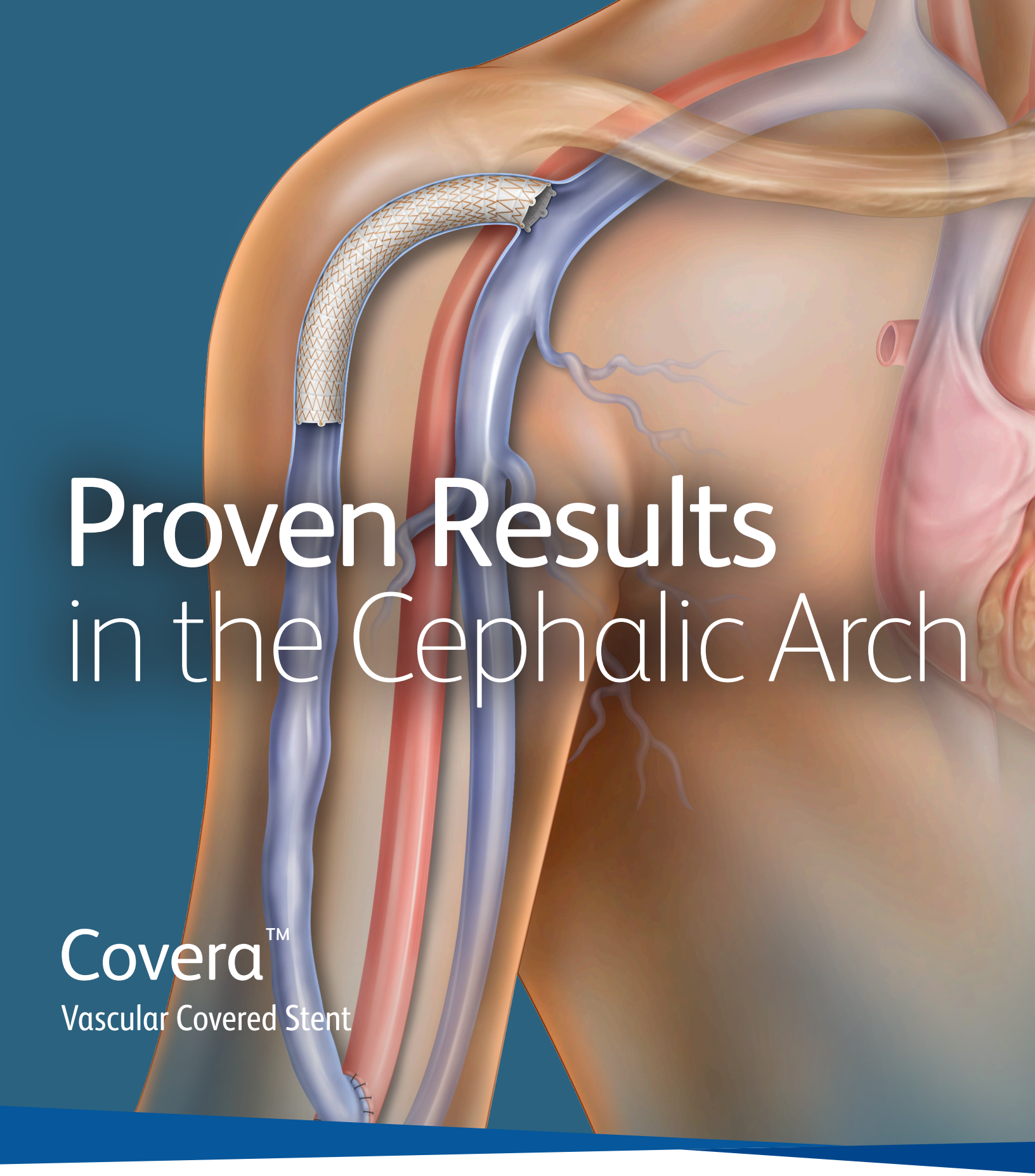


Proven Results in the Cephalic Arch

Covera™

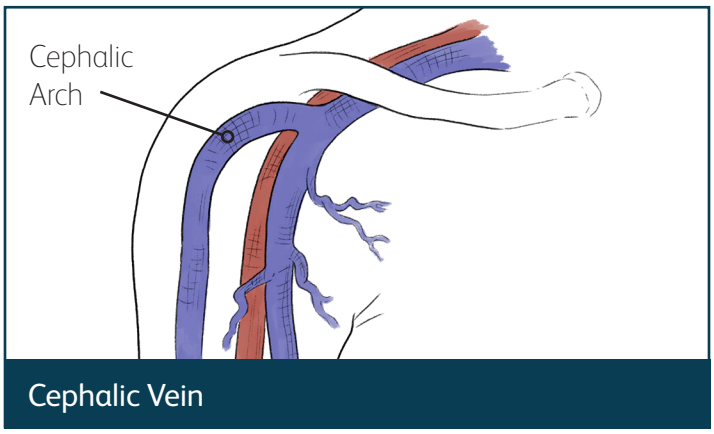
Vascular Covered Stent

BD

The Cephalic Vein Arch

The cephalic vein is the **most frequently used vessel** for patients in need of a native arterio-venous fistula (AVF).

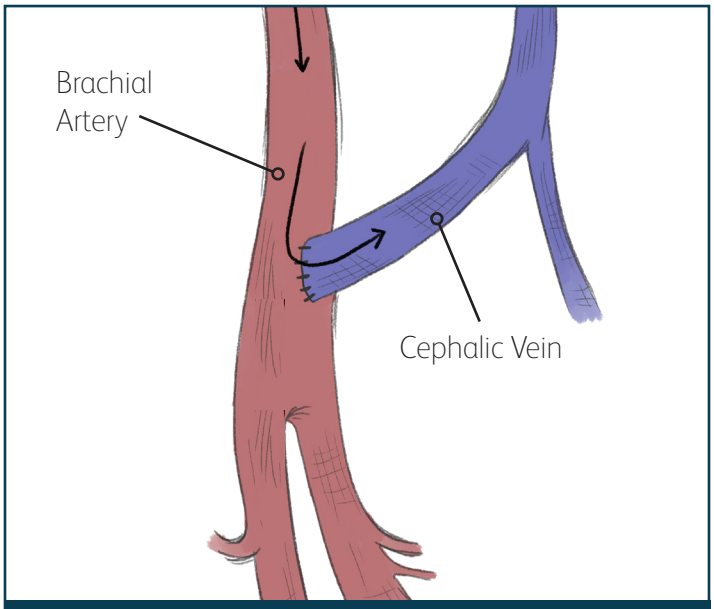
The **cephalic arch proximal to the ostium** is a common area where high restenosis and rupture rates occur due to this site's unique architecture.



Cephalic Vein

Challenges of the Cephalic Arch

- Natural Curvature - limited diametric vein expansion
- Hemodynamic Forces - pressure increase in the venous outflow leading to medial thickening
- "Tenting Effect" - straightening of the cephalic arch at the cephalic-axillary vein junction
- High concentration of valves



Brachiocephalic Fistula

Cephalic Arch Stenosis (CAS)

Cephalic Arch Stenosis (CAS) is a common cause of hemodialysis AVF failure in patients with a functioning brachiocephalic AVF that can lead to:

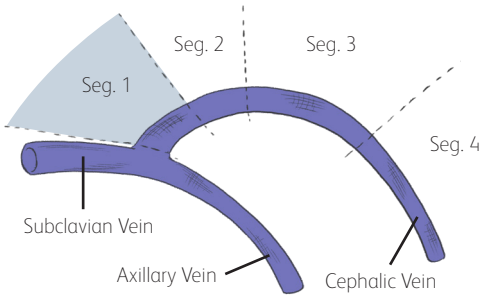
- High venous pressures
- Greater rupture rates, prolonged bleeding after hemodialysis
- Dysfunctional hemodialysis
- AVF thrombosis
- AVF failure

Lesion Location and Treatment

Treatment of lesions in the cephalic arch can differ depending on its location. The cephalic arch is often divided into four segments to determine appropriate treatment when stenosis occurs.

