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 for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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.

*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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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

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)

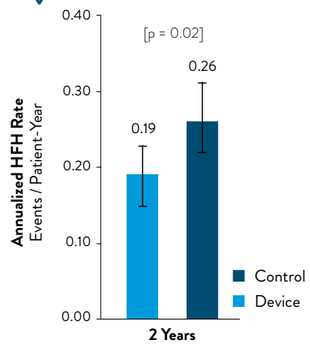
The primary end point was met: **TriClip™ TEER was superior to medical therapy,** primarily driven by improvements in KCCQ score.[1]

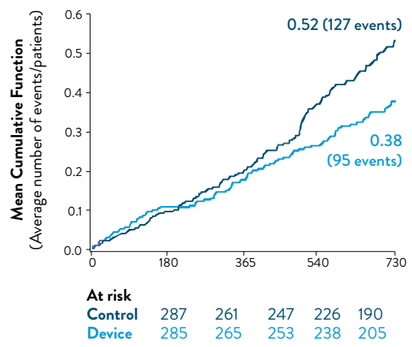
Secondary Endpoints (2-Year)

- ✓ Heart failure hospitalization (HFH) reduced at 24 months in Device group (p=0.02)[1]
- ✓ 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)[1]

Significant Reduction in Heart Failure Hospitalization

28% REDUCTION IN HFH AT 2 YEARS
compared to medical therapy alone[1]





Sustained Improvements in Quality of Life

15 POINT IMPROVEMENT IN KCCQ-OS SCORE AT 2 YEARS
compared to baseline[1]

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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[2]

4.4±0.7cm
TRICUSPID VALVE ANNULUS DIAMETER[2]

>35%
OF PATIENTS WITH PRIOR VALVULAR INTERVENTION[2]

15%
OF PATIENTS HAD A CRT, CRT-D, ICD, OR PERMANENT PACEMAKER[2]

Exceptionally Safe at 30 Days

98.3% FREEDOM FROM MAEs[2]

99.4% SURVIVAL[2]

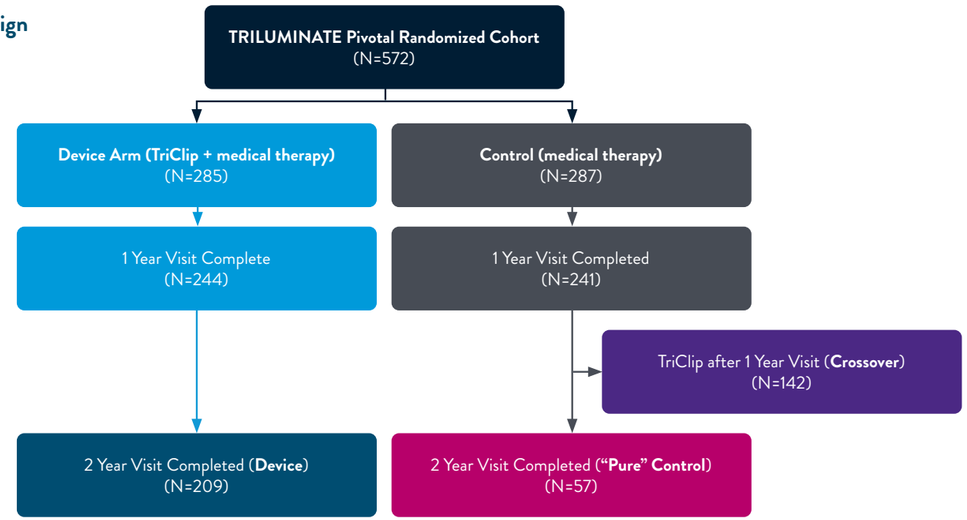
0.6% NEW PACEMAKER IMPLANTATION[2]

0% NONELECTIVE CV SURGERY FROM DEVICE-RELATED AE[2]

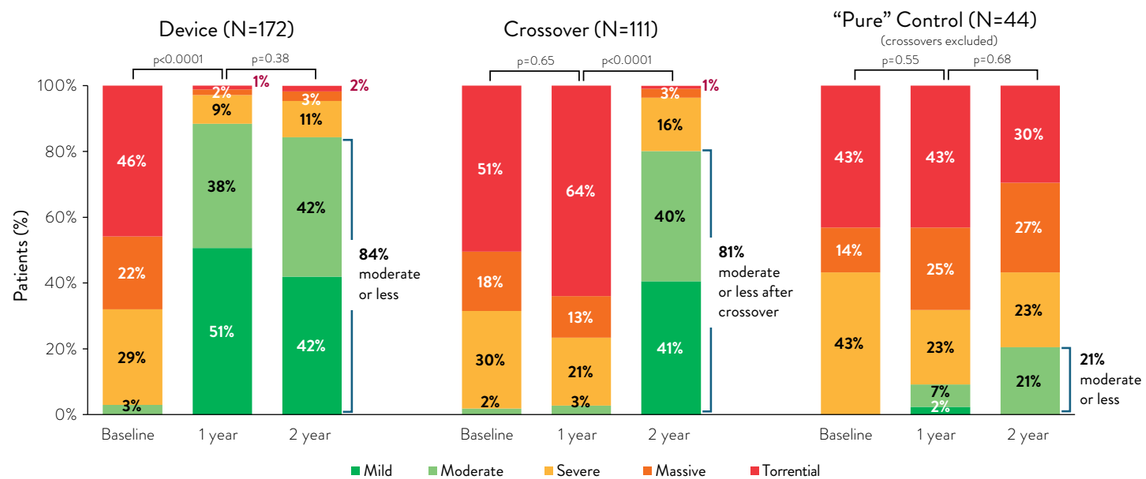
0% DEVICE THROMBUS[2]

0% DEVICE EMBOLIZATION[2]

Study Design



Remarkable and Sustained TR Reduction in Patients Treated with TriClip at 1 and 2 years[1]



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**[1]
- 92% (130/142) of crossover procedures occurred within 6 months of the 1-year visit[1]
- Patients who crossed over were **more symptomatic with a higher prevalence of torrential TR and more HFH prior to crossover**[1]

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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