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

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Disclosures

Aimee K. Armstrong, MD

- Medtronic: Research/Research Grants
- Edwards Lifesciences: Research/Research Grants
- Siemens Healthcare AX: Consultant Fees/Honoraria
- St. Jude Medical: Consultant Fees/Honoraria

Disclosures

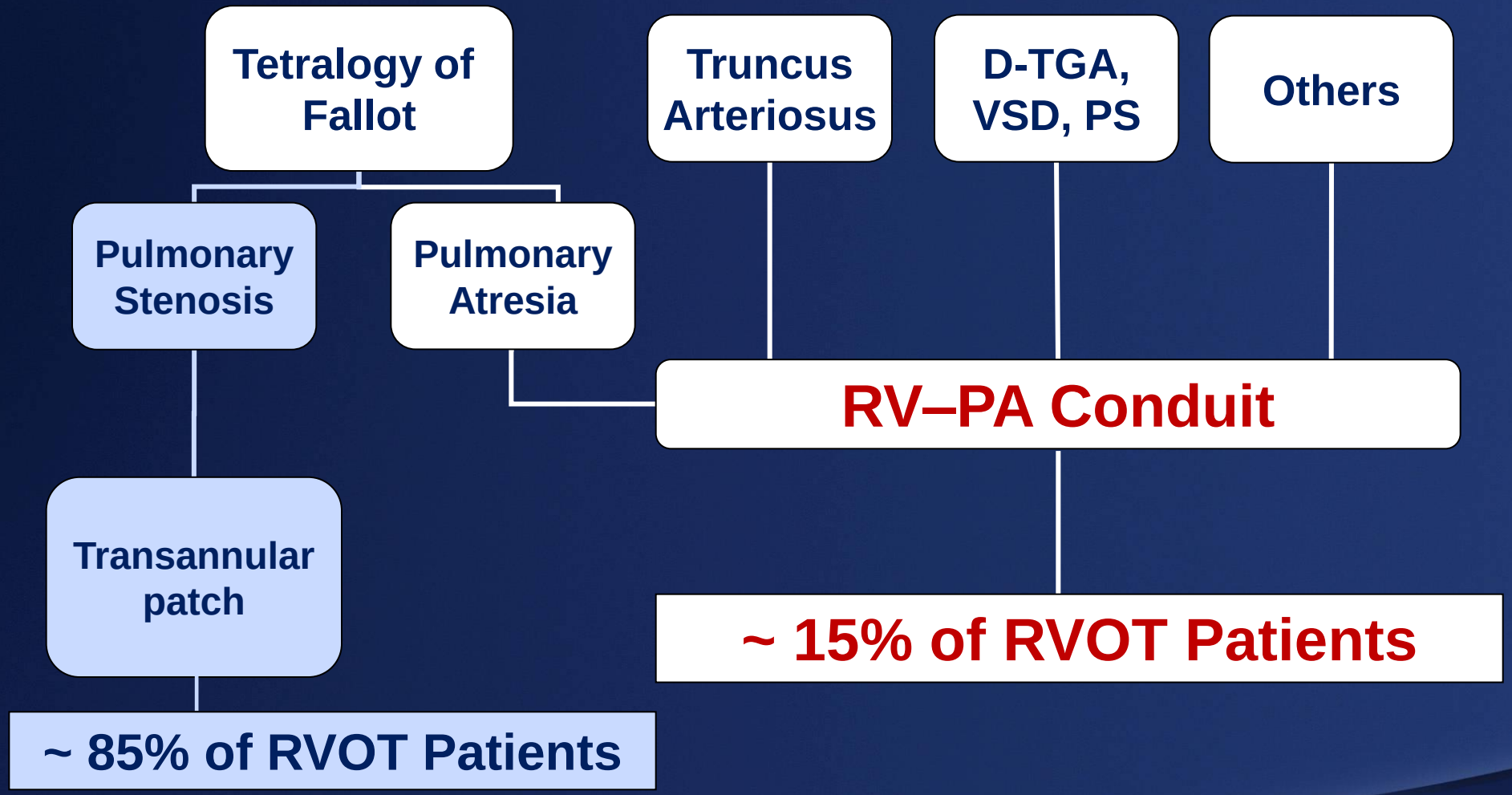
Melody™ Transcatheter Pulmonary Valve (TPV) is approved as a Humanitarian Use Device.

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).