Cephalic Arch Treatment

- Difference in diameter between the inflow and outflow vein:
  - Consider a flared configuration covered stent
- Proximal cephalic arch placement, covered stent length must:
  - Fully cover the ostial lesion so that it does not compromise flow in the axillary / subclavian vein
  - Extend ≥ 10 mm beyond the arch curvature into the straight distal cephalic vein segment



68% of all cephalic arch stenoses studied involved the ostium (seg.1) in some way, while 34% of all lesions occurred only in the ostium or ostial segment (seg.1)[1]

1 In a BD-conducted imaging studies of cephalic arch stenosis treated with a stent or stent graft (N=79), the exact lesion location within the terminal cephalic vein was determined. Data on File. Bard Peripheral Vascular Inc., Tempe AZ

The ONLY Covered Stent Indicated

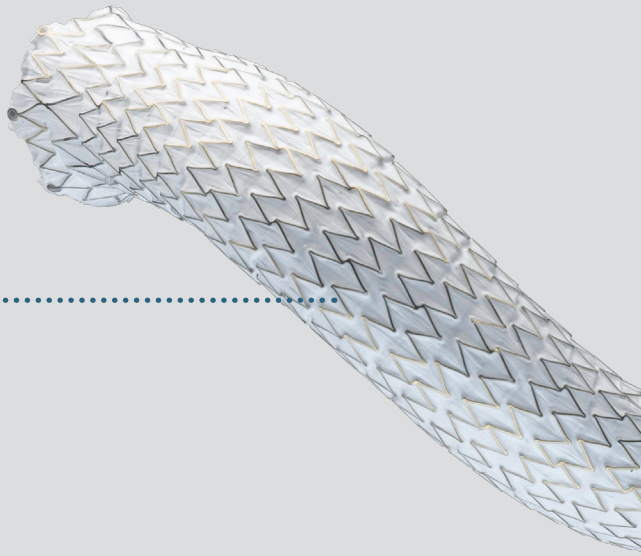
The Covera™ Vascular Covered Stent innovative design builds upon proven technologies from the category leader in AV Access. Designed with a patient-focused mindset, the Covera™ Vascular Covered Stent is engineered to provide a unique balance of attributes to help treat challenging lesions in tortuous vessel segments from the terminal cephalic arch, to the basilic swingpoint segments, to the AV graft venous anastomosis.

Flexibility

Helical design for radial strength and flexibility that offers a unique, flexible base stent architecture designed to conform to native vessel in challenging AV anatomy.

A review by BD of 46 imaging studies determined that the smallest mean curvature of the cephalic arch required without the guidewire in place was 26.9mm.[2]

- The Covera™ Vascular Covered Stent demonstrated a **minimum radius curvature of 15mm** without internal or external support in a 37°C (body temperature) water bath.[3]



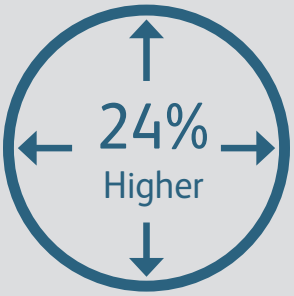
2 In a BD-conducted imaging study to determine cephalic arch inside radius (N=46), the smallest mean radius of curvature required was determined . Data on File. Bard Peripheral Vascular Inc., Tempe AZ

3 Results based on bench testing. Bench testing may not be indicative of clinical performance. Different tests may yield different results. Data on File. Bard Peripheral Vascular Inc., Tempe AZ

