One Year Follow-up of the Melody™ Transcatheter Pulmonary Valve Multicenter Post-Approval Study

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Disclosures

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- Siemens Healthcare AX: Consultant Fees/Honoraria
- St. Jude Medical: Consultant Fees/Honoraria
Disclosures

Melody™ Transcatheter Pulmonary Valve (TPV) is approved as a Humanitarian Use Device.

Authorized by Federal law (USA) for use in pediatric and adult patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (≥ 16 mm in diameter when originally implanted).

The effectiveness of this device for this use has not been demonstrated.
RV-PA Conduits
Congenital Heart Defects

- Tetralogy of Fallot
  - Pulmonary Stenosis
  - Pulmonary Atresia
    - Transannular patch

- Truncus Arteriosus
- D-TGA, VSD, PS
- Others

RV–PA Conduit

~ 15% of RVOT Patients

~ 85% of RVOT Patients
RV-PA Conduit Dysfunction
Melody™ TPV

- Designed to:
  - Delay the time until surgical RV-PA conduit replacement is needed
  - Reduce the total number of open heart surgeries over a patient’s lifetime
Melody™ TPV

- Bovine Jugular Vein Valve
- Platinum Iridium Frame
  - Expandable to 18mm, 20mm or 22mm
- Delivered on the Ensemble® Delivery System
  - 22Fr Balloon-in-Balloon (BIB) catheter
- FDA Approval with HDE designation in 2010
Melody TPV Post-Approval Study

Objective

• To confirm that short-term hemodynamic effectiveness of the Melody TPV achieved by real-world providers is equivalent to the historical results established in the five-center IDE trial
Endpoints

- **Primary Endpoint**
  - Acceptable hemodynamic function at 6 months post-implant
    - RVOT echocardiographic mean gradient ≤ 30 mmHg
    - Regurgitation < moderate by echocardiogram
    - Freedom from conduit reintervention and reoperation

- **Secondary Endpoints**
  - Procedural success
  - Freedom from serious adverse events
  - Freedom from TPV dysfunction
Methods

• Prospective, non-randomized, 10-center study
• Patients with a stenotic and/or regurgitant conduit
  – $\geq 16$ mm at implantation
• No weight or age limit
• Planned 5-year follow-up
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics (N=120)</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>19.9 ± 9.7</td>
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<tr>
<td>Weight (kg)</td>
<td>59.4 ± 21.7</td>
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<tr>
<td>RVOT Mean Gradient (mmHg)</td>
<td>34.6 ± 14.5</td>
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<tr>
<td>Primary Indication (%)</td>
<td></td>
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<tr>
<td>Stenotic</td>
<td>20.8</td>
</tr>
<tr>
<td>Regurgitant</td>
<td>47.5</td>
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<td>Mixed</td>
<td>31.7</td>
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</tbody>
</table>
Subject Disposition

120 Patients

101 Attempted

100 Implanted

99 Implanted >24 Hours

1 Implant aborted due to pulmonary hemorrhage

1 surgical removal ≤24 hours due to coronary compression

19 Not Attempted

98% Procedural Success:
- Peak cath gradient <35 mmHg
- No more than mild regurgitation

Follow-up: 22 ±18.9 months
Primary Endpoint

6-month Acceptable Hemodynamic Function

- **Implanted Cohort with Evaluable Data (N=90)**: 96.7%, p<0.01
- **Implanted Cohort (N=99)**: 87.9%, p<0.01

Performance Goal: 75%
One Year Acceptable Hemodynamic Function

- Implant Cohort with Evaluable Data (N=87): 94.3%
- Implant Cohort (N=99): 82.8%
RVOT Mean Gradient

Baseline (N=97)
33.3 ± 14.1

Discharge (N=92)
16.3 ± 7.1

6 Months (N=91)
15.0 ± 9.9

1 Year (N=85)
15.1 ± 7.1

Post-Approval Study
Pulmonary Regurgitation

<table>
<thead>
<tr>
<th>Time</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>Trace</th>
<th>None</th>
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</thead>
<tbody>
<tr>
<td>Baseline (N=100)</td>
<td>7.1%</td>
<td>44.4%</td>
<td>5.1%</td>
<td>40.4%</td>
<td>2.0%</td>
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<tr>
<td>Discharge (N=99)</td>
<td>3.1%</td>
<td>32.3%</td>
<td>25.5%</td>
<td>64.6%</td>
<td>6.1%</td>
</tr>
<tr>
<td>6 Months (N=94)</td>
<td>6.4%</td>
<td>25.5%</td>
<td>12.2%</td>
<td>68.1%</td>
<td>6.1%</td>
</tr>
<tr>
<td>1 Year (N=90)</td>
<td>12.2%</td>
<td>24.4%</td>
<td>63.3%</td>
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Freedom from TPV Dysfunction, Reoperation, and Reintervention

Number At Risk

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<tr>
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Freedom From Event %

- Catheter Reintervention
- Reoperation
- TPV Dysfunction

Months Post-Implant

- 0  1  2  3  4  5  6  7  8  9  10  11  12
Freedom from TPV Dysfunction, Reoperation, and Reintervention

IDE Trial: 93.5± 2.4% at 1 year
Complications

• Serious Adverse Events
  – Procedural: 16 of 120 patients (13.3%)
    • Confined conduit tear (n=6)
      – All resolved with covered stent
    • Vascular complications (n=4)
    • Other adverse events included coronary compression, distal PA perforation, arrhythmia, fever, paravalvular leak, and pulmonary edema
  – In First Year: 8 of 99 implants >24 hours (8.1%)
    • Endocarditis (n=3), 1 with reoperation
    • Sepsis (n=1)
    • Major stent fracture requiring reoperation (n=1)
    • Pulmonary embolism (n=1)
    • Arrhythmia / palpitations (n=2)
Conclusions

- This study confirms the strong performance of the Melody TPV achieved by real-world providers with results comparable to the US IDE trial
  - Excellent hemodynamic function at 6 months (96.7%)
  - High Procedural Success (98.0%)
  - Serious Adverse Events:
    - Procedural: 13.3%
    - First year: 8.1%
  - High freedom from TPV dysfunction at 1 year (96.9%)