TMTT Today

Your source for information on Edwards' innovations in transcatheter mitral and tricuspid therapies

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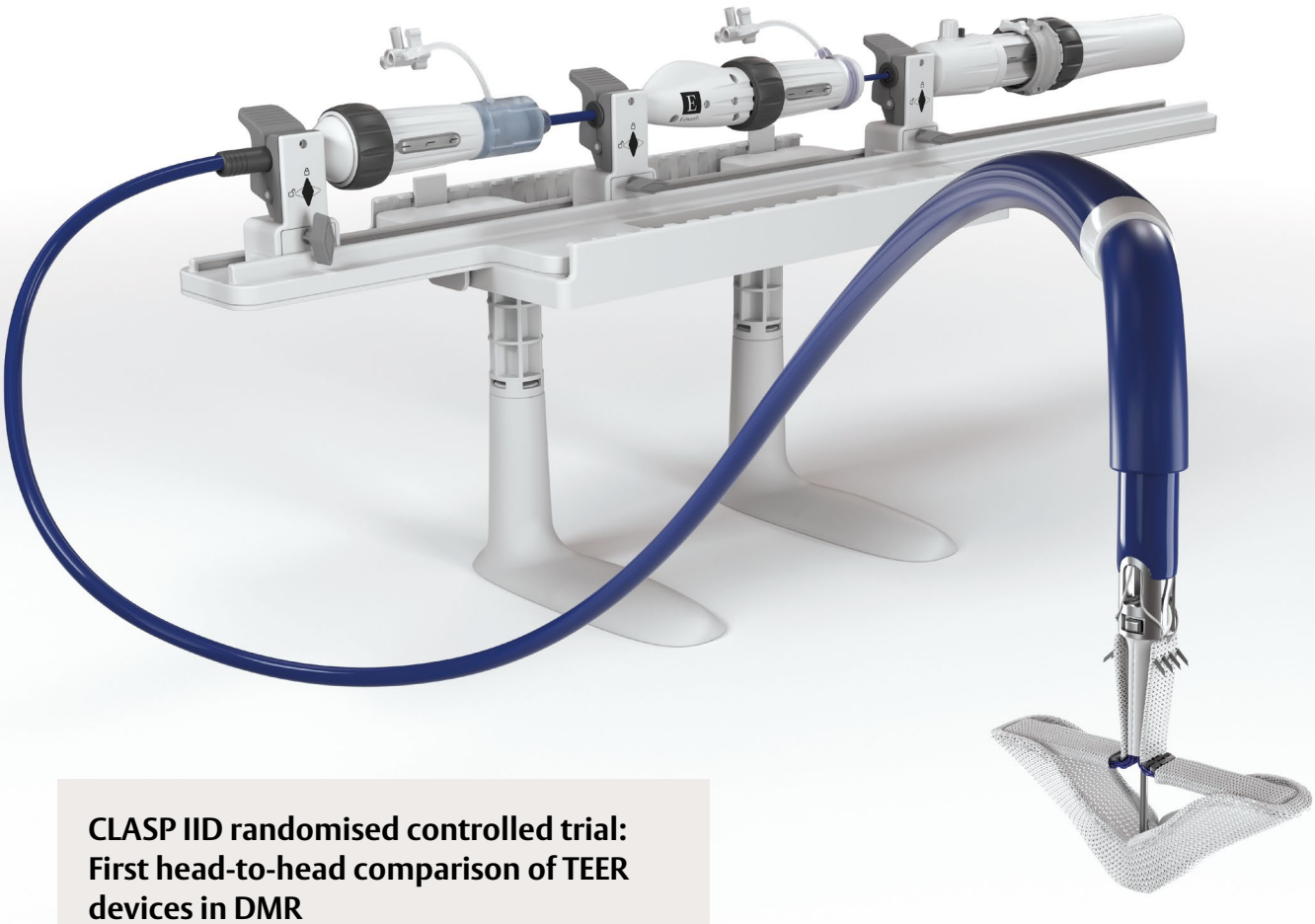
PASCAL Precision System:

Designed for precise placement with accurate, intuitive control*



CLASP IID randomised controlled trial: First head-to-head comparison of TEER devices in DMR

PASCAL repair system provides significant and sustained MR reduction

84% MR 0/1+

at 6 months[1]

Also inside: First impressions from early users of the PASCAL Precision system in MR and TR

*Performance data on file and marketing evaluation.

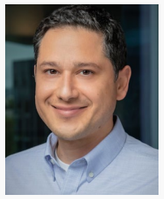
Edwards

Dear Reader,

At Edwards Lifesciences, we are passionate about helping patients, and to do so, we continuously work with practising physicians to develop new technologies that meet their – and their patients' –needs. Thanks to close collaboration between interventional cardiologists and our Research and Development team, we brought the PASCAL Precision system to the European market in 2022. The user-friendly delivery system has greater stability and improved responsiveness, enabling additional control and smooth navigation during PASCAL repair system procedures.* As always, the final verdict on the success of an updated system lies with the operators. In this issue of *TMTT Today*, we bring you perspectives from early users of the PASCAL Precision system in patients with mitral regurgitation (MR) and tricuspid regurgitation (TR).

Also in this issue, we present early data from the CLASP IID trial, which is the first randomised controlled trial (RCT) comparing outcomes with two different transcatheter edge-to-edge repair (TEER) devices – the PASCAL repair system and MitraClip system – in patients with degenerative MR at prohibitive surgical risk.[1] These data demonstrate the positive safety and efficacy of contemporary TEER in these patients and highlight that the PASCAL repair system is non-inferior to the MitraClip system,[1,2] despite most centres having limited experience with the PASCAL repair system. In addition, they illustrate sustained MR reduction with the PASCAL repair system at 6 months.[1] We also present early data from the CLASP IID registry, which demonstrated efficacy and safety of the PASCAL repair system in patients at prohibitive surgical risk and ineligible for treatment with the MitraClip system based on their complex anatomy.[3]

Enjoy reading!



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*Design and performance data on file and marketing evaluation.

