and PASCAL Ace implant (right), with a narrower profile and central spacer designed to complement the PASCAL repair system and further optimise treatment for patients.[3,4]

PASCAL Implant* PASCAL Ace Implant*

'The essential difference between the conventional PASCAL implant and the PASCAL Ace implant is its smaller [closed medial-lateral] width (6 mm versus 10 mm).

The opportunity to combine both sizes makes the platform far more versatile.'
Professor Volker Rudolph and Dr Kai Friedrichs

The PASCAL Ace implant optimises leaflet capture during initial positioning or repositioning, and allows direct manoeuvring in three planes with a flexible delivery system comprising the following features:[3-6]

Usability/learning curve

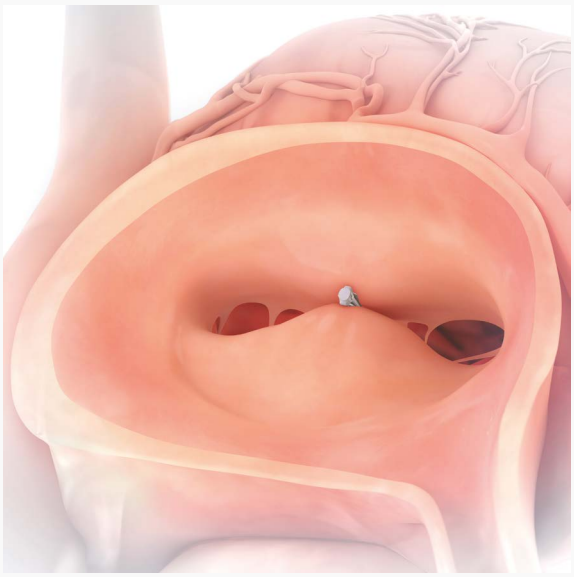
- A narrow profile to help optimise treatment of MR and TR
- Implant elongation to allow for more confident subvalvular navigation, particularly in challenging patient anatomies
- Optimised leaflet capture with independent activation and distinct clasp design
- Leaflet configuration ensures leaflets can be captured even at extreme angles and with constant equal forces regardless of device opening
- Slim profile minimises risks of entanglement during repositioning

Leaflet safety

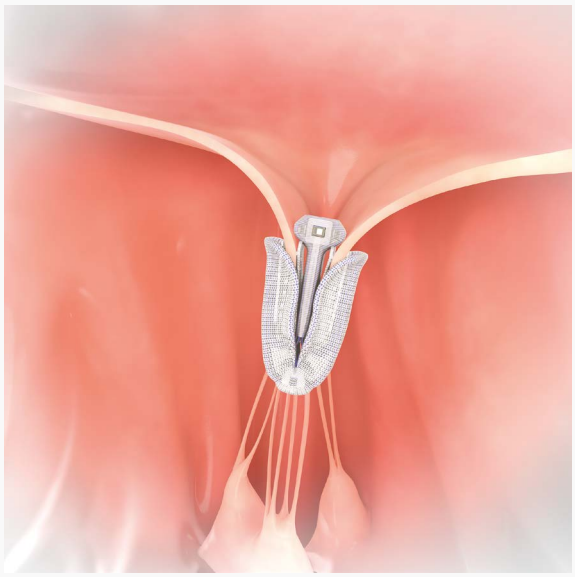
- Nitinol design allows for passive closure and acute implant flexing
- Clasps made of a single layer of nitinol, shaped to achieve the desired geometry and pinch force
- A spacer composed of multiple layers of braid, which fills the regurgitant orifice reducing leaflet stress

Figure 4. PASCAL Ace implant in the mitral valve (a) top view, (b) side view (schematic representation).

(a)



(b)



The narrower paddle width of the PASCAL Ace implant improves navigation through chordae as well as improving visualisation, therefore increasing confidence during leaflet capture, resulting in precise placement.[3] The paddles also closely follow the centreline, with the spacer shape allowing the paddles to close nearly parallel.[3] The PASCAL Ace implant system can complement the PASCAL repair system when smaller gaps must be filled.[3]

Similarly to the PASCAL implant, the PASCAL Ace implant is released from the atrial side, leaving the central spacer in the regurgitation orifice after device deployment.[3]

'Although the PASCAL Ace implant is small, there is no need to increase the number of devices; the PASCAL Ace implant is now our standard device.' Professor Jörg Hausleiter

