

## Getting up to speed with the PASCAL Platform

Make the most of the PASCAL platform to deliver  
optimal outcomes for your MR and TR patients



### Short learning curve

- PASCAL platform training
- Insights from the Edwards TMTT Clinical Specialist Team
- Getting up to speed with the PASCAL platform

### Performance

- Latest evidence in TR patients

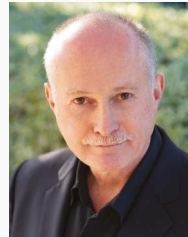
## Dear Reader,

The Transcatheter Mitral and Tricuspid Therapies (TMTT) team at Edwards Lifesciences is developing innovative solutions aimed at increasing your opportunities to treat patients with MR or TR. Preparing you for your early PASCAL platform experience is at the core of this issue of *TMTT Today*. We share valuable insights on how to set a solid foundation during the early stages of PASCAL platform adoption so you can quickly gain confidence in your procedural flow.

We also provide you with more data about the PASCAL Ace implant system, a recent addition to the PASCAL platform. With its narrower profile, the PASCAL Ace implant shows great promise for optimising the treatment of MR and TR. Here at Edwards Lifesciences, we strongly believe in the TMTT portfolio approach, inspired by the growing volume of data with the PASCAL platform and by insights shared by our community. We see the PASCAL platform as a game changer in the treatment of patients with MR or TR, and we encourage you to expand your treatment horizons with Edwards Lifesciences by your side.



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Enjoy reading!

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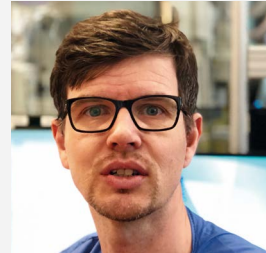
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## ► PASCAL Platform training

# Our PASCAL Platform training experience

### **Dr Andreas Rück, Karolinska Institute, Stockholm, Sweden**

Dr Andreas Rück is an interventional cardiologist and Head of the Mitral and Tricuspid Intervention programme at the Karolinska University Hospital in Stockholm. Dr Rück is also Chairman of the Swedish Percutaneous Valve Registry.



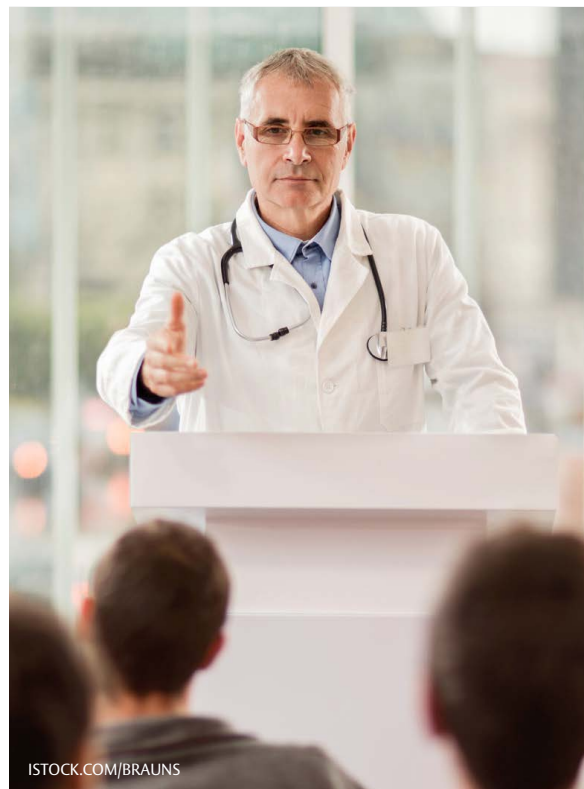
### **Dr Chris Meduri, Karolinska Institute, Stockholm, Sweden**

Dr Chris Meduri is a structural interventional cardiologist at the Karolinska University Hospital in Stockholm. Dr Meduri has served as the National Primary Investigator of several valve trials and on numerous steering committees. He has performed a number of first-in-US and first-in-world procedures, including the first-in-world transcatheter tricuspid repair in a patient with a pacemaker.