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The PASCAL Repair System in patients with degenerative MR

Early outcomes from the CLASP IID randomised controlled trial and the CLASP IID registry

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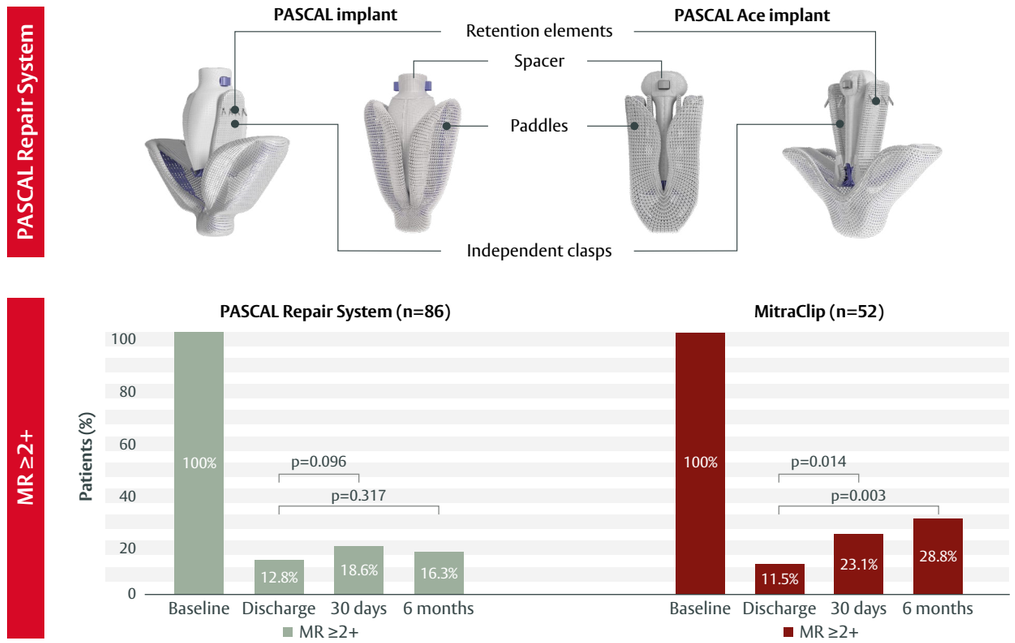
Professor Jörg Hausleiter is Professor of Medicine and the Deputy Clinic Director at LMU in Munich. His primary research interest is the development of new percutaneous treatments for patients with coronary and valvular diseases. Professor Hausleiter has been Principal Investigator in several clinical trials, including TRICuspid, MiCLASP, TRILUMINATE, CLASP IID/IIF and PASTE.

Transcatheter mitral valve repair (TMVr) using the PASCAL repair system significantly reduces MR grade and improves symptoms and quality of life for patients with MR.[4,5] Until now, no RCT data have been published comparing outcomes from TMVr using different TEER devices. Here, Professor Jörg Hausleiter highlights early data from the CLASP IID RCT comparing clinical and echocardiographic outcomes in patients with significant symptomatic degenerative MR and at prohibitive surgical risk, following treatment with the PASCAL repair system or the MitraClip system.[1] In addition, Professor Hausleiter discusses early outcomes from the CLASP IID registry, which documents those patients not randomisable in the CLASP IID trial due to complex mitral valve anatomy as described in the current MitraClip Instructions for Use,[6] but still eligible for treatment with the PASCAL repair system.[3]

Central illustration: Reduction in MR ≥2+ was sustained to 6 months after TEER with the PASCAL repair system in the CLASP IID RCT (paired analysis).[1]



CLASP IID (NCT03706833) is a prospective, multicentre, multinational RCT comparing the safety and effectiveness of the PASCAL repair system with the MitraClip system in patients with significant symptomatic degenerative MR (grade 3–4+) who are at prohibitive risk for surgery.[1] It is a noninferiority trial with primary endpoints of safety (based on a composite major adverse event [MAE] rate comprising cardiovascular mortality, stroke, myocardial infarction, new need for renal replacement therapy, severe bleeding and non-elective mitral valve re-intervention at 30 days) and effectiveness (based on the proportion of patients with MR ≤2+ at 6 months).[1]

Patients were enrolled in the CLASP IID RCT if they were deemed suitable by a central screening committee and echocardiographic core laboratory for treatment with the PASCAL repair system and the MitraClip system. Patients considered suitable for treatment with the PASCAL repair system but not with the MitraClip system, based on complex anatomy,[a] were enrolled in the CLASP IID registry. Inclusion and exclusion criteria for the CLASP IID RCT and the CLASP IID registry are outlined in Table 1.[1,3]

> In my experience, the lower the MR grade following treatment, the less likely the patient will be to have a major adverse event, including death or heart failure hospitalisation.
> **Professor Jörg Hausleiter**

Table 1. Patient eligibility criteria for the CLASP IID RCT and the CLASP IID registry.[1,3]

CLASP IID RCT NCT03706833	CLASP IID registry
Common Inclusion criteria	
• Age ≥18 years • Prohibitive risk for mitral valve surgery • Candidate for M-TEER with the PASCAL repair system • Degenerative MR (3+ to 4+) • Suitable valve and regurgitant jet morphology • LVEF ≥20%, LVEDD ≤80 mm	
Specific inclusion criteria	
• Candidate for M-TEER with the MitraClip system	• None
Common exclusion criteria	
• TEE is contraindicated or screening TEE is unsuccessful • Severe right ventricular dysfunction • Active rheumatic heart disease or rheumatic MR aetiology • Other severe valve disorders requiring intervention or left ventricular outflow obstruction • Clinically significant, untreated coronary artery disease • Severe renal insufficiency with eGFR ≤25 mL/min or requiring chronic renal replacement therapy	
Specific exclusion criteria	
Presence of any of the following anatomical features precluding use of the MitraClip system:[a] • Moderate to severe calcification in the grasping area • Significant cleft or perforation in the grasping area • ≥2 independent significant jets • 1 significant jet in the commissural area • Mitral valve orifice area <4.0 cm² • Leaflet mobility length <8 mm • Severe bileaflet/multi-scallop prolapse involvement	• None

eGFR, estimated glomerular filtration rate; LVEDD, left ventricular end-diastolic dimension; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; M-TEER, mitral valve transcatheter edge-to-edge repair; RCT, randomised controlled trial; TEE, transoesophageal echocardiography.

[a]Based on the anatomical considerations in the special patient populations section of the current MitraClip system Instructions for Use.[6]

Adapted from Lim DS *et al.* 2022 and Hausleiter J *et al.* 2023.

