Merit WRAPSODY™

Cell-Impermeable* Endoprosthesis

INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

* Based upon evaluation of the device in an ovine external iliac artery model

MERITMEDICAL®

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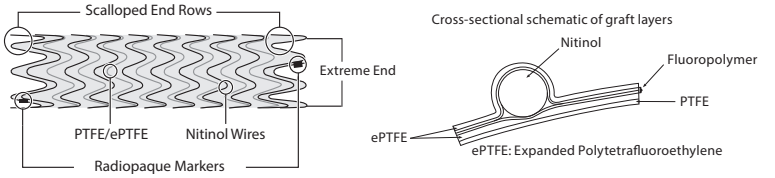
DESCRIPTION

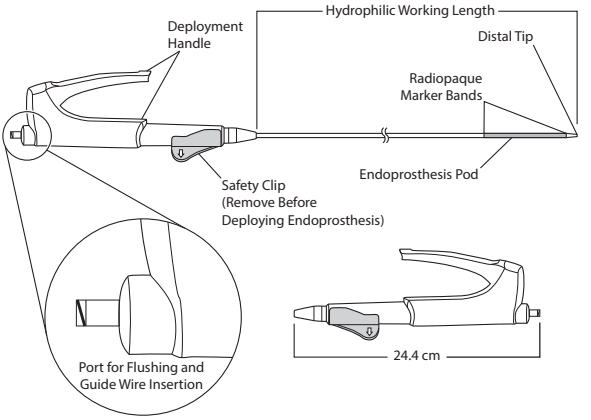
The Merit WRAPSODY® Cell-Impermeable Endoprosthesis is comprised of the WRAPSODY Cell-Impermeable Endoprosthesis (CIE) and the WRAPSODY delivery catheter system. The WRAPSODY CIE is a flexible, self-expanding endoprosthesis designed for placement in the vasculature. The WRAPSODY CIE is made from nitinol wire that is encapsulated between layers of fluoropolymer, including an expanded fluoropolymer abluminal layer, cell-impermeable mid layer, and rotationally spun luminal layer. Placement of the WRAPSODY CIE is facilitated by radiopaque markers, three on each end, that are located on both end rows of the WRAPSODY CIE (see Figure 1). Both ends of the WRAPSODY CIE are trimmed in a scalloped manner.

Figure 1.



The WRAPSODY CIE 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 CIE. 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 CIE.

Figure 2.



HOW SUPPLIED

The Merit WRAPSODY® Cell-Impermeable Endoprosthesis is supplied STERILE. Sterilization is done with ethylene oxide. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

INDICATIONS FOR USE

The Merit WRAPSODY® Cell-Impermeable Endoprosthesis is a flexible, self-expanding endoprosthesis indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis access outflow circuit, including stenosis or occlusion;

- in the peripheral veins of individuals with an arteriovenous (AV) fistula,
- at the venous anastomosis of a synthetic AV graft.

CONTRAINDICATIONS

- Do not use in patients who have a known hypersensitivity to nickel or titanium.

WARNINGS

- Do not use in patients whose lesions cannot be crossed with a wire and/or balloon catheter and cannot be dilated sufficiently to allow passage of the delivery system.
- This device is intended for use by physicians who have received appropriate training and are familiar with the complications, side effects, and dangers associated with intravascular endoprosthesis procedures.
- Both the proximal and distal reference vessel/graft diameters (see Table 1) should be measured accurately to reduce the possibility of endoprosthesis migration, undersizing or excessive oversizing as defined in Table 1.

- Do not use if full expansion of an appropriately sized Percutaneous Transluminal Angioplasty (PTA) balloon catheter cannot be achieved during pre-dilation.
- 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. If a stiff guidewire is not used, optimal device trackability/pushability may be compromised.
- Repositioning of the WRAPSODY delivery catheter may be necessary prior to deploying the endoprosthesis; however, once the endoprosthesis struts make contact with the vessel wall, repositioning (advancing forward) should be avoided to prevent vessel damage.
- Once deployed, the WRAPSODY CIE cannot be retracted or resheathed onto the delivery catheter.
- Placing a device across a side branch may obstruct blood flow and prevent or hinder future access or other procedures.
- Placing a device 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 CIE if it cannot be flushed prior to use. Guide wire lumen and CIE 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 CIE may require surgical intervention.
- Do not force passage if resistance is encountered at any time during delivery of the CIE delivery system. This may cause damage to the CIE, the CIE delivery system, or vessel or may lead to partial deployment.
- If the endoprosthesis cannot be deployed, remove the entire delivery system and re- assess the procedure. If the problem persists, replace with a new device. A partially deployed endoprosthesis may require surgical removal.
- Do not push or advance the CIE delivery system forward once the endoprosthesis struts make contact with the vessel wall.
- Do not attempt to recapture a partially deployed endoprosthesis using the CIE delivery system.
- Do not force removal of the delivery system if resistance is encountered at any time during withdrawal (post endoprosthesis deployment). Applying excessive force could result in loss of delivery system components or damage to the endoprosthesis, delivery system, or vessel.
- Do not use in patients with allergy or sensitivity to contrast media.
- 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 CIE is not designed to treat fresh, soft thrombotic or embolic material.
- Do not use in an immature fistula in patients where AV access grafts have been implanted less than 30 days.
- Do not use in an immature fistula in patients where an AV fistula has been created; the fistula must have been created at least 30 days prior to placing a WRAPSODY CIE.
- Do not place a WRAPSODY CIE in the cannulation zone.
- Avoid placing a WRAPSODY CIE in lesions involving known external compression.
- Additional imaging from varying angles may be required prior to deploying the WRAPSODY CIE to ensure precise placement of the device.
- This device contains nitinol, an alloy of nickel (Ni) and titanium (Ti). Persons with allergic reactions to these metal elements may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these metallic components.

PRECAUTIONS

- Follow the Instructions for Use with all devices that are used together with the WRAPSODY CIE.
- The WRAPSODY delivery catheter is not intended for any use except to deploy the WRAPSODY CIE
- The use of an introducer or guide sheath for the implant procedure is recommended to protect the access site.
- The WRAPSODY delivery catheter can only deploy the WRAPSODY CIE after the safety clip is removed. This should not be done until the WRAPSODY CIE is about to be released. See DIRECTIONS FOR USE.
- Higher deployment forces may be encountered on longer lengths of WRAPSODY CIE devices.
- Post-dilation of the WRAPSODY CIE must be performed using an appropriately sized PTA balloon catheter to avoid damage to the device. The WRAPSODY CIE should not be balloon expanded beyond its stated diameter. Refer to Table 1 for the appropriately sized balloon diameter.
- Serious complications, such as migration to the heart, may occur if the WRAPSODY CIE is not sized appropriately.
- Do not use a balloon that is longer than the labeled length of the WRAPSODY CIE.
- When passing any accessory device through the WRAPSODY CIE use caution and ensure that the WRAPSODY CIE does not dislodge.
- The delivery system must be carefully withdrawn to ensure delivery catheter tip does not catch on the WRAPSODY CIE, which could cause endoprosthesis dislodgement.
- Do not withdraw or reposition a balloon catheter within the lumen of the WRAPSODY CIE unless the balloon is completely deflated.
- Clinical evaluation of the 6 mm diameter WRAPSODY CIE is not yet available.
- 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 or compression such as the clavicle, popliteal fossa, and antecubital fossa.
- Testing has not been conducted for the use of the WRAPSODY CIE in an overlapped condition with bare metal stents or with other competitive endoprostheses (or covered stents).
- The safety and effectiveness of using the device across the anastomosis of an AV fistula has not been evaluated.

- Testing has not been conducted for tracking and deployment of the WRAPSODY CIE around an AV loop graft.
- The WRAPSODY delivery catheter has not been tested with 0.014" or 0.018" guide wires.
- The safety and effectiveness of the device when placed in the central veins has not been evaluated.
- The safety and effectiveness of the device when placed in the forearm across the antecubital fossa has not been fully established.
- The safety and effectiveness of the device has not been evaluated in pediatric patients.
- 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 CIE after the expiration date.
- Care should be used to avoid puncturing or cutting the WRAPSODY CIE
- 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 CIE.

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.

