FLAIR™

Endovascular Stent Graft

Instructions for Use

BARD PERIPHERAL VASCULAR

PK1143500 Rev. 2 7/07

***FLAIR*™ Endovascular Stent Graft**
Instructions for Use
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

Implant

The ***FLAIR*™** Endovascular Stent Graft (implant) is a flexible, self-expanding endoprosthesis comprised of expanded polytetrafluoroethylene (ePTFE) encapsulating a Nitinol stent framework. Nitinol is an alloy that can be processed to assume a pre-defined final configuration upon exposure to body temperature.
The Nitinol stent, including distal and proximal ends, is encapsulated within two layers of ePTFE. The inner lumen of the stent graft (blood contacting surface) is carbon impregnated. The ePTFE outer wall of the stent graft, which contacts with the AV Access graft and native vein, contains cutouts which expose the Nitinol stent.
The ***FLAIR*™** Endovascular Stent Graft is available in both flared (Figure 1) and straight (Figure 2) configurations. The distal end of the flared configuration device is approximately 4mm larger in diameter than the body section.

Figure 1. Flared configuration

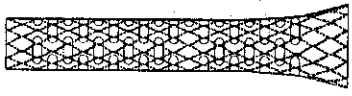
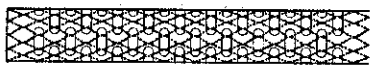


Figure 2. Straight configuration

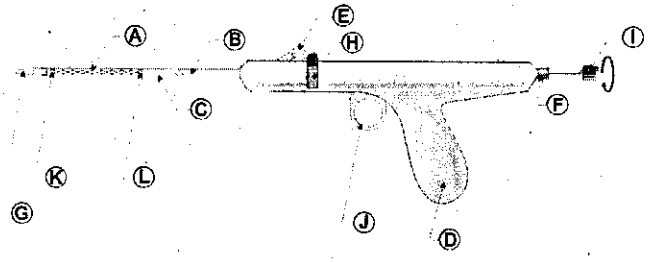


Flared devices are intended for use in lesions where the vein diameter is larger than the graft diameter, with the distal flared end of the device to be placed in the vein. Straight devices are intended for all lesions in which the vein diameter is equivalent to or less than that of the Access graft.

Delivery System (Figure 3)

The stent graft (A) is supplied premounted between the inner catheter (B) and the outer sheath (C) on the distal section of the delivery system. The delivery system features an ergonomically shaped handgrip (D) with two syringe adapters (E) and (F) for flushing with sterile normal saline prior to introduction of the delivery system. The soft and atraumatic catheter tip (G) is tapered to fit with a 0.035" guidewire. There is a blue safety seal (H) attached to the pistol handgrip to prevent premature stent graft release. This safety seal should not be removed until the stent graft has been positioned across the lesion and is ready to be deployed. A stainless steel stylet is inserted in the delivery system to protect the device from kinking during transport. This stylet must be removed after removal of the device from packaging by unthreading the hub (I) located on the back end of the pistol handle. Pulling on the trigger (J) on the pistol handle causes the outer catheter sheath to retract in incremental steps and release the stent graft.

Figure 3



32

The ***FLAIR***™ Endovascular Stent Graft delivery system has a 70cm working length and is compatible with 9F introducer sheaths.

X-Ray Markers

Before deployment, each end of the stent graft is marked by a radiopaque band. The distal end (venous side) of the stent graft (K) is marked by the radiopaque marker on the OUTER catheter/sheath of the deployment system. The proximal end (graft side) of the stent graft is marked by a radiopaque stainless steel cap on the INNER catheter of the coaxial deployment system (L). During stent graft deployment, the proximal marker must remain stationary and should be used as a fixed reference point. The distal marker will move back towards the proximal marker during stent graft deployment.

STENT GRAFT SIZE SELECTION

Special care must be taken to ensure that the appropriate size ***FLAIR***™ Endovascular Stent Graft is selected.

- The stent graft body diameter should be approximately 1mm larger than the synthetic AV Access graft diameter.
- The diameter of the angioplasty balloon for post dilation should be equal to the stent graft body diameter.
- Select a stent graft length that ensures that the entire lesion is well covered with the device and that the stent graft extension into the healthy vein is minimal. Approximately 10mm of the stent graft should extend into the AV Access graft. Approximately 10mm of the stent graft should extend beyond the stenosis into the vein

HOW SUPPLIED

The ***FLAIR***™ Endovascular Stent Graft is supplied sterile (by ethylene oxide gas) unless the package has been opened or damaged. For single patient use only. Do not reuse. Do not resterilize. Store in a cool (room temperature), dry place. Protect the packaged product from direct sunlight.

INDICATIONS FOR USE

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

- This product has been designed for single patient use only. Do not reuse. Do not resterilize.
- Do not expose the stent graft to temperatures higher than 500 °F (260 °C). ePTFE decomposes at elevated temperatures, producing highly toxic decomposition products.
- The sterile packaging and devices should be inspected prior to use. Verify that the packaging and the device are undamaged and that the sterile barrier is intact. If damaged, do not use.
- Do not use in patients with uncorrectable coagulation disorders.
- Do not use in patients with septicemia.
- Do not use in patients with known allergy or sensitivity to contrast media, which cannot be adequately pre-medicated.
- Do not use in patients with known hypersensitivity to nickel-titanium.
- Do not use in patients whose AV Access graft is infected.
- Do not use in patients whose AV Access grafts have been implanted less than 30 days.
- Do not use the device in patients in which full expansion of an appropriately sized angioplasty balloon could not be achieved during primary balloon angioplasty.
- The delivery catheter is not intended for any use except stent graft deployment.
- The stent graft cannot be repositioned after total or partial deployment.
- Once partially or fully deployed, the ***FLAIR***™ Endovascular Stent Graft cannot be retracted or remounted onto the delivery system. Device removal after deployment can only be done with a surgical approach.
- An appropriate guidewire is required for the introduction of the stent graft delivery system into the body. The guidewire must remain in place during the introduction, manipulation and eventual removal of the deployment system.

- If the trigger ring on the pistol handle jams during stent graft deployment and further stent graft release is not possible, it is recommended to break apart the grip shells of the pistol handle and unsheath the remainder of the device by pulling back the Y adapter (pull-back mode).
- After use, the ***FLAIR***™ Endovascular Stent Graft deployment system is a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

PRECAUTIONS

- This device should be used only by physicians who are familiar with the complications, side effects, and hazards commonly associated with dialysis shunt revisions and endovascular procedures.
- Faulty placement techniques may lead to failure in stent graft deployment.
- Do not kink the delivery system.
- The delivery system can function only after the blue safety tab is removed. This should not be done until the stent graft is positioned across the lesion and is ready to be deployed.
- Careful attention of the operator is warranted to mitigate the potential for distal migration of the endoprosthesis during deployment. After deployment of approximately 15mm of the stent graft, wait approximately 30 seconds to allow the distal end of the stent graft to fully expand.
- After full stent graft deployment, wait a minimum of 1 minute to allow for complete device expansion before removing the delivery system over the guidewire.
- Post dilation of the stent graft must be performed with a PTA balloon catheter indicated for post dilation of stents. The ***FLAIR***™ Endovascular Stent Graft cannot be balloon expanded beyond its stated diameter.
- The effects of direct cannulation of the ***FLAIR***™ Endovascular Stent Graft have not been evaluated in a clinical study. Notify the patient that the stent graft should not be directly cannulated and that applying pressure to the implant area should be avoided.
- In case the placement of two stent grafts (overlap), use the same device diameter in both cases. If a flared device is used to overlap, do not deploy the flared end inside the first stent graft. Ensure a minimum 10mm overlap of the devices.
- The safety and effectiveness of the device if placed across an angle that is greater than 90° have not been established.
- The safety and effectiveness of the device in patients in which it is required to be deployed across the antecubital fossa have not been established.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

Complications and Adverse Events associated with the use of the ***FLAIR***™ Endovascular Stent Graft may include the usual complications associated with endovascular stent and stent graft placement and dialysis shunt revisions. Previously reported complications include: thrombotic occlusion, restenosis requiring reintervention, pseudoaneurysm, vessel rupture, perforation, pain, infection, hemorrhage, hematoma, arm or hand edema, steal syndrome, congestive heart failure, cerebrovascular accident and death. Stent Graft specific events that could be associated with clinical complications include stent graft misplacement, stent graft migration, stent graft fracture, stent graft kinking, insufficient stent graft expansion and stent graft embolism.

A list of all Adverse Events observed during the ***FLAIR***™ Endovascular Stent Graft clinical trial can be found in the chapter "Summary of Safety" (Table 6) of the Clinical Study section of this document.

