

TriClip™

Transcatheter  
Edge-to-Edge Repair

ADVANCING  
TRICUSPID  
THERAPY  
FOR YOUR  
PATIENTS

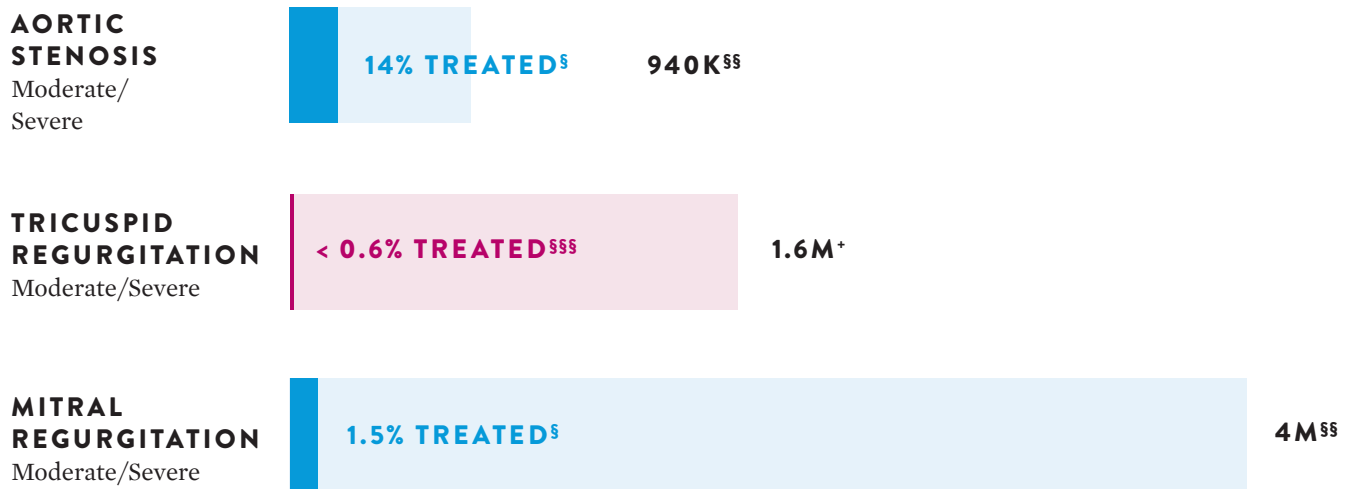


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# TRICUSPID REGURGITATION (TR) IS HIGHLY PREVALENT AND UNDERTREATED<sup>1</sup>

## AMONG VALVE DISEASES, TR IS ONE OF THE MOST UNDERTREATED<sup>1</sup>



<sup>§</sup>Calculations performed by Abbott based on: Mills J, Furlong C; on behalf of Canaccord Genuity. Industry Overview. 2016<sup>2</sup>; and Millennium Research Group, Inc. *US Markets for Heart Valve Devices 2014*. 2013.<sup>3</sup>

<sup>§§</sup>Calculations performed by Abbott based on: Nkomo VT, et al. *Lancet*. 2006.<sup>4</sup>

<sup>§§§</sup>Calculations performed by Abbott based on: Enriquez-Sarano M, et al. *Progress in Cardiovascular Diseases*, 2019.<sup>1</sup>

<sup>†</sup>Stuge O, Liddicoat J. *J Thorac Cardiovasc Surg*. 2006.<sup>6</sup>

## ~1 IN 30 PATIENTS OVER THE AGE OF 65 HAS MODERATE-TO-SEVERE OR SEVERE TR<sup>++</sup>



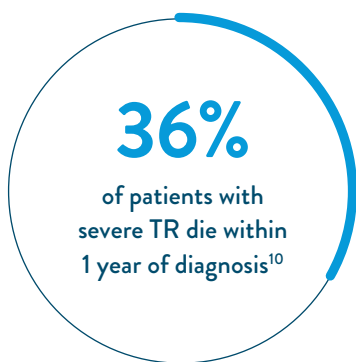
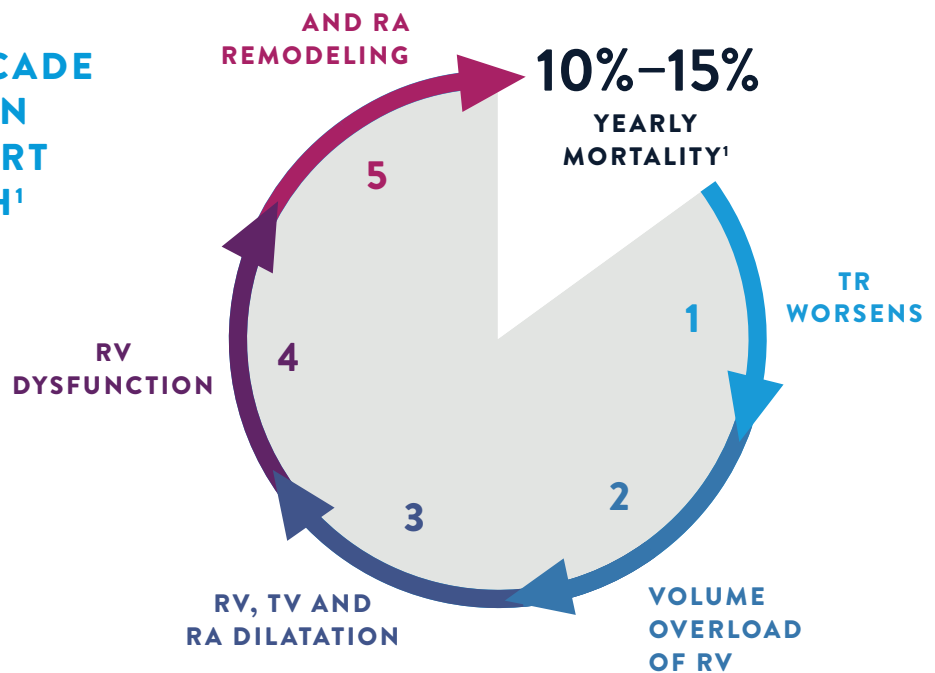
<sup>++</sup>Calculations performed by Abbott based on: Topilsky Y. Presented at: ESC Congress 2019<sup>7</sup>; and Howden LM, Meyer JA. *Age and Sex Composition: 2010*. 2011.<sup>8</sup>

**66%**  
FEMALE<sup>9</sup>

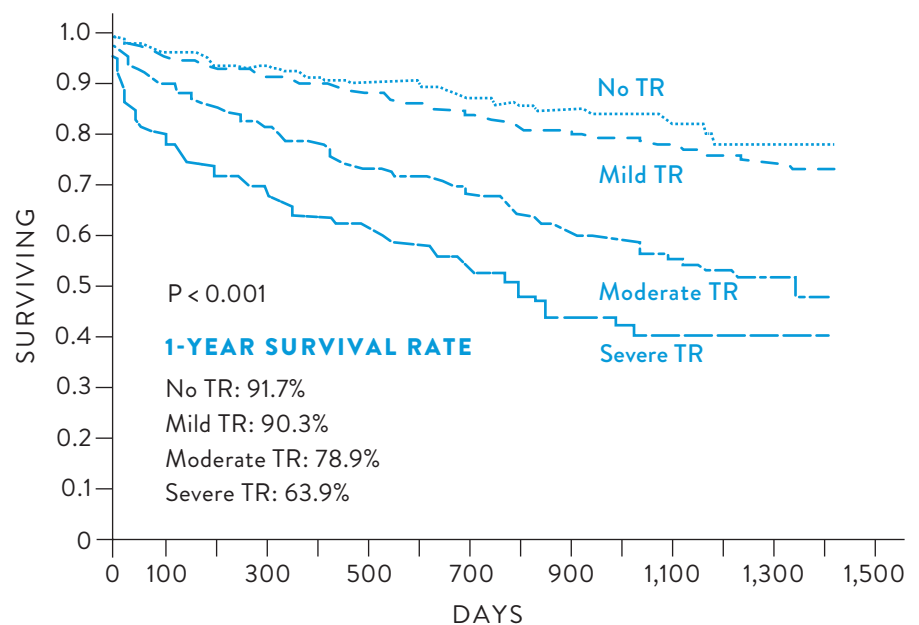
**77.8** <sup>+ 7.9</sup>  
YEARS<sup>9</sup>  
MEAN AGE

