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>
</table>
| PB1016            | • Melody TPV 20  
                    • 16mm BJV valve  
                    • Acceptable deployment: up to 20mm |
| PB1018            | • Melody TPV 22  
                    • 18mm BJV valve  
                    • Acceptable deployment: up to 22mm |

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 (30mm length for PB1016 and 28mm 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 (see sizing information below).

Ensemble® Transcatheter Delivery System

<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>NU1018</td>
<td>18mm</td>
<td>22</td>
<td>100cm</td>
</tr>
<tr>
<td>NU1020</td>
<td>20mm</td>
<td>22</td>
<td>100cm</td>
</tr>
<tr>
<td>NU1022</td>
<td>22mm</td>
<td>22</td>
<td>100cm</td>
</tr>
</tbody>
</table>

Description

- Balloon-in-balloon catheter delivery system with a retractable polytetrafluoroethylene (PTFE) sheath covering.
- Nylon inner and outer balloons available in three sizes: 18mm, 20mm and 22mm. At inflation, the inner balloon is half the diameter of the outer balloon.
- Sheath with side port for flushing the system and a hemostatic sleeve to minimize bleeding at the insertion site.

Torque Wrench

<table>
<thead>
<tr>
<th>Product Order No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>01-0055</td>
<td>Reusable jar opener</td>
</tr>
</tbody>
</table>

Proven Performance, Simply Delivered
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 resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis. For additional information, please refer to the Instructions For Use provided with the product.

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The intended lifetime for the Melody device is 2 years.

Contraindications:
- Venous anatomies that would limit the use of a 22 Fr size introducer sheath.
- Implantation in left heart.
- Unfavorable right ventricular outflow tract for good stent anchorage.
- 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.
- Stent fracture 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.
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