MRI SAFETY

Non-clinical testing has demonstrated that the ***FLAIR***™ Endovascular Stent Graft is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 3-Tesla or less;
2. Spatial gradient field of 720 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

In non-clinical testing, the ***FLAIR***™ Endovascular Stent Graft produced a temperature rise of less than or equal to 0.5°C at a maximum whole body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3-Tesla, Excite, General Electric Healthcare MR scanner.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ***FLAIR***™ Endovascular Stent Graft. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

SUMMARY OF CLINICAL STUDIES

A total of 227 patients were treated at 16 U.S. investigational sites to evaluate the safety and effectiveness of the ***FLAIR***™ Endovascular Stent Graft. This study compared the ***FLAIR***™ Endovascular Stent Graft to balloon angioplasty in patients with stenoses at the venous anastomosis of a synthetic AV access graft. Physicians unfamiliar with the system enrolled "roll-in" patients before starting the randomized phase of the trial. A total of 37 "roll-in" patients and 190 randomized patients, 97 in the treatment arm and 93 in the control arm, were enrolled in the clinical study.

Study Endpoints

Treatment Area Primary Patency (TAPP) at six months was the primary outcome used to compare the effectiveness of the study device to the PTA Control. The primary safety endpoint was evaluated based on the incidence of adverse events observed within the same time interval.

Secondary endpoints included: 1) the ability to successfully deliver the ***FLAIR***™ Endovascular Stent Graft, 2) procedural success 3) 2-month treatment area primary patency, 3) 2- and 6-month access circuit primary patency, 4) 2- and 6-month assisted access circuit primary patency, 5) 2- and 6-month access circuit cumulative (i.e., secondary) patency, and 6) 2- and 6-month percent stenosis of the treatment area.

Patients Studied

Eligible patients had a hemodynamically significant stenosis (≥ 50% reduction of normal vessel diameter) accompanied by a hemodynamic, functional or clinical abnormality (defined by K/DOQI, SIR guidelines), without thrombotic occlusion, at the synthetic AV access graft-vein-anastomosis. To be included in the study, total stenosis length could not exceed 70mm, and the entire lesion had to be located within 70mm of the venous anastomosis. The AV access graft must have also been implanted at least 30 days and undergone at least one hemodialysis.

Patients were excluded from the study if they had had a thrombosis of the AV access graft within 7 days before the index procedure. Patients were also excluded for a variety of conditions which would make the implantation procedure more difficult or dangerous or would confound the interpretation of the results of the study.

Methods

Patients were prospectively randomized to treatment with the ***FLAIR***™ Endovascular Stent Graft or PTA. Cross-overs were not allowed. Clinical follow-up visits were conducted two months and six months after the index procedure. Interim visits were conducted as clinically indicated. Quantitative angiography was conducted in conjunction with the scheduled follow-up visits. Antiplatelet and anticoagulation therapy was at the discretion of the physician. Patients were monitored for adverse events throughout their participation in the trial.
An independent Clinical Events Committee (CEC) adjudicated all occurrences of death, acute graft occlusion during the index procedure, cerebrovascular accident, congestive heart failure, graft dysfunction or failure, hematoma, graft or wound infection, other infection, wound complications, peripheral thromboembolism, pseudoaneurysm, pulmonary embolism, restenosis (angiographic), significant hand or arm edema, steal syndrome, subacute graft occlusion (out of lab but <24 hours post-procedure) and thrombotic occlusion (>24 hours post-procedure). In addition, the CEC reviewed all adverse events related to study device failure or malfunction. The CEC was also to review all unanticipated adverse events; however, no such events were observed during the study.

Results

Patient Demographics and Baseline Characteristics

The randomization process resulted in 97 patients treated with the study device and 93 patients treated with balloon angioplasty as a control. Tables 1 - 4 summarize the patient demographics, medical history, AV access graft characteristics and AV access graft type for the two study groups. The 37 "roll-in" FLAIR patients are also noted in each table of this results section (Section D); however, the statistical comparisons and p-values are from the randomized population only.

Table 1. Patient Demographics

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Male	37.84% (14/37)	34.02% (33/97)	38.71% (36/93)	0.548
Age of patients (yrs)				
Mean±SD (N)	62.16±11.84 (37)	61.83±14.63 (97)	59.83±13.58 (93)	0.331
Range (min,max)	(37.60, 84.67)	(30.85, 87.37)	(24.13, 90.53)	--

Note: p-values are unadjusted for multiple comparisons

Table 2. Medical History

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Hypertension	91.89% (34/37)	98.7% (96/97)	93.55% (87/93)	0.061
Coronary Artery Disease	30.56% (11/36)	36.67% (33/90)	38.64% (34/88)	0.877
Congestive Heart Failure	25.00% (9/36)	28.09% (25/89)	22.09% (19/86)	0.388
Diabetes	51.35% (19/37)	60.82% (59/97)	62.37% (58/93)	0.882
COPD	2.70% (1/37)	7.69% (7/91)	5.75% (5/87)	0.767
Hypercoagulability	0.00% (0/37)	1.10% (1/91)	0.00% (0/83)	1.000
Glomerulonephritis	5.88% (2/34)	5.56% (5/90)	3.57% (3/84)	0.721

Note: p-values are unadjusted for multiple comparisons

Table 3. AV Access Graft Location

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Age of AV Graft (yrs)				
Mean±SD (N)	2.15±1.83 (36)	2.19±1.89 (87)	2.65±2.14 (88)	0.134
Range (min,max)	(0.00, 7.26)	(0.00, 10.55)	(0.11, 11.98)	
Location				
Right	16.22% (6/37)	23.71% (23/97)	23.66% (22/93)	0.993
Left	83.78% (31/37)	76.29% (74/97)	76.34% (71/93)	
Forearm	24.32% (9/37)	20.62% (20/97)	26.09% (24/92)	0.637*
Upper arm	67.57% (25/37)	75.26% (73/97)	72.83% (67/92)	
Across elbow joint (forearm with jump graft)	13.51% (5/37)	2.06% (2/97)	1.09% (1/92)	
Forearm + Elbow	--	2.06% (2/97)	0.00% (0/92)	
Configuration				0.624
Loop	51.35% (19/37)	43.30% (42/97)	39.78% (37/93)	
Straight	48.65% (18/37)	56.70% (55/97)	60.22% (56/93)	
Arterial Anastomosis				0.280
Axillary	5.41% (2/37)	2.06% (2/97)	2.15% (2/93)	
Brachial	89.19% (33/37)	94.85% (92/97)	93.55% (87/93)	
Radial	5.41% (2/37)	1.03% (1/97)	4.30% (4/93)	
Ulnar	0.00% (0/37)	0.00% (0/97)	0.00% (0/93)	
Other	0.00% (0/37)	2.06% (2/97)	0.00% (0/93)	
Venous Anastomosis				0.009
Axillary	29.73% (11/37)	22.68% (22/97)	32.26% (30/93)	
Basilic	51.35% (19/37)	57.73% (56/97)	54.84% (51/93)	
Brachial	10.81% (4/37)	14.43% (14/97)	3.23% (3/93)	
Cephalic	5.41% (2/37)	3.09% (3/97)	9.68% (9/93)	
Other	2.70% (1/37)	2.06% (2/97)	0.00% (0/93)	
Prior Procedure				
AV Access Graft	48.57% (17/35)	58.51% (55/94)	55.56% (50/90)	0.766
Venous Anastomosis	62.86% (22/35)	68.09% (64/94)	67.42% (60/89)	1.000
Venous Outflow Tract	61.76% (21/34)	44.44% (40/90)	33.72% (29/86)	0.166

* The p-value does not include category "Forearm + Elbow" which consists of two patients who have checked both forearm and elbow.

Note: p-values are unadjusted for multiple comparisons

Table 4. AV Access Graft Type

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Graft Type				0.341
Tapered	15.63% (5/32)	17.50% (14/80)	12.99% (10/77)	0.509
Straight	78.13% (25/32)	66.25% (53/80)	79.22% (61/77)	0.076
Stepped	6.25% (2/32)	10.00% (8/80)	6.49% (5/77)	0.565
Other	0.00% (0/32)	6.25% (5/80)	1.30% (1/77)	0.210
Graft Size (mm)				0.373
5	0.00% (0/32)	0.00% (0/81)	0.00% (0/80)	--
6	65.63% (21/32)	66.67% (54/81)	68.75% (55/80)	0.866
7	9.38% (3/32)	6.17% (5/81)	8.75% (7/80)	0.565
8	0.00% (0/32)	0.00% (0/81)	2.50% (2/80)	0.245
4/7	15.63% (5/32)	20.99% (17/81)	20.00% (16/80)	1.000
5/8	0.00% (0/32)	1.23% (1/81)	0.00% (0/80)	1.000
3/6	0.00% (0/32)	0.00% (0/81)	0.00% (0/80)	--
4.5/6.5	0.00% (0/32)	1.23% (1/81)	0.00% (0/80)	1.000
Other	9.38% (3/32)	3.70% (3/81)	0.00% (0/80)	0.245

Note: p-values are unadjusted for multiple comparisons

Pre-Procedural (Baseline) Angiographic Characteristics

Table 5 summarizes the angiographic characteristics of the test and control groups.