CLINICALLY RELATED COMPLICATIONS

The WRAPSODY CIE may result in failures or complications similar to other peripheral stents/endoprostheses with similar indications for use. Prior human use and preclinical studies of the WRAPSODY CIE have not shown any additional risks. Documented risks of peripheral stents/endoprostheses and/or the endovascular treatment procedure include, but are not limited to (potential risks are listed in alphabetical order and not per risk level):

Potential endoprosthesis-related adverse effects:
- Aneurysm
- Embolism and/or vessel thrombosis
- Emergency or non-emergency access circuit intervention
- Endoprosthesis compression
- Endoprosthesis embolization
- Endoprosthesis kinking
- Endoprosthesis malfunction
- Endoprosthesis migration
- Endoprosthesis misplacement
- Endoprosthesis occlusion / thrombosis
- Fracture of the endoprosthesis that may or may not lead to embolism, serious injury or surgical intervention
- Infection or fever, including device infection
- Insufficient endoprosthesis expansion
- Ischemia
- New lesion or total occlusion of the vascular access circuit
- Placement of a bailout stent / stent graft
- Pseudoaneurysm
- Restenosis of the treated segment
- Serious injury requiring surgical intervention
- Steal syndrome
- Vascular complications that may require surgical repair (conversion to open surgery)

Potential delivery catheter system-related adverse effects:
- Access-site complications
- Bond joint failure
- Delivery system kinking
- Delivery system malfunction that may or may not lead to device embolism, serious injury, or surgical intervention.
- Detachment of part
- Failure to deploy
- Fracture of the guide wire or any component of the delivery catheter system that may or may not lead to embolism, serious injury or surgical intervention
- Hematoma
- High deployment forces
- Inability to track to the target location
- Inaccurate deployment
- Incompatibility with accessory devices
- Premature deployment
- Seroma

Potential procedure-related adverse effects:
- Access-site complications
- Allergic reaction to contrast media / medications
- Arteriovenous (AV) fistula
- Bleeding complications
- Cardiac arrest
- Cardiac arrhythmia
- Death
- Extravasation of contrast media
- Hematoma
- Infection or fever
- Ischemia
- Myocardial infarction or coronary ischemia

- Neurological deficit
- Pain
- Radiation exposure
- Reaction to contrast media / medication
- Respiratory distress or failure
- Serious injury requiring surgical intervention
- Seroma
- Stroke or TIA
- Swelling or edema
- Transfusion
- Vascular complications that may require surgical repair (conversion to open surgery)
- Vessel dissection
- Vessel perforation
- Vessel rupture
- Vessel spasm

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 CIE is required with a balloon equal in diameter to that of the selected WRAPSODY CIE diameter.
- Prescribed anticoagulation pre-procedure, during and post-procedure should follow physician and institutional standards, including dual antiplatelet treatment if appropriate.

MRI SAFETY AND COMPATIBILTY INFORMATION

MRI Safety Information

Non-clinical testing has demonstrated that the WRAPSODY CIE is MR Conditional. A patient with a WRAPSODY CIE implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WRAPSODY® Cell-Impermeable Endoprosthesis
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. In non-clinical testing, image artifact caused by the WRAPSODY CIE extends approximately 3 mm from device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. The lumen of the WRAPSODY CIE can be visualized on T1-weighted, spin echo and gradient echo pulse sequences

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

WRAPSODY CELL-IMPERMEABLE ENDOPROSTHESIS SIZING AND SELECTION
It is essential to ensure that the appropriate diameter and length are chosen for the WRAPSODY CIE prior to introduction. To ensure adequate fixation (or vessel wall apposition), it is recommended to oversize the diameter of the WRAPSODY CIE relative to the healthy (non-diseased) portion of the vessel or arteriovenous graft, see Table 1. The endoprosthesis selected should extend at least 1 cm beyond the proximal and distal margins of the lesion to be treated.

For lesions that start 30 mm or less from a prosthetic graft venous anastomosis in an arteriovenous access, the endoprosthesis should overlap the prosthetic graft by at least 1 cm and should not extend more than 1 cm past the lesion.

The WRAPSODY CIE does not exhibit noticeable foreshortening during deployment. If deployed as instructed, the endoprosthesis length should not appreciably change, i.e., shorten or lengthen.

Table 1.

Reference Vessel/ Graft Diameter[1] (mm)	WRAPSODY CIE Diameter (mm)	Delivery Catheter Outer Diameter (Fr)	Available WRAPSODY CIE Lengths[2] (mm)	Guide Wire Diameter	Delivery Catheter Working Length (cm)	Recommended Balloon Diameter for Post-Dilation (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 oversizing is approximately 10-25% greater than the reference vessel/graft diameter

[2] Labeled lengths are nominal and are measured from each extreme end of the endoprosthesis

REQUIRED SUPPLIES

- Merit WRAPSODY® Cell-Impermeable Endoprosthesis (CIE)
- 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 WRAPSODY CIE, 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 Cell-Impermeable Endoprosthesis

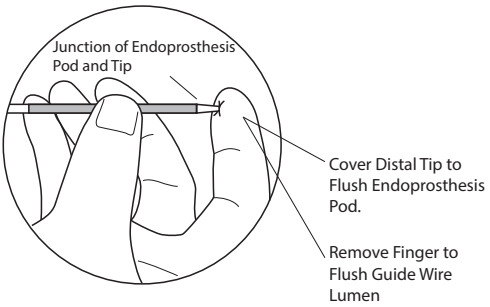
- Assess the vessel or AV graft to determine the diameter and length of the WRAPSODY CIE needed. It is recommended to use the reference vessel/graft diameter immediately adjacent to the lesion (both proximally and distally) to determine the endoprosthesis diameter. Use Table 1 to select the most appropriate WRAPSODY CIE.

  CAUTION: Undersizing of the WRAPSODY CIE diameter may result in device migration.
- The WRAPSODY CIE 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 or AV graft anastomosis.
- 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 (e.g., 12 mm to 14 mm overlap is acceptable).
  - 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 CIE devices 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 CIE should be performed prior to placing the second device. Then post-dilation of the second (and subsequent devices, if applicable) 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, (refer to Table 1 for capability of sheath/introducer size per endoprosthesis size) 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 WRAPSODY CIE

- 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.

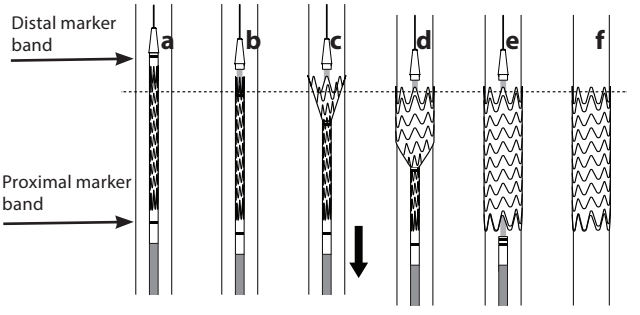
Figure 3.



- 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 hemostasis 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, remove the device and re-assess the procedure. If the problem persists, replace with a new device.
- 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 or graft segment.

Deploying the WRAPSODY Cell-Impermeable Endoprosthesis: Standard Deployment

Figure 4 a-f



- Advance the WRAPSODY CIE delivery catheter until the distal marker band (see Figure 4a) is just past the desired endoprosthesis landing zone.
- Deployment of the WRAPSODY CIE 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 CIE marker bands (see Figure 4b).
  NOTE: Priming step process may take longer with longer length endoprostheses.
- 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 CIE. A short segment of the WRAPSODY CIE 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 catheter should not be advanced forward once any portion of the endoprosthesis is apposing the vessel wall.

  CAUTION: The endoprosthesis is not designed to be pushed forward once the endoprosthesis struts contact the vessel wall. The endoprosthesis delivery system is not designed for reloading/recapturing a partially or fully deployed endoprosthesis.

- Continue depressing the WRAPSODY delivery catheter system handle, while applying light tension to the catheter during endoprosthesis deployment until the endoprosthesis is completely released from delivery system (see Figure 4e).
  CAUTION: The proximal marker band on the WRAPSODY delivery catheter should be visualized and remain in stable position during deployment.
- Once the WRAPSODY CIE 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 CIE, which could cause endoprosthesis dislodgement. Maintain position of the guide wire through the WRAPSODY CIE.
- 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 CIE. 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 CIE, to perform post-dilation. Inflate the PTA balloon along the entire length of the WRAPSODY CIE. Multiple inflations may be required if the WRAPSODY CIE length is longer than the PTA balloon. Avoid balloon dilation beyond the ends of the WRAPSODY CIE.
- After completion of the post-dilation procedure, fully deflate PTA balloon and carefully remove it.
- Use contrast angiography to evaluate the treated vessel segment and distal flow circuit prior to removing the guidewire and completing the procedure (see Figure 4f).

SUMMARY OF CLINICAL STUDY (WAVE)

The WRAPSODY CIE was evaluated in the prospective, multi-center, multi-cohort WAVE study consisting of a randomized (1:1) concurrently-controlled AVF cohort and a single arm AVG cohort. Safety and effectiveness measures of subjects receiving the WRAPSODY CIE are presented with information derived from clinical literature as well as other prospective pivotal studies to provide clinical context for the results. The WAVE study enrolled 246 subjects in the AVF Peripheral cohort and 112 subjects in the AVG Anastomosis cohort at 43 investigational sites in the United States, United Kingdom, Canada, and Brazil. Results through 6 months are currently available; subjects will be followed through 24 months.

Study Endpoints

The primary safety outcome measure was the proportion of subjects without any localized or systemic safety events through 30 days post-procedure that affected the access or venous outflow circuit and resulted in reintervention, hospitalization, or death; specific events of CD TLR or reintervention due to target lesion thrombosis were counted as failures of primary effectiveness and not included as failures of primary safety. The following hypotheses were tested for the primary safety endpoint:

- AVF cohort: The event-free rate is determined to be non-inferior in the treatment are compared to the control arm based on the Farrington-Manning test (p-value < 0.05).
- AVG cohort: The primary safety endpoint was evaluated against a literature-based performance goal (PG) of 89% freedom from safety events. The safety PG is met if the binomial exact test resulted in a single-sided p-value less than 0.05.

The primary effectiveness outcome measure was Target Lesion Primary Patency (TLPP) at 6 months, defined as freedom from clinically-driven target lesion revascularization (CD-TLR) or target lesion thrombosis measured through 6 months post-procedure, which is the time interval of uninterrupted patency after the study procedure to the next intervention performed on the target lesion or uncorrectable target lesion occlusion. The following hypotheses were tested for the primary effectiveness endpoint:

- AVF cohort: The proportion of subjects achieving TLPP at 6 months for the treatment arm is superior to that in subjects treated with PTA alone. A two-sided p-value was calculated based on the chi-square test. The study device is considered to have achieved the effectiveness objective if the two-sided p-value is less than 0.05.
- AVG cohort: The primary effectiveness endpoint was evaluated against a literature-based PG of 60%, which represents the average 6-month TLPP reported for stent grafts utilized for this indication. The effectiveness PG is considered met if the one-sided p value is less than 0.05 based on the binomial exact test.

