# Merit WRAPSODY™

## Endoprosthesis

**INSTRUCTIONS FOR USE**

MERITMEDICAL®

English

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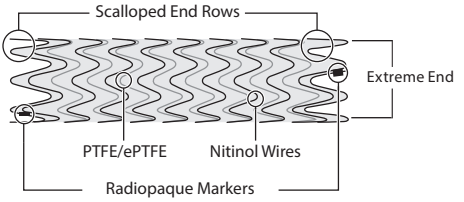
## INSTRUCTIONS FOR USE

### DESCRIPTION

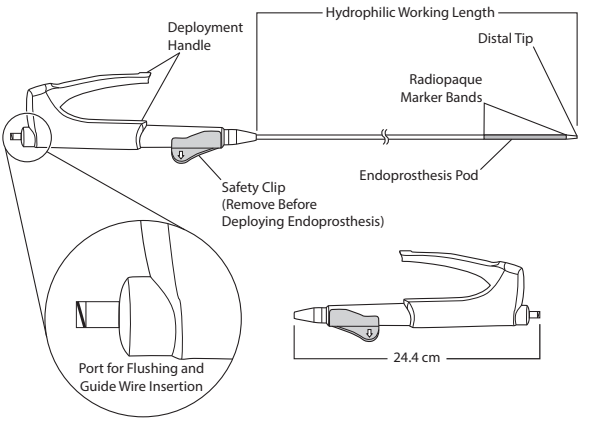
The Merit WRAPSODY™ Endoprosthesis is comprised of the WRAPSODY Endoprosthesis and the WRAPSODY Delivery Catheter System. The WRAPSODY Endoprosthesis is a flexible, self-expanding endoprosthesis designed for placement in the vasculature. The WRAPSODY Endoprosthesis is made of nitinol that is encapsulated between layers of fluoropolymer. Placement of the WRAPSODY Endoprosthesis is facilitated by radiopaque markers, three on each end, that are located on both end rows of the WRAPSODY Endoprosthesis (see Figure 1). Both ends of the WRAPSODY Endoprosthesis are trimmed in a scalloped manner.

Figure 1.




The WRAPSODY Endoprosthesis is compressed and preloaded onto the WRAPSODY Delivery Catheter System and is housed in the endoprosthesis Pod (Figure 2). The WRAPSODY Delivery Catheter System is designed for single-handed deployment and consists of a deployment handle (see Figure 2) that allows for controlled delivery of the WRAPSODY Endoprosthesis. The working length (see Figure 2) of the WRAPSODY Delivery Catheter has a hydrophilic coating. The WRAPSODY Delivery Catheter System has one port with a female luer connection for flushing both the guide wire lumen and the endoprosthesis Pod. The WRAPSODY Delivery Catheter shaft has radiopaque marker bands, corresponding to the proximal and distal ends of the endoprosthesis Pod, to provide guidance during placement of the WRAPSODY Endoprosthesis.

Figure 2.




### HOW SUPPLIED

The Merit WRAPSODY Endoprosthesis System is supplied STERILE. Sterilization is done with ethylene oxide.

### INDICATIONS FOR USE

The Merit WRAPSODY Endoprosthesis System is a flexible self-expanding endoprosthesis indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft.

### CONTRAINDICATIONS

- Do not use if full expansion of a PTA balloon cannot be achieved during pre-dilation.
- Do not use in patients who have a hypersensitivity to nickel.

### WARNINGS

- This device is intended for use by physicians who are familiar with the complications, side effects, and dangers associated with intravascular endoprosthesis procedures.
- Keep dry. Protect the packaged product from direct exposure to sunlight.
- The sterile packaging and devices should be inspected prior to use. Verify that the packaging and the devices are undamaged and that the sterile barrier is intact. If damaged, do not use.
- Do not use the WRAPSODY device after the expiration date.
- Care should be used to avoid puncturing or cutting the WRAPSODY Endoprosthesis.
- Do not use a kinked WRAPSODY Delivery Catheter or kinked valved introducer sheath as this may result in difficulty or inability to deploy the WRAPSODY Endoprosthesis.
- An appropriately stiff guide wire is required to be in place before introduction of the WRAPSODY Delivery Catheter into the body. The guide wire must remain in place during the introduction, manipulation, deployment, and eventual removal of the WRAPSODY Delivery Catheter.