Table 5. Baseline Angiographic Characteristics

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Lesion side				
Right	16.22% (6/37)	23.71% (23/97)	23.66% (22/93)	1.000
Left	83.78% (31/37)	76.29% (74/97)	76.34% (71/93)	1.000
Lesion Length (mm)				
Mean±SD (N)	32.17±11.35 (30)	35.28±13.94 (95)	37.78±12.70 (90)	0.206
Range (min,max)	(13.89, 60.12)	(9.86, 71.49)	(9.61, 66.92)	
Eccentric	0.00% (0/30)	1.04% (1/96)	0.00% (0/90)	1.000
Bend >90 degrees	0.00% (0/30)	0.00% (0/96)	0.00% (0/90)	--
Thrombus	0.00% (0/30)	2.08% (2/96)	0.00% (0/90)	0.498
Tortuosity	0.00% (0/30)	0.00% (0/96)	0.00% (0/90)	--
Calcification	0.00% (0/24)	0.00% (0/73)	0.00% (0/71)	--
Ulcerated	0.00% (0/30)	3.13% (3/96)	4.44% (4/90)	0.714
Aneurysm	3.33% (1/30)	4.17% (4/96)	7.78% (7/90)	0.360
Intimal Flap	0.00% (0/30)	0.00% (0/96)	0.00% (0/90)	--
Ectasia	0.00% (0/30)	5.21% (5/96)	3.33% (3/90)	0.722
Interpolated Reference Vessel Diameter (mm)				
Mean±SD (N)	8.38±2.25 (30)	8.28±1.54 (96)	8.71±1.72 (90)	0.069
Range (min,max)	(4.99, 13.44)	(5.35, 14.30)	(5.87, 13.53)	
MLD (mm)				
Mean±SD (N)	2.56±1.27 (30)	2.37±0.88 (96)	2.32±0.80 (90)	0.655
Range (min,max)	(0.75, 6.23)	(0.54, 4.92)	(0.00, 4.81)	
% Interpolated stenosis				
Mean±SD (N)	70.09%±9.94% (30)	70.93%±10.46% (96)	72.92%±8.95% (90)	0.167
Range (min,max)	(51.28%, 88.89%)	(49.88%, 91.84%)	(42.64%, 100.00%)	

Note: p-values are unadjusted for multiple comparisons

Table 5 is based on angiographic core laboratory analysis except for lesion location information which is site reported, specifically, not from the core laboratory.

Patient Accountability

A total of 13 of the 190 randomized patients missed their 6-month follow-up examination, 6 in the test group and 7 in the control group. Compliance in the test group was 93.8% (91/97), and compliance in the control group was 92.5% (86/93).

SUMMARY OF SAFETY

A total of 227 patients were treated at 16 U.S. investigational sites to evaluate the safety and effectiveness of the ***FLAIR***™ Endovascular Stent Graft. This study compared the ***FLAIR***™ Endovascular Stent Graft to balloon angioplasty in patients with stenoses at the venous anastomosis of a synthetic AV access graft. Physicians unfamiliar with the system enrolled "roll-in" patients before starting the randomized phase of the trial. A total of 37 "roll-in" patients and 190 randomized patients were enrolled in the clinical study. Adverse Event rates (through 210 days) for randomized and "roll-in" patients are presented in table 6. The statistical comparisons and p-values presented in Table 6 are from the randomized population only.

Table 6. Adverse Events through 6 Months

Adverse Events	ROLL-IN PATIENTS FLAIR Device (N=37)	RANDOMIZED PATIENTS FLAIR Device (N=97)	RANDOMIZED PATIENTS PTA Only (N=93)	P-value
Death	2.78% (1/36)	5.26% (5/95)	5.56% (5/90)	1.000
Infection	0.00% (0/36)	6.32% (6/95)	2.22% (2/90)	0.280
Stenosis	41.67% (15/36)	40.00% (38/95)	76.67% (69/90)	<0.001
Thrombotic occlusion	33.33% (12/36)	32.63% (31/95)	21.11% (19/90)	0.098
Vessel rupture	0.00% (0/36)	3.16% (3/95)	1.11% (1/90)	0.621
Pseudoaneurysm	2.78% (1/36)	5.26% (5/95)	2.22% (2/90)	0.445
Hemorrhage	0.00% (0/36)	0.00% (0/95)	0.00% (0/90)	--
Hematoma	0.00% (0/36)	2.11% (2/95)	0.00% (0/90)	0.498
Significant arm or hand edema	2.78% (1/36)	3.16% (3/95)	2.22% (2/90)	1.000
Steal syndrome	2.78% (1/36)	2.11% (2/95)	1.11% (1/90)	1.000
Congestive heart failure	2.78% (1/36)	4.21% (4/95)	2.22% (2/90)	0.683
Cerebrovascular accident	0.00% (0/36)	2.11% (2/95)	3.33% (3/90)	0.676
Device kinking	0.00% (0/36)	0.00% (0/95)	N/A	--
Device migration	0.00% (0/36)	4.21% (4/95)	N/A	--
Embolism	0.00% (0/36)	0.00% (0/95)	N/A	--
Permanent deformation of the Endoluminal Device	2.78% (1/36)	1.05% (1/95)	N/A	--

Note: p-values are unadjusted for multiple comparisons

SUMMARY OF EFFECTIVENESS

A total of 125 stent grafts were implanted in the randomized test group (49 stent grafts in the "roll-in" test group) as summarized in table 7.

Table 7. Device and Procedure Characteristics

	ROLL-IN PATIENTS FLAIR Device (N=37)	RANDOMIZED PATIENTS FLAIR Device (N=97)
Total Devices Used	49	125
Delivery success by Device	89.80% (44/49)	94.40% (118/125)
Patients with device implanted	37	97
0	0.00% (0/37)	0.00% (0/97)
1	72.97% (27/37)	75.26% (73/97)
2	21.62% (8/37)	21.65% (21/97)
3	5.41% (2/37)	2.06% (2/97)
4	0.00% (0/37)	1.03% (1/97)
Total Length Delivered (mm)		
Mean±SD (N)	52.70±21.56 (37)	52.58±26.07 (97)
Range (min,max)	(30.00, 120.00)	(30.00, 200.00)
Delivery success by Patient	100.00% (37/37)	98.97% (96/97)
Length of Procedure (hours)		
Mean±SD (N)	1.13±0.53 (37)	1.08±0.56 (95)
Median	1.17	0.98
Range (min,max)	(0.25, 2.42)	(0.25, 3.42)
Fluoroscopy time (min)		
Mean±SD (N)	8.38±3.81 (18)	11.01±12.46 (90)
Median	7.56	8.60
Range (min,max)	(4.03, 18.00)	(2.47, 88.30)

Primary Effectiveness Results (randomized patients)

Treatment Area Primary Patency (TAPP) at six months was the primary outcome used to compare the effectiveness of the study device to the PTA Control.

Per protocol, the TAPP was defined as patency (open to blood flow) after the study index procedure until reintervention in the treatment area (within 5 mm proximal or 5 mm distal to the study device or index balloon angioplasty treated area), or thrombotic occlusion that involved the treatment area. Percutaneous or surgical treatment in areas outside the treatment area did not affect TAPP. Treatment Area Primary Patency ended when: 1) there was a reintervention in the treatment area, 2) a thrombotic occlusion involved the treatment area, 3) a surgical intervention excluded the treatment area from the access circuit, or 4) the AV graft was abandoned due to an inability to treat the primary lesion.

The Treatment Area Primary Patency at six months in the study device group was significantly higher than that observed in the PTA Control group as noted in the table 8. This demonstrated superiority of the study device over the PTA Control with respect to treatment area primary patency.

Table 8. Treatment Area Primary Patency

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Treatment Area Primary Patency				
2-month	89.2% (33/37)	80.21% (77/96)	77.17% (71/92)	0.722
6-month	60.0% (21/35)	50.55% (46/91)	23.28% (20/86)	<0.001

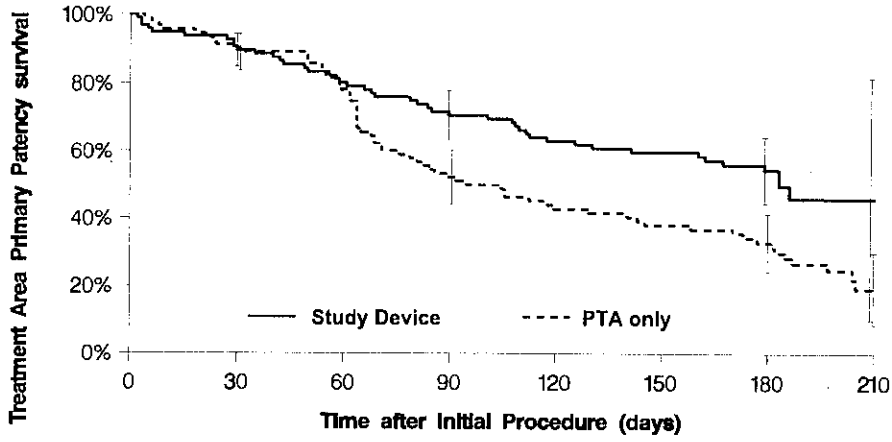
The reasons for TAPP failures are noted in table 9.

