PROCEDURE PREPARATION TIP CARDS

Melody™ Transcatheter Pulmonary Valve Therapy (TPV)
Ensemble™ II Delivery System

Proven Performance. Simply Delivered.
These tip cards provide information on procedure planning and preparation for Melody™ Transcatheter Pulmonary Valve (TPV) implantation:

- Patient Selection
- Assessment of RVOT
- Cath Lab Case Supply Checklist
- Valve and Delivery System Selection
- Dysfunctional Surgical Bioprosthetic Pulmonary Valves
- Product Ordering Information
- Product Verification
- Acceptable Leaflet Variation
- Ensemble™ II Delivery System Component Identification
- MRI Safety Information
- 2-minute Rinse Procedure
- Valve Crimping and Loading Instructions

For complete instructions, please see the Instructions for Use, available on http://manuals.medtronic.com.

These tip cards are not intended to constitute medical advice or replace the independent medical judgment of a licensed and trained physician with respect to any patient needs or circumstances. The physician is solely responsible for all decisions and medical judgments relating to the treatment of their patients.
MELODY™ TPV
PATIENT SELECTION

Patient Selection Criteria

- Objective evidence of Right Ventricular Outflow Tract (RVOT) conduit or surgical bioprosthetic pulmonary valve (BPV) dysfunction
  - Moderate or severe regurgitation
  - Stenosis
  - Landing zone able to accommodate Melody TPV

The Following Patients Should Not Be Considered Candidates for This Procedure:

- Active endocarditis
- Significant obstruction of the central veins
- Venous anatomy unable to accommodate the 22 Fr size Ensemble™ II delivery system
ASSSESSMENT OF RVOT

- **Existence of dysfunctional RVOT conduit or surgical BPV?**
  - **YES**
  - **Perform RVOT angiography**
  - **NO**

- **Is narrowest diameter ≤ 22 mm?**
  - **YES**
    - **Balloon size conduit or surgical bioprosthesis/compliance testing**
  - **NO**

- **Pre-dilate with high-pressure balloon**

- **Is balloon waist ≥ 14 mm and ≤ 22 mm?**
  - **YES**
    - **RVOT suitable: deploy Melody™ TPV**
  - **NO**

*Reference sizing chart on Valve Delivery and System Selection, page 7

For complete instructions, please see the Instructions for Use, available on manuals.medtronic.com.
Medtronic Product
- Melody” Transcatheter Pulmonary Valves — Melody 20 (16 mm) and Melody 22 (18 mm) — at least one back-up valve should be available at all times
- Ensemble™ II Delivery Systems — all 3 sizes (18 mm, 20 mm and 22 mm) — at least one back-up of each size delivery system should be available at all times
- Medtronic torque wrench to assist with opening the jar (reusable)

Other supplies to have in the lab:
- Hemodynamic and angiographic catheters for arterial and venous pressure recording, angiography, and guidewire placement
- Standard pressure angioplasty balloon catheters for conduit compliance testing and measurement to ensure the nominal landing zone diameter is between 16 mm and 22mm
- High-pressure balloon angioplasty catheters for pre-dilation of stenotic conduits and post dilation of conduit pre-stents or the implanted Melody valve
- Arterial and venous introducers 5 Fr (A) and 9 Fr (V)
- Large-diameter introducers (16, 18, or 22 Fr) to facilitate conduit preparation with large-diameter balloon catheters and/or long sheaths for conduit presenting
- 75 cm 12 or 14 Fr sheaths for conduit presenting
- Selection of pre-stent delivery balloon catheters
- Selection of balloon expandable bare stents for conduit pre-stenting
- Selection of covered C-P stents for management of conduit tears
- 22 Fr venous dilator to dilate the vein at insertion site