**Dr Rück and Dr Meduri were trained to use the PASCAL platform by the Edwards TMTT training team. Here, they describe their training experience and offer helpful guidance for using the PASCAL platform to treat MR and TR.**

We were trained on the PASCAL platform in two sessions, each 4–5 hours long, at a centre close to our home institute, the Karolinska Institute, in Stockholm. The first session focused on the use of the PASCAL platform to treat MR. After we had performed 3–4 mitral procedures (enough to feel comfortable with the device), we attended a second session to learn how to treat TR with the PASCAL platform. The training took place in a wet lab so we could practise imaging techniques, and then we simulated implanting the PASCAL and PASCAL Ace devices in the tricuspid valve.



For operators with extensive MitraClip experience, learning to use the PASCAL platform is about making adjustments to the leaflet-clasping technique. We practised manoeuvring the PASCAL implant, clasping leaflets, and maintaining effective positioning of the implant. A key element for successful leaflet-clasping is learning how to angle the implant and lay the leaflets down before clasping. The educational team was very informative here, demonstrating the concept of laying down leaflets for passive clasping, as opposed to actively gripping leaflets with MitraClip.

In our experience, only 3–4 cases are needed before we felt comfortable using the PASCAL platform, and following 10–20 cases we had achieved a solid understanding. Clinical outcomes with the PASCAL platform are quite remarkable, especially on the tricuspid side. The PASCAL implant is a forgiving device; it is unlikely to get stuck in chords and is gentle on the leaflets. The safety profile supports its use in complex cases with commissural defects.

The Edwards training was a good experience; the trainers did an outstanding job offering additional tips and recommendations in order to support us and achieve a successful procedure, with the right amount of time for both theoretical and 'hands-on' learning.

## Reason #5

## Atraumatic retention elements

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

Designed to enable implant repositioning during procedures of mitral or tricuspid valve repair.

Its retention elements are orientated horizontally, in line with the collagen fiber orientation<sup>1,2</sup>, which allows recapturing the leaflet multiple times without clinically significant damage.

<sup>1</sup> Noack T, et al. Ann Cardiothorac Surg 2013; 2: 787-795.

<sup>2</sup> Rausch MK et al. Biomech Model Mechanobiol. 2013; 12: 1053–1071.



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## Insights from the Edwards TMTT Clinical Specialist Team

The Edwards TMTT training team helps heart teams get a hands-on experience with the unique features of the PASCAL platform and helps them understand how this technology differs from other edge-to-edge repair technologies. The European training team includes clinical specialists Addis Abebaw, Thorsten Baeumer and Jarmo Rahkolin, who answer questions below on the training process and what to expect from your early experiences with the PASCAL platform.

**Q:** What is the best way to start with the PASCAL therapy platform?

*I would strongly recommend starting with PASCAL Ace implant for the first cases. Our growing experience with the device shows that PASCAL Ace implant helps with the early learning curve thanks to its manoeuvrability. Its thinner profile, while keeping the benefit of the central spacer, also facilitates imaging while navigating more easily in the dense chord anatomy*

**Q:** Can you describe the overall training process for new users of the PASCAL platform?

*As we welcome heart teams to the PASCAL platform, Edwards aims to create an educational partnership tailored to individual needs and ensuring optimal patient outcomes from the first procedure. A menu of training opportunities is available for all, but the cornerstone of our training is the core programme*

*The event lasts 4–6 hours, and can be experienced locally through our mobile training centres (TIMMI & LISA), at a suitable local venue, or by travelling to one of our satellite training centres*

*Training will include device and procedural training, preparation for your first case, and an immersive full Heart Team experience on our beating heart simulator*

