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Ensemble™ II
Transcatheter Valve Delivery System

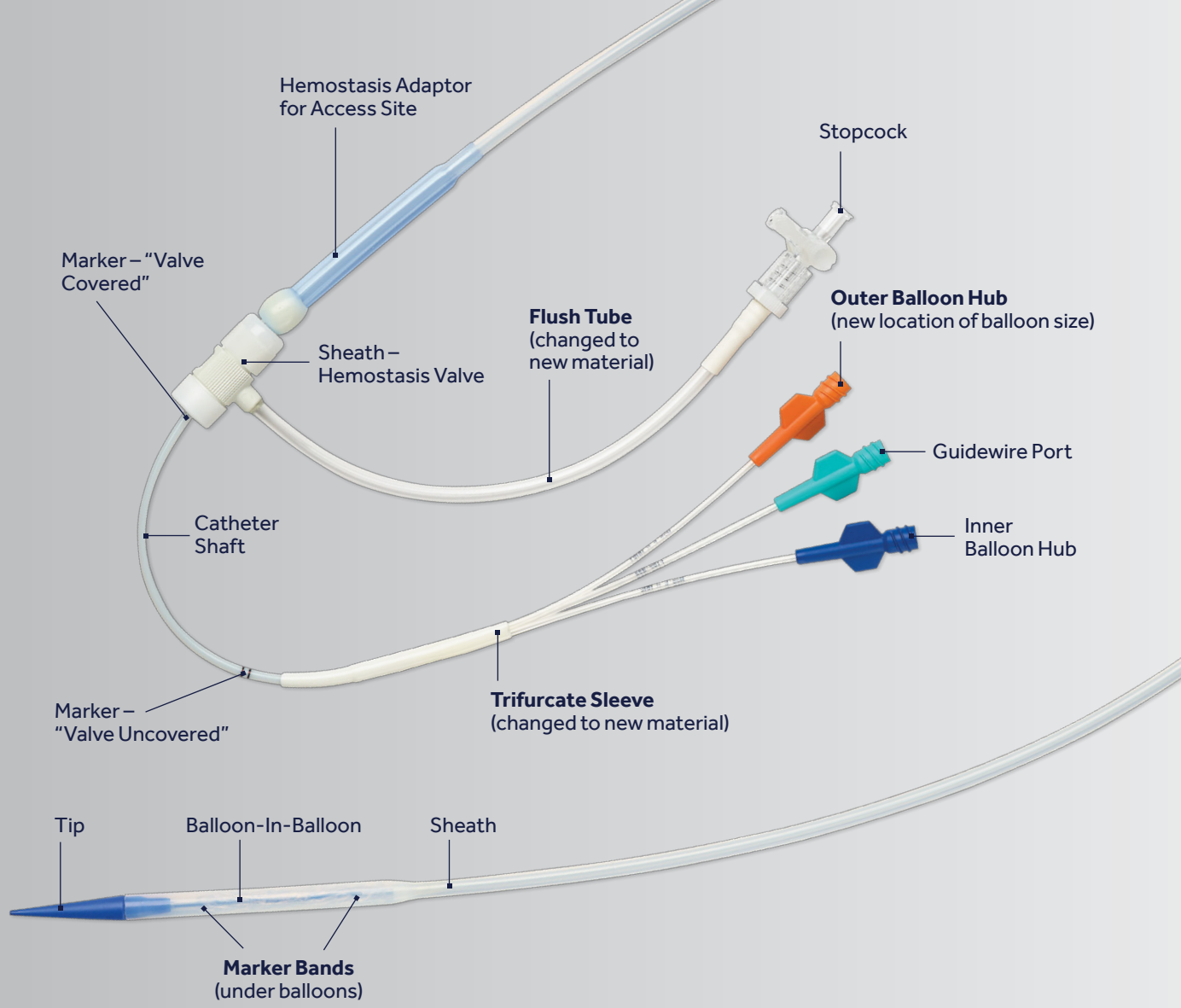
The Ensemble II Delivery System is the second generation delivery system designed to deliver the Melody™ Transcatheter Pulmonary Valve (TPV). The Ensemble II Delivery system received FDA and CE Mark approval in September 2016.

WHAT'S NEW?

- Addition of marker bands to improve visibility of valve position on the balloons under flouroscopy prior to unsheathing and during valve deployment.
- The device size marking previously located on the trifurcate sleeve is being relocated to the outer balloon inflation luer hub.
- Trifurcate sleeve and flush tube materials are being changed to phthalate free variants.
- New Product Ordering Numbers (ENS1018, ENS1020, ENS1022)

WHAT HASN'T CHANGED?

- Balloon-in-Balloon (BIB) 22Fr delivery catheter with integrated retractable polytetrafluoroethylene (PTFE) sheath covering (no need for a delivery sheath).
- Nylon inner and outer balloons available in 3 sizes: 18mm, 20mm, 22mm (outer).
- At full inflation, the inner balloon is half the diameter of the outer balloon.



Ensemble II Delivery System

Product Order Number	Balloon Size
ENS1018	18mm
ENS1020	20mm
ENS1022	22mm

Ensemble Delivery System (1st Gen)

Product Order Number	Balloon Size
NU1018	18mm
NU1020	20mm
NU1022	22mm

SOON TO BE DISCONTINUED

Medtronic
Further, Together

FREQUENTLY ASKED QUESTIONS

Are there any changes to the Melody valve product or Melody valve product order numbers?

No, this is a change to the Ensemble Delivery System only. There are currently no changes to the Melody valve product or Melody valve product order numbers (PB1016 for deployment up to 20mm and PB1018 for deployment up to 22mm).

Can I swap Ensemble Delivery System devices for the new Ensemble II device?

Medtronic will not swap out any Ensemble devices which were previously purchased. The first generation of the Ensemble Delivery Catheter will be completely phased out once inventory is depleted.

Who can I contact for additional information?

If you have questions, please contact your Medtronic Melody Therapy Development Specialist, or you may contact CardioVascular Technical Support.

Melody Transcatheter Pulmonary Valve, Ensemble II Transcatheter Valve Delivery System

Important Labeling Information for United States

Indications: The Melody TPV is indicated for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted AND
- Dysfunctional RVOT conduits with a clinical indication for intervention, AND
  - regurgitation: ≥ moderate regurgitation, AND/OR
  - stenosis: mean RVOT gradient ≥ 35 mm Hg

Contraindications: None known.

Warnings/Precautions/Side Effects:

- DO NOT implant in the aortic or mitral position. Preclinical 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 size 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 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.

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

For complete deployment specifications, please see the Melody TPV and Ensemble II Instructions for Use, available on http://manuals.medtronic.com, or visit www.melody-tpv.com.

Important Labeling Information for Geographies Outside of the United States

Indications: The Melody Transcatheter Pulmonary Valve is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic Right Ventricular Outflow Tract (RVOT) conduits with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits where the risk of worsening regurgitation is a relative contraindication to balloon dilation or stenting.
- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted.

The intended lifetime for the Melody device is 2 years.

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath; implantation in left heart.
- Unfavorable right ventricular outflow tract for good stent anchorage.
- Severe right ventricular outflow obstruction, which cannot be dilated by balloon.
- Obstruction of the central veins.
- Clinical or biological signs of infection.
- Active endocarditis.
- Known allergy to aspiring 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 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 Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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