INSTRUCTIONS FOR USE

EndoForce™ Connector for Endovascular Venous Anastomosis

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

Read the EndoForce™ Connector for Endovascular Venous Anastomosis Instructions for Use thoroughly. Also, thoroughly review the Instructions for Use provided with the vascular graft and other equipment used in conjunction with these instructions.

DEVICE DESCRIPTION

The EndoForce™ Connector for Endovascular Venous Anastomosis (herein referred to as the EndoForce™ System) includes an implantable component, the EndoForce™ Connector and a delivery system, EndoForce™ Connector Delivery System. The EndoForce Connector™ is a venous anastomosis implant used in conjunction with a 6 mm inner diameter expanded polytetrafluoroethylene (ePTFE) arteriovenous graft (not provided). The graft is sutured to the artery using a conventional anastomosis. The graft, and not the EndoForce™ Connector, is to be used for vascular access during hemodialysis in patients with end stage renal disease. The EndoForce™ Connector is provided pre-loaded within the EndoForce™ Connector Delivery System.

Implant

The EndoForce™ Connector is a flexible, self-expanding endoprosthesis comprised of a nitinol framework encapsulated in ePTFE in the midsection and uncoated at the ends. The venous end is flared and includes 4 anchoring barbs that extend into the vein wall. The EndoForce™ Connector is deployed within a vein that is 4-7 mm in diameter at the venipuncture site (**Figure 1**). Upon deployment, the flared end allows for expansion of the EndoForce™ Connector up to 10 mm. Approximately 22 mm is implanted inside the vein and 40 mm inside the vascular access graft.

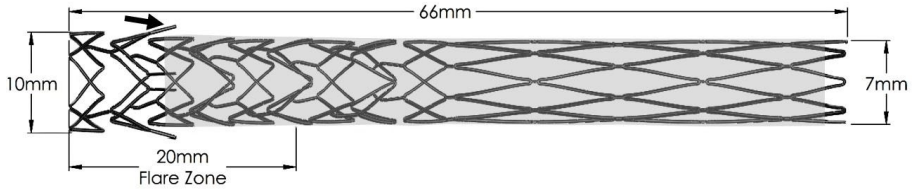


Figure 1: EndoForce™ Connector
Large arrow denotes one of the four total anchoring barbs at flared end.

EndoForce™ Connector Delivery System

The EndoForce™ Connector is provided pre-mounted and constrained within a sterile, single-use EndoForce™ Connector Delivery System for transcatheter over-the-wire delivery (**Figure 2**). The inner catheter (F) contains the guidewire lumen. The outer sheath (D) includes a radiopaque marker band (E) located 3mm from the tip that is used as a visual reference while advancing the EndoForce™ Connector Delivery System to the target site in the vein. The outer sheath marker band is also observed during retraction

of the sheath to deploy the EndoForce™ Connector and during removal of the EndoForce™ Connector Delivery System after completing deployment.

The distal catheter assembly (~12 cm, **Figure 2 inset**) houses the EndoForce™ Connector (implant) that is compressed onto the inner catheter (J). A blue handle lock (B) prevents premature release of the EndoForce™ Connector. The safety lock must be removed prior to deployment (see Figure 6). Radiopaque marker bands on the inner catheter (H and I) are used to guide positioning of the EndoForce™ Connector for deployment. To deploy the EndoForce™ Connector, the operator removes the handle lock (B), pins Y-adapter 1 (A), and slowly retracts Y-adapter 2 (C), which also retracts the outer sheath (D). The pusher rod (G) supports and maintains alignment of the EndoForce™ Connector during deployment. The ideal deployment rate is 1 mm per second of Connector exposure, as observed under fluoroscopic guidance.

The EndoForce™ Connector Delivery System has a working length of 23 cm and is compatible with an 11Fr introducer sheath and an 0.018" guide wire.

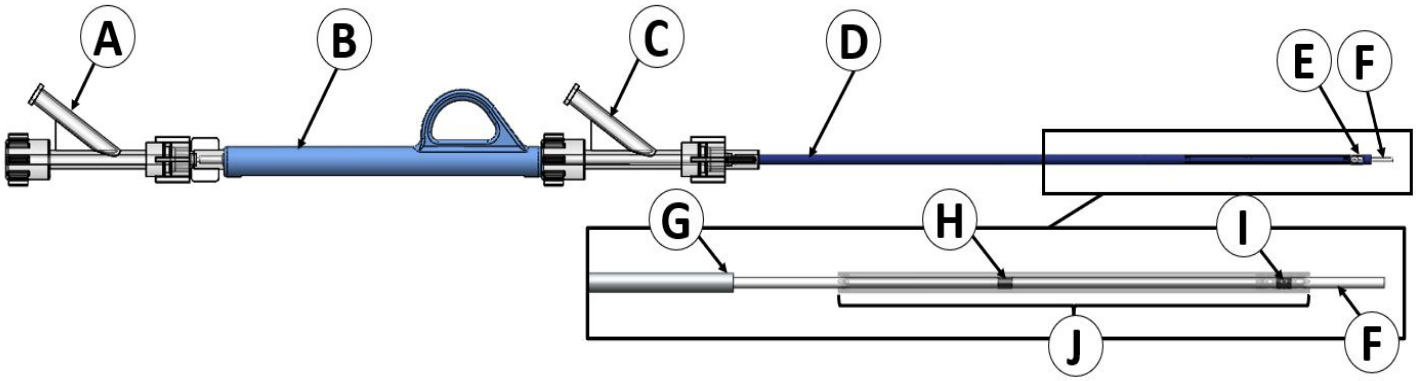


Figure 2: EndoForce™ Connector Delivery System

Top: A- Y-adapter 1 with hemostatic valve; B- handle lock; C- Y-adapter 2 with hemostatic valve; D- outer sheath; E-marker band on outer sheath; F- inner catheter. Figure 2 Inset (outer sheath has been removed to show underlying components): F- inner catheter; G- pusher rod; H- marker band 1 on inner catheter; I- marker band 2 on inner catheter; J- EndoForce™ Connector compressed within EndoForce™ Connector Delivery System.

INDICATION FOR USE

The EndoForce™ Connector for Endovascular Venous Anastomosis is indicated to provide an endovascular method for attachment of an arteriovenous graft to a vein in the upper arm in patients with end stage renal disease requiring hemodialysis. The EndoForce™ Connector is used together with conventional suturing of the graft to the artery during the implantation procedure. The graft is then used for vascular access during hemodialysis.

CONTRAINDICATIONS

The EndoForce™ Connector for Endovascular Venous Anastomosis is contraindicated in:

- Patients who have an allergy or hypersensitivity to nickel, titanium or ePTFE.
- Patients who have an allergy or sensitivity to contrast dye that cannot be adequately premedicated.

WARNINGS

- This device should be used only by physicians who are familiar with the complications, side effects, and hazards commonly associated with dialysis access shunt implantation, revisions, and endovascular procedures.
- The EndoForce™ System is intended for single patient use only. Do not re-use or re-sterilize.
- Inspect the sterile package prior to use. Do not use if the sterile barrier is not intact or if the package contents appear to be damaged.
- Failure to follow the handling and implantation technique warnings and precautions may result in serious adverse events such as excessive blood loss or the need for an intervention.
- Do not cannulate the EndoForce™ Connector. Notify the patient that the EndoForce™ Connector should not be directly cannulated for hemodialysis and that applying pressure to the implant area should be avoided.
- This device is not intended for creation of an arterial anastomosis
- This device has not been evaluated in:
    - Patients with hypercoagulable or bleeding disorder
    - Patients requiring treatment with warfarin, Aggrenox and heparin
    - Patients with sensitivity to heparin
    - Patients with a previous instance of Heparin Induced Thrombocytopenia type 2 (HIT-2)
    - Patients with uncorrectable coagulation disorders.
    - Patients with unsuccessfully treated ipsilateral central venous stenosis as determined by imaging.
    - Patients with connective tissue disorders.
    - Women who are pregnant.
    - Pediatric patients.
- Once deployed, the EndoForce™ Connector cannot be repositioned or remounted onto the EndoForce™ Connector Delivery System. Device removal after deployment can only be performed using a surgical approach.