Table 9. Treatment Area Primary Patency Failure Reasons

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Two Month Treatment Area PP Failure	10.8% (4/37)	19.79% (19/96)	22.83% (21/92)	0.722
Reintervention in the treatment area	10.8% (4/37)	12.50% (12/96)	20.65% (19/92)	0.169
Thrombotic occlusion that involves treatment area	8.1% (3/37)	13.54% (13/96)	9.78% (9/92)	0.499
Surgical intervention that excludes the treatment area from the access circuit	0.0% (0/37)	5.21% (5/96)	3.26% (3/92)	0.721
AV graft abandoned due to inability to treat primary lesion	2.7% (1/37)	0.00% (0/96)	3.26% (3/92)	0.115
Six Month Treatment Area PP Failure	40.0% (14/35)	49.45% (45/91)	76.74% (66/86)	<0.001
Reintervention in the treatment area	34.3% (12/35)	30.77% (28/91)	75.58% (65/86)	<0.001
Thrombotic occlusion that involves treatment area	34.3% (12/35)	34.07% (31/91)	22.09% (19/86)	0.095
Surgical intervention that excludes the treatment area from the access circuit	5.7% (2/35)	18.68% (17/91)	12.79% (11/86)	0.309
AV graft abandoned due to inability to treat primary lesion	5.7% (2/35)	9.89% (9/91)	8.14% (7/86)	0.796

Figure 4 presents the Kaplan-Meier curves for freedom from treatment area loss of primary patency. Freedom from treatment area loss of primary patency was significantly better (p=0.008) in the study device group (45.8% through 210 days) than in the PTA Control (19.3% through 210 days). Empirically, the separation between the curves was observed between 60 and 90 days after the index procedures and persisted throughout the remaining follow-up time.

Figure 4. Freedom from Loss of Treatment Area Primary Patency (Randomized Patients)



Secondary Effectiveness Results:

The results for the secondary study endpoints are listed in Table 10.

Table 10. Secondary Effectiveness Results

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Device delivery success by patient	100.00% (37/37)	98.97% (96/97)	N/A	N/A
*Procedural Success	94.59% (35/37)	93.81% (91/97)	73.12% (68/93)	<0.001
**Access Circuit Primary Patency				
2-month	86.5% (32/37)	79.17% (76/96)	77.17% (71/92)	0.860
6-month	42.9% (15/35)	38.04% (35/92)	19.77% (17/86)	0.008
***Access Circuit Assisted Primary Patency				
2-month	91.9% (34/37)	86.46% (83/96)	89.13% (82/92)	0.659
6-month	65.7% (23/35)	65.56% (59/90)	73.81% (62/84)	0.253
****Access Circuit Cumulative Patency				
2-month	97.3% (36/37)	94.79% (91/96)	95.65% (88/92)	1.000
6-month	91.4% (32/35)	81.32% (74/91)	85.88% (73/85)	0.542
*****Binary Restenosis Rate of the Treatment Area				
2-month	0.00% (0/27)	20.00% (16/80)	70.59% (48/68)	<0.001
6-month	25.00% (7/28)	27.63% (21/76)	77.61% (52/67)	<0.001

Note: p-values are unadjusted for multiple comparisons

***Procedural Success:** Anatomic success (achievement of a post procedure residual stenosis <30% measured at the narrowest point of the lumen, as indicated by angiography) and at least one indicator of hemodynamic or clinical success.

****Access Circuit Primary Patency:** Patency (open to blood flow) following the index study procedure until access thrombosis or an intervention of a lesion anywhere within the access circuit (arterial anastomosis to the superior vena cava-right atrial junction). Access primary patency ends when: 1) there was an intervention for a stenosis anywhere within the access circuit, 2) there was an occlusion anywhere within the access circuit, or 3) there was a surgical intervention that excluded the index stenotic area from the access circuit.

*****Access Circuit Assisted Primary Patency:** Patency (open to blood flow) following the index study procedure until access thrombosis or a surgical intervention that excludes the treated lesion from the access circuit. Percutaneous treatment(s) of either restenosis of the previous treated lesion or a new arterial or venous outflow stenosis/occlusion, excluding access thrombosis, are compatible with assisted primary patency. Assisted primary patency ends when: 1) there is an occlusion anywhere within the access circuit, or 2) there is a surgical intervention that excludes the index stenotic area from the access circuit.

******Access Circuit Cumulative Patency (i.e., secondary patency):** Patency (open to blood flow) following the index study procedure until the access is surgically revised or abandoned because of inability to treat the original lesion. Multiple/repetitive treatments for occlusions that restore patency are compatible with cumulative patency. Cumulative patency ends when: 1) there is a surgical intervention that excludes the index stenotic area from the access circuit, or 2) the AV access venous anastomosis is surgically revised, or 3) the AV graft is abandoned due to an inability to treat the primary lesion.

*******Binary Restenosis Rate of the Treatment Area:** Binary restenosis rates, as demonstrated by procedural, 2 and 6-month follow-up angiograms, were calculated by the core lab. Quantitative vessel analysis was performed to identify the restenosis rate at 2 and 6-months. Lesions within, just proximal to or just distal to the study device or index balloon angioplasty treatment area with a ≥50% diameter stenosis were categorized as restenotic.

Figure 5 presents the Kaplan-Meier curves for freedom from loss of access circuit primary patency. Freedom from loss of access circuit primary patency was 32.0% through 210 days in the study device group and 16.3% through 210 days in the PTA Control (p=0.044).

Figure 5. Freedom from Loss of Access Circuit Primary Patency (Randomized Patients)

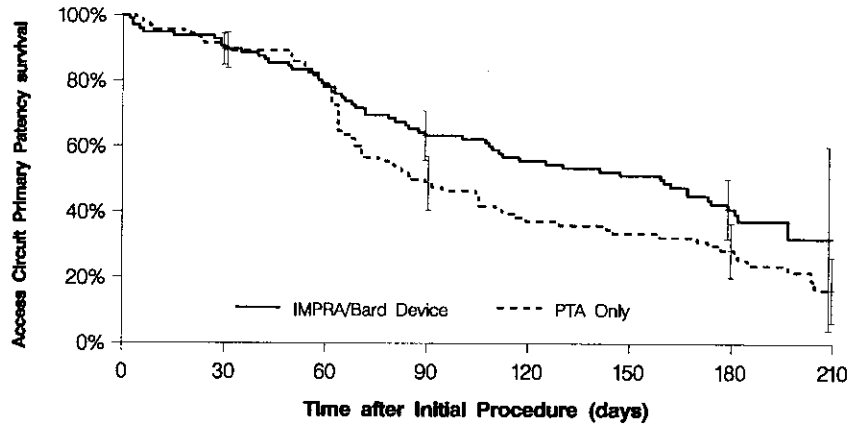


Figure 6 presents the Kaplan-Meier curves for freedom from loss of access circuit assisted primary patency. Freedom from loss of access circuit assisted primary patency was 60.4% through 210 days in the study device group and 72.9% through 210 days in the PTA Control (p=0.149).

Figure 6. Freedom from Loss of Access Circuit Assisted Primary Patency (Randomized Patients)

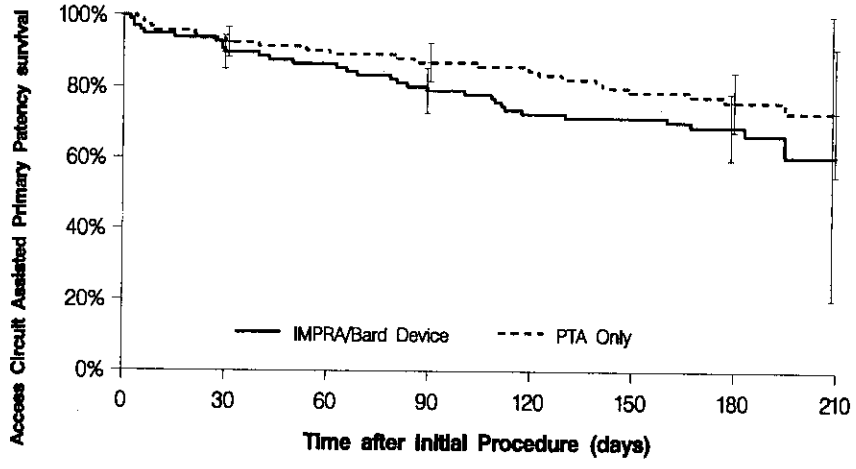
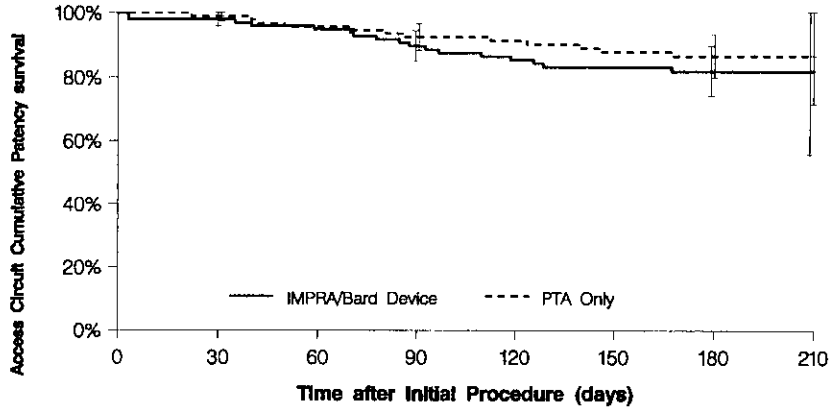


Figure 7 presents the Kaplan-Meier curves for freedom from loss of access circuit cumulative patency. Freedom from loss of access circuit cumulative patency was 81.7% through 210 days in the study device group and 86.3% through 210 days in the PTA Control (p=0.374).