PGs for evaluation of safety and effectiveness in the AVG cohort were established based on literature for other stent grafts, including results from clinical investigations for the FLAIR® Endovascular Stent Graft, GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface (REVISE study), FLUENCY® PLUS Endovascular Stent Graft (RESCUE study), and Bard COVERA™ Vascular Covered Stent (AVeVA study).

Secondary effectiveness endpoints with hypothesis testing include:

- TLPP at 12 and 24 months
- Access Circuit Primary Patency (ACPP) at 6, 12, and 24 months, defined as time to loss of Primary Patency of the access circuit, which is the time from post-procedure until any venous outflow circuit re-intervention, or access thrombosis or abandonment.

Other important secondary endpoints that are summarized with descriptive statistics include:

- Post-Procedure Secondary Patency defined as the interval post-procedure until access circuit abandonment.
- Rate of device observations and potential malfunctions or failures.
- Rate of Serious Adverse Events (SAE).
- Rate of SAE involving the AV access circuit.
- Number of target lesion reinterventions to maintain target lesion patency.
- Number of interventions to maintain access circuit patency.
- Percentage of subjects with Device and Procedure Success.
  - Device Success: Successful delivery to the target lesion, deployment and retrieval of delivery system at index procedure.
  - Procedure Success: At least one indicator of hemodynamic success (e.g., physical examination with restoration of a thrill, direct measurement of flow) in the absence of peri-procedural (index procedure through discharge) Serious Adverse Device Effects.

Exploratory endpoints:

- Clinical Success defined as resumption of successful dialysis through existing access for at least one session following initial study procedure.
- Index of Patency Function at months 6, 12 and 24 defined as time after study procedure to complete access abandonment divided by number of venous outflow circuit re-interventions to maintain hemodialysis.

PATIENTS STUDIED

Eligible patients included hemodialysis patients ≥18 years with a dysfunctional AVF due to stenosis in their peripheral venous outflow circuit who met the inclusion/exclusion criteria. To be included in the study, the target lesion was required involve a de novo stenotic or non-stented restenotic lesion with a target lesion reference vessel/graft diameter between 5.0 mm and 14.0 mm. The subject was required to have either a mature AVF or AVG in the arm. Subjects were excluded from the study if they had a known or suspected infection of the hemodialysis access site, systemic infection and/or septicemia, a stroke diagnosis within 3 months prior to enrollment, history of unstable angina or myocardial infarction within 60 days prior to enrollment, or if the subject was pregnant, breastfeeding, or intending to become pregnant within the next year.

METHODS

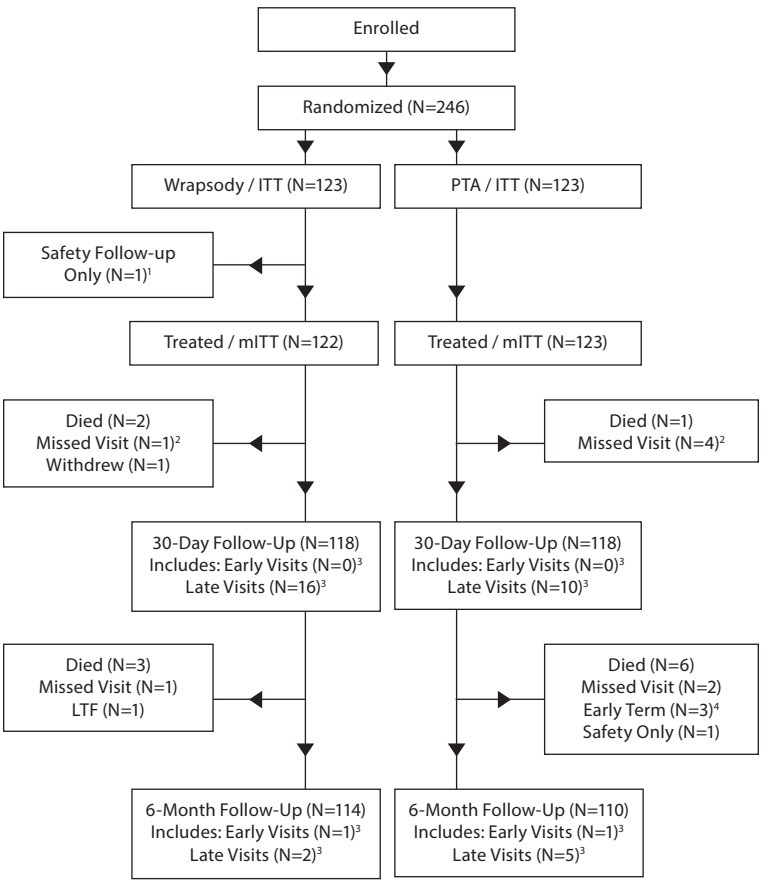
All patients underwent a clinical evaluation at screening (prior to index procedure); following consent, a baseline angiogram was obtained, and angiographic criteria were confirmed. Subjects in the AVF cohort were randomized 1:1 to treatment with the WRAPSODY CIE or PTA; all subjects in the AVG cohort were treated with the WRAPSODY CIE. Clinical assessments and evaluations of the dialysis access circuit were performed at the index procedure and at the 30- and 180-day follow-up visits; telephone assessments were conducted 90 days following the index procedure. Safety events were monitored and adjudicated by an independent Clinical Events Committee and an independent core laboratory reviewed angiographic images.

RESULTS

Subject Accountability

The number of subjects available for analysis at each time point is shown in Figure 5 for the AVF cohort and Figure 6 for the AVG cohort.

Figure 5.
Patient Accountability for AVF Cohort



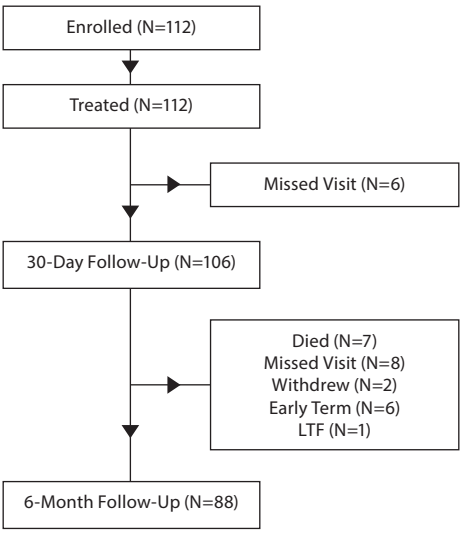
[1] One patient was not treated with the WRAPSODY CIE due to procedural complication of extravasation after pre-dilation and randomization that required treatment on an emergent basis with a commercial stent

[2] Subjects with missed visits at 30 days are not exited from study and remain eligible for 6-month follow-up.

[3] Early and Late Visits occurred outside of the protocol-defined follow-up windows (i.e., 30 ± 10 days, 180 ± 30 days)

[4] Reasons for early termination (early term) include, but are not limited to, subjects who proceed to kidney transplant and access circuit abandonment

Figure 6.
Patient Accountability for AVG Cohort



Subject Demographics and Baseline Characteristics
The demographics of the study population are typical for a vascular access intervention study performed in the US. Demographics and Medical history are reported in Table 2 and Table 3.

In the AVF and AVG cohorts respectively, 43% and 54% of subjects were female, 52% and 30% were Caucasian / white, 41% and 62% were African American / black, and 32% and 25% reported Hispanic / Latino ethnicity. The rate of unstable angina was higher in the PTA group compared to the WRAPSODY CIE group, while the rates of congestive heart failure and peripheral vascular disease were higher in the WRAPSODY CIE group compared to the PTA group.

Baseline characteristics of the access circuit and target lesion are provided in Table 4 and Table 5. Based on core laboratory measurements, the length of the stenosis being treated was longer in the WRAPSODY CIE group compared to the PTA group. Overall, 60% of AVF lesions and 53% of AVG lesions enrolled in the study were being treated for restenosis.

The number of subjects implanted with each size of WRAPSODY CIE is provided in Table 6.

