

2020 Investor Conference

Transcatheter Mitral and
Tricuspid Therapies



Edwards

TMTT is guided by our vision to lead and transform treatment for patients with mitral and tricuspid valve disease

Today, patients with **Mitral and Tricuspid regurgitation** remain **undertreated** and suffer poor quality of life and high mortality

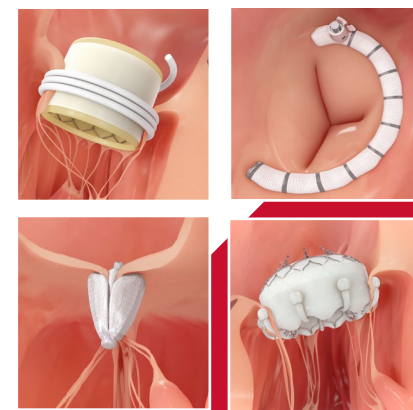
TMTT is delivering a **portfolio of therapies** – including leaflet repair, annular reduction, and valve replacement – to **address the diversity and complexity of Mitral and Tricuspid disease**

To achieve this vision, TMTT is focused on 3 key value drivers

- 1 Our **portfolio of differentiated therapies**
- 2 **Positive** results from our **pivotal trials**
- 3 **Favorable real-world outcomes**

TMTT will double revenue in 2021

Ongoing innovation & clinical evidence will support the development of a **\$3B MR/TR opportunity in 2025**, with significant growth beyond 2025