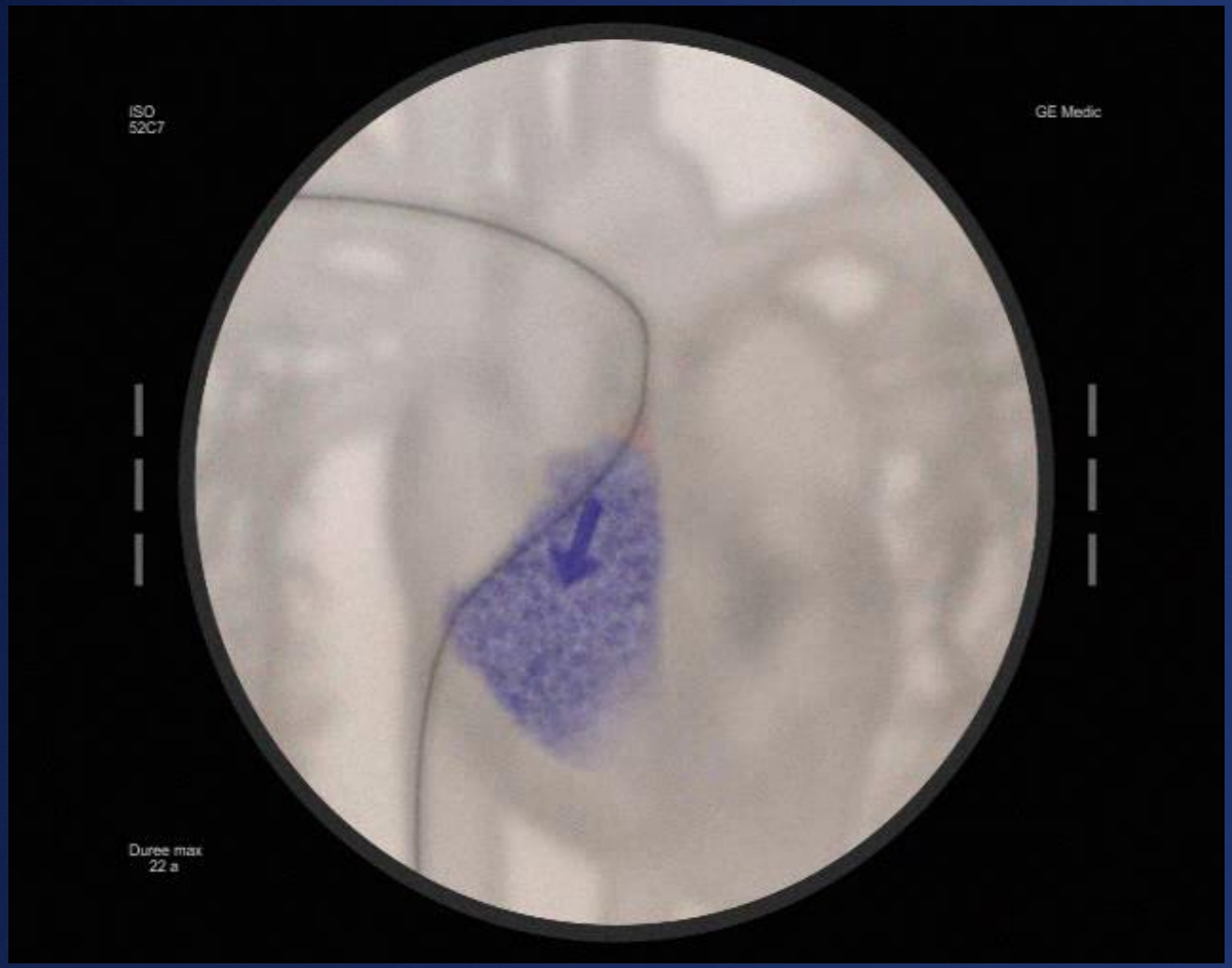
The effectiveness of this device for this use has not been demonstrated.

