# 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 Hemodiaylsis patients with AV fistula (AVF) or AV graft (AVG) in upper limbs<br><br>Clinical relevant stenosis or obstruction (≥ 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<br><br>**Effectiveness:** Proportion of subjects with Target Lesion Primary Patency at 30 days | 30 Days, 3 Months, 6 Months & 12 Months<br><br>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

| | COVERED STENT | | | | | DCB | | | WRAPSODY FIRST |
|---|---|---|---|---|---|---|---|---|---|
| Study | 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 | Investiga-tor-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 ACPP** | **NA** | **24%** | **21.4%** | **17.9%** | **28.9%** | **NA** | **NA** | **55.1%** | **65.9%** |

## Conclusions From The Authors[1]

- "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 ACPP 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



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