

TRILUMINATE CLINICAL TRIAL

TriClip™
Transcatheter
Edge-to-Edge Repair



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.”

Georg Nickenig

M.D., TRILUMINATE
Principal Investigator

Significant Improvements in NYHA Functional Class³

83%

of patients in NYHA
Functional Class I/II at
1 year vs. 31% at baseline²

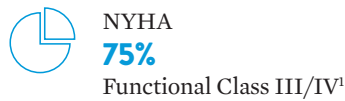
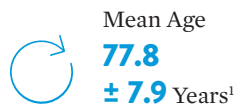
Consistently High Rates of Success¹

100%

implant
success rate¹

STUDY DESIGN

The TRILUMINATE™ Clinical Trial was published by *The Lancet* for its scientifically sound **safety** and **performance** endpoints. This 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



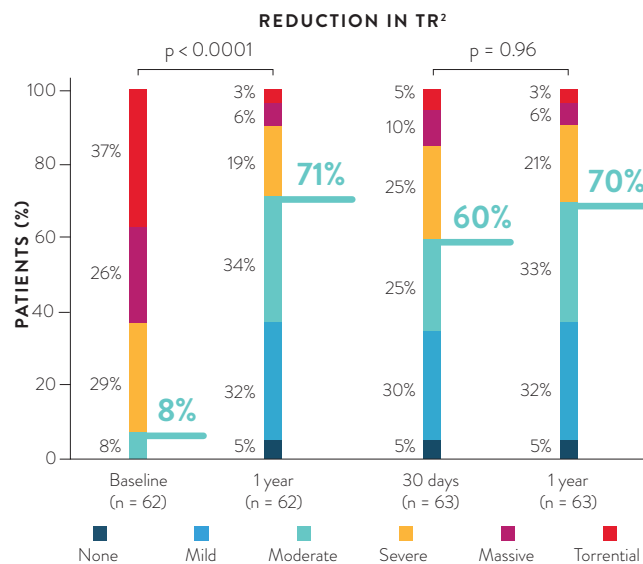
*Studied in a fragile,
high-surgical risk
patient population²*

Primary Safety and Efficacy Endpoints Met

86%
of patients with
TR reduction of ≥ 1
grade at 30 days¹

94%
freedom from MAEs
at 6 months¹

Significant, Sustained TR Reduction²



87%
TR reduction of
≥ 1 grade at 1 year²

70%
TR reduction to
moderate or less
at 1 year vs. 8%
at baseline²

*Durable outcomes
through 2 years³*

A Safe Procedure²

93%
survival at 1 year in
a fragile population at
high surgical risk

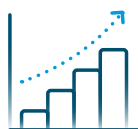
7.7%
SLDA rate*

0%
embolization*

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MEANINGFUL OUTCOMES BACKED BY ROBUST EVIDENCE

Life-changing Improvements in Quality of Life and Function²

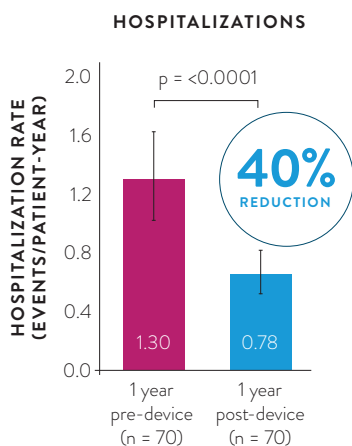


**20-POINTS KCCQ-OS
IMPROVEMENT IN
HEALTH-RELATED
QUALITY OF LIFE
AT 1 YEAR**

31 METER

improvement in
6MWD at 1 year³

TriClip™ TEER Continues to Reduce Hospitalizations²



*Durable outcomes
through 2 years³*

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.

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. 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.

3. Von Bardeleben RS, Lurz P, Sitges M, et al. Percutaneous edge-to-edge repair for tricuspid regurgitation: 2-year outcomes from the TRILUMINATE trial. Presented at: EuroPCR; 2021.

*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: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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Cruz, TriClip™ TEER Patient

3 years after the
TRILUMINATE™ Clinical Trial

“

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*