*We also offer on-site training with demo devices, reviewing recorded cases, and discussing patient cases while highlighting important procedural steps*

**Q:** Can you provide any tips and tricks for using the PASCAL platform?

- ✓ *Be open to a new experience with the PASCAL platform: 'feel free' to steer to wherever you want to be in the valve*
- ✓ *Tailor your imaging views to the different steps: imaging is the most challenging part of the procedure, and the echocardiographer would agree that successful treatment comes with being able to see the procedure*
- ✓ *Plan in advance to avoid surprises once you are in the valve: use imaging to fully assess the valve before starting the procedure*

**Q:** Can you describe any differences in training required to use the PASCAL platform in MR and TR?

It is helpful to have some experience using the PASCAL repair system in the mitral valve before training in the tricuspid valve as new techniques are easier to master in the less complicated mitral valve. For users with prior MitraClip experience, the mitral setting is a more forgiving environment when learning to use the highly manoeuvrable PASCAL delivery system

The mitral side of the heart is relatively easy to image – the probe is closer and there is no shadowing. By comparison, the tricuspid side is more challenging, especially for new users with less experience imaging the tricuspid valve. The Edwards training programme helps new users to optimise views of the tricuspid valve, showing them the angles they need to use and the correct probe rotations and movement

**Q:** How important is prior experience of edge-to-edge repair for new customers learning to use the PASCAL platform?

While it is helpful to have experience in structural heart therapies and echo guidance, prior experience in leaflet approximation is not essential. It is useful to have a trained eye for the echo and for the transseptal puncture

**Q:** Do HCPs receive imaging training to support their use of the PASCAL platform?

Yes – and this differentiates Edwards Lifesciences from other providers. We have a dedicated team of experts who provide imaging training through the full patient journey, from image acquisition to screening, procedure and follow-up. Imaging and clinical specialists are present throughout the device training for the first mitral and tricuspid cases to support site imaging independence

Customers are trained to identify structures within the device, such as the spacer, the paddles and the clasps, in order to overcome shadowing and to guide the independent grasping of leaflets

**Q:** What is the typical profile of new users?

Most new users are interventional cardiologists who perform percutaneous coronary intervention or transcatheter aortic valve implantation. Some have experience treating MR and may be looking for TR-repair training, whereas others have no experience in edge-to-edge repair technologies. Therefore, we have a tailored, individual approach based on prior experience

**Q:** What do you consider to be the most important learnings for new customers?

Small differences in design can have a big impact on patient outcomes. We want customers to understand the unique features of the PASCAL platform and how these are important to their individual patients. The PASCAL platform is more flexible and has a greater reach than some other devices, so taking the time to understand how to optimise the PASCAL platform will lead to the outcomes you want to see for your patients

Customers also gain an understanding and appreciation of how important correct imaging is and how to achieve successful outcomes in a busy cath lab

**Q:** What post-training support is provided?

Our high touch model means that we support 100% of the cases so you get dedicated support all the time



## Ask your questions...

We can be reached at [TMTT\\_HCPtraining@edwards.com](mailto:TMTT_HCPtraining@edwards.com) to answer your questions about the PASCAL platform.

## ► Transcatheter tricuspid leaflet repair

# Latest evidence on tricuspid repair using the PASCAL Platform

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

Professor Dr Jörg Hausleiter is Professor of Medicine and the Deputy Clinic Director at the Ludwig-Maximilians Universität (LMU) in Munich, Germany. As an interventional cardiologist expert in the field of valvular and coronary heart diseases, Professor Hausleiter is focused on bringing new percutaneous treatments to patients with coronary and valvular diseases.



### **Dr med. Mirjam Wild, LMU University Hospital, Munich, Germany**

Dr Mirjam Wild is a Research Fellow in the Valvular Heart Team at LMU University Hospital in Munich, Germany and recently completed a fellowship in the Structural Heart Team at Bern University Hospital, Switzerland. Dr Wild's research interests include new devices and treatment strategies for percutaneous mitral and tricuspid valve interventions, and cardiovascular imaging.



