Abbott

TriClip™
Transcatheter
Edge-to-Edge Repair

IMPROVING QUALITY OF LIFE WITHOUT COMPROMISE[1]

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.**

Baseline

Mean Age	KCCQ-OS Mean Age
78.0 ± 7.3 Years	**55.0** ± 24 Points

Primary Endpoint

The primary end point was met: **TriClip™ TEER was superior to medical therapy,** primarily driven by improvements in KCCQ score. Hospitalization for heart failure and morbidity rates were very low, and comparable between the two arms.

TRILUMINATE™
PIVOTAL TRIAL

RANDOMIZED
CONTROLLED TRIAL
1-YEAR RESULTS IN
350 PATIENTS

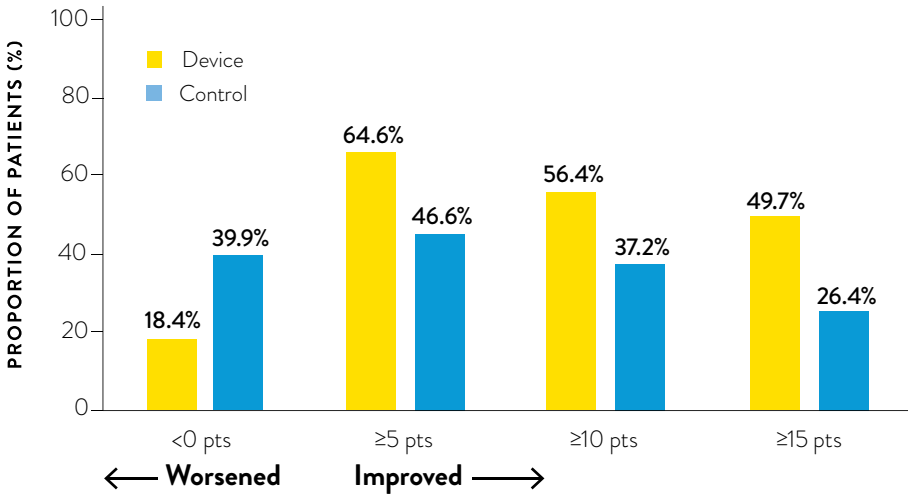
"What this trial has shown is that we have an **incredibly effective and safe therapy that improves quality of life**. This is what patients want."*

Dr. Paul Sorajja
TRILUMINATE Pivotal Trial
Principal Investigator

Quality of Life Improvements, Baseline to 1 Year

15 POINTS

49.7% of patients in the device group experienced ≥15 points improvement in KCCQ-OS health-related quality of life.



See Important Safety Information referenced within.

IMPROVING QUALITY OF LIFE WITHOUT COMPROMISE[1]

TRILUMINATE™ Pivotal Trial: 1-year Follow-up, Randomized Data

Patient Baseline Characteristics

71%
OF PATIENTS HAD MASSIVE OR TORRENTIAL TR

4.4±0.7cm
TRICUSPID VALVE ANNULUS DIAMETER

>35%
OF PATIENTS WITH PRIOR VALVULAR INTERVENTION

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

Extremely Safe at 30 Days

98.3% FREEDOM FROM MAEs

99.4% SURVIVAL

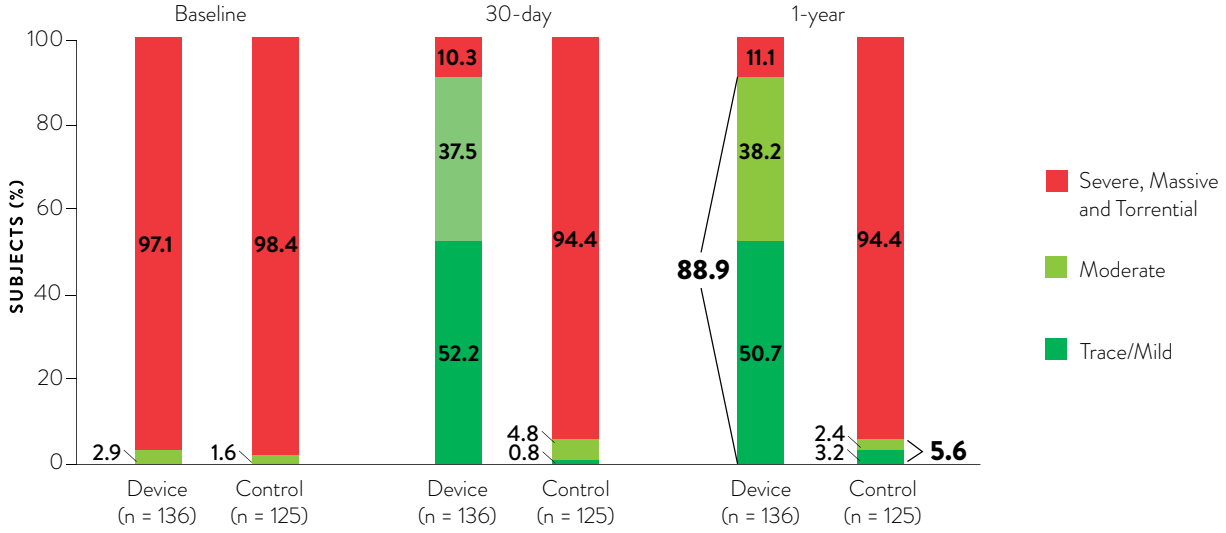
0.6% NEW PACEMAKER IMPLANTATION

0% NONELECTIVE CV SURGERY FROM DEVICE-RELATED AE

0% DEVICE THROMBUS

0% DEVICE EMBOLIZATION

Remarkable and Sustained TR Reduction



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. Sorajja P, Whisenant B, Hamid N, et al. TRILUMINATE Pivotal: A Landmark Randomized Clinical Trial of Transcatheter Tricuspid Valve Edge-to-Edge Repair For Tricuspid Regurgitation." Presented at ACC; March 4, 2023; New Orleans, LA; USA.

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).

*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.

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 https://www.eifu.abbott/ for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902

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