Abbott

TriClip™
Transcatheter
Edge-to-Edge Repair

bRIGHT STUDY 1-YEAR DATA[1]

Objective
Evaluating the safety and effectiveness of TriClip™ TEER in patients with severe TR in a real-world, post-market setting.

Study Design
Prospective, single-arm, multicenter registry (minimum **500** subjects at approximately **30** sites in Europe).

Mean Age	NYHA
78 ± 8 Years	**81%** Functional Class III/IV

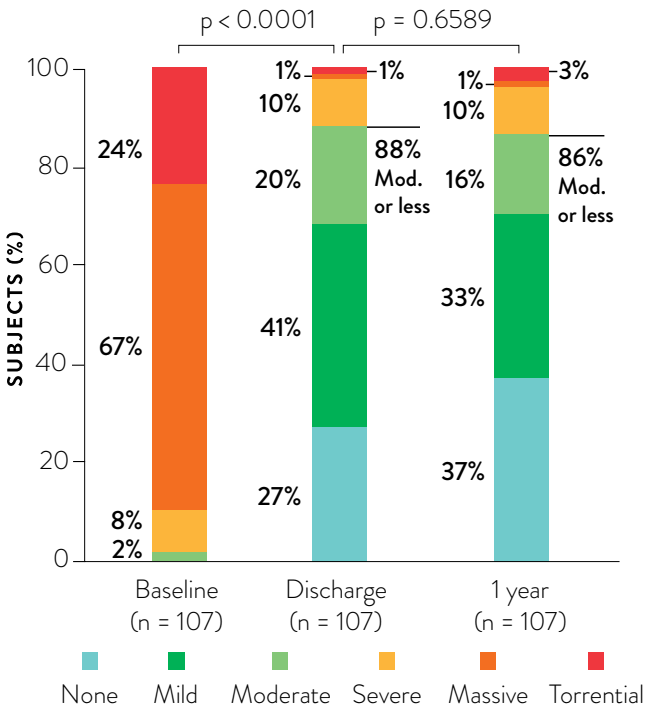
Studied in an elderly, fragile, real-world patient population

bRIGHT STUDY
REAL-WORLD REGISTRY

"We see very **short learning curves** and the ability to adopt the therapy **safely and effectively.** We see a **great safety profile** and confirm the previous effectiveness results of the TRILUMINATE trial. ... It's confirmed looking at much more centers and **reflecting real-world practice.**"*

Prof. Dr. Philipp Lurz
bRIGHT Principal Investigator

TR GRADE (CORE LAB)[1]



TR moderate or less at 1 year

See Important Safety Information referenced within.

PROVEN IN THE LARGEST BODY OF REAL-WORLD EVIDENCE TO DATE[1,2]

bRIGHT Study 30-day Procedural Data[3]

High rates of success across diverse patient anatomies

2.5–7.6 cm
RANGE OF ANNULAR DIAMETERS

2.6–20.8 mm
MEASURED GAP SIZES

21%
OF PATIENTS WITH > 3 LEAFLETS

19%
OF PATIENTS HAD A PACEMAKER LEAD

High Procedural Success

98% IMPLANT SUCCESS RATE

Short Device Time

78 ± 41 AVERAGE DEVICE TIME (MINUTES)

High Safety Profile at 30 Days

99% FREEDOM FROM MAES

99.7% SURVIVAL

0.3% NONELECTIVE CV SURGERY, TVRS DEVICE-RELATED AE

0% EMBOLIZATION

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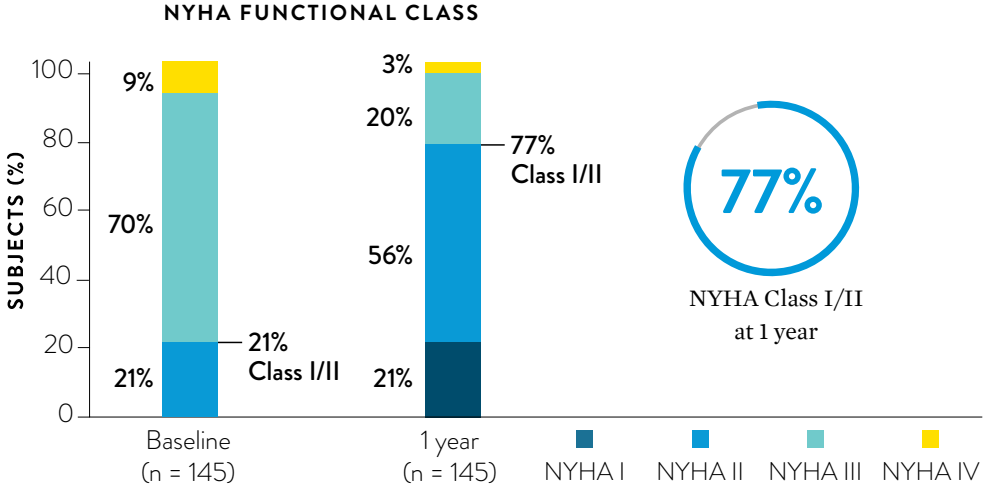
bRIGHT Study Life-changing Outcomes at 1-year[1]



NYHA Class I/II at 1 year

21 POINTS
significant improvement in KCCQ-OS health-related quality of life

AE = adverse event
CV = cardiovascular
MAE = major adverse event
NYHA = New York Heart Association
TEER = transcatheter edge-to-edge repair
TR = tricuspid regurgitation
KCCQ-OS = Kansas City Cardiomyopathy Questionnaire Overall Summary Score

1. Lurz P, Schmitz T, Bekeredjian R, et al. Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 1 Year Outcomes from the bRIGHT trial. Presented at PCR London Valves; November 27-29, 2022; London, England.
2. ClinicalTrials.gov. Find a Study. Accessed November 12, 2021. https://clinicaltrials.gov/study/NCT04483089?term=TriClip&rank=1
3. Lurz P, Lapp H, Schueler R, et al. Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 30-Day Results from the TriClip™ bRIGHT Study. Presented at: EuroPCR; May 17-18, 2022; Paris, France.

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.

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