The tricuspid valve presents a challenging environment for leaflet repair. Its annulus is larger than that of the mitral valve and it has many fragile chordae and thin, delicate, variable leaflets.<sup>1</sup> In a presentation at PCR Valves 2020, Professor Hausleiter recounted his early experiences with the PASCAL platform and highlighted how the unique features of the PASCAL repair system and the PASCAL Ace implant system facilitate their use in TTVr.

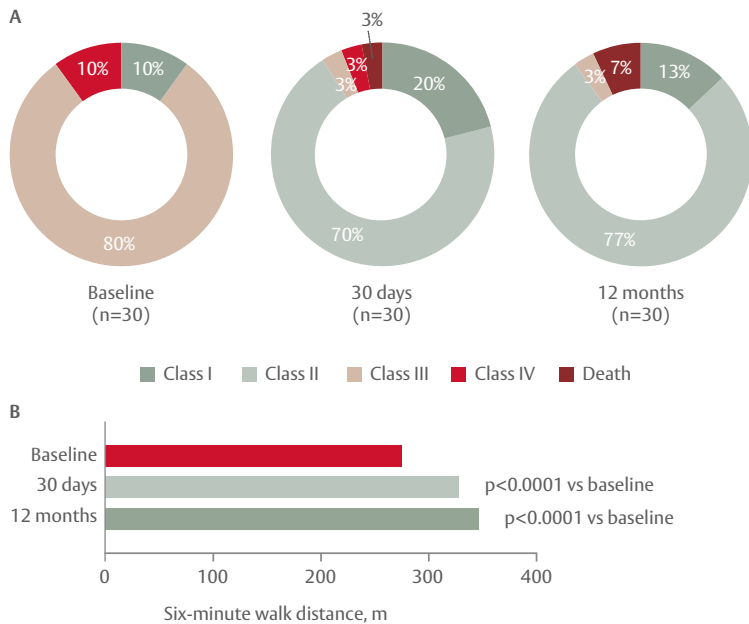
### **Compassionate use data**

Published data on the PASCAL repair system from a compassionate use experience demonstrated a sustained early reduction of TR in a population of patients with severe TR and large coaptation gaps, with 85% of patients achieving TR grade  $\leq 2+$  at 30 days following the procedure.<sup>2</sup> A 6-month follow-up of 28 patients from this experience confirmed sustained residual TR grade  $\leq 2+$  in 89% of patients, with 89% of patients in NYHA class I or II.<sup>3</sup> One-year outcomes showed sustained clinical improvement following TTVr; most patients were in NYHA class I or II at 1 year, and there was a significant improvement in the 6-minute walk distance between baseline and 1 year (**Figure 1**).<sup>4,5</sup>

*'The PASCAL Ace is well on its way to joining the PASCAL repair system as an inherent part of the toolbox for tricuspid valve repair'*  
Professor Jörg Hausleiter



**Figure 1. Functional outcomes following TTVr using the PASCAL repair system.**  
 (A) NYHA class; (B) 6-minute walk distance.<sup>4,5</sup> Adapted from Kitamura M *et al.* 2021



*'The PASCAL repair system gives you, the operator, a high range of possible movement due to its steering flexibility'*  
 Professor Jörg Hausleiter

Longer-term follow-up of five patients treated in Munich as part of the compassionate use study has demonstrated a durable reduction in TR at 6–24 months following implantation of the PASCAL device (Figure 2).<sup>4</sup>

**Figure 2. Echocardiography showing TR before implantation, at discharge and up to 2 years in five patients who received the PASCAL repair system implant as part of the compassionate use study.<sup>4</sup>**





