



Dilation of Arteriovenous Fistula with Cell Impermeable Endoprosthesis

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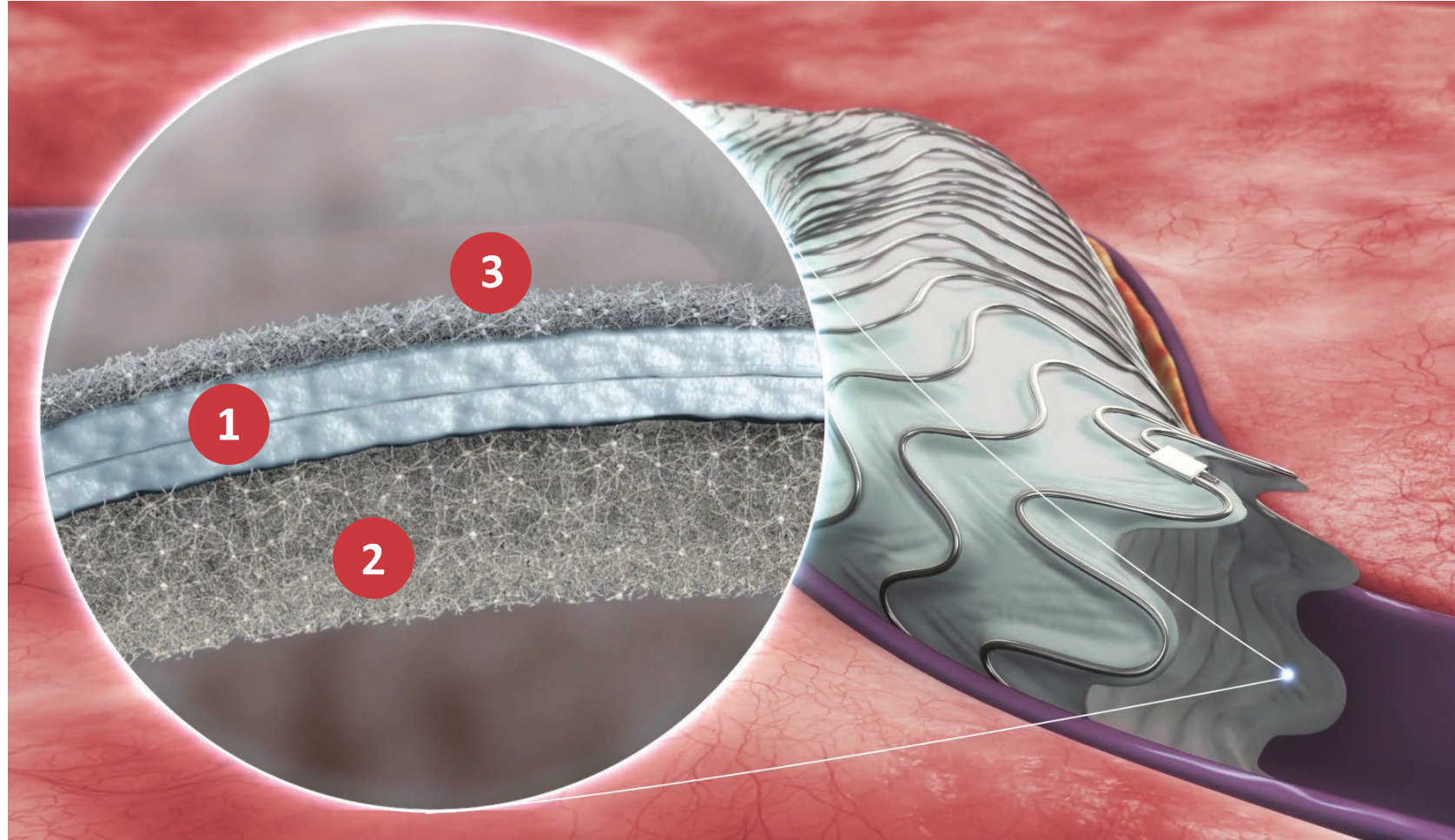
Chris Geiger MA, RHIA, CCS, CRC



