Abbott

TRILUMINATE CLINICAL TRIAL

Scan to learn more about TriClip™ TEER System

"There was no real treatment option for patients with tricuspid regurgitation. TRILUMINATE™ was the first [TEER] study to really look thoroughly at a treatment option with a device ... the data is extremely valid and reproducible."

Dr. Georg Nickenig
TRILUMINATE Principal Investigator

Significant Improvements in NYHA Functional Class[2]

82%
of patients in NYHA Functional Class I/II at 3 years vs. 24% at baseline[2]

Consistently High Rates of Success[1]

100%
implant success rate[1]

TriClip™
Transcatheter Edge-to-Edge Repair

STUDY DESIGN

The TRILUMINATE™ Clinical Trial was a **prospective, single-arm, multicenter study,** including **85 patients** and conducted at **21 sites** in the United States and Europe, with **independent core lab adjudication.**[1]

Mean Age
77.8
± 7.9 Years[1]

NYHA
75%
Functional Class III/IV[1]

8.7%
± 10.7%
EuroSCORE II[1]

63%
had TR Massive or Torrential at baseline

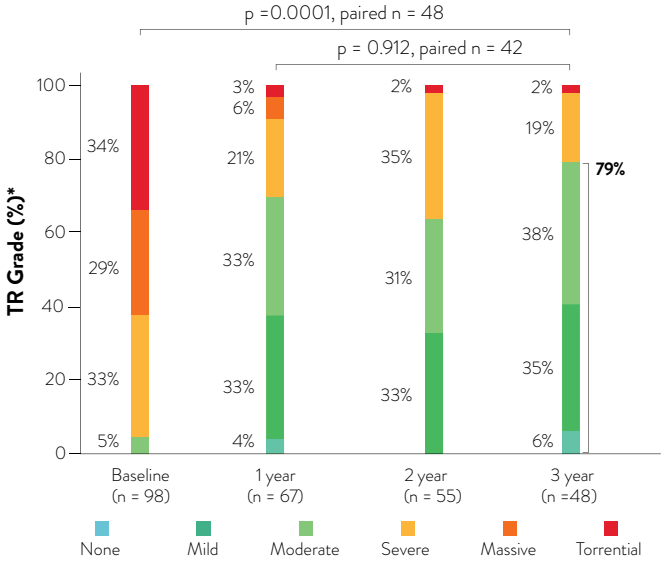
Studied in a fragile, high-surgical risk patient population[2]

Primary Safety and Efficacy

79%
of patients with TR moderate or less at 3 years[2]

99%
freedom from MAEs at 30 days[1]

Significant, Sustained TR Reduction[2]



TR reduction achieved at 1 year is durable through 3 years

A Safe Procedure[1]

0%
Stroke at 30 days

0%
Non-Elective Cardiovascular Surgery for Device-Related AE at 30 days

0%
Embolization*

See Important Safety Information referenced within.

MEANINGFUL OUTCOMES BACKED BY ROBUST EVIDENCE

Life-changing Improvements in Quality of Life and Function

≥10 POINT

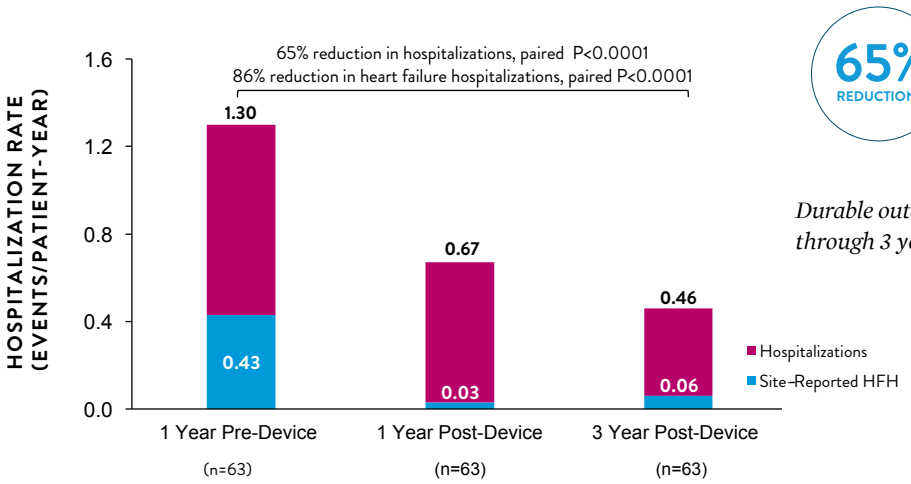
KCCQ-OS SCORE IMPROVEMENT WAS OBSERVED IN 50% OF SUBJECTS AT 3 YEARS[2]

31 METER

IMPROVEMENT IN 6MWD AT 1 YEAR[3]

Cruz, TriClip™ TEER Patient
3 years after the TRILUMINATE™ Clinical Trial

TriClip™ TEER Continues to Reduce Hospitalizations[2]



65% REDUCTION

Durable outcomes through 3 years[2]

> "The progress after the intervention was impressive because by the second day, my mother was already out."*
>
> **Cruz's son**

> "[My] heart is doing well ... [I] go grocery shopping, on little walks, take care of the chores, cook ... a normal life."**
>
> **Cruz**

6MWD = six-minute walk distance
KCCQ-OS = Kansas City Cardiomyopathy Questionnaire overall summary
MAE = major adverse event
NYHA = New York Heart Association
SLDA = single-leaflet device attachment
TEER = transcatheter edge-to-edge repair
TR = tricuspid regurgitation

*Data available at 1 year.

**Among patients with moderate or less TR.

References:

1. Nickenig G, Weber M, Lurz P, et al. Transcatheter edge-to-edge repair for reduction of tricuspid regurgitation: 6-month outcomes of the TRILUMINATE single-arm study. *The Lancet*. 2019;394(10213):2002-2011.
2. Nickenig, G. Percutaneous edge-to-edge repair for tricuspid regurgitation: 3-year outcomes from the TRILUMINATE trial. Presented at PCR London Valves; November 19, 2023.
3. Lurz P, Stephan von Bardeleben R, Weber M, et al. Transcatheter Edge-to-Edge Repair for Treatment of Tricuspid Regurgitation. *J Am Coll Cardiol*. 2021 Jan 26;77(3):229-239.

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.

**This testimonial relates an account of an individual's response to the treatment. This patient's account is genuine, typical and documented. However, it does not provide any indication, guide, warranty or guarantee as to the response other persons may have to the treatment. Responses to the treatment discussed can and do vary and are specific to the individual patient.

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.

Photo on file at Abbott.

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