### Real-world data from the LMU

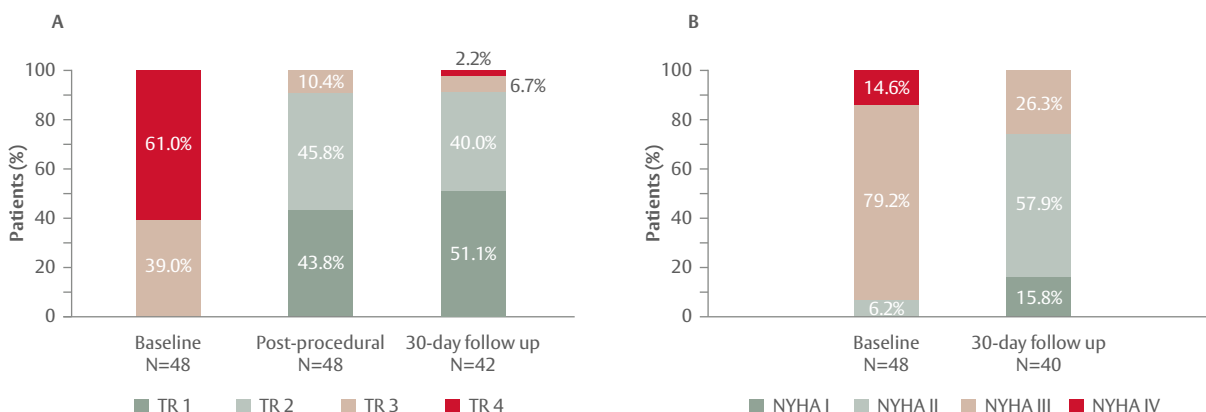
Data are being collected from experiences using the PASCAL repair system to treat patients with severe TR. Real-world data from 48 consecutive patients at the LMU, presented at PCR Valves 2020, show that all patients had TR  $\geq 3+$  (29 of these patients had TR  $\geq 4+$ ) at baseline, most (81.2%) presented with functional TR, and the mean coaptation gap size was  $0.7 \pm 0.3$  cm. On average,  $1.8 \pm 0.7$  devices were implanted per patient, predominantly in the anteroseptal line of coaptation (22.9% anteroseptal alone; 64.6% anteroseptal and posteroseptal).<sup>4</sup> The independent grasping feature of the PASCAL repair system was used in almost 90% of cases.<sup>4</sup>

Short-term follow-up of the LMU experience reinforces the outcomes from the compassionate use study, with over 90% of patients achieving

*'Over 90% of patients achieved TR grade  $\leq 2+$  and over 70% of patients were in NYHA class I or II at 30-day follow-up'*  
Professor Jörg Hausleiter

TR  $\leq 2+$  and over 70% of patients in NYHA class I or II at 30 days (**Figure 3**).<sup>4</sup> In addition, the tricuspid annular diameter was reduced by 5 mm at 30 days, and there was a significant reduction in the diameter of the inferior vena cava, suggesting less backflow and hepatic congestion.<sup>4</sup> There was also a modest increase in inflow gradient, from 1.2 mmHg to 2.3 mmHg, between baseline and 30 days (**Table 1**).<sup>4</sup>

**Figure 3. (A) TR severity and (B) functional outcomes at 30 days following deployment of the PASCAL repair system at the LMU.<sup>4</sup> ©2020 Hausleiter. Reproduced with permission (data are preliminary and ongoing).**



## Reason #6

# Implant elongation



## One more reason to adopt the PASCAL Repair System

Be even more confident during your procedure thanks to the possibility of elongating in case of entanglement into dense subvalvular chordae.<sup>1</sup>