Unique Tri-Layered Endoprosthesis Microstructure

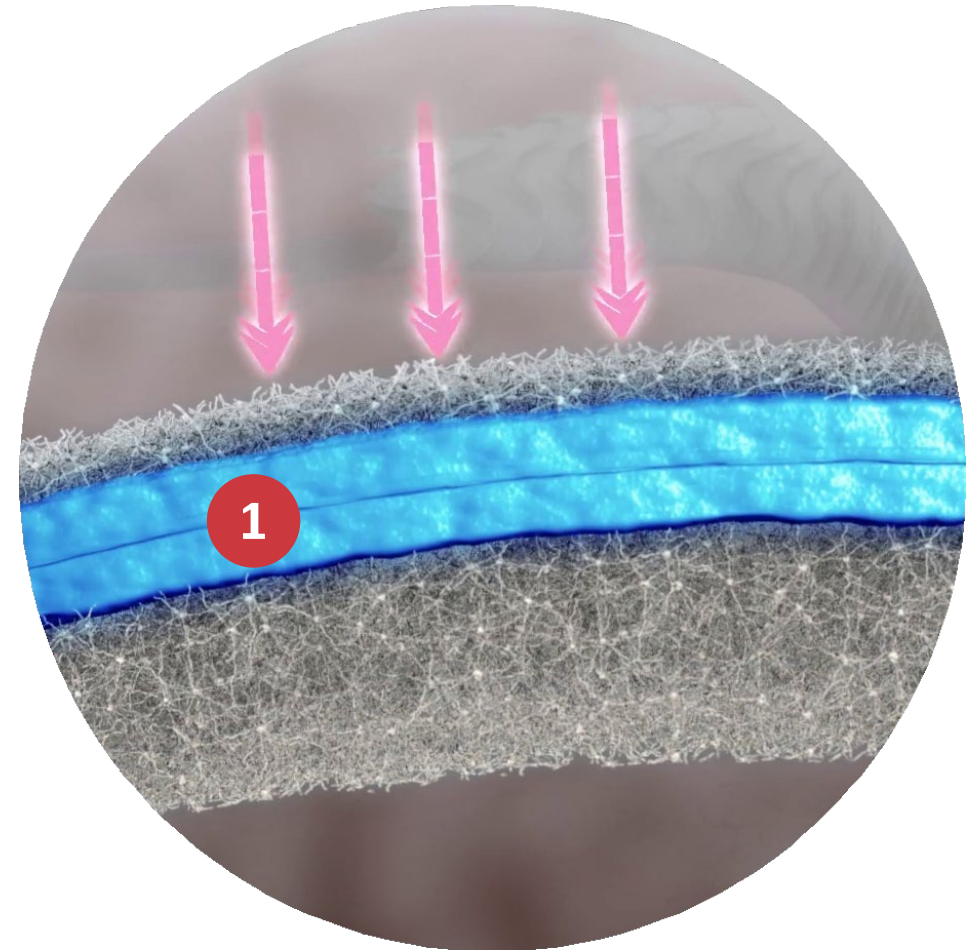
- 1 Middle Cell-Impermeable Layer
- 2 Inside Novel-Spun PTFE Layer
- 3 Outer ePTFE Standard Layer

Polytetrafluoroethylene ePTFE



1 | Middle Cell-Impermeable Layer

The Merit WRAPSODY® is engineered with an impermeable middle layer built to prevent transmural cellular migration without the use of drug bonding.

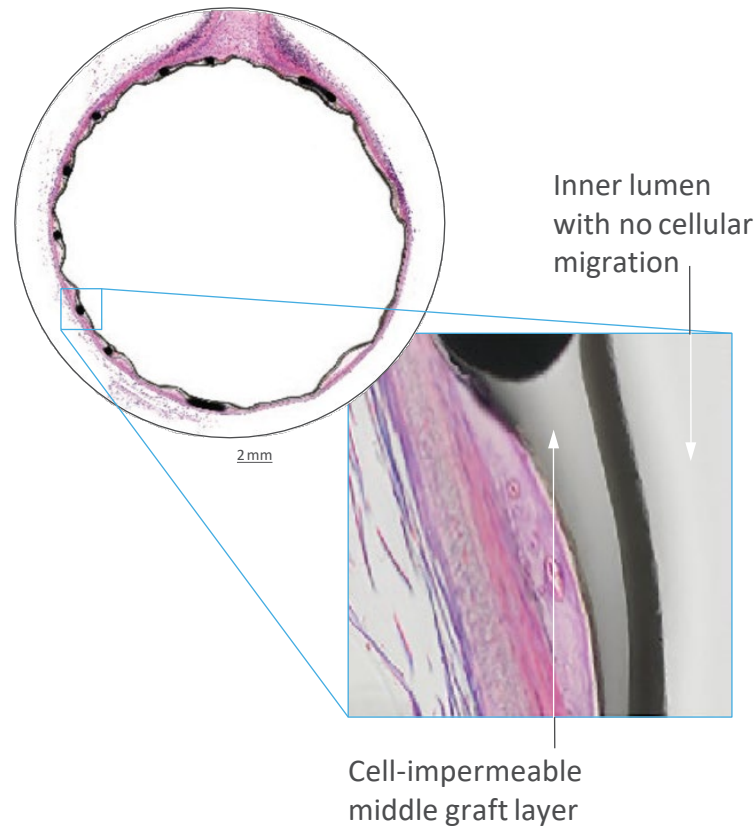


1 | Middle Cell-Impermeable Layer

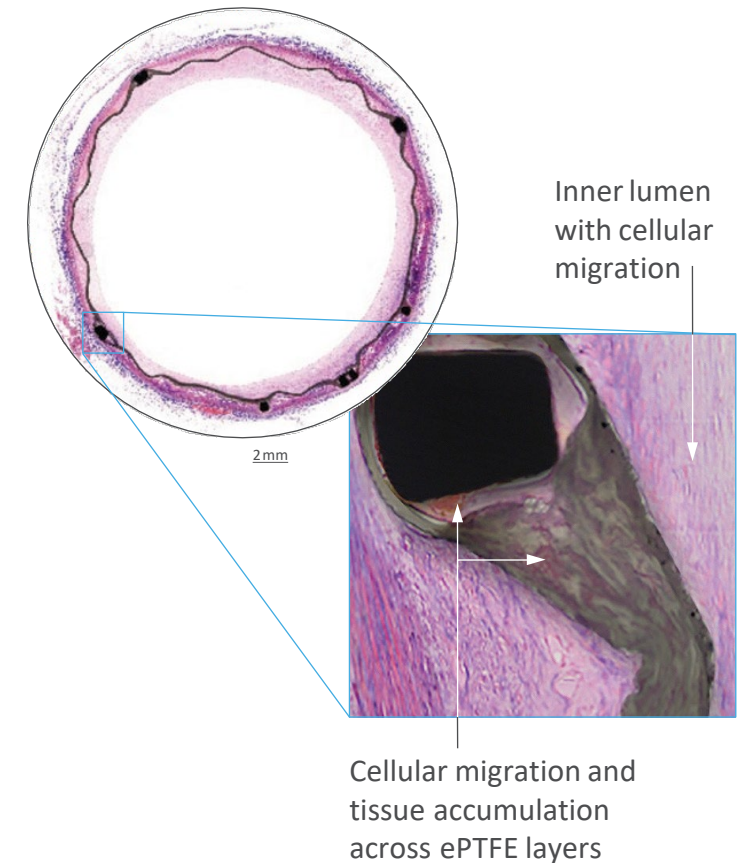
Cross-Sectional Histology
Images: Left External Iliac,
Animal, 180 days¹

Dolmatch, et al. JVIR.
2020; 31: 494–502.