PRECAUTIONS

- Always use an introducer sheath during delivery of the EndoForce™ Connector to protect the vein and puncture site.
- Always use an appropriate guide wire to introduce the EndoForce™ Connector Delivery System within the vein. The guide wire should remain in place during manipulation and removal of the Delivery System.
- The EndoForce™ Connector should only be used with 6 mm inner diameter ePTFE grafts.
- The EndoForce™ Connector is not designed for deployment across the antecubital fossa.
- If resistance is encountered at any time during delivery or deployment of the EndoForce™ Connector, do not force passage. Resistance may cause damage to the device or vein. Carefully withdraw the EndoForce™ Connector Delivery System without deploying the EndoForce™ Connector.
- To avoid possible migration of the EndoForce™ Connector, using fingertips, always secure the Connector segment extending from the venipuncture site after deployment and until placement within the graft is completed.
- Do not manipulate the EndoForce™ Connector using surgical forceps with teeth or other sharp instruments. Manipulation with sharp instruments may cause irreparable damage. Handling should be limited to clean sterile gloves.
- If desired, the EndoForce™ Connector may be smoothed or more fully seated against the vein wall by inflating an angioplasty balloon. The balloon diameter used should be no larger than 6mm when inflated within the EndoForce™ Connector. To avoid possible displacement of the EndoForce™ Connector, ensure that the balloon is fully deflated prior to carefully removing the balloon. Over-inflation or use of inappropriately sized balloons may damage the EndoForce™ Connector.

- Assure that the tacking suture is placed through both the graft and the nitinol framework of the EndoForce™ Connector. Failure to do so has resulted in dislodgement of the EndoForce™ Connector. Serious complications including hemorrhage, hematoma formation, and the need for additional surgical intervention may occur if the tacking suture is not properly placed.
- When suturing surgical incisions at the end of the graft implantation procedure, care should be taken to avoid puncturing the extravascular portion of the EndoForce™ Connector.
- The EndoForce™ Connector Delivery System is not designed for use with power injection systems.
- As with conventional anastomosis of grafts, the EndoForce™ Connector may occlude in patients with the following conditions: insufficient graft arterial inflow; untreated vascular stenosis; coagulability disorders or insufficient anticoagulation medication; kinked graft; or inadequate thrombus removal or stenosis treatment during graft intervention.
- Do not use mechanical-rotational thrombectomy devices with spinning parts in the EndoForce™ Connector, as internal damage may occur.
- If surgical excision of an infected graft is required, the EndoForce™ Connector should also be removed. Removal of the EndoForce™ Connector should be completed with surgical excision, manually freeing the barbs from the vein lumen.

MRI SAFETY AND COMPATIBILITY



MRI Safety Information

A person with the Phraxis EndoForce™ Connector may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	EndoForce™ Connector
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	For 1.5 T MR Scanner: Whole-body SAR £ 1.5 W/kg
	For 3.0 T MR Scanner: Whole-body SAR £ 1.0 W/kg

Scan Duration	Scan for up to 60 minutes.
Scan Regions	If RF Conditions above are applied, any landmark is acceptable. If Whole-body SAR is limited to £ 2.0 W/kg, patient landmark must assure device is at least 35 cm from isocenter.
MR Image Artifact	The presence of this implant may produce an image artifact.

RF Heating
In non-clinical testing, the EndoForce™ Connector maximum predicted *in vivo* change in temperature above background for the device following 900 s of exposure to a whole-body SAR level of 2.0 W/kg at 64 MHz (1.5 Tesla)was 3.8 ºC . Power level reduction to 1.5 W/kg or landmark limitation (device 35 cm or more from isocenter) required.

In non-clinical testing, the EndoForce™ Connector maximum predicted *in vivo* change in temperature above background for the device following 900 s of exposure to a whole-body SAR level of 2.0 W/kg at 128 MHz (3.0 Tesla) was 5.1 ºC. Power level reduction to 1.0 W/kg or landmark limitation (device 35 cm or more from isocenter) required.

Image Artifact
The 3-T image artifact extends approximately 75 mm in length (GRE, PE direction H-F) and approximately 16 mm in diameter (GRE) from the device when scanned in nonclinical testing using the sequence: Gradient Recalled Echo (GRE) sequence in a 3.0 Tesla, GE Signa HDxt, software version HD16.0_V02_1131.a, MR system with Birdcage Body transmit coil. The lumen of the EndoForce™ Connector is obscured by the image artifact.

Magnetic resonance imaging parameters may need to be optimized to compensate for the presence of this implant.

ADVERSE EVENTS

Potential adverse events that may occur and/or require intervention with the use of the EndoForce™ System include the following: access circuit intervention, allergic reaction; arm edema bleeding complications and/or hemorrhage; death; Embolism and/or vessel thrombosis, failure/malfunction of any component of the device that may lead to injury and/or need for surgical intervention including device compression, insufficient stent graft expansion, loss of permanent access, embolization, kinking, migration, misplacement, occlusion or thrombosis; Fracture of the endoprosthesis that may or may not lead to embolism, serious injury or surgical intervention; Infection or fever, including device infection; Inflammation; Insufficient device expansion; Ischemia; New lesion or total occlusion of the vascular access circuit; Numbness; pain; Paresthesia Placement of bailout stent/stent graft; Pruritus, stiffness or swelling of the implanted arm; Serious injury requiring surgical intervention; Steal Syndrome; Venous spasm; Vessel rupture; Thrombosis; Vessel or AVG injury (e.g., vessel spasm, stenosis, artery dissection, perforation, aneurysm or pseudoaneurysm), which may require surgical repair (conversion to open surgery); Wound site complications (e.g., bruising, edema, hematoma, erythema, seroma)

The EndoForce™ Connector is used in conjunction with a standard 6mm ePTFE vascular access graft. Potential complications that may occur with the use of any vascular graft are described in the manufacturer's Instructions for Use.

Protocol-specified serious adverse events observed during the clinical study are shown in **Table 7**. Reported adverse events related to the EndoForce™ Connector and/or graft implant procedure are shown in **Table 8** and **Table 9**.

SUMMARY OF CLINICAL STUDY

A prospective, multicenter, single-arm, pivotal study was performed to evaluate the safety and effectiveness of arteriovenous graft (AVG) implantation using the device for the venous anastomosis throughout a six-month follow-up period. A total of 158 patients were enrolled at 10 sites in the USA. Prior to starting enrollment in the pivotal study, investigators were required to enroll a roll-in patient as part of the training requirements. A total of 13 roll-in patients were treated and followed according to the same protocol that was applied to pivotal study patients.

The EndoForce™ Connector was initially called the Venous InterGraft Connector. The pivotal study described in this section was conducted using the Venous InterGraft Connector. The investigational device is referred to as the Connector in this summary.

Subsequent to the completion of the pivotal clinical study, modifications were made to the device that included changing the ePTFE material to an ultralow porosity ePTFE and an update to the manufacturing process and location. These modifications were made due to a change to the contract manufacturer. These device modifications did not warrant additional clinical evaluation because comparative bench testing assessments between the original and modified device as well as the battery of biocompatibility testing confirmed that the changes are not associated with any negative impacts on device performance.

A summary of the pivotal study is presented in the following section.

Study Endpoints

Primary Endpoint and Choice of Performance Goal

The primary endpoint was cumulative patency at 6 months, defined as the percentage of patients free from loss of access of the implanted graft for hemodialysis, assessed at 6 months. The primary endpoint was compared to a Performance Goal of 75% that was derived using published data on AVG patency.

The primary study endpoint was evaluated in the following testable hypotheses:

H_0: $(\text{Cumulative Patency Rate})_{6\ \text{Months}} \leq PG$

H_1: $(\text{Cumulative Patency Rate})_{6\ \text{Months}} > PG$

Where, PG = Performance Goal, here equal to 75%.

The observed published data on cumulative patency rate at 6 months for standard AVG implants ranged from 65% to 98%. The lower two-sided 95% confidence bound for cumulative patency was estimated to be 79.9%.

Secondary Endpoints
Secondary endpoints included: acute device success, primary unassisted patency at six months, time to first cannulation, the number and type of AVG interventions to maintain patency, and the number and type of the following serious adverse events (SAEs) through six months: emergent surgery, graft infection requiring treatment, significant bleeding, pseudoaneurysm, and death (all cause).

Sample Size
The required sample size for the study was estimated using the following assumptions:

- Test basis: Kaplan-Meier estimate of cumulative patency rate at 6 months, with exact binomial estimation for purposes of sample size
- Type I error (alpha): 0.025 (one-sided)
- Statistical power: 80%
- Performance Goal (PG): 75%
- Expected cumulative patency for grafts implanted using the Connector for the venous anastomosis, at 6 months: 84.6%.

Based on the above assumptions, a total of 146 evaluable patients were required to compare observed cumulative patency to a PG of 75%. With an expected loss-to-follow-up rate of 8% over 6 months, a total of 158 patients were enrolled in the evaluation phase.

No interim analyses were performed. Patients who were withdrawn for reasons other than loss of cumulative patency were included in the analysis up until the time of withdrawal and were considered censored in the analysis, according to usual convention, after withdrawal.

Patients Studied
Patients with end stage renal disease and at least 18 years of age were eligible for the study if they were scheduled to have an AVG for hemodialysis implanted in an upper arm, baseline imaging showing a suitable artery measuring at least 3.5 mm in diameter, and if examination at the time of surgery showed a target vein that was 4-7 mm in diameter at the planned anastomosis location, with no significant central stenoses and no significant vessel lesions or abnormalities that could limit the ability to safely deploy the Connector.

