

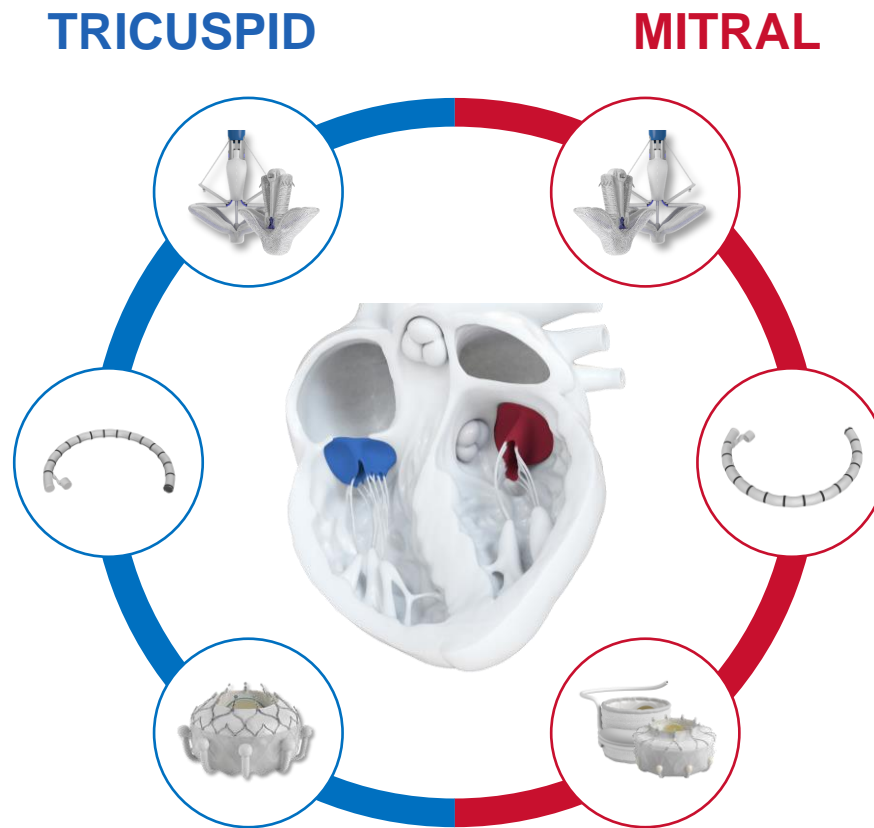
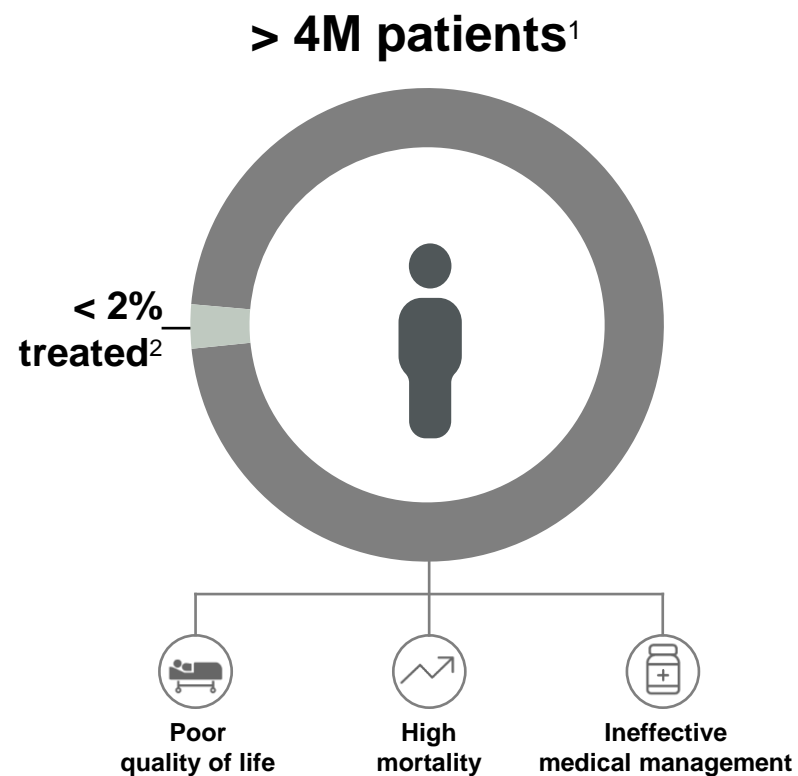
Transcatheter Mitral and Tricuspid Therapies

Bernard J. Zovighian
Corporate Vice President
Transcatheter Mitral and Tricuspid Therapies



Edwards

TMTT has a bold vision to transform care for the many patients with Mitral and Tricuspid valve disease...



