



## IMPROVING QUALITY OF LIFE WITHOUT COMPROMISE<sup>1</sup>

### 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
<b>78.0</b> ± 7.3 Years	<b>55.0</b> ± 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.



RANDOMIZED  
CONTROLLED TRIAL  
1-YEAR RESULTS IN  
350 PATIENTS

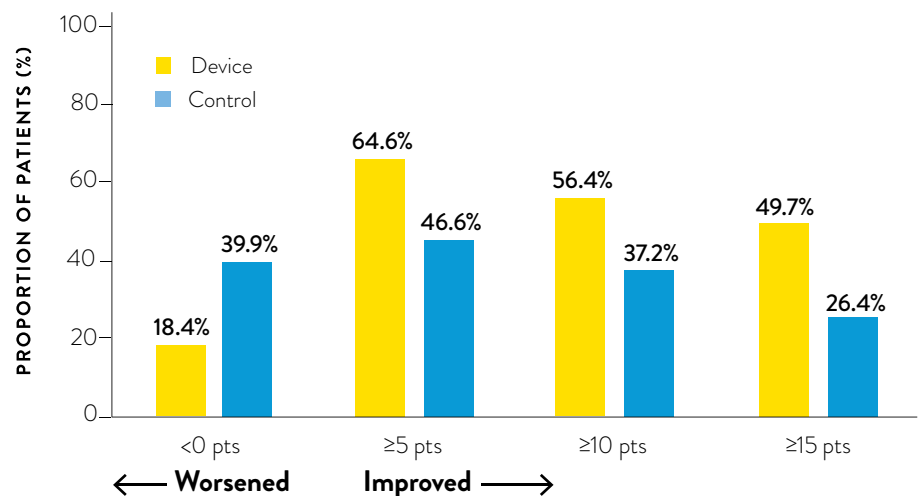
“What this trial has shown is that we have an **incredibly effective and safe therapy that improves quality of life**. This is what patients want.”\*

**Dr. Paul Sorajja**  
TRILUMINATE Pivotal Trial  
Principal Investigator

## 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

**0.6%**

NEW PACEMAKER IMPLANTATION

**0%**

DEVICE THROMBUS

**99.4%**

SURVIVAL

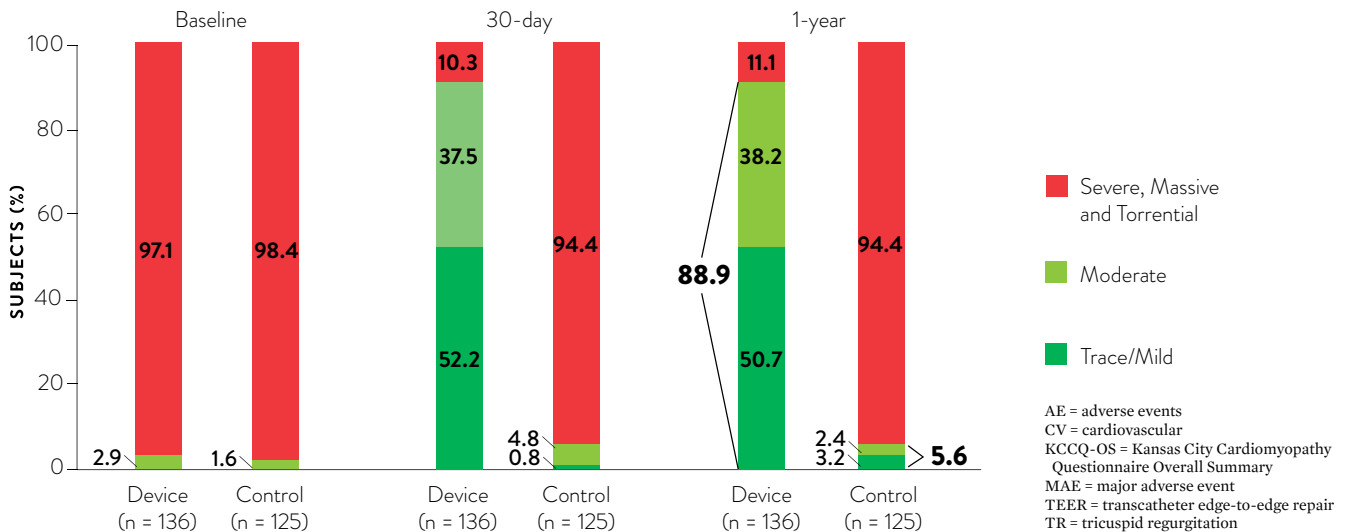
**0%**

NONELECTIVE CV SURGERY FROM DEVICE-RELATED AE

**0%**

DEVICE EMBOLIZATION

### Remarkable and Sustained TR Reduction



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.

\*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.

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