Patients were excluded if they had any of the following: more than two previous vascular accesses in the treatment arm, a hypercoagulable or bleeding disorder, sensitivity to heparin, life expectancy less than 12 months, pregnancy, or if they were currently receiving maintenance immunosuppression therapy or taking aspirin-dipyridamole.

Methods
The study protocol and informed consent form were approved by the Institutional Review Board at each site. Written informed consent was obtained for all patients prior to study participation.

Patients were prospectively enrolled and underwent AVG implantation within an upper arm using the Connector for the venous anastomosis. In addition to a 2-week visit following the procedure, monthly follow-up visits were performed for 6 months to collect data regarding vascular access circuit status, adverse events (AEs), graft interventions performed, and changes in applicable medications. Investigators and dialysis centers followed their institutional procedures for hemodialysis access surveillance.

A Clinical Events Committee (CEC) reviewed and adjudicated all AEs and deaths reported during the study. An independent Data and Safety Monitor Board was responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, and for monitoring the overall conduct of the study.

Statistical analyses were performed by an independent statistician in accordance with an approved statistical analysis plan.

Results
Results shown in tables below also include data for roll-in patients. Table values shown are number (%) unless otherwise indicated.

Patient demographics, baseline characteristics and vascular access history are shown in **Table 1**. The demographics and co-morbidities of the study population are typical for an AVG study performed in the US with the exception of a higher proportion of females and African Americans. However, there were no clinically meaningful differences within these subgroups (male vs. female, African American vs. non-African American). Therefore, the results can be considered generalizable to the broader patient population.

Summary of the AVG implant procedure using the Connector for the venous anastomosis and standard suturing for the arterial anastomosis is shown in **Table 2**. The Connector was successfully used to create the venous anastomosis in all AVG implantation procedures. At discharge, patency was confirmed in all AVGs.

Table 1. Demographics, Baseline Characteristics, and Vascular Access History

Characteristic	Roll-in Patients (N=13)	Pivotal Study (N=158)
Age, years, mean ± SD (range)	63.7 ± 12.3 (41.0 -84.0)	62.6 ± 14.8 (24.0 - 92.0)
Gender: Male Female	 7 (54) 6 (46)	 61 (39) 97 (61)
Ethnicity: Hispanic or Latino Not Hispanic or Latino UNK/not reported	 0 13 (100) 0	 3 (2) 154 (97) 1 (1)
Race: Asian Black or African American White	 0 10 (77) 3 (23)	 1(1) 123 (78) 34 (22)
Diabetes mellitus	12 (92)	98 (62)
Obesity	8 (62)	51 (32)
Hypertension	5 (38)	89 (56)
Cardiovascular disease	8 (62)	78 (49)
Previous permanent vascular accesses for hemodialysis, any location: 0 1 ≥ 2	 7 (54) 4 (31) 2 (15)	 64 (41) 66 (42) 28 (18)
Previous permanent vascular access for hemodialysis in target limb: 0 ≥ 1	 8 (62) 5 (38)	 90 (57) 68 (43)
Current vascular access using catheter	12 (92)	134 (85)
Duration of hemodialysis:		

Characteristic	Roll-in Patients (N=13)	Pivotal Study (N=158)
< 6 months	5 (38)	69 (44)
≥ 6 and <12 months	0	15 (9)
≥ 12 months	7 (54)	59 (37)
NA (no current hemodialysis)	1 (8)	15 (9)

Table 2. Summary of the Implant Procedure

Parameter	Roll-in Patients (N=13)	Pivotal Study (N=158)
Implanted graft location:		
Left upper arm	7 (54)	96 (61)
Right upper arm	6 (46)	62 (39)
Vein used for anastomosis:		
Axillary	7 (54)	63 (40)
Basilic	5 (38)	24 (15)
Brachial	1 (8)	69 (44)
Cephalic	0	2 (1)
Graft type implanted:		
Early cannulation	12 (92)	118 (75)
Standard ePTFE	1 (8)	40 (25)
Heparin during procedure	11 (85)	81 (51)
Amount used, IU, mean ± SD	4018.2 ± 2309.5	4067.9 ± 1887.0
Contrast dye during procedure, ml, mean ± SD	75.1 ±112.8	64.1 ± 94.7
Procedure time, minutes, mean ± SD *[Time from 'first incision to tunnel AVG' to 'AVG connected and flow confirmed']*	59.8 ± 21.2	45.4 ± 15.9

Patient Accountability

Study results were available for 158 pivotal patients (144 evaluable at six months, 14 censored with partial follow up observation). Reasons for censoring included death (n=3), lost to follow-up (n=3), withdrew from the study (n=6), and six-month visit < 166 days (n=2). An additional 12 of the 144 evaluable patients did not complete their six-month follow up because of graft abandonment, and their outcomes were included in the endpoint assessments.

Primary Endpoint Result

The 6-month primary endpoint analysis was based on 144 evaluable patients (132 reached the 6-month visit, and 12 patients had an abandoned graft prior to the 6-month visit).The primary endpoint of cumulative graft patency at 6 months with comparison to a target Performance Goal of 75% was met (P-value < .001). Kaplan Meier survival analysis is shown in **Figure 3**. Cumulative patency was 92.08% [estimated at 180 days] with a lower 95% Confidence Bound of 86.98% [Survival – 1.96 SE).

Figure 3. Kaplan-Meier Survival for Cumulative Patency (Primary Endpoint)

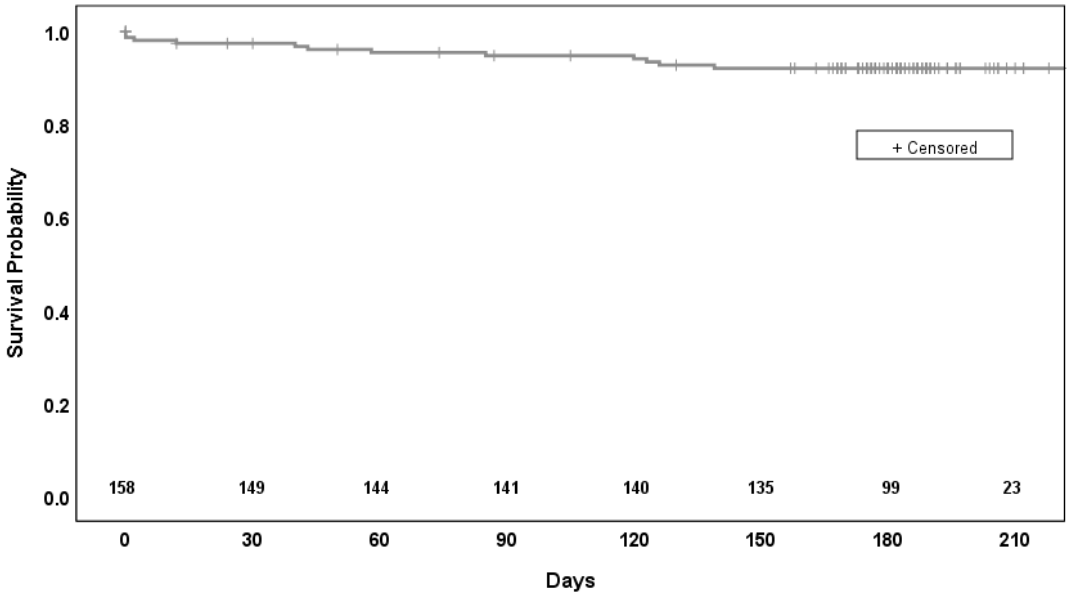


Table 3. Primary Endpoint Results – Cumulative Patency

Endpoint	Roll-in Patients (N=13)	Pivotal Study (N=158)
Cumulative patency at 6 months (primary endpoint)	77% (10/13)	92.08%[1]

[1] Calculated based on Kaplan-Meier survival estimates

Secondary Endpoint Results

Study endpoint results are summarized in this section.

In the pivotal study, acute device success was achieved in 100% of the 158 patients, with time to first cannulation at approximately 20 days (**Table 4**) The implanted graft type and Initial cannulation were at the physician's discretion. Initial cannulation timing was not impacted by use of the Connector for the venous anastomosis.

Table 4. Acute Device Success and Time to First Cannulation

Endpoint	Roll-in Patients	Pivotal Study
Acute device success: % of patients (n/N)	100% (13/13)	100% (158/158)
Time to first cannulation of AVG, days All subjects/grafts: Mean ± SD (range)	27.6 ± 24.8 (1.0 - 81.0)	20.1 ± 23.5 (1.0 - 134.0)

Primary Unassisted Patency was 60.21% [estimated at 180 days] with a lower 95% Confidence Bound at 180 days of 50.84% [Survival – 1.96 SE][1] as shown in **Table 5** . Kaplan-Meier survival analysis is shown in **Figure 4**.

