The PASCAL repair system - a differentiated technology to treat MR patients

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Potential conflicts of interest

Speaker's name: Susheel Kodali

I have the following potential conflicts of interest to report:

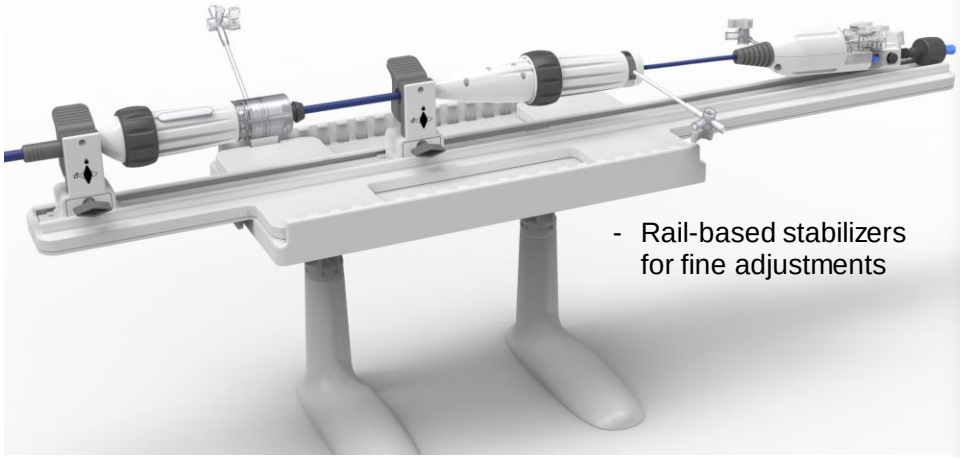
CONSULTING FEES/HONORARIA: Meril Lifesciences, Admedus, Phillips, Edwards Lifesciences

RESEARCH/RESEARCH GRANTS: Edwards Lifesciences, Dura Biotech

Edwards PASCAL Transcatheter Valve Repair System

One Delivery System for MR and TR

- Independent coaxial catheters allow maneuvering within three planes



- Rail-based stabilizers for fine adjustments

Atraumatic Clasps

Independent reclasp capability with single row of retention elements

PASCAL Ace

Versatile Implant

Wide range of mobility, including full elongation to adapt to the specific anatomy

Nitinol Construction

Conform to native anatomy and flex during the cardiac cycle

PASCAL

For Professional use. See instructions for use. CE Marked medical device.

PASCAL and PASCAL Ace Implants

Two distinct implants designed with the same functionalities

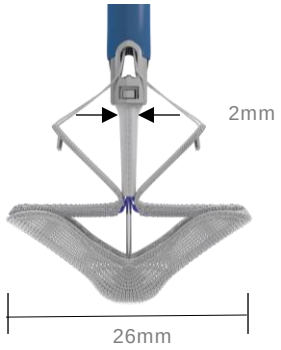
PASCAL Ace

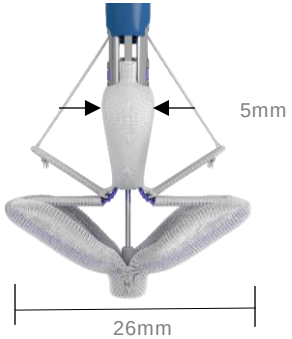
A narrow profile with a smaller central spacer

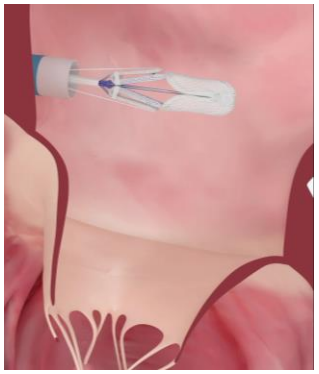
PASCAL

Wide contoured paddles with a larger central spacer

Same wingspan







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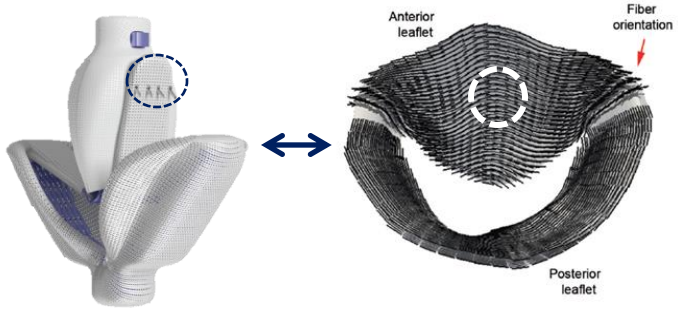
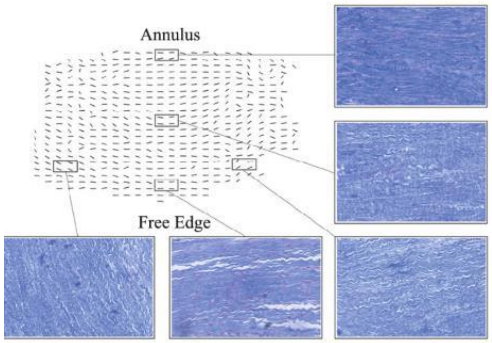
NOTE: All dimensions are in millimeters (mm).