Table 2.
Demographics

Parameter	AVF Cohort		AVG Cohort
	WRAPSODY (n=122)	**PTA (n=123)**	**WRAPSODY (n=112)**
Age at enrollment (years)	61.6 ± 13.9	60.1 ± 14.5	64.1 ± 13.3
BMI	29.6 ± 6.5	29.5 ± 7.5	27.0 ± 6.3
Sex			
Male	70 / 122 (57.4%)	69 / 123 (56.1%)	51 / 112 (45.5%)
Female	52 / 122 (42.6%)	54 / 123 (43.9%)	61 / 112 (54.5%)
Race			
Caucasian / White	66 / 122 (54.1%)	62 / 123 (50.4%)	34 / 112 (30.4%)
African American / Black	49 / 122 (40.2%)	51 / 123 (41.5%)	69 / 112 (61.6%)
American Indian or Alaska Native	2 / 122 (1.6%)	0 / 123 (0.0%)	1 / 112 (0.9%)
Pacific Islander	1 / 122 (0.8%)	0 / 123 (0.0%)	0 / 112 (0.0%)
Asian	3 / 122 (2.5%)	6 / 123 (4.9%)	3 / 112 (2.7%)
Other	3 / 122 (2.5%)	4 / 123 (3.3%)	5 / 112 (4.5%)
Ethnicity			
Non-Hispanic / Latino	81 / 122 (66.4%)	86 / 123 (69.9%)	83 / 111 (74.8%)
Hispanic / Non-Latino	41 / 122 (33.6%)	37 / 123 (30.1%)	28 / 111 (25.2%)

Table 3.
Medical History

Parameter	AVF Cohort		AVG Cohort
	WRAPSODY (n=122)	**PTA (n=123)**	**WRAPSODY (n=112)**
Cerebrovascular Accident (CVA) or Stroke	18 / 122 (14.8%)	16 / 123 (13.0%)	18 / 111 (16.2%)
Transient Ischemic Attack (TIA)	11 / 122 (9.0%)	10 / 121 (8.3%)	8 / 109 (7.3%)
Cardiac Arrythmia	30 / 121 (24.8%)	18 / 120 (15.0%)	19 / 109 (17.4%)
Hypertension	115 / 122 (94.3%)	116 / 123 (94.3%)	106 / 112 (94.6%)
History of / or current hypercholesterolemia / dyslipidemia	71 / 121 (58.7%)	74 / 119 (62.2%)	62 / 109 (56.9%)
Premature atherosclerotic disease	18 / 119 (15.1%)	21 / 121 (17.4%)	17 / 110 (15.5%)
Unstable angina	1 / 121 (0.8%)	7 / 120 (5.8%)	1 / 112 (0.9%)
Previous MI	18 / 121 (14.9%)	21 / 123 (17.1%)	22 / 111 (19.8%)
Previous PCI	13 / 119 (10.9%)	20 / 118 (16.9%)	15 / 109 (13.8%)
Previous CABG	10 / 122 (8.2%)	13 / 121 (10.7%)	15 / 112 (13.4%)
Congestive Heart Failure (CHF)	42 / 121 (34.7%)	27 / 122 (22.1%)	35 / 110 (31.8%)
Peripheral Vascular Disease (PVD)	20 / 122 (16.4%)	8 / 118 (6.8%)	21 / 109 (19.3%)
Smoking	51 / 120 (42.5%)	50 / 122 (41.0%)	52 / 110 (47.3%)
Current	8 / 51 (15.7%)	12 / 50 (24.0%)	13 / 52 (25.0%)
Diabetes Mellitus	88 / 122 (72.1%)	79 / 122 (64.8%)	70 / 112 (62.5%)
Type I	4 / 88 (4.5%)	11 / 79 (13.9%)	11 / 70 (15.7%)
Type II	82 / 88 (93.2%)	67 / 79 (84.8%)	57 / 70 (81.4%)
Unknown	2 / 88 (2.3%)	1 / 79 (1.3%)	2 / 70 (2.9%)
Gastro-Intestinal (GI) / Genito-Urinary (GU) bleeding	11 / 122 (9.0%)	5 / 120 (4.2%)	13 / 109 (11.9%)
Substance abuse	9 / 119 (7.6%)	7 / 119 (5.9%)	14 / 110 (12.7%)
Other significant medical history	66 / 122 (54.1%)	52 / 122 (42.6%)	60 / 112 (53.6%)

Table 4.
Access Circuit Assessment at Baseline

Parameter	AVF Cohort		AVG Cohort
	WRAPSODY (n=122)	**PTA (n=123)**	**WRAPSODY (n=112)**
Arm / Side of access			
Right	26 / 122 (21.3%)	28 / 123 (22.8%)	30 / 112 (26.8%)
Left	96 / 122 (78.7%)	95 / 123 (77.2%)	82 / 112 (73.2%)
Current Access Position			
Upper arm	113 / 122 (92.6%)	108 / 122 (88.5%)	105 / 112 (93.8%)
Across elbow	8 / 122 (6.6%)	10 / 122 (8.2%)	0 / 112 (0.0%)
Forearm	1 / 122 (0.8%)	4 / 122 (3.3%)	7 / 112 (6.3%)
AVF location			
Radiocephalic	2 / 122 (1.6%)	3 / 121 (2.5%)	Not applicable
Brachiocephalic	89 / 122 (73.0%)	83 / 121 (68.6%)	
Brachiobasilic	31 / 122 (25.4%)	35 / 121 (28.9%)	
AVF transposition			
Transposed	41 / 120 (34.2%)	43 / 121 (35.5%)	Not applicable
Translocated	1 / 120 (0.8%)	0 / 121 (0.0%)	
Not transposed	78 / 120 (65.0%)	78 / 121 (64.5%)	
AVG material type			
Synthetic	Not applicable		109 / 112 (97.3%)
Biological			3 / 112 (2.7%)
AVG venous anastomosis location			
Axillary	Not applicable		50 / 112 (44.6%)
Basilic			42 / 112 (37.5%)
Brachial			14 / 112 (12.5%)
Cephalic			4 / 112 (3.6%)
Other			2 / 112 (1.8%)
Unknown			0 / 112 (0.0%)
AVG arterial anastomosis location			
Axillary	Not applicable		15 / 112 (13.4%)
Brachial			92 / 112 (82.1%)
Radial			0 / 112 (0.0%)
Ulnar			0 / 112 (0.0%)
Other			1 / 112 (0.9%)
Unknown			4 / 112 (3.6%)
AVG configuration			
Straight	Not applicable		71 / 112 (63.4%)
Looped			41 / 112 (36.6%)

Table 5.
Target Lesion Characteristics

Parameter		AVF Cohort		AVG Cohort
		WRAPSODY (n=122)	**PTA (n=123)**	**WRAPSODY (n=112)**
Site Assessments				
Proximal RVD[1] (mm)		9.7 ± 2.3 (122)	9.1 ± 1.9 (123)	8.2 ± 1.6 (113)
Distal RVD[1] (mm)		9.5 ± 2.0 (122)	9.2 ± 1.8 (123)	8.0 ± 2.0 (113)
Total Lesion Length (mm)		34.4 ± 20.3 (122)	32.7 ± 23.6 (123)	28.7 ± 21.2 (113)
Number of WRAPSODY CIE Implanted per Subject	1	117 / 122 (95.9%)	n/a	107 / 112 (95.5%)
	2	5 / 122 (4.1%)	n/a	5 / 112 (4.5%)
Type				
De novo		46 / 122 (37.7%)	53 / 123 (43.1%)	53 / 113 (46.9%)
Restenotic		76 / 122 (62.3%)	70 / 123 (56.9%)	60 / 113 (53.1%)
Pre-procedure Diameter Stenosis (%)		75.6 ± 11.8 (122)	75.9 ± 13.4 (123)	75.0 ± 12.6 (113)
Post-procedure Diameter Stenosis (%)		1.93 ± 9.48 (121)	11.8 ± 12.3 (123)	1.68 ± 3.67 (112)
Core Laboratory Assessments				
Target Lesion Vessel				
Axillary Vein		4 / 117 (3.4%)	4 / 117 (3.4%)	34 / 103 (33.0%)
Brachial Vein		1 / 117 (0.9%)	0 / 117 (0.0%)	5 / 103 (4.9%)
Cephalic Vein		77 / 117 (65.8%)	77 / 117 (65.8%)	4 / 103 (3.9%)
Basilic Vein		30 / 117 (25.6%)	30 / 117 (25.6%)	38 / 103 (36.9%)
Subclavian Vein		0 / 117 (0.0%)	2 / 117 (1.7%)	0 / 103 (0.0%)
Brachiocephalic Vein		4 / 117 (3.4%)	2 / 117 (1.7%)	0 / 103 (0.0%)
Other		1 / 117 (0.9%)	2 / 117 (1.7%)	22 / 103 (21.4%)
Stenosis Length (mm)		39.8 ± 15.7 (117)	33.8 ± 17.0 (116)	36.5 ± 18.4 (102)
Pre-Procedure				
Minimum Lumen Diameter		3.6 ± 1.5 (117)	3.7 ± 1.6 (117)	2.9 ± 1.3 (102)
Diameter Stenosis (%)		63.6 ± 12.0 (117)	61.5 ± 12.9 (117)	64.5 ± 13.8 (102)
Post-Procedure				
Minimum Lumen Diameter		8.5 ± 1.9 (112)	7.2 ± 1.6 (82)	7.1 ± 1.1 (112)
Diameter Stenosis (%)		17.4 ± 8.2 (112)	27.8 ± 11.2 (82)	15.4 ± 6.8 (96)

[1] RVD = reference vessel/graft diameter

Table 6.
Number of Subjects Implanted per WRAPSODY CIE Size

WRAPSODY CIE Diameter (mm)	Number of Subjects Implanted								
	WRAPSODY CIE Length (mm)								
	30	40	50	60	70	75	80	100	125
AVF Cohort									
6	Not offered		0	Not offered		0	Not offered	0	0
7			0			3		1	0
8			13			4		1	0
9			12			10		4	1
10			15			11		11	0
12	0	6	2	12	0	Not offered	6	Not offered	
14	0	2	4	6	0		0		
16	0	1	0	0	0		2		
AVG Cohort									
6	Not offered		0	Not offered		0	Not offered	0	0
7			11			5		3	0
8			35			19		3	0
9			15			11		3	1
10			7			2		0	0
12	0	0	0	0	0	Not offered	0	Not offered	
14	0	0	1	0	0		1		
16	0	0	0	0	0		0		

Summary of Safety
In the AVF cohort, the proportion of subjects free from primary safety events was 96.6% in the WRAPSODY arm and 95.0% in the PTA arm and the non-inferiority hypothesis was met ($p < 0.0001$). In the AVG cohort, the proportion of subjects free from primary safety events was 95.4%, which met the performance goal of 89% ($p = 0.0157$). All primary safety events were adjudicated by the Clinical Events Committee (CEC). The results for the AVF and AVG cohorts are presented in Table 7 and Table 8, respectively.

