**Expand Your AV Access Options**

- Central Veins
- AV Fistulae
- AV Grafts (ISR)
- AV Grafts (Venous Outflow)

*Central Veins = Subclavian Vein and Brachiocephalic Vein.*
A broad range of implant diameters and lengths for the treatment of in-stent restenotic peripheral and central lesions in patients with AV grafts and AV fistulae, and non-stented lesions in patients with AV grafts. Small incremental stent graft lengths to help maintain venous real estate and cannulation area.

MORE sizes

* Central Veins=Subclavian Vein and Brachiocephalic Vein
CONTROLLED delivery

Minimal shortening and radiopaque markers aid in excellent placement accuracy
The multi-braided delivery system with a tipless inner catheter designed to reduce the risk of catheter entanglement during withdrawal

proven DESIGN
Dual layer ePTFE encapsulation demonstrated a significant reduction at 90 days in the incidence of in-stent restenosis compared to PTA
Proprietary bioactive carbon impregnation designed to reduce early stage platelet adhesion
Flexible implant that demonstrated kink resistance after placement in tortuous AV access lesions presenting with ISR or non-stented lesions in patients with AV grafts

** Data on file and based on the RESCUE Trial
† AV=Arteriovenous
†† ISR=In-stent restenosis
RESCUE TRIAL - 24 MONTH FOLLOW-UP RESULTS

A Prospective, Multi-Center, Randomized, Concurrently-Controlled Study of the FLUENCY® PLUS Endovascular Stent Graft in the Treatment of In-stent Restenosis in the AV Access Venous Outflow Circuit.

Study Highlights at a Glance
- 23 Clinical Study Sites in the United States
- Pre-determined follow-up evaluation at 1, 3, 6, 12, 18 and 24 months
- 90 - Day Mandatory Angiogram
- 275 Patients included in 24 Month Intent-to-Treat Analysis
  - Balloon Angioplasty Alone - 143 Patients
  - Balloon Angioplasty & FLUENCY® PLUS Endovascular Stent Graft - 132 Patients

Post Intervention Lesion Patency through 24 months

The p-value is based on a one-sided, stratified log-rank test with strata of AV graft and AV fistula. Figure includes data through 24 month visit (± 30 day visit window).

Access Circuit Primary Patency through 6 Months

Access Circuit Primary Patency: Interval following the index intervention until next access thrombosis or repeat intervention anywhere in the access circuit

Index of Patency Function through 24 Months

Index of Patency Function: Time to access abandonment divided by the number of reinterventions to maintain vascular access.

*Averages
### Prescriptive Information

Prior to use, please see the complete “Instructions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator’s Instructions.

### Indications

The FLUENCY® PLUS Endovascular Stent Graft is indicated for use in the treatment of in-stent restenosis in the venous outflow of hemodialysis patients dialyzing by either an arteriovenous (AV) fistula or AV graft and for the treatment of stenosis in the venous outflow of hemodialysis patients dialyzing by an AV graft.

### Contraindications

There are no known contraindications for the FLUENCY® PLUS Endovascular Stent Graft.

### Warnings

The use of this device carries the risks associated with dialysis shunt revisions and endovascular procedures, and should not be placed in patients with infected AV access graft/fistula, immature fistula, or in anatomies which would require placement of the FLUENCY® PLUS Endovascular Stent Graft across a vessel.

### Precautions

The safety and effectiveness of the device when placed across a tight bend including the terminal cephalic arch, across the elbow joint, or across a fractured bare metal stent has not been evaluated. Care should be taken to select an appropriate length device(s) so that the stent graft extends at least 10 mm distally (outflow) and 10 mm proximally (inflow) beyond the lesion into the non-diseased vessel. The stent graft implant cannot be expanded with an angioplasty balloon beyond its stated diameter.

### Potential Adverse Events

Adverse Events associated with use of the FLUENCY® PLUS Endovascular Stent Graft may include the usual complications associated with endovascular stent and stent graft placement and dialysis shunt revisions, including but not limited to: thrombotic occlusion; restenosis; infection; arm or hand edema; steal syndrome; allergic reaction; stent graft migration; and, stent graft fracture.

**Caution**

Federal law (USA) restricts this device to sale by or on the order of a physician.

Please consult package insert for more detailed safety information and instructions for use.

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**Expanded Stent Diameter (mm)**

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**Compatible with 0.035” guidewire.**