FIGURE 4. Kaplan-Meier Survival for Primary Unassisted Patency

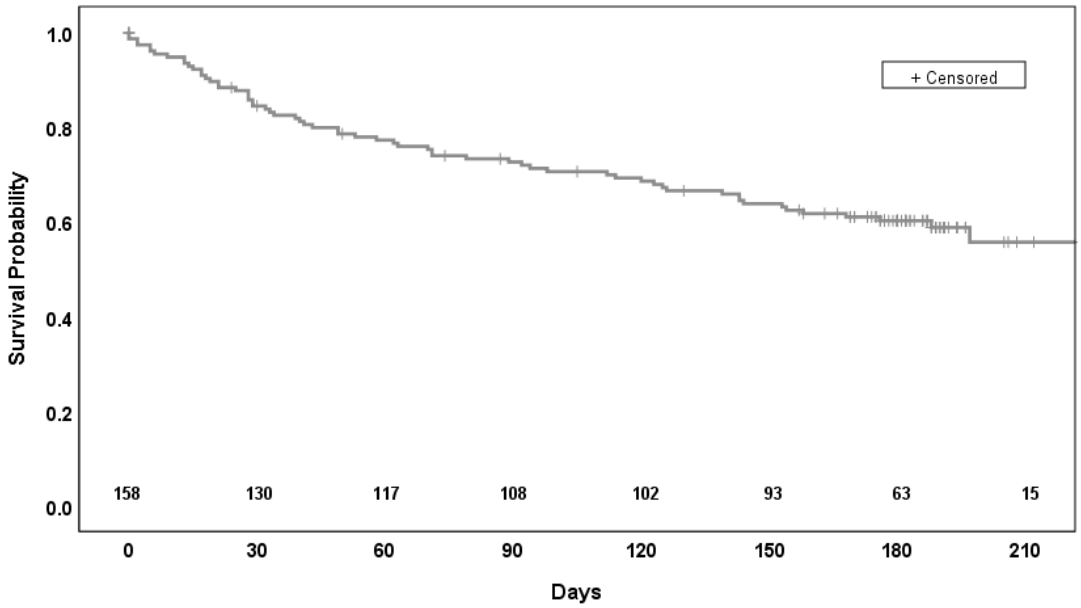


Table 5. Primary Unassisted Patency

Endpoint	Roll-in Patients	Pivotal Study
Primary unassisted patency at 6 months	46% (6/13)	60.21%[1]

[1] Calculated based on Kaplan-Meier survival estimates

Graft interventions to maintain secondary patency were performed in 55 pivotal patients. A total of 97 interventions were performed and clinically driven in all cases. Stenoses were treated in 83 of the 97 interventions. In 14 interventions, there was no stenosis identified, and the intervention was performed for graft banding (5 patients), thrombectomy only (7 patients), and surgical revision (2 patients). Among the roll-in patients, a total of 4 interventions were performed in 4 patients. No AEs occurred during the intervention procedures. Types of procedures performed during interventions are shown in **Table 6**. During all interventions, the Connector was observed to be intact and properly positioned. There was no evidence that the Connector had moved or migrated from the implantation site. Two pivotal patients had an initial unsuccessful intervention that was subsequently followed with a successful repeat intervention. All other interventions were successful.

Table 6: Summary of Additional Interventions

Endpoint	Roll-in Patients	Pivotal Study
Patients with at least 1 intervention to maintain AVG patency by 6 months: % of patients (n/N)	31% (4/13)	35% (55/158)
1 intervention	0% (0/13)	21% (33/158)
2 interventions	8% (1/13)	9% (14/158)

[1] Hypothesis tests were not pre-specified for this endpoint and no multiplicity adjustment was applied.

Endpoint	Roll-in Patients	Pivotal Study
≥ 3 interventions	23% (3/13)	5% (8/158)[1]
Types of procedures during intervention[2]: % of procedures (n/N) *(NOTE: multiple types of procedures may have been performed during a single intervention.)*		
Angioplasty	76% (13/17)	79% (77/97)
Thrombectomy	76% (13/17)	71% (69/97)
Thrombolytic infusion	47% (8/17)	10% (10/97)
Stent placement	6% (1/17)	24% (23/97)
Embolectomy	0% (0/17)	1% (1/97)
Other surgery *(AVG banding, revision)*	18% (3/17)	13% (13/97)

[1] The majority of interventions were angioplasties; in 6 subjects the intervention was in the location of the device; a hematoma was noted in 2 cases; all others were completed without complication.

[2] Interventions were based on clinically driven best practices and standard of care in vascular access surveillance and monitoring at the discretion of the treating physician.

Adverse Events that Occurred in the PMA Clinical Study

The overall protocol-defined SAE rate in the pivotal study was 5.70%. Graft infections occurred in 6 patients (3.80%) in the pivotal study. None of the infections were related to the Connector. One (1) roll-in patient developed an upper-extremity hematoma the day after graft implantation requiring emergent surgery. During the surgery it was noted that the tacking suture had not engaged the Connector and the Connector dislodged from the graft. The Connector was re-inserted into the graft and the tacking suture properly placed without further sequelae. All deaths (3 in roll-in patients and 3 in pivotal patients) were unrelated to the study device or the AVG implant procedure. No patients had significant bleeding or pseudoaneurysm.

Table 7. Summary of Safety Endpoint Results

Endpoint	Roll-in Patients (N=13)	Pivotal Study (N=158)
Patients with protocol-specified SAEs:		
Death	23% (3/13)	2% (3/158)
AVG infection	0% (0/13)	4% (6/158)
Emergent surgery	8% (1/13)	0% (0/158)
Significant bleeding	0% (0/13)	0% (0/158)
Pseudoaneurysm	0% (0/13)	0% (0/158)

Protocol-specified SAEs and additional SAEs that were reported as related to the Connector (study device) or AVG implant procedure are listed in **Table 8**. Non-serious AEs that were reported as related to the study device or AVG implant procedure are listed in **Table 9**. All AEs were reviewed and adjudicated by a Clinical Events Committee (CEC).

Table 8. Relatedness of Serious Adverse Events[1]

SAE Type *(*denotes protocol-specified SAE)*	Number of Patients	Relationship to Study Device			Relationship to AVG Implant Procedure[7]		
		Related	Possibly related	Not related	Related	Possibly related	Not related
Pivotal Study (N=158)							
Bacteremia	1	0	0	1	1	0	0
*Bleeding, significant	0	-	-	-	-	-	-
Cellulitis	1	0	0	1	1	0	0
*Death[2]	3	0	0	3	0	0	3
*Emergent Surgery	0	-	-	-	-	-	-
Hospitalization, prolonged[3]	3	0	1	2	2	1	0
*Infection, implanted AVG[4]	6	0	0	6	1	0	5
Ischemia/Vascular steal, implanted arm	5	0	0	5	5	0	0
*Pseudoaneurysm	0	-	-	-	-	-	-
Roll-in Patients (N=13)							
*Bleeding, significant	0	-	-	-	-	-	-
*Death[2]	3	0	0	3	0	0	3
*Emergent Surgery[5]	1	1	0	0	1	0	0
*Infection, implanted AVG	0	-	-	-	-	-	-
Ischemia/Vascular steal	1	0	0	1	1	0	0
Seroma, infected[6]	1	0	1	0	0	1	0

[1] All events were reviewed and adjudicated by the CEC.

[2] All deaths were adjudicated as unrelated to the Connector or AVG implant procedure. The deaths in the 3 pivotal patients were due to 1) atrial fibrillation 4 days post-procedure, 2) patient with coronary artery disease was found deceased at home 3 months post-procedure, and 3) patient went to ER with volume overload and died in the hospital 15 days post-procedure. The deaths in the 3 roll-in patients were due to 1) septic shock 2.5 months post-procedure, 2) cardiac arrest/anoxic brain injury 3 months post-procedure, and 3) cardiac arrest 2 days post-procedure.

[3] Three pivotal patients had extended hospitalization following the implant procedure for further monitoring. All were subsequently discharged without sequelae.

[4] The AVG infections were adjudicated as unrelated to the Connector by the CEC.

[5] One roll-in patient developed an upper-extremity hematoma the day after graft implantation requiring emergent surgery. During surgery it was noted that the tacking suture had not engaged the Connector and the Connector dislodged from the graft.

[6] One roll-in patient underwent evacuation of an infected seroma noted at the post-implant follow up visit.

