SUSTAINED MR ELIMINATION
QUALITY TIME SECURED

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TENDYNE™ TMVI:
FIRST-IN-CLASS TRANSCATHETER MITRAL VALVE IMPLANTATION THERAPY

The Tendyne clinical program spans several years and includes more than 300 patients,¹ with more studies to come.

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First Chronic Case
October 2014

GLOBAL FEASIBILITY / CE STUDY
Initiated November 2014
Evaluate the safety and performance of Tendyne TMVI in patients with severe, symptomatic MR who are not suitable for surgical mitral valve replacement

100th Study Patient Enrolled
November 2017

SUMMIT IDE
Initiated July 2018
Evaluate the safety and efficacy of Tendyne TMVI in patients with symptomatic MR (≥3+), or severe MAC, and who are not suitable for open mitral valve surgery

RESOLVE MR (PMCF)
Initiated 2020
Post-approval study of Tendyne TMVI

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Tendyne TMVI is a breakthrough therapy that can eliminate mitral regurgitation at discharge and sustain it through 2 years. 100% of survivors had MR grade 1+ or less at 1 and 2 years, and 0% structural valve dysfunction was detected at 2 years.²
SECURE MORE QUALITY TIME FOR YOUR PATIENTS

Tendyne™ patients report clinically significant improvements in function and quality of life. The two-year mortality outcomes (39%) were clinically acceptable considering the advanced age and underlying comorbidities of the population.²

![6-Minute Walk Test](image)

**61.8%**
IMPROVED BY ≥24 m
AT 1 YEAR⁴

![Quality of Life](image)

**>19 POINT**
IMPROVEMENT FROM BASELINE²
(paired comparison)
CLINICALLY SIGNIFICANT REDUCTION IN HEART FAILURE HOSPITALIZATIONS

Assessed over a 6-month duration both before and after the procedure, heart failure hospitalizations were reduced by nearly 50% per patient-year.²

HEART FAILURE HOSPITALIZATION RATE

<table>
<thead>
<tr>
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<th>Baseline</th>
<th>Post TMVI</th>
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<tbody>
<tr>
<td>Events/patient-year</td>
<td>1.5</td>
<td>1.3</td>
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P=0.01

50%
REDUCTION IN HEART FAILURE HOSPITALIZATION EVENTS PER PATIENT-YEAR*²

* in the 6 months pre- and post-procedure

BACKED BY AN EXCELLENT SAFETY PROFILE

Tendyne demonstrated outstanding acute and 30-day outcomes in clinical study.

• Beating heart procedure—no requirement for CPB or rapid pacing
• Low major adverse events (CEC-adjudicated)⁴

96% technical success rate*¹

1% major apical bleeding rate¹

0 procedural deaths¹
0 procedural strokes¹
0 emergency conversions to surgery¹
0 patients requiring ECMO¹

0.76 observed-to-expected mortality ratio¹

7.8% Low 6% 30-day observed mortality rate was favorable compared to 7.8% STS PROM score for surgical valve replacement.

6% 7.8%
WITH TENDYNE™ TMVI, YOU CAN IMPLANT WITH CONFIDENCE

Tendyne is designed with the unique challenges of the mitral anatomy in mind.

- Valve sealing and securement enabled by anchoring system
- Fully repositionable and retrievable intraprocedurally
- Controlled and predictable procedure

TENDYNE TMVI PROCEDURE

1

A delivery system positions the Tendyne valve in the heart via an incision in the left side of the chest.

2

The valve is secured by applying tension to the tether, which is attached to an apical pad placed over the access site.

3

Once the Tendyne valve is optimally positioned within the mitral annulus, the delivery system is removed.
REACH A BROAD RANGE OF PATIENTS WITH FLEXIBLE DESIGN AND SIZING

The distinct design enables safe and effective treatment for a broad range of patients.

- Low risk for paravalvular leak
- Reduce risk of LVOT obstruction with 2 valve profiles
- Wide range of annular dimensions addressed with multiple frame sizes

VALVE
Dual-frame design with ability to customize fit to individual patient anatomies

Outer frame
Contoured design supports a secure seal within native anatomy

Inner frame
Self-expanding, tri-leaflet, bioprosthetic valve

ANCHORING SYSTEM
Tether and pad
Safely secures valve
REACH MORE MR PATIENTS WITH TENDYNE™ TMVI

- First-in-class breakthrough therapy
- Predictable and sustained MR elimination through 2 years
- Significant improvement of heart failure symptoms
- Excellent procedural safety
- Enhanced quality of life

“Six months after the operation, I began working. I became a normal person again.”

– Sribalan, Tendyne patient

Elimination of MR is possible. Screen your patients for a new, minimally invasive mitral valve replacement therapy:

TENDYNE TMVI

References:

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