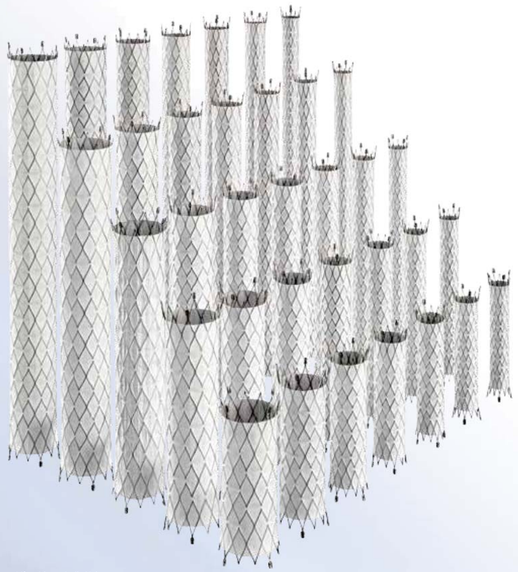
MORE sizes.

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



*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

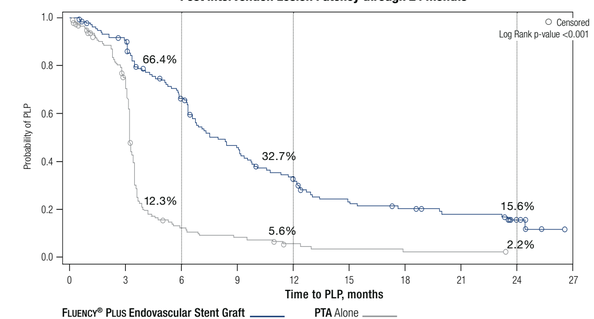
RESCUE TRIAL - 24 MONTH FOLLOW-UP RESULTS

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

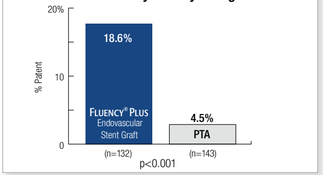


Fluency® Plus Endovascular Stent Graft ——— **PTA** Alone ———

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).

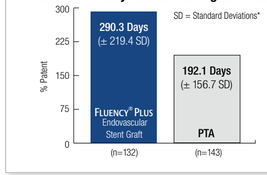
Post Intervention Lesion Patency: Interval following the index intervention until the next re-intervention at the original treatment site or until the extremity (access) is abandoned for permanent access.

Access Circuit Primary Patency through 6 Months



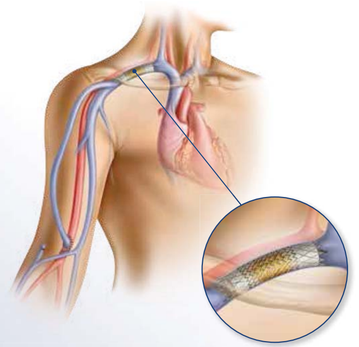
Access Circuit Primary Patency: Interval following the index intervention until next access thrombosis or repeat intervention anywhere in the access circuit

Index of Patency Function through 24 Months*

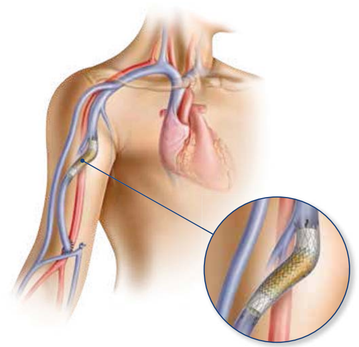


Index of Patency Function: Time to access abandonment divided by the number of reinterventions to maintain vascular access.
*Averages

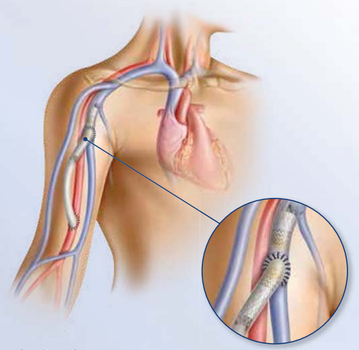
MORE indications.



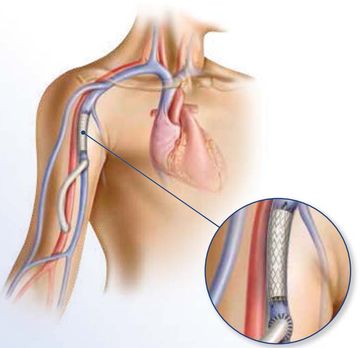
Central Veins*



AV Fistulae



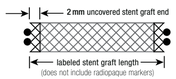
AV Grafts (ISR)



AV Grafts** (Venous Outflow)

*Central Veins = Subclavian Vein and Brachiocephalic Vein
**Non-stented lesions in AV grafts