Evaluation of
a Novel Spun
Polytetrafluoroethylene
Stent Graft in an
Ovine External Iliac
Artery Model



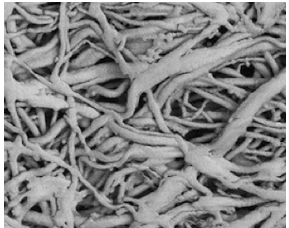
Merit WRAPSODY



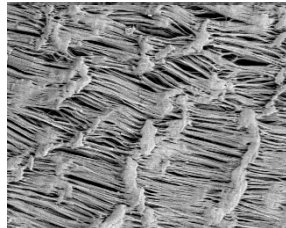
Leading Covered Stent

2 | Inside Novel-Spun PTFE Layer

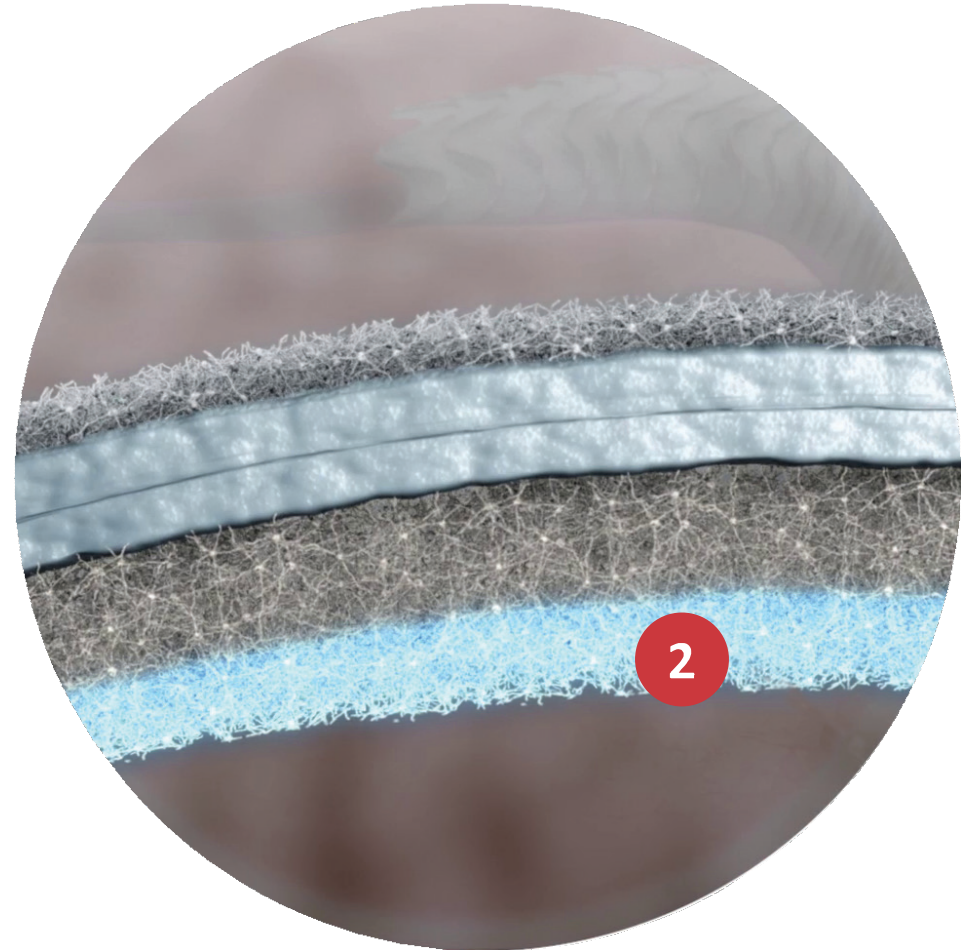
The innermost layer of the Merit WRAPSODY® is made of a biocompatible, novel-spun PTFE layer designed to limit inflammation and thrombus formation without coatings, chemicals, or drugs.