RV-PA Conduits

Congenital Heart Defects

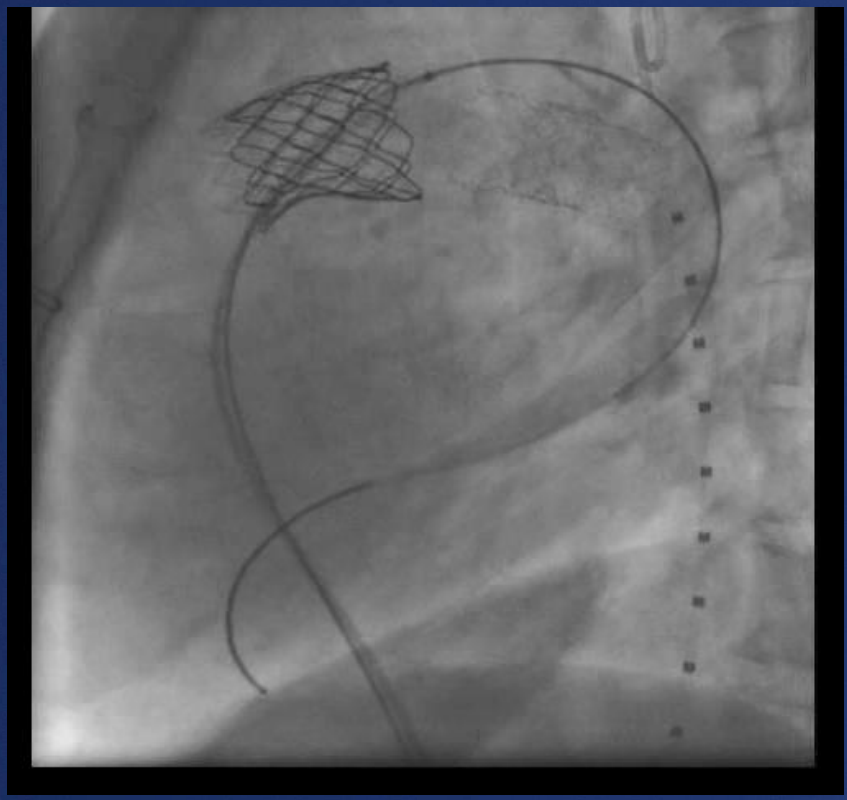


RV-PA Conduit Dysfunction



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

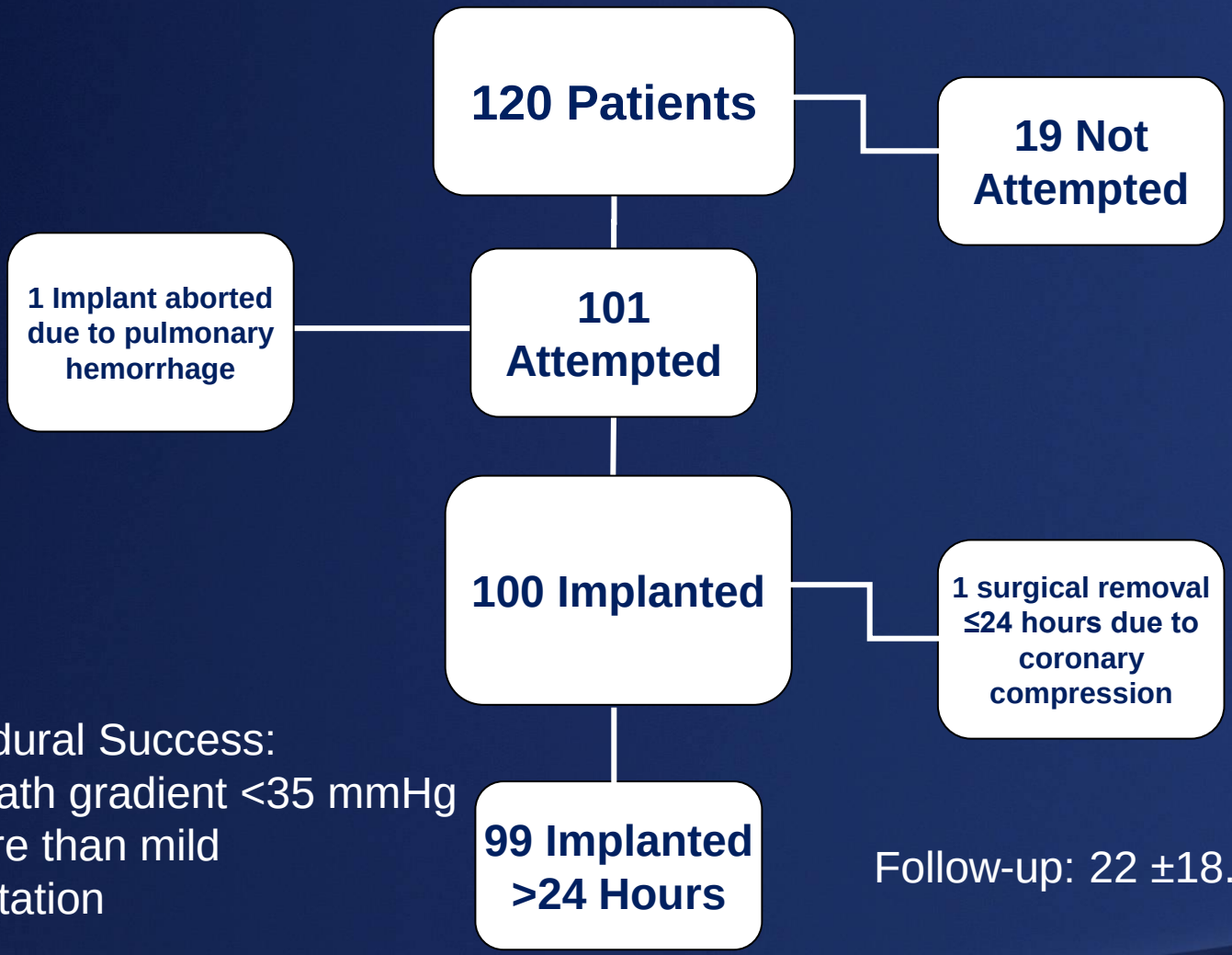
Methods

- Prospective, non-randomized, 10-center study
- Patients with a stenotic and/or regurgitant conduit
  - ≥ 16 mm at implantation
- No weight or age limit
- Planned 5-year follow-up

