### Deployment Specifications

#### Sizing Information

<table>
<thead>
<tr>
<th>Delivery System Size</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></td>
<td>atm</td>
<td>kPa</td>
<td>atm</td>
<td>kPa</td>
</tr>
<tr>
<td><strong>Size 18mm</strong></td>
<td>5 atm</td>
<td>506 kPa</td>
<td>4 atm</td>
<td>405 kPa</td>
</tr>
<tr>
<td>9mm x 3.5cm/18mm x 4cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Size 20mm</strong></td>
<td>5 atm</td>
<td>506 kPa</td>
<td>4 atm</td>
<td>405 kPa</td>
</tr>
<tr>
<td>10mm x 3.5cm/20mm x 4cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Size 22mm</strong></td>
<td>4.5 atm</td>
<td>456 kPa</td>
<td>3 atm</td>
<td>304 kPa</td>
</tr>
<tr>
<td>11mm x 3.5cm/22mm x 4cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

### Deciding the Appropriate Valve Size

**Melody TPV 20 (PB1016)**
- 16mm BJV tissue
- Acceptable deployment: up to 20mm

**Melody TPV 22 (PB1018)**
- 18mm BJV tissue
- Acceptable deployment: up to 22mm

### Will the Melody TPV be delivered to an inside diameter >20mm or post dilated >20mm?

**NO**
- Melody TPV 20

**YES**
- Melody TPV 22

---

1. Medtronic bench testing data on file
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. For additional information, please refer to the Instructions For Use provided with the product.

* The term “stent fracture” refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis. fracture* resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction.

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.

The intended lifetime for the Melody device is 2 years.

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 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.

The intended lifetime for the Melody device is 2 years.

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 complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.

Potential complications/adverse events 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.

The intended lifetime for the Melody device is 2 years.