[7] AVG Implant Procedure includes the implantation of the AVG using the study device (Connector)

TABLE 9. Relatedness of Non-Serious Adverse Events

Non- Serious AE type	Number of patients	Relationship to Study Device			Relationship to AVG Implant Procedure[1]		
		Related	Possibly related	Not related	Related	Possibly related	Not related
Pivotal Study (N=158)							
Bleeding	2	1[2]	0	1	2	0	0
Desquamation	1	0	0	1	1	0	0
Erythema	1	1	0	1	1	0	0
Ischemia *(mild vascular steal, numbness in implanted limb)*	8	0	0	8	5	3	0
Pain	3	1	0	2	3	0	0

Non- Serious AE type	Number of patients	Relationship to Study Device			Relationship to AVG Implant Procedure[1]		
		Related	Possibly related	Not related	Related	Possibly related	Not related
Paresthesia	1	0	0	1	0	1	0
Pruritus	2	0	0	2	2	0	0
Seroma	1	0	1	0	0	0	1
Stiffness, arm	1	0	0	1	1	0	0
Swelling, arm	7	0	2	5	4	3	0
Roll-in Patients (N=13) There were no non-serious AEs related to study device or AVG implant procedure							

[1]AVG Implant Procedure includes the implantation of the AVG using the study device (Connector)

[2] During the procedure, gutter bleeding with ~600 cc of blood noted and was subsequently controlled by placing a purse string suture at the venotomy site. The patient was hemodynamically stable and did not require pressors for hypotension.

Additional Analyses

Two sub-group analyses were conducted to assess potential differences in key baseline criteria. The gender analysis was prespecified in the protocol. The analysis evaluating potential differences between African Americans and non-African Americans was conducted post-hoc due to the proportion of African Americans in the study being higher than what would be expected in the general population.

Cumulative Patency by Gender

In the pivotal study, cumulative patency for females estimated at 180 days was 90.4% (Peto SE 3.4%), with a 95% confidence interval of (83.7%, 97.1%); and for males, 94.9% (Peto SE 3.8%), with a 95% confidence interval of (87.5%, 100.0%). Although cumulative patency for males was higher, the difference was not statistically significant (logrank p-value = 0.343). The lower 95% confidence bounds for both genders exceeded the Performance Goal of 75%.

Cumulative Patency by Race Category

A higher percentage of Black or African American patients participated in the pivotal study (77.8%) than is present in the general US population. Cumulative patency at 6 months in Black or African American patients was 93.5%, compared to 88.6% in non-Black or African American subjects No baseline factors were found to contribute to the nonsignificant but observed difference between cumulative patency results in the racial subgroups.

Extended Follow-up Study of Pivotal Patients with Graft Interventions

Among the 158 patients enrolled in the pivotal study, 55 had one or more graft interventions performed to maintain patency during the six-month follow-up period. The Extended Follow-up Study was conducted to collect an additional six months of follow-up information to establish the rate of post-intervention patency for subjects with a Connector in their access circuit.

Patients and Methods

Five study sites participated in the Extended Follow-up Study. Participating patients or their legally authorized representative provided consent in accordance with IRB requirements. The participating IRBs granted a waiver of consent for patients who were discovered to be deceased since completing the pivotal study. Follow-up data were collected from patient interviews and/or review of medical records, including post-intervention

graft patency information and the number and details of any new graft interventions during an additional six months of follow-up, starting from the date of the last reported graft intervention in the pivotal study. Extended follow-up data were available for 37 patients.

Results

A comparison of demographic and baseline characteristics of pivotal study patients with and without graft interventions is shown in **Table 10**. Baseline characteristics were similar in both groups. Details of the study index procedure were also similar, as shown in **Table 11**.

Table 10.
Pivotal Study Patients With and Without AVG Interventions: Demographic and Baseline Characteristics

Characteristic	**Group WITH AVG intervention (N=55)** *Values shown are number (%) unless otherwise indicated.*	**Group WITHOUT AVG intervention (N= 103)** *Values shown are number (%) unless otherwise indicated.*	**Pivotal Study Population (N=158)** *Values shown are number (%) unless otherwise indicated.*
Age, years, mean ± SD (range)	60.9 ± 15.0 (26.0 - 86.0)	63.4 ± 14.7 (24.0 - 92.0)	62.6 ± 14.8 (24.0 - 92.0)
Gender: Male Female	21 (38) 34 (62)	40 (39) 63 (61)	61 (39) 97 (61)
Body Mass Index, mean ± SD	30.2 ± 10.1	29.9 ± 7.7	30.0 ± 8.6
Ethnicity: Hispanic or Latino Not Hispanic or Latino UNK/not reported	 2 (4) 52 (95) 1 (2)	 1 (1) 102 (99) 0 (0)	 3 (2) 154 (97) 1 (1)
Race: Asian Black or African American White	 1 (2) 38 (69) 16 (29)	 0 (0) 85 (83) 18 (17)	 1 (1) 123 (78) 34 (22)
Diabetes mellitus	32 (58)	66 (64)	98 (62)
Obesity	16 (29)	35 (34)	51 (32)
Hypertension	28 (51)	61 (59)	89 (56)
Cardiovascular disease	24 (44)	54 (52)	78 (49)
Previous permanent vascular accesses for hemodialysis, any location: 0 1 ≥ 2	 18 (33) 27 (49) 10 (18)	 46 (45) 39 (38) 18 (17)	 64 (41) 66 (42) 28 (18)
Previous permanent vascular access for hemodialysis in target limb: 0 ≥ 1	 27 (49) 29 (53)	 46 (45) 57 (55)	 90 (57) 68 (43)
Current vascular access using catheter	48 (87)	86 (83)	134 (85)
Duration of hemodialysis: < 6 months ≥ 6 months and <12 months ≥ 12 months	 27 (49) 4 (7) 21 (38) 3 (5)	 42 (41) 11 (11) 38 (37) 12 (12)	 69 (44) 15 (9) 59 (37) 15 (9)

Characteristic	Group WITH AVG intervention (N=55) *Values shown are number (%) unless otherwise indicated.*	Group WITHOUT AVG intervention (N= 103) *Values shown are number (%) unless otherwise indicated.*	Pivotal Study Population (N=158) *Values shown are number (%) unless otherwise indicated.*
NA (not currently receiving hemodialysis)			

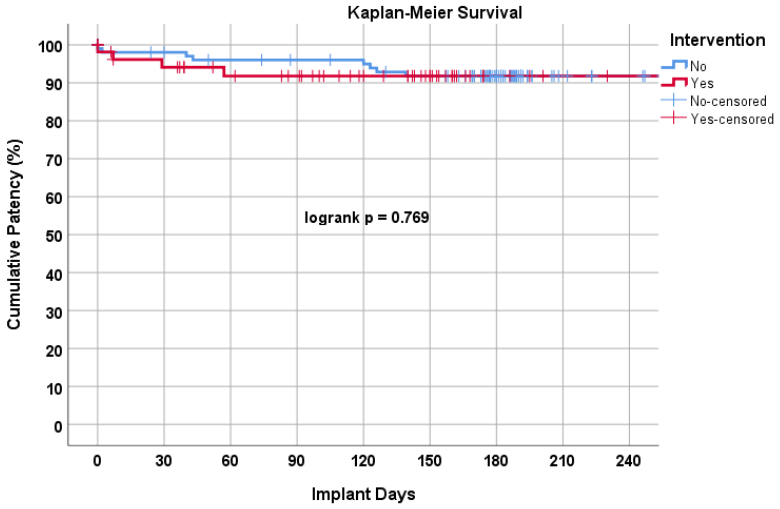
Table 11.
Pivotal Study Patients With and Without Interventions: Summary of the Index Procedure

Parameter	Group WITH AVG intervention (N=55) *Values shown are number (%) unless otherwise indicated.*	Group WITHOUT AVG intervention (N= 103)	Pivotal Study Population (N=158) *Values shown are number (%) unless otherwise indicated.*
Implanted graft location:			
Left upper extremity	37 (67)	59 (57)	96 (61)
Right upper extremity	18 (33)	44 (43)	62 (39)
Vein used for graft anastomosis using VIG:			
Axillary	19 (35)	44 (43)	63 (40)
Basilic	8 (15)	16 (16)	24 (15)
Brachial	28 (51)	41 (40)	69 (44)
Cephalic	0 (0)	2 (2)	2 (1)
Graft configuration:			
Loop	36 (65)	50 (49)	86 (54)
Straight	19 (35)	51 (50)	70 (44)
Tapered	0 (0)	2 (2)	2 (1)
Graft length, in situ, cm, mean ± SD	31.3 ± 9.4	31.7 ± 9.1	31.6 ± 9.2
Additional treatment during index procedure:			
Angioplasty	9 (16)	13 (13)	22 (14)
Stent	13 (24)	24 (23)	37 (23)
Thrombectomy	0 (0)	1 (1)	1 (1)
Endarterectomy	2 (4)	4 (4)	6 (4)
Graft banding	3 (5)	0 (0)	3 (2)
Other	0 (0)	1 (1)	1 (1)
Heparin during procedure	28 (51)	53 (51)	81 (51)
Amount used, iu, mean ± SD	4196.4 ± 2144.5	4000.0 ± 1754.1	4067.9 ± 1887.0
Contrast dye during procedure, ml, mean ± SD	51.2 ± 74.3	70.7 ± 103.4	64.1 ± 94.7
Procedure times, minutes, mean ± SD:			
Time from 'VIG introduced' to graft connected *(anastomoses completed, graft flow confirmed)'*	24.9 ± 11.0	26.4 ± 13.4	25.9 ±12.6
Time from first incision for graft tunneling to graft connected	45.3 ± 13.7	45.4 ± 17.0	45.4 ± 15.9

Kaplan-Meier analysis was performed to compare cumulative patency outcomes in patients with and without graft interventions during the pivotal study (**Figure 5).** Time to loss of patency events was measured from the date of implant for those without intervention, and from the date of the first intervention for those with one or

more. Although patients without interventions showed somewhat higher early survival rates, there was no evidence of a difference in the survival curves (logrank p = 0.769). The cumulative patency at 6 months and subsequently in both groups was nearly identical (91.79% vs. 91.80%).