Novel-spun PTFE
microstructure,
Merit WRAPSODY®

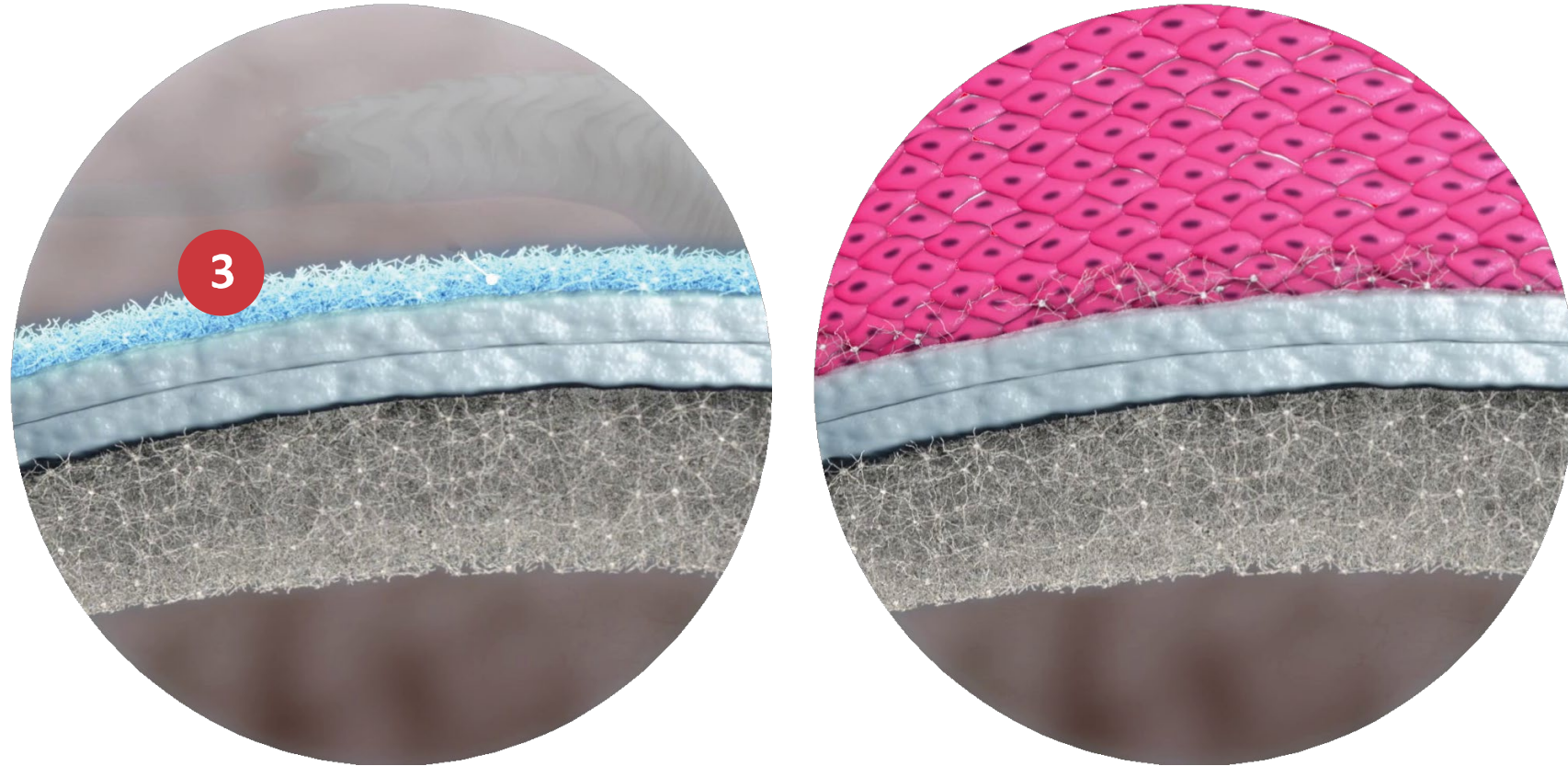


Traditional ePTFE
microstructure,
Leading Covered Stent
Manufacturer



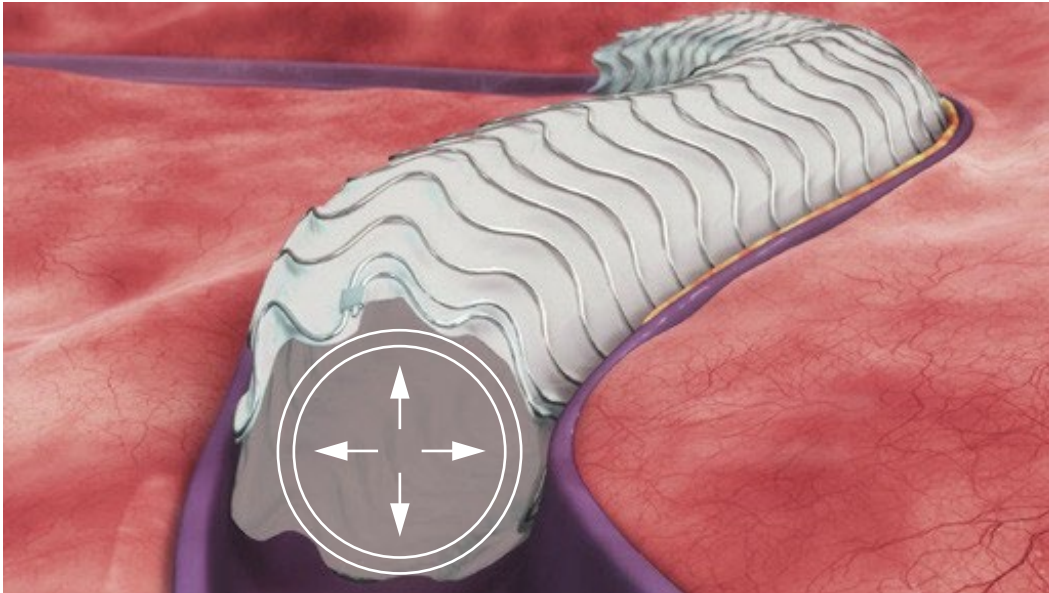
3 | Outer ePTFE Standard Layer

The outer layer of the Merit WRAPSODY® is engineered with a standard, biocompatible ePTFE material that allows for necessary tissue ingrowth to prevent endoprosthesis migration.