CLASP IID RCT outcomes

In an interim analysis of 180 patients randomised 2:1 to treatment with either the PASCAL repair system (n=117) or the MitraClip (n=63), no significant differences in baseline characteristics were observed between the two groups. Among patients receiving the PASCAL repair system, 67% received the PASCAL implant, 24% received the PASCAL Ace implant and 9% received a combination of the two. Successful implantation rates[a] were high for both the PASCAL repair system (99%) and the MitraClip (100%). Procedure times[b] and device times[c] were shorter with the MitraClip *versus* the PASCAL repair system; however, as operators became more experienced with the PASCAL repair system, procedural times for the device decreased. Total hospital length of stay was similar in the two groups (1 day [interquartile range 1–2 days] for both systems).[1]

> Edge-to-edge repair could be performed very safely in this elderly and fragile patient cohort and there was no difference in terms of the safety of the devices.
> **Professor Jörg Hausleiter**

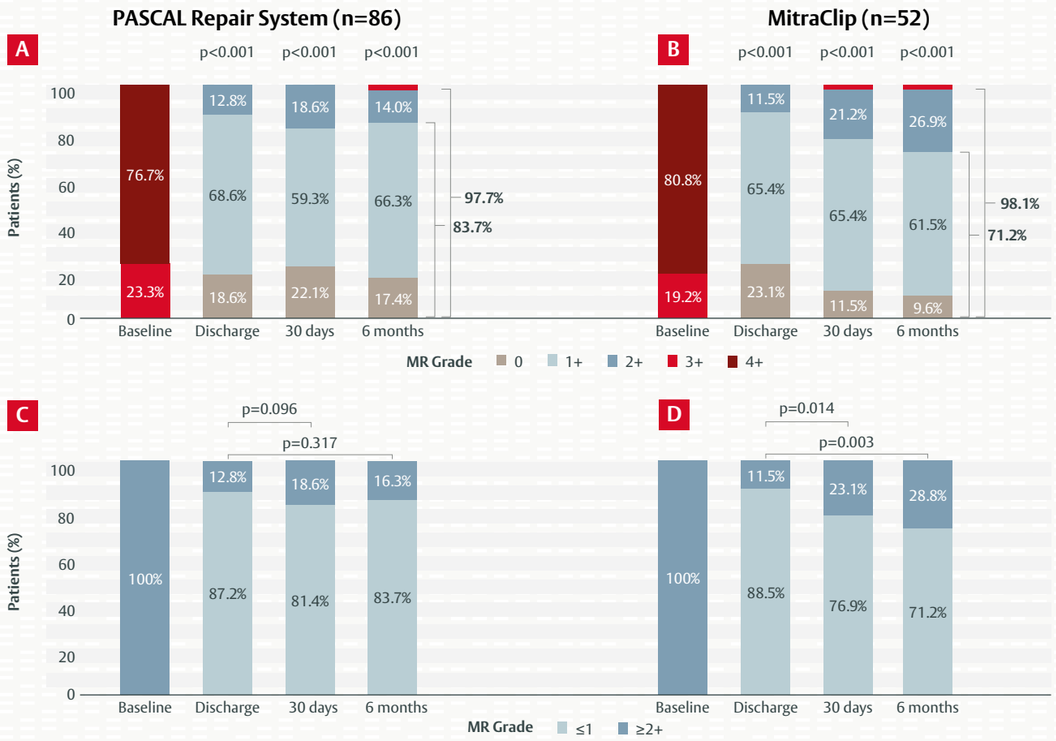


Figure 1. MR reduction following treatment of patients with degenerative MR. Paired analysis using (A) the PASCAL repair system and (B) the MitraClip in the CLASP IID RCT. Panels C and D show the durability of MR reduction to MR ≤1+ with (C) the PASCAL repair system and (D) the MitraClip.[1]

Graphs show paired analyses; p values relative to baseline (Panels A and B) calculated using the Wilcoxon signed rank test; p values relative to discharge (Panels C and D) calculated using the McNemar's test. MR, mitral regurgitation; RCT, randomised controlled trial.

Adapted from Lim DS *et al.* 2022.

[a]Proportion of patients with the study device implanted and deployed as intended, and the delivery system retrieved successfully.
[b]Time from procedure start (femoral vein puncture/skin incision) to femoral vein access closure.
[c]Time from PASCAL implant system or MitraClip delivery system insertion into left atrium to guide sheath or steerable guide removal.

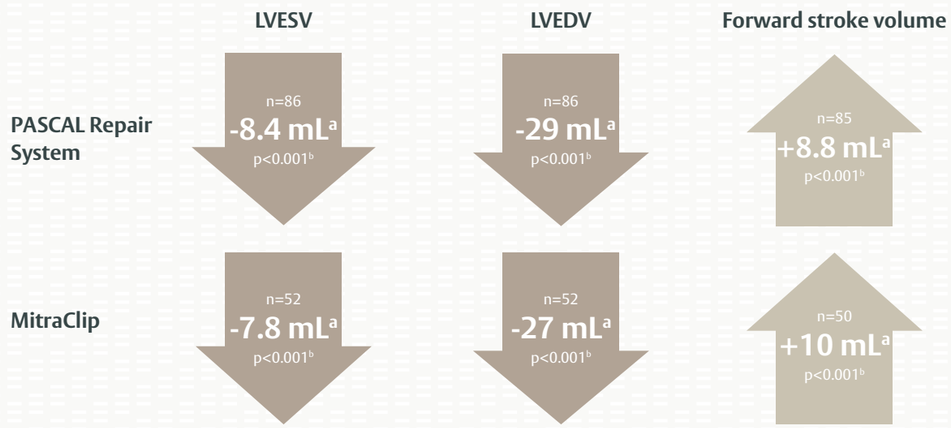


Figure 2. Change in echocardiographic parameters from baseline to 6 months following treatment with the PASCAL repair system or the MitraClip in the CLASP IID RCT.[7]

[a]Adjusted least square mean change; [b]intragroup p values from analysis of covariance (ANCOVA) model.
LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; RCT, randomised controlled trial.

The CLASP IID RCT met its primary endpoints, with the PASCAL repair system demonstrating noninferiority *versus* the MitraClip in both safety and effectiveness. The composite MAE rate at 30 days was 3.4% with the PASCAL repair system and 4.8% with the MitraClip. These interim results further confirm the safety and effectiveness of TEER for prohibitive surgical risk patients with significant symptomatic degenerative MR.[1]

Almost all patients (97.7% with the PASCAL repair system; 98.1% with the MitraClip system) achieved MR ≤2+ at 6 months following treatment (Figure 1). The proportion of patients achieving MR ≤1+ was sustained from discharge to 6 months in those treated with the PASCAL repair system (87.2% *versus* 83.7%; p=0.317) system, but not in those treated with the MitraClip (88.5% *versus* 71.2%; p=0.003; Figure 1).[1]

In both treatment groups, transmitral gradients were maintained below 5 mmHg for at least 6 months after treatment, with no differences between the PASCAL repair system and the MitraClip. There was also evidence of left ventricular remodelling: between baseline and 6 months after the procedures, left ventricular end-systolic and -diastolic volumes were significantly reduced, and forward stroke volume between baseline and 6 months had significantly improved in both groups (p<0.001; Figure 2).[7]

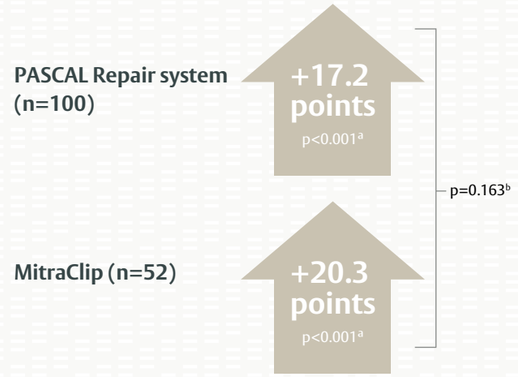


Figure 3. Change in KCCQ score from baseline to 6 months following treatment with the PASCAL repair system or the MitraClip in the CLASP IID RCT (paired analysis).[1]

[a]p values calculated using Student's t-test; [b]p value calculated using the analysis of covariance (ANCOVA) model adjusted for baseline values and planned treatment as covariates.
KCCQ, Kansas City Cardiomyopathy Questionnaire; RCT, randomised controlled trial.