TMTT is innovating a broad transcatheter portfolio

TRICUSPID

Leaflet Repair



PASCAL



PASCAL Ace

Annular Reduction



Cardioband

Valve Replacement



EVOQUE

MITRAL



PASCAL



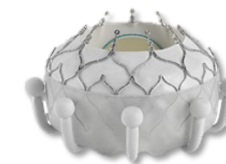
PASCAL Ace



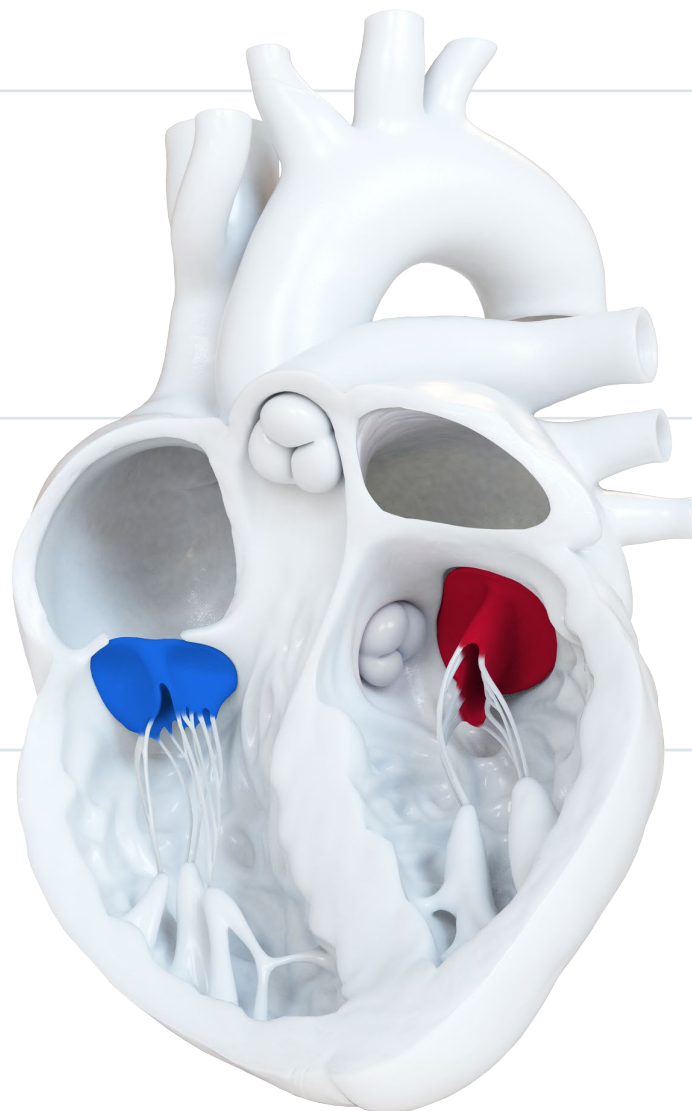
Cardioband



SAPIEN M3



EVOQUE



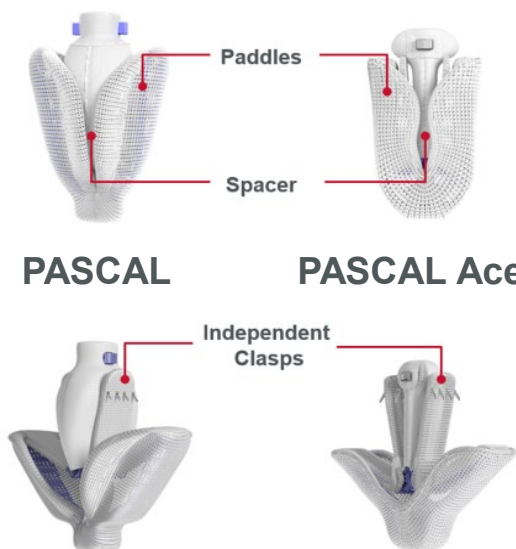
Mitral Innovations: PASCAL for Leaflet Repair



PASCAL Ace

CE Marked in 2020

New implant with **narrower profile** and spacer to achieve optimal outcomes for more patients



PASCAL & PASCAL Ace share **differentiated features**

A **nitinol design** to allow strong and yet flexible closure

A **central spacer** to bridge the coaptation gap and prevent backflow across the valve

The **ability to elongate** the device to navigate dense chords

Independent clasps, which can be used without restriction, to optimize MR reduction

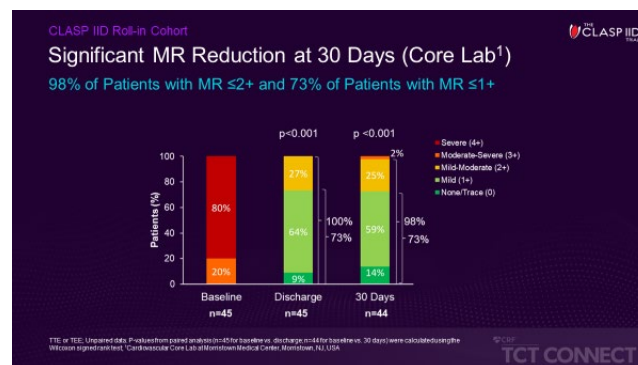
Bringing a consistent cadence of advancements to the PASCAL platform, including a next-gen delivery system in 2021

High rates of MR reduction are achieved with PASCAL, starting from physicians' earliest experience

CLASP IID Roll-In Data

73%

Percentage of patients with MR $\leq 0/1+$ at 30 days¹



CLASP CE Mark Study

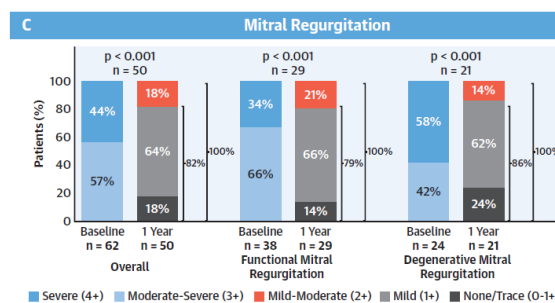
82%

Percentage of patients with MR $\leq 0/1+$ at 1 year²

JACC: CARDIOVASCULAR INTERVENTIONS
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1-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study

John G. Webb, MD,¹ Mark Hensey, MB, BSc, BAQ,² Molly Szerlip, MD,³ Ulrich Schäfer, MD,⁴ Gideon N. Cohen, MD,⁴ Saibal Kar, MD,⁵ Raj Makkar, MD,⁶ Robert M. Kipperman, MD,⁷ Konstantinos Spargias, MD,⁸ William W. O'Neill, MD,⁹ Martin K.C. Ng, MBBS, PhD,¹⁰ Neil P. Fam, MD,¹¹ Michael J. Rinaldi, MD,¹² Robert L. Smith, MD,¹³ Darren L. Walters, MBBS,¹⁴ Christopher O. Raffel, MBBS,¹⁵ Justin Levisay, MD,¹⁶ Azeem Latib, MD,¹⁷ Matteo Montorfano, MD,¹⁸ Leo Marconi, MD,¹⁹ Maithili Shrivastava, PhD,²⁰ Robert Boone, MD,²¹ Suzanne Gilmore, MPA,²² Ted E. Feldman, MD,²³ D. Scott Lim, MD²⁴



