



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 Class²

82%

of patients in NYHA
Functional Class I/II
at 3 years vs. 24%
at baseline²

Consistently High Rates of Success¹

100%

implant
success rate¹

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 Years¹

8.7%
 $\pm 10.7%$

EuroSCORE II¹

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

NYHA
75%
Functional Class III/IV¹

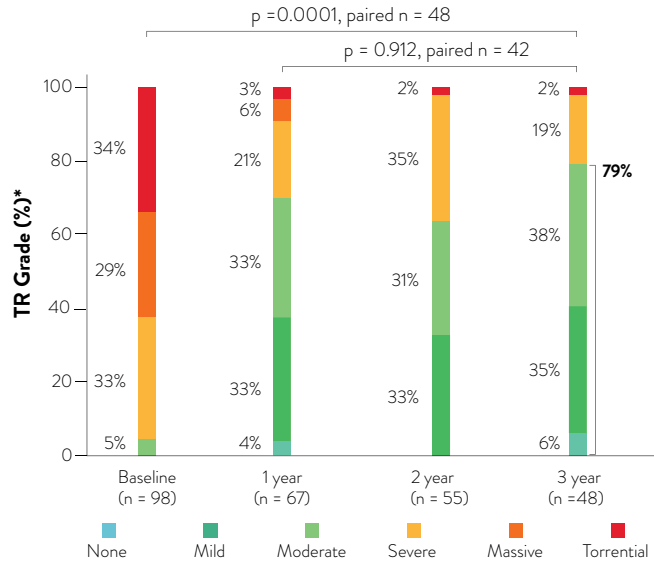
63%
had TR Massive or
Torrential at baseline

Primary Safety and Efficacy

79%
of patients with TR
moderate or less at 3
years²

99%
freedom from MAEs
at 30 days¹

Significant, Sustained TR Reduction²



TR reduction achieved
at 1 year is durable
through 3 years

A Safe Procedure¹

0%
Stroke at 30 days

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

0%
Embolization*

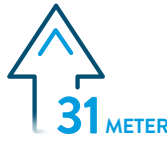
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MEANINGFUL OUTCOMES BACKED BY ROBUST EVIDENCE

Life-changing Improvements in Quality of Life and Function



≥10 POINT
KCCQ-OS SCORE IMPROVEMENT
WAS OBSERVED IN 50%
OF SUBJECTS AT 3 YEARS²

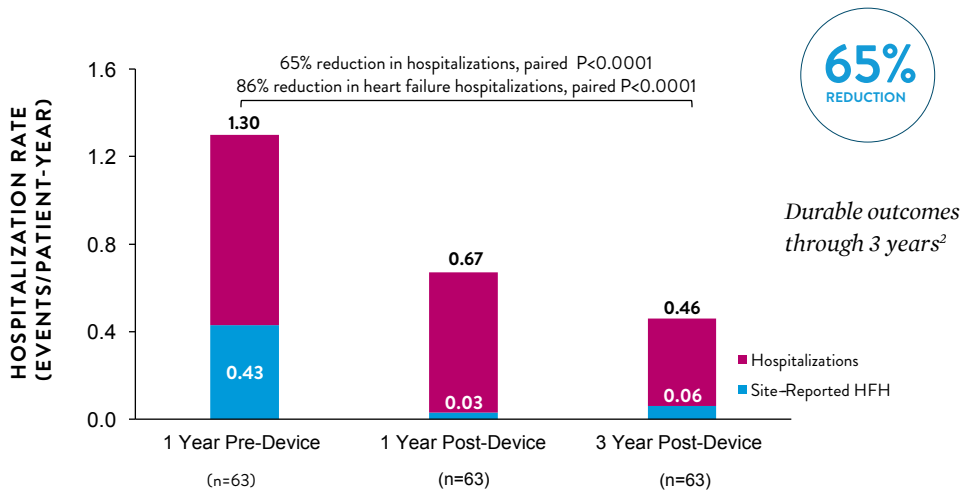


31 METER
IMPROVEMENT IN
6MWD AT 1 YEAR³



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

TriClip™ TEER Continues to Reduce Hospitalizations²



“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:

- 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.
- 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.
- 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.

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**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.

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