

First Clinical Results of the Merit **WRAPSODY™** Cell-Impermeable Endoprosthesis for Treatment of Access Circuit Stenosis in Haemodialysis Patients: [CardioVascular and Interventional Radiology \(CVIR\), 2021](#)

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

WRAPSODY™ is composed of a helically-wound nitinol stent with a multi-layer fluoropolymer graft covering.

It is the only self-expanding endoprosthesis currently on the market with 14 mm and 16 mm diameter options specifically designed to treat thoracic central veins.



The WRAPSODY First Study

Design	Purpose	Subject Population	Primary Study Objectives	Follow-up
Prospective, 3 Centre, Single arm, Feasibility Study	Safety & effectiveness of WRAPSODY in treatment of stenosis or occlusion within dialysis access circuit	46 Hemodialysis patients with AV fistula (AVF) or AV graft (AVG) in upper limbs Clinical relevant stenosis or obstruction ($\geq 50\%$) in the peripheral outflow veins, at the graft-vein anastomosis, or in the central veins up to the SVC without additional thrombus or secondary lesions	Safety: Proportion of subjects without any localized or systemic safety events through 30 days that affect the access or venous outflow circuit and resulted in surgery, hospitalization, or death Effectiveness: Proportion of subjects with Target Lesion Primary Patency at 30 days	30 Days, 3 Months, 6 Months & 12 Months An independent DMC/CEC adjudicated all study reinterventions and the device/procedure-relatedness for adverse events

12 Month Safety Results

Safety Objective	n/N (%)	Summary of Events
Primary safety -Freedom from Safety Events Through 30 days	45/46 (97.8%)	Thrombosis of Access Circuit*
Device-related adverse events	1	Thrombosed fistula**

* DMC/CEC adjudicated as not device related.

** Listed as possibly device-related as the access circuit was not salvageable so there was no imaging to assess device-relatedness.

12 Month Performance Results

Target Lesion Primary Patency

Time	n/N (%)
30 Days	45/45 (100%)
3 Months	44/44 (100%)
6 Months	42/43 (97.7%)
12 Months	33/39 (84.6%)

Access Circuit Primary Patency

Time	n/N (%)
30 Days	43/45 (95.6%)
3 Months	40/45 (88.9%)
6 Months	38/45 (84.4%)
12 Months	29/44 (65.9%)

12 Month Target Lesion Primary Patency by Cohort

Time	AVF Peripheral [n/N(%)] N=16	AVG Peripheral [n/N(%)] N=10	AVG Anastomosis [n/N(%)] N=9	AVF/AVG Central [n/N(%)] N=11	Total [n/N(%)] N=46
30 Days	16/16 (100%)	10/10 (100%)	8/8 (100%)	11/11 (100%)	45/45 (100%)
3 Months	16/16 (100%)	10/10 (100%)	8/8 (100%)	10/10 (100%)	44/44 (100%)
6 Months	16/16 (100%)	9/10 (90%)	8/8 (100%)	9/9 (100%)	42/43 (97.7%)
12 Month	11/14 (78.6%)	7/9 (77.8%)	6/7 (85.7%)	9/9 (100%)	33/39 (84.6%)

12 Month Access Circuit Primary Patency by Cohort

Time	AVF Peripheral [n/N(%)] N=16	AVG Peripheral [n/N(%)] N=10	AVG Anastomosis [n/N(%)] N=9	AVF/AVG Central [n/N(%)] N=11	Total [n/N(%)] N=46
30 Days	15/16 (93.8%)	10/10 (100%)	8/8 (100%)	10/11 (90.9%)	43/45 (95.6%)
3 Months	14/16 (87.5%)	9/10 (90%)	8/8 (100%)	9/11 (81.8%)	40/45 (88.9%)
6 Months	13/16 (81.3%)	9/10 (90%)	8/8 (100%)	8/11 (72.7%)	38/45 (84.4%)
12 Months	10/15 (66.7%)	7/10 (70%)	5/8 (62.5%)	7/11 (63.6%)	29/44 (65.9%)

AV Access Covered Stent and DCB Trial Data

Study	COVERED STENT					DCB			WRAPSODY FIRST
	Flair Pivotal	Flair RENVOVA	Viabahn REVISE	Covera AVeVA	Covera AVeNEW	Lutonix AVF	Lutonix PAVE	Admiral In.Pact AVF	
Sponsor	BD Bard	BD Bard	Gore	BD Bard	BD Bard	BD Bard	Investigator-led	Medtronic	Merit
NCT Number clinicaltrials.gov	00678249	00677235	00737672	02790606	02649946	03506308	NA	03041467	03644017
Design	RCT	RCT	RCT	Registry	RCT	RCT	RCT	RCT	Registry
Control	PTA	PTA	PTA	N/A	PTA	PTA	PTA	PTA	N/A
Sample Size (study arm)	227 (97)	270 (138)	293 (131)	110 (110)	280 (142)	285 (141)	212 (106)	330 (170)	46 (46)
AVF	0	0	0	0	142	141	106	170	16
Central	0	0	0	0	0	0	0	0	11
AVG	97	138	131	110	0	0	0	0	19
6 Month TLLP	50.6%	NA	52.9%	71.7%	78.7%	71.4%	71.7%	82.2%	97.7%
6 Month ACCP	38.0%	NA	43.4%	40%	50.7%	NA	NA	72.5%	84.4%
12 Month TLPP	NA	47.6%	30.2%	54.2%	57.5%	44.4%	52.5%	65.3%	84.6%
12 Month ACCP	NA	24%	21.4%	17.9%	28.9%	NA	NA	55.1%	65.9%

Conclusions From The Authors¹

- “Study device can safely and effectively treat stenoses in the peripheral outflow and central veins of AV access circuits.”
- “6- and 12-month TLPP and ACCP rates were unexpectedly high.”
- “While needing further confirmation, the study device’s design may be a contributing factor in limiting restenosis.”
- “This degree of patency preservation should reduce revision frequency and access abandonment rates, leading to less hospitalisation and lower healthcare costs.”
- “Additional follow-up in larger RCTs is needed to verify these results.”

Next Steps

- Wrapsody WAVE Study (NCT04540302)
 - Multi-Cohort, Multi-Centre trial
 - AVF peripheral: RCT, N = 244, 1:1 vs PTA
 - AVF/AVG central: RCT, N = 120, 1:1 vs PTA
 - AVG venous anastomosis: PG, N = 113
- Global WRAP Registry
 - Real world clinical data
 - Up to 50 centres to participate
 - Up to 500 patients to be enrolled

1: Gilbert J, et al.; CardioVascular and Interventional Radiology (2021). <https://doi.org/10.1007/s00270-021-02953-8>

This product is intended for sale and/or use only in the European Union, 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. 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.



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