Atraumatic clasps with a single row of retention elements

Goal: To ensure firm leaflet capture while preserving leaflet integrity*



Horizontal orientation of retention elements in line with collagen fiber orientation and density in mitral leaflets[1,2]



- Free edge of the mitral leaflet is primarily a soft spongiosa structure[3,4]
- PASCAL implants targets mid-point of leaflet to engage retention elements

[1]Noack T, et al. Ann Cardiothorac Surg. 2013; 2:787–795; [2]Rausch M, et al. Biomech Model Mechanbiology 2013; 12: 1053-1071. [3]Stephens EH, et al. Circulation 2008; 118: S243-S249 ; [4]Kunzelman K, et al. The Journal of Heart Valve Disease 1993; 2: 236-244, *Simulation Data on file

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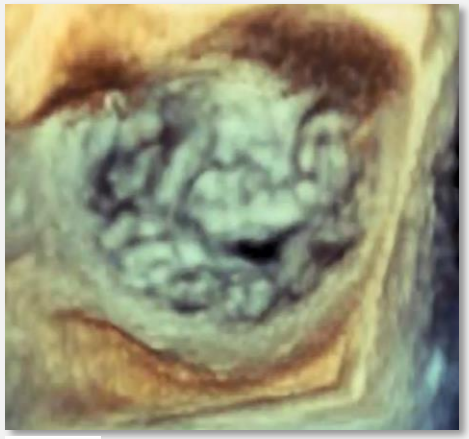
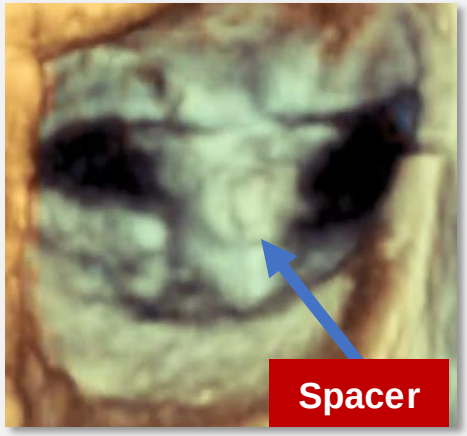
PASCAL spacer technology

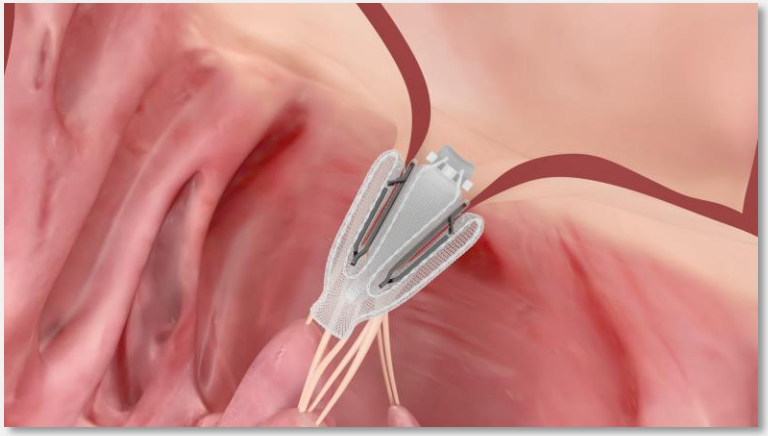
Goal: To fill the regurgitant orifice and block backflow



Pre-implant



Post-implant



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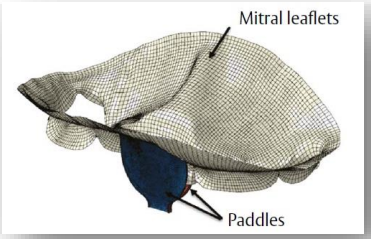
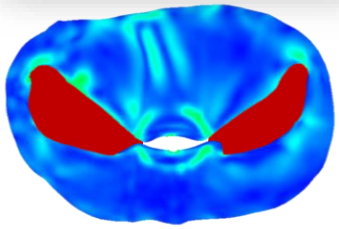
PASCAL repair system spacer technology

Goal: To reduce leaflet stress and increase open orifice area for lower gradients