> Following edge-to-edge repair, we can achieve MR 0/1+ in a very high proportion of patients.
> **Professor Jörg Hausleiter**

> In both studies, there was a very positive MR reduction with the PASCAL repair system which translated into a significant clinical improvement based on NYHA class.[1,3]
> **Professor Jörg Hausleiter**

At 6 months, freedom from all-cause mortality was 94.9% for the PASCAL repair system group and 93.7% for the MitraClip group. Significant improvements were seen between baseline and 6 months in New York Heart Association (NYHA) functional class (p<0.001 for both groups), 6-minute walk distance (6MWD; p=0.027 for the PASCAL repair system; p=0.016 for the MitraClip) and quality of life (KCCQ score: p<0.001 for both groups [Figure 3]; EQ-5D-5L score: p<0.001 for the PASCAL repair system, p=0.031 for the MitraClip). No significant differences in 6MWD and quality-of-life outcomes were seen between the PASCAL repair system and MitraClip groups at 6 months.[1]

Together, these results suggest that the PASCAL repair system is a beneficial therapy for patients with significant symptomatic degenerative MR, expanding the transcatheter treatment options for patients at prohibitive surgical risk.[1]

CLASP IID registry outcomes

Due to anatomical considerations described in the special patient populations section of the current MitraClip Instructions for Use,[6] 98 patients were ineligible for randomisation in the CLASP IID RCT. They were, however, suitable for treatment with the PASCAL repair system and their outcomes were recorded in the CLASP IID registry. Freedom from all-cause mortality was 97.9% at 30 days and 93.7% at 6 months, while freedom from MAEs was 88.8% at 30 days and 85.6% at 6 months. In a paired analysis, there was a significant reduction in MR at all timepoints following treatment. While less than 2% of patients had MR ≤2+ at baseline, this increased to 92.4% at 6 months after treatment (Figure 4).[3]

Even in this patient population with complex anatomy, post-procedural transmitral gradients were maintained below 5 mmHg, and NYHA functional class and quality of life (based on KCCQ) improved significantly between baseline and 6 months (both p<0.001), as in the CLASP IID trial.[1,3]

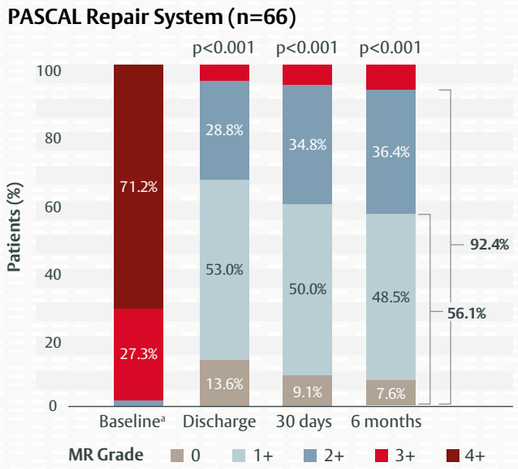


Figure 4. MR reduction with the PASCAL repair system in patients with significant symptomatic degenerative MR and complex anatomy precluding use of the MitraClip system (CLASP IID registry).[3,6]

Graph shows paired analysis; p values relative to baseline calculated using the Wilcoxon signed rank test.

[a]Echocardiographic core laboratory assessed MR severity by transthoracic echocardiography. Baseline qualification for some patients included transoesophageal echocardiography.

MR, mitral regurgitation; RCT, randomised controlled trial.

Adapted from Hausleiter J *et al*. 2023.

This suggests that the PASCAL repair system can improve symptoms and MR in patients with complex anatomy, without causing significant mitral stenosis.[8]

Conclusion

The CLASP IID RCT and CLASP IID registry support the effectiveness and safety of the PASCAL repair system in patients with severe symptomatic degenerative MR. In both studies, treatment with the PASCAL repair system provided significant improvements in MR, functional status and quality of life over the 6-month study period.[1,3] In the CLASP IID RCT, a sustained reduction in MR in patients treated with the PASCAL repair system was accompanied by favourable ventricular remodelling.[1,7] In addition, the CLASP IID registry provided early data indicating the effectiveness and safety of the PASCAL repair system in those patients ineligible for treatment with the MitraClip based on their complex anatomy.[3,6,8]

Development of the PASCAL Precision System

Seung Yi
Vice President, Engineering, Edwards Lifesciences

Seung Yi is a Vice President of Research and Development at Edwards Lifesciences. He is responsible for developing new leaflet edge-to-edge repair technologies in transcatheter mitral and tricuspid therapies, including the PASCAL Precision system.

The PASCAL Precision system is a second-generation delivery system to complement the PASCAL platform of transcatheter valve repair technologies developed by Edwards Lifesciences. The PASCAL Precision system provides physicians with a versatile tool to improve accuracy and control during their transcatheter mitral and tricuspid valve repair procedures.* Here, Seung Yi explains the driving force behind the development of the PASCAL Precision system and describes how the key components have been carefully designed to achieve these goals by enhancing stability and responsiveness.