The PASCAL Ace implant complements the PASCAL platform, providing all the benefits of PASCAL therapy and now including a narrower profile, which has the potential to expand the range of MR settings that can be treated.[3] The PASCAL Ace implant is particularly helpful when dealing with constrained landing zones due to dense chordae, and can be helpful when imaging is difficult during right-sided procedures.[3]

Adding the PASCAL Ace implant provides you with more capabilities, more control and more options when treating patients with mitral or tricuspid regurgitation.[3]

'In my experience, the PASCAL Ace implant is easier to work with than the original PASCAL implant, because it is smaller and can be more accurately positioned due to fewer problems with the chordae and fewer problems with echocardiographic shadowing, which means visibility of the leaflets is better, improving safety during the procedure.' Professor Jörg Hausleiter

The power of the PASCAL Repair System and PASCAL Ace Implant System combination

Professor Dr med. Volker Rudolph,
Herz-und Diabeteszentrum Nordrhein-Westfalen (NRW), Universitätsklinik der Ruhr-Universität Bochum, Bad Oeynhausen, Germany

Professor Rudolph is Director of the Clinic for General and Interventional Cardiology/ Angiology at the Heart and Diabetes Center NRW, Bad Oeynhausen (University Clinic of the Ruhr University Bochum). His clinical work focuses on the treatment of heart valve diseases, with a focus on the mitral and tricuspid valves, as well as catheter-supported therapy of coronary heart disease. Professor Rudolph is the spokesperson for the working group for catheter-supported mitral valve therapy of the German Cardiac Society.

Dr med. Kai Friedrichs,
Herz-und Diabeteszentrum NRW, Universitätsklinik der Ruhr-Universität Bochum, Bad Oeynhausen, Germany

Dr Friedrichs is Senior Physician of the Clinic for General and Interventional Cardiology/ Angiology and Head of the TMTT programme at the Heart and Diabetes Center NRW, Bad Oeynhausen (University Clinic of the Ruhr University Bochum). He is a member of the German Cardiac Society (DGK).

Dr Friedrichs described a 78-year-old female patient with body mass index 25.2 kg/m^2 (weight 56 kg; height 149 cm) who presented with severe NYHA class III MR of mixed aetiology.[7] She had a history of three-vessel coronary artery disease, for which she had undergone coronary artery bypass graft surgery in 2009 and percutaneous transluminal coronary angioplasty with stents in 2009 and 2019. She also had hypertension and hyperlipoproteinaemia, and had experienced three strokes in 1966, 1967 and 2000. She was taking ASA, torasemide, simvastatin, pantoprazole, metoprolol, ramipril and ranolazine.

Prior to mitral valve repair, pre-procedural transthoracic echocardiography (Figure 5a) and 3D assessment (Figure 5b) demonstrated MR grade 4.[7] Initial intervention involved implanting the PASCAL device, with leaflet clasping in a central position (Figure 6a). Assessment of leaflet insertion after deployment of the first device (Figure 6b) showed a residual MR jet of 1+ lateral to the first device (Figure 6c) and a mean gradient of 2.7 mmHg (Figure 6d).

Given the residual lateral MR jet after implantation of the first device, a decision was made to implant a second device, with the PASCAL Ace implant system preferred due to the small valve anatomy and narrow jet morphology.[7] The PASCAL Ace implant was implanted in a lateral position close to the first device. No increase in mean gradient was observed after deployment of the second device (Figure 7a). The final result showed trace residual MR, with the PASCAL Ace implant eliminating the lateral jet (Figure 7b–d).

Figure 5. Transthoracic echocardiogram showing pre-procedural MR grade 4 (a) and pre-procedural 3D assessment of the mitral valve (b).[7]

(a) (b)