Baseline Characteristics

Characteristics (N=120)	*Mean ± SD*
Age (years)	19.9 ± 9.7
Weight (kg)	59.4 ± 21.7
RVOT Mean Gradient (mmHg)	34.6 ± 14.5
Primary Indication (%)	
Stenotic	20.8
Regurgitant	47.5
Mixed	31.7

Subject Disposition

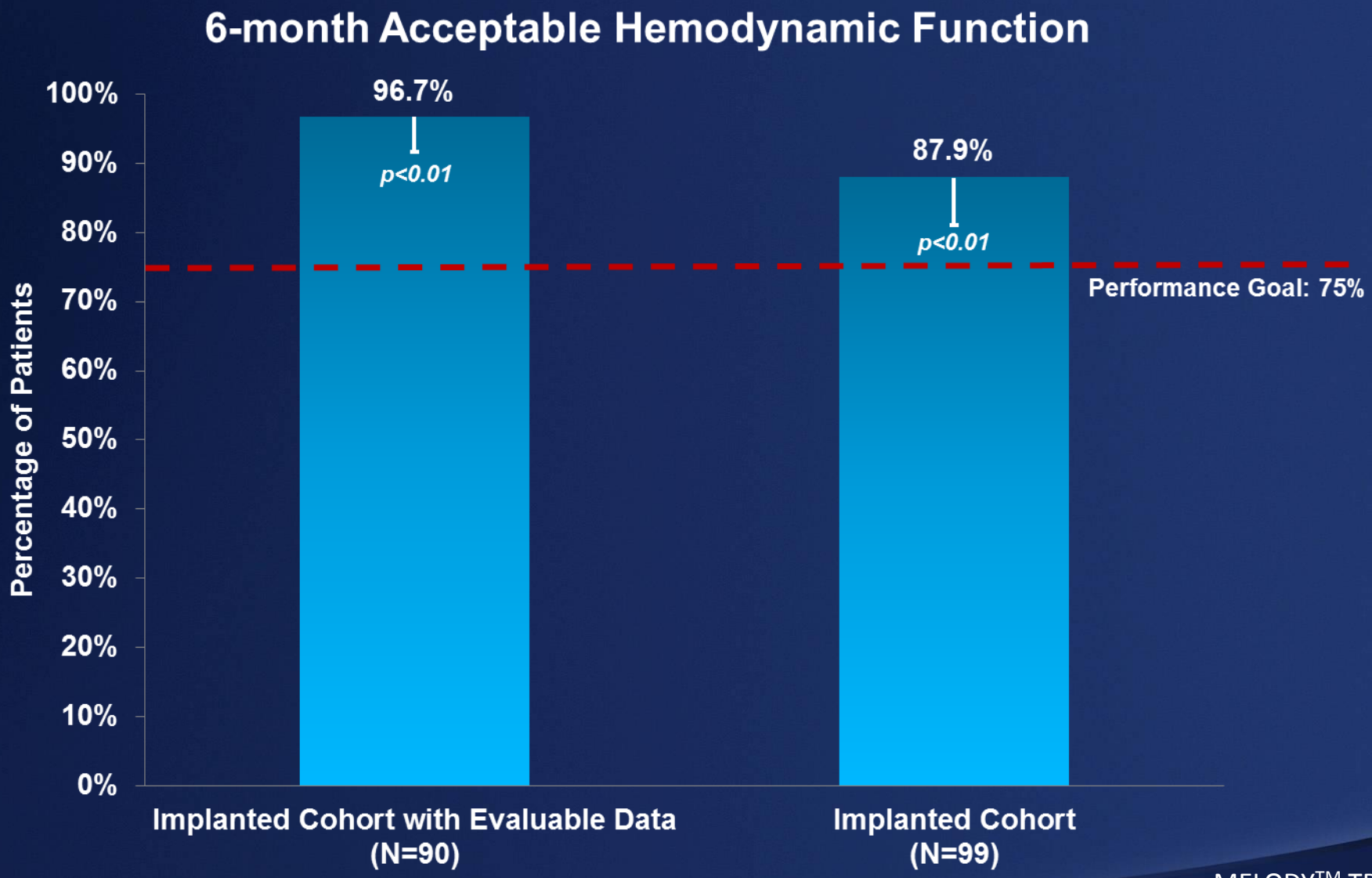


98% Procedural Success:

- Peak cath gradient <35 mmHg
- No more than mild regurgitation

Follow-up: 22 ±18.9 months

Primary Endpoint



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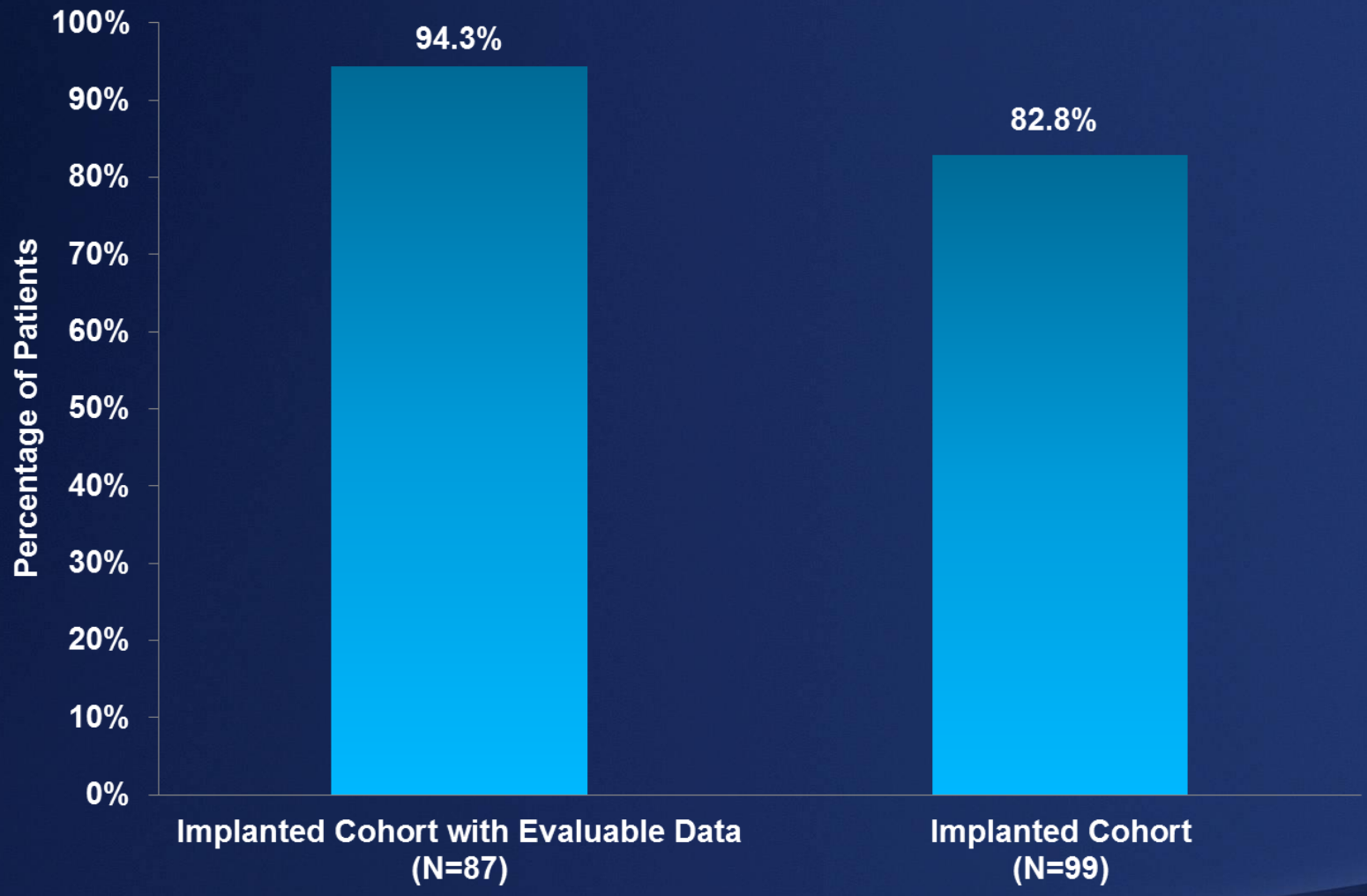
Post-Approval Study