In the Research and Development department at Edwards Lifesciences, we are constantly striving to improve our products by partnering with physicians on the front line of heart valve repair. With the introduction of the PASCAL stabilizer Rail System (PASCAL SRS) in 2021, comprising a single rail and three secure stabilizers,* we were able to reduce unintended catheter movements during PASCAL repair procedures and enable operators to make stable, incremental movements and fine adjustments. In close collaboration with practising physicians, we have now developed the PASCAL Precision system (Figure 5), a delivery system targeting greater stability, improved responsiveness and a more user-friendly design.*

'The PASCAL Precision system is an updated delivery system, with many of the components completely redesigned.'
Seung Yi

The PASCAL Precision system comprises three main interfaces:[9] the guide sheath handle, the steerable catheter handle and the implant catheter handle. These are secured within the three stabilizers of the PASCAL SRS, which is mounted on a single table, and enable physicians to manoeuvre implants within three planes. Proprietary laser-cut hypotubes (Figure 6) specific for each section of the delivery system have now been included in the catheter shafts to provide a balance of stiffness and flexibility. The laser-cut hypotubes are also one of several features that have improved catheter responsiveness, alongside a hydrophilic coating on the implant catheters and an increased clearance between catheters to reduce friction. Secure stabilizers, including a third stabilizer for the implant catheter handle, provide incremental movements and fine adjustments to advance, retract and manoeuvre the catheters. Together, these features optimise torque transfer and enable the implant to move almost instantaneously with rotations of the catheter handles, achieving nearly one-to-one responsiveness.*

'Secure stabilizers, including a third stabilizer for the implant catheter handle, provide incremental movements and fine adjustments to advance, retract and manoeuvre the catheters.'
Seung Yi

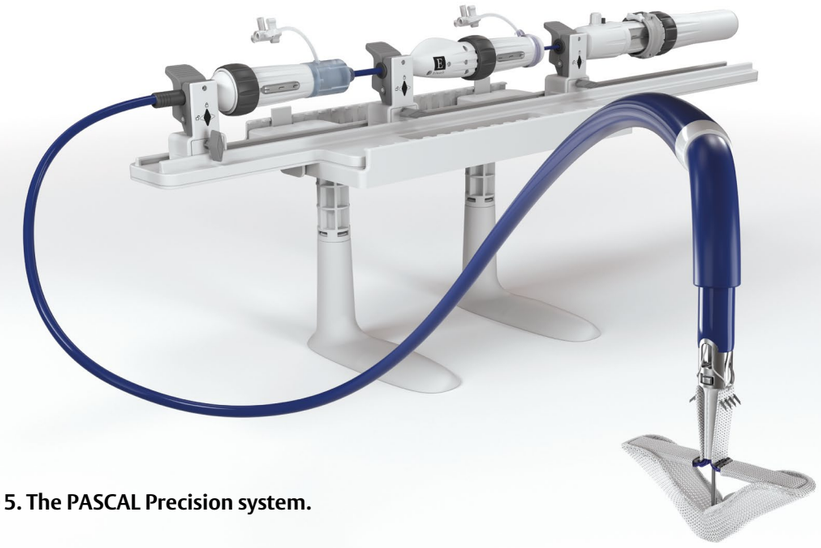
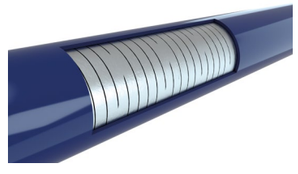


Figure 5. The PASCAL Precision system.

'Proprietary laser-cut hypotubes specific for each section of the delivery system provide a balance between stiffness and flexibility, and contribute to catheter responsiveness.'
Seung Yi

In response to physicians' feedback, we have redesigned the implant catheter handle to make it more intuitive and easier to operate. Its ergonomics have been improved to avoid inadvertent interactions with the controls and to enable the user to concentrate on the most important movements. The clasp sliders have been redesigned for ease of use and to maintain the ability to clasp leaflets both independently and simultaneously, while the implant actuation knob provides full control of the implant configuration. The locking mechanism on the clasp sliders has been adjusted and the sliders are now on a 180° 'wrap-around' arc, allowing full access irrespective of rotation in the handle.*

Laser-cut hypotubes



- Tubes containing specific patterns of holes that are formed using a laser cutter
- Patterns can be tailored to customise the performance characteristics of the hypotubes, including strength and flexibility

Figure 6. The proprietary laser-cut hypotubes included in the catheter shafts.

*Design and performance data on file and marketing evaluation.

*Design and performance data on file and marketing evaluation.

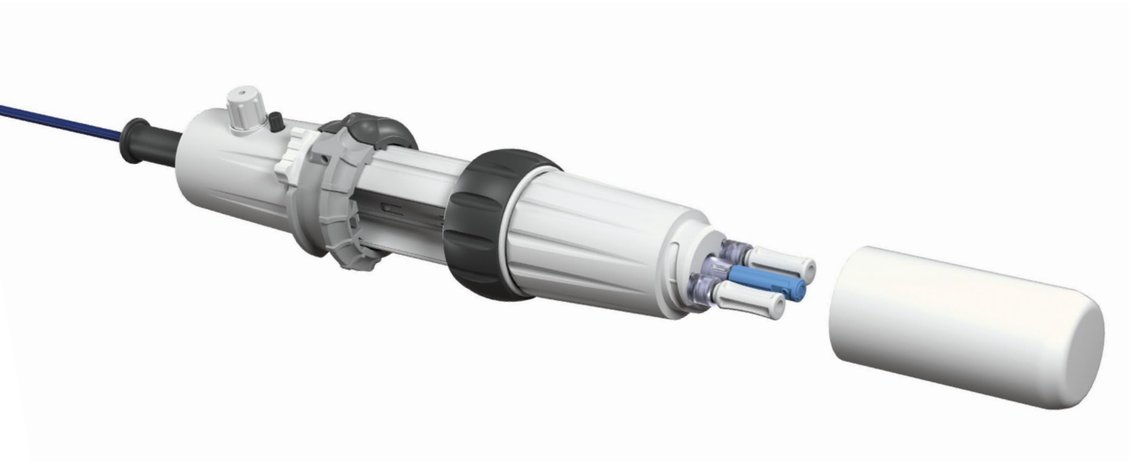


Figure 7. The implant release mechanism of the PASCAL Precision system.

'The implant release mechanism is now hidden beneath a cover on the implant catheter handle. This feature prevents the operator from inadvertently disengaging clasp control or releasing the implant prematurely.'
Seung Yi

An important feature for usability and mistake proofing is that the implant release mechanism is now hidden beneath a cover on the implant catheter handle and remains until the implant is ready to be deployed (Figure 7). This feature enables physicians to focus on the primary controls on the implant catheter handle controlling the paddles and clasps, and prevents them from inadvertently disengaging clasp control or releasing the implant prematurely.*

When developing any product, acute attention to detail is key. Alongside the major changes highlighted above, we subtly enhanced the design to further improve the operator's experience. For example, the steerable catheter handle now has a rotatable flush port, which is particularly convenient when monitoring atrial pressure as it eliminates the potential for kinking in the line. In addition, we improved aspiration on the guide sheath handle and optimised the overall delivery system for single-operator use.*

'The PASCAL Precision system unlocks the full potential of the PASCAL and PASCAL Ace implants.'
Seung Yi

Conclusion

The PASCAL Precision system has been designed to unlock the full potential of the PASCAL and PASCAL Ace implants by enabling them to be positioned for optimal patient benefit during transcatheter valve repair procedures. In partnership with practising physicians, we have completely redesigned many features of this second-generation delivery system to improve stability, responsiveness and ease of use of the system. These enhancements should enable operators to benefit to the full extent from the key features of the PASCAL repair system – including enhanced leaflet capture with atraumatic clasp and closure to help preserve leaflet integrity, versatile implant configuration to navigate even challenging anatomies,[10] and predictable implant release.*

*Design, performance and/or simulation data on file.