Global Transcatheter Mitral and Tricuspid Market

expected to grow
from ~\$1B in 2021 to

\$5B

by 2028

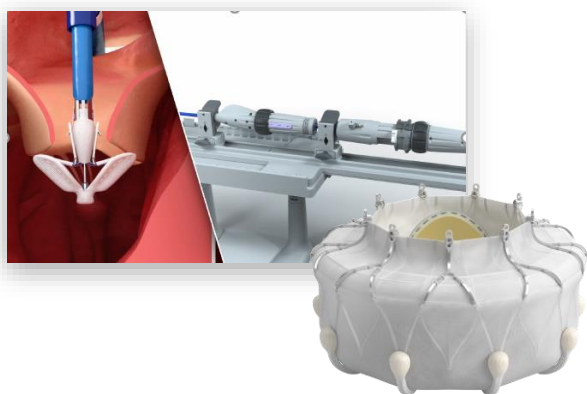
and continue strong growth
beyond 2028

...a comprehensive portfolio uniquely positions TMTT to realize this vision, and lead this rapidly growing opportunity

TMTT overcame numerous obstacles to achieve our ambitious milestones in 2021...

Differentiated Portfolio

- Initial clinical experience with next-gen PASCAL Precision System
- Initial clinical experience with next-gen TMVR (EVOQUE Eos)



Robust Clinical Evidence

- Continued pivotal enrollment
- Meaningful data publication



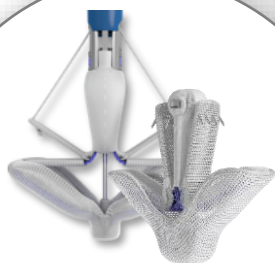
Real-World / Commercial Outcomes

- Enroll CLASP IID trial by year-end supporting late 2022 PASCAL DMR U.S. approval
- Enrolled TRISCEND study supporting late 2022 EVOQUE TR EU approval
- 2x Revenue



...establishing a strong foundation for 2022 and beyond

PASCAL's adoption is driven by an increasingly large and compelling body of Mitral evidence and experience

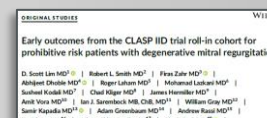


PASCAL

>4,500
total patients treated
with PASCAL Mitral¹

>3,800
patients with
reported data²

>450 study patients
@ 1-year follow-up³



Pivotal Trials

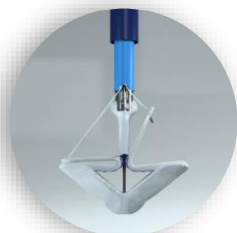


TMTT is delivering a rapid cadence of innovation in transcatheter edge-to-edge repair (TEER)

PASCAL is designed to address meaningful patient needs...



Versatile implant
to safely navigate even challenging anatomies



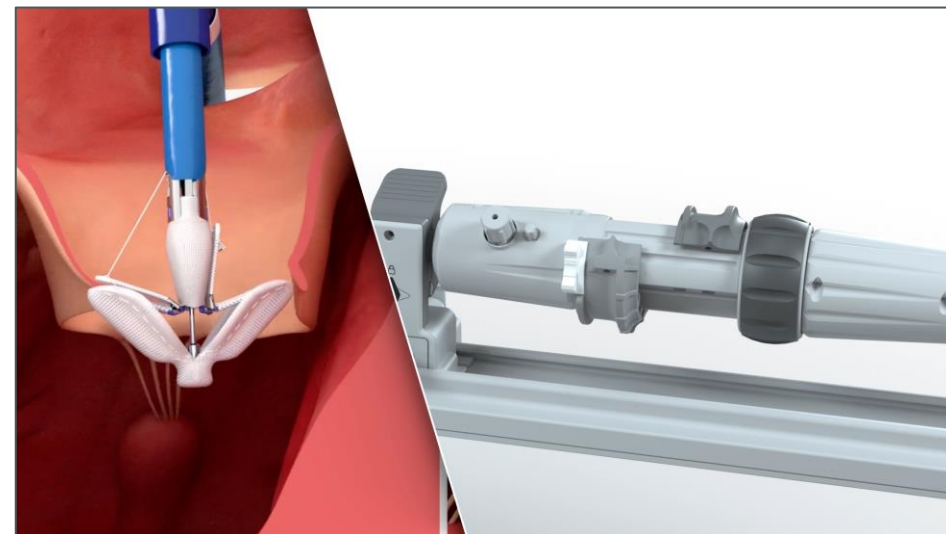
Atraumatic clasp control
to optimize patient outcomes