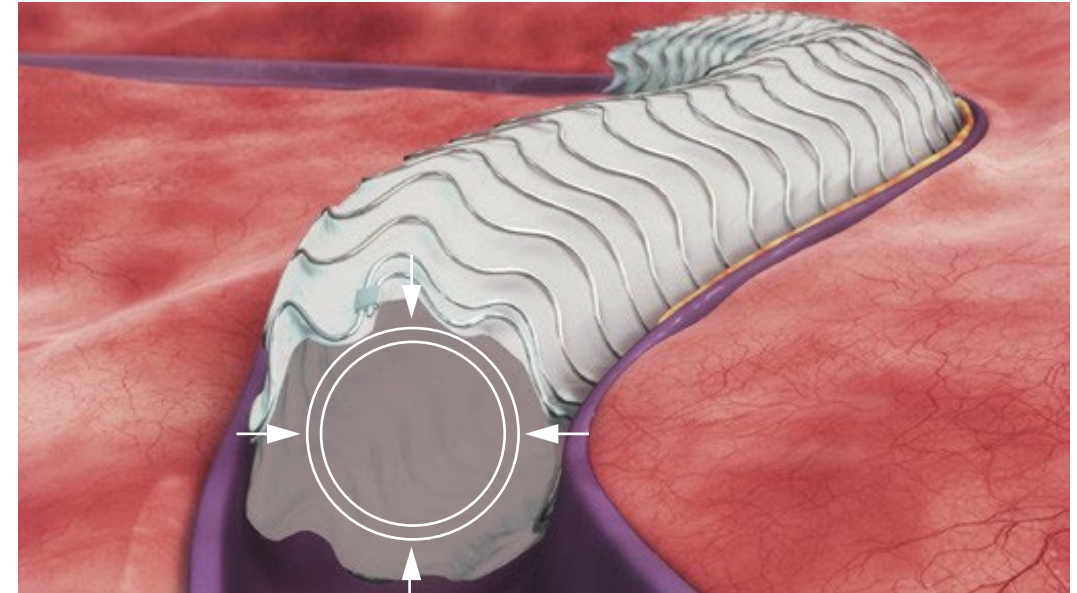


Outer PTFE (left), Tissue ingrowth (right)

| Optimized Radial Strength and Compression Resistance



Consistent Radial Force: Helps prevent vessel trauma once the endoprosthesis is deployed within the vessel.