Higher Radial Force

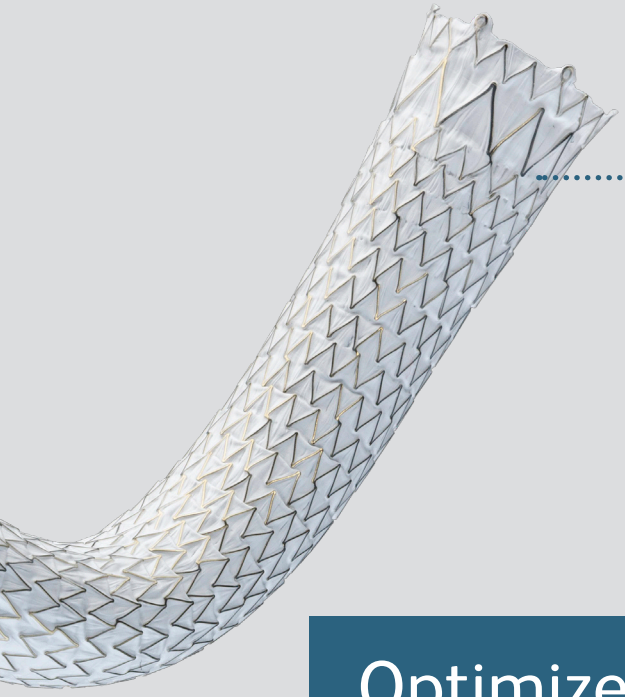
Engineered for flexing, compression, and torsion, with helical struts and angled bridges.

The Covera™ Vascular Covered Stent demonstrated a **24% higher mean radial force** compared to the Gore™ Viabahn™ Endoprosthesis, for use at the venous anastomosis of an ePTFE or other synthetic AV graft.[4]



4 Covera™ Vascular Covered Stent is being compared to the Gore™ Viabahn™ Endoprosthesis on the basis of that each are indicated for the treatment of stenosis in the venous outflow at the venous anastomosis of a synthetic arteriovenous (AV) graft. These products, however, do not otherwise share the same indications for use and their product labels and instructions for use should be consulted for their respective indications, contraindications, hazards, warnings and precautions.
N=13; COVERA™ Vascular Covered Stent implant size 7x60mm; GORE™ Viabahn™ implant size 7x50mm; Test performed at 1mm oversizing, (0.17 N/mm vs. 0.13 N/mm).
Results based on bench testing. Bench testing may not be indicative of clinical performance. Different tests may yield different results. Data on File. Bard Peripheral Vascular Inc., Tempe AZ

for use in dysfunctional AV fistulae.



Flared Ends

The **ONLY** covered stent offered in a **straight and flared** configuration.[3]

The Covera™ Vascular Covered Stent offers an additional 3mm in diameter on the flared configuration stent to:

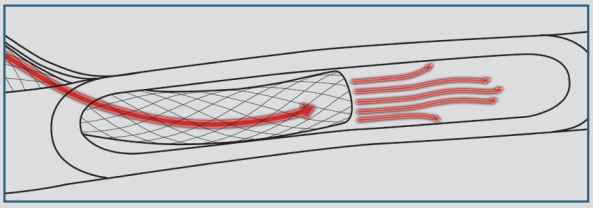
- Support precise sizing and apposition to the vessel wall
- Avoid excessive oversizing when the outflow vein diameter is greater than the inflow diameter

[3] 30 mm lengths available in straight configurations only

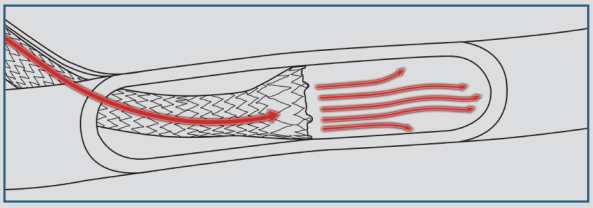
Optimized Hemodynamic Flow

To address the distinct hemodynamics of the AV access circuit post-fistula creation. The Covera™ Vascular Covered Stent is designed to:

- Optimize hemodynamic flow in an AV fistula or AV graft-vein anastomosis
- Help minimize the degree of disturbed flow when the diameter of the outflow vein is greater than the inflow vein