- Repositioning of the WRAPSODY Delivery Catheter may be necessary prior to deploying the endoprosthesis.
- Once deployed, the WRAPSODY Endoprosthesis cannot be retracted or resheathed onto the delivery catheter.
- Placing a endoprosthesis across a side branch may obstruct blood flow and prevent or hinder future access or other procedures.
- Placing a endoprosthesis beyond the ostium of the cephalic vein into the axillary/ subclavian vein may hinder or prevent future access and is not recommended.
- Do not use the WRAPSODY device if it cannot be flushed prior to use. Guide wire lumen and endoprosthesis Pod flushing are required prior to insertion or reinsertion.
- After use, the WRAPSODY Delivery Catheter is a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.
- Inadvertent, partial, or failed deployment or migration of the WRAPSODY Endoprosthesis may require surgical intervention.
- The safety and effectiveness of the device when placed in the Superior Vena Cava has not been evaluated.
- The safety and effectiveness of the device has not been evaluated in pediatric patients.
- Do not use in patients with uncorrectable coagulation disorders.
- Do not use in patients when there is clinical evidence of infection which could spread to the implanted endoprosthesis.
- Do not use in patients with functional relevant obstruction of the inflow path, poor outflow or no distal runoff.
- The WRAPSODY Endoprosthesis is not designed to treat fresh, soft thrombotic or embolic material.

**PRECAUTIONS**

- Follow the Instructions for Use with all devices that are used together with the Merit WRAPSODY Endoprosthesis.
- The WRAPSODY Delivery Catheter is not intended for any use except to deploy the WRAPSODY Endoprosthesis.
- The WRAPSODY Delivery Catheter can only deploy the WRAPSODY Endoprosthesis after the safety clip is removed. This should not be done until the WRAPSODY Endoprosthesis is about to be released. See DIRECTIONS FOR USE.
- Higher deployment forces may be encountered on longer lengths of WRAPSODY Endoprosthesiss.
- The WRAPSODY Endoprosthesis should not be balloon expanded beyond its stated diameter. Refer to Table 1 for the appropriately sized balloon diameter.
- Do not use a balloon that is longer than the labeled length of the WRAPSODY Endoprosthesis.
- When passing any accessory device through the WRAPSODY Endoprosthesis use caution and ensure that the WRAPSODY Endoprosthesis does not dislodge.
- Do not withdraw or reposition a balloon catheter within the lumen of the WRAPSODY Endoprosthesis unless the balloon is completely deflated.
- The safety and effectiveness of the device when placed across an aneurysm or a pseudo-aneurysm has not been evaluated.
- The safety and effectiveness of the device has not been evaluated in areas of extreme flexion such as the clavicle, popliteal fossa, and antecubital fossa.
- Testing has not been conducted for the use of the WRAPSODY Endoprosthesis in an overlapped condition with bare metal stents or with other competitive endoprosthesiss (or covered stents).

**PRECAUTION STATEMENT**

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the superintendent authority of the applicable Member State.

**CLINICALLY RELATED COMPLICATIONS**

All clinical complications that have been reported in association with conventional vascular stents and endoprosthesiss may also occur during or after insertion of the WRAPSODY Endoprosthesis. These include allergic reaction, aneurysm, arm or hand oedema, bleeding at access site, cellulitis, cerebrovascular accident, congestive heart failure, face or neck oedema, fever, haematoma, haemoptysis, haemorrhage, infection, pain, perforation, prolonged bleeding, pseudoaneurysm, rash, reaction to contrast, restenosis requiring intervention, sepsis, steal syndrome, endoprosthesis embolism, thrombotic and non-thrombotic occlusion, vasospasm, vasoconstriction, ventricular fibrillation, vessel rupture, and death.

**DEVICE RELATED COMPLICATIONS**

All device related complications that have been reported in association with conventional vascular stents and endoprosthesiss may also occur when using the WRAPSODY Endoprosthesis. These include bond joint failure, delivery system kinking, detachment of part, failure to deploy, high deployment forces, inability to track to the target location, inaccurate deployment, incompatibility with accessory devices, insufficient endoprosthesis expansion, premature deployment, endoprosthesis fracture, endoprosthesis kinking, endoprosthesis migration, endoprosthesis misplacement, and occlusion.

**NOTES**

- Before introduction into the patient, the hydrophilic coating on the WRAPSODY Delivery Catheter must be wetted with sterile heparinized saline, and the guide wire lumen and endoprosthesis Pod must be flushed with sterile heparinized saline.
- Post-dilation of the implanted WRAPSODY Endoprosthesis is required with a balloon equal in diameter to that of the selected WRAPSODY Endoprosthesis diameter.
- Prescribed anticoagulation pre-, during and post- procedure should follow institutional standards, including dual antiplatelet treatment if appropriate.

