

PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT

INDICATIONS FOR USE

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

What is the Merit WRAPSODY Endoprosthesis System?

The Merit Wrapsody Endoprosthesis System consists of two main parts:

Merit WRAPSODY Endoprosthesis: The Merit WRAPSODY Endoprosthesis is a flexible, self-expanding endoprosthesis designed for placement in the vasculature. It is made of nitinol that is encapsulated between layers of fluoropolymer material.

Placement of the Merit WRAPSODY in the vasculature is facilitated by radiopaque markers, three on each end, located on both end rows. These end rows are trimmed in a scalloped manner.

The Merit WRAPSODY Endoprosthesis is compressed and preloaded into the Merit WRAPSODY Endoprosthesis Delivery Catheter System.

Merit WRAPSODY Delivery Catheter System: The Merit WRAPSODY Delivery Catheter System is designed for single-handed deployment and consists of a deployment handle that allows for controlled delivery of the Merit WRAPSODY Endoprosthesis.

The Merit WRAPSODY Delivery Catheter System also has one port with a female luer connection for flushing both the guide wire lumen and the endoprosthesis. The working length of the Merit WRAPSODY Delivery Catheter has a hydrophilic coating. The delivery catheter shaft has radiopaque marker bands, corresponding to the proximal and distal ends of the endoprosthesis, to provide guidance during placement of the Merit WRAPSODY Endoprosthesis.

IMPLANTATION WITH THE MERIT WRAPSODY ENDOPROSTHESIS

What is the potential clinical benefit of using the Merit WRAPSODY Endoprosthesis?

The intended clinical benefit of the Merit WRAPSODY Endoprosthesis is to restore and maintain blood flow through an occluded (blocked) or stenosed (narrowed) venous dialysis outflow circuit.

When can the Merit WRAPSODY Endoprosthesis be used?

The Merit WRAPSODY Endoprosthesis is indicated for haemodialysis patients who are experiencing a narrowing of or blockage within the dialysis outflow circuit of their AV fistula or AV graft.

How long is the Merit WRAPSODY Endoprosthesis designed to last?

The Merit WRAPSODY Endoprosthesis has a design lifetime of 10 years.

Merit WRAPSODY Endoprosthesis Care Tips

Always follow your doctor's or nurse's instructions and promptly tell your care team about any unusual symptoms or pain.

Your doctor will discuss with you how often you will need follow-up appointments.

MERIT WRAPSODY ENDOPROSTHESIS RISKS AND PRECAUTIONS

When Should the Merit WRAPSODY Endoprosthesis Not Be Used?

The Merit WRAPSODY Endoprosthesis should not be used:

- If full expansion of a PTA balloon cannot be achieved during pre-dilation.
- In patients who have a hypersensitivity to nickel.
- In patients with uncorrectable coagulation disorders.
- In patients when there is clinical evidence of infection which could spread to the implanted endoprosthesis.
- In patients with functional relevant obstruction of the inflow path, poor outflow, or no distal runoff.

The safety and effectiveness of the Merit WRAPSODY Endoprosthesis has not been evaluated when placed:

- In the superior vena cava.
- In paediatrics patients.
- Across an aneurysm or a pseudoaneurysm.
- In areas of extreme flexion, such as the clavicle, popliteal fossa, and antecubital fossa.

Testing has not been conducted for the use of the Merit WRAPSODY Endoprosthesis in an overlapped condition with bare metal stents or with other competitive covered stents.

What are potential complications associated with using the Merit WRAPSODY Endoprosthesis?

The Merit WRAPSODY Endoprosthesis provides an important means of treating patients who require haemodialysis, but the potential exists for serious side effects, which include the following:

Potential Clinically Related Complications

- 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
- Death

Potential Device-Related Complications

- 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
- Occlusion

QUALITATIVE/QUANTITATIVE INFORMATION ON PATIENT EXPOSURE TO MATERIALS AND SUBSTANCES¹

Material	Duration of Exposure	Level of Patient Exposure	
		Stent Size (diameter (mm) x length (mm))	Approximate Exposure (cm ²)
Fluoropolymer	≥30 days	6 x 50	18.85
		6 x 75	28.27
		6 x 100	37.70
		6 x 125	47.12
		7 x 50	21.99
		7 x 75	32.99
		7 x 100	43.98
		7 x 125	54.98
		8 x 50	25.13
		8 x 75	37.70
		8 x 100	50.27
		8 x 125	62.83
		9 x 50	28.27
		9 x 75	42.41
		9 x 100	56.55
		9 x 125	70.60
		10 x 50	31.42
		10 x 75	47.12
		10 x 100	62.83
		10 x 125	78.54
		12 x 30	22.62
		12 x 40	30.16
		12 x 50	37.70
		12 x 60	45.24
		12 x 70	52.78
		12 x 80	60.32
		14 x 30	26.39
		14 x 40	35.19
		14 x 50	43.98
		14 x 60	52.78
14 x 70	61.58		
14 x 80	70.37		
16 x 30	30.16		
16 x 40	40.21		
16 x 50	50.27		
16 x 60	60.32		
16 x 70	70.37		
16 x 80	80.43		
Nitinol	≥30 days	*covered completely by fluoropolymer	
Platinum-Iridium	≥30 days	*covered completely by fluoropolymer	

MAGNETIC RESONANCE IMAGING (MRI): SAFETY INFORMATION

Non-clinical testing¹ has demonstrated that the Merit WRAPSODY Endoprosthesis is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under:

- A static magnetic field of 1.5-Tesla and 3-Tesla, only.
- A maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m).
- A 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).

ARTIFACT INFORMATION

In non-clinical testing¹, image artifact caused by the Merit WRAPSODY Endoprosthesis extends approximately 3 mm from the device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. The lumen of the Merit WRAPSODY Endoprosthesis can be visualised on T1-weighted, spin echo, and gradient echo pulse sequences.

GENERAL PRECAUTIONS

- This device is intended for use by physicians who are familiar with the complications, side effects, and dangers associated with intravascular endoprosthesis procedures.
- Before introduction into the patient, the hydrophilic coating on the Merit 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.
- Prescribed anticoagulation pre, during, and post procedure should follow institutional standards, including dual antiplatelet treatment if appropriate.
- The Merit WRAPSODY Endoprosthesis should not be balloon expanded beyond its stated diameter.
- Post dilation of the implanted Merit WRAPSODY Endoprosthesis is required with a balloon equal in diameter to that of the selected Merit WRAPSODY Endoprosthesis diameter.
- Do not use a balloon that is longer than the labeled length of the Merit WRAPSODY Endoprosthesis.

- Higher deployment forces may be encountered on longer lengths of the Merit WRAPSODY Endoprosthesis.
- When passing any accessory device through the Merit WRAPSODY Endoprosthesis, use caution and ensure that the Merit WRAPSODY Endoprosthesis does not dislodge.
- Do not withdraw or reposition a balloon catheter within the lumen of the Merit WRAPSODY Endoprosthesis unless the balloon is completely deflated.
- Do not use a kinked Merit WRAPSODY Delivery Catheter or kinked valved introducer sheath, as this may result in difficulty or inability to deploy the Merit WRAPSODY Endoprosthesis.
- An appropriately stiff guide wire is required to be in place before introduction of the Merit WRAPSODY Delivery Catheter into the body. The guide wire must remain in place during the introduction, manipulation, deployment, and eventual removal of the Merit WRAPSODY Delivery Catheter.
- Repositioning of the Merit WRAPSODY Delivery Catheter may be necessary prior to deploying the endoprosthesis.
- Once deployed, the Merit WRAPSODY Endoprosthesis cannot be retracted or resheathed onto the delivery catheter.
- Placing an endoprosthesis across a side branch may obstruct blood flow and prevent or hinder future access or other procedures.
- Placing an 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 Merit WRAPSODY device if it cannot be flushed prior to use. Guide wire lumen and Endoprosthesis Pod flushing are required prior to insertion or reinsertion.
- Inadvertent, partial, or failed deployment or migration of the Merit WRAPSODY Endoprosthesis may require surgical intervention.
- The Merit WRAPSODY Delivery Catheter can only deploy the Merit WRAPSODY Endoprosthesis after the safety clip is removed. This should not be done until the Merit WRAPSODY Endoprosthesis is about to be released.

Any serious incident that occurs in relation to the Merit WRAPSODY Endoprosthesis should be reported to the manufacturer and to the Therapeutic Goods Administration at www.tga.gov.au.

REFERENCES

1. Data on file.



For more information on the Merit WRAPSODY Endoprosthesis, please refer to its Instructions for Use.