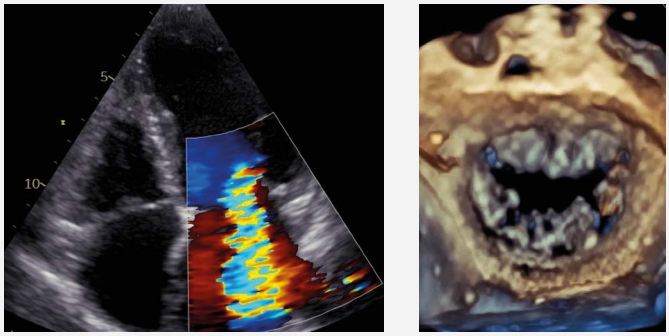
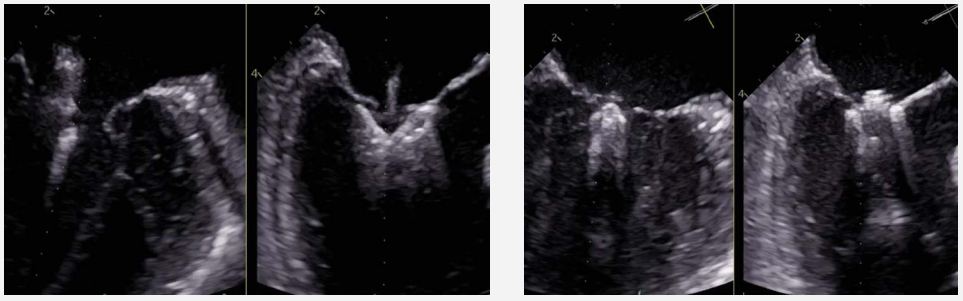
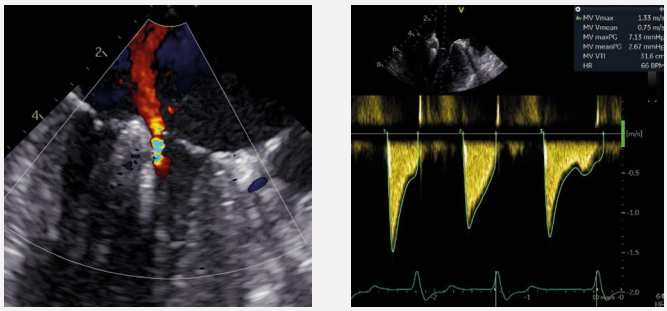


Figure 6. Imaging after initial implantation of the PASCAL implant: leaflet clasping in central position (a), leaflet insertion after deployment of first device (b), residual jet 1+ lateral to first device (c), and mean gradient (2.7 mmHg) (d).[7]

(a) (b)



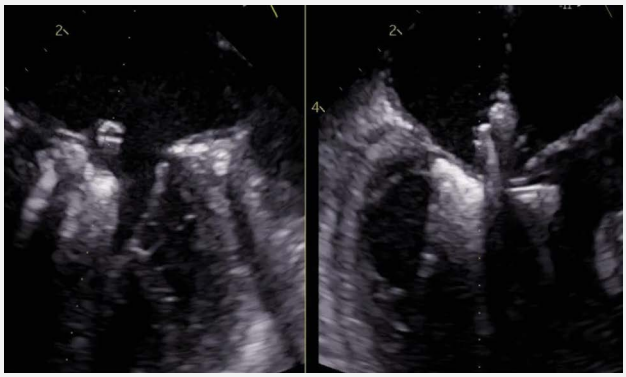
(c) (d)



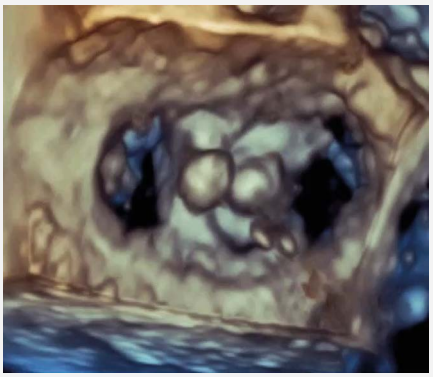
'In some cases, a residual MR jet can remain after implantation of the PASCAL device, even after leaflet optimisation. As these residual jets are often very circumscribed, they do not require the whole width of another conventional device. At the same time, with the ability to now employ a smaller device, one reduces the risk of an increased postprocedural gradient. In addition, residual jets can be located near the commissures, and the smaller device facilitates steering in these challenging situations.' Professor Volker Rudolph and Dr Kai Friedrichs

Figure 7. Imaging after implantation of the PASCAL Ace implant as a second device: leaflet clasping (PASCAL Ace implant) in a lateral position close to the first device (a), final 3D assessment at the end of the procedure (b), no increase in mean gradient after deploying the second device (c), and trace residual MR on final imaging (d).[7]