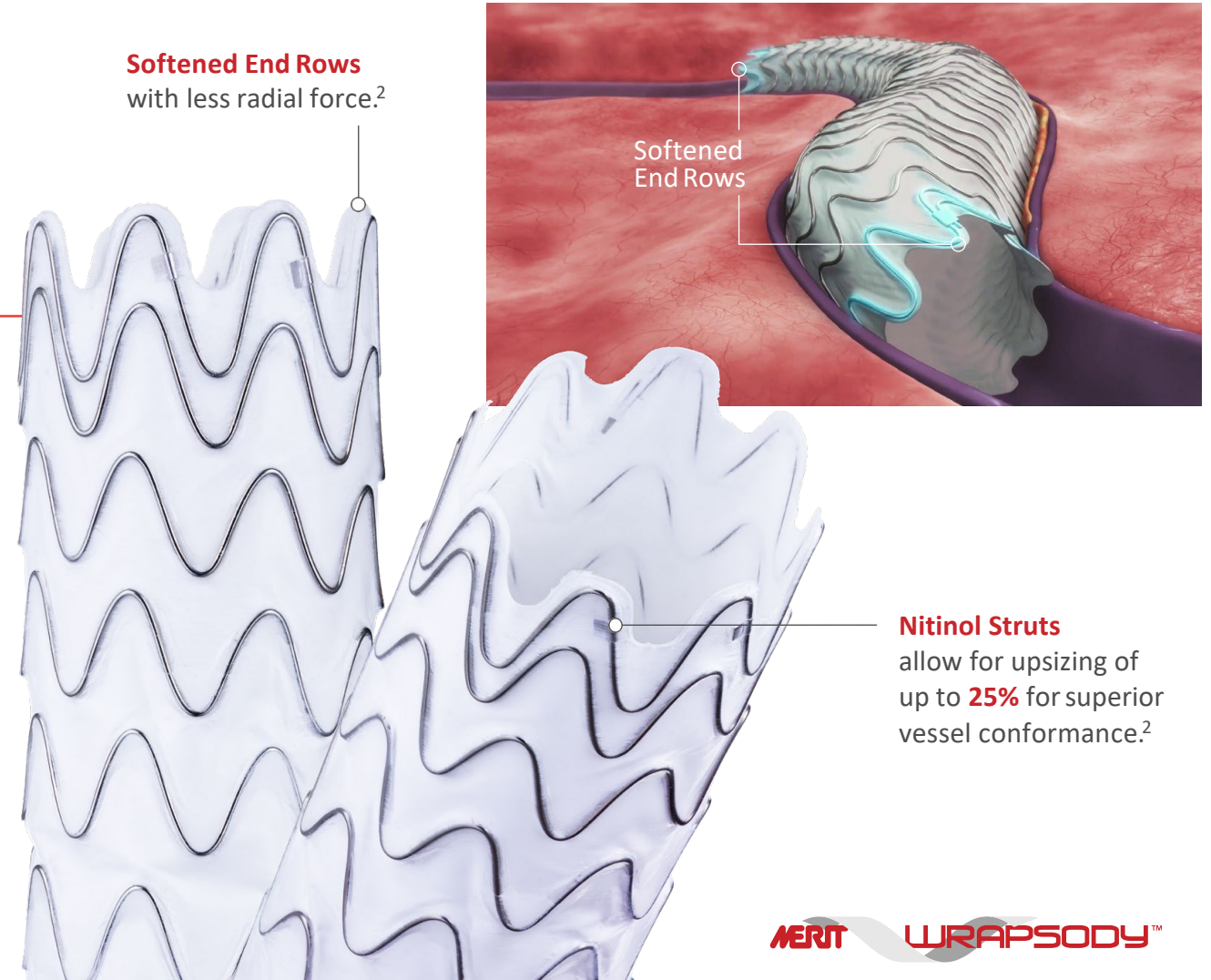


Compression Resistance: Designed to withstand extrinsic pressures placed on the device.

| Optimized Radial Strength and Softened End Rows

Excessive endoprosthesis oversizing leads to edge stenosis and a gradual decrease in vessel patency.

Softened end rows better conform to healthy tissue, prevent vessel trauma, and improve long-term patency.



| Optimized Radial Strength



8 mm x 100 mm Merit WRAPSODY

First Human Trial (2019)—Outflow stenosis within the thoracic central veins, up to the superior vena cava, in arteriovenous fistula patient.



Merit WRAPSODY® deployed within medical grade silicone. Centre of the endoprosthesis pouches, whereas end rows taper down. (Representation)

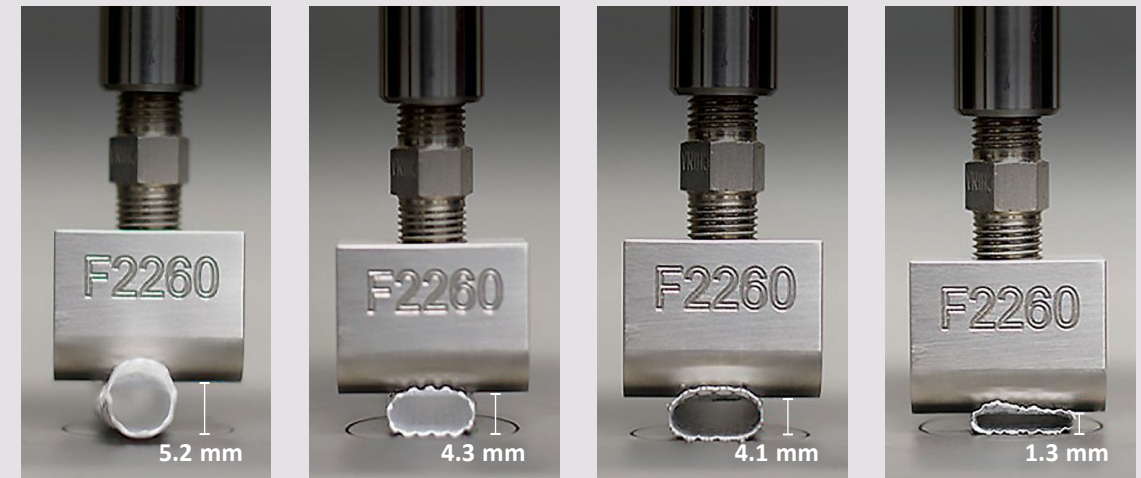
| Optimized Compression Resistance

Internal tests applied 1.8 N of force to the Merit WRAPSODY®, compressing the center of the endoprosthesis by 50%. The same force was applied to three leading self-expanding covered endoprotheses.

The Merit WRAPSODY®:

- Provides robust local compression resistance across all diameter sizes.
- Allows the endoprosthesis to withstand extrinsic pressures.