**MRI SAFETY AND COMPATIBILTY INFORMATION**

Non-clinical testing has demonstrated that the WRAPSODY Endoprosthesis is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only.
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the Merit WRAPSODY Endoprosthesis is expected to produce a maximum temperature rise of 1.6 °C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, image artifact caused by the Merit WRAPSODY Endoprosthesis extends approximately 3 mm from device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. The lumen of the Merit WRAPSODY Endoprosthesis can be visualized on T1-weighted, spin echo and gradient echo pulse sequences.

**CLINICAL BENEFITS**

The intended clinical benefit of the WRAPSODY System is the restoration and maintenance of blood flow through an occluded or stenosed venous dialysis outflow circuit.

**MERIT WRAPSODY ENDOPROSTHESIS SIZING AND SELECTION**

It is essential to ensure that the appropriate diameter and length are chosen for the WRAPSODY Endoprosthesis prior to introduction. To ensure adequate fixation (or vessel wall apposition), it is recommended to oversize the diameter of the WRAPSODY Endoprosthesis relative to the healthy (non-diseased) portion of the vessel, see Table 1. The endoprosthesis selected should extend at least 1 cm beyond the proximal and distal margins of the obstruction or dissection.

**Table 1**

| Reference Vessel Diameter[1] (mm) | Merit endoprosthesis Diameter (mm) | Delivery Catheter Outer Diameter (Fr) | Available endoprosthesis Lengths[2] (mm) | Guide Wire Diameter | Delivery Catheter Working Length (cm) | Recommended Balloon Diameter for endoprosthesis Touch-up (mm) | Recommended Introducer Sheath Size (Fr) |
|---|---|---|---|---|---|---|---|
| 4.6-5.3 | 6 | 8 | 50, 75, 100, 125 | 0.035" (0.889 mm) | 80, 120 | 6 | 8 |
| 5.4-6.1 | 7 | 9 | 50, 75, 100, 125 | 0.035" (0.889 mm) | 80, 120 | 7 | 9 |
| 6.2-7.2 | 8 | 9 | 50, 75 | 0.035" (0.889 mm) | 80, 120 | 8 | 9 |
| | 8 | 10 | 100, 125 | 0.035" (0.889 mm) | 80, 120 | 8 | 10 |
| 7.3-8.1 | 9 | 10 | 50, 75 | 0.035" (0.889 mm) | 80, 120 | 9 | 10 |
| | 9 | 11 | 100, 125 | 0.035" (0.889 mm) | 80, 120 | 9 | 11 |
| 8.2-9.0 | 10 | 11 | 50, 75 | 0.035" (0.889 mm) | 120 | 10 | 11 |
| | 10 | 12 | 100, 125 | 0.035" (0.889 mm) | 120 | 10 | 12 |
| 9.0-10.8 | 12 | 12 | 30, 40, 50, 60, 70, 80 | 0.035" (0.889 mm) | 120 | 12 | 12 |
| 10.9-12.6 | 14 | 12 | 30, 40, 50 | 0.035" (0.889 mm) | 120 | 14 | 12 |
| | 14 | 14 | 60, 70, 80 | 0.035" (0.889 mm) | 120 | 14 | 14 |
| 12.7-14.4 | 16 | 14 | 30, 40, 50, 60, 70, 80 | 0.035" (0.889 mm) | 120 | 16 | 14 |

1 Recommended endoprosthesis compression within the vessel is approximately 10-25%
2 Labeled lengths are nominal and are measured from each extreme end of the endoprosthesis

**REQUIRED SUPPLIES**

- Merit WRAPSODY Endoprosthesis System
- Marker guide wire or catheter (for calibrated measurement reference)
- Sterile heparinized saline and sterile saline
- Sterile syringes
- 0.035" (0.889 mm) stiff guide wire at least twice as long as the length of the delivery catheter system
- Valved introducer sheath with appropriate inner diameter
- Balloon angioplasty catheter and accessories for pre and/or post dilation
- Guide catheters and accessories
- Contrast medium

**DIRECTIONS FOR USE**

**Initial Preparation**

- Select the appropriate vessel to access. Use the appropriate local anesthesia. A percutaneous Seldinger technique is preferred. A cutdown may be performed when necessary.
- Once vascular access is gained, insert an appropriately sized, valved introducer sheath for insertion of the WRAPSODY Delivery Catheter.
- Prepare an appropriate guide wire per its Instructions For Use and advance the guide wire under fluoroscopy across the lesion.
- Prior to placement of the Merit WRAPSODY Endoprosthesis, pre-dilate the lesion with percutaneous transluminal angioplasty (PTA) in accordance with the manufacturer's Instructions For Use. Ensure full expansion of the balloon within the lesion.
- Following deflation of the angioplasty balloon, evaluate the results angiographically.