Compliant implant
designed to respect native anatomy



...and the new PASCAL Precision System extends this differentiated performance



Engineered for
intuitive user experience

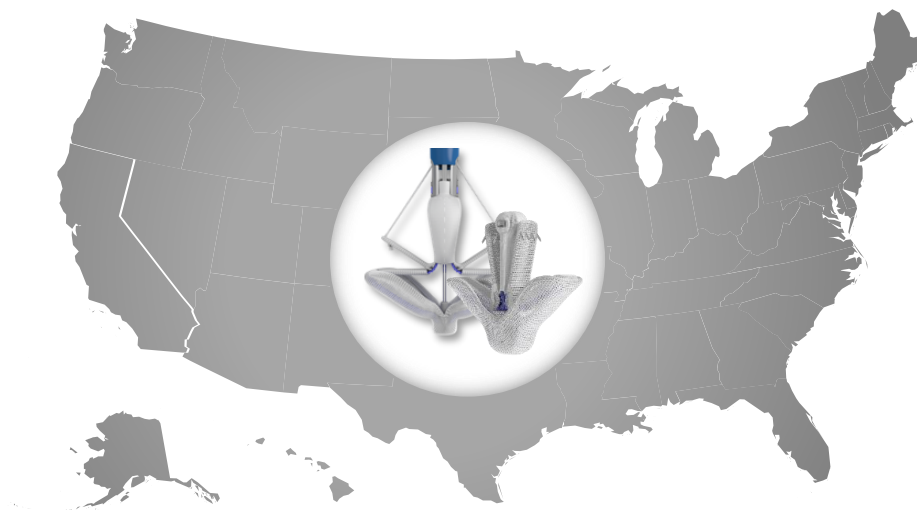
Optimized catheters
enhance navigation

Impressive performance
in clinical use

TMTT's innovation continues with a **novel next-generation PASCAL device**, initiating **first clinical use in 2022**

TMTT expects FDA approval of PASCAL Precision for DMR in late 2022

Controlled launch planned in the U.S. with a **dedicated field team** deploying our **high-touch clinical support model**



**Support
patient screening**



**Comprehensive
physician training**



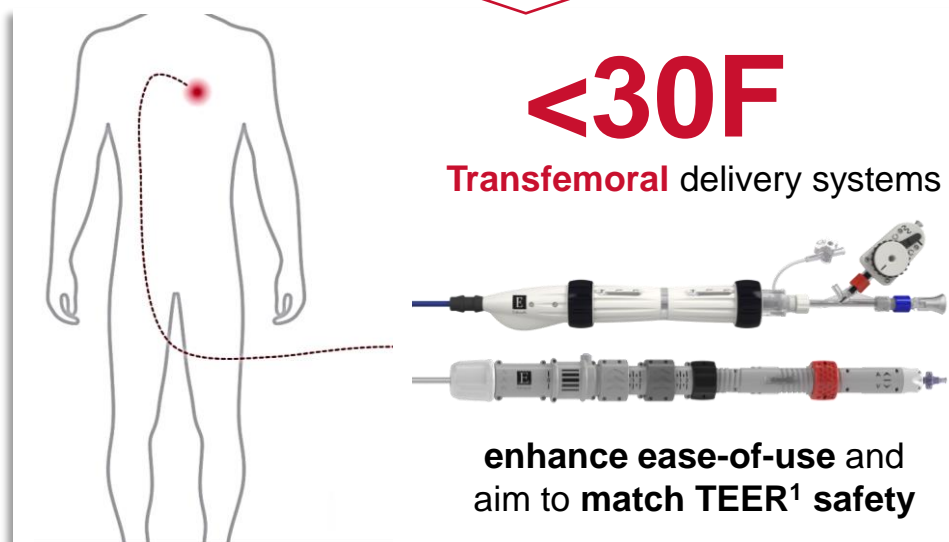
**100%
case support**

Transfemoral replacement is expected to significantly expand the Mitral opportunity in the mid-term