One Year Acceptable Hemodynamic Function



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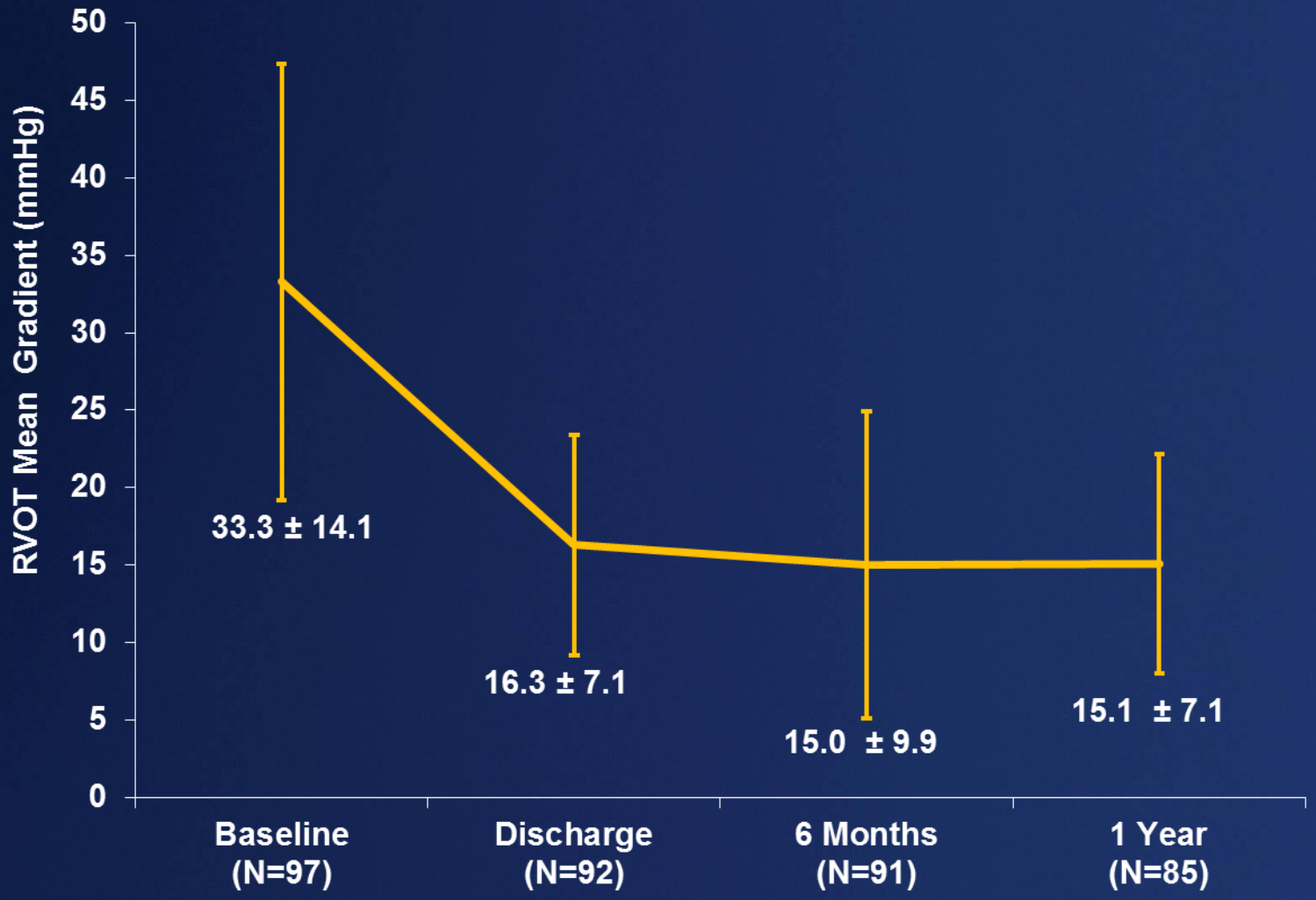
RVOT Mean Gradient