Implant Without Spacer



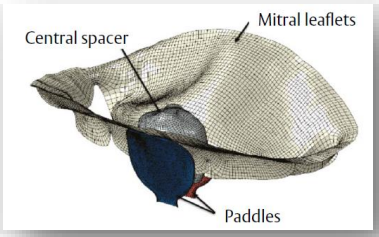


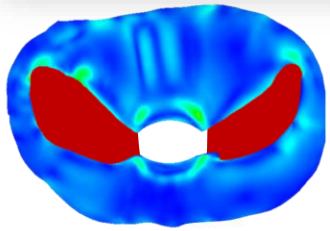
Open orifice area = **156.3mm²** *

Finite Element Analysis (FEA) in a mitral valve simulates leaflet response to an implant

- **Lower** stress concentration
- **Higher** stress concentration
- **Diastolic open orifice area**

PASCAL Implant





Open orifice area = **188.1mm²** *

PASCAL implant demonstrated*

Reduced stress on leaflets*

20% increase in open orifice area during diastole*

*Simulation Data on file

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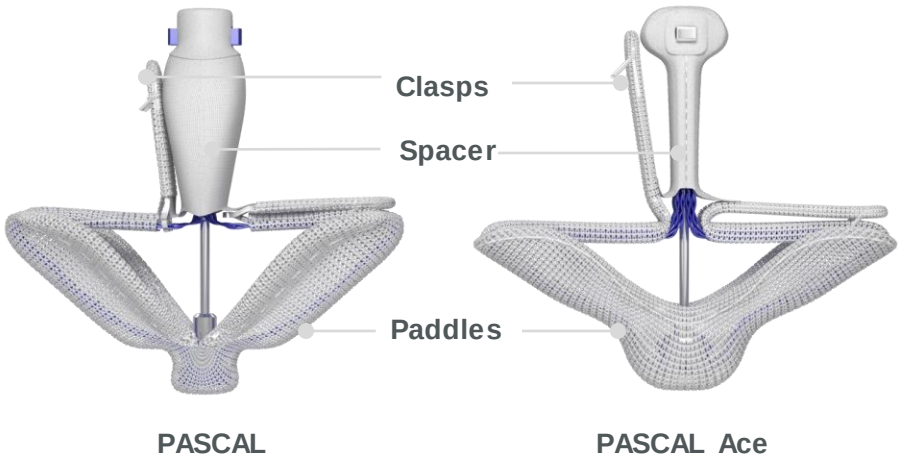
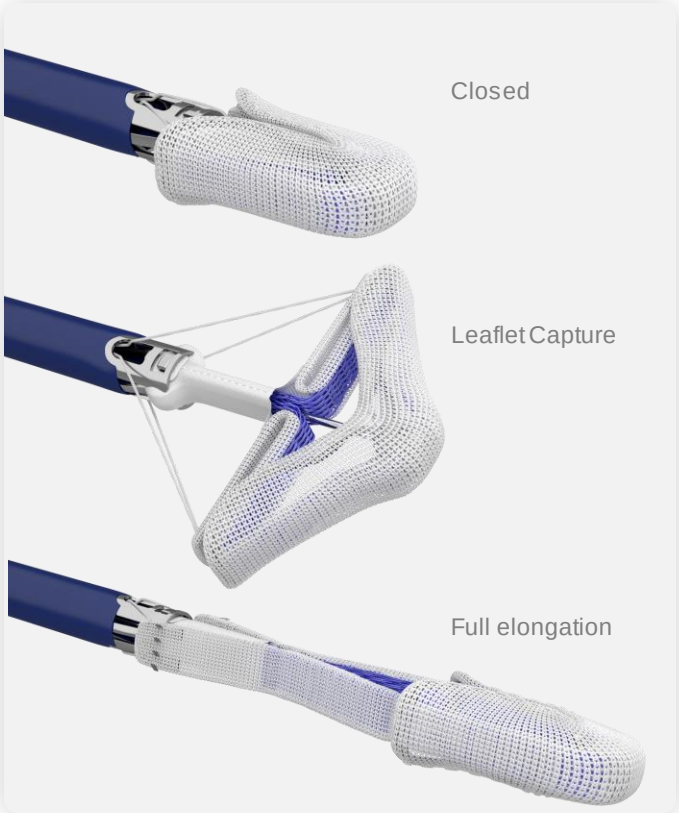
Versatile Implant Configuration

Goal: To navigate even challenging anatomies[1*]





[1].Fam N, et al. Compassionate Use of the PASCAL Transcatheter Valve Repair System for Severe Tricuspid Regurgitation. JACC Cardiovasc Interv. 2019; 12(24):2488-2495
*Performance data on file