In the WRAPSODY arm of the AVF cohort, six safety events occurred in four patients:

- All six events were access circuit non-target lesion revascularizations, including five new lesions and one restenosis. One lesion was treated with PTA and a drug eluting stent, all other lesions were treated with PTA only. All lesions were resolved with functional dialysis access restored.

In the PTA arm of the AVF cohort, seven safety events occurred in six patients:

- Two patients had non-clinically driven target lesion revascularization; both were treated with PTA only and lesions were resolved with functional dialysis access restored.
- Five patients had access circuit non-target lesion revascularization. Three patients had new lesions, one treated with a drug eluting stent and two treated with PTA only; lesions were resolved with functional dialysis access restored. One patient had a restenosis treated with PTA; lesion was resolved with functional dialysis access restored. One patient had both a new lesion and restenosis treated with bare metal stents and thrombectomy in addition to PTA; the dialysis access site was abandoned for this patient.

In the AVG cohort, six safety events occurred in five patients:

- One patient had non-clinically driven target lesion revascularization treated with PTA only; lesion was resolved with functional dialysis access restored.
- Five patients had access circuit non-target lesion revascularization, including three new lesions treated with PTA and two thromboses, one treated with PTA and thrombectomy and one treated with a covered stent and thrombectomy. All lesions were resolved with functional dialysis access restored.

Table 7.
AVF Freedom from Localized or Systemic Safety Events1 through 30 days

Group	Primary Safety Event Rate, n/N (%), [95% CI]		Difference % [95% CI]	Non-inferiority P-value
	WRAPSODY (n=122)	PTA (n =123)		
Modified Intent to Treat[2]	115 / 119 (96.6%) [91.6%, 99.1%]	115 / 121 (95.0%) [89.5%, 98.2%]	1.6% [-3.4%, 6.6%]	< 0.0001[†]
Per Protocol	112 / 116 (96.6%) [91.4%, 99.1%]	113 / 118 (95.8%) [90.4%, 98.6%]	0.8% [-4.1%, 5.7%]	< 0.0001[†]

[1] CEC adjudicated
[2] mITT includes all subjects as randomized who received treatment
[†] Statistically significant, $p < 0.05$

Table 8.
AVG Freedom from Localized or Systemic Safety Events1 through 30 Days

Group	Primary Safety Event Rate n/N (%), [95% CI]	Performance Goal	P-value
	WRAPSODY (n=112)		
Intent to Treat[2]	104 / 109 (95.4%) [89.6%, 98.5%]	89%	0.0157[†]
Per Protocol	98 / 102 (96.1%) [90.3%, 98.9%]	89%	0.0097[†]

[1] CEC adjudicated

[2] All subjects enrolled were treated as planned, therefore the ITT and mITT groups are identical

[†] Statistically significant, $p < 0.05$

Adverse events are reported in Table 9 – Table 11 for the AVF cohort and Table 12 – Table 14 for the AVG cohort. Separate tables report all reported adverse events, procedure related events, and device related events. Rates were generally similar between the WRAPSODY and PTA arms other than a higher rate of target lesion restenosis reported in the PTA arm. As indicated in the study protocol, device related events were adjudicated by the CEC.

Table 9.
AVF All Site-Reported Adverse Events Through 6 Months (210 Days)

Event Type	WRAPSODY		PTA	
	Event Count	Event Rate per Patient, n/N (%)	Event Count	Event Rate per Patient, n/N (%)
Total	158	73 / 122 (59.8%)	247	98 / 123 (79.7%)
Abrupt vessel closure of treated segment (abrupt occlusion)	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)
Access (puncture) site complication requiring surgery or transfusion	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Amputation	2	2 / 122 (1.6%)	0	0 / 123 (0.0%)
Anemia	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Aneurysm	4	3 / 122 (2.5%)	5	5 / 123 (4.1%)
Angina	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Arterial perforation or rupture	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Atrial fibrillation	3	3 / 122 (2.5%)	1	1 / 123 (0.8%)
Bacteremia or septicemia	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Bleeding complication	2	2 / 122 (1.6%)	4	4 / 123 (3.3%)
Bronchitis or bronchiolitis	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Cardiac arrest	3	3 / 122 (2.5%)	4	4 / 123 (3.3%)
Cardiac arrhythmia	1	1 / 122 (0.8%)	5	3 / 123 (2.4%)
Cardiogenic shock	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Congestive Heart Failure (CHF)	1	1 / 122 (0.8%)	0	0 / 123 (0.0%)
Coronary Artery Disease (CAD)	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Dialysis Access Complications	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Dissection	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Edema, significant	1	1 / 122 (0.8%)	3	3 / 123 (2.4%)
Extravasation of contrast media / Perforation	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Fever (> 38.3°C/101°F)	2	2 / 122 (1.6%)	0	0 / 123 (0.0%)
Gastro-intestinal bleeding	1	1 / 122 (0.8%)	0	0 / 123 (0.0%)
Hematoma <5 cm at puncture site	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Hyperglycemia	2	2 / 122 (1.6%)	3	3 / 123 (2.4%)

Hypertension	3	2 / 122 (1.6%)	4	4 / 123 (3.3%)
Hypotension	2	2 / 122 (1.6%)	4	3 / 123 (2.4%)
Infection, localized	4	4 / 122 (3.3%)	4	4 / 123 (3.3%)
Infection, puncture site	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Inflammation	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Myocardial infarction	3	2 / 122 (1.6%)	3	3 / 123 (2.4%)
Myocardial ischemia	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Pain	9	9 / 122 (7.4%)	4	4 / 123 (3.3%)
Pneumonia	3	3 / 122 (2.5%)	3	2 / 123 (1.6%)
Pseudoaneurysm	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Pulmonary edema	2	2 / 122 (1.6%)	0	0 / 123 (0.0%)
Renal failure/renal insufficiency	2	2 / 122 (1.6%)	2	2 / 123 (1.6%)
Respiratory distress	2	2 / 122 (1.6%)	2	2 / 123 (1.6%)
Restenosis (non-target lesion)	28	20 / 122 (16.4%)	25	18 / 123 (14.6%)
Restenosis of treated segment (target lesion)	15	14 / 122 (11.5%)	66	52 / 123 (42.3%)
SARS, COVID-19	3	3 / 122 (2.5%)	2	2 / 123 (1.6%)
Sepsis or systemic infection	4	4 / 122 (3.3%)	0	0 / 123 (0.0%)
Steal syndrome	3	3 / 122 (2.5%)	5	4 / 123 (3.3%)
Stenosis (non-target)	21	19 / 122 (15.6%)	18	17 / 123 (13.8%)
Stroke or other neurological complications	2	2 / 122 (1.6%)	1	1 / 123 (0.8%)
Thrombosis	3	3 / 122 (2.5%)	2	1 / 123 (0.8%)
Total occlusion of the vascular access circuit	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Transient ischemic attack (TIA)	1	1 / 122 (0.8%)	0	0 / 123 (0.0%)
Urinary tract infection (UTI)	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)
Vascular access complications	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Ventricular tachycardia	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Vessel rupture	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)
Vessel spasm or recoil	0	0 / 122 (0.0%)	4	4 / 123 (3.3%)
Other event	20	15 / 122 (12.3%)	48	24 / 123 (19.5%)

Table 10.
AVF Site-Reported Procedure Related[1] Adverse Events Through 6 Months (210 Days)

Event Type[1]	WRAPSODY		PTA	
	Event Count	Event Rate per Patient, n/N (%)	Event Count	Event Rate per Patient, n/N (%)
Total	11	9 / 122 (7.4%)	41	33 / 123 (26.8%)
Abrupt vessel closure of treated segment (abrupt occlusion)	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)
Access (puncture) site complication requiring surgery or transfusion	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Arterial perforation or rupture	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Dissection	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Edema, significant	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Extravasation of contrast media / Perforation	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Hematoma <5 cm at puncture site	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Inflammation	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Restenosis (non-target lesion)	3	3 / 122 (2.5%)	2	2 / 123 (1.6%)
Restenosis of treated segment (target lesion)	4	4 / 122 (3.3%)	17	17 / 123 (13.8%)
Steal syndrome	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)
Stenosis (non-target)	1	1 / 122 (0.8%)	1	1 / 123 (0.8%)
Thrombosis	0	0 / 122 (0.0%)	1	1 / 123 (0.8%)
Vascular access complications	1	1 / 122 (0.8%)	0	0 / 123 (0.0%)
Vessel rupture	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)
Vessel spasm or recoil	0	0 / 122 (0.0%)	4	4 / 123 (3.3%)
Other event	1	1 / 122 (0.8%)	3	2 / 123 (1.6%)

[1] Possibly, probably or definitely procedure related according to the investigative site

Table 11.
AVF CEC Adjudicated Device Related[1] Adverse Events Through 6 Months (210 Days)