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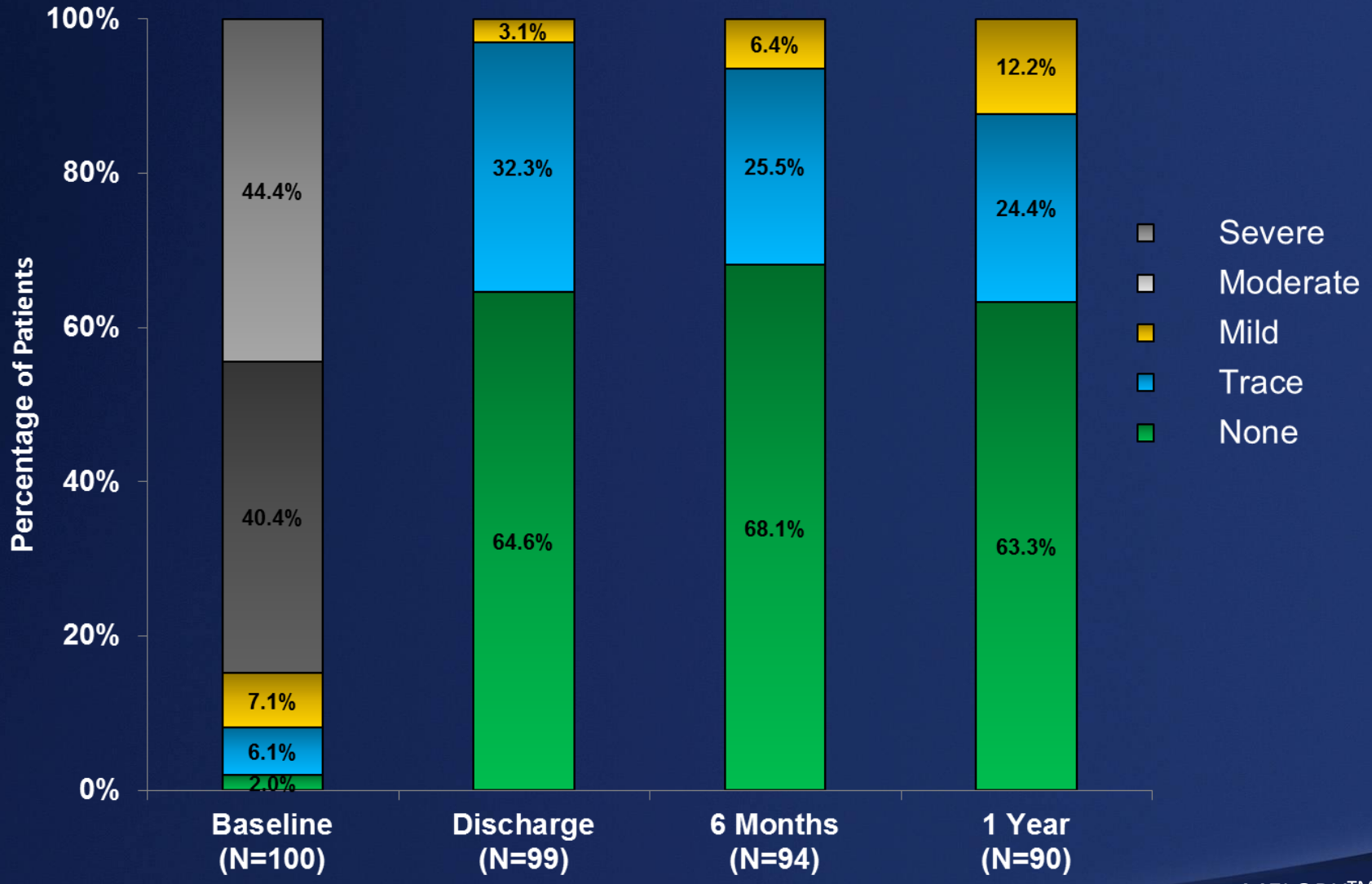
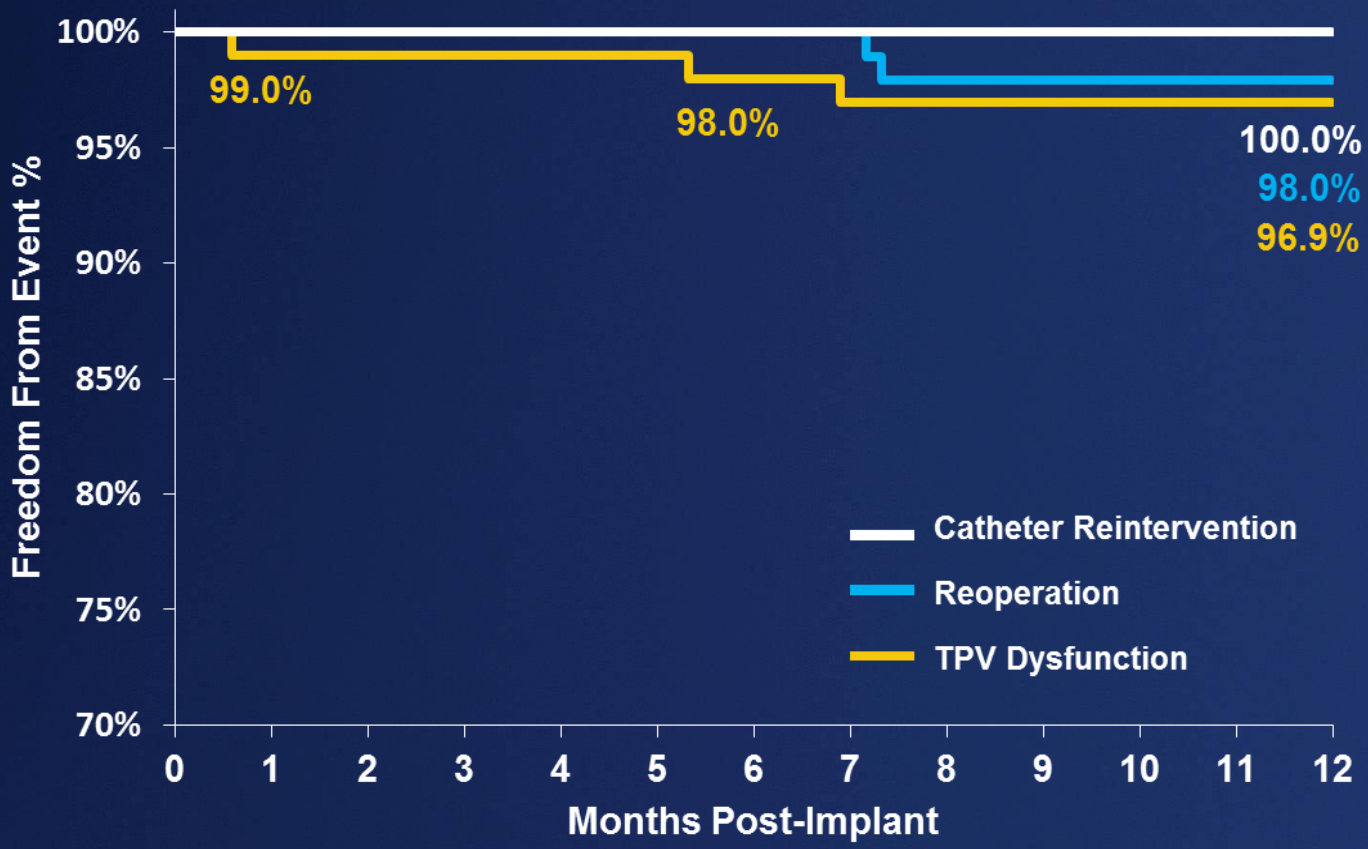
Pulmonary Regurgitation