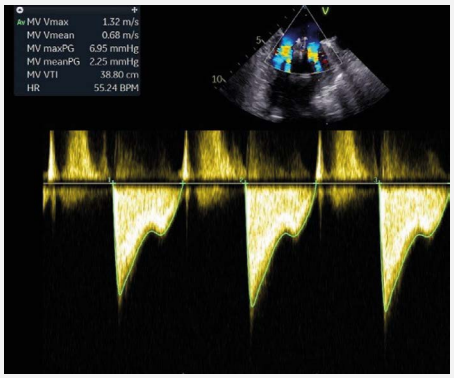
(a)



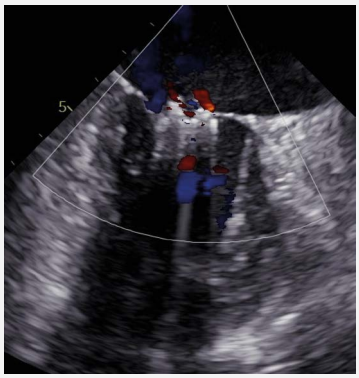
(b)



(c)



(d)



'We have so far used the PASCAL Ace implant in anatomies with smaller mitral orifice areas, with the idea of reducing post-procedural gradients, as well as in commissural anatomies, where the risk of chordal interactions is smaller with the PASCAL Ace implant. However, clearly the system also works in presumably straightforward cases, and we still have to learn when to use which device.' Professor Volker Rudolph and Dr Kai Friedrichs

'We have achieved very satisfactory results. In all cases MR could be reduced to grade 1. One particular case had a dehiscent annuloplasty ring, where steering of the catheter was additionally restricted by the ring, which we could manage with the implantation of one PASCAL Ace implant.' Professor Volker Rudolph and Dr Kai Friedrichs

A new solution for the mitral and tricuspid valve repair challenge

Professor Dr med. Jörg Hausleiter,
Medizinische Klinik und Poliklinik I, Munich, Germany

An interventional cardiologist expert in the field of valvular and coronary heart diseases, Professor Dr Jörg Hausleiter is Professor of Medicine and the Deputy Clinic Director at the Ludwig-Maximilians Universität in Munich, Germany. He is invested in bringing new percutaneous treatments to patients with coronary and valvular diseases.

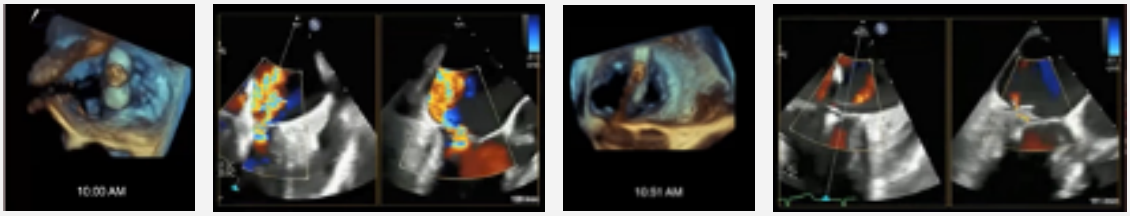
Unlike the mitral valve, tricuspid valves have dense, delicate chordae; thin, fragile and variable leaflets; and a large annulus.[8] The unique features of the PASCAL repair system facilitate its use in the repair of this complex and delicate structure, and the specific features of the PASCAL Ace implant system may make this a good solution for tricuspid valve repair, preferable even to the original PASCAL repair system.

Professor Hausleiter described one of the first patients in whom the PASCAL Ace implant was used to treat secondary MR (Figure 8a).[9] The patient was initially treated with the PASCAL repair system, but despite repeated attempts to grasp the leaflets using different optimisation procedures, satisfactory MR reduction could not be achieved as the posterior mitral leaflet was very short and tended to curl in the device (Figure 8b). After 40 minutes, a decision to use the PASCAL Ace implant was made (Figure 8c). With one grasp from the smaller device and a total procedural time of two minutes, the patient was successfully treated, with no trace residual MR (Figure 8d). This outcome was achieved because the small PASCAL Ace implant allowed for an easier and better grasp of the posterior leaflet. The patient also had severe TR in addition to MR, and the PASCAL Ace implant was also used to repair the tricuspid valve, with an excellent outcome achieved in little time.

Professor Hausleiter then described a colleague's case of a patient older than 80 years who was very symptomatic despite a small gap in the tricuspid valve.[9] The initial strategy was to place two PASCAL Ace implants, with one on the anteroseptal line of coaptation and one on the posteroseptal line of coaptation. However, positioning the PASCAL Ace implant on the anteroseptal line of coaptation led to an almost perfect result, with only minimal residual TR. At this point, a decision had to be made whether to continue to implant the second device to further reduce the TR to a trace level. After discussion, a second PASCAL Ace implant was used to repair the tricuspid valve, resulting in a perfect reduction in TR.