First impressions of the PASCAL Precision System in MR and TR

The PASCAL Precision system is a second-generation delivery system for the PASCAL platform of transcatheter valve repair technologies. The PASCAL Precision system offers enhanced stability and improved responsiveness compared with its predecessor, providing operators with a greater degree of confidence when performing mitral and tricuspid valve repair procedures. Here, early users give their insights into the benefits of the PASCAL Precision system in patients with MR and TR.

Dr med. Niklas Schofer
University Medical Center Hamburg-Eppendorf - UKE, Hamburg, Germany

Dr Niklas Schofer is Senior Physician and Head of Program for transcatheter mitral and tricuspid valve therapies at the University Heart and Vascular Center Hamburg. He is a Principal Investigator or Investigator in a number of ongoing clinical studies, including CLASP IID/IIF, TriCLASP, bRIGHT, TRiC-I-HF, HighLife, Target and AHEAD trial.

Professor Dr med. Tanja Rudolph
Universitätsklinikum der Ruhr-Universität Bochum, Bad Oeynhausen, Germany

Professor Tanja Rudolph has been the Director of Interventional Cardiology at Universitätsklinikum der Ruhr-Universität Bochum, Bad Oeynhausen since 2018. She is a Senior Physician within the Heart and Diabetes Centre Nordrhine-Westfalia, and has extensive experience using the PASCAL repair system.

Derived from author inputs*

PASCAL Precision System in patients with MR

Dr Niklas Schofer, from the University Medical Center Hamburg-Eppendorf, and Professor Tanja Rudolph, from Universitätsklinikum der Ruhr-Universität Bochum, have extensive experience using the PASCAL repair system. Since its release, both have used the PASCAL Precision system in eight patients with MR.

'Catheter responsiveness and stability have improved compared with the original delivery system.'
Dr Niklas Schofer

Their first impressions of the updated delivery system were positive. Dr Schofer noted how the PASCAL Precision system is a culmination of many incremental improvements over the original delivery system, resulting in an easy-to-use system with a good balance between stability and responsiveness.

Professor Rudolph was similarly impressed by the improved stability that the three stabilizers provided to the system and found torquability more reliable than with other TEER systems. Professor Rudolph also described how the tip of the catheter and the PASCAL implant move exactly as intended after only a small rotation of the handle.

'With just a small rotation of the handle, the tip of the catheter and the PASCAL implant move exactly as intended.'
Professor Tanja Rudolph

*Expert opinions, advice and all other information represent contributors' views and not necessarily those of Edwards Lifesciences.

'When you have a straightforward case, I think the system helps to reduce procedure times because every step is a little bit easier.'
Dr Niklas Schofer

Design features considered most important in MR

The use of laser-cut hypotubes and reduced friction between catheters were the key features contributing to the increased responsiveness and stability of the system, according to Dr Schofer. He was also impressed that the stability improvements had not impacted flexibility, and noted how they had led to an improvement in sustained clocking.

Professor Rudolph found the handle to be particularly intuitive and easy to use, and its design helped separate release of the implant from the rest of the procedure. In addition, she found implant positioning with the PASCAL Precision system was more precise than with the previous generation.

'Navigation is easy and the implant positioning is very precise; this is particularly advantageous in patients with difficult anatomy.'
Professor Tanja Rudolph

Learning curve with the PASCAL Precision System in MR

As experienced implanters, both Dr Schofer and Professor Rudolph found it very easy to adapt to the PASCAL Precision system, and all their MR cases so far have been successful. They also felt that less experienced operators would find the system easy to learn, as manoeuvring and releasing the implant is very straightforward.

'Catheter responsiveness is excellent – it is very precise for fine movements.'
Professor Tanja Rudolph

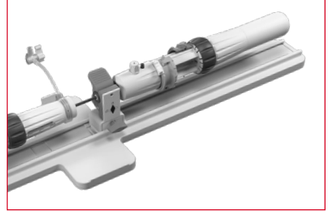
'Some new users may find it stiff compared with the original delivery system, but I would advise colleagues to just try it out.'
Professor Tanja Rudolph

Messages to colleagues considering the PASCAL Precision System for MR

Dr Schofer and Professor Rudolph agreed that the PASCAL Precision system was an improvement on the original delivery system and would recommend it to their colleagues, even if some first-time users may find the second-generation delivery system stiff compared with its predecessor. However, Dr Schofer noted that the updated system retains the original benefits of the first-generation system, including the option to elongate the implant to avoid entrapment and the ability to minimise tension on the leaflets during capture and deployment.

The PASCAL Precision system is now the main delivery system in both centres for MR and TR repair procedures using PASCAL implants, and, according to both users, clinical outcomes are just as good as with the first-generation delivery system. They also think it may help to reduce procedural times compared with the first-generation delivery system, especially for straightforward cases.

Accurate, intuitive control



'The PASCAL Precision system makes us even more comfortable when manoeuvring and releasing the implant.'
Dr Niklas Schofer

Case study 1: PASCAL Precision System for the treatment of MR

Dr. Schofer described the case of a 58-year-old female patient with severe primary mitral regurgitation (MR). The patient was initially admitted to the hospital for symptomatic ventricular tachycardia, most likely due to valvular cardiomyopathy. She had a complex medical history with cervical cancer that was treated with surgery and chemoradiotherapy 6 years prior to presentation. Unfortunately, radiotherapy was complicated by paraplegia and the patient has been dependent on a wheelchair since then. Echocardiography showed severe primary MR with a massive flail of the posterior mitral valve leaflet (see red arrows in Figure 8). Due to her comorbidities the patient was considered to be at high risk for surgical mitral valve repair, thus, the interdisciplinary Heart Team recommended mitral valve transcatheter edge-to-edge repair (M-TEER). Accordingly, the patient was treated using the PASCAL Precision system with implantation of two PASCAL Ace into the A2/P2 segment. The procedure was uneventful and resulted in only trace residual MR (Figure 8) in the absence of a relevant mitral valve stenosis (mean mitral valve gradient at discharge 1 mmHg). This case highlights the safety and efficacy of the PASCAL Precision system for the treatment of MR even in very complex primary mitral valve pathologies.