Addressing patients' needs with product design



Eliminating residual MR offers significant patient benefits

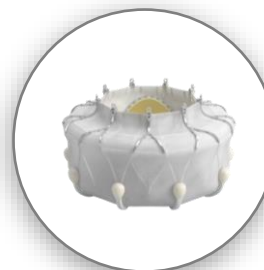


Two-platform strategy positions TMTT for leadership



SAPIEN M3

- On-track to be the first commercially available sub-30F TMVR²
- Leverages the proven SAPIEN valve
- Actively enrolling ENCIRCLE pivotal trial



EVOQUE Eos

- Designed specifically for Mitral valve replacement and sub-30F
- Fully repositionable to enhance patient safety
- Clinical experience in the MISCEND early feasibility study is encouraging



1. Transcatheter edge-to-edge repair

2. Transfemoral mitral valve replacement. Caution: Investigational Devices. Limited to investigational use only.

TMTT is well positioned to achieve critical Mitral milestones in 2022, setting up a strong 2023

Differentiated Portfolio

- > Initial clinical experience with novel next-generation PASCAL System
- > Expanded clinical experience with EVOQUE Eos

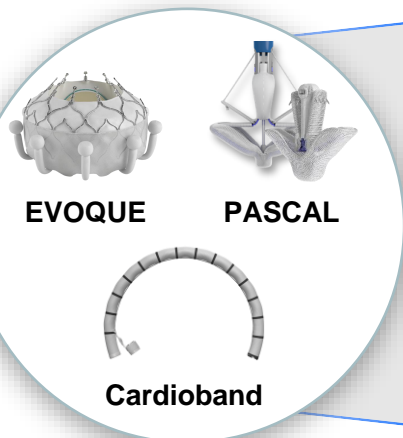
Robust Clinical Evidence

- > FDA submission with CLASP IID: mid-year 2022
- > CLASP IID presentation: 2H 2022 and prior to approval
- > Continued enrollment in CLASP IIF & ENCIRCLE pivotal trials
- > Presentation and publication of significant clinical data

Favorable real-world / commercial outcomes

- > PASCAL Precision DMR approval in US: Late 2022
- > PASCAL Precision approval in EU: Late 2022

Early tricuspid clinical evidence is promising, and demonstrates the diversity of patients' needs...