MELODY™ TPV

Post-Approval Study

Freedom from TPV Dysfunction, Reoperation, and Reintervention



Number At Risk												
	99	99				98					89	
	99	99				98					89	
	99	98				96					88	

MELODY™ TPV
Post-Approval Study

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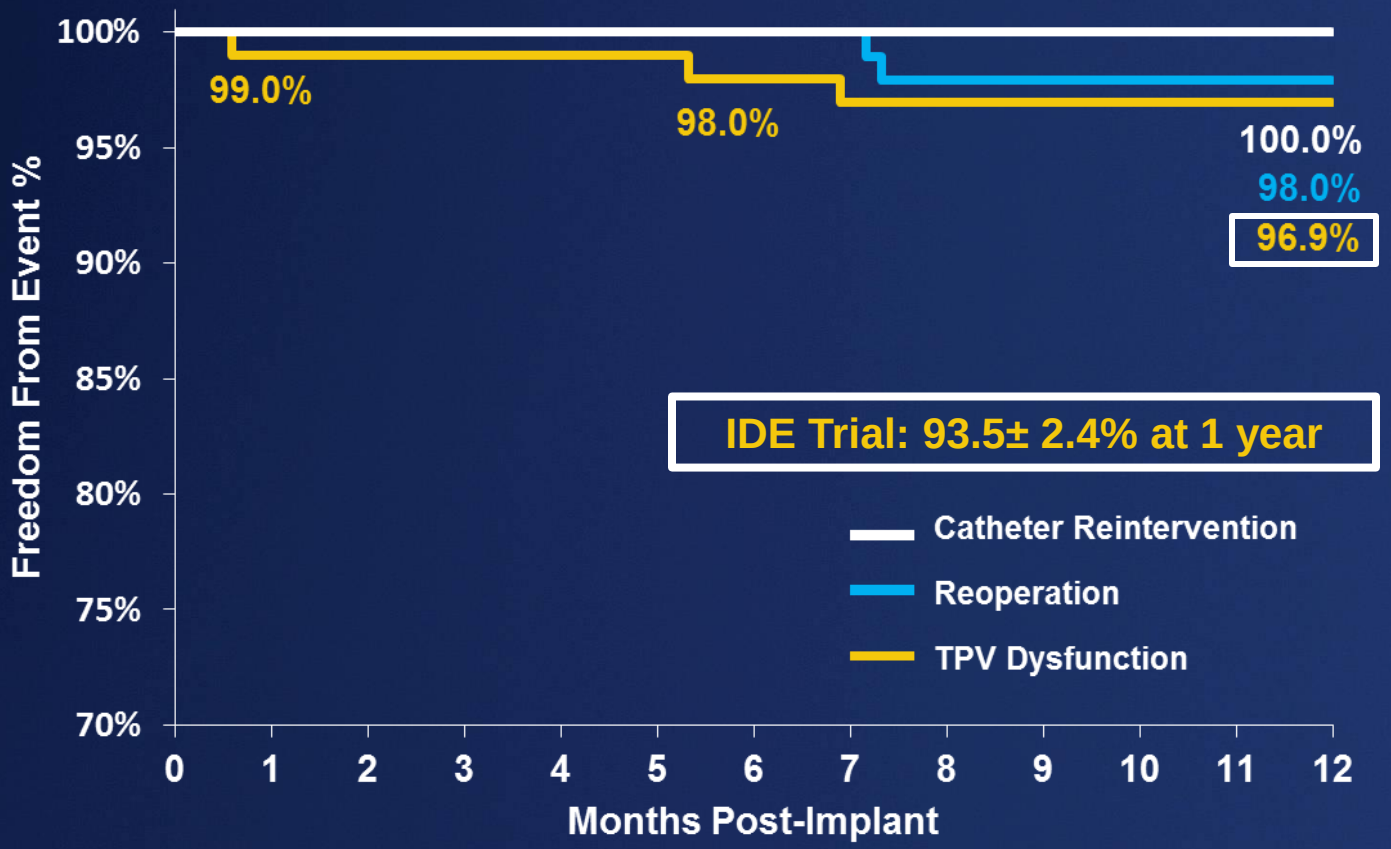

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	99	98					96						88

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Post-Approval Study

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%)