



Treatment of left subclavian vein occlusion from a large sheath in the upper arm with a 16mm diameter Wrapsody



Dr. Matthew Gibson
Interventional Radiologist
Royal Berkshire Hospital, Reading, UK

CLINICAL HISTORY

An 85-year-old male patient on haemodialysis for 15 years with swollen left arm and reduced AV circuit competence.

The image to the right shows a clinically significant subclavian stenosis.



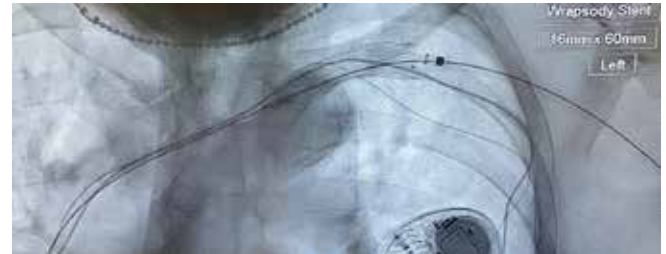
INTERVENTIONAL TREATMENT

Initial access was gained using a Merit MAK™ (Mini Access Kit), and venography was performed using a basic access sheath to evaluate the venous vasculature within the dialysis outflow circuit. Once the appropriate WRAPSODY Cell-Impermeable Endoprosthesis size was determined and selected per the IFU, the access sheath in the arm was upsized to a Cook Medical Check-Flo® Introducer (14F x 13 cm) to accommodate the WRAPSODY delivery system.

First, percutaneous angioplasty was performed with a BD Atlas™ Gold high-pressure balloon. Then, a **WRAPSODY Cell-Impermeable Endoprosthesis (16 mm x 60 mm)** was implanted in the subclavian vein.



Percutaneous angioplasty with a BD Atlas Gold high-pressure balloon



WRAPSODY (16 mm x 60 mm) implanted

TAKEAWAYS

The 16 mm WRAPSODY is a unique size option for a cell-impermeable endoprosthesis or covered stent.

A stenosis or occlusion within the subclavian vein is a technically challenging vessel to treat; the stenosis can be resistant to standard PTA, and the vein can be compressed by the clavicle bone.

A cell-impermeable endoprosthesis or covered stent must have high radial force and compressive resistance to ensure long-term patency is maintained.

The Merit WRAPSODY is the only device available that can satisfy the above mentioned requirements.

RESULTS

The WRAPSODY demonstrated **good apposition** (no endoleak). The inflow and outflow showed **no impingement on the lumen** (device wide open).

Post operatively, the oedema in the patient's left arm reduced dramatically. The dialysis flow rates improved to enable **effective treatment**.



VOICE OF CUSTOMERS

"With the position and tightness of the stenosis, I was worried the WRAPSODY wouldn't be able to hold the lumen of the vein open adequately. I wouldn't expect any covered stent to perform this well. **The WRAPSODY has done a great job.** It's **extremely easy to use**; I didn't have to change my operating protocol. The **ratchet handle** gives me **good control** when deploying it, and I like it.

I understand the concern some physicians may have about making a large hole (14F) in a peripheral vein when using a large-diameter endoprosthesis. I do, however, have experience using a purse string suture to achieve haemostasis. I've found this technique to be a safe and effective way to achieve haemostasis with my patients."

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.



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Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
1.801.253.1600
1.800.35.MERIT

Merit Medical Europe, Middle
East & Africa (EMEA)
Amerikalaan 42, 6199 AE
Maastricht-Airport
The Netherlands
+31 43 358 82 22

Merit Medical Australia
53 Canterbury Road
Braeside VIC
Australia
+61 1300 696 374

Merit Medical New Zealand
4/4 Rawiri Place
Hobsonville, Auckland
New Zealand
+64 9 964 0591