Figure 8. Use of the PASCAL repair system in a patient with secondary MR: (a) before first procedure with standard PASCAL implant, (b) residual MR after attempted implantation of standard PASCAL implant due to a short posterior leaflet; (c) before second procedure with the PASCAL Ace implant, and (d) trace MR after implantation of the PASCAL Ace implant.[9]

(a) (b) (c) (d)



Tips and tricks from the experts

Optimising the use of the PASCAL Ace Implant System to reach great outcomes across mitral and tricuspid repair

We asked our contributors for their top advice on using the PASCAL Ace implant based on their experience.

Professor Hausleiter

For an interventional cardiologist with experience with other devices, the learning curve for the PASCAL Ace implant is likely to be short – probably 5–20 patients before they are confident enough to treat patients very efficiently. For an interventional cardiologist with no experience at all in this field, their focus should be more on echocardiography and how to treat valve disorders, so it is more about the disease than the device. In Europe, the Edwards Lifesciences team provides excellent support for interventionists starting to use new devices.

Communication with the echocardiographer is key, not only during the procedure, but also, and perhaps more importantly, during pre-procedural planning to decide the procedural strategy.

Professor Rudolph and Dr Kai Friedrichs

'PASCAL Ace builds on the existing PASCAL implant and the device can be used in the same way as the conventional implant. Upon bringing the PASCAL Ace implant into the grasping position, the device does open quite suddenly compared to the conventional implant, but this is unproblematic if the implanter is aware of the difference. Steering, however, appears easier with PASCAL Ace, particularly if one is used to the original PASCAL repair system'

Atrial pressure monitoring during mitral and tricuspid procedures

Assistant Professor Sinisa Markovic,
Managing Senior Physician, Universitätsklinikum Ulm, Germany

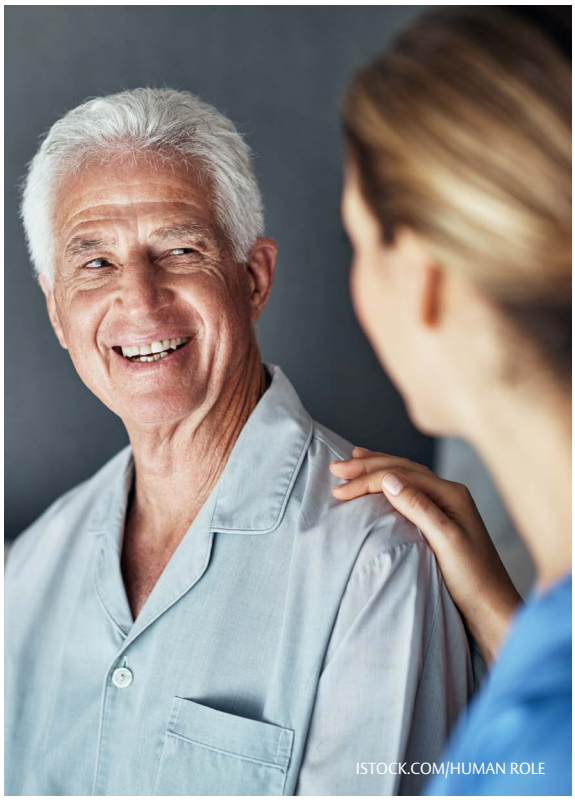
Dr Sinisa Markovic is a Senior Physician in the Department of Cardiology at the University Hospital Ulm. He has board certification in internal medicine, cardiology and interventional cardiology, and an interest in innovations in the field of coronary heart disease as much as in the field of transcatheter atrioventricular valve interventions. Dr Markovic is a member of the German Cardiac Society, the German Interventional Cardiology Group and European Society of Cardiology.