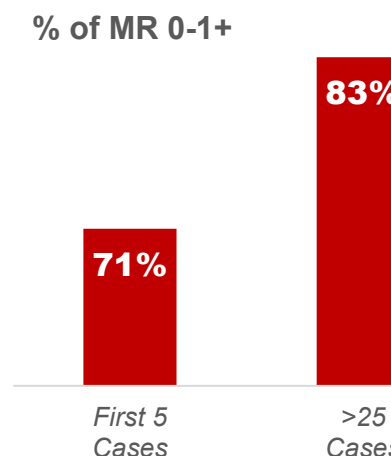
Webb, J.G. et al. J Am Coll Cardiol Interv. 2020;13(20):2344-57.

Real-World Experience

83%

Percentage of patients with MR $\leq 0/1+$ at discharge³

after 25 case experience



Expect a steady cadence of evidence from CLASP, CLASP IID/IIF, and post market studies

Mitral Innovations: Two-platform strategy positions TMTT for transfemoral replacement leadership



SAPIEN M3

Leverages the **proven SAPIEN valve**, coupled with a novel docking system



EVOQUE

Delivers a **dedicated mitral valve replacement** therapy

Both transfemoral delivery systems are

<30F

ensuring **safety and ease-of-use** during femoral puncture and septal crossing

“The **strength of the Edwards mitral program is the diverse portfolio...**

to be able to treat a wide range of patients percutaneously and be able to discharge them as soon as the next day.”

Dr. Raj Makkar

*Cedars-Sinai
Medical Center*



We have initiated the ENCIRCLE pivotal study for SAPIEN M3, and will begin clinical experience with our next generation EVOQUE mitral system early next year