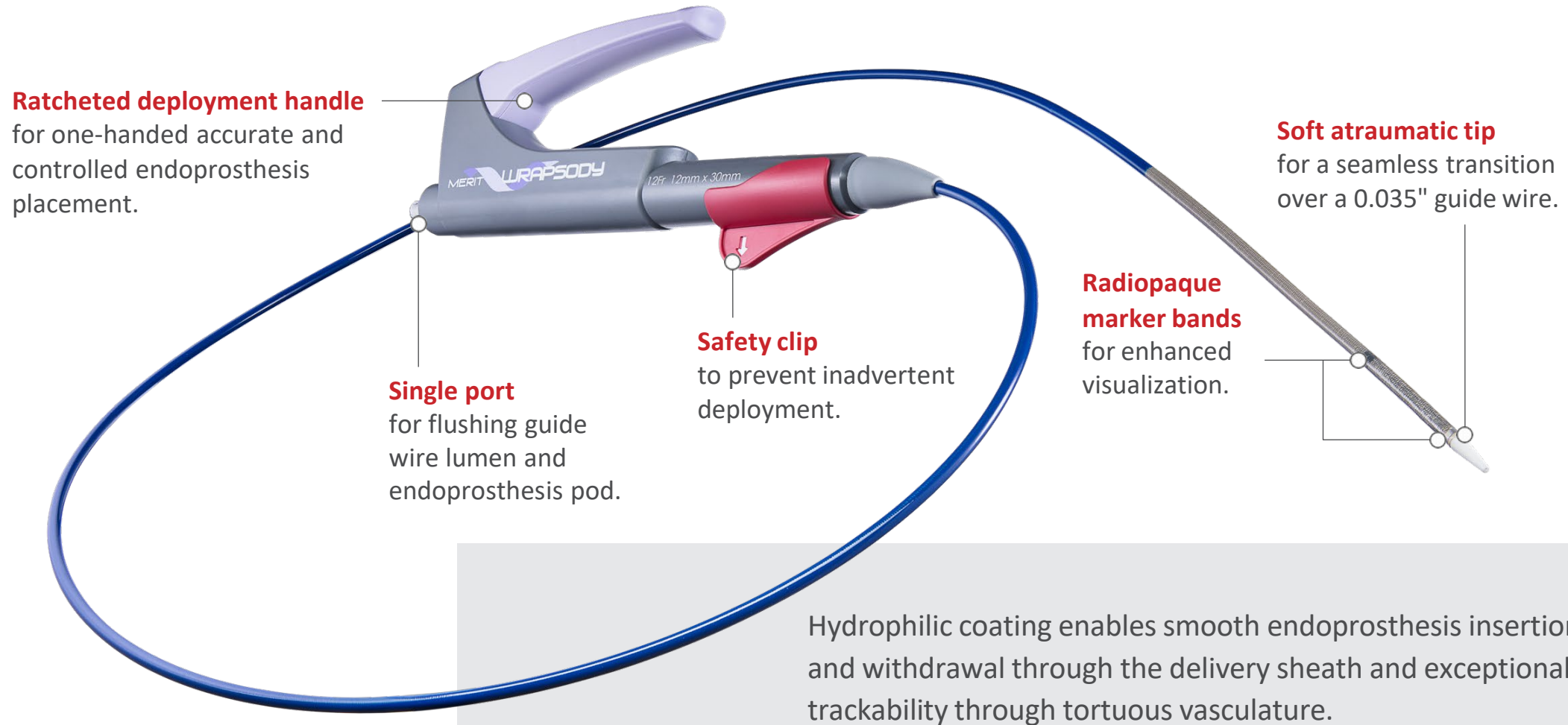
LOCAL COMPRESSION DEVICE COMPARISON²
(1.8 N applied to each device)



