Deliver the Only AV Access Stent Graft Flared to Optimize Flow

FLAIR® Endovascular Stent Graft. Setting the Pace

Advancing Lives and the Delivery of Health Care
Carbon Impregnation

2-layer ePTFE (expanded polytetrafluoroethylene) encapsulation reduces the incidence of restenosis in the treatment area.

Reduce Restenosis

Optimize Flow

Flared outflow configuration optimizes flow in anatomies where the vein diameter is larger than the graft.

Decrease Platelet Accumulation

Proprietary inner surface carbon impregnation technology is designed to decrease platelet accumulation in the acute phase after implantation.

The only endovascular intervention proven in a controlled clinical trial to improve AV graft function over the first endovascular intervention, balloon angioplasty.
**Level 1 Clinical Evidence**\(^1\) supports a significant patency advantage of the FLAIR\(^\text{®}\) Endovascular Stent Graft versus balloon angioplasty.

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**More than Twice the Treatment Area Primary Patency of PTA**

<table>
<thead>
<tr>
<th></th>
<th>PTA Randomized</th>
<th>FLAIR(^\text{®}) Randomized</th>
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</thead>
<tbody>
<tr>
<td>Index Area + 5 mm Distal &amp; Proximal</td>
<td>23.3%</td>
<td>50.6%</td>
</tr>
</tbody>
</table>

At 6 Months

\(p<0.001\)

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**Access Circuit Primary Patency Nearly Doubled over PTA**

<table>
<thead>
<tr>
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<th>PTA Randomized</th>
<th>FLAIR(^\text{®}) Randomized</th>
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<tbody>
<tr>
<td>Arterial Anastomosis to SVC/Right Atrial Junction</td>
<td>19.8%</td>
<td>38.0%</td>
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</table>

At 6 Months

\(p=0.008\)

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**64% Reduction in the Binary Restenosis Rate over PTA**

<table>
<thead>
<tr>
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<th>PTA Randomized</th>
<th>FLAIR(^\text{®}) Randomized</th>
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</thead>
<tbody>
<tr>
<td>Stenosis ≥ 50% of Treatment Area During Angiographic Evaluation</td>
<td>27.6%</td>
<td>77.6%</td>
</tr>
</tbody>
</table>

At 6 Months

\(p<0.001\)

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84% of FLAIR\(^\text{®}\) patients received a flared device.
Exemplary Case from FLAIR® PIVOTAL Study

A 62-year-old patient with hemodialysis-dependent end-stage renal disease for 6 years, Type-II diabetes mellitus, peptic ulcer disease and moderate obesity underwent multiple catheter interventions over a 3-year period. The patient was enrolled in the FLAIR® Endovascular Stent Graft Pivotal Trial, randomized to the stent graft group and treated with PTA followed by placement of an 8 mm x 50 mm FLAIR® Endovascular Stent Graft with a flared configuration. Mandatory follow-up ended at 6 months for the clinical trial but the patient continued to be treated at the study center.

The FLAIR® Endovascular Stent Graft remained free of any evidence of recurrent stenosis for more than 3 years after placement.

Patient presented with elevated venous pressure and recurrent 60% – 70% anastomotic stenosis

10 months: The FLAIR® Endovascular Stent Graft and access circuit patent at 10 months

35 months: The FLAIR® Endovascular Stent Graft and access circuit patent at 35 months

Case Information Provided by:
Bart Dolmatch, MD, Interventional Radiologist
The Palo Alto Medical Foundation
El Camino Hospital – Mountain View, California

The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician preparing the case study receives product royalties and has been compensated by Bard Peripheral Vascular, Inc., for time and effort involved in preparing the case study.
**Fluid Dynamics Optimized**

Designed to optimize flow characteristics, reduce flow turbulence and promote laminar blood flow at the AV graft venous anastomosis.*

**Straight Stent Graft**

- High velocity jet
- Strong backflow
- Vein inflow hindered

Hemodynamic flow patterns in a venous anastomosis through a straight stent graft.

**Flared Stent Graft**

- High velocity jet
- Distal outlet sealed
- Reduced flow turbulence

Hemodynamic flow patterns in a venous anastomosis through a flared FLAIR® Endovascular Stent Graft.

Flared end accommodates the frequent difference between the diameter of the synthetic AV graft and the diameter of the outflow vein.

Hans Scholz, MD and Ulf Krueger, PhD Queen Elisabeth Hospital – Berlin, Germany


*Per FLAIR® IFU, flared devices are intended for use in lesions where the vein diameter is larger than the graft diameter, with the distal (outflow) flared end of the device to be placed in the vein. Straight devices are intended for all lesions in which the vein diameter is equivalent to or less than that of the access graft.
FLAIR® Endovascular Stent Graft
Ordering Information

*The flared distal stent graft end diameter of the FLAIR® Endovascular Stent Graft is approximately 4 mm larger than the labeled diameter of the stent graft body section.

<table>
<thead>
<tr>
<th>Expanded Stent Graft Diameter (mm)</th>
<th>Stent Graft Length (mm)</th>
<th>Product Code</th>
<th>Product Code</th>
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</thead>
<tbody>
<tr>
<td>Straight Configuration</td>
<td>Flared Configuration</td>
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Delivery System Total Length: 120 cm
Delivery System Working Length: 80 cm
Recommended Guidewire: 0.035"
Delivery System Outer Diameter: 9F

FLAIR® Endovascular Stent Graft
Prescriptive Information: Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator’s Instructions.

Indications: The FLAIR® Endovascular Stent Graft is indicated for use in the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arteriovenous (AV) access grafts.

Contraindications: There are no known contraindications for the FLAIR® Endovascular Stent Graft.

Warnings: The safety and effectiveness of this device for use in the arterial system have not been established. The use of this device carries the risks commonly associated with dialysis shunt revisions and endovascular procedures. Do not use in patients whose AV access graft is infected or been implanted less than 30 days. Do not use in patients with septicaemia or who have uncorrectable coagulation disorders.

Precautions: The safety and effectiveness has not been established for the device if placed across an angle that is greater than 90º or deployed across the antecubital fossa. In case two stent grafts are placed (overlapped), use the same device diameter. If a flared device is used to overlap, do not deploy the flared end inside the first stent graft and ensure a minimum 10 mm overlap of the devices. Careful attention should be paid to ensure the device is appropriately sized to the graft diameter and takes into account previous interventions. Please note, clinical investigations of the safety and effectiveness of the device have been limited to devices placed within AV access grafts located in the upper extremities.

Potential Adverse Events: Complications and Adverse Events associated with the use of this device may include but are not limited to: Thrombotic Occlusion • Misplacement • Migration • Fracture • Kinking • Restenosis • Premature Deployment • Failure to Deploy • Delivery System Kinking • Dialysis Shunt Damage Leading to Surgical Revision • Pseudoaneurysm • Vessel Rupture • Perforation • Pain • Infection • Hematoma • Arm or Hand Edema • Steal Syndrome • Congestive Heart Failure • Cerebrovascular Accident • Death

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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