Event Type[1]	WRAPSODY		PTA	
	Event Count	Event Rate per Patient, n/N (%)	Event Count	Event Rate per Patient, n/N (%)
Total	5	4 / 122 (3.3%)	9	9 / 123 (7.3%)
Non-target lesion stenosis (new lesion)	3	2 / 122 (1.6%)	0	0 / 123 (0.0%)
Target lesion restenosis	2	2 / 122 (1.6%)	3	3 / 123 (2.4%)
Vascular Complication (AVF related)[2]	0	0 / 122 (0.0%)	4	4 / 123 (3.3%)
Other[3]	0	0 / 122 (0.0%)	2	2 / 123 (1.6%)

[1] Possibly, probably or definitely device related according to the CEC
[2] Includes events of perforation (2), dissection, and extravasation
[3] Includes events of vessel spasm or recoil and recoil/PTA failure

Table 12.
AVG All Site-Reported Adverse Events Through 6 Months (210 Days)

Event Type	Event Count	Event Rate per Patient, n/N (%)
Total	258	77 / 112 (68.8%)
Allergic reaction (medication, contrast media, device, etc.)	1	1 / 112 (0.9%)
Amputation	4	3 / 112 (2.7%)
Anemia	6	3 / 112 (2.7%)
Aneurysm	1	1 / 112 (0.9%)
Angina	4	3 / 112 (2.7%)
Arterial bypass surgery	1	1 / 112 (0.9%)
Atrial fibrillation	1	1 / 112 (0.9%)
Bacteremia or septicemia	5	5 / 112 (4.5%)
Bleeding complication	3	3 / 112 (2.7%)
Bronchitis or bronchiolitis	1	1 / 112 (0.9%)
Cardiac arrest	2	2 / 112 (1.8%)
Cardiac arrhythmia	3	3 / 112 (2.7%)
Dialysis Access Complications	5	3 / 112 (2.7%)
Edema, significant	2	1 / 112 (0.9%)
Fever (> 38.3°C/101°F)	1	1 / 112 (0.9%)
Gastro-intestinal bleeding	5	1 / 112 (0.9%)
Hemorrhage, with or without transfusion	1	1 / 112 (0.9%)
Hypertension	6	3 / 112 (2.7%)
Hypotension	2	2 / 112 (1.8%)
Infection, access circuit, stent graft	1	1 / 112 (0.9%)
Infection, localized	6	5 / 112 (4.5%)
Pain	22	8 / 112 (7.1%)
Peripheral ischemia	1	1 / 112 (0.9%)
Pneumonia	3	3 / 112 (2.7%)
Pseudoaneurysm	5	4 / 112 (3.6%)
Pulmonary edema	3	3 / 112 (2.7%)
Renal failure/renal insufficiency	1	1 / 112 (0.9%)
Respiratory arrest	1	1 / 112 (0.9%)
Respiratory distress	3	2 / 112 (1.8%)
Respiratory failure	3	1 / 112 (0.9%)
Restenosis (non-target lesion)	22	13 / 112 (11.6%)
Restenosis of treated segment (target lesion)	7	7 / 112 (6.3%)
SARS, COVID-19	6	6 / 112 (5.4%)
Seizure	1	1 / 112 (0.9%)
Sepsis or systemic infection	6	5 / 112 (4.5%)
Steal syndrome	3	3 / 112 (2.7%)
Stenosis (non-target)	34	23 / 112 (20.5%)
Stroke or other neurological complications	4	4 / 112 (3.6%)
Thrombosis	20	13 / 112 (11.6%)
Total occlusion of the vascular access circuit	1	1 / 112 (0.9%)
Transient ischemic attack (TIA)	1	1 / 112 (0.9%)
Vascular access complications	1	1 / 112 (0.9%)
Vessel rupture	3	3 / 112 (2.7%)
Other event	46	26 / 112 (23.2%)

Table 13.
AVG Site-Reported Procedure Related[1] Adverse Events Through 6 Months (210 Days)

Event Type[1]	Event Count	Event Rate per Patient, n/N (%)
Total	24	16 / 112 (14.3%)
Dialysis Access Complications	2	2 / 112 (1.8%)
Edema, significant	2	1 / 112 (0.9%)
Infection, localized	1	1 / 112 (0.9%)
Pseudoaneurysm	3	2 / 112 (1.8%)
Pulmonary edema	1	1 / 112 (0.9%)
Steal syndrome	1	1 / 112 (0.9%)
Stenosis (non-target)	2	2 / 112 (1.8%)
Thrombosis	7	3 / 112 (2.7%)
Total occlusion of the vascular access circuit	1	1 / 112 (0.9%)
Vessel rupture	3	3 / 112 (2.7%)
Other event	1	1 / 112 (0.9%)

[1] Possibly, Probably or Definitely Procedure Related

Table 14.
AVG CEC Adjudicated Device Related[1] Adverse Events Through 6 Months (210 Days)

Event Type[1]	Event Count	Event Rate per Patient, n/N (%)
Total	10	9 / 112 (8.0%)
Access Circuit Abandonment	1	1 / 112 (0.9%)
Non-target lesion thrombosis	1	1 / 112 (0.9%)
Target lesion restenosis	1	1 / 112 (0.9%)
Target lesion thrombosis	4	4 / 112 (3.6%)
Vascular Complication (AVG Related)[2]	2	2 / 112 (1.8%)
Other[3]	1	1 / 112 (0.9%)

[1] Possibly, probably or definitely device related according to the CEC
[2] Includes events of pseudoaneurysm (2)
[3] Includes event of steal syndrome

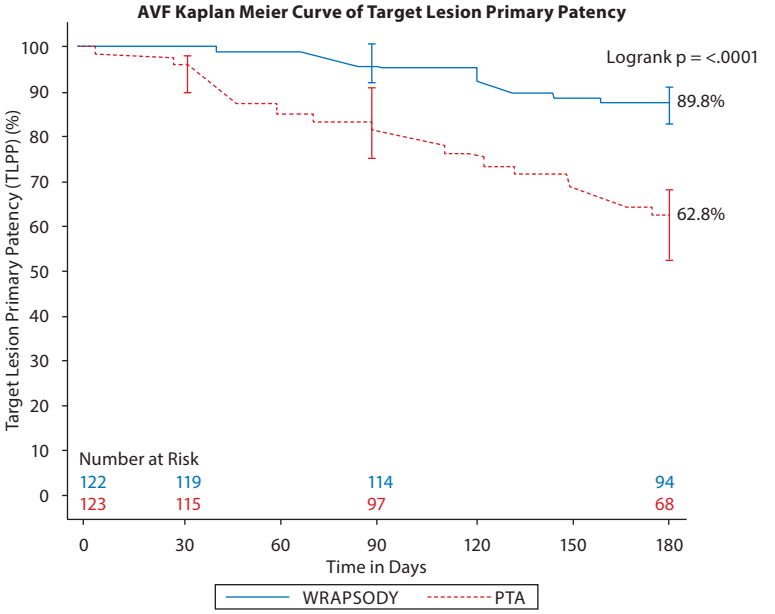
Summary of Effectiveness
In the AVF cohort, TLPP at 6 months was 90% in the WRAPSODY arm, which was significantly higher than the 62% rate in the PTA arm ($p < 0.0001$). The proportion of subjects with TLPP at 6 months in the AVG cohort was 81%, which was greater than the effectiveness PG of 60% ($p < 0.0001$). Therefore, the primary effectiveness endpoint was met. Pre-specified Kaplan-Meier time to event analysis was consistent with the primary endpoint analysis at 6 months, indicating 90% TLPP for the WRAPSODY CIE and 63% TLPP for PTA in the AVF cohort (log-rank $p < 0.0001$), and 82% TLPP for the WRAPSODY CIE in the AVG cohort. Effectiveness results are presented in Table 15 and Table 16 and Figure 7 and Figure 8.

Table 15.
AVF Target Lesion Primary Patency[1] at 6 Months

Group	WRAPSODY	PTA	Difference (95% CI)[2]	P-value[2]
TLPP – Modified Intent to Treat[2]	103 / 115 (89.6%) (95% CI: 82.5%, 94.5%)	71 / 114 (62.3%) (95% CI: 52.7%, 71.2%)	27.3% (16.8%, 37.8%)	< 0.0001†
Clinically driven target lesion revascularization (CD-TLR)	12 / 115 (10.4%) (95% CI: 5.5%, 17.5%)	43 / 114 (37.7%)	-27.3%	Not Applicable
Target lesion thrombosis	2 / 114 (1.8%) (95% CI: 0.2%, 6.2%)	2 / 111 (1.8%)	-0.0%	
TLPP – Per Protocol[3]	101 / 112 (90.2%) (95% CI: 83.1%, 95.0%)	71 / 112 (63.4%) (95% CI: 53.8%, 72.3%)	26.8% (16.3%, 37.3%)	< 0.0001†
Clinically driven target lesion revascularization (CD-TLR)	11 / 112 (9.8%) (95% CI: 5.0%, 16.9%)	41 / 112 (36.6%)	-26.8%	Not Applicable
Target lesion thrombosis	2 / 111 (1.8%) (95% CI: 0.2%, 6.4%)	2 / 109 (1.8%)	-0.0%	

[1] CEC adjudicated
[2] mITT includes all subjects as randomized who received treatment
[3] PP includes all mITT subjects who additionally met all inclusion/exclusion criteria
† Statistically significant, $p < 0.05$