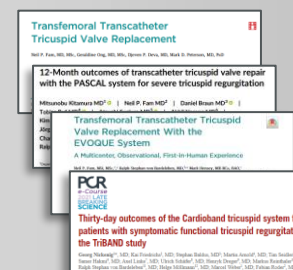
>1,500

**total patients treated with
TMTT's Tricuspid Portfolio¹**

~500

**patients with
reported data²**

>150 study patients
@ 1-year follow-up³

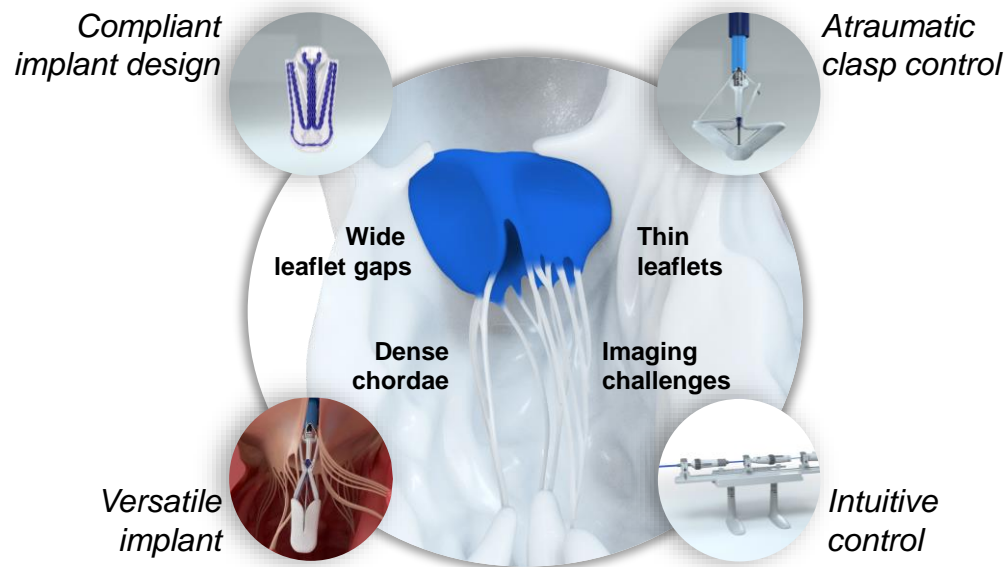


Pivotal Trials



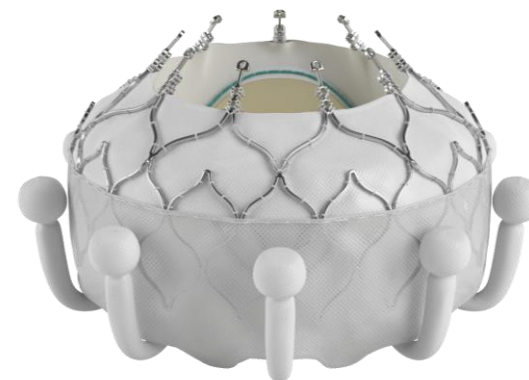
...which TMTT's Tricuspid portfolio is designed to treat, with safety, efficacy, and ease-of use

Tricuspid Repair: PASCAL Precision System



PASCAL's differentiated features are highly applicable to Tricuspid Valve anatomy

Tricuspid Replacement: EVOQUE



3 Valve Sizes

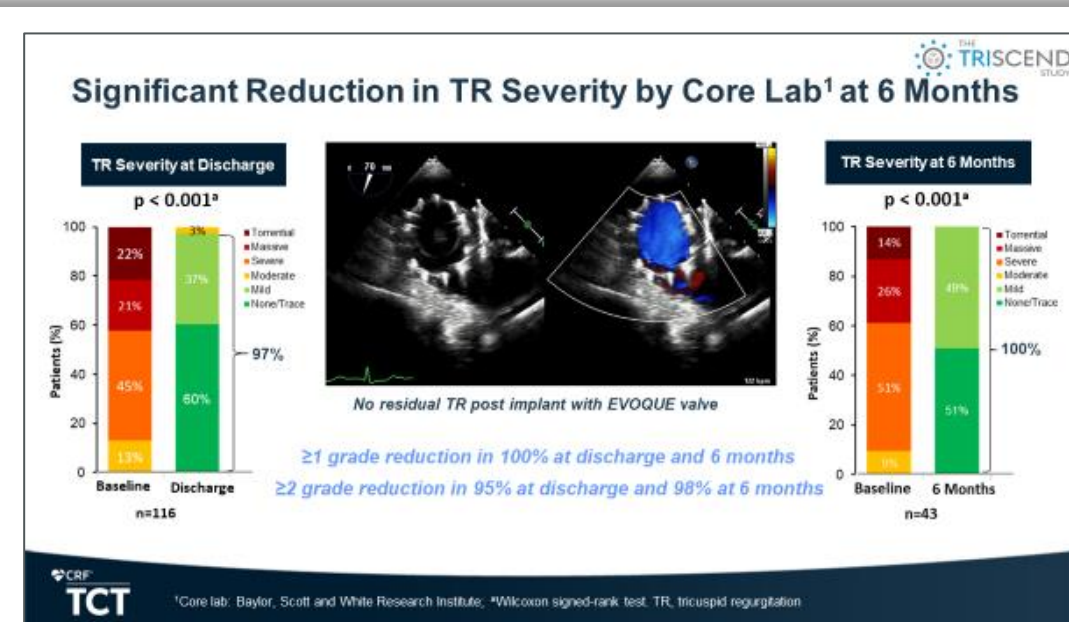
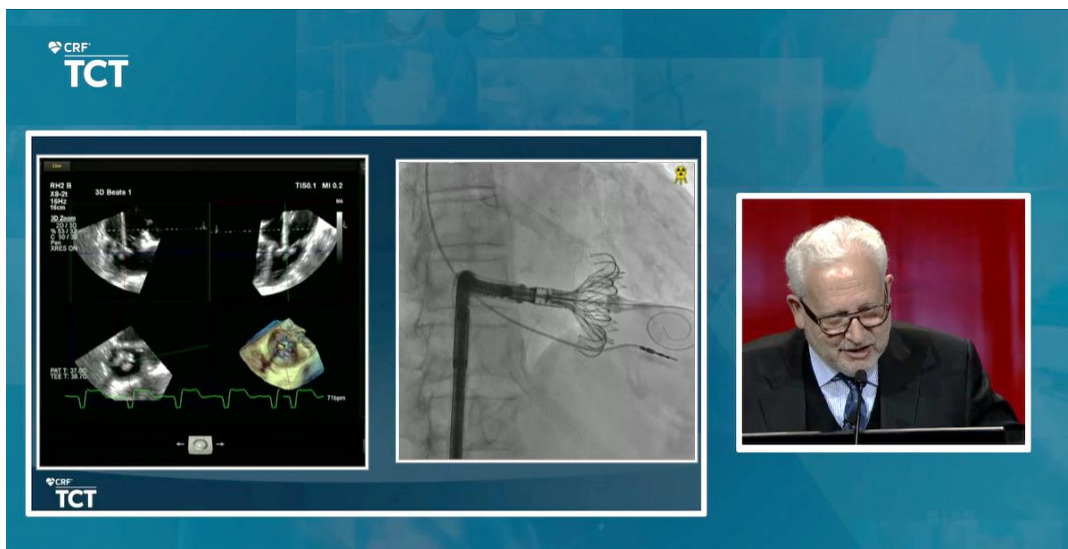
Enable treatment in a **wide** range of patient anatomies