Figure 5. Pivotal Study:
Kaplan-Meier Survival for Cumulative Patency for Patients With and Without Interventions



Acute device success (successful Connector implantation, without major adverse) was achieved in all patients. The mean time to first cannulation of the graft for hemodialysis was 23.1 ± 24.5 days for patients with interventions, and 18.4 ± 22.9 days for patients without interventions. Among the group with interventions, 2 patients had graft infections and there were no deaths during the pivotal phase, as compared to the group without interventions, in which graft infections occurred in 4 patients and death in 3 patients. Thus, it was concluded that baseline characteristics and pivotal study outcomes in patients with and without graft interventions were similar, and no important differences were identified.

Among all 37 patients with extended follow-up data, continued vascular access at the end of the extended follow-up period was reported in 29 patients. Graft patency and intervention information are summarized in **Table 12**. Five patients had abandoned grafts and three patients died during the extended follow-up period. The deaths were not related to the device as reported by the sites. One or more additional graft interventions were performed in 13 patients. All interventions were successful and there were no major procedural adverse events reported. There were no reports of migration, kink, compression, or other damage/defect to the implanted Connector.

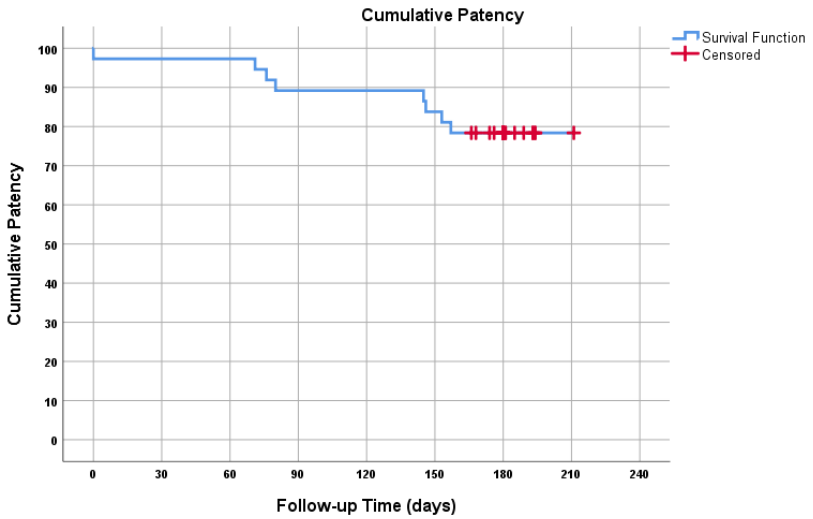
Kaplan-Meier estimate for cumulative patency at 180 days into the extended follow-up period was 78.4% (**Figure 6**). The rate of interventions per patient-year for the extended follow-up period was 1.32. This rate was similar to the rate of 1.22 interventions per patient-year observed for the entire pivotal study cohort (N=158).

Table 12. Extended Follow-up Study: Summary of Graft Interventions and Outcomes (N=37)

Parameter	Value *(Number of subjects, unless otherwise indicated)*
Continued access at end of extended follow-up period	29
Terminal events during extended follow-up period Death	8 3

AVG abandoned	5
Additional AVG interventions to maintain patency, during extended follow-up period 1 intervention 2 interventions ≥ 3 interventions	13 8 3 2
Total # of AVG interventions during extended follow-up *(among all 13 subjects with additional interventions)*	22
Reason(s) for AVG intervention: Thrombosis Poor flow Outflow stenosis Cannulation difficulty Arm swelling Hand/arm pain	 16 1 1 3 2 1
Stenosis identified Stenosis location(s): AVG Edge stent Central vein Outflow vein Inflow artery VIG	22 9 1 6 8 2 8
Intervention success	22
Major procedural complications during AVG interventions	0
Evidence of VIG migration, kinking, compression, fracture or other damage noted during extended follow-up	0
Total AVG interventions, pivotal study PLUS extended follow-up 1 intervention 2 interventions ≥ 3 interventions	 15 10 12

Figure 6.
Kaplan-Meier Estimate of Cumulative Patency in the Extended Follow-up Period



Conclusions From the Extended Follow-up Study
The results of the Extended Follow-up Study demonstrate an acceptable rate of post-intervention patency for patients with a Connector in their vascular access circuit.

Continued Access Study

A Continued Access Study was conducted under **G140221** with similar study methods and data collection to those used in the pivotal study. A total of 12 patients were enrolled. Six-month follow-up was completed in accordance with the protocol.

Acute device success was achieved in all patients. There were no procedural complications. Five subjects completed the study with cumulative patency at six months. Death occurred in two subjects (unrelated to the Connector or AVG implant as reported by the sites) and one other subject was removed early from the study after receiving a kidney transplant. Reasons for AVG abandonment in four subjects included: graft infection (n=1), recurrent thrombosis (n=2), and puncture site hematoma with graft damage (n=1); all reasons were unrelated to the Connector, as determined by the site investigators. Twelve AVG intervention procedures were performed among 5 subjects and all interventions were successful (graft flow restored), with no adverse events. There were no reports of migration, damage, or defect to the implanted Connector.

Overall Conclusions from Clinical Studies

The prospective, multicenter, single-arm pivotal study and the Extended Follow-up Study evaluated the safety and effectiveness of the Connector for venous anastomosis during arteriovenous graft implantation. The primary endpoint of cumulative graft patency at 6 months was met and cumulative patency was 92.08%. Primary unassisted patency was 60.21%. An acceptable safety profile was demonstrated. These data provide reasonable assurance that the Connector is safe and effective when used in accordance with its labeling.

HOW SUPPLIED:

The EndoForce™ System is supplied sterile (by ethylene oxide) and is for single use only. Do not re-use or re-sterilize.

PACKAGE STORAGE AND HANDLING

The EndoForce™ System should be stored in controlled environmental conditions and must be used before the expiration date printed on the label.

To open the package, peel back the tray lid. Using sterile technique, carefully remove the EndoForce™ Connector Delivery System which includes the EndoForce™ Connector, and place in the sterile field. Always use sterile atraumatic instruments when handling the device. Inspect for any damage or defects. Do not use if damage is observed.

DEVICES/MATERIALS REQUIRED BUT NOT SUPPLIED

- 4F micro-puncture access kit (catheter, needle, wire)
- 11F introducer kit, up to 11 cm in length (sheath, dilator and 0.035” wire)
- 0.018” guide wire, flexible, soft-tip, recommended length 150 cm

- sterile stopcocks or flow switches
- ePTFE vascular graft, 6 mm inner diameter
- graft tunneling equipment
- heparinized saline
- radiographic contrast media
- standard surgical supplies

PATIENT SELECTION CONSIDERATIONS

Ensure proper patient selection by venous mapping or other imaging.

Vessel inner diameter at planned venipuncture site

	Minimum diameter (mm)	Maximum diameter (mm)
Outflow vein	4.0	7.0

As with conventional anastomosis of grafts, the EndoForce™ Connector may occlude in patients with the following conditions: insufficient graft arterial inflow; untreated vascular stenosis; coagulability disorders or insufficient anticoagulation medication; kinked graft; or inadequate thrombus removal or stenosis treatment during graft intervention.

In accordance with standard practices, oral anticoagulant medications should be discontinued prior to elective surgery.

PROCEDURAL STEPS:

Graft Preparation and Tunneling

The graft should be prepared and tunneled subcutaneously in accordance with the manufacturer's IFU. Either a straight or looped configuration is acceptable. After tunneling, trim the graft to the planned venipuncture site to accommodate insertion of the 'graft end' of the EndoForce™ Connector, with consideration to the patient's body weight and arm size. To avoid excessive tension at the graft anastomoses, the graft should never be too short.