Figure 8.
AVF Kaplan Meier Curve of Target Lesion Primary Patency



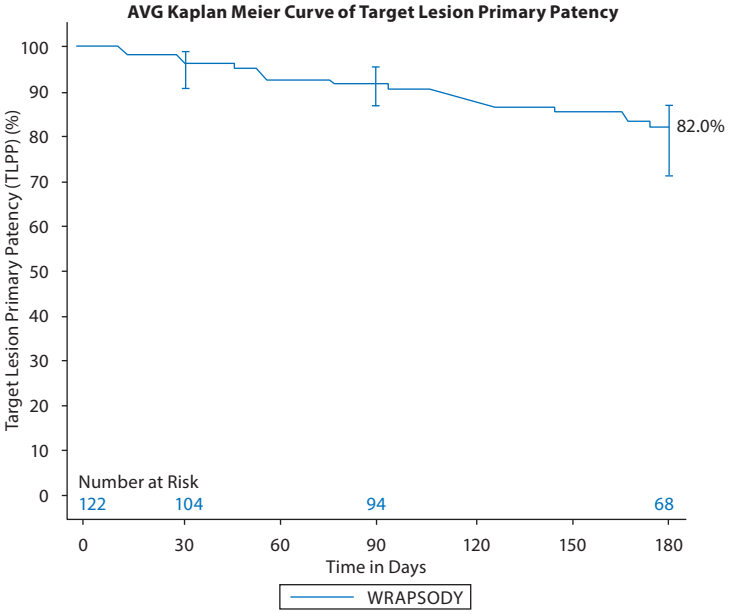
Timepoint	Day 0	Day 30	Day 90	Day 180	Logrank P-value
WRAPSODY					<0.0001
TLPP (95% CI)	100% (-,-)	100% (-,-)	96.6% (91.3%,98.7%)	89.8% (82.7%,94.0%)	
Number with Event	0	0	4	12	
PTA					
TLPP (95% CI)	100% (-,-)	95.0% (89.3%,97.7%)	83.2% (75.2%,88.9%)	62.8% (53.2%,70.9%)	
Number with Event	0	6	20	43	

Table 16.
AVG Target Lesion Primary Patency[1] at 6 Months

Group	WRAPSODY	Performance Goal	P-value[2]
TLPP – Modified Intent to Treat[2]	79 / 97 (81.4%) (95% CI: 72.3%, 88.6%)	60%	< 0.0001[†]
Clinically driven target lesion revascularization (CD-TLR)	18 / 97 (18.6%)	Not applicable	
Target lesion thrombosis	11 / 94 (11.7%)		
TLPP – Per Protocol[3]	75 / 90 (83.3%) (95% CI: 74.0%, 90.4%)	60%	< 0.0001[†]
Clinically driven target lesion revascularization (CD-TLR)	15 / 90 (16.7%)	Not applicable	
Target lesion thrombosis	9 / 88 (10.2%)		

[1] CEC adjudicated
[2] mITT includes all subjects as randomized who received treatment
[3] PP includes all mITT subjects who additionally met all inclusion/exclusion criteria
[†] Statistically significant, $p < 0.05$

Figure 9.
AVG Kaplan Meier Curve of Target Lesion Primary Patency



Timepoint	Day 0	Day 30	Day 90	Day 180
WRAPSODY				
ACPP (95% CI)	100% -	96.3% (90.5%,98.6%)	91.6% (84.5%,95.6%)	82.0% (72.9%,88.3%)
Number with Event	0	4	9	18

Subgroup Analyses

Sex, race, and age were evaluated for potential association with outcomes. The primary safety and effectiveness analyses were performed on these subgroups for evaluable subjects and are reported in Table 17 – Table 20. Safety results were generally comparable between groups. For effectiveness, the WRAPSODY CIE continued to have higher TLPP compared to PTA across subgroups. TLPP in the AVF cohort was somewhat higher for female compared to male subjects, for African American / black compared to Caucasian / white subjects, and for younger patients compared to older patients in both the WRAPSODY and PTA arms. Similarly, female subjects also had somewhat higher TLPP compared to male subjects in the AVG cohort; TLPP by race and age was comparable.

Table 17.
AVF Freedom from Localized or Systemic Safety Events Through 30 days by Sex, Race, and Age

Parameter	WRAPSODY	PTA	Difference
Sex			
Male	67 / 68 (98.5%)	64 / 69 (92.8%)	5.8%
Female	48 / 51 (94.1%)	51 / 52 (98.1%)	-4.0%
Race			
Black	46 / 48 (95.8%)	47 / 50 (94.0%)	1.8%
Asian	3 / 3 (100.0%)	6 / 6 (100.0%)	-
Non-Black / Non-Asian	66 / 68 (97.1%)	62 / 65 (95.4%)	1.7%
Age			
≤ Median	59 / 59 (100.0%)	56 / 61 (91.8%)	8.2%
> Median	56 / 60 (93.3%)	59 / 60 (98.3%)	-5.0%

Table 18.
AVG Freedom from Localized or Systemic Safety Events Through 30 days by Sex, Race, and Age

Parameter	WRAPSODY
Sex	
Male	45 / 49 (91.8%)
Female	59 / 60 (98.3%)
Race	
Black	64 / 68 (94.1%)
Asian	3 / 3 (100.0%)
Non-Black / Non-Asian	37 / 38 (97.4%)
Age	
≤ Median	52 / 55 (94.5%)
> Median	52 / 54 (96.3%)

Table 19.
AVF Target Lesion Primary Patency at 6 Months by Sex, Race, and Age

Parameter	WRAPSODY	PTA	Difference
Sex			
Male	57 / 66 (86.4%)	37 / 65 (56.9%)	29.4%
Female	46 / 49 (93.9%)	34 / 49 (69.4%)	24.5%
Race			
Black	44 / 46 (95.7%)	33 / 48 (68.8%)	26.9%
Asian	3 / 3 (100.0%)	4 / 4 (100.0%)	-
Non-Black / Non-Asian	56 / 66 (84.8%)	34 / 62 (54.8%)	30.0%
Age			
≤ Median	55 / 58 (94.8%)	40 / 60 (66.7%)	28.2%
> Median	48 / 57 (84.2%)	31 / 54 (57.4%)	26.8%

Table 20.
AVG Target Lesion Primary Patency at 6 Months by Sex, Race, and Age

Parameter	WRAPSODY
Sex	
Male	32 / 42 (76.2%)
Female	47 / 55 (85.5%)
Race	
Black	49 / 61 (80.3%)
Asian	2 / 2 (100.0%)
Non-Black / Non-Asian	28 / 34 (82.4%)
Age	
≤ Median	40 / 49 (81.6%)
> Median	39 / 48 (81.3%)

Secondary and Other Endpoints

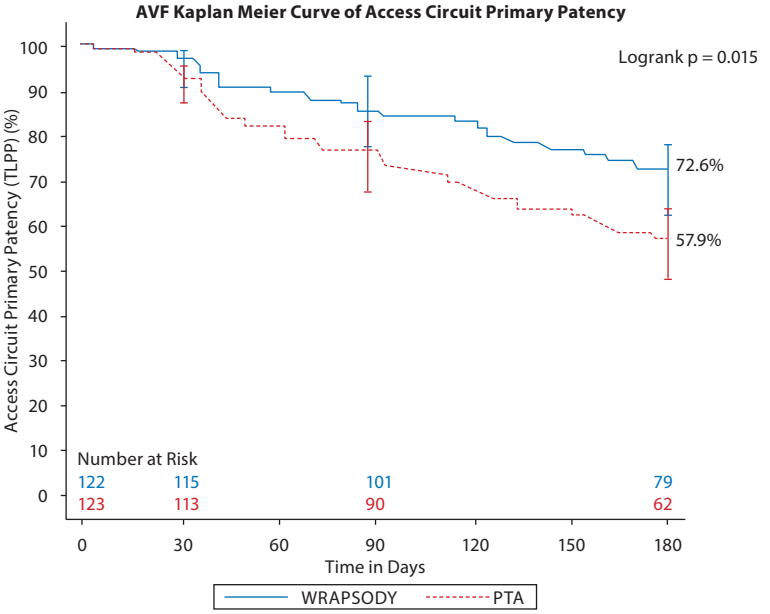
Access circuit primary patency (ACPP) is an important effectiveness endpoint evaluated in the WAVE study and is defined as time to any venous outflow circuit re-intervention or access thrombosis or abandonment; ACPP is inclusive of all patency events, including those that occurred at the target lesion (i.e. inclusive of TLPP). In the AVF cohort, ACPP for the WRAPSODY arm was 72% at 6 months compared to 57% in the PTA arm ($p = 0.016$) (Table 21). ACPP in the AVG cohort was 68% at 6 months (Table 22). As specified in the statistical analysis plan, supplemental analyses were conducted using the Kaplan-Meier method. Figure 9 and Figure 10 show the Kaplan-Meier curves for the ACPP endpoint through 6 months in the AVF and AVG cohorts, respectively. The Kaplan-Meier rates were consistent, indicating 73% ACPP for the WRAPSODY CIE and 58% ACPP for PTA in the AVF cohort (log-rank $p = 0.015$), and 69% ACPP for the WRAPSODY CIE in the AVG cohort. Through 6 months, reintervention was required for inflow circuit lesions in two additional patients in the WRAPSODY arm of the AVF cohort and three additional patients in the AVG cohort.

Table 21.
AVF Access Circuit Primary Patency (mITT Subjects)

Endpoint	n/N (%) (95% CI)[1]			
	WRAPSODY	PTA	Difference (95% CI)[2]	P-value[2]
Access Circuit Primary Patency (ACPP) at 6 months (180 days)	83 / 115 (72.2%) (63.0%, 80.1%)	65 / 114 (57.0%) (47.4%, 66.3%)	15.2% (2.9%, 27.4%)	0.016

[1] Exact 95% confidence intervals.
[2] P-value from the Z-test for the difference in proportions with pooled variance (two-group chi-square test equivalent). Confidence interval from the corresponding normal approximation.

