



RANDOMIZED CONTROLLED TRIAL 1-YEAR RESULTS IN 350 PATIENTS

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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





IMPROVING QUALITY OF LIFE WITHOUT COMPROMISE'

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 morbidity with tricuspid valve surgery.

Study Design

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

Baseline

Mean Age KCCQ-OS Mean Age

78.0 55.0

± 7.3 Years ± 24 Points

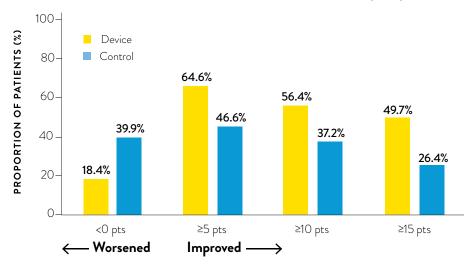
Primary Endpoint

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

Quality of Life Improvements, Baseline to 1 Year



49.7% of patients in the device group experienced ≥15 points improvement in KCCQ-OS health-related quality of life.



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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%

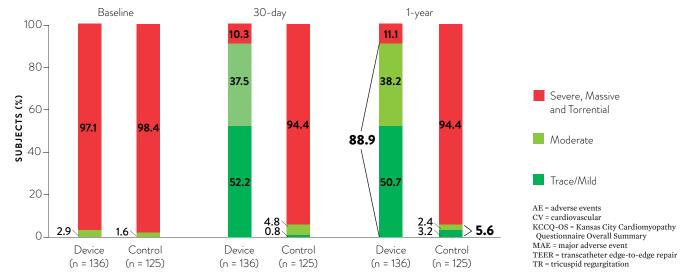
NEW PACEMAKER IMPLANTATION

NONELECTIVE CV
SURGERY FROM
DEVICE-RELATED AE

O% DEVICE THROMBUS

O% DEVICE EMBOLIZATION

Remarkable and Sustained TR Reduction



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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