Straight Configuration - Outflow = Inflow



Flared Configuration - Outflow > Inflow

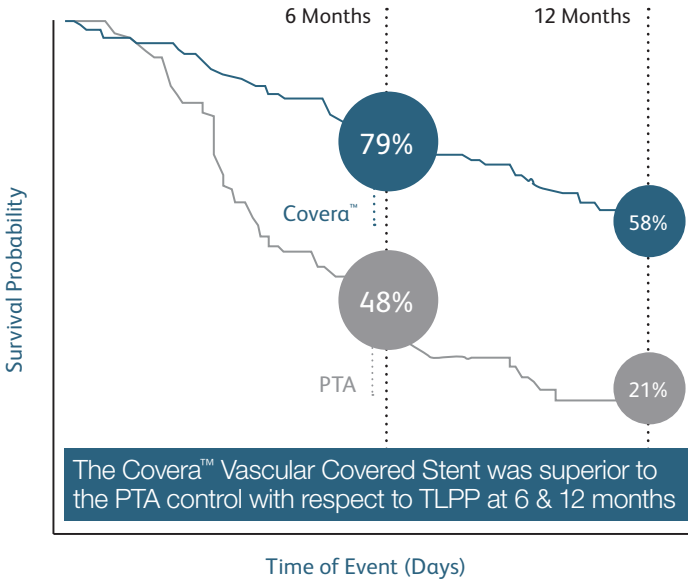
Images are provided for illustrative purposes only. May not be indicative of clinical performance.

AVeNEW Clinical Study

The Covera™ Vascular Covered Stent delivered effective results and demonstrated the benefits of its innovative design in two separate clinical trials. The **AVeVA Clinical trial** for patients dialyzing with AV Grafts and the **AVeNEW Clinical Trial** for patients dialyzing with AV Fistulae.

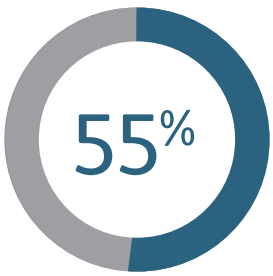
Study Design	Prospective, Multi-Center, Randomized, Concurrently-Controlled
Objective	To assess the safety and effectiveness of the Covera™ Vascular Covered Stent for the treatment of stenotic lesions in the upper extremity venous outflow of the AV Access circuit vs. PTA alone
Number of Subjects/Sites	280 randomized subjects at 24 active investigational sites (US, EU, & ANZ)
Primary Effectiveness Endpoint	Target Lesion Primary Patency TLPP - 6 months
Primary Safety Endpoint	Freedom from any serious protocol-defined safety event(s) involving the AV access circuit through 30 days

MET BOTH PRIMARY END POINTS

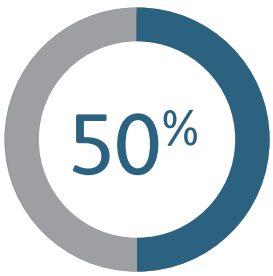


Cephalic Arch Subgroup

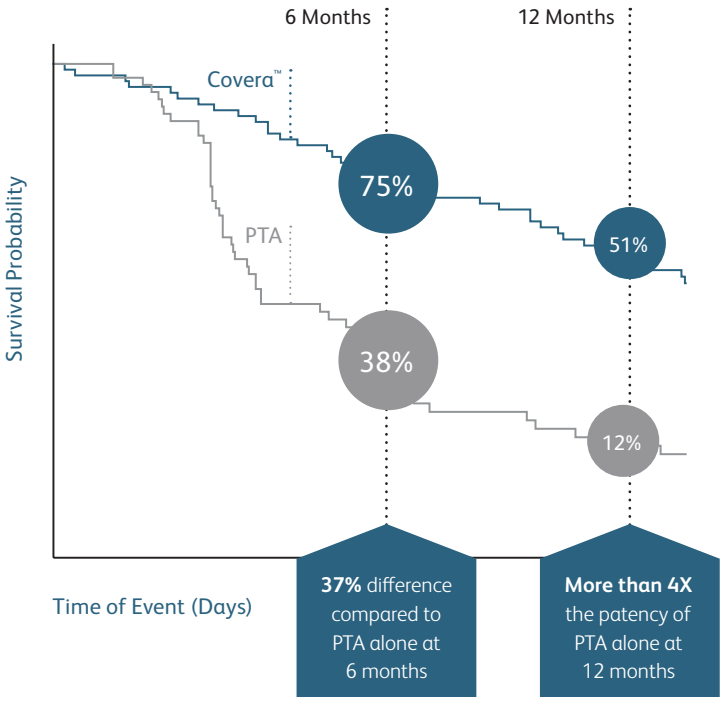
At 6 months, the Covera™ Vascular Covered Stent demonstrated greater TLPP compared to PTA alone in all target lesions treated at the cephalic vein arch.



