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 interventional on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has a moderate to severe obstruction, and/or a mean RVOT gradient ≥ 35 mm Hg.

Contraindications: None known.

Warnings/Precautions/Side Effects:
- DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.
- DO NOT use if patient’s anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary 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 1.10% 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, arrhythmia, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hemoptysis, 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, 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.

GAINING A NEW PERSPECTIVE

Melody™ Transcatheter Pulmonary Valve (TPV) Therapy Augmented Reality App

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UC201908354a EN 03/2019

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An easy and interactive way to learn more about Melody TPV therapy.

The app contains:
- Melody TPV augmented reality experience (interactive)
- Melody TPV procedure animation
- Melody TPV patient information brochure (PDF)
- CHD patient self-care tips brochure (PDF)
- Link to www.Melody-TPV.com website

Where you can find the app:
Simply go to the Apple® App Store® or Google Play™ Store and search for “Melody TPV AR”.

How to use the app:
- Getting the valve to appear: find a flat surface in a room with decent lighting until the screen says “Tap to Place,” then use one finger to tap the screen to add a valve floating above the surface
- Enlarging or shrinking the valve: pinch together or widen two fingers apart on the screen at the same time
- Spinning the valve from side to side: move one finger up while moving the other finger down
- Lock mode: allows user to move device around a stationary valve

What you need to run this app:
Most phones and tablets made after 2016 should support the app. However, the augmented reality buttons may not function properly on older devices. A full list of compatible devices can be found on the app markets.