Figure 10.
AVF Kaplan Meier Curve of Access Circuit Primary Patency



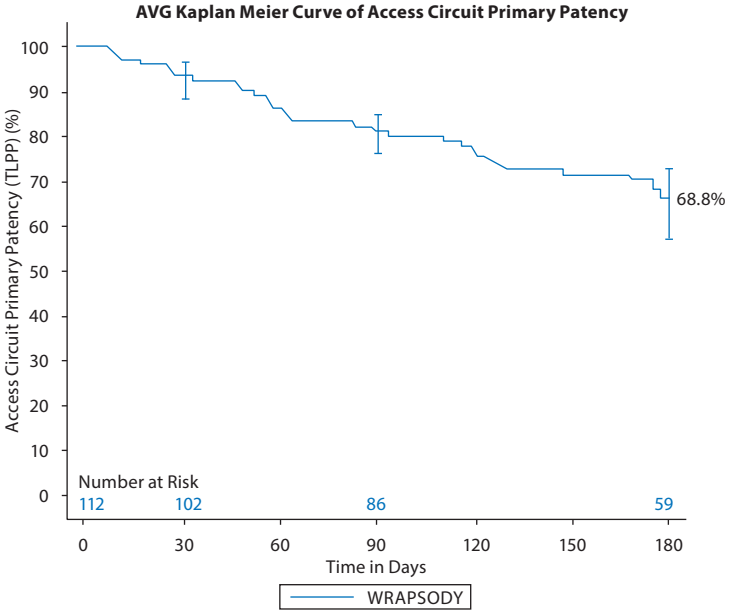
Timepoint	Day 0	Day 30	Day 90	Day 180	Logrank P-value
WRAPSODY					0.015
Survival (95% CI)	100% (-,-)	96.6% (91.3%,98.7%)	85.7% (78.0%,90.9%)	72.6% (63.5%,79.8%)	
Number with Event	0	4	17	32	
PTA					
Survival (95% CI)	100% (-,-)	93.4% (87.2%,96.6%)	77.4% (68.8%,83.9%)	57.9% (48.3%,66.3%)	
Number with Event	0	8	27	49	

Table 22.
AVG Access Circuit Primary Patency (mITT Subjects)

Endpoint	n/N (%) (95% CI)[1] WRAPSODY
ACPP at 6 months (180 days)	68 / 100 (68.0%) (57.9%, 77.0%)

[1] Exact 95% confidence intervals.

Figure 11.
AVG Kaplan Meier Curve of Access Circuit Primary Patency



Timepoint	Day 0	Day 30	Day 90	Day 180
WRAPSODY				
ACPP (95% CI)	100% -	93.6% (87.0%,96.9%)	82.4% (73.8%,88.4%)	68.8% (58.7%,76.8%)
Number with Event	0	7	19	32

Other secondary outcomes evaluated include:

- Assisted target lesion primary patency (aTLPP) defined as time to from post-procedure until uncorrectable target lesion occlusion.
- Post-procedure secondary patency defined as the interval post-procedure until access circuit abandonment.
- Rate of SAE and rate of SAE involving the AV access circuit.
- Rate of device observations and potential malfunctions or failures.
- Number of target lesion reinterventions to maintain target lesion patency and number of interventions to maintain access circuit patency.
- Device success defined as successful delivery to the target lesion, deployment and retrieval of delivery system at index procedure; and procedure success defined as at least one indicator of hemodynamic success in the absence of peri-procedural serious adverse device effects.
- Index of patency function defined as time from initial study procedure to complete access abandonment divided by number of venous outflow circuit reinterventions to maintain hemodialysis.
- Clinical success defined as the resumption of successful dialysis through existing access for at least one session following initial study procedure.

These results are reported in Table 23 for the AVF cohort and Table 24 for the AVG cohort.

Table 23.
AVF Other Secondary Outcomes through 6 Months

	WRAPSODY	PTA
Post-procedure secondary patency through 6 months	100%	100%
Rate of SAE through 24 months	38 / 122 (31.1%) (95% CI: 23.1%, 40.2%)	45 / 123 (36.6%) (95% CI: 28.1%, 45.7)
Rate of SAE involving the AV access circuit through 6 months	4 / 114 (3.5) (95% CI: 1.0%, 8.7%)	5 / 110 (4.5) (95% CI: 1.5%, 10.3%)
Number of target lesion reinterventions to maintain target lesion patency through 6 months	0.18 ± 0.51 (115) (95% CI: 0.09,0.28) (Range: 0 to 3)	0.47 ± 0.65 (114) (95% CI: 0.35,0.60) (Range: 0 to 3)
Number of interventions to maintain access circuit patency through 6 months	0.48 ± 0.91 (115) (95% CI: 0.31,0.65) (Range: 0 to 5)	0.78 ± 1.12 (114) (95% CI: 0.57,0.99) (Range: 0 to 6)
Device success	120 / 122 (98.4%)[1] (95% CI: 94.2%, 99.8%)	-
Procedure success	121 / 122 (99.2%)[1] (95% CI: 95.5%, 100%)	123 / 123 (100.0%) (95% CI: 97.0%, 100%)

[1] The failures of device and procedure success were associated with inaccurate deployment

Table 24.
AVG Other Secondary Outcomes through 6 Months

	WRAPSODY
Post-procedure secondary patency through 6 months	95.0% (95% CI: 88.4%,97.9%)
Rate of SAE through 24 months	50 / 112 (44.6%) (95% CI: 35.2%, 54.3%)
Rate of SAE involving the AV access circuit through 6 months	6 / 95 (6.3) (95% CI: 2.4%, 13.2%)
Number of target lesion reinterventions to maintain target lesion patency	0.19 ± 0.42 (97) (95% CI: 0.10,0.27) (Range: 0 to 2)
Number of interventions to maintain access circuit patency	0.26 ± 0.71 (98) (95% CI: 0.11,0.40) (Range: 0 to 5)
Device success	12 / 112 (100.0%) (95% CI: 96.8%, 100.0%
Procedure success	112 / 112 (100.0%) (95% CI: 96.8%, 100.0%)

SUMMARY OF DEATHS AND ADVERSE EVENTS
There were no device-related serious adverse events in the AVF cohort as adjudicated by the CEC. There was a single device related serious adverse event of access circuit abandonment in the AVG cohort as adjudicated by the CEC.

A total of 36 deaths were reported in the AVF cohort, 14 in the WRAPSODY arm and 22 in the PTA arm. No deaths were adjudicated by the CEC as related to the study device or procedure. One death in the PTA arm was adjudicated as possibly related to the procedure. A total of 15 deaths were reported in the AVG cohort and none were adjudicated as related to the study device or procedure. Deaths were typically determined to be cardiovascular related, with general causes including cardiac/cardiopulmonary arrest, sepsis, and renal failure.

CONCLUSIONS DRAWN FROM WAVE STUDY
The WRAPSODY WAVE study was a prospective, multi-center, multi-cohort study consisting of a randomized concurrently-controlled AVF cohort and a single arm AVG cohort.

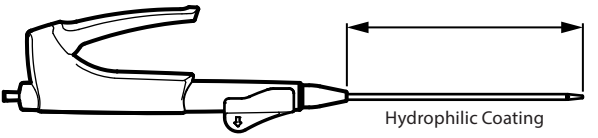
In the AVF cohort, primary safety at 30 days in the WRAPSODY arm was found to be non-inferior to the PTA arm (96.6% vs. 95.0%, $p<0.0001$). In the AVG cohort, 95.4% of patients exhibited freedom from safety events, thereby meeting the performance goal of 89% ($p=0.0162$).

In the AVF cohort, the primary effectiveness endpoint of TLPP through 6 months was significantly higher in subjects treated with the WRAPSODY CIE compared to subjects receiving PTA (89.6% vs. 62.3%, $p<0.0001$). The 6-month TLPP rate for the WRAPSODY CIE in the AVG cohort was 81.4%, and this rate compares favorably to the established performance goal of 60% ($p<0.0001$). Furthermore, this significant improvement in primary patency extended to the entire access circuit, with a 6-month ACPP rate of 72.2% in the the WRAPSODY arm of the AVF cohort as compared to 57.0% for PTA ($p=0.016$). A high 6-month ACPP rate of 68.0% was also observed in the WRAPSODY CIE AVG cohort. The need for target lesion and access circuit reinterventions through 6 months was also reduced with the WRAPSODY CIE compared to PTA. Secondary patency was maintained in 100% of all AVF cohort subjects (treatment and control) and 95% of the AVG cohort subjects through 6 months.

The overall clinical results provide a reasonable assurance of the safety and effectiveness of the WRAPSODY CIE in hemodialysis patients for treatment of stenosis or occlusion within the dialysis access outflow circuit in the peripheral veins of individuals with an arteriovenous (AV) fistula and at the venous anastomosis of a synthetic AV graft when used in accordance with its labeling.

INFORMATION ON PACKAGING

Symbol	Designation
	Caution
	Do Not Use If Package is Damaged and Consult Instruction for Use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
	Keep away from sunlight
	Keep dry
	Non-pyrogenic
MR	MR Conditional
	Max guide wire
	Minimum Introducer Size



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