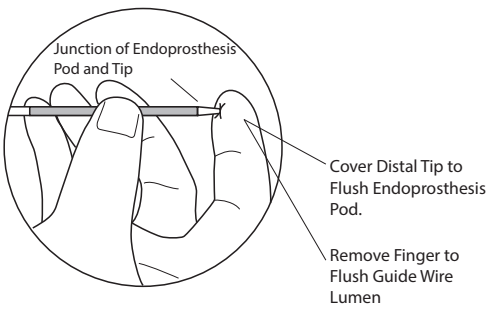
**Sizing and Selection of the WRAPSODY Endoprosthesis**

- Assess the vessel to determine the diameter and length of the WRAPSODY Endoprosthesis needed. It is recommended to use the healthy vessel diameter immediately adjacent to the lesion to determine the endoprosthesis diameter. Use Table 1 to select the most appropriate WRAPSODY Endoprosthesis. Undersizing of the WRAPSODY Endoprosthesis diameter may result in device migration.
- The WRAPSODY Endoprosthesis lengths listed in Table 1 are nominal. When determining the length of the endoprosthesis, please note that the endoprosthesis should overlap the healthy vessel at least 1 cm beyond the proximal and distal margins of the lesion.
- If multiple devices are to be overlapped, the recommended tips should be followed:
  - The diameter of devices being overlapped should not differ by more than 2 mm.
  - If unequal device diameters are used, the **smaller** device should be placed **first** and then the larger device should be placed inside the smaller device.
  - To ensure that all overlapped WRAPSODY Endoprosthesiss are in good apposition to each other, it is recommended that the overlap distance be a minimum of 1 cm across devices being used.
  - Post-dilation of the first WRAPSODY Endoprosthesis should be performed prior to placing the second device. Then post-dilation of the second device is performed.
- Check expiration date on product package. If product is expired, do not use. Make sure there is no damage to the package or the sterile barrier – if there is damage or the sterile barrier has been compromised do not use. Remove the outer pouch and place the inner pouch (which is sterile) onto the sterile field. Carefully remove contents of the inner pouch and inspect for damage such as kinks, bends, or other damage. If any damage is found, do not use.
- Prior to inserting the WRAPSODY Delivery Catheter into the valved introducer sheath, check that the diameter and length of the endoprosthesis as well as the delivery catheter length are correct for the lesion being treated.

**Introduction and Positioning of the Merit WRAPSODY Endoprosthesis System**

- When pre-deployment PTA has been successfully completed, be sure to remove the deflated balloon catheter while maintaining position of the guide wire beyond the target lesion.
- Ensure that the stiff guide wire is 0.035" (0.889 mm).
- Before inserting the WRAPSODY Delivery Catheter into the patient, prepare the delivery catheter. First, flush the endoprosthesis Pod. This is done by placing a finger to occlude the distal end of the delivery catheter (see Figure 3) followed by injecting sterile heparinized saline through the flushing port (see Figure 2). Watch for drops of saline to emerge at the junction of the endoprosthesis Pod and the tip, as this will indicate that the endoprosthesis Pod has been successfully flushed (see Figure 3). Second, flush the guide wire lumen. This is done by removing the finger followed by injecting sterile heparinized saline through the flushing port (see Figure 3). Watch for saline to emerge from the end of the delivery catheter. Finally, wet the hydrophilic coating of the delivery catheter using sterile heparinized saline to ensure smooth introduction through the valved introducer sheath.

Figure 3.

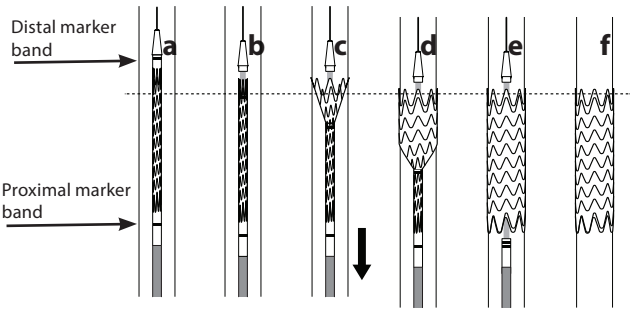



- With the WRAPSODY Delivery Catheter as straight as possible, insert the "back end" of guide wire into the tip of the delivery catheter (see Figure 2) making sure to maintain guide wire position. Carefully advance the WRAPSODY Delivery Catheter through the valved introducer sheath continuing to wet the hydrophilic coating as needed, and into the access vessel. Note: If excessive resistance is felt as the delivery catheter is introduced through the haemostasis valve, remove and inspect the delivery catheter for damage. Do not reuse if damaged. Ensure the valved introducer sheath diameter is compatible with the given delivery catheter outer diameter (see Table 1), and that the valved introducer sheath is free of kinks.