Preparation of the EndoForce™ Delivery System

1. Attach stopcocks to both Y-Adapters and flush the Delivery System using a syringe with 5 ml heparinized saline. Close the stopcocks.

2. To load the guide wire, open the hemostatic valve on Y-Adapter 1. Back-load the guide wire into the EndoForce™ Connector Delivery System. Close the hemostatic valve on Y-Adapter 1.

Delivery and Deployment of the EndoForce™ Connector Within the Vein

1. Open the 4F micro-puncture access kit. Access the vein using the micro-puncture access needle.

2. Insert the micro-puncture access wire through the needle, then remove the needle.

3. Place the 4F micro-catheter into the vein over the wire.

4. Evaluate the central vasculature with a venogram and treat any hemodynamically significant lesions.

5. Open the 11F introducer kit. Insert the 0.035" guide wire into the 4 F micro-catheter.

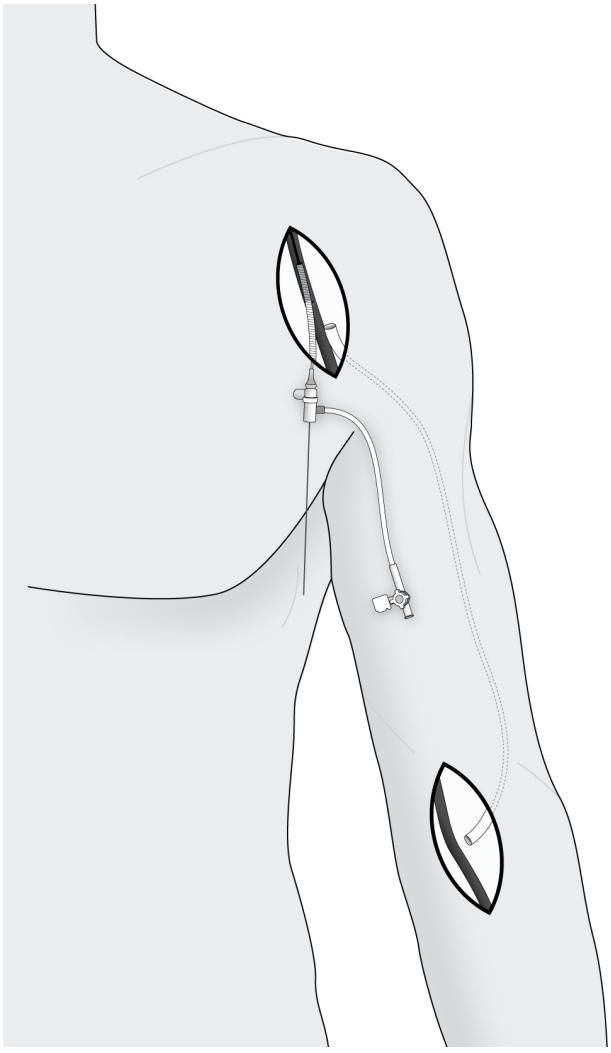
6. Remove the 4Fmicro-catheter if not already removed for central intervention.

7. Place an 11F introducer sheath over the wire (**Figure 7**). If desired, initially place a smaller introducer, then remove and replace with the 11F introducer sheath to expand venipuncture site.

8. Place a radiopaque marker such as a clamp tip at the venipuncture site as a reference point.

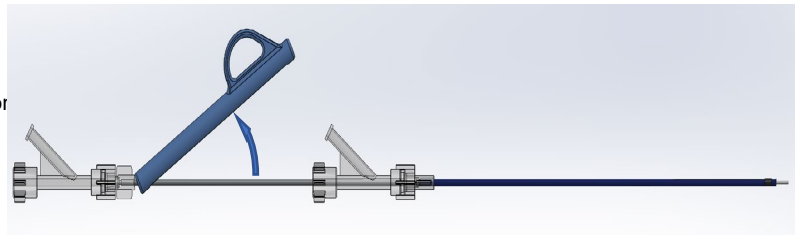
9. Under fluoroscopic guidance, remove the 0.035” wire, introduce an 0.018” guide wire together with EndoForce™ Connector Delivery System into the vein, and advance the wire into the central vasculature.

Figure 7: Tunneling of graft is completed and venous access obtained in preparation for delivery of the EndoForce™ Connector.



10. Remove Handle Lock on the Delivery System (**Figure 8**).

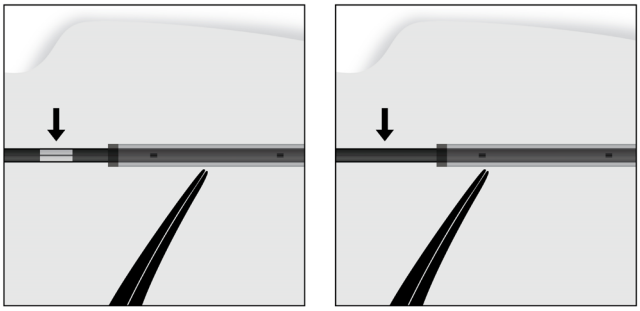
Figure 8: To remove handle lock, grasp at loop and lift (arrow)



11. Open the hemostatic valve in Y-Adapter 2.

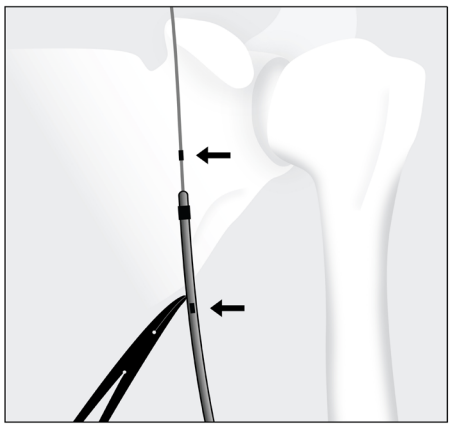
12. Under fluoroscopic guidance, identify the Pusher Rod and advance by pinning Y-Adapter 2 and pushing Y-Adapter 1 toward Y-Adapter 2 until there is no radiolucent gap (**Figure 9**).

Figure 9: Fluoroscopic depiction of EndoForce™ Connector Delivery System delivered over the wire within the vein. Clamp tip marks the venipuncture site where EndoForce™ Connector will exit from the vein upon deployment. LEFT: Gap (space) is identified between Pusher Rod and Connector within Delivery System (arrow). RIGHT: Pusher Rod is advanced to close the gap (arrow).



13. Under fluoroscopic guidance, align Inner Catheter Marker Band 1 and Marker Band 2 so that the venipuncture site lies between the two Inner Catheter Marker Bands (**Figure 10**).

Figure 10: Fluoroscopic depiction of marker band alignment prior to EndoForce™ Connector deployment. Clamp tip marks the venipuncture site. Arrows denote Inner Catheter marker bands.



14. While visualizing Marker Bands 1 and 2 on the Inner Catheter, retract the 11F introducer sheath until it is out of the vein.

15. Under fluoroscopic guidance, use a ‘pin and pull’ technique to pin Y-Adapter 1 and pull Y-Adapter 2 to deploy the EndoForce™ Connector, while keeping Marker Band 1 and the reference venipuncture site marker aligned.

16. Remove the EndoForce™ Connector Delivery System and guide wire together as a single unit.

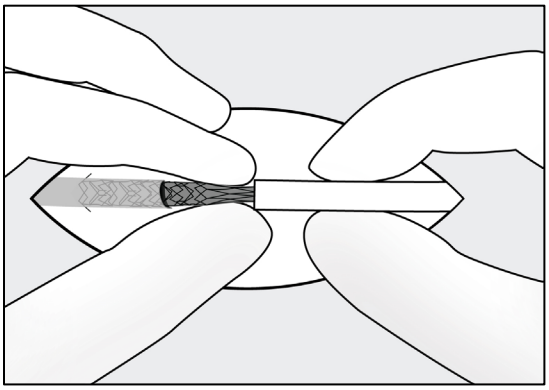
17. Gently grasp with fingertips the extravascular segment of the EndoForce™ Connector as it exits from the vein.

    CAUTION: To avoid possible migration of the EndoForce™ Connector, using fingertips, always secure the Connector segment extending from the venipuncture site after deployment and until placement within the graft is completed.

Placement of EndoForce™ Connector within the Graft

1. Confirm back flow of blood through the EndoForce™ Connector, then gently pinch the end with fingers to minimize bleeding and to facilitate insertion into the graft. While holding the “vein end” of the tunneled graft, insert the ‘graft end’ of the EndoForce™ Connector within the graft so there is at least 3 cm of overlap (**Figure 11**).

Figure 11: Graft-end of EndoForce™ Connector inserted within graft.