(Continued on back)
- Angiography catheters, for both right and left side
- 0.035 ultra-stiff, super-stiff, or extra-stiff guidewire
- Bowl with 1/4 contrast to 3/4 saline for the balloon inflation, both inner and outer balloons
- Manometer syringes to monitor inflation pressure to a maximum of 4 ATM for both the 18 mm and the 20 mm balloon delivery systems and a maximum of 3 ATM for the 22 mm balloon
- Three (3) sterile rinsing bowls
- One (1) one-liter bag of sterile saline — 0.9% NaCl
- Sterile transfer spike straw for end of liter saline bag for sterile transfer (pouring) into 2 bowls divided evenly, 500 ml each bowl
- One (1) sterile 2.5 cc or 3 cc syringe used in crimping the Melody valve to an intermediate size, prior to placing on the Ensemble II delivery system to complete the crimping process
- Sterile saline for flushing and de-airing the Ensemble II delivery system
- Sterile forceps or mosquito clamp to remove Melody™ from its container
- Mosquito scissors or clean #11 scalpel to cut the identification tab suture
- Timer or clock to check valve rinse cycles, two (2) rinses, at least one (1) minute in each bowl
- Torque device for guidewire (if needed)

**Miscellaneous considerations as you prepare to implant the Melody TPV**

- Surgical consultation in patient selection and case planning
- General anesthesia (ECG, BP, and O2 saturation monitoring)
- Emergency resuscitation equipment
- Two transducers for continuous, simultaneous pressure recording
- Limit room traffic — a controlled sterile environment
- Sterile techniques to be observed throughout the procedure, as this is a biological implant to minimize the risk of bacterial endocarditis
- Scrubs, hats, shoe covers, and masks are required for everyone in the room from setup to removing the sheaths at the end of the procedure

For complete instructions, please see the Instructions for Use, available on manuals.medtronic.com.
Once a patient’s conduit or surgical bioprosthesis has been sized and prepped, select the appropriate Melody™ Valve and Ensemble™ II Delivery System based on the prepared conduit inside diameter and intended final implant size.

### SIZING INFORMATION

<table>
<thead>
<tr>
<th>Delivery System Size</th>
<th>Inner Balloon/Outer Balloon</th>
<th>Inner Balloon Maximum Applied Pressure (RBP)</th>
<th>Outer Balloon Applied Pressure (RBP)</th>
<th>Corresponding Valve Outside Diameter (Balloon Inflated)</th>
<th>Deployed Length (After Balloon Deflated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size 18 mm</td>
<td>9 mm x 3.5 cm/18 mm x 4 cm</td>
<td>5 atm 506 kPa</td>
<td>4 atm 405 kPa</td>
<td>20.1 mm</td>
<td>26 mm</td>
</tr>
<tr>
<td>Size 20 mm</td>
<td>10 mm x 3.5 cm/20 mm x 4 cm</td>
<td>5 atm 506 kPa</td>
<td>4 atm 405 kPa</td>
<td>22.4 mm</td>
<td>24 mm</td>
</tr>
<tr>
<td>Size 22 mm</td>
<td>11 mm x 3.5 cm/22 mm x 4 cm</td>
<td>4.5 atm 456 kPa</td>
<td>3 atm 304 kPa</td>
<td>24.1 mm</td>
<td>21 mm</td>
</tr>
</tbody>
</table>

BJV = Bovine Jugular Vein | RBP = Rated Burst Pressure = Maximum Applied Pressure | atm = atmosphere | kPa = kilopascal

For complete instructions, please see the Instructions for Use, available on http://manuals.medtronic.com.
MELODY™ TPV IN DYSFUNCTIONAL BIOPROSTHETIC PULMONARY VALVES

UNDERSTANDING THE FAILED BPV

Consider BPV actual inner diameter when evaluating Melody TPV implantation.

Manufacturer’s Inner Diameter (B)
- Diameter of space inside of the stent
- Usually does not include the tissue mounted in the stent

Actual Inner Diameter (C)
- Takes into account the space taken up by the tissue
- Will always be smaller than the manufacturer’s inner diameter

Labeled Valve Size (A)
- Manufacturer’s labeled valve size by the outside diameter of the stent

<table>
<thead>
<tr>
<th>Labeled Valve Size (A)</th>
<th>Manufacturer’s Inner Diameter (B)</th>
<th>Actual Inner Diameter (C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: 27 mm valve</td>
<td>27</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>24–x*</td>
</tr>
</tbody>
</table>

*Actual inner diameter will be approximately 1 to 2 mm smaller than the manufacturer’s inner diameter.
Balloon sizing is used to define the diameter and contour of the intended implant site.

- High pressure balloon predilatation can be performed in BPVs with stenosis to maximize the inner diameter.

- Red arrows show waist at the level of the calcified valve leaflets.