FLUENCY® PLUS Endovascular Stent Graft



Expanded Stent Graft Diameter (mm)	Stent Graft Length (mm)	Endovascular System Working Length (cm)	Endovascular System Diameter	Product Code
6	40	80	8F	FEM06040
	60	80	8F	FEM06060
	80	80	8F	FEM06080
	100	80	8F	FEM06100
	120	80	8F	FEM06120
	40	117	8F	FEL06040
	60	117	8F	FEL06060
	80	117	8F	FEL06080
	100	117	8F	FEL06100
	120	117	8F	FEL06120
7	40	80	8F	FEM07040
	60	80	8F	FEM07060
	80	80	9F	FEM07080
	100	80	9F	FEM07100
	120	80	9F	FEM07120
	40	117	8F	FEL07040
	60	117	8F	FEL07060
	80	117	9F	FEL07080
	100	117	9F	FEL07100
	120	117	9F	FEL07120
8	40	80	9F	FEM08040
	60	80	9F	FEM08060
	80	80	9F	FEM08080
	100	80	9F	FEM08100
	120	80	9F	FEM08120
	40	117	9F	FEL08040
	60	117	9F	FEL08060
	80	117	9F	FEL08080
	100	117	9F	FEL08100
	120	117	9F	FEL08120
9	40	80	9F	FEM09040
	60	80	9F	FEM09060
	80	80	9F	FEM09080
	100	80	9F	FEM09100
	120	80	9F	FEM09120

Expanded Stent Graft Diameter (mm)	Stent Graft Length (mm)	Endovascular System Working Length (cm)	Endovascular System Diameter	Product Code
9	40	117	9F	FEL09040
	60	117	9F	FEL09060
	80	117	9F	FEL09080
	100	117	9F	FEL09100
	120	117	9F	FEL09120
10	40	80	9F	FEM10040
	60	80	9F	FEM10060
	80	80	9F	FEM10080
	100	80	9F	FEM10100
	120	80	9F	FEM10120
	40	117	9F	FEL10040
	60	117	9F	FEL10060
	80	117	9F	FEL10080
	100	117	9F	FEL10100
	120	117	9F	FEL10120
12	40	80	10F	FEM12040
	60	80	10F	FEM12060
	80	80	10F	FEM12080
	100	80	10F	FEM12100
	120	80	10F	FEM12120
	40	117	10F	FEL12040
	60	117	10F	FEL12060
	80	117	10F	FEL12080
	100	117	10F	FEL12100
	120	117	10F	FEL12120
13.5	40	80	10F	FEM14040
	60	80	10F	FEM14060
	80	80	10F	FEM14080
	100	80	10F	FEM14100
	120	80	10F	FEM14120
	40	117	10F	FEL14040
	60	117	10F	FEL14060
	80	117	10F	FEL14080
	100	117	10F	FEL14100
	120	117	10F	FEL14120

Compatible with 0.035" guidewire.

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 product labels and instructions for use for indications, contraindications, hazards, additional warnings and precautions.

BPV/SGF2/0816/0042

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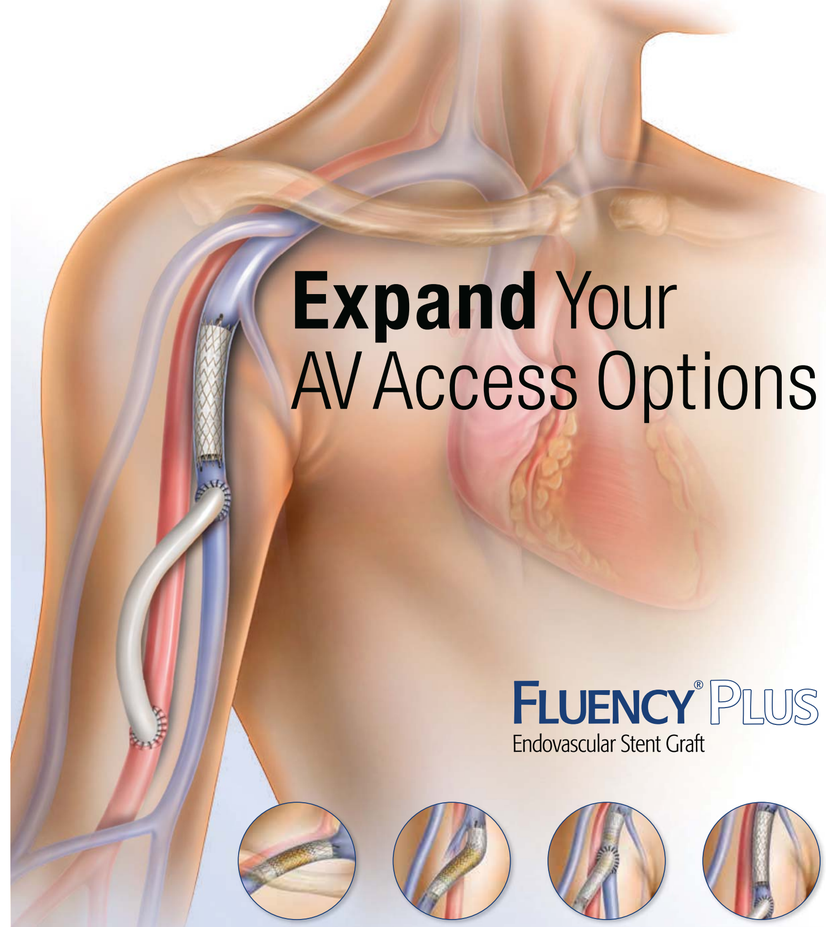

Expand Your AV Access Options

FLUENCY® PLUS
Endovascular Stent Graft

Central Veins*

AV Fistulae

AV Grafts (ISR)

AV Grafts (Venous Outflow)

*Central Veins = Subclavian Vein and Brachiocephalic Vein.

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