- Using fluoroscopic guidance, advance the WRAPSODY Delivery Catheter. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, reassess procedure.
- Continue to advance delivery system until the leading edge of the endoprosthesis is past the lesion. Then, maintaining tip position, pull slightly to straighten the delivery system.
- Using fluoroscopy, verify that delivery catheter is optimally positioned for deployment and that the selected endoprosthesis length covers the entire lesion and both ends of the endoprosthesis extend at least 1 cm into a non-diseased vessel segment.

**Deploying the Merit WRAPSODY Endoprosthesis : Standard Deployment**

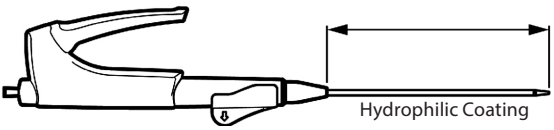
Figure 4 a-f




- Advance the Merit WRAPSODY Endoprosthesis Delivery Catheter until the distal marker band (see Figure 4a) is just past the desired endoprosthesis landing zone.
- Deployment of the WRAPSODY Endoprosthesis requires a priming step prior to full deployment of the endoprosthesis. Prime the system by performing several micro-clicks (partial depression of the handle) until the catheter outer sheath begins to retract and the distal marker band aligns with the WRAPSODY Endoprosthesis marker bands (see Figure 4b).
- Confirm desired deployment location and adjust by pulling or advancing the catheter.
- Continue performing micro-clicks of the delivery handle to further retract the outer sheath of the delivery catheter, uncovering the leading edge of the unconstrained WRAPSODY Endoprosthesis. A short segment of the WRAPSODY Endoprosthesis will begin to expand or flare from the end of the catheter. Continue to deploy until the first row of the endoprosthesis has deployed and contacts the vessel wall (see Figure 4c). At this point, the endoprosthesis may be pulled back to the target deployment location (see Figure 4d). **Note:** The WRAPSODY Delivery System should not be advanced forward once any portion of the endoprosthesis is apposing the vessel wall.
- Continue depressing the WRAPSODY Endoprosthesis handle, while applying light tension to the catheter during endoprosthesis deployment until the endoprosthesis is completely released from delivery system (see Figure 4e).
- **Note:** The proximal marker band on the WRAPSODY Delivery Catheter should be visualized and remain in stable position during deployment.
- Once the WRAPSODY Endoprosthesis is fully deployed and no longer constrained by the delivery catheter, carefully withdraw the delivery system under fluoroscopic imaging, to ensure delivery catheter tip does not catch on the WRAPSODY Endoprosthesis, which could cause endoprosthesis dislodgement. Maintain position of the guide wire through the WRAPSODY Endoprosthesis.
- Excessive force during delivery catheter removal may damage the delivery catheter or the valved introducer sheath. If resistance is encountered when removing the delivery catheter, it is recommended to remove the delivery catheter and valved introducer sheath as a unit, maintaining guide wire position through the deployed WRAPSODY Endoprosthesis. Then, insert a new valved introducer sheath of identical size as the one that was removed.
- Select an appropriately sized PTA balloon (Table 1), no greater in diameter than the WRAPSODY Endoprosthesis, to perform post deployment dilation. Inflate the PTA balloon along the entire length of the WRAPSODY Endoprosthesis. Multiple inflations may be required if the WRAPSODY Endoprosthesis length is longer than the PTA balloon. Avoid balloon dilation beyond the ends of the WRAPSODY Endoprosthesis.
- After completion of the touch-up procedure, deflate PTA balloon and carefully remove it.
- Use contrast angiography to evaluate the treated vessel segment and distal flow circuit prior to completing the procedure (see Figure 4f).

**INFORMATION ON PACKAGING**

| Symbol | Designation |
|---|---|
| | Use By |
| LOT | Batch code |
| REF | Catalog number |
| | Do not resterilize |
| | Do not use if package is damaged and consult instructions for use |
| | Keep away from sunlight |
| | Keep dry |
| | Single use |
| | Caution: Consult accompanying documents |
| | Non-pyrogenic |
| STERILE EO | Sterilized using ethylene oxide |
| MR | MR Conditional |
| ℞ ONLY | Federal (USA) law restricts this device to sale by or on the order of a physician. |
| | Max Guide Wire |
| | Minimum Introducer Size |
| | Consult instructions for use. For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service. |
| | Manufacturer |
| | Double Sterile Barrier System |
| Reference Vessel Diameter Range | |

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