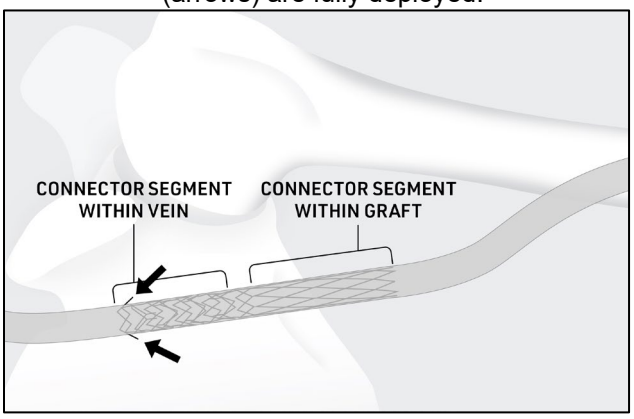


2. The graft should be positioned to be in close proximity to the vein (e.g., within 4mm), minimizing the extravascular exposure of the EndoForce™ Connector.

3. Clamp the graft using an atraumatic clamp to occlude blood flow.

4. To confirm proper positioning of the EndoForce™ Connector, attach a syringe with contrast media to the arterial end of the graft, then remove the graft clamp. Under fluoroscopic guidance, inject contrast media into end of the graft, toward the venous anastomosis. Observe for any bends or kinks, adjust as needed (**Figure 12**). If desired, the EndoForce™ Connector may be smoothed or more fully seated against the vein wall by inflating an angioplasty balloon. The balloon diameter used should be no larger than 6mm when inflated within the EndoForce™ Connector. To avoid possible displacement of the Connector, ensure that the balloon is fully deflated prior to carefully removing the balloon.

Figure 12. Fluoroscopic depiction of completed placement of EndoForce™ Connector within graft.
Imaging confirms that Connector is expanded and sealed against inner wall of graft and vein, and Connector barbs (arrows) are fully deployed.



5. Flush the graft and EndoForce™ Connector with 20 ml of heparinized saline to prevent thrombus formation while the sutured arterial anastomosis is being prepared.

6. Clamp the graft.

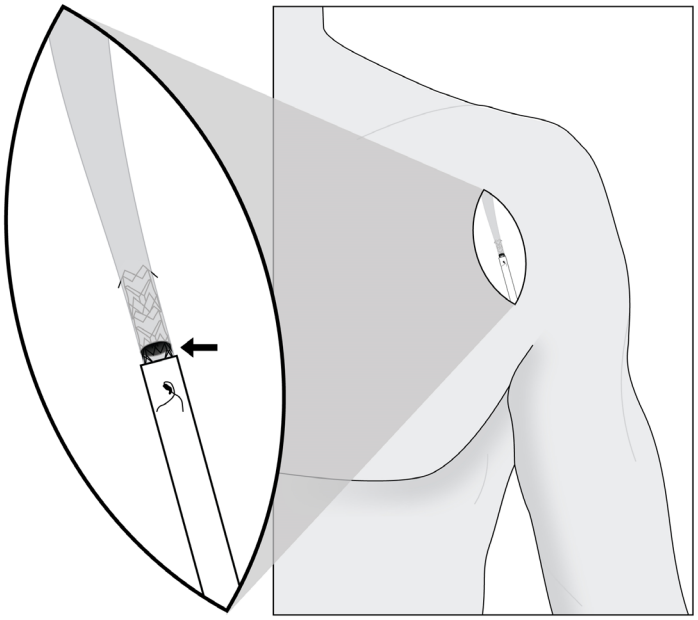
7. Assure that there is adequate hemostasis at the venipuncture site and that the clamped graft lays in an unstressed position before proceeding.

8. Place a tacking suture to further secure the EndoForce™ Connector to the graft (**Figure 13).** The tacking suture (single stitch, 4-0 or thicker) should be placed through a segment of the graft and the EndoForce™ Connector within the graft at least 1 cm peripheral to the venipuncture site (graft edge) but no farther than the penetration of the EndoForce™ Connector into the lumen of the graft. The suture should capture the graft and the nitinol framework of the EndoForce™ Connector.

9. Test the integrity of the tacking suture by pulling on the graft to make sure there is no separation of the graft from the EndoForce™ Connector.

   CAUTION: Failure to confirm the integrity of the tacking suture has resulted in dislodgement of the EndoForce™ Connector from the graft, and serious complications including hemorrhage, hematoma formation, and the need for additional surgical intervention.

Figure 13: Single stitch tacking suture placed to capture graft and nitinol framework of EndoForce™Connector.
Arrow denotes venipuncture.



Sutured Graft Arterial Anastomosis and Completion of Graft Implantation

1. Complete the graft sutured arterial anastomosis using standard methods.

2. Unclamp the graft to allow blood flow. Inspect the graft anastomoses for kinks and to confirm adequacy of hemostasis. Absorbable hemostatic gel or sponge or similar agents may be used to facilitate hemostasis. Position and tuck the EndoForce™ Connector under skin.
3. Confirm blood flow through the graft. An optimal method to confirm blood flow is to assess for a Doppler signal. Auscultation using a sterile or covered stethoscope may also be used.

4. Suture the surgical incision sites using standard methods and taking care to avoid puncturing the EndoForce™ Connector while suturing.

CANNULATION

Cannulation of grafts placed with the EndoForce™ Connector should be performed in accordance with the graft manufacturer's Instructions for Use.

Do not directly cannulate the EndoForce™ Connector.

Do not cannulate the segment of EndoForce™ Connector within the graft.

SURGICAL/ENDOVASCULAR INTERVENTIONS

Similar with sutured hemodialysis grafts, maintenance interventions may also be required in grafts placed using the EndoForce™ Connector. Embolectomy or angioplasty balloons may be used within the EndoForce™ Connector. The balloon size should not exceed 6 mm in diameter when inflated within the EndoForce™ Connector portion in the AVG.

CAUTION: Do not use mechanical-rotational thrombectomy devices with spinning parts in the EndoForce™ Connector, as internal damage may occur.

CAUTION: Avoid balloon over-inflation and/or excessive pulling as this may damage the EndoForce™ Connector.

CAUTION: If surgical excision of an infected graft is required, the EndoForce™ Connector should also be removed. Removal of the EndoForce™ Connector should be completed with surgical excision, manually freeing the barbs from the lumen vein.

PATIENT INFORMATION

Following implantation, the patient should be instructed that the venous anastomosis area should never be cannulated, and that applying pressure that compresses the EndoForce™ Connector should be avoided.

The patient should be provided with a completed Patient Implant Information Card and instructed on the card contents and use.

WARRANTY DISCLAIMER

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TECHNICAL SUPPORT

To obtain technical support or additional information about the EndoForce™ Connector for Endovascular Venous Anastomosis , contact customer service at: customerservice@phraxis.com



Legal Manufacturer:
Phraxis™, Inc.
333 Hennepin Ave E., #1903
Minneapolis, MN 55414
www.phraxis.com

SYMBOLS USED IN LABELING

Rx Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
	Use by/expiration date
	Consult Instructions for Use
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Sterilized using ethylene oxide
	Keep dry
	MR conditional
	Batch code
	Catalog number
	Legal manufacturer
	Packaging unit
	Non-pyrogenic
	Keep away from sunlight

Phraxis™ and EndoForce™ are registered trademarks of Phraxis, Inc. USA and international patents are pending.

PATIENT IMPLANT INFORMATION CARD

Instructions to patients: Carry this card with you. Prior to any treatment in your implanted arm, please show it to all medical personnel caring for you.

Front:

EndoForce™ Connector for Endovascular Venous Anastomosis

Phraxis

IMPLANT CARD

Important Health Information

PATIENT NAME:

Date of Implant: **Implant site** *(check one)*:

Upper arm ☐ LEFT ☐ RIGHT

ENDOFORCE™ CONNECTOR INFORMATION:

Model ID: EFORCE-100 **LOT:** XXXXXX

UDI:

MR **This device is classified as MR conditional. For details of MR compatibility, refer to the product Instructions for Use.**

Manufactured for Phraxis Inc., Minneapolis, MN

customerservice@phraxis.com www.Phraxis.com

Back:

MR

MRI Safety Information

A person with the Phraxis EndoForce Connector may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	EndoForce Connector
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	For 1.5 T MR Scanner: Whole-body SAR ≤ 1.5 W/kg
	For 3.0 T MR Scanner: Whole-body SAR ≤ 1.0 W/kg
Scan Duration	Scan for up to 60 minutes.
Scan Regions	If RF Conditions above are applied, any landmark is acceptable. If Whole-body SAR is limited to ≤ 2.0 W/kg, patient landmark must assure device is at least 35 cm from isocenter.
MR Image Artifact	The presence of this implant may produce an image artifact.