of stenosis was located in the **cephalic vein arch**
N=78



of Covera™ Vascular Covered Stent placements in the cephalic arch were **flared** configuration



Stent Diamater (mm)	Stent Length (mm)	Sheath Profile	Working Length		
			80 cm		120 cm
			Straight	Flared	Straight
6	30	8F	☐ AVSM06030		☐ AVSL06030
	40	8F	☐ AVSM06040	☐ AVFM06040	☐ AVSL06040
	60	8F	☐ AVSM06060	☐ AVFM06060	☐ AVSL06060
	80	8F	☐ AVSM06080	☐ AVFM06080	☐ AVSL06080
	100	8F	☐ AVSM06100	☐ AVFM06100	☐ AVSL06100
7	30	8F	☐ AVSM07030		☐ AVSL07030
	40	8F	☐ AVSM07040	☐ AVFM07040	☐ AVSL07040
	60	8F	☐ AVSM07060	☐ AVFM07060	☐ AVSL07060
	80	8F	☐ AVSM07080	☐ AVFM07080	☐ AVSL07080
	100	8F	☐ AVSM07100	☐ AVFM07100	☐ AVSL07100
8	30	8F	☐ AVSM08030		☐ AVSL08030
	40	8F	☐ AVSM08040	☐ AVFM08040	☐ AVSL08040
	60	8F	☐ AVSM08060	☐ AVFM08060	☐ AVSL08060
	80	8F	☐ AVSM08080	☐ AVFM08080	☐ AVSL08080
	100	9F	☐ AVSM08100	☐ AVFM08100	☐ AVSL08100
9	30	8F	☐ AVSM09030		☐ AVSL09030
	40	8F	☐ AVSM09040	☐ AVFM09040	☐ AVSL09040
	60	8F	☐ AVSM09060	☐ AVFM09060	☐ AVSL09060
	80	8F	☐ AVSM09080	☐ AVFM09080	☐ AVSL09080
	100	9F	☐ AVSM09100	☐ AVFM09100	☐ AVSL09100
10	30	8F	☐ AVSM10030		☐ AVSL10030
	40	8F	☐ AVSM10040	☐ AVFM10040	☐ AVSL10040
	60	8F	☐ AVSM10060	☐ AVFM10060	☐ AVSL10060
	80	9F	☐ AVSM10080	☐ AVFM10080	☐ AVSL10080
	100	9F	☐ AVSM10100	☐ AVFM10100	☐ AVSL10100

REPRESENTATIVE NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

AVeNEW Clinical Studies data on file. At 6 months in AVeNEW (N = 280), TLPP was 78.7% vs. 47.9% for PTA alone (p-value < 0.001.) TLPP is defined as the interval following the index intervention until the next clinically-driven reintervention at or adjacent to the original treatment site or until the extremity was abandoned for permanent access. In AVeNEW TLPP at 6 Months – Subgroup Analysis is provided as observational data without p-values. In AVeNEW study, patients who received Covera™ Vascular Covered Stent had 103 reinterventions involving a new lesion compared to 72 reinterventions in the PTA only group. At 30 days in AVeNEW, primary safety event rate of 95.0% vs. 96.4% for PTA alone (p-value <0.0022.) Freedom from primary safety events is defined as freedom from any adverse events, localized or systemic, that reasonably suggests the involvement of the AV access circuit (not including stenosis or thrombosis) that require or result in any of the following alone or in combination: additional interventions (including surgery); in-patient hospitalization or prolongation of an existing hospitalization; or death.

Covera™ Vascular Covered Stent
Indication For Use: The Covera™ Vascular Covered Stent is indicated for use in hemodialysis patients for the treatment of stenoses in the venous outflow of an arterio-venous (AV) fistula and at the venous anastomosis of an ePTFE or other synthetic AV graft.

Contraindications: There are no known contraindications for the Covera™ Vascular Covered Stent.