Merit WRAPSODY®

Three Leading Covered Stents

| Intuitive Delivery System for Pinpoint Accuracy

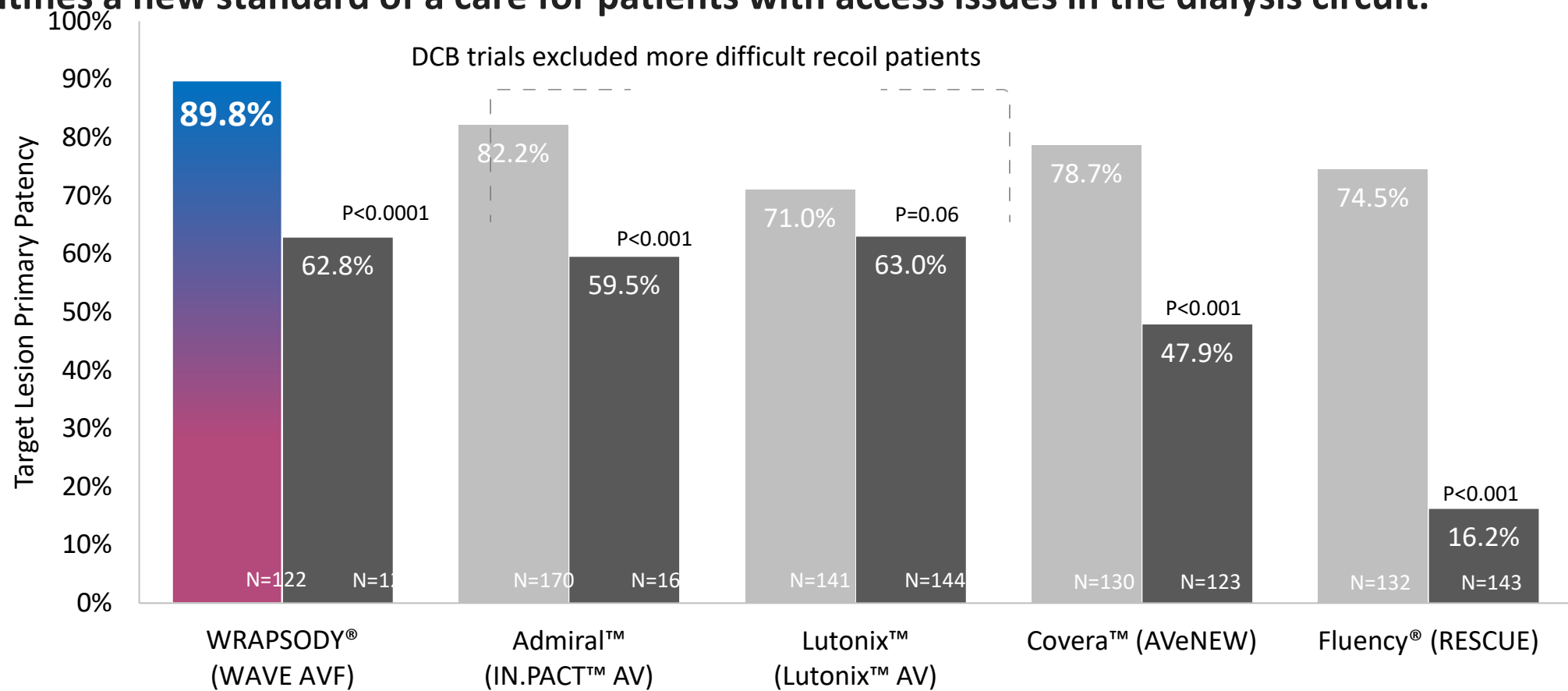


Contemporary Study Comparisons

	COVERED STENT					DCB		WRAPSODY®		
STUDY	Flair RENOVA	Fluency RESCUE	Viabahn REVISE	Covera AVeVA	Covera AVeNEW	Lutonix AVF	Admiral IN.PACT AVF	FIRST	WAVE AVF	WAVE AVG
Sponsor	BD Bard	BD Bard	Gore	BD Bard	BD Bard	BD Bard	Medtronic	Merit	Merit	Merit
NCT Number (clintrials.gov)	00677235	01257438	00737672	02790606	02649946	03506308	03041467	03644017	04540302	04540302
Design	RCT	RCT	RCT	Registry	RCT	RCT	RCT	Registry	RCT	Registry
Study Device	Flair	FLUENCY	Viabahn	Covera	Covera	Lutonix DCB	IN.PACT DCB	WRAPSODY	WRAPSODY	WRAPSODY
Control	PTA	PTA	PTA	N/A	PTA	PTA	PTA	N/A	PTA	N/A
Sample Size (Study arm)	270 (138)	265 (128)	293 (131)	110 (110)	280 (142)	285 (141)	330 (170)	46 (46)	233 (115)	112 (0)
AVF	0	69	0	0	142	141	170	16	105	0
Central	0	(41)	0	0	0	0	0	11	0	0
AVG	138	59	131	110	0	0	0	19	0	112
6 Month TLPP	50.6%	65.2%	52.9%	71.7%	*78.7%	*71.4%	86.1%	97.7%	89.8%	82.0%
PTA 6mo TLPP	23.3%	10.4%	35.5%	NA	47.9%	63.0%	68.9%	NA	62.8%	NA
6 Month ACPP	38.0%	16.7%	43.4%	40%	*50.7%	*NA	72.5%	84.4%	72.6%	68.8%
PTA 6mo ACPP	20.3%	3.0%	29.4%	NA	43.8%	NA	56.1%	NA	57.9%	NA
12 Month TLPP	NA	6.2%	30.2%	54.2%	57.5%	44.4%	65.3%	84.6%	TBD	TBD
12 Month ACPP	24.1%	1.5%	21.4%	17.9%	28.9%	NA	55.1%	65.9%	TBD	TBD

*Did not meet statistical endpoint

Multicenter RCT results of the arteriovenous fistula (AVF) patency or open vessel at 6 months.
 Wrapsody demonstrates a statistically significant improvement of vessel patency when compared to covered stents, bare metal stents, or drug coated balloons, the current standards to treat AVF occlusions. **The clinical evidence identifies a new standard of a care for patients with access issues in the dialysis circuit.***



*Patency rates are defined differently; results are from different studies and may vary in head-to-head comparison, graphics are for illustrative purposes only

PTA

WAVE AVF arm: IDE trial data presented at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Sept 14-18, 2024 in Lisbon, Portugal (Rates based on Kaplan-Meier estimate)
 Admiral™ IN.PACT AV: Lookstein et al. 2020. doi: 10.1056/NEJMoa1914617 (Rates based on actual rates)
 Lutonix™ Lutonix AV: Trerotola et al. 2018. doi: 10.2215/CJN.14231217 (Rates based on Kaplan-Meier estimate)
 Covera™ AVeNEW: Dolmatch et al. 2023. doi: 10.1016/j.kint.2023.03.015 (Rates based on Kaplan-Meier estimate)
 Fluency® RESCUE: Falk et al. 2016. doi: 10.1016/j.jvir.2016.06.014 (Rates based on actual rates)



WRAPSODY® Minimizes Morbidity

The WRAPSODY® was designed to solve an unmet clinical need for dialysis patients with stenosis in the outflow circuit.

- Improved primary patency
- Reduced revision frequency
- Less hospitalization
- Avoid catheterization



PMA P240023 FDA Approved 12/19/2024 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.

Only self-expanding covered stent on the market with 14 mm and 16 mm diameter options specifically designed to treat thoracic central veins.

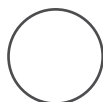
6 mm



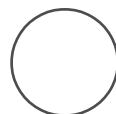
7 mm



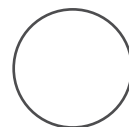
8 mm



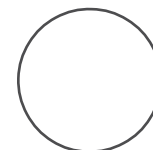
9 mm



10 mm

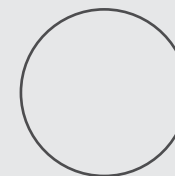


12 mm

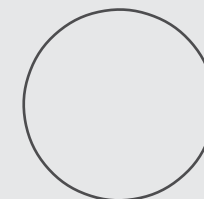


Thoracic central vein options

14 mm



16 mm



The Merit WRAPSODY® is available in lengths ranging from 30 mm to 125 mm.

WRAPSODY® Cell Impermeable Endoprosthesis a flexible, self-expanding endoprosthesis

- Wrapsody® placement will be documented by the interventional radiologist or surgeon in the procedure note or the operative report.
- Wrapsody® may also be documented in the implant portion of the operating room documents.
- It may be reported after balloon angioplasty.
- Key words: WRAPSODY®, WRAPSODY® Cell Impermeable Endoprosthesis, Wrapsody® CIE, flexible self-expanding endoprosthesis.



MERIT WRAPSODY™

This product is intended for sale and/or use only in the European Union, 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. This product is not approved, cleared, or available for sale or use in the United States and may not be approved, cleared, or available for sale or use in other countries. Before using any product, refer to the Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and directions for use.