Figure 7. Freedom from Loss of Access Circuit Cumulative Patency (Randomized Patients)



Angiographic Results:

Table 11 summarizes the angiographic characteristics of the test and control groups at six months.

Table 11. Six-Month Angiographic Evaluation

	ROLL-IN PATIENTS	RANDOMIZED PATIENTS		
	FLAIR Device (N=37)	FLAIR Device (N=97)	PTA Only (N=93)	P-value
Lesion Length (mm)				
Mean±SD (N)	17.54±10.22 (11)	18.02±12.54 (41)	32.12±14.32 (50)	<0.001
Range (min,max)	(6.70, 37.70)	(4.52, 52.68)	(6.96, 69.51)	
Eccentric	3.57% (1/28)	0.00% (0/70)	0.00% (0/55)	--
Bend >90 degrees	0.00% (0/28)	0.00% (0/70)	0.00% (0/55)	--
Thrombus	3.57% (1/28)	0.00% (0/70)	0.00% (0/55)	--
Tortuosity	0.00% (0/28)	0.00% (0/70)	0.00% (0/55)	--
Calcification	0.00% (0/20)	0.00% (0/54)	0.00% (0/36)	--
Ulcerated	0.00% (0/28)	0.00% (0/70)	0.00% (0/55)	--
Aneurysm	0.00% (0/28)	4.29% (3/70)	7.27% (4/55)	0.698
Intimal Flap	0.00% (0/28)	0.00% (0/70)	0.00% (0/55)	--
Ectasia	0.00% (0/28)	0.00% (0/70)	1.82% (1/55)	0.440
Interpolated Reference Vessel Diameter (mm)				
Mean±SD (N)	7.35±1.44 (28)	7.59±1.19 (70)	8.36±1.71 (55)	0.004
Range (min,max)	(4.76, 11.10)	(4.35, 10.03)	(5.47, 13.37)	
MLD (mm)				
Mean±SD (N)	4.63±2.00 (28)	5.10±1.49 (70)	3.32±1.46 (55)	<0.001
Range (min,max)	(0.00, 7.89)	(0.00, 8.30)	(0.00, 6.53)	
% Interpolated stenosis				
Mean±SD (N)	0.35±0.27 (28)	32.07%±19.76% (70)	59.22%±19.55% (55)	<0.001
Range (min,max)	(0.08, 1.00)	(2.01%, 100.00%)	(7.13%, 100.00%)	
Binary Restenosis Rate	25.00% (7/28)	27.63% (21/76)	77.61% (52/67)	<0.001
Stent Graft MLD (mm)				
Mean±SD (N)	5.41±1.82 (28)	5.76±1.34 (70)	N/A	N/A
Range (min,max)	(0.00, 7.89)	(0.00, 8.40)		
% Interpolated stent graft stenosis				
Mean±SD (N)	0.24±0.27 (28)	22.94%±18.88% (70)	N/A	N/A
Range (min,max)	(-0.25, 1.00)	(-9.97%, 100.00%)		
Edge MLD (mm)				
Mean±SD (N)	5.67±1.82 (28)	6.38±1.41 (70)	N/A	N/A
Range (min,max)	(0.00, 7.87)	(0.00, 9.97)		
% Interpolated edge stenosis				
Mean±SD (N)	0.20±0.29 (28)	14.35%±20.92%	N/A	N/A
Range (min,max)	(-0.27, 1.00)	(-26.20%, 100.00%)		

Note: p-values are unadjusted for multiple comparisons

Table 11 is based on angiographic core laboratory analysis except for lesion location information which is site reported, specifically, not from the core laboratory.

Patient Death Summary

There were eleven (11) deaths among the randomized patients, including 5 patients in the test group and 6 patients in the control group, and 1 death among the "roll-in" patients. None of these deaths were attributed to the study device.

The five (5) deaths in the study device group and one (1) death in the "roll-in" group occurred between 52 days and 197 days following the index procedure. Causes of death included: stroke (day 163), MI (day 60), cardiac arrest (day 101), respiratory failure (day 197), HIV complications (day 52) and one (1) unknown (day 136).

The six (6) deaths in the PTA Control group occurred between 45 and 222 days following the index procedure. Causes of death included: stroke (day 45, day 59 and day 111), pulmonary edema (day 160), pericardial effusion (day 176), and complications from adenocarcinoma (day 222). Please note that the sixth death in the PTA group (day 222) was not included as an adverse event because it did not fall within the 6-month reporting period as pre-defined in the protocol (i.e., 180 ± 30 days).

Observed Device Malfunctions

There were eleven (11) observations regarding performance of the study device reported in 8 patients. Five (5) devices were reported to be placed improperly, such that the stent-graft did not deploy where intended, requiring implantation of an additional stent graft in four cases. In addition, four (4) device migrations, three (3) of which occurred during the index procedure, and one (1) instance each of permanent device deformation and delivery system malfunction were reported.

CONCLUSIONS DRAWN FROM THE STUDY

Results of the randomized, prospective, multi-center clinical trial demonstrated that the ***FLAIR***™ Endovascular Stent Graft was superior to the PTA Control with respect to six-month Treatment Area Primary Patency (TAPP), the primary effectiveness endpoint, and no different than the PTA Control with respect to safety.

Data from the clinical trial provide a reasonable assurance that the ***FLAIR***™ Endovascular Stent Graft is safe and effective for the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arteriovenous (AV) access grafts when used in accordance with its labeling.

NOTE:

- Read all instructions for use thoroughly.
- The use of a stiff guide wire is recommended for stent graft placement.
- Prophylactic antibiotic therapy should be prescribed at the physician's discretion.

CLINICAL USE INFORMATION

PRECAUTION: This device should be used only by physicians who are familiar with the complications, side effects, and hazards commonly associated with dialysis shunt revisions and endovascular procedures and who have successfully completed the appropriate physician training program.

Patient and Device Selection

- **WARNINGS: Do not use in patients**
  - **With uncorrectable coagulation disorders**
  - **With septicemia**
  - **With known allergy or sensitivity to contrast media which cannot be adequately pre-medicated**
  - **Whose AV Access graft is infected**
  - **Whose AV Access grafts have been implanted less than 30 days**
- **WARNING: Do not use the device in patients in which full expansion of an appropriately sized angioplasty balloon could not be achieved during primary balloon angioplasty.**
- **PRECAUTION: The safety and effectiveness of the device if placed across an angle that is greater than 90° have not been established.**
- **PRECAUTION: The safety and effectiveness of the device in patients in which it is required to be deployed across the antcubital fossa have not been established.**
- **PRECAUTION: In case the placement of two stent grafts (overlap) use the same device diameter in both cases. If a flared device is used to overlap, do not deploy the flared end inside the first stent graft. Ensure a minimum 10mm overlap of the devices.**
- Physicians should have knowledge of radiographic image interpretation, device selection and sizing (**see page 2, Stent Graft Size Selection**)

Materials Required for Device Placement

- 0.035" (0.89mm) guidewire
- 9F introducer sheath
- Sterile syringes
- Contrast agent
- Saline solution
- Appropriate diagnostic catheters and accessories
- Appropriate angioplasty balloon (equal diameter to the stent graft body diameter)

DIRECTIONS FOR USE

Preparation

1. Access the graft at a convenient site. The use of an introducer sheath is recommended for the implant procedure.
2. Insert a 0.035 inch guidewire into the graft access site. Dilate the stenosis with a balloon catheter that has a rated diameter appropriate for the lesion to be treated.
3. Select the ***FLAIR***™ Endovascular Stent Graft length required to traverse the stenosis. This will involve selection of an appropriate device diameter and length. Allow approximately 10mm of the stent graft to be situated beyond the stenosis into the non-diseased AV graft, and approximately 10mm of the stent graft to extend beyond the stenosis into the non-diseased vein.
4. Carefully remove the delivery system from its packaging and inspect for any damage or defects. Do not use if a compromise to the sterile barrier is suspected.

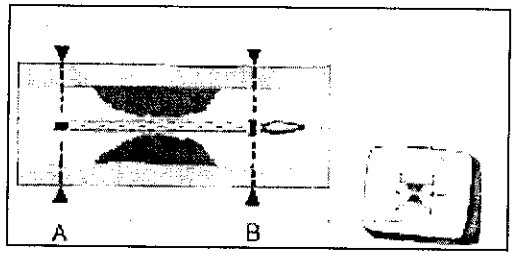
Note: Do not remove the blue safety tab until you are ready to deploy the stent graft.

5. Remove the stylet from the proximal injection port on the pistol handle and discard.
6. Using a 10 cc syringe, flush the delivery system with sterile saline through the proximal port until saline appears at the distal tip of the delivery system.
7. Remove and retain the protective cap from the injection port on top of the pistol handle and prime with saline until saline leaks from the tip of the catheter and all air is removed. Remove the syringe and replace the cap.

