

LivaNova

Health innovation that matters

LivaNova Investor Day

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TMVR

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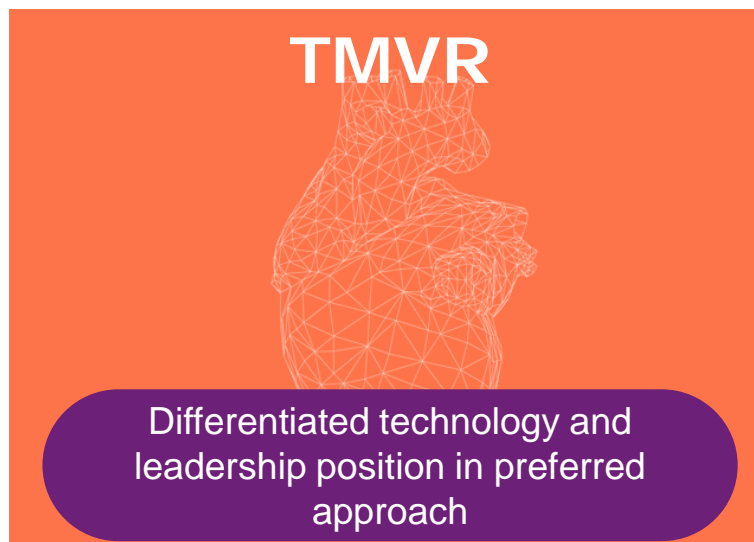


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We are in a leadership position in TMVR



CUSTOMERS

Interventional cardiologists
Cardiac surgeons
Echocardiographers

DISEASE STATE

Mitral regurgitation
Heart failure

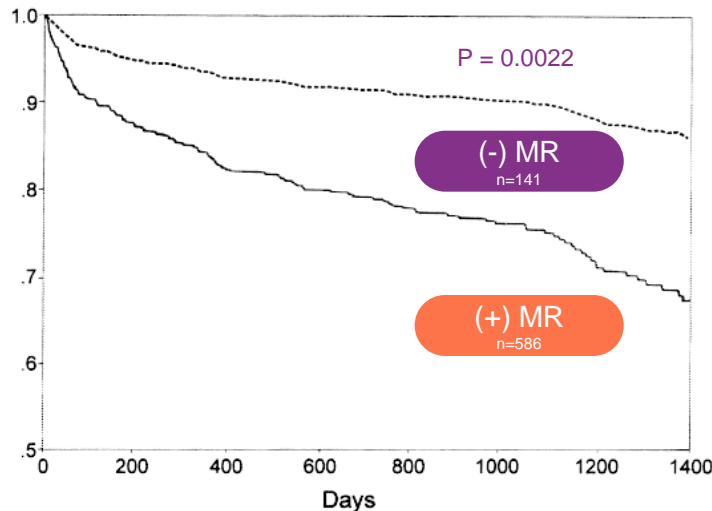
MARKET

Potential to become 2-3 times the size of Transcatheter Aortic Valve Replacement (TAVR)

Mitral Regurgitation (MR) is a reliable predictor of health outcomes, including mortality

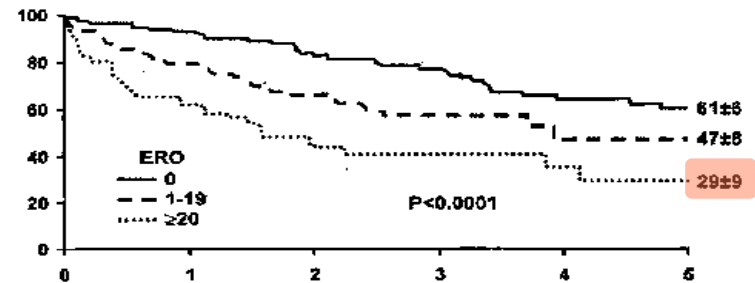
SAVE sub study, n=727

Cardiovascular survival



16 days after Q-wave MI, n=303, 194 with IMR

Survival, %






“Mild MR is an independent predictor of post-MI mortality.”

Lamas et al: Circ, 1997;96:827

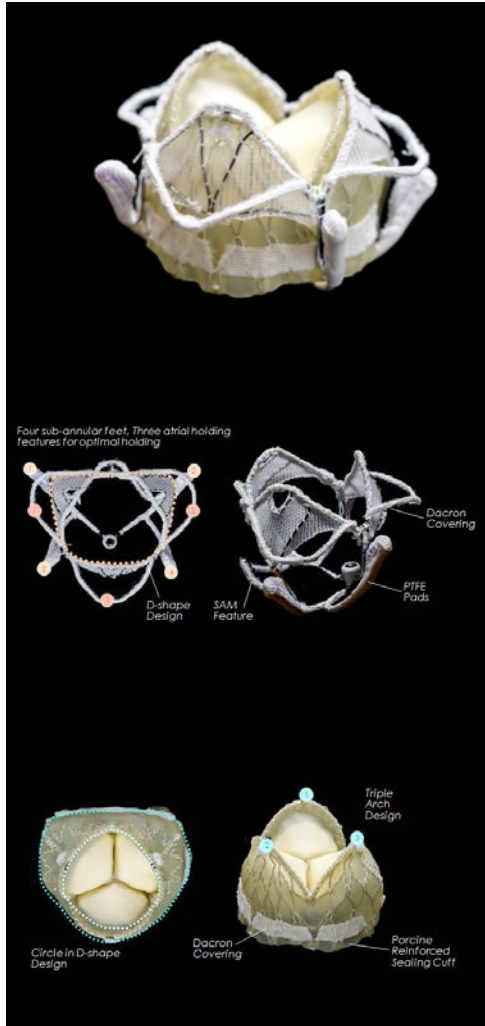
“The mortality risk is related directly to the degree of IMR.”

Grigioni et al: Circ, 2001;103:1759

Surgical treatments are imperfect, creating opportunity for new interventional approaches

Established Surgical (open chest)	Repair	“Gold standard”	Challenging surgery, 30%+ recurrence	
	Replace	Excellent mechanical durability	Lifetime anticoagulation, poor tissue durability	
Emerging Interventional (percutaneous)	Repair	Strong safety	Modest efficacy, 30%+ recurrence after 1 year	
	Replace	Open race for TMVR leadership. Best clinical outcome and ease of use will be key.		

LivaNova TMVR Concept



- **Delivery System**

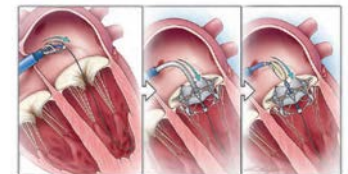
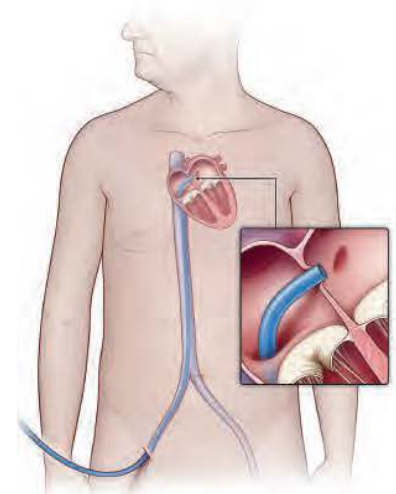
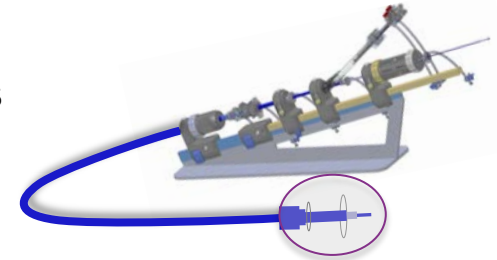
- Completely transvenous percutaneous approach
- 2-step implant
- Fully reversible

- **Anchor**

- 4 sub-annular anchoring feet
- SAM management feature
- Nitinol self-expanding frame
- Covered with polyester and ePTFE

- **Valve**

- Porcine pericardium
- 3 leaflet circular valve, EOA > 3.0 cm²
- D-shaped outer stent
- Nitinol self-expanding



LivaNova TMVR Animation

TMVR is giving new hope to patients with little to no other options

Typical patient

Female (79%), ~79 years old,
generally too sick for surgery

Severe MR	Grade 3-4	100%
Heart disease	CAD	64%
	Previous procedure	55%
Heart failure	NYHA III/IV	81%
Pulmonary dysfunction	COPD	46%
Kidney disease	Renal insufficiency	46%



TMVR advantages have recently created significant interest from leading players

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Caisson Interventional

\$120M

 Edwards


Internal Fortis development

Not disclosed

 Edwards

CardiAQ Valve Technologies

\$400M

 Edwards

Valtech

\$690M

 Abbott

Tendyne

\$250M

 Abbott

Cephea Valve Technologies

Not disclosed

 Medtronic

Twelve Intrepid

\$458M

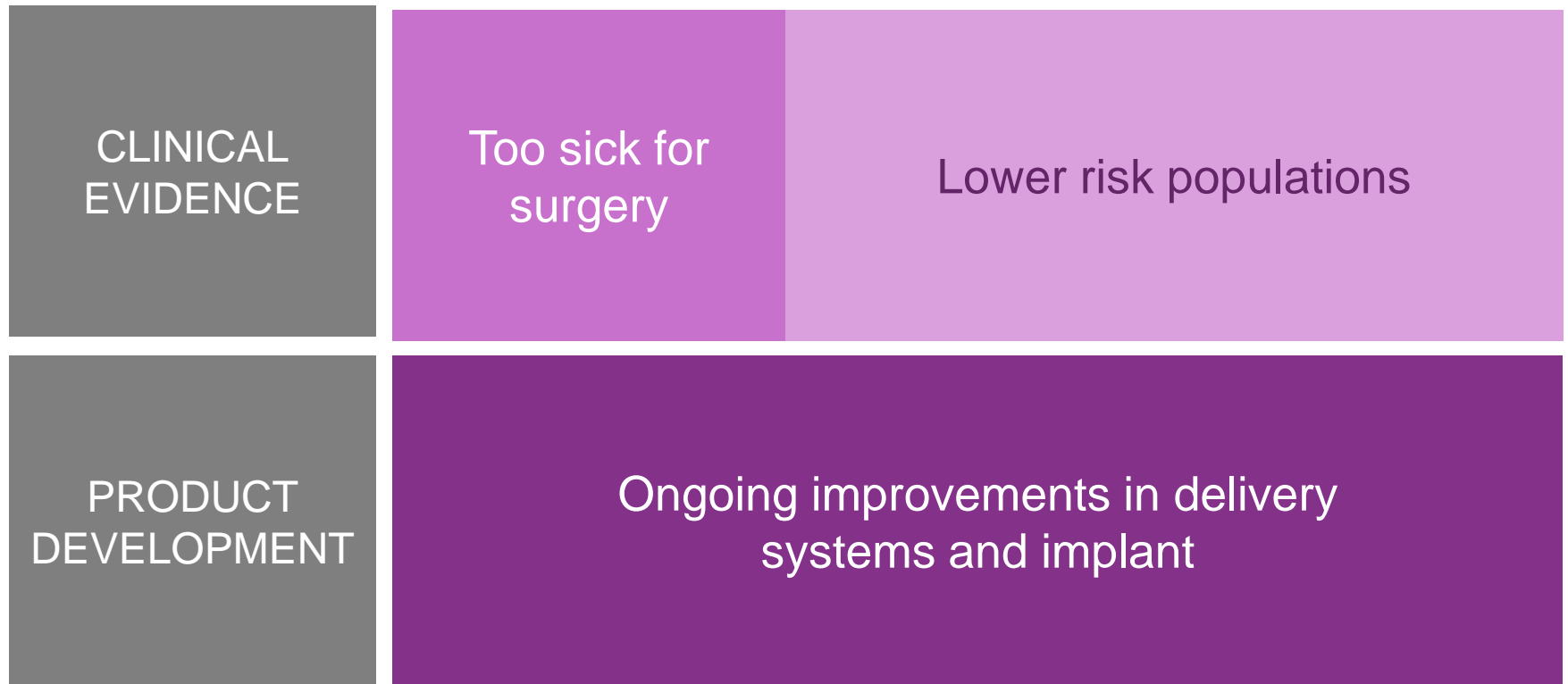
 Boston Scientific

Option to buy MValve

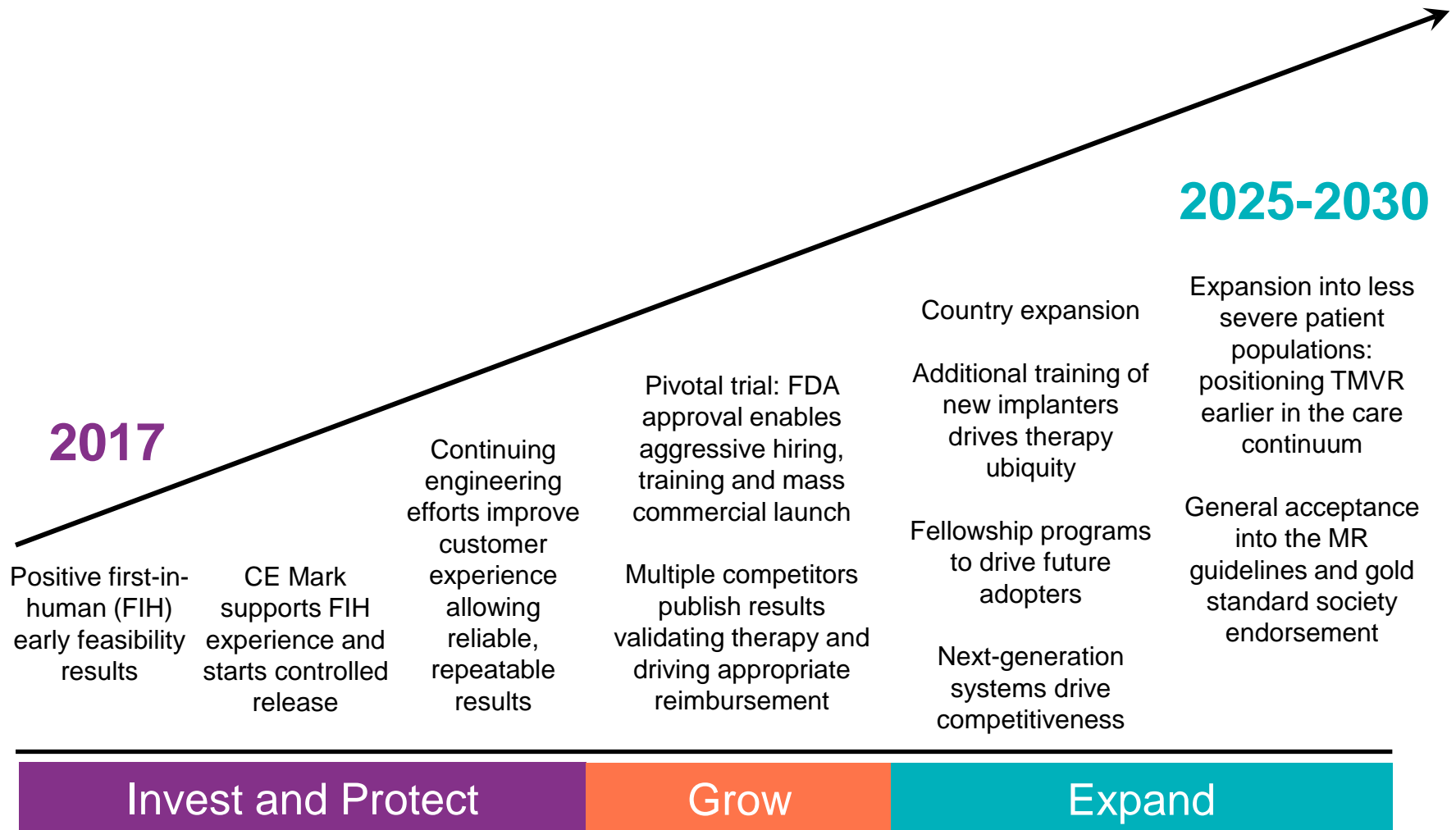
Reportedly
\$200M

Key investments to creating a TMVR market that is 2-3 times larger than TAVR







Current  Future



We have the patience to build and are committed to investing in the market



Executing on a clinical data development plan designed to enable commercialization

		Patients	Centers	Objective	Status
		20	8-10	FIH study proving TMVR concept	Continuing enrollment
		75	15	Confirmatory study to secure CE Mark in Europe	Started to enroll
		400	20-30	U.S. IDE study to build on FIH and CE Mark study to secure FDA approval	Finalizing protocol with enrollment planned in 2019

A proven approach to ensuring physician competence and confidence

Patient selection

- Therapy awareness tools to drive local education and awareness
- Joint screening activities with clinical sites
- Virtual implant fit to ensure proper sizing













Physician training/tools

- On-site instruction at hospital
- Full day didactic and hands-on training
- Modeling of ideal approach for patient case
- On-site refresher training and virtual implant simulation in actual hospital catheterization lab

Procedure support

- Expertise for onsite training and case support
- Procedure observation worksheet on every case to institutionalize learning and continuously improve

Competitive advantage in TMVR and opportunity to lead the transseptal market

TRANSSEPTAL	LivaNova	Caisson	
	Edwards	CardiAQ	
	Abbott	Cephea	
	Edwards	Valtech	
TRANSAPICAL	Edwards	CardiAQ	
	Abbott	Tendyne	
	Medtronic	Twelve	
	MValve		
	Neovasc		
	HighLife		
	Sinomed		
	Direct Flow		

Summary: positioning for leadership in TMVR

Technology	<ul style="list-style-type: none">• Transseptal delivery• Distinct competitive advantages
Clinical evidence	<ul style="list-style-type: none">• Investment in clinical trials• Post-market studies for reimbursement and/or expanded indications
Physician focus	<ul style="list-style-type: none">• Collaboration and responsiveness• World-class training• Procedural support• Podium presence• Advocacy

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