- Black arrow shows splayed commissural post during balloon inflation, indicating extensive and thick calcified material between the balloon and post.
Melody™ Transcatheter Pulmonary Valve
A bovine jugular vein (BJV) valve sutured within a platinum iridium frame, available in two sizes:

<table>
<thead>
<tr>
<th>Product Order No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PB1016</td>
<td>▪ Melody TPV 20</td>
</tr>
<tr>
<td></td>
<td>▪ 16 mm BJV valve</td>
</tr>
<tr>
<td></td>
<td>▪ Acceptable deployment: up to 20 mm</td>
</tr>
<tr>
<td>PB1018</td>
<td>▪ Melody TPV 22</td>
</tr>
<tr>
<td></td>
<td>▪ 18 mm BJV valve</td>
</tr>
<tr>
<td></td>
<td>▪ Acceptable deployment: up to 22 mm</td>
</tr>
</tbody>
</table>

Note: To facilitate manufacturing (sewing of the tissue onto the TPV frame), the initial “out of the jar” lengths of the two valves will differ slightly (30 mm length for PB1016 and 28 mm length for PB1018). Once crimped on the delivery system, the length of both TPV sizes will be the same and will remain as such during deployment to any size.

Ensemble™ II Transcatheter Delivery System
A balloon-in-balloon catheter delivery system with a retractable polytetrafluoroethylene (PTFE) sheath covering, with nylon inner and outer balloons available in three sizes.

<table>
<thead>
<tr>
<th>Product Order No.</th>
<th>Balloon Size</th>
<th>French Size</th>
<th>Overall Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENS1018</td>
<td>18 mm</td>
<td>22</td>
<td>100 cm</td>
</tr>
<tr>
<td>ENS1020</td>
<td>20 mm</td>
<td>22</td>
<td>100 cm</td>
</tr>
<tr>
<td>ENS1022</td>
<td>22 mm</td>
<td>22</td>
<td>100 cm</td>
</tr>
</tbody>
</table>

Note: At inflation, the inner balloon is half the diameter of the outer balloon.

Torque Wrench

<table>
<thead>
<tr>
<th>Product Order No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-0055</td>
<td>Reusable jar opener</td>
</tr>
</tbody>
</table>
In the United States and Canada, fill out the Implant Registration Form (found in the box) and return to Medtronic. The temporary implant card should be given to the patient prior to discharge.

Melody™ valve sterility is compromised if each tamper-evident seal is broken, the container is damaged, or leakage is evident. Outside of container is non-sterile and should not be placed in sterile field.

The Ensemble™ II Delivery System is sterile only if both pouches are undamaged and unopened (do not use if outer pouch was previously opened or damaged). Outer surfaces of outer pouch are non-sterile and must not be placed in sterile field.

Check the valve serial number on the box, and confirm that it matches the serial number on the jar.

Accept

Reject

Check temperature indicator on top of valve packaging (do not use valve if temp indicator has turned black).

In the United States and Canada, fill out the Implant Registration Form (found in the box) and return to Medtronic. The temporary implant card should be given to the patient prior to discharge.

Serial number stickers are provided as Product Traceability Labels for hospital use.

For complete instructions, please see the Instructions for Use, available on http://manuals.medtronic.com.
ACCEPTABLE LEAFLET VARIATION

Leaflet variation is common as Melody™ TPV is a natural tissue valve. Examples of acceptable leaflet variations:

Variation 1
Outflow

Variation 2
Outflow

Variation 3
Outflow

Variation 4
Outflow

Quality Control for Valve Competency

Every Melody™ TPV is Rigorously Tested for Competency Prior to Release

- Valves will only be accepted if they pass a leak test that simulates in vivo conditions
- Only valves that pass the leak test will be packaged for shipment

NOTE: “DUNK TEST” IS NOT A VALID TEST TO ASSESS VALVE FUNCTION AND COMPETENCY

When rinsing the valve prior to implant, the Basin “Dunk Test” is often performed in Cath Lab. This test is only equivalent to ~1.5 mm Hg (0.8 inches of water) — pressures that are too low to accurately test for valve competency.
ENSEMBLE™ II DELIVERY SYSTEM COMPONENT IDENTIFICATION