Introduction of the Delivery System

8. Under radiographic guidance, advance the stent graft over the guidewire across the lesion. Use the radiopaque markers to center the stent graft across the lesion. Confirm the exact position of the radiopaque marker bands. It is recommended that the position of the stent graft ends (A) and (B) be marked on the monitor or that radiopaque skin markers be placed as reference points for stent graft ends (Figure 8).

Figure 8



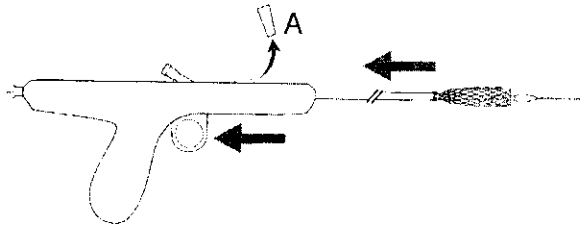
A = proximal marker (radiopaque stainless steel spring coil)
B = distal radiopaque marker band

Note: It is recommended to advance the delivery system past the lesion and then pull back slightly on the entire system prior to deployment to attain correct positioning of the radiopaque markers and to ensure the delivery catheter is straight.

Stent Graft Deployment

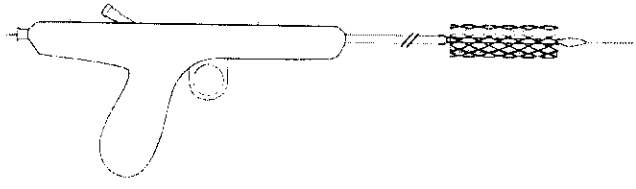
9. Remove the blue safety tab (A) from the handle. Operate the system by pulling the trigger on the handle with a finger. This directly retracts the outer sheath and exposes a corresponding portion of the stent graft. While maintaining the handle in a fixed position and under slight back tension, pump the trigger on the handle slowly until approximately 15mm of the stent graft have been exposed by the sheath. Wait approximately 30 seconds to allow the distal end of the stent graft to expand (Figure 9).

Figure 9



10. Continue to pump the trigger until full deployment is achieved (Figure 10).

Figure 10



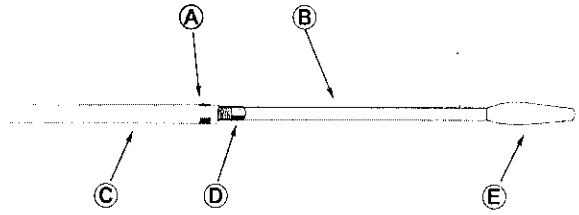
Note: Ensure that only the distal marker band on the outer sheath moves during stent graft deployment, and the proximal marker band remains stationary.

11. Full release of the stent graft is achieved when the moving radiopaque marker band is visually observed to move past the stationary marker proximal to the stent graft.

12. After full deployment, wait a minimum of 1 minute to allow for complete device expansion and remove the delivery system over the guidewire. Visually confirm that the complete system has been removed (Figure 11).

Figure 11

(A) Distal Marker Band
(B) Inner Catheter
(C) Outer Catheter
(D) Proximal Marker (stainless steel spring coil)
(E) Distal Tip



13. Dilate the stent graft with a balloon catheter of an inflated diameter equal to the size of the stent graft body diameter.
14. Using standard procedures, verify location and patency of the stent graft.

Post Procedure Precaution

The effects of direct cannulation of the ***FLAIR***™ Endovascular Stent Graft have not been determined in a clinical study. Notify the patient that the stent graft should not be directly cannulated and that applying pressure to the implant area should be avoided.

Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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Variously protected by one or more of the following U.S. Patent Numbers: 5,827,327, 6,124,523, 6,383,214, 6,436,135, 5,707,386, 5,860,999, 6,053,941, 5,716,393, 6,770,087. Other patents pending.


Contents


Contents Sterile and Non-Pyrogenic Unless Package is Damaged or Opened

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Be sure to read your guidebook. If you have any questions or do not understand something, please ask your doctor or nurse for an explanation.

Be sure to take this "Guidebook of Care" with you at all times. It provides your doctors, nurses, and caregivers with critical information about your ***FLAIR™ Endovascular Stent Graft.***

Table of Contents

What Is Kidney Disease?

In patients like yourself, the kidneys no longer work well and do not efficiently clean your blood. Like you, an estimated 452,000 patients were diagnosed in 2003 with long-term, progressive kidney disease called chronic kidney disease. The two most common causes for this disease are diabetes* and high blood pressure*. Chronic kidney disease is rarely curable. Successful treatments, however, such as filtering your blood to clean waste products (peritoneal dialysis* or hemodialysis*) or replacing your diseased kidney with a functioning kidney from another person (kidney transplantation*), can help you carry on with daily life.

What Is Hemodialysis?

Today, the most common treatment for patients like you with chronic kidney disease is hemodialysis. Hemodialysis is a process where your blood is passed through a hemodialysis machine outside your body, called a dialyzer*. The dialyzer contains special filters and liquids that remove waste products from your blood. Your blood, once "cleaned", is then returned to your body. Most patients undergo hemodialysis three times per week, and each session lasts 3-4 hours.

To safely and quickly draw your blood and pass it through the dialyzer, your doctor placed a tube made of a special plastic (called an arteriovenous* or A-V access graft*) under the skin in your arm. The tube or A-V access graft joins together two different types of blood vessels called an artery* and a vein*. A-V access grafts are most commonly made of ePTFE* (expanded Polytetrafluoroethylene*), a strong yet flexible plastic material that feels similar to a natural blood vessel. The area where the A-V access graft is connected to your blood vessel is called the A-V anastomosis*. An example of an A-V access graft is shown in *Figure 1*.

Please see glossary for definition

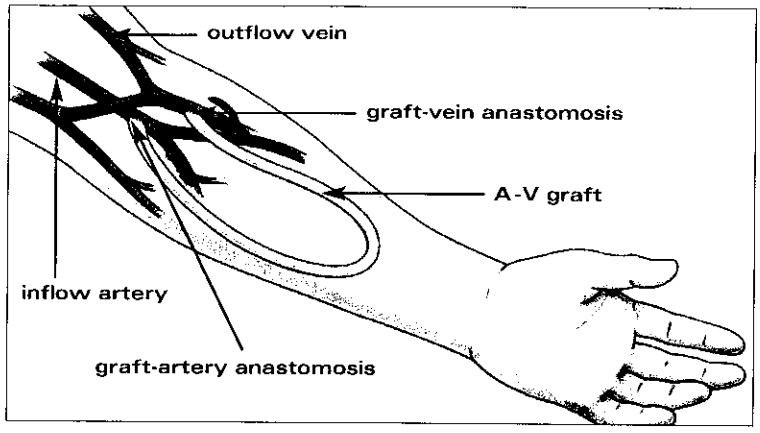

Figure 1: **Forearm loop ePTFE A-V Access Graft**

Your A-V access graft becomes an artificial blood vessel that can be used over and over again to draw blood with a needle during hemodialysis. During your hemodialysis session, two hollow needles are inserted into your A-V access graft. One needle is used to draw blood out of your body and bring it to the dialyzer while the second one returns the clean blood to your body.

How Do I Know My A-V Access Graft Is Working?

Your A-V access graft is your lifeline*.

CAUTION: Each day you should check your A-V access graft to make sure it is working properly. Make sure you feel a pulse* or the vibration of blood (called thrill*) along the entire length of your A-V access graft. Your A-V access graft may not be working properly if you notice any of the following signs:

- The feeling of increased pressure in your A-V access graft during dialysis treatment;
- Continued bleeding at the needle sites after dialysis;
- No feeling of blood vibrating through your access graft (i.e., no thrill); or
- Arm swelling.

Please see glossary for definition

Blockage of Your A-V Access Graft

Tissue* and cells* can build up at the connection point between your A-V access graft and natural blood vessel (i.e., vein). This causes a narrowing or blockage called a stenosis* that limits blood flow *(See Figure 2)*.

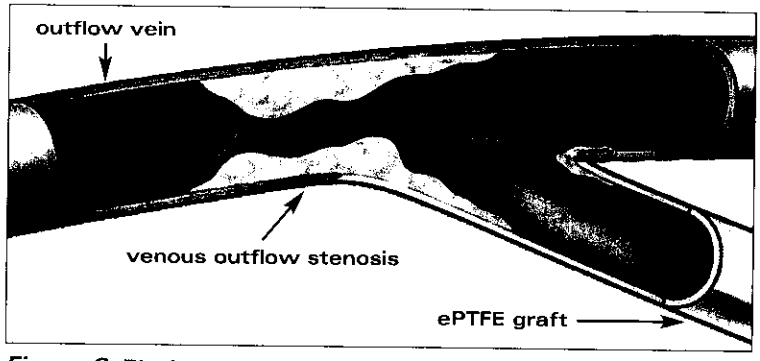

Figure 2: **Blockage or stenosis at the connection point between an A-V access graft and blood vessel**

A blockage in your A-V access graft can cause the graft to not work properly and prevent you from undergoing hemodialysis *(See Figure 3)*.

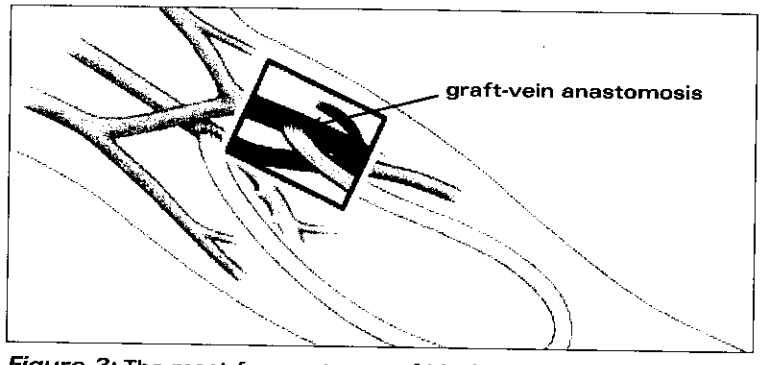

Figure 3: **The most frequent area of blockage**

CAUTION: Signs of a blockage or stenosis include:

- Loss of pulse along the length of your A-V access graft;
- Continued bleeding at the needle sites after your dialysis has ended;

Please see glossary for definition

- No feeling of blood vibrating through your access graft (i.e., no thrill); or
- Arm swelling.

CAUTION: **Your graft will last longer if complete blockage (i.e., thrombosis*) can be avoided. Therefore, inform your doctor immediately if you notice any of the above warning signs so that he/she can reopen your A-V access graft as soon as possible (Note: additional treatment may be necessary to avoid complete blockage and reopen your A-V access graft).**

Treatment Options

Three options can be used by your doctor to reopen a blocked A-V access graft:

1 ***Balloon Inflation (Balloon Angioplasty*):*** First, a small, hollow tube (access sheath*) is inserted into your A-V access graft. Second, dye is injected through the tube by your doctor so that he/she can see the area of blockage. A second, smaller, spaghetti-sized hollow tube (catheter*) with a small balloon on one end is then placed through the slightly larger tube that is already in your A-V access graft. Next, the balloon is moved to the area of blockage by your doctor using an x-ray camera (fluoroscopy*) for guidance. Finally, the balloon is positioned in the narrowed part of your A-V access graft and inflated to open the blockage.

In some cases, balloon inflation opens the narrowed area sufficiently; but in other cases, balloon inflation may not open the area enough to achieve lasting results. Narrowing may return several weeks after balloon inflation, again resulting in a blocked A-V access graft. Also, the narrowed area may open temporarily with inflation of the balloon, but immediately narrow again once the balloon is deflated. In both cases, the above mentioned signs of blockage may return.

Please see glossary for definition

2 ***Surgery (Operation):*** A doctor (i.e., surgeon*) can perform an operation to remove the blockage surrounding the connection between your blood vessel and A-V access graft. The blocked area is either replaced or passed around using a new piece of A-V access graft material or a portion of your natural blood vessel (i.e., vein).

3 ***Placement of the*** **FLAIR™ Endovascular Stent Graft:** This is a new method of treating blockages in your A-V access graft. This treatment combines the use of balloon inflation (see Option 1) followed by placement of a metal support tube covered with material similar to your A-V access graft to keep the blocked area open. The metal support tube and material covering the metal are together called a stent graft*.

As described above, balloon inflation is first performed to open the narrowed segment in your A-V access graft. The **FLAIR™ Endovascular Stent Graft**, mounted on the end of another hollow tube or catheter similar to the balloon, is inserted through the same pathway in your access graft and placed across the narrowed segment that has just been opened with the balloon. The **FLAIR™ Endovascular Stent Graft** is then opened by your doctor in the previously narrowed area. When opened, the device presses against your A-V access graft and blood vessel to keep the area open *(See Figure 4)*.

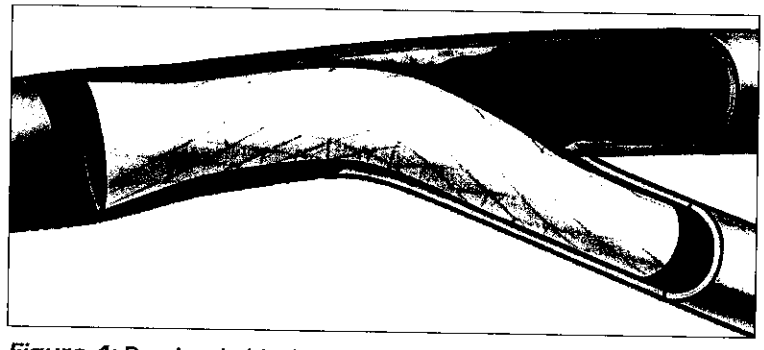

Figure 4: **Previously blocked area after use of the *FLAIR™ Endovascular Stent Graft***

****Please see glossary for definition***

The benefit of the **FLAIR™ Endovascular Stent Graft** over balloon inflation alone has been shown in a study in the United States of patient volunteers with A-V access graft blockages like yours. Please ask your doctor for more information about the results of the study.

What Is the *FLAIR™ Endovascular Stent Graft* (Device Description)?

The **FLAIR™ Endovascular Stent Graft** is a flexible support tube made of a special metal called Nitinol* covered with the same kind of material that makes up your A-V access graft (ePTFE). Nitinol is a metal designed to expand to a predetermined size once it is warmed by the heat of your body.

The **FLAIR™ Endovascular Stent Graft** is available in both flared *(Figure 5)* and cylinder shapes *(Figure 6)*.

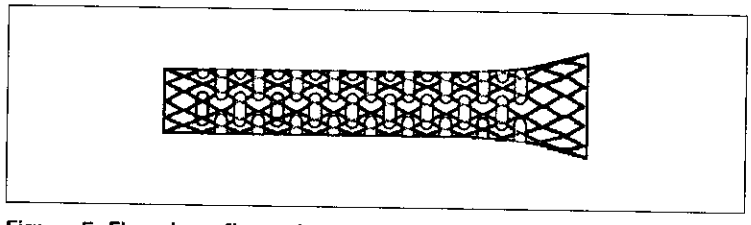

Figure 5: Flared configuration

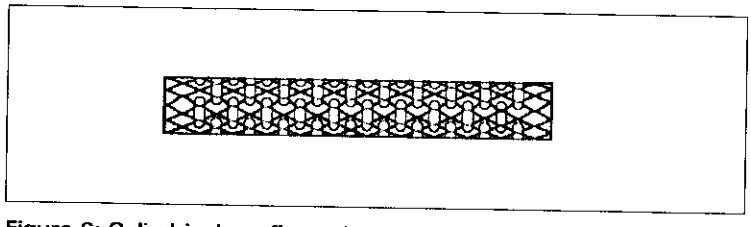

Figure 6: Cylindrical configuration

Please see glossary for definition

When can the device be used (Indication for Use)?*
The **FLAIR™ Endovascular Stent Graft** is indicated for use in the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arteriovenous (A-V) access grafts. **In other words, the device can be used to support or hold open a blocked area at the connection of your A-V access graft and natural blood vessel (i.e., vein).**

When should the device not be used (Contraindications)?* There are no known reasons not to use the **FLAIR™ Endovascular Stent Graft** for the treatment of blockages at the connection of your A-V access graft and blood vessel.

Important Questions to Ask Your Doctor Before the Procedure

What additional tests can I expect if my doctor suspects a blockage of my A-V access graft?

Your doctor might evaluate your A-V access graft with a sound-wave test called ultrasound*. Using an instrument placed on top of your skin, your doctor can measure the size of your blood vessels and the flow of your blood from outside your body.

You may also be referred for an x-ray test called a venogram*. Dye is injected into your blood vessels through a small tube placed in your arm. The dye is visible with x-ray, and allows your doctor to see the narrowing in your A-V access graft.

Please see glossary for definition

How do I know whether the *FLAIR™ Endovascular Stent Graft* is right for me?

You are considered a candidate for treatment with the **FLAIR™ Endovascular Stent Graft** unless you have any of the following conditions:

- Blood-clotting* disorders;
- Blood poisoning (called septicemia*);
- Allergy or sensitivity to nickel-titanium*, the metals that make up the special nitinol support tube;
- Allergy or sensitivity to x-ray dye that can not be treated with drugs given to you by your doctor prior to the procedure;
- Infected A-V access graft; or
- New A-V access graft (the graft has been in your arm for less than 30 days).

Please talk to your doctor to determine whether the **FLAIR™ Endovascular Stent Graft** is right for you. Your doctor should consult the **FLAIR™ Endovascular Stent Graft** "Instructions for Use" (available on www.bardpv.com or call 1-800-562-0027) for a complete list of warnings and precautions.

Please see glossary for definition

Below is a partial list that might help you decide whether the **FLAIR™ Endovascular Stent Graft** is right for you:

WARNINGS: The FLAIR™ Endovascular Stent Graft is designed to stay in your body permanently. It can only be removed by a doctor through an operation (i.e., surgical removal).

PRECAUTIONS: The safety and effectiveness of the device if placed across an angle that is greater than 90° (a full L-shaped bend) have not been established.

The safety and effectiveness of the device placed across the elbow (resulting in repeated bending of the device) have not been established.

What risks can I face as a result of the procedure with the *FLAIR™ Endovascular Stent Graft*?