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 revisions and endovascular procedures. • DO NOT expose the covered stent to temperatures higher than 500 °F (260 °C). ePTFE decomposes at elevated temperatures, producing highly toxic decomposition byproducts. • DO NOT use the device if packaging / pouch is damaged. • The Covera™ Vascular Covered Stent device is supplied STERILE and is intended for SINGLE USE ONLY. DO NOT RESTERILIZE AND/OR REUSE this device. • DO NOT use in patients with uncorrectable coagulation disorders. • DO NOT use in patients with bacteremia or septicaemia and/or evidence of fistula or graft infection.• DO NOT use in patients that cannot be adequately premedicated and have a known allergy or sensitivity to contrast media.• DO NOT use in patients with known hypersensitivity to nickel-titanium or tantalum. • DO NOT use in an immature fistula or in patients whose AV Access grafts have been implanted less than 30 days.• DO NOT use the device in patients where full expansion of an appropriately sized PTA balloon catheter could not be achieved during pre-dilation with an angioplasty balloon.• Placing a covered stent across a vessel side branch may impede blood flow and hinder or prevent future procedures. • Covered stent placement beyond the ostium of the cephalic vein into the axillary/subclavian vein may hinder or prevent future access.• DO NOT place a flared covered stent with the flared end in a straight vessel segment since this may lead to flow turbulences. The flared end is not intended to provide additional device fixation.

Precautions: Prior to covered stent implantation refer to the sizing table and read the Instructions for Use. Careful attention should be paid to ensure the device is appropriately sized to the vessel diameter, taking into account any change in the vessel diameter that may have resulted from previous interventions. For an AV graft access, utilize the graft diameter as the reference vessel and for an AV fistula access, utilize the inflow vein diameter as the reference vessel. • The appropriate length device should be selected so that the stent graft extends beyond the stenosis into at least 5 mm of the non-diseased fistula or graft towards the arterial inflow and into the non-diseased vein approximately 5 mm beyond the stenosis. • The delivery system is not intended for any use other than covered stent deployment. • The covered stent (implant) cannot be repositioned after total or partial deployment. • Once partially or fully deployed, the covered stent cannot be retracted or remounted onto the delivery system. Device removal after deployment can only be done with a surgical approach. • If unusual resistance is met during covered stent system introduction, the system should be removed and another covered stent system should be used. • DO NOT introduce, manipulate or remove the delivery system without an appropriately sized guidewire in place and without fluoroscopic guidance. • DO NOT kink or use a kinked delivery system. • During covered stent release DO NOT hold the 30 cm long distal catheter assembly segment as it must be free to move and slide into the white stability sheath. • Careful attention by the operator is warranted to mitigate the potential for distal migration of the covered stent during deployment. • Post dilation of the covered stent must be performed using an appropriately sized PTA balloon catheter to avoid damage to the covered stent. The covered stent cannot be post dilated beyond its labeled diameter. The flared distal end does not require post dilation. • The effect of placing the device across an aneurysm or a pseudo-aneurysm has not been evaluated. • The effect of using the device in central veins has not been evaluated. • The effect of placing the device across a previously placed bare metal stent has not been evaluated. • The effect of placing the device across the antecubital fossa has not been evaluated. • The effect of using the device in pediatrics has not been evaluated.• The effect of using the device across the anastomosis of an AV fistula has not been evaluated.• Vessel angulation was not measured as part of the clinical study, as such limitations in covered stent angulation are unknown. • DO NOT cannulate the covered stent. Notify the patient that the covered stent should not be directly cannulated for hemodialysis and that applying pressure to the implant area should be avoided. • The device has not been tested for use in an overlapped condition with a bare metal stent or covered stent. • Higher deployment force may be encountered with longer length covered stents. • The device has not been tested for tracking and deployment around an AV loop graft. • Serious complications, such as migration to the heart or lungs, may occur post-discharge when covered stents have not been appropriately sized. • Stent graft dislodgement may occur during removal of the delivery system; therefore, careful attention should be paid during this portion of the procedure to prevent such occurrences.

Potential Complications and Adverse Events: Complications and Adverse Events associated with the use of the Covera™ Vascular Covered Stent may include the usual complications associated with endovascular stent and covered stent placement and dialysis shunt revisions. In the clinical study of treatment of stenoses in the venous outