TRILUMINATE™
PIVOTAL TRIAL

RANDOMIZED
CONTROLLED TRIAL
1-YEAR RESULTS IN
350 PATIENTS

TriClip™
Transcatheter
Edge-to-Edge Repair

IMPROVING QUALITY OF LIFE WITHOUT COMPROMISE[1]

> "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

Scan to learn more about
TriClip™ TEER data

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 mortality with tricuspid valve surgery.

Study Design

Prospective, randomized, multi-center, controlled clinical trial to compare **TriClip™ TEER System vs. medical therapy.**

Baseline

Mean Age
78.0
± 7.3 Years

KCCQ-OS
55.0
± 24 Points

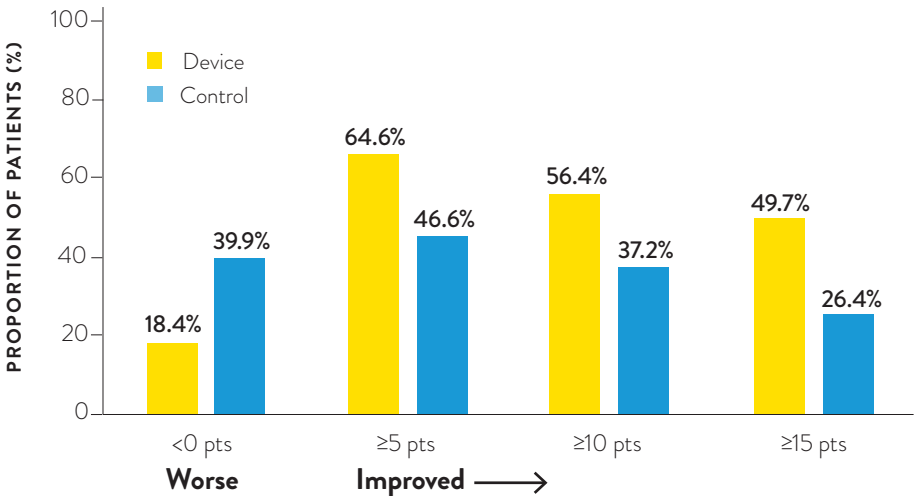
Primary Endpoint

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 mortality rates were very low, and comparable between the two arms.

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.



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

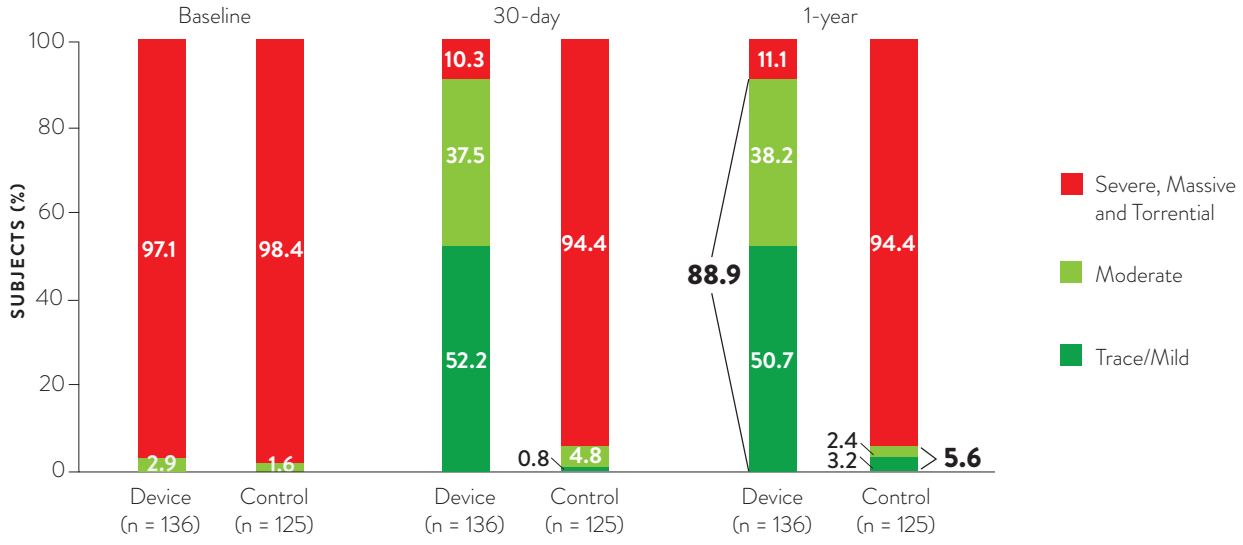
0.6% NEW PACEMAKER IMPLANTATION

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.

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