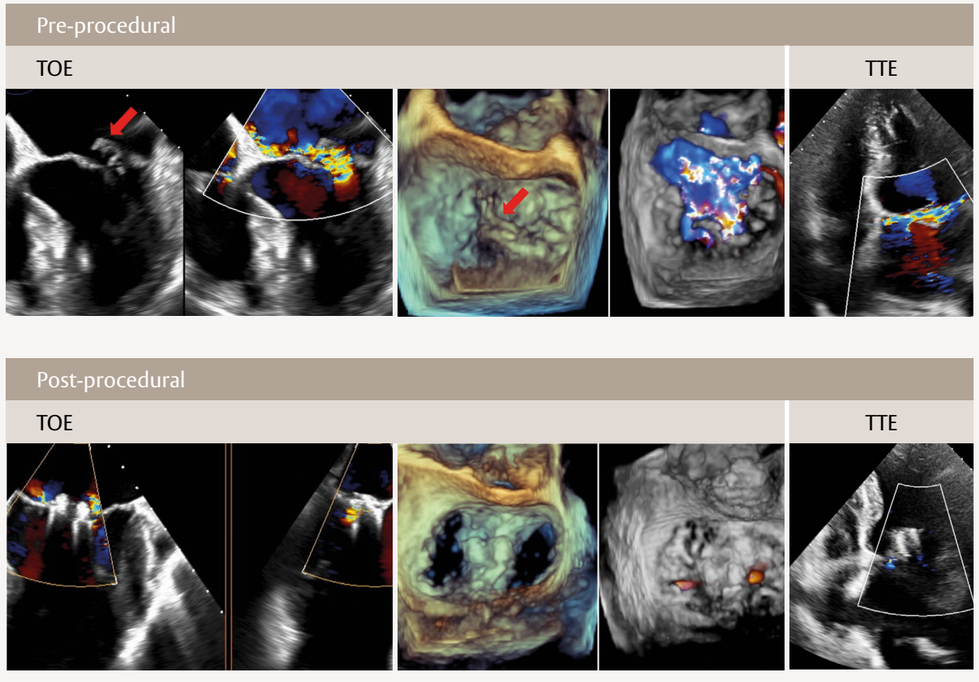


Figure 8. Pre- and post-procedural imaging of PASCAL repair system implantation for MR.

MR, mitral regurgitation; TOE, transoesophageal echocardiography; TTE, transthoracic echocardiography.
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Dr med. Mirjam Keßler
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Dr Mirjam Keßler is an interventional cardiologist and Senior Physician at the University Hospital, Ulm. She has 5 years' experience in edge-to-edge repair and has been using the PASCAL repair system since 2019. She is Principal Investigator in several ongoing trials, including CLASP IID/IIF and TriCLASP.

Dr med. Johannes Mörike
Department of Cardiology, Ulm University Medical Center, Ulm, Germany

Dr Johannes Mörike is a Senior Physician at the University Hospital, Ulm and interventional cardiologist, regularly performing transcatheter aortic, mitral and tricuspid valve interventions. Dr Mörike has performed many TEER procedures using the PASCAL repair system.

'The whole system is much more predictable than the first-generation system and you arrive in exactly the position you want when advancing through the valve.'
Dr Mirjam Keßler

PASCAL Precision System in patients with TR

Dr Mirjam Keßler and Dr Johannes Mörike from Ulm University Medical Center have conducted 65 tricuspid valve repair procedures using the PASCAL repair system in 2022, 18 of which were using the PASCAL Precision system.

Both Dr Keßler and Dr Mörike had a positive first impression of the PASCAL Precision system when they used it to treat patients with TR. Dr Keßler found the PASCAL Precision system more comfortable, accurate and intuitive to use than its predecessor. Dr Mörike had switched from a competitor device to test the PASCAL Precision system, and immediately felt confident with the procedure as he had total control over the system and its movements.

'My first impression of the system was 'this is how it should be.' You have an immediate feeling of total control over the system and its movements.'
Dr Johannes Mörike

Learning curve with the PASCAL Precision System in TR

Dr Keßler and Dr Mörike both found the PASCAL Precision system simple to learn. Dr Keßler thought users would experience no difficulties using the second-generation system because of its improved ease of use compared with the first-generation system, while Dr Mörike felt his procedural outcomes were already improved after only a few cases using the system. In their opinion, once you have become familiar with it, the PASCAL Precision system shortens procedural times.

'Since the PASCAL Precision system is so responsive, there are hardly any situations where you have to look at the handle or the steerable catheter.'
Dr Mirjam Keßler

Design features considered most important in TR

Dr Keßler highlighted the advanced catheter design as the main improvement of the PASCAL Precision system. She noted how torque transfer and stability are especially crucial in TR when advancing through the complex anatomy of the tricuspid valve and found that the PASCAL Precision system allows the user to deliver the implant precisely where intended. In her opinion, this makes the procedure not only faster and more accurate, but also safer as there is less interaction with the chords.

Dr Keßler also commented on how the updated handle design enables easier leaflet capture. Since the PASCAL Precision system is so responsive, the user rarely needs to look at the handle or the steerable catheter during the procedure, allowing more time to focus on the echocardiographic imaging.

In addition, she considers the safety attributes, such as the ability to fully elongate the device, make retraction easier and the procedure safer.

Dr Mörike agreed that stability regarding rotation and clocking is a key feature of the system as it reduces the need for corrections during the procedure and enables the primary operator to perform many of the steps without assistance, allowing for faster implantation. He also complimented the catheter responsiveness, noting the one-to-one translation of the user's movements to movement of the implant

'We are currently using the PASCAL Precision system for all our TR cases.'
Dr Mirjam Keßler

Messages to colleagues considering the PASCAL Precision System for TR

Dr Keßler and Dr Mörike were enthusiastic advocates of the PASCAL Precision system for tricuspid valve repair. Dr Keßler would recommend the system to colleagues based on the catheter responsiveness and stability, and noted how her first procedures with the PASCAL Precision system in TR were as fast as with the first-generation delivery system. Dr Mörike would encourage colleagues to make use of the practice models provided by Edwards Lifesciences before using the system in patients. He would advise them to trust the system and allow time for their manoeuvres to translate to the tip.