- Tip
- Marker – “Valve Uncovered”
- Marker Bands (under balloons)
- Balloon-In-Balloon
- Trifurcate Sleeve (changed to new material)
- Catheter Shaft
- Marker – “Valve Covered”
- Flush Tube (changed to new material)
- Sheath – Hemostasis Valve
- Hemostasis Adaptor for Access Site
- Inner Balloon Hub
- Guidewire Port
- Stopcock
- Outer Balloon Hub (new location of balloon size)
- Sheath
MRI Safety Information

Nonclinical testing and modeling has demonstrated that the Melody™ TPV is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-T and 3-T
- Maximum spatial gradient magnetic field of 2500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (Normal Operating Mode)

Based on nonclinical testing and modeling, under the scan conditions defined above, the Melody™ TPV is expected to produce a maximum in vivo temperature rise of less than 2.1°C after 15 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. In nonclinical testing, the image artifact caused by the device extends approximately 3 mm from the Melody™ TPV when imaged with a spin echo pulse sequence, and 6 mm when imaged with a gradient echo pulse sequence and a 3-T MRI System. The lumen of the device was obscured.

Scanning under the conditions defined above may be performed immediately after implantation.

The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters.

For complete instructions, please see the Instructions for Use, available on http://manuals.medtronic.com.
The Melody™ valve should be rinsed continuously for a minimum of 2 minutes to reduce the glutaraldehyde concentration from the valve.

1. Using aseptic technique, prepare three sterile bowls, two of which contain isotonic saline solution.

2. Change gloves and remove the Melody valve by grasping the serial number tag with atraumatic forceps and lifting it from the jar.

3. Drain the residual storage solution from the valve into the empty discard bowl by holding the valve with the serial tag (outflow) downward.

4. Transfer the empty Melody valve to the first rinse bowl.

5. Fill the Melody valve with rinse solution and alternately fill and empty by inverting and swirling, gently squeezing, emptying and filling the valve for 1 minute.

6. Transfer the empty Melody valve to the second rinse bowl and repeat Step 5 for a minimum of 1 minute.

7. Empty the rinse solution from the valve before applying it to the delivery system.

For complete instructions, please see the Instructions for Use, available on http://manuals.medtronic.com.
CRIMPING AND LOADING INSTRUCTIONS

1. Remove the serial number tag by cutting the suture attaching the tag to the Melody™ valve when implantation is imminent.

   NOTE: Prepare delivery system by flushing guidewire lumen and side port and completely deflating balloons with fluid-filled syringe. Connect inflation syringes to inner and outer balloon lumens.

2. Reduce the size of the Melody valve while crimping it using mandrels of decreasing size. It is recommended to use a 2.5/3-mL syringe for initial crimping.

3. When reduced to the intermediate size, slide the Melody valve over the tip of the delivery system to center on the balloons.

4. Verify that the blue suture on the valve is oriented toward the distal end (blue tip) of the catheter.

5. Gently crimp the Melody valve onto the balloon using finger pressure and a “rolling action” to exert equal pressure on all sides of the valve. Crimp only until no movement is felt on the catheter (AVOID BENDING OR TWISTING THE VALVE).

6. Carefully slide the sheath over the Melody valve and balloons, ensuring that the crowns at the inflow side of the stent do not get caught on the sheath as it is advanced over the stent.

7. Flush the sheath using the sidearm to remove air from the Ensemble™ II delivery system. Continue advancing the sheath and flushing until the sheath fits snugly over the proximal end of the blue tip.

   NOTE: Ensure the blue suture on the valve is adjacent to the blue tip of the catheter.

   NOTE: Ensure the blue suture on the valve is adjacent to the blue tip on the Ensemble II delivery system. It is recommended that a second person in the cath lab routinely confirms this prior to completely sheathing the device.
Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System

Important Labeling Information for the United States

Indications: The Melody™ TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥ 35 mm Hg.

Contraindications: None known.

Warnings/Precautions/Side Effects:

- DO NOT use if patient’s anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a TPV size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biologic signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.

- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.

- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.

- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.

- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

- Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

- Potential device-related adverse events that may occur following device implantation include the following: stent fracture, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

- The term “stent fracture” refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Important Labeling Information for Geographies Outside of the United States

Indications: The Melody™ TPV is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR

- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling, or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term “stent fracture” refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody Frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.