How AP monitoring can provide procedural guidance and a proxy for outcomes

AP monitoring offers an additional solution to aid clinical decision-making during transcatheter mitral and tricuspid valve repair procedures.[10,11] Monitoring can be achieved by connecting to the PASCAL steerable catheter, which ensures that the pressure signal comes from the atrium, and produces reliable atrial pressure values to compare pre- and post-implant results.[10]

AP monitoring can provide both procedural guidance and a proxy for outcomes.[10,11]

- In terms of **procedural guidance**, AP monitoring provides continuous monitoring of pressure reduction and the haemodynamic status of the patient.[10,11] Monitoring helps to determine the adequacy of MR reduction for a specific PASCAL implant grasping site, which is important because changes in left atrial pressure (LAP) and V-wave after leaflet grasping can guide the decision to reposition and deploy the PASCAL implant.[10]
- As a **proxy for outcomes**, AP monitoring can facilitate greater reductions in MR. Changes in LAP in patients with primary MR are associated with improvements in exercise capacity, and post-implantation increases in mean LAP are significantly associated with heart failure and rehospitalisation at follow-up.[10,11]



ISTOCK.COM/HUMAN ROLE

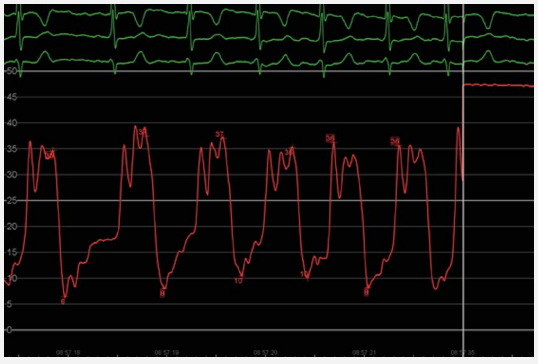
'Continued intra-procedural assessment of the atrial pressure, in addition to the other parameters, brings further information of procedure success.' Dr Sinisa Markovic

The value of AP monitoring during tricuspid valve repair using the PASCAL delivery system

This case study is taken from Dr Markovic's presentation at a Radcliffe Cardiology webinar in 2020.[12]

Dr Markovic described the case of a frail, 84-year-old male patient with a history of heart failure decompensations who presented with very advanced heart failure. The patient had previously received an edge-to-edge procedure in the mitral valve position, was NYHA class IV with pleural effusions, and had intractable ascites and leg oedema. A PASCAL device was implanted into the anteroseptal commissure to treat TR. Two techniques were useful in measuring the success of deployment of the PASCAL repair system for treatment of TR: first, a reduction in the retrograde V-wave of the hepatic vein wave form indicated a reduction in TR; second, the PASCAL repair system facilitated periprocedural AP monitoring (Figure 9), which allowed opening and replacing of the device to optimise haemodynamic outcomes. At nine months following the procedure, the patient demonstrated good outcomes with no relapse of ascites during the interim period and a successful 6-minute walk test. The case demonstrates the use of right atrial haemodynamic monitoring during tricuspid valve repair using the PASCAL delivery system. Left atrial pressure monitoring can be equally useful in mitral valve repair.

Figure 9. Invasive haemodynamic assessment during percutaneous tricuspid valve repair using the PASCAL delivery system.[12]



'The implantation of the first PASCAL implant showed a decent reduction of the ventricularisation, and after slight repositioning of the implant with readjusting and independent recapture of the cusps, a haemodynamically satisfactory reduction of the TR was achieved.' Dr Sinisa Markovic

Conclusion

One-year outcomes from the CLASP study demonstrate the continued success of the PASCAL repair system. To complement the PASCAL platform, we have now introduced the PASCAL Ace implant system, which provides all the benefits of PASCAL therapy but with a narrower profile.

With its smaller size, the PASCAL Ace implant can be used in challenging anatomies, either alone or in combination with the PASCAL implant, and potentially expands the range of patients with MR or TR who may be treated.

The addition of AP monitoring, a new solution achieved through connection to the PASCAL steerable catheter, can aid clinical decision-making during transcatheter mitral and tricuspid valve repair procedures by providing both procedural guidance and a proxy for outcomes.

Together, these technologies are helping to optimise outcomes for patients with MR and TR.