'The PASCAL Precision allows us to repair valves that we would not have attempted to repair before.'
Dr Johannes Mörike

'The frequent need for counter-movements during device positioning was a challenge that has been eliminated with the PASCAL Precision system.'
Dr Mirjam Keßler

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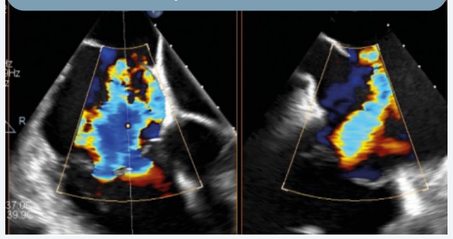
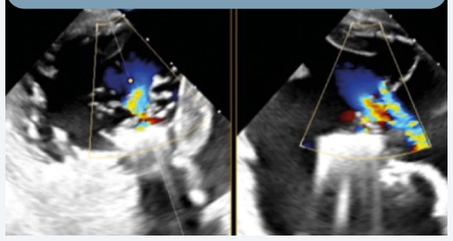
Case study 2

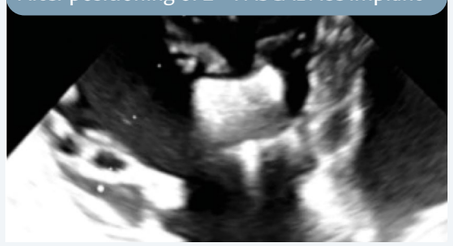
Before device implantation



After positioning of 1st PASCAL Ace implant



After positioning of 2nd PASCAL Ace implant

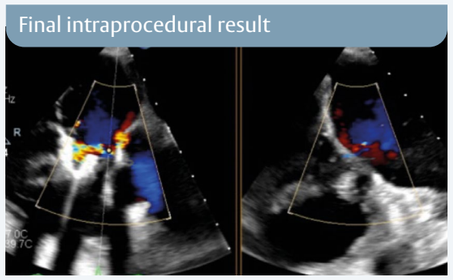


Dr Keßler and Dr Mörike described the case of an 87-year-old female patient with progressive symptoms of right HF (extensive peripheral oedema and dyspnoea). Her underlying grade IV TR was caused by atrial and consecutive annular dilatation (4.0 x 4.5 cm), with large coaptation gaps (8 mm in the centre of the valve) and a restrictive septal leaflet. The interdisciplinary Heart Team recommended transcatheter edge-to-edge repair of the tricuspid valve (T-TEER). She was treated with the PASCAL repair system using the PASCAL Precision system for implant delivery.

Using the clover technique, (Figure 9) two PASCAL Ace implants were implanted. The first implant was inserted in an anterior-septal position, and leaflets were captured simultaneously; the second implant was positioned centrally into a posterior (P1)-position, and leaflets were again captured simultaneously, but the septal leaflet was re-captured to achieve better leaflet insertion. Following the procedure, the patient's TR was reduced from grade IV to grade I.

At Day 35 after the procedure, the reduction in TR severity was sustained (grade I; Figure 10) and the patient reported reduced peripheral oedema and improved functional capacity. This case demonstrates that T-TEER using the PASCAL repair system and the PASCAL Precision system for implant delivery is a feasible option for TR, even in elderly patients with significant comorbidities and complex anatomies, such as large coaptation gaps.

Final intraprocedural result



Short-term result

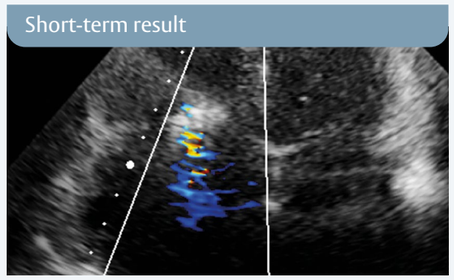


Figure 9. Transoesophageal echocardiograms before, during and after device implantation using the PASCAL Precision system.

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Figure 10. Transthoracic echocardiogram at Day 35 follow-up (four-chamber view).

Conclusion

The PASCAL repair system offers interventional cardiologists an effective tool for the treatment of MR and TR. In patients with degenerative MR, the most recent data from the CLASP IID RCT show a sustained reduction in MR and favourable ventricular remodelling after treatment with the PASCAL repair system,[1,7] and similar outcomes were even achieved in patients ineligible for treatment with the MitraClip system based on data from the CLASP IID registry.[3,6] With the introduction of the PASCAL Precision system, it is now easier than ever to deliver PASCAL implants to the mitral and tricuspid valves accurately and safely, allowing users to tackle complex cases with confidence.

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We can be reached at TMTT-Today@edwards.com to answer your questions about the portfolio of therapies for transcatheter mitral and tricuspid valve therapies.

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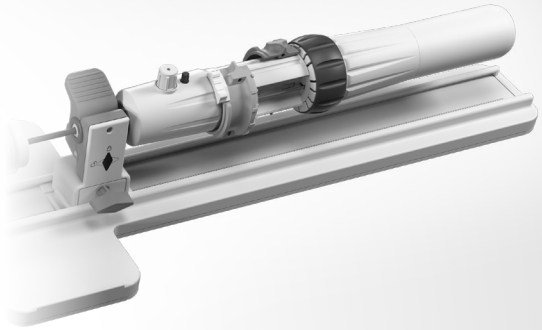
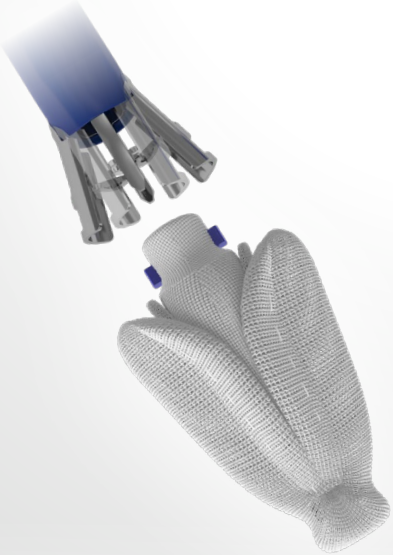
PASCAL Precision System

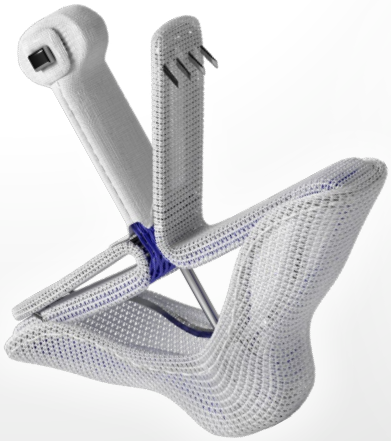
For mitral and tricuspid valve repair



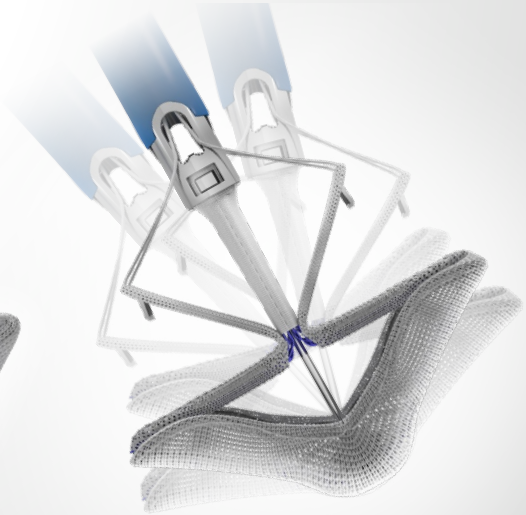
Accurate,
intuitive control



Predictable
release



Atraumatic
clasp and closure



Versatile implant
configuration

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