Innovations & Evidence In Tricuspid Repair



PASCAL

Differentiated leaflet repair leverages mitral platform



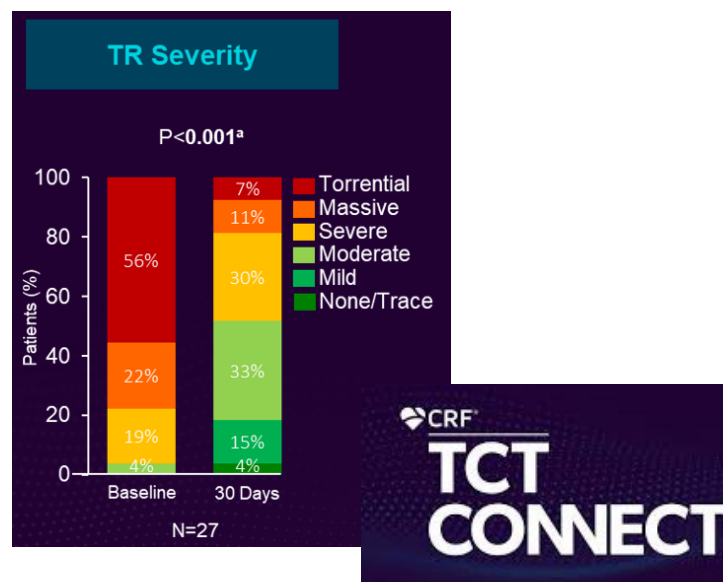
Cardioband

Strong and durable results to 2 years; investing in next generation system

PASCAL: CLASP TR EFS Study

70%

Percentage of patients with ≥ 2 TR grade reduction¹



Cardioband: Tri-Repair CE Mark Study

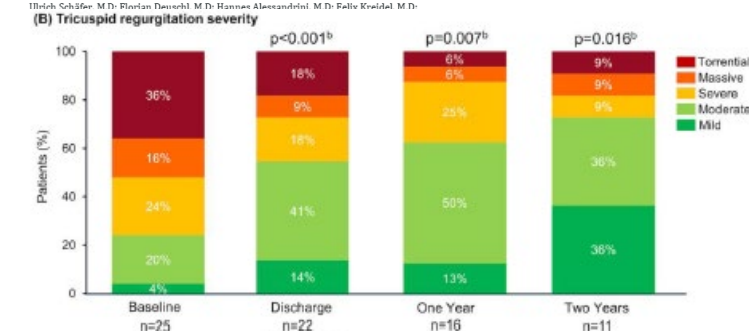
72%

Percentage of patients with TR $\leq$ moderate at 30 days²

jaa EuroIntervention

Title: Two-year Outcomes with the Cardioband Tricuspid System from the Multicentre, Prospective TRI-REPAIR Study.

Authors: Georg Nickenig, M.D.; Marcel Weber, M.D.; Robert Schüller, M.D.; Jörg Hausleiter, M.D.; Michael Nibauer, M.D.; Ralph S. von Bardeleben, M.D.; Efthymios Sotiriou, M.D.; Thibaut Gohlke, M.D.; Florian Dariusch, M.D.; Hannes Alaeedndri, M.D.; Felix Kneidel, M.D.



Experience with next generation PASCAL expected next year

Innovations & Evidence In Tricuspid Valve Replacement



EVOQUE

Tricuspid platform with three valve sizes to address diverse tricuspid anatomy

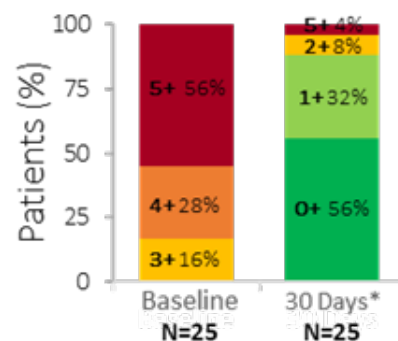
All three valves use the same **<30F** transfemoral delivery system

EVOQUE Compassionate Use

88%

Percentage of patients with TR $\leq 0/1+$ at 30 days¹

TR severity



Average procedure time of ~1 hour



*Mean TV gradient: 3.2 ± 0.6 mmHg

*“Having **all of these options** simultaneously in your toolbox **expands dramatically the number of patients you are able to treat.**”*

Dr. Stephan vonBardeleben

Heart Valve Center,
Mainz Germany



Initiating the TRISCEND II randomized pivotal study based on the FDA's breakthrough designation pathway

A dedicated team of talented people executing our high touch model to deliver outstanding patient outcomes

The TMTT high touch model

- Commitment to initial and ongoing physician training
- Highly trained clinical specialists providing full case coverage and support



Transforming treatment for patients with mitral and tricuspid valve disease to change standard of care

What to expect from TMTT in 2021

Additional Innovations

Continued innovations on each platform

Initial clinical experience with our:

- Next generation EVOQUE Mitral System
- Next generation PASCAL Delivery System

Clinical Evidence

Expanding our body of **clinical evidence**, including:

- Continued enrollment in our 5 pivotal trials
- Meaningful follow-up data publications and presentations across the portfolio

TMTT Revenue

Doubling TMTT revenue led by PASCAL and PASCAL Ace for both mitral and tricuspid patients

And in late 2022 – expect U.S. approval for PASCAL DMR and EU approval for EVOQUE Tricuspid

2021 Global Sales Outlook

Headwinds

Slower adoption of novel TMTT therapies

Competition for clinical trial enrollment

Doubling
2020 to
~\$80M

2021E

TMTT
Estimated Global Sales

Tailwinds

PASCAL differentiation driving faster site activation in Europe

Rapid enrollment in CLASP IID trial

Executive Summary

- Patients with Mitral and Tricuspid regurgitation **remain undertreated** and suffer from poor quality of life
- TMTT is delivering a **portfolio of therapies, backed by clinical evidence**, to address the diversity and complexity of Mitral and Tricuspid disease
- **Doubling revenue** in 2021

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Edwards

Helping Patients is Our Life's Work, and

life is now