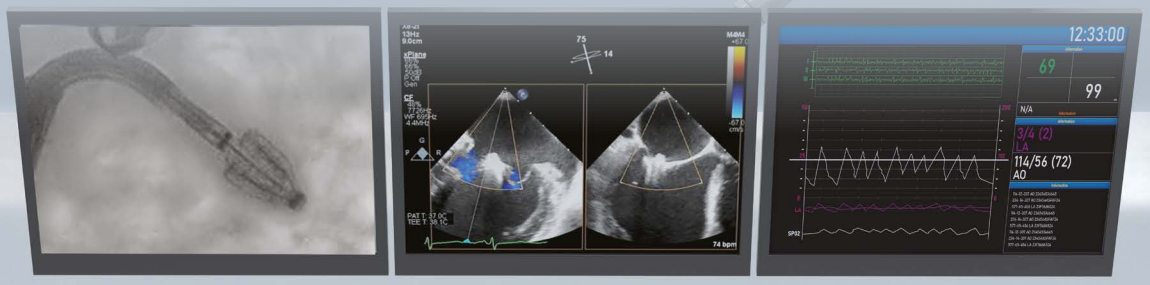
References

1. Lim DS, Kar S, Spargias K *et al*. Transcatheter valve repair for patients with mitral regurgitation: 30-day results of the CLASP study. *Journal of the American College of Cardiology: Cardiovascular Interventions*. 2019; **12**: 1369–78.
2. Webb JG, Hensey M, Szerlip M *et al*. One-Year Outcomes for Transcatheter Repair in Patients with Mitral Regurgitation from the CLASP Study. *Journal of the American College of Cardiology: Cardiovascular Interventions*. 2020; **13**: 2344–57.
3. Edwards Lifesciences LLC. Data on file TMTT.
4. Edwards Lifesciences LLC. PASCAL Transcatheter Valve Repair System Instructions for Use. 2020.
5. Pfister R. Verbesserung der Ergebnisse für Patienten mit Mitralklappeninsuffizienz mit dem Klappensegel Reparatursystem. DGK Herztage 2020.
6. Edwards Lifesciences LLC. Data on file: PASCAL ACE Implant component design enhancement. 2020.
7. Rudolph V. PASCAL Repair System Platform in action. Presentation at *PCR Valves e-Course 22-24 November 2020*.
8. Pozzoli A, Zuber M, Reisman M *et al*. Comparative Anatomy of Mitral and Tricuspid Valve: What Can the Interventionlist Learn From the Surgeon. *Frontiers in Cardiovascular Medicine*. 2018; **5**: 80.
9. Edwards Lifesciences LLC. Data on file: TMTT Quarterly Forum. 2020.
10. Edwards Lifesciences LLC. Data on file: Edwards PASCAL Transcatheter Valve Repair System Atrial Pressure Monitoring Opportunity. 2020.
11. Kuwata S, Taramasso M, Czopak A *et al*. Continuous direct left atrial pressure: intraprocedural measurement predicts clinical response following MitraClip therapy. *Journal of the American College of Cardiology: Cardiovascular Interventions*. 2019; **12**: 127–36.
12. Markovic S. Pascal Repair System for TR: Case presentations. 2020. Available at: https://www.radcliffecardiology.com/pascal-repair?utm_medium=email&utm_source=radcliffe_adestra&utm_campaign=1677&utm_launch [Accessed 29 October 2020].

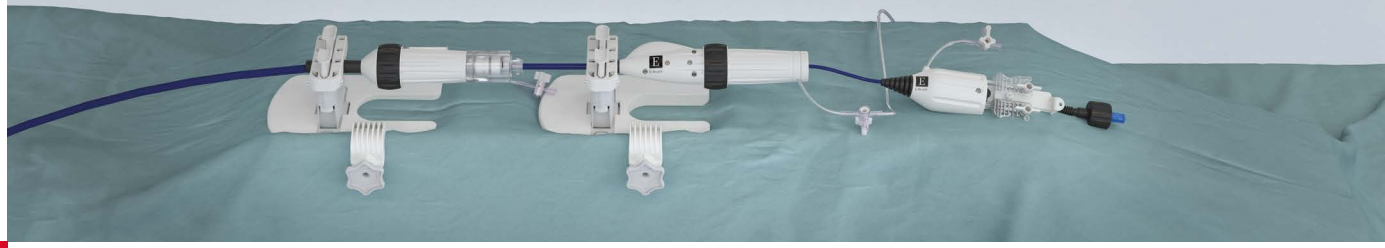
PASCAL Transcatheter Valve Repair System

Now Available: Continuous Atrial Pressure Monitoring

During Mitral and Tricuspid Leaflet Repairs



You can now measure left and right atrial pressures through the steerable catheter of the Edwards PASCAL repair system, using a commercially available pressure monitor. This function of the PASCAL repair system helps provide procedural guidance and a proxy for outcomes—another important feature to consider with the PASCAL platform.



Find out more at **Edwards.com/PASCAL**

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

Edwards