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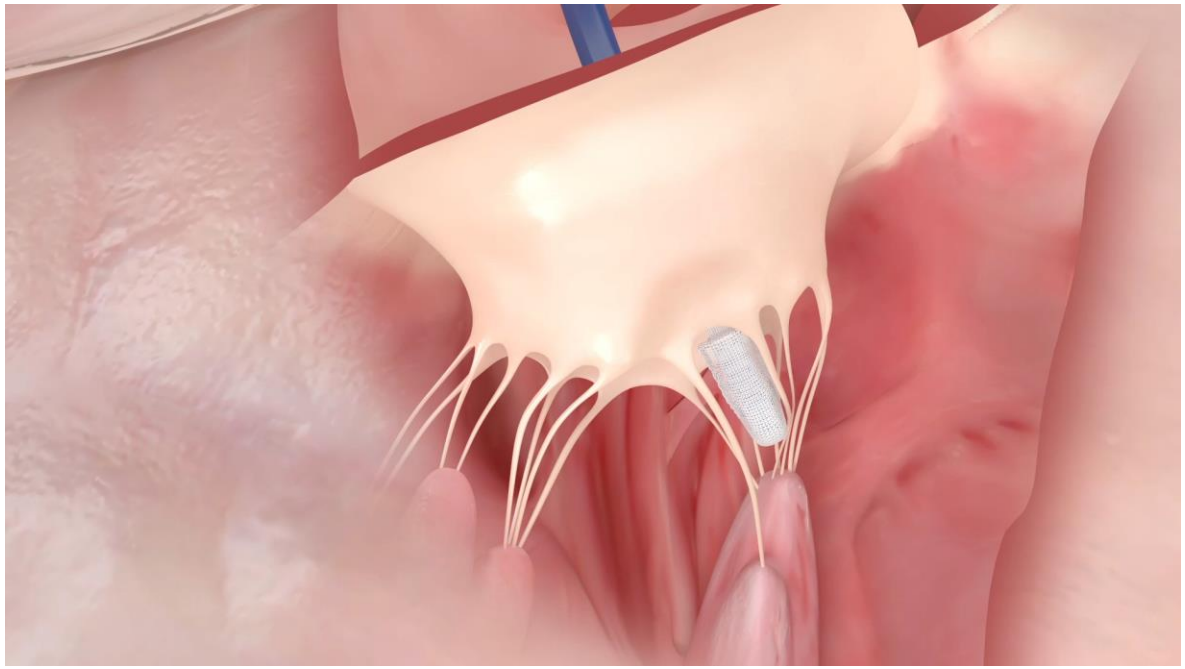
Versatile Implant Configuration

Goal: To facilitate subvalvular maneuvering even in challenging anatomies[1]



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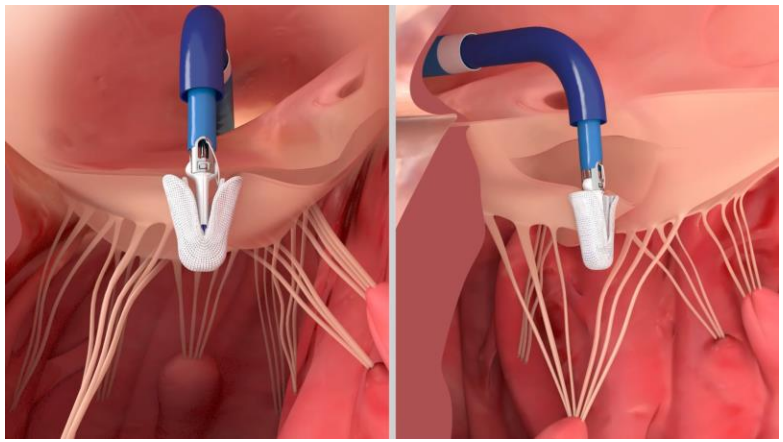
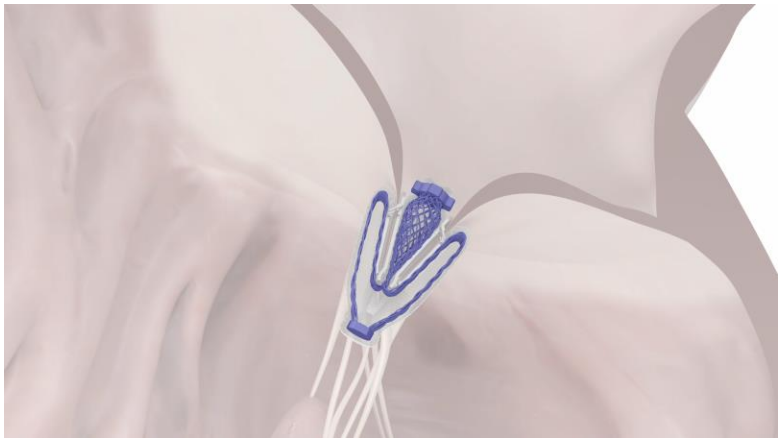
Nitinol construction

Goal: To conform to native anatomy and preserve leaflet integrity





Spring-like closure and dynamic implant flexing

Thank You

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