<sup>1</sup> PASCAL Ace Composant Design Enhancement, Edwards Lifesciences



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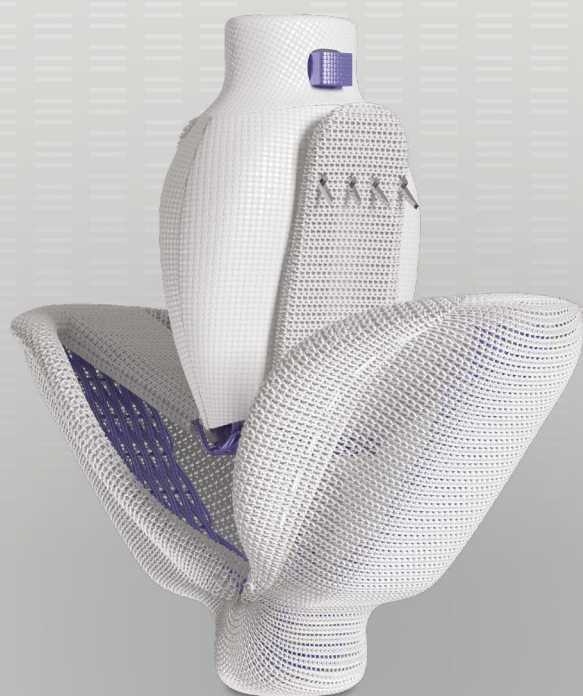
**Table 1. Echocardiography outcomes at 30-day follow-up with the PASCAL repair system at the LMU.<sup>4</sup>**

	Baseline	30 days	p value
Tricuspid annulus diameter (mm)	45.5 ± 7.5	40.1 ± 6.4	<0.01
Inferior vena cava diameter (mm)	28.0 ± 8.0	23.9 ± 7.9	<0.01
Inflow gradient (mmHg)	1.2 ± 0.4	2.3 ± 1.3	<0.01

### Conclusion

Based on the compassionate use data and from real-world data at the LMU, the PASCAL platform is a valuable tool for the treatment of TR. It achieves sustained TR reduction and clinical improvements post-procedure, and it has an excellent safety profile. Outcomes are optimised due to the unique features of the PASCAL repair system and the PASCAL Ace implant. These include excellent manoeuvrability within the tricuspid valve, safe and independent leaflet-grasping, a flexible nitinol construction, and the ability to bridge large coaptation gaps using a central spacer. A multicentre German experience study focusing on the PASCAL repair system and the PASCAL Ace implant to treat TR is currently underway.

## Getting the most out of the PASCAL Platform: In conversation with Professor Lurz



### **Professor Dr med. Philipp Lurz, Herzzentrum Leipzig, Universitätsklinik für Kardiologie, Leipzig, Germany**

Professor Philipp Lurz, an interventional cardiologist, is the Deputy Head of Cardiology at Heart Center Leipzig of University Leipzig and leads the programme for Grown-up Congenital Heart Disease and for mitral/tricuspid interventions. He is PI of the MiCLASP Registry and an investigator in the CLASP IID/IIF trial as well as trials for multiple other therapies.

*'The PASCAL platform has a very high level of safety and its design enables an extremely low risk of damage to the leaflets'*