<30F

Delivery system designed for **safety and ease-of-use**

Excitement is building for EVOQUE, which kicked off TCT 2021 with a live case, and presented 6-month late breaking trial data



96%

Survival

94%

Freedom from
Heart Failure Hospitalization

At 6-month follow-up

TMTT's understanding of Tricuspid clinical needs drives an ability to achieve significant milestones in 2022

Differentiated Portfolio

- Initial clinical experience with novel next-generation PASCAL system
- Initial clinical experience with the next-generation Cardioband system

Robust Clinical Evidence

- Continued enrollment of TRISCEND II and CLASP II TR pivotal trials
- Presentation and publication of significant clinical data

Favorable real-world / commercial outcomes

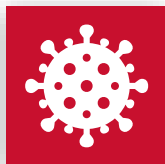
- EVOQUE approval in Europe
Late 2022

2022 Global Sales Outlook

Headwinds



The new European regulatory system



COVID recovery

\$170M

\$140M

Tailwinds

European Mitral market returns more quickly to higher growth



High quality evidence across the TMTT portfolio



2022E

Global TMTT
Estimated Sales

TMTT is committed to continue delivering on our vision in 2022, with significant sales growth and major product approvals...



- PASCAL Precision DMR approval in U.S.:
Late 2022
- PASCAL Precision approval in EU:
Late 2022
- EVOQUE approval in EU:
Late 2022
- >6,000 patients treated in 2022
- Revenue of \$140-\$170M

...setting the stage for 2023 and beyond

IMPORTANT SAFETY INFORMATION

SAPIEN M3 Transcatheter Heart Valve System

INVESTIGATIONAL DEVICES. CAUTION: The SAPIEN M3 System consists of investigational devices, limited by Federal (United States) law to investigational use. These devices are not available for marketing or commercial sale. See instructions for use for full information, including indications, contraindications, warnings, precautions, and adverse events.

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The Edwards EVOQUE System and EVOQUE Eos System, the Edwards Cardioband System, and the Edwards Pascal and Pascal Precision Systems

INVESTIGATIONAL DEVICES. CAUTION: Limited to investigational use. These devices are not available for marketing or commercial sale. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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Edwards Pascal System

For professional use. For a listing of indications, contraindications, warnings, precautions and 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.

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Helping Patients is Our Life's Work, and

life is now