Your doctor should discuss the procedure in detail with you and explain the possible risks and potential benefits of the device. Please make sure that your doctor answers all of your questions.

The procedure may cause some pain and discomfort. You may feel pressure in your arm when the balloon is inflated and possibly pressure and a burning sensation when x-ray dye is injected into your access graft.

WARNING: Although rare, dye injection may produce an allergic reaction causing low blood pressure and breathing difficulties. It is important that you tell your doctor about any allergies you might have before the procedure.

[redacted]

CAUTION: The procedure used to place the *FLAIR™ Endovascular Stent Graft* may involve certain risks. These risks include but are not limited to:

- Complete blockage of your A-V access graft (i.e., thrombosis*);
- Re-narrowing of your A-V access graft (i.e., restenosis*) requiring another procedure;
- A bulge or enlargement of your blood vessel (i.e., pseudoaneurysm*);
- A tear or break in your blood vessel;
- A hole in your blood vessel;
- Pain;
- Infection;
- Excessive bleeding;
- Arm or hand swelling;
- A lack of blood flow to the area around your A-V access graft and blood vessel that can prevent enough blood from flowing to other parts of your body (i.e., steal syndrome*);
- Heart failure caused by loss of pumping power by the heart, resulting in fluids collecting in the body (i.e., congestive heart failure*);
- Bleeding or blockage of blood flow in the brain sometimes leading to loss of consciousness, feeling, and motion (i.e., stroke*); or
- Death.

Please see glossary for definition

[redacted]

CAUTION: Specific risks associated with stent grafts like the *FLAIR™ Endovascular Stent Graft* include:

- Placement of the device in the wrong spot;
- Movement of the device once it is placed in your body;
- Breakage of the metal support tube (i.e., fracture*);
- Bending or kinking of the device;
- The device not opening enough in your body; or
- Movement of the device causing blockage of blood flow.

The above device-related events might result in additional procedures and/or the placement of a second **FLAIR™ Endovascular Stent Graft**.

What is the potential benefit of using the *FLAIR™ Endovascular Stent Graft*?

The benefit of the **FLAIR™ Endovascular Stent Graft** over balloon inflation alone has been demonstrated in a study in the United States of patient volunteers with A-V access graft blockages like yours. For more details about the study and the benefits of the **FLAIR™ Endovascular Stent Graft**, please talk to your doctor.

Please see glossary for definition

Treatment After Placement of Your *FLAIR™ Endovascular Stent Graft*

WARNINGS: **It is important that you explain to your caregivers and nurses that you have a *FLAIR™ Endovascular Stent Graft*. When performing dialysis, they need to avoid:**

- Placing a dialysis needle directly into the **FLAIR™ Endovascular Stent Graft**, or
- Applying constant pressure directly over the area where the **FLAIR™ Endovascular Stent Graft** has been placed.

If you have questions or concerns about the care of your **FLAIR™ Endovascular Stent Graft** after placement, please contact your doctor.

Safety During Magnetic Resonance Imaging (MRI*)

After placement of your **FLAIR™ Endovascular Stent Graft,** your doctor may request a special test that uses electric waves from a magnet to obtain images of the inside of your body, called an MRI. Your **FLAIR™ Endovascular Stent Graft** is classified as MR-Conditional. This means that an MRI can be done safely if specific testing conditions are followed.

For further details on how an MRI can be performed safely following placement of your device, your doctor can refer to the "Instructions for Use" for the **FLAIR™ Endovascular Stent Graft** available on www.bardpv.com or call 1-800-562-0027.

Please see glossary for definition

Glossary

Arteriovenous (A-V)	A term that refers to two different kinds of blood vessels — an artery and a vein.
Access Sheath	A hollow tube used to enter the body.
A-V Access Graft	A tube made of a special plastic that joins together an artery and a vein. Your doctor placed an A-V access graft under the skin in your arm so that blood can be drawn safely and quickly with a needle to be filtered and cleaned.
A-V Anastomosis	The connection between an A-V access graft and blood vessel.
Artery	A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.
Balloon Angioplasty	A procedure where a small hollow tube with a balloon on one end is inflated inside of a blood vessel to open a blocked or narrowed area.
Blood Clot	A clump of blood cells that blocks or prevents normal blood flow.
Blood Vessel	A series of natural tubes in the body that carry blood from (artery) or to (vein) the heart.
Catheter	A thin, hollow tube that is generally used to carry fluids into or out of the body. It can also be used to place something in the body, like a balloon or stent graft.
Cell	The smallest basic unit of all living organisms. Sometimes called the "building block of life."
Congestive Heart Failure	Heart disease caused by loss of pumping power of the heart. A condition where a diseased heart can not pump out all of the blood. As a result, fluid builds up in the blood vessels and body tissues.
Contraindications	A condition that makes a specific treatment or procedure improper or undesirable.
Diabetes	A disease where the body does not properly control the amount of sugar in the blood. As a result, the level of sugar in the blood is too high. Diabetes can lead to kidney problems like yours.

Dialyzer	A machine that filters blood. Used for patients like you with chronic kidney disease. Blood containing waste products is run through filters outside of your body and then returned once it is cleaned.
ePTFE	Expanded Polytetrafluoroethylene. A strong, flexible plastic that is used to make artificial blood vessels. More than likely your A-V access graft is made of ePTFE. It is the most popular material to make A-V access grafts, and is used as the covering for the **FLAIR™ Endovascular Stent Graft**.
Fluoroscopy	A medical procedure that involves a moving x-ray image of the body. By injecting dye and using a moving x-ray machine, your doctor can see a movie of the inside of your blood vessels rather than just a still photo.
Fracture	A break or crack. In this case, a break or crack in the metal support tube of a stent graft.
Hemodialysis	A procedure that uses a machine outside of your body to filter or clean your blood because your kidneys are not working properly.
High Blood Pressure	Called hypertension. A condition where there is too much pressure inside of your blood vessels. Blood is pushed too hard by the heart against the blood vessel walls. High blood pressure can lead to kidney problems like yours.
Indications for Use	When a device or procedure can be used.
Kidney Transplantation	A procedure that replaces a diseased kidney from one person with a healthy kidney from another person.
Lifeline	A term that refers to a support that enables people to live. In this case, it is used to indicate the importance of your A-V access graft.
MRI	MRI stands for Magnetic Resonance Imaging. A test that uses electric waves from a moving magnet to obtain images of the inside of your body.

Nickel-Titanium	Two metals that when combined make nitinol (defined below). Some people are allergic to nickel-titanium, so it is important that you tell your doctor about any allergies that you may have before your procedure.
Nitinol	A special metal made of nickel and titanium that remembers its shape. Nitinol can be compressed when cold and expands back to its original shape and size when heated. Nitinol is used as the support tube in many stent grafts, including the **FLAIR™ Endovascular Stent Graft**. The special properties of a tube made of nitinol allow it to expand to fit your blood vessel once it is heated by the temperature of your body.
Peritoneal Dialysis	A method used to filter your blood when the kidneys are not working properly. First, a soft plastic tube called a catheter (see definition above) is surgically inserted into your abdomen (belly). The tube is used to fill the abdomen with a special fluid called dialysis solution. Your blood is then filtered through this solution that pulls wastes from your blood. The special fluid and waste can then be drained from your body.
Pseudoaneurysm	Also known as a false aneurysm. A bulging or enlargement of a blood vessel or A-V access graft caused by some kind of damage. For example, a false aneurysm can be created in an A-V access graft by repeated needle sticks in the same spot.
Pulse	A rhythm or beat felt when touching the skin over your blood vessels. Your pulse is created by the beating of your heart.
Septicemia	Blood poisoning.
Steal Syndrome	A lack of blood flow to the area around your A-V access graft. This condition can prevent enough blood from flowing to other parts of your body such as your hands and fingers. The lack of blood flow can cause the hands and fingers to be painful, discolored, or cold.

Stenosis or Restenosis	The narrowing or blockage of an A-V access graft or blood vessel caused by the buildup of tissue and cells. Restenosis refers to a return of the narrowing or blockage after the area has already been opened.
Stent Graft	A metal support tube that is covered by a material similar to the material that makes up your A-V access graft. A stent graft provides support for a blood vessel that has been narrowed or blocked.
Stroke	Temporary or permanent loss of blood supply to the brain. This condition can lead to a loss of feeling, motion, speech, or death.
Surgery	The treatment of diseases or other medical conditions by operating on a patient to remove or repair parts of the body.
Surgeon	A medical doctor that specializes in doing surgery or operations.
Thrill	The vibration or tremble of blood that you can feel flowing through your A-V access graft.
Thrombosis	A complete blockage inside your A-V access graft.
Tissue	A group of cells ("building blocks") that work together to perform a specific function. Your A-V access graft can become blocked by the buildup of cells and tissue.
Ultrasound	A sound wave test. Using an instrument placed over your blood vessel on top of your skin, your doctor can measure the size of your blood vessels and the flow of your blood without entering your body.
Vein	A blood vessel that carries blood from the organs of the body back to your heart.
Venogram	An x-ray test where dye is first injected into your blood vessels through a catheter. The dye is visible with x-ray, and allows your doctor to see a narrowing or blockage in your blood vessel or A-V access graft.

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