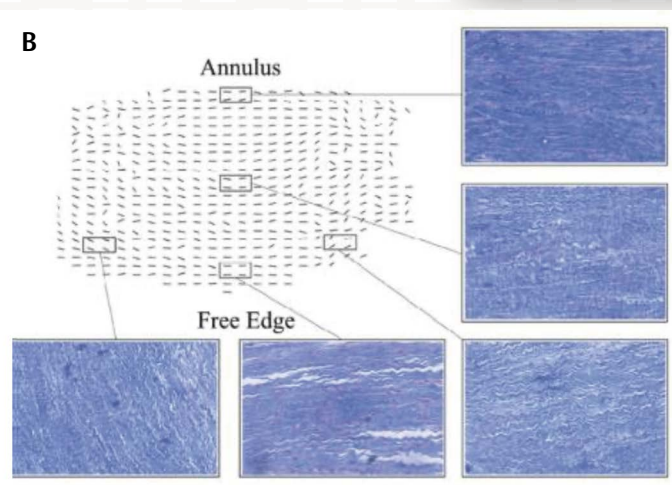
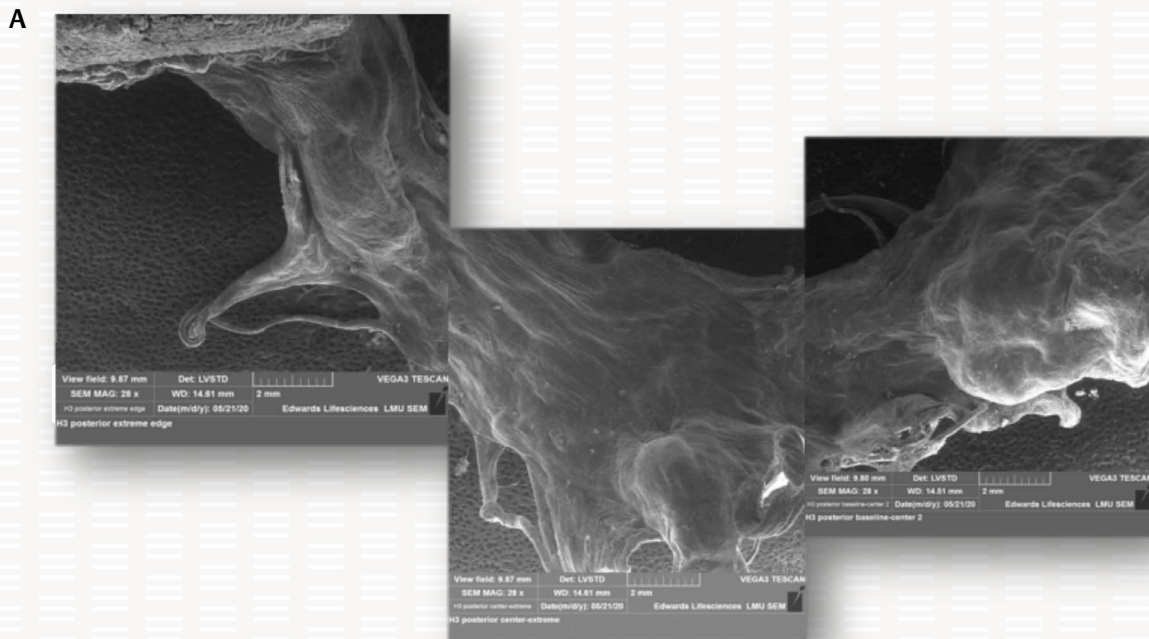
Professor Phillip Lurz

### **Having performed well over 100 PASCAL implants, Professor Lurz speaks from experience when he offers advice to new users on adopting the PASCAL platform to treat MR and TR.**

The PASCAL platform offers two key safety features:

1. a passive closing mechanism to capture leaflets without injuring them, and
2. a flexible design that allows the user to disentangle the implant from the subvalvular apparatus without damaging the chordae

**Figure 4. Structure of the mitral valve leaflets (A) following multiple leaflet captures using the PASCAL implant system, as assessed by scanning electron microscopy, and (B) histological sections showing fibre orientation of the leaflets.<sup>8,9</sup>**



*'The leaflets are clasped towards the central area where the leaflet is more stable – this is probably why we see minimal leaflet injury'*  
 Professor Phillip Lurz

Although not essential, prior transcatheter procedural experience capturing leaflets and imaging heart valves is useful when learning to use the PASCAL platform. Adjustments to technique may be required in order to efficiently steer the flexible, three-component PASCAL implant system within the dynamic environment of the mitral and tricuspid valves.

Several features of the PASCAL platform optimise leaflet capture while minimising leaflet damage. Retraction elements\* in the PASCAL implants are

positioned in a horizontal orientation at the distal end of the paddles. As a result, clasping occurs towards the central part of the leaflet and away from the line of coaptation. Histological analysis shows that the leaflet centre is more stable than the free edge due to the composition and quality of fibrous tissue.<sup>6,7</sup> This anatomical difference helps explain how the capture mechanism reduces the potential for leaflet damage (Figure 4).<sup>8,9</sup>

\* Commonly referred to as 'retention elements' in training materials



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*'If you have suboptimal results, you should check to see if both leaflets are captured nicely. You can clasp multiple times with minimal risk of damage to the leaflets due to the specific features of the PASCAL implants'*

Professor Phillip Lurz

In the PASCAL platform, the combination of broad paddles with a central spacer is designed to provide an effective seal between the implant and leaflets in order to reduce the likelihood of leaks.<sup>10</sup> The PASCAL implants also have a flexible nitinol construction with biomechanical properties that allow them to open and close dynamically with diastole and systole, further reducing stress on leaflets. Finally, the PASCAL platform has a flexible connection between the implants and the delivery system, enabling outcomes to be consistent or even improved after deploying the implants.

The design of the PASCAL platform supports both simultaneous and individual leaflet capture. Use of these different approaches offers user-friendly choice of techniques.

For patients with MR, my preferred approach is to perform an initial simultaneous leaflet capture, as this can avoid distortion of the anatomy sometimes seen with single-leaflet capture. Once the leaflets have been simultaneously captured, a single-leaflet optimisation approach can then be carried out in which one or the other clasp is reopened, to obtain a better grasping of the leaflet.

For patients with TR, simultaneous grasping may not be possible if large coaptation gaps exist. In these cases, leaflets may need to be captured sequentially, one at a time.

An advantage of the PASCAL platform is that leaflet capture can be repeated without inflicting clinically significant damage to the leaflets,<sup>8</sup> providing an opportunity to make adjustments to overcome suboptimal outcomes during the procedure.

**Mastering a range of leaflet repair devices will foster a high-quality mitral and tricuspid valve programme**, similar to that of transcatheter aortic valve replacement (TAVR) in which balloon- and self-expandable valves offer different options for patients. As new data become available for various edge-to-edge technologies, we will be able to determine which is most appropriate for each patient, based on specific anatomy and individual circumstances. In our experience, the PASCAL platform helps us achieve low rates of residual MR and TR and a high level of safety with low risk of leaflet damage.

## Conclusion

The PASCAL platform offers physicians the opportunity to safely achieve low rates of residual MR and TR for their patients. For new users, Edwards Lifesciences provides a comprehensive training experience, encompassing use of the PASCAL repair system with the PASCAL Ace implant in both TMVr and TTVr. The training is taught by imaging and clinical specialists to optimise learning, and provides a hands-on experience with the PASCAL platform using a state-of-the-art simulator. With this training, new users are able to master the procedure for the PASCAL platform in a short time, allowing them to bring the many benefits of the technology to their patients with MR and TR.

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# Reason #7

## Reduced Leaflet Stress

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

Designed to minimize mitral or tricuspid leaflet stress:

- Its inner frame is made of a unique material: Nitinol. Its elastic properties enable passive closure and acute implant flexing.<sup>1</sup>
- Its Central Spacer helps to bridge the coaptation gap without over-pulling the leaflets.<sup>2</sup>
- Its paddles have round-contoured shape.<sup>2</sup>

<sup>1</sup> Masiero et al. Mini-invasive Surg 2020;4:71

<sup>2</sup> Lim et al. JACC Cardiovasc Interv 2019;12(14):1369-1378

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Speaking about reduced leaflet stress...

The PASCAL transcatheter tricuspid valve repair system shows clinically and statistically significant improvement at 30 days. Scan the QR code and download the CLASP TR EFS summary.

Kodali, S., et al. (2021). "Feasibility Study of the Transcatheter Valve Repair System for Severe Tricuspid Regurgitation." JACC 77(4): 345-356.