



**TriClip™**  
Transcatheter  
Edge-to-Edge Repair

## REDUCING HEART FAILURE HOSPITALIZATION AND EMPOWERING PATIENTS TO LIVE THEIR BEST LIVES

### Objective

Evaluate the safety and effectiveness of tricuspid transcatheter edge-to-edge repair (TEER) with the TriClip™ TEER device in symptomatic patients, with severe tricuspid regurgitation, who are intermediate or greater estimated risk for morbidity with tricuspid valve surgery.

### Study Design

Prospective, randomized, multi-center, controlled clinical trial to compare TriClip™ TEER System vs. medical therapy.

### Primary Endpoint (1-Year)

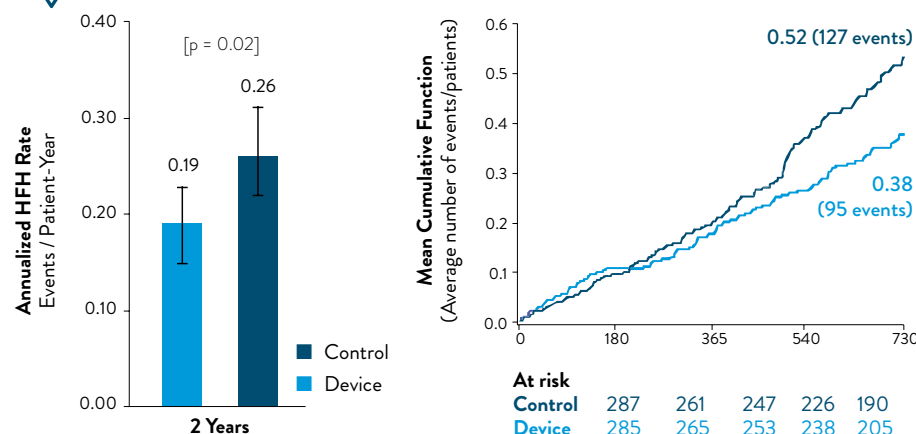
The primary end point was met: **TriClip™ TEER was superior to medical therapy**, primarily driven by improvements in KCCQ score.<sup>1</sup>

### Secondary Endpoints (2-Year)

- ✓ Heart failure hospitalization (HFH) reduced at 24 months in Device group ( $p=0.02$ )<sup>1</sup>
- ✓ Higher freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention at 24 months in Device group, driven by tricuspid valve intervention in the Control group ( $p<0.0001$ )<sup>1</sup>

### Significant Reduction in Heart Failure Hospitalization

**28% REDUCTION IN HFH AT 2 YEARS**  
compared to medical therapy alone<sup>1</sup>



### Sustained Improvements in Quality of Life

**15 POINT IMPROVEMENT IN KCCQ-OS SCORE AT 2 YEARS**  
compared to baseline<sup>1</sup>

**TRILUMINATE™**  
PIVOTAL TRIAL

RANDOMIZED  
CONTROLLED TRIAL  
2-YEAR RESULTS IN  
572 PATIENTS

“With the TRILUMINATE Pivotal two-year results, tricuspid transcatheter edge-to-edge repair with the TriClip device for severe, symptomatic tricuspid regurgitation reduced heart failure hospitalizations compared to the control group. Improvements in tricuspid regurgitation severity and quality of life were sustained through two years”\*

**Dr. Saibal Kar**

TRILUMINATE Pivotal Trial  
Study Investigator



For U.S. audience, see Important Safety Information referenced within.  
For audiences outside of the U.S.: always check the regulatory status of the device in your region.

# REDUCING HOSPITALIZATION AND EMPOWERING PATIENTS TO LIVE THEIR BEST LIVES

## TRILUMINATE™ Pivotal Trial: 2-year Follow-up, Randomized Data

### Device Patient Baseline Characteristics

**71%**

OF PATIENTS HAD  
MASSIVE OR  
TORRENTIAL TR<sup>2</sup>

**4.4±0.7cm**

TRICUSPID VALVE  
ANNULUS DIAMETER<sup>2</sup>

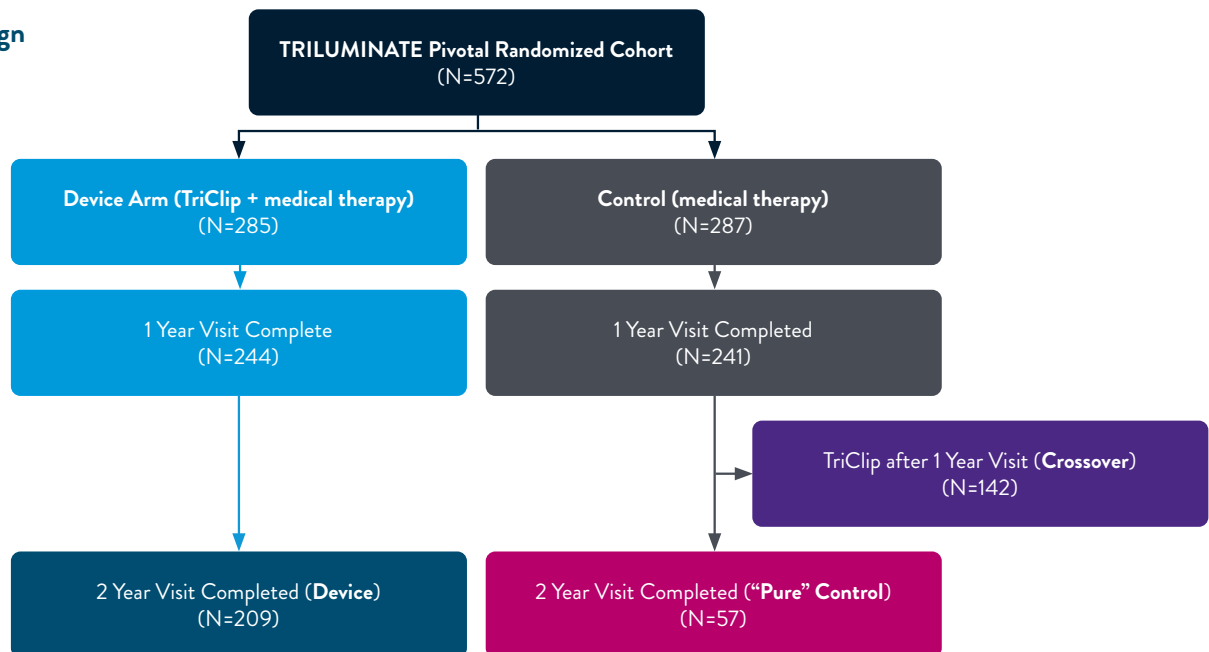
**>35%**

OF PATIENTS WITH  
PRIOR VALVULAR  
INTERVENTION<sup>2</sup>

**15%**

OF PATIENTS HAD A  
CRT, CRT-D, ICD, OR  
PERMANENT PACEMAKER<sup>2</sup>

### Study Design



### Crossover Patient Characteristics

- Of the 241 Control patients eligible for crossover after 1-year follow-up, **142 (59%) patients crossed over prior to 2-year follow-up<sup>1</sup>**
- 92% (130/142) of crossover procedures occurred within 6 months of the 1-year visit<sup>1</sup>
- Patients who crossed over were **more symptomatic with a higher prevalence of torrential TR and more HFH prior to crossover<sup>1</sup>**

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## Exceptionally Safe at 30 Days

**98.3%** FREEDOM FROM MAEs<sup>2</sup>

**0.6%** NEW PACEMAKER IMPLANTATION<sup>2</sup>

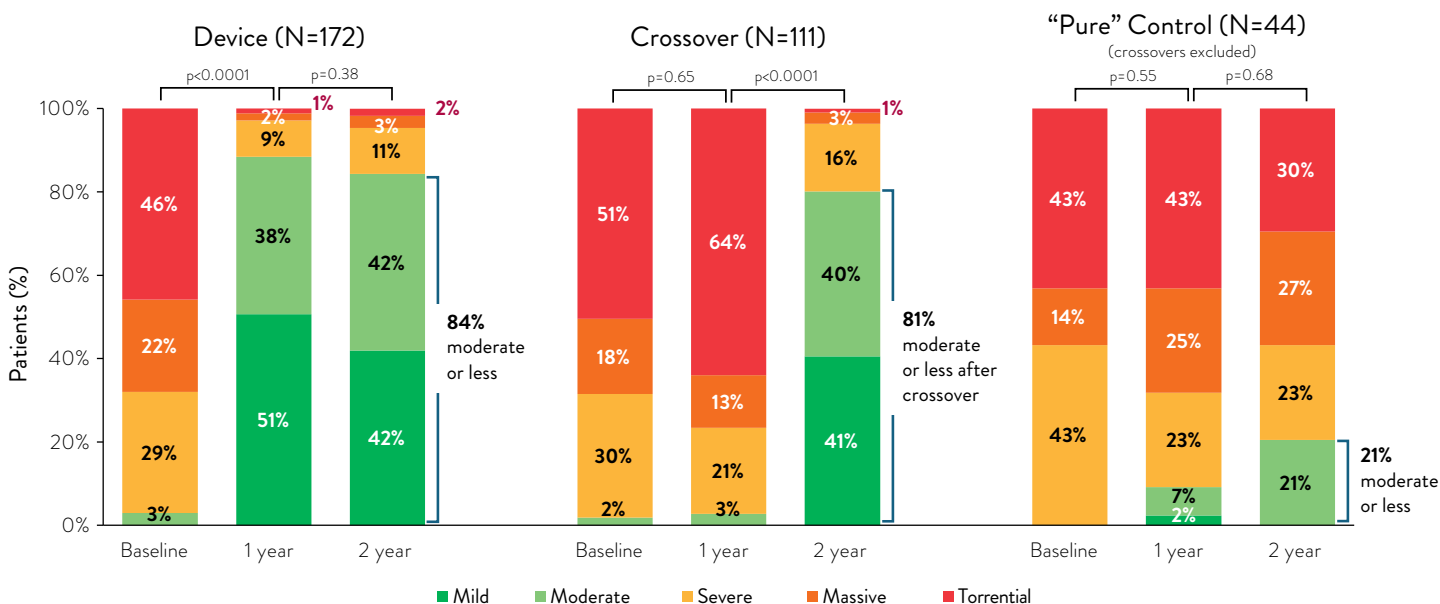
**0%** DEVICE THROMBUS<sup>2</sup>

**99.4%** SURVIVAL<sup>2</sup>

**0%** NONELECTIVE CV SURGERY FROM DEVICE-RELATED AE<sup>2</sup>

**0%** DEVICE EMBOLIZATION<sup>2</sup>

## Remarkable and Sustained TR Reduction in Patients Treated with TriClip at 1 and 2 years<sup>1</sup>



AE = adverse events

CV = cardiovascular

KCCQ-OS = Kansas City Cardiomyopathy Questionnaire Overall Summary

MAE = major adverse event

TEER = transcatheter edge-to-edge repair

TR = tricuspid regurgitation

1. Kar, S., et al. Two-year Outcomes of Transcatheter Edge-to-edge Repair for Severe Tricuspid Regurgitation: The TRILUMINATE Pivotal Randomized Trial. *Circulation*. March 30, 2025. doi:10.1161/CIRCULATIONAHA.125.000000

2. Tang GHL, Hahn RT, Whisenant BK, et al. Tricuspid Transcatheter Edge-to-Edge Repair for Severe Tricuspid Regurgitation: 1-Year Outcomes From the TRILUMINATE Randomized Cohort. *J Am Coll Cardiol*. 2025;85(3):235-246. doi:10.1016/j.jacc.2024.10.086

## For U.S. audience only.

### Rx Only

### Important Safety Information

### TRICLIP™ G4 SYSTEM

#### INDICATIONS

The TriClip™ G4 System is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.

#### CONTRAINDICATIONS

The TriClip G4 System is contraindicated in patients with the following conditions: Intolerance, including allergy or untreatable hypersensitivity, to procedural anticoagulation; Untreatable hypersensitivity to Implant components (nickel-titanium alloy, cobalt-chromium alloy); Active endocarditis or other active infection of the tricuspid valve.

#### POTENTIAL ADVERSE EVENTS

The following events have been identified as possible complications of the TriClip G4 Procedure. Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials and drug reactions to anticoagulation, or antiplatelet drugs; Additional treatment/surgery from device-related complications; Bleeding; Blood disorders (including coagulopathy, hemolysis, and heparin induced thrombocytopenia (HIT)); Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, unstable angina, and stable angina); Cardiac perforation; Cardiac tamponade; Chest pain; Death; Dyspnea; Edema; Embolization (device or components of the device); Endocarditis; Fever or hyperthermia; Fluoroscopy and transesophageal echocardiogram (TEE) related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation, Esophageal perforation, Gastrointestinal bleeding; Hypotension/hypertension; Infection including: Septicemia; Nausea or vomiting; Pain; Pericardial effusion; Stroke/cerebrovascular accident (CVA) and transient ischemic attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction or failure or atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Thrombosis; Tricuspid valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement/rupture, Single leaflet device attachment (SLDA), Dislodgement of previously implanted devices, Tissue damage, Tricuspid valve stenosis, Worsening, persistent or residual regurgitation; Vascular access complications which may require additional intervention, including: Wound dehiscence, Bleeding of the access site, Arteriovenous fistula pseudoaneurysm, aneurysm, dissection, perforation (rupture), vascular occlusion, Embolism (air, thrombus), Peripheral nerve injury; Venous thrombosis (including deep vein thrombosis) and thromboembolism (including pulmonary embolism).

CAUTION: Product(s) intended for use by or under the direction of a physician. Prior to use, reference to the Instructions for Use, inside the product carton (when available) or at [www.eifu.abbott](http://www.eifu.abbott) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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\*The testimonial does not provide any indication, guide, warranty or guarantee as to the response patients may have to the treatment or effectiveness of the product or therapy in discussion. Opinions about the treatment discussed can and do vary and are specific to the individual's experience and might not be representative of others.

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