# SEVERE TR IS AN INDEPENDENT PREDICTOR OF MORTALITY

IF LEFT UNTREATED, TR INITIATES A CASCADE OF EVENTS THAT CAN LEAD TO RIGHT HEART FAILURE AND DEATH<sup>1</sup>



Retrospective analysis of 5,223 patients (age 66.5 ± 12.8 years) adjusted for age, LVEF, inferior vena cava size and RV size and function



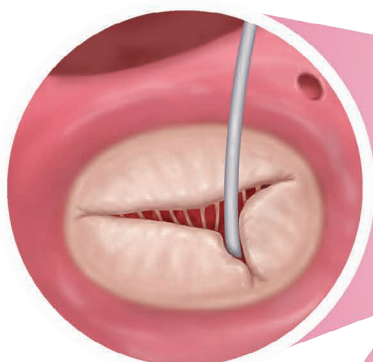
Graph adapted from: Nath J, et al. *J Am Coll Cardio.* 2004.<sup>10</sup>

# TR IS COMPLEX WITH MANY CAUSES

## PATIENTS WITH MODERATE OR GREATER TR HAVE SIGNIFICANTLY IMPAIRED QUALITY OF LIFE

- Shortness of breath
- Peripheral edema
- Ascites
- Fatigue
- Declining exercise capacity

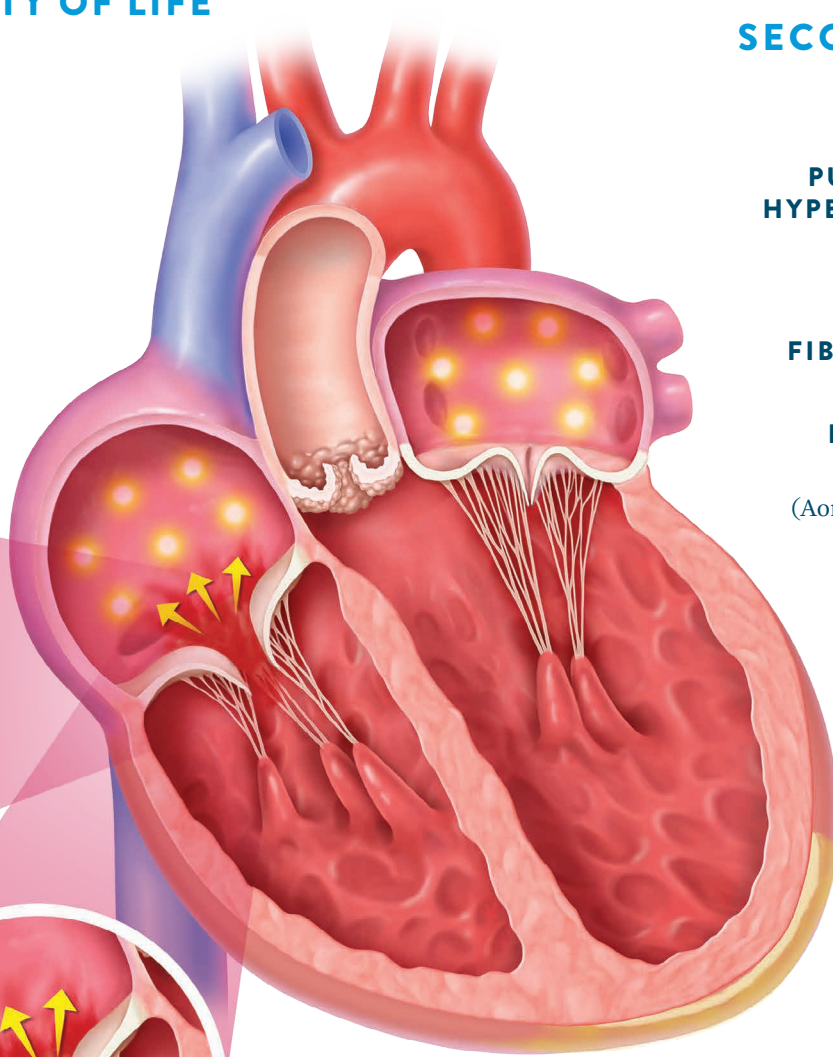
### PRIMARY



**PACEMAKER  
LEAD**



**PROLAPSE**



### SECONDARY

(Functional)

**PULMONARY  
HYPERTENSION**

**●  
ATRIAL  
FIBRILLATION**

**LEFT VALVE  
DISEASE  
(Aortic and Mitral)**

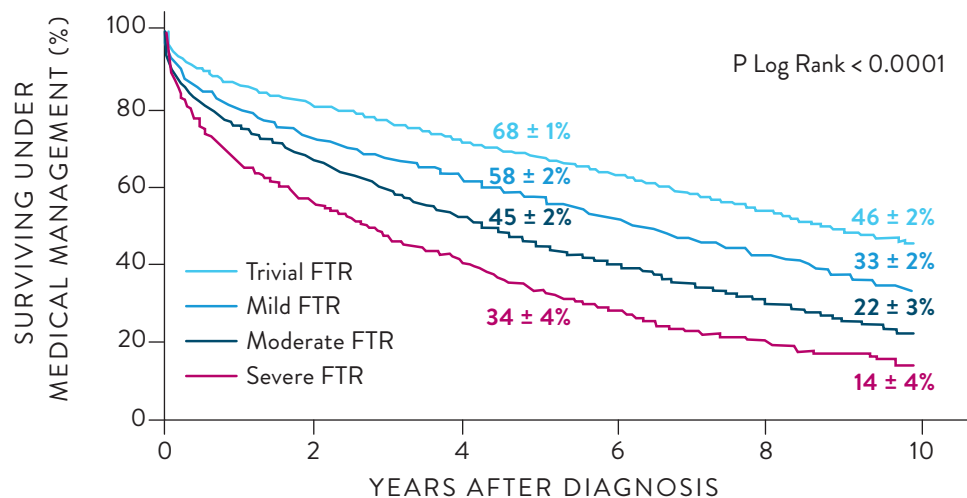
**LEFT  
HEART  
DISEASE**

# PATIENTS HAVE FEW TREATMENT OPTIONS

## FOR MANY PATIENTS WITH TR, MEDICAL THERAPY IS NOT ENOUGH



**MEDICATIONS FOR TR HAVE LIMITED IMPACT ON SURVIVAL**



Retrospective analysis of 13,026 patients with HFrEF Stage B or C with EF < 50%. Exclusions criteria included previous valve surgery, PPML and moderate or severe organic, mitral or aortic valve disease<sup>11</sup>

Graph adapted from: Benfari G, et al. *Circulation*. 2019.<sup>11</sup>



**SURGERY IS SELDOM PERFORMED<sup>1,12</sup>**

## FACTORS PROHIBITING SURGERY INCLUDE

- High operative risk (8%–13% operative mortality)
- Multiple comorbidities
- Advanced age
- Lack of effectiveness

# TriClip™

Transcatheter  
Edge-to-Edge Repair

## FOR PATIENTS WITH SYMPTOMATIC SEVERE TR

TriClip™ Transcatheter Edge-to-Edge Repair offers a sustained reduction of TR with significant improvement in clinical outcomes and proven safety.<sup>13</sup>



G4 NT

G4 NTW

G4 XT

G4 XTW

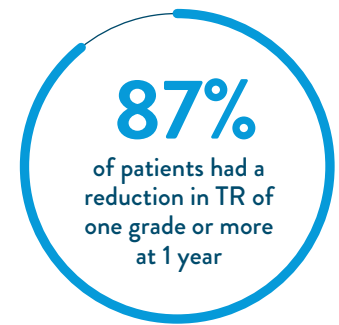
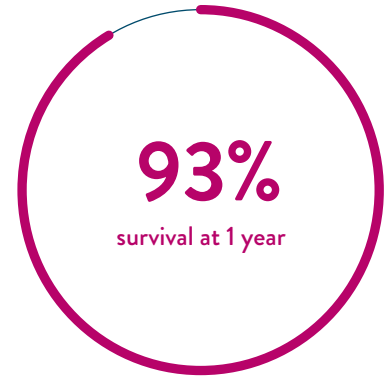
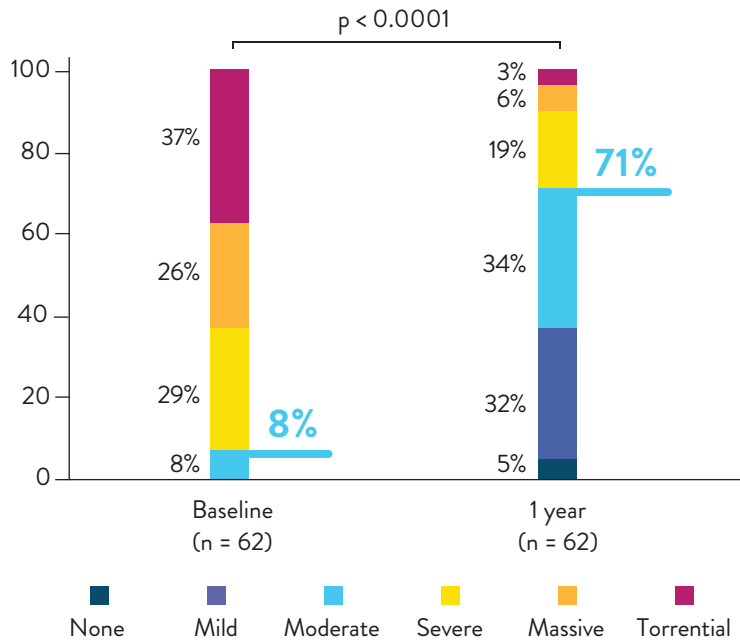


## TRILUMINATE™ CLINICAL TRIAL

# MEANINGFUL OUTCOMES BACKED BY ROBUST EVIDENCE<sup>13</sup>

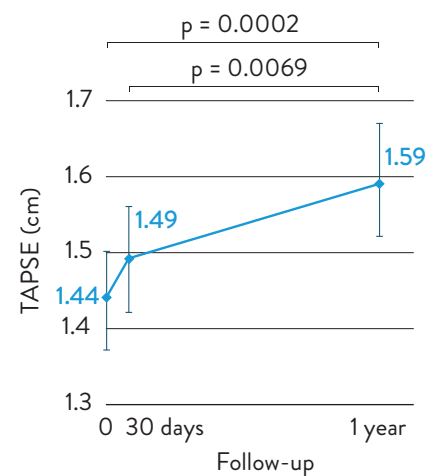
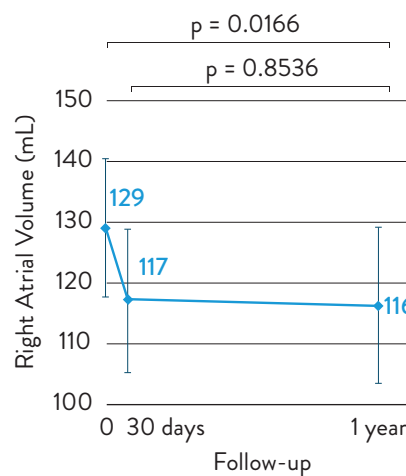
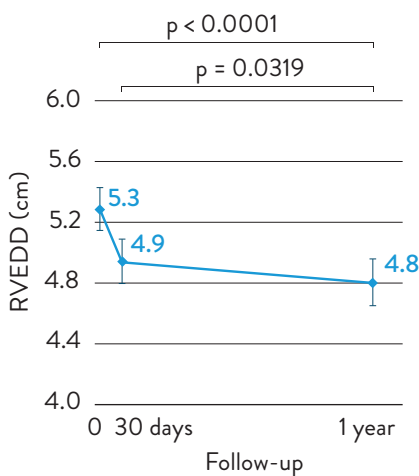
### SIGNIFICANT AND DURABLE TR REDUCTION

The proportion of subjects with moderate or less TR increased from 8% at baseline to 71% at 1 year. Results observed at 30 days were sustained out to 1 year.



### REDUCTION IN TR LEADS TO REVERSE RV REMODELING

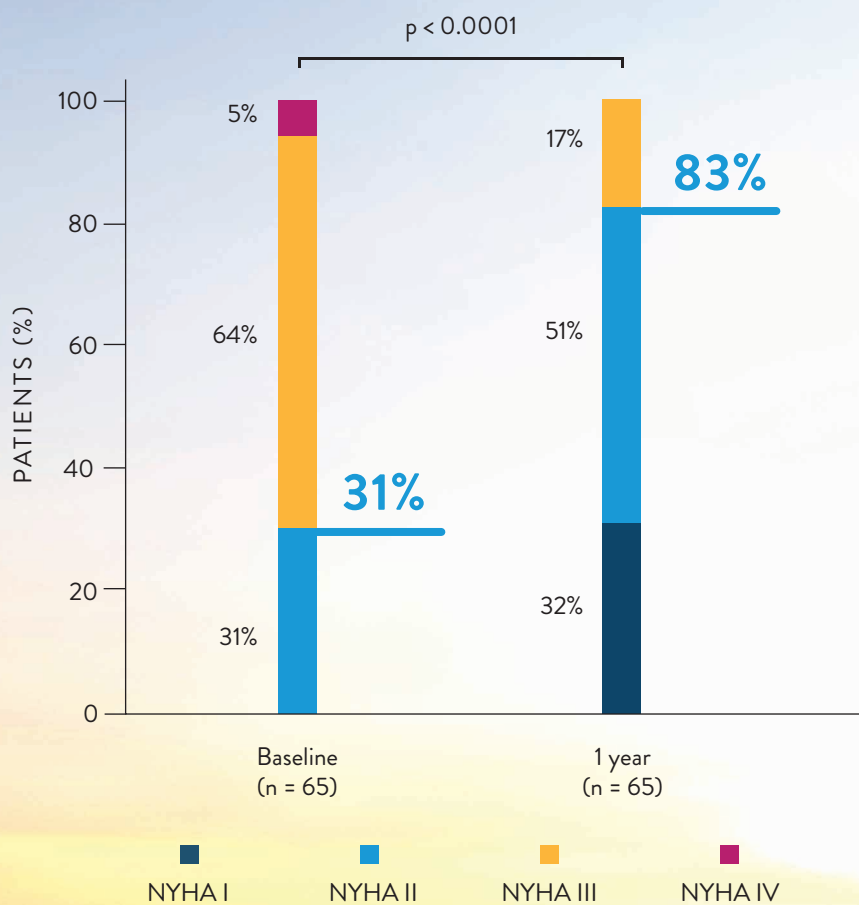
At 1 year, the reduction of TR was associated with significantly decreased right atrial and ventricular dimensions and reverse RV remodeling with significant improvement in RV function.



# TRILUMINATE™ CLINICAL TRIAL SHOWS LIFE-CHANGING IMPROVEMENTS IN FUNCTION AND SYMPTOMS<sup>13</sup>

## SUSTAINED IMPROVEMENTS IN NYHA

The proportion of subjects classified as NYHA Functional Class I/II increased from 31% at baseline to 83% at 1 year.

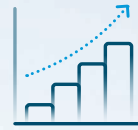
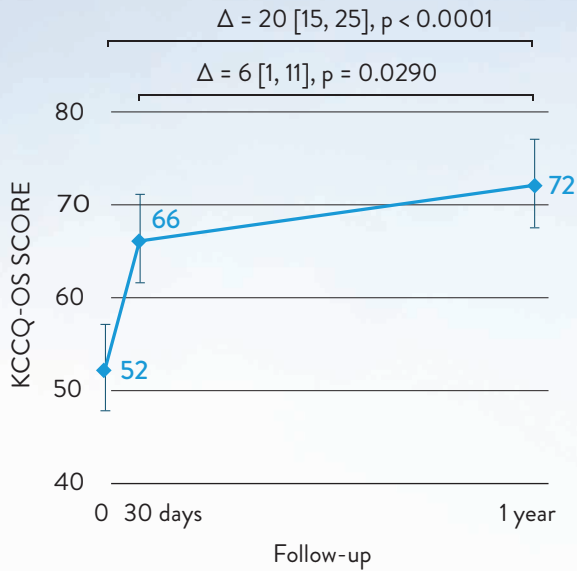


**83%**  
of patients were  
in NYHA  
Functional Class  
I/II at 1 year



## LIFE-CHANGING IMPROVEMENTS IN HEALTH-RELATED QUALITY OF LIFE

Self-assessed heart failure symptoms showed a significant improvement from baseline to 1 year, with 65% of subjects experiencing  $\geq 10$ -point improvement in KCCQ-OS score.

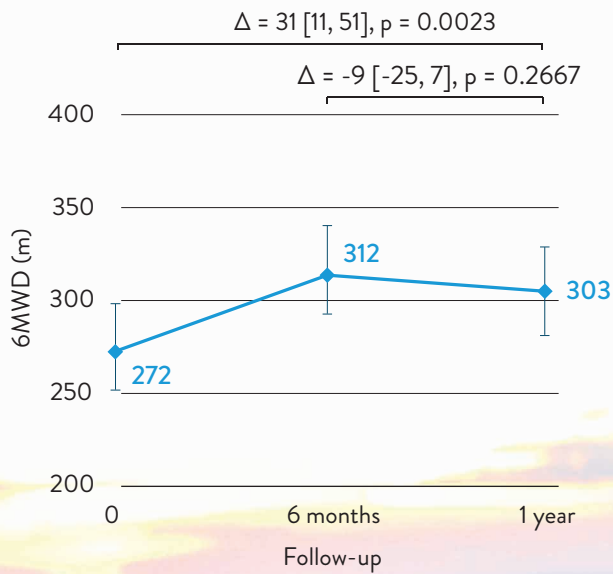


**20-POINT  
IMPROVEMENT  
AT 1 YEAR**

A 5-point improvement is considered clinically meaningful. MVARC recommends 10-point improvement for MR.

## INCREASE IN WALK DISTANCE

6MWD significantly increased from baseline to 1-year follow-up.



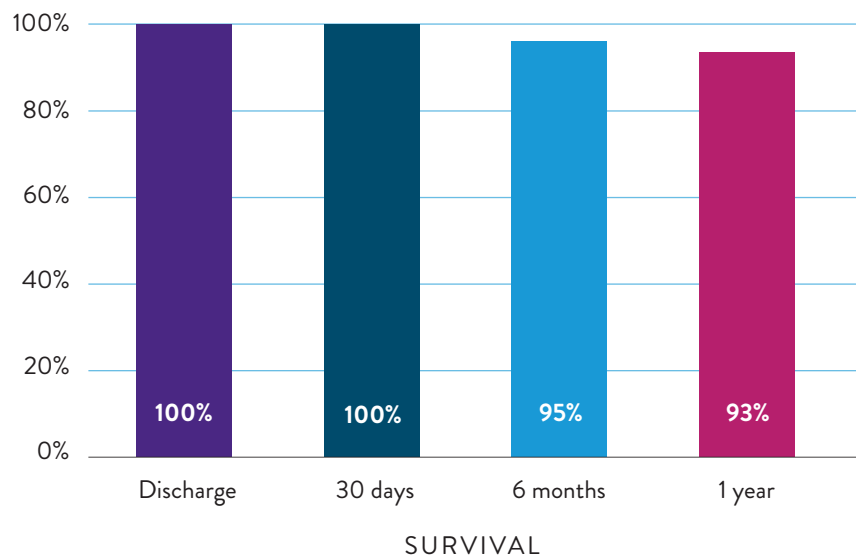
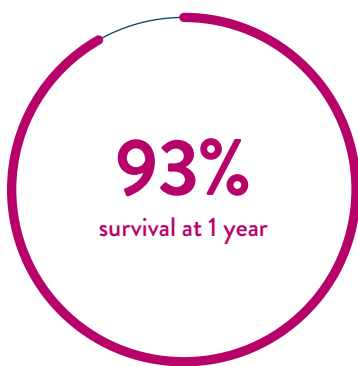
**31 METER**  
improvement in  
6MWD



# TRILUMINATE™ CLINICAL TRIAL DEMONSTRATES HIGH SAFETY PROFILE<sup>13</sup>

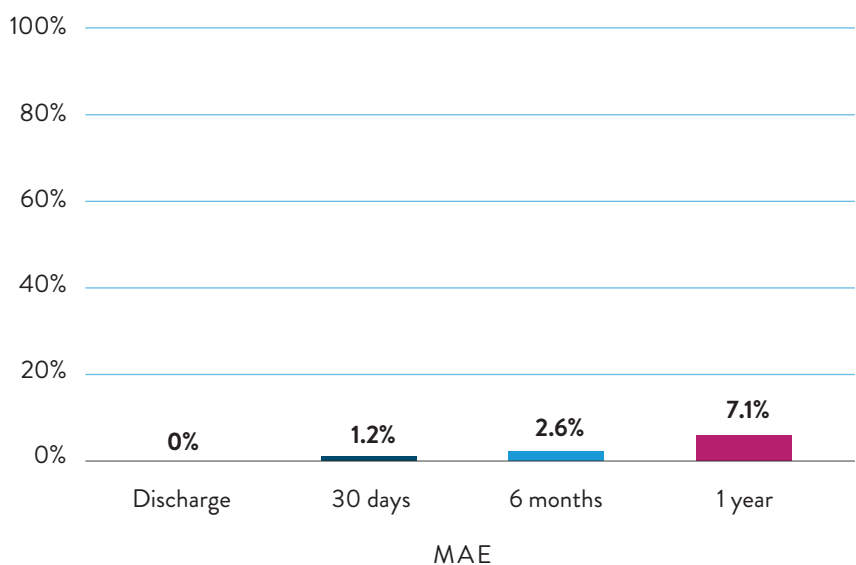
## HIGH SURVIVAL IN A FRAGILE PATIENT POPULATION

The TRILUMINATE™ Clinical Trial showed a 93% survival rate at 1 year following transcatheter tricuspid valve repair with TriClip™ Transcatheter Edge-to-Edge Repair.



## LOW RATES OF ADVERSE EVENTS

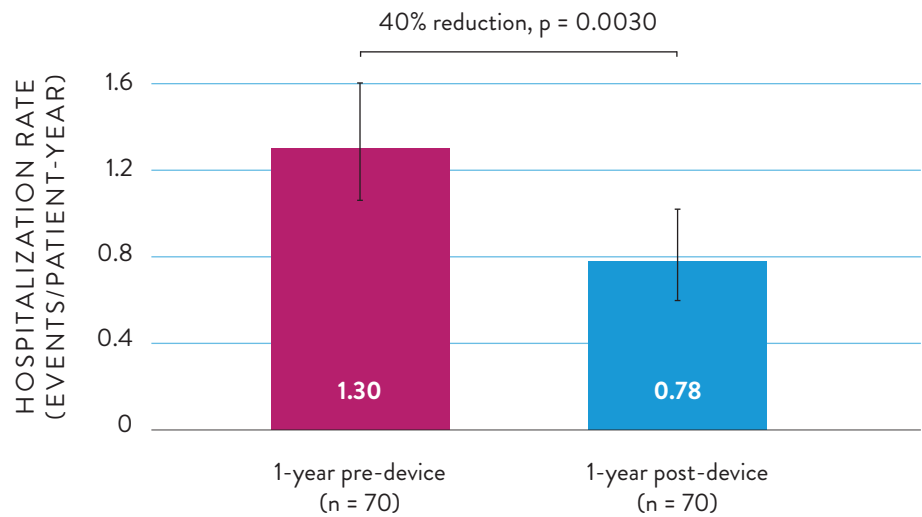
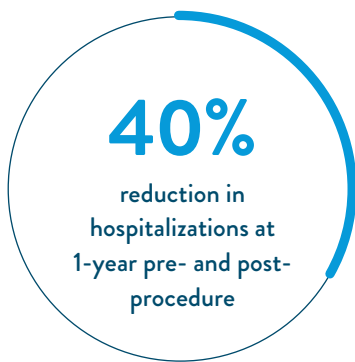
The TRILUMINATE Clinical Trial demonstrated low major adverse event rates of 7.1% at 1 year.



# PATIENTS SAW SIGNIFICANT REDUCTION IN HOSPITALIZATIONS<sup>13</sup>

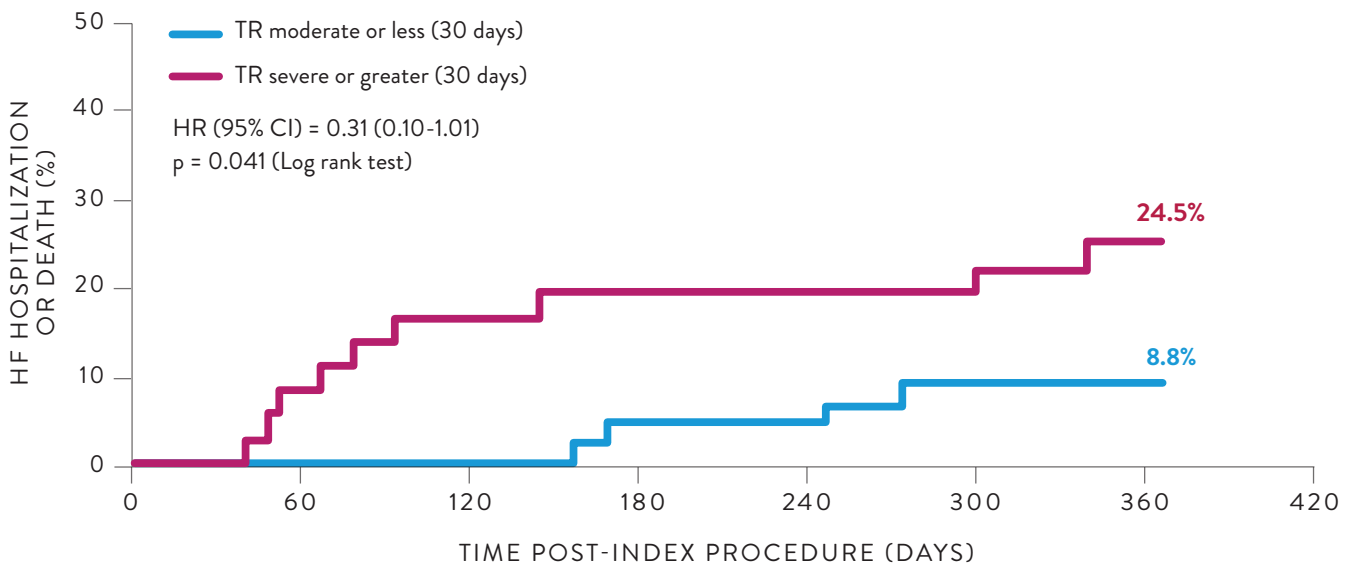
## REDUCED HOSPITALIZATION RATE

A 40% reduction in hospitalization rate was observed after TR reduction following TriClip™ Therapy.



## PROCEDURAL SUCCESS PREDICTIVE OF MORTALITY AND HEART FAILURE HOSPITALIZATIONS AT 1 YEAR

Reduction to moderate or less TR resulted in a three-fold decrease in mortality or heart failure hospitalizations at 1 year.



# INTENTIONALLY DESIGNED FOR TRICUSPID SUCCESS

The TriClip™ G4 Transcatheter Edge-to-Edge Repair System empowers you with stable navigation and precise delivery for complex conditions.



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# 100%

IMPLANT SUCCESS RATE

in the TRILUMINATE™  
Clinical Trial<sup>9</sup>

## CONSISTENTLY HIGH SAFETY AND PROCEDURAL SUCCESS RATES

0

Procedural  
deaths<sup>9</sup>

0

Procedural  
strokes<sup>9</sup>

0

Conversion to  
surgery<sup>9</sup>

90.5%

Acute procedural  
success rate<sup>9\*</sup>

0%

In-hospital  
mortality<sup>9</sup>

0%

Mortality at  
30 days<sup>9</sup>

# TRICLIP™ G4 TEER SYSTEM: A TREATMENT OPTION FOR PATIENTS AT HIGH RISK FOR SURGERY

- Transcatheter beating heart procedure – no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimize TR reduction
- Femoral venous access
- Can be used in a standard Cath Lab or hybrid room
- No pre-procedural CT required
- Fast recovery times; many patients go home the next day

## S/L KNOB

Enables movement in septal or lateral directions

## TRICLIP™ STEERABLE GUIDE CATHETER

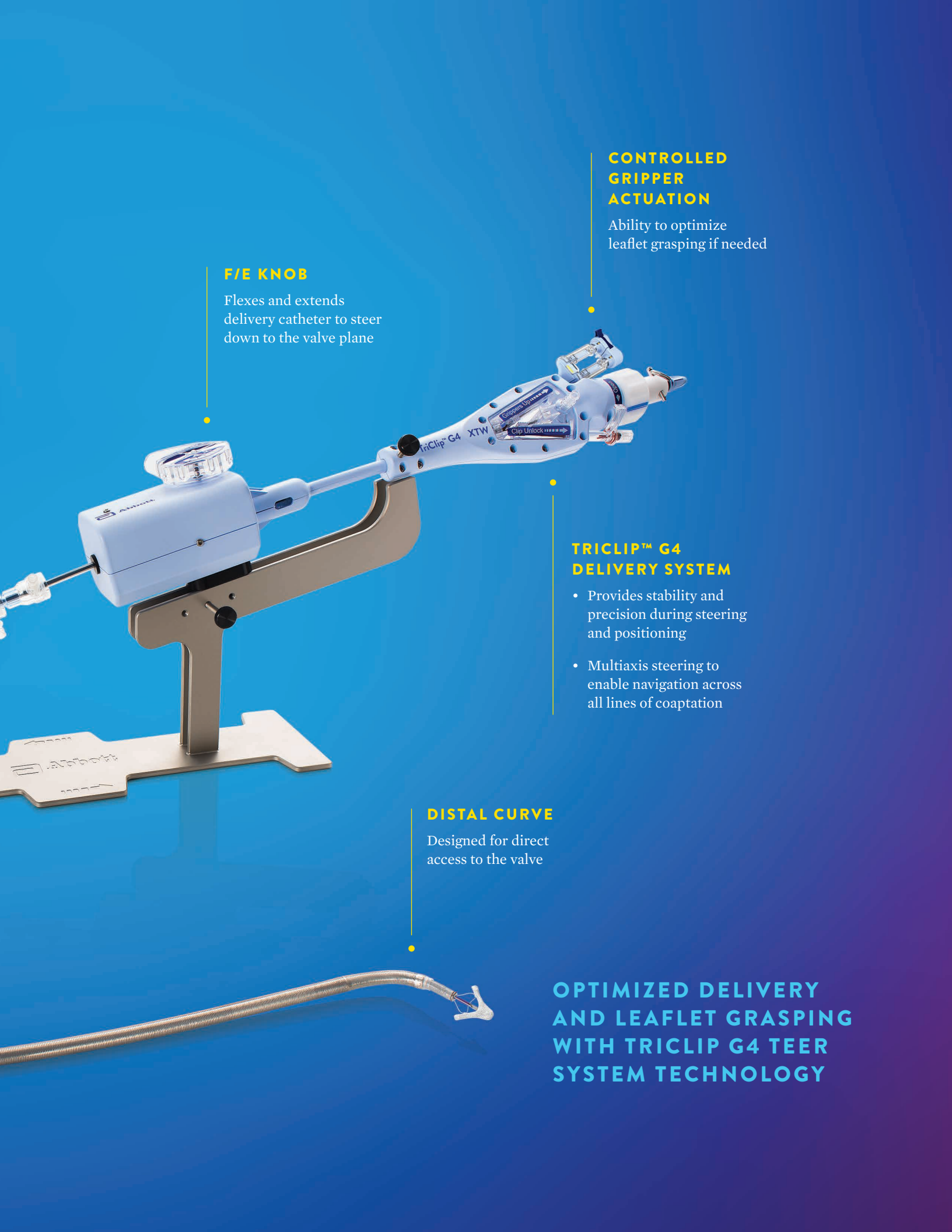
Designed for the right side

- Provides adequate height over the valve
- Enables physicians to maintain coaxial position during steering and positioning
- Allows sweeping away from the septum to optimize delivery catheter perpendicularity to the tricuspid valve

## +/- KNOB

Straightens and curves guide for height adjustment above the valve





**F/E KNOB**

Flexes and extends delivery catheter to steer down to the valve plane

**CONTROLLED GRIPPER ACTUATION**

Ability to optimize leaflet grasping if needed

**TRICLIP™ G4 DELIVERY SYSTEM**

- Provides stability and precision during steering and positioning
- Multiaxis steering to enable navigation across all lines of coaptation

**DISTAL CURVE**

Designed for direct access to the valve

**OPTIMIZED DELIVERY AND LEAFLET GRASPING WITH TRICLIP G4 TEER SYSTEM TECHNOLOGY**

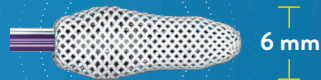
# BUILDING ON A LEGACY OF UNMATCHED TEER EXPERIENCE

**BROAD RANGE OF SIZES FOR TAILORED TREATMENT**

**G4 NT**

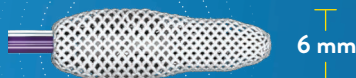


**G4 NTW**

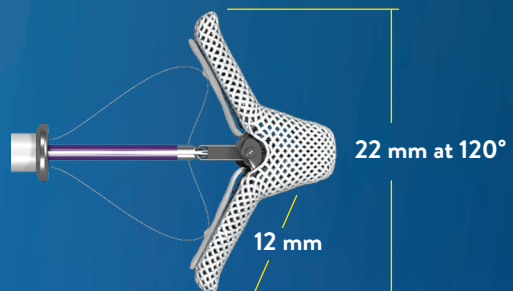
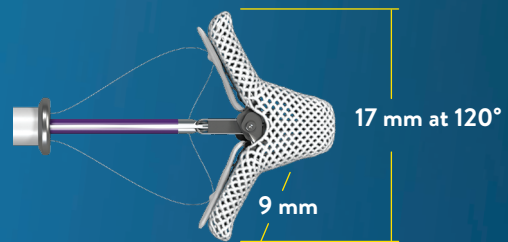


**50% WIDER**  
in the grasping area

**G4 XTW**



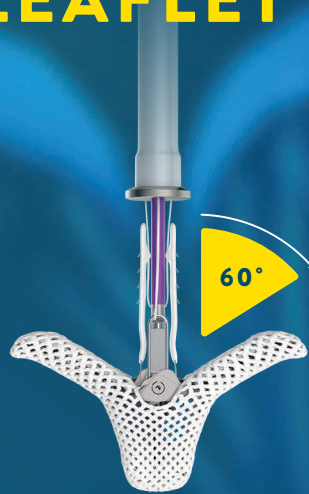
**G4 XT**



- Cobalt-chromium and nitinol construction
- Polyester cover designed to promote tissue growth
- All implants are safe under labeled MRI scanning conditions\*\*



# RELIABLE REDUCTION OF TR<sup>13</sup> EFFECTIVE LEAFLET CAPTURE<sup>15,16</sup>



## WIDE GRASPING OPENING

For optimizing the amount of leaflet tissue insertion while minimizing leaflet tension

## INTENTIONALLY DESIGNED FOR TRICUSPID SUCCESS

Retention forces distributed across the implant arms. Strong at the base and gentle at the tips



G4 NT

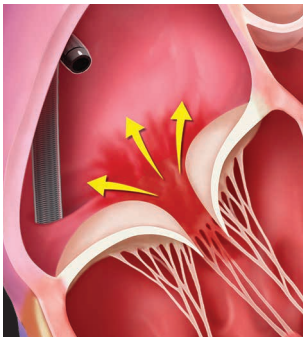
G4 NTW

G4 XT

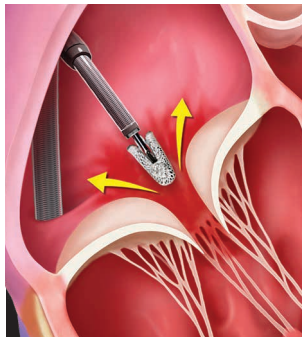
G4 XTW

# TRICLIP™ EDGE-TO-EDGE REPAIR A MINIMALLY INVASIVE PROCEDURE

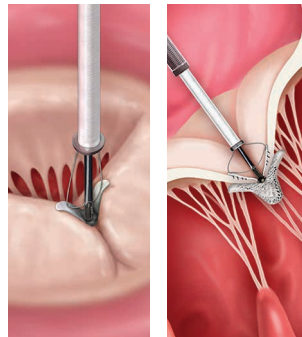
## TRICLIP™ TEER PROCEDURE STEPS



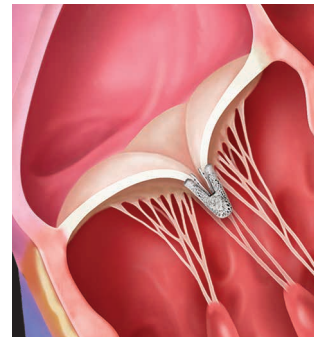
Guide insertion into RA



TriClip™ Delivery System insertion, positioning and steering in the RA



Crossing the valve and leaflet grasping

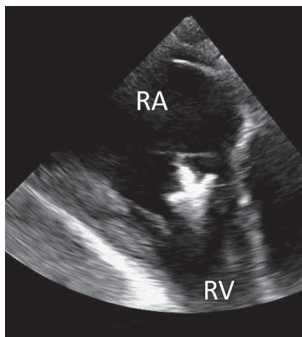


Clip deployed and system removed

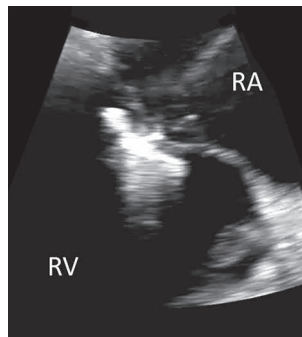
## IMAGING INVOLVED



- Long-axis
- RV inflow-outflow/ commissural view
- Four-chamber
- Bicaval
- Fluoroscopy



- Long-axis
- RV inflow-outflow/ commissural view
- Four-chamber
- Transgastric SAX
- 3D echo
- Fluoroscopy



- Long-axis
- RV inflow-outflow/ commissural view
- Four-chamber
- Transgastric SAX
- 3D echo
- Fluoroscopy



- Long-axis
- RV inflow-outflow/ commissural view
- Four-chamber
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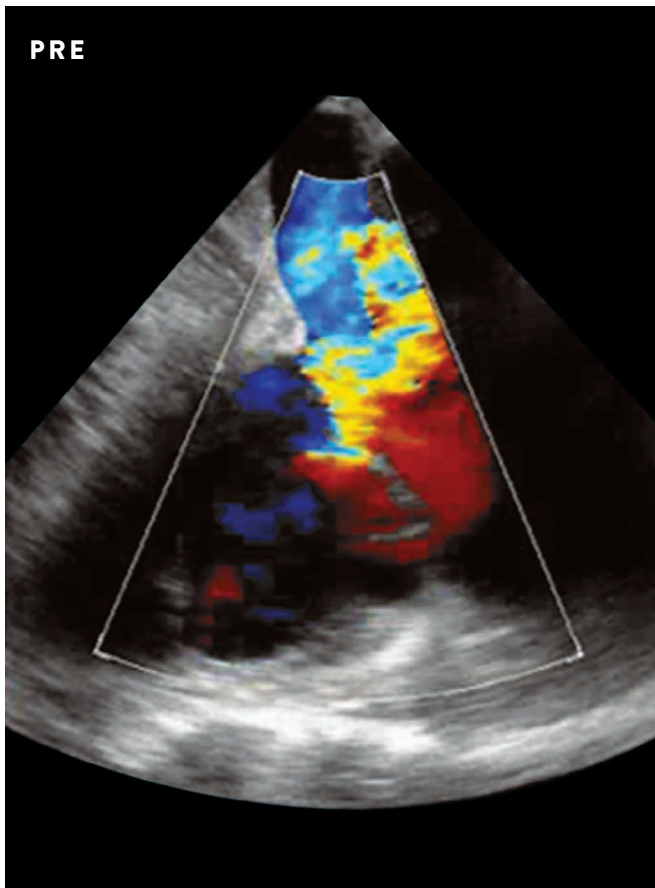
Images courtesy of Dr. Rebecca Hahn,  
Chief Scientific Officer, CRF Echo Core Lab

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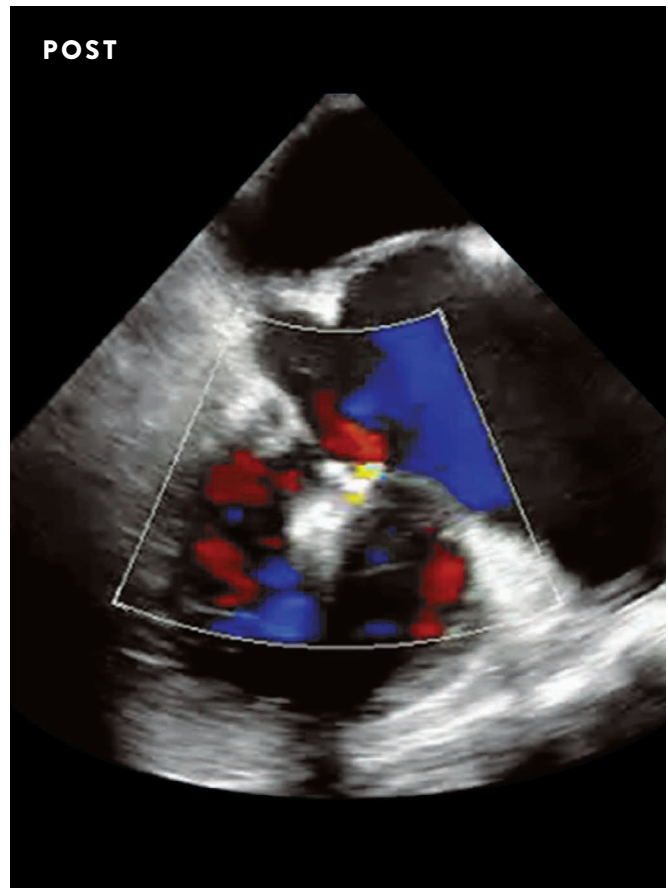
# RELIABLE REDUCTION OF TR<sup>13</sup>

## PRE- AND POST-TRICLIP™ THERAPY

TriClip™ Edge-to-Edge Repair\*\*\*



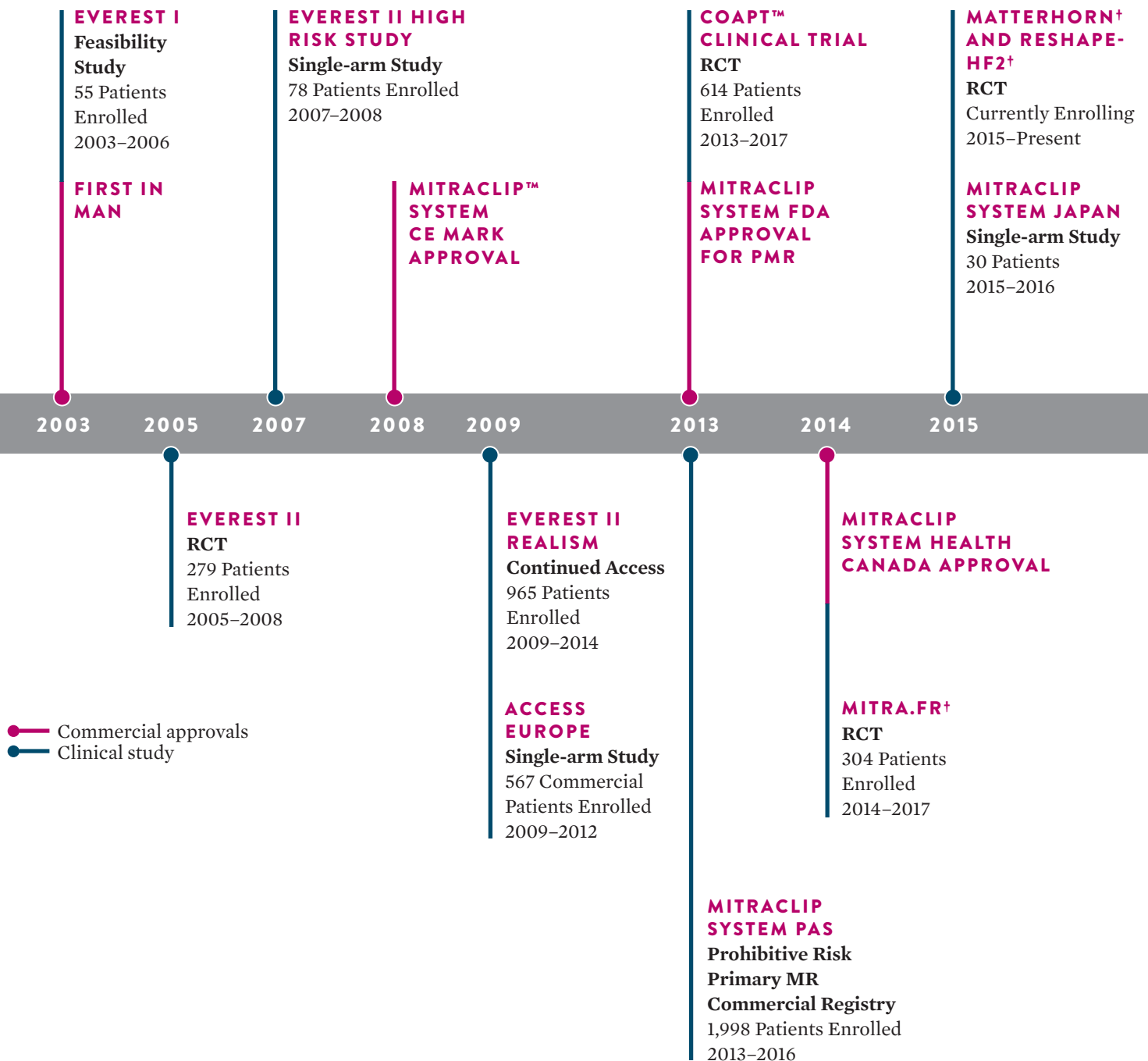
Baseline TR

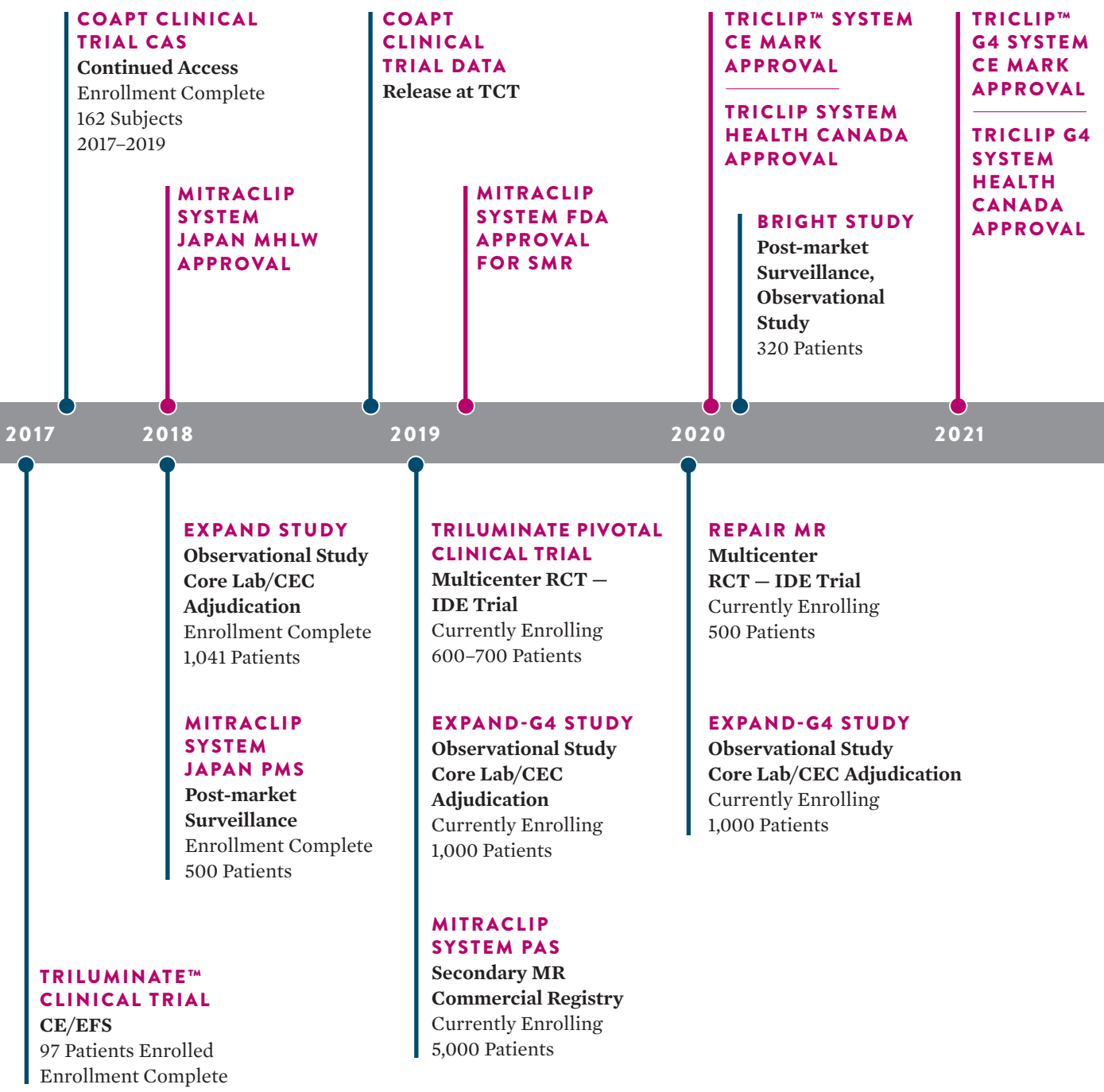


Visible TR reduction after TriClip™ TEER procedure

Images courtesy of Dr. Rebecca Hahn,  
Chief Scientific Officer, CRF Echo Core Lab

# ADVANCING MITRAL AND TRICUSPID THERAPY THROUGH UNMATCHED CLINICAL EVIDENCE





# ABBOTT'S ONGOING COMMITMENT TO TRANSCATHETER MITRAL AND TRICUSPID THERAPIES

**INNOVATION AND EVIDENCE<sup>17</sup>**



**16+ YEARS OF  
TRANSCATHETER  
CLINICAL AND IMAGING  
EXPERIENCE**



**OVER 100K MITRAL  
PATIENTS TREATED WITH  
MITRACLIP™ THERAPY  
WORLDWIDE**



**OVER 2,000  
TRICUSPID  
PATIENTS TREATED**



**OVER 2,050  
PUBLICATIONS**



**2 RCTS COMPLETED  
AND ONE UNDERWAY  
IN MITRAL AND 1 RCT  
UNDERWAY IN TRICUSPID**



**OVER \$250 MILLION  
INVESTED IN EVIDENCE**

# EXPERTISE TO ENABLE NEW THERAPY FOR PATIENTS

## SETTING THE STANDARD FOR EDUCATION AND SUPPORT

Abbott Structural Heart is dedicated to building transcatheter programs, supporting first-in-class therapies and providing imaging, screening and procedural training.

### THERAPY TRAINING AND CASE SUPPORT

- Physician peer-to-peer training programs covering every step from screening to procedure
- Dedicated on-site procedural support with best-in-class field representatives

### EDUCATION

- Multispecialty physician education
- Community-based physician training tools
- Patient education (where allowed)
- Therapy education to support peer-to-peer programs

<b>6MWD</b>	6-minute walk distance	<b>IDE</b>	investigational device exemption	<b>RV</b>	right ventricle
<b>CAS</b>	Continued Access Study	<b>KCCQ-OS</b>	Kansas City Cardiomyopathy Questionnaire Overall Summary	<b>RVEDD</b>	right ventricular end diastolic diameter
<b>CEC</b>	Clinical Event Committee	<b>LVEF</b>	left ventricular ejection fraction	<b>S/L</b>	septal/lateral
<b>CI</b>	confidence interval	<b>MAE</b>	major adverse event	<b>SAR</b>	specific absorption rate
<b>CRF</b>	Cardiovascular Research Foundation	<b>MR</b>	mitral regurgitation	<b>SAX</b>	short-axis
<b>CT</b>	computerized tomography	<b>MRI</b>	magnetic resonance imaging	<b>SMR</b>	secondary mitral regurgitation
<b>ECL</b>	Echocardiography Core Laboratory	<b>MVARC</b>	Mitral Valve Academic Research Consortium	<b>TA</b>	tricuspid annulus
<b>EF</b>	ejection fraction	<b>NYHA</b>	New York Heart Association	<b>TAPSE</b>	tricuspid annular plane systolic excursion
<b>EFS</b>	early feasibility study	<b>PAS</b>	post-approval study	<b>TCT</b>	Transcatheter Cardiovascular Therapeutics
<b>F/E</b>	flex/extend	<b>PMR</b>	primary mitral regurgitation	<b>TEER</b>	Transcatheter Edge-to-Edge Repair
<b>FTR</b>	functional tricuspid regurgitation	<b>PMS</b>	post-market study	<b>TR</b>	tricuspid regurgitation
<b>HF</b>	heart failure	<b>PPML</b>	posterior leaflet of the mitral valve	<b>TV</b>	tricuspid valve
<b>HFREF</b>	heart failure with reduced ejection fraction	<b>RA</b>	right atrium		
<b>HR</b>	hazard ratio	<b>RCT</b>	randomized controlled trial		

\*Successful delivery and deployment of the clip(s) with achievement of leaflet approximation(s) and retrieval of the delivery catheter. Acute Procedure Success: Successful implantation of the TVRS clip with at least 1 grade reduction in TR severity as determined by the ECL assessment of a discharge echocardiogram.

\*\*Nonclinical testing has demonstrated that the TriClip™ transcatheter tricuspid valve repair procedure implants are MR Conditional. A patient with this device can be safely scanned in a magnetic resonance (MR) system meeting the following conditions:

- Static magnetic field of 1.5 Tesla (1.5 T) or 3 Tesla (3.0 T)
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged SAR of 2 W/kg (normal operating mode)

\*\*\*The TriClip™ Implant was implanted successfully in all patients.

†Investigator-sponsored studies.

1. Enriquez-Sarano M, Messika-Zeitoun D, Topilsky Y, et al. Tricuspid regurgitation is a public health crisis [published online ahead of print November 9, 2019]. *Prog Cardiovasc Dis*. November-December 2019;62(6):447-451. doi:10.1016/j.pcad.2019.10.009.
2. Mills J, Furlong C; on behalf of Canaccord Genuity. Industry Overview: Uniquely qualified KOL opines on TAVR & TMVR; we remain bullish about prospects in both. November 8, 2016.
3. Millennium Research Group, Inc. *US Markets for Heart Valve Devices 2014*. RPUS12HV13. Toronto, Ontario; September 2013.
4. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. *Lancet*. 2006;368:1005-11. doi:10.1016/S0140-6736(06)69208-8.
5. Kilic A, Saha-Chaudhuri P, Rankin JS, Conte JV. Trends and Outcomes of Tricuspid Valve Surgery in North America: An Analysis of More Than 50,000 Patients From The Society of Thoracic Surgeons Database. *The Annals of Thoracic Surgery*. November 1, 2013;96(5):P1546-1552. doi:10.1016/j.athoracsur.2013.06.031.
6. Stuge O, Liddicoat J. Emerging opportunities for cardiac surgeons within structural heart disease. *J Thorac Cardiovasc Surg*. 2006;132:1258-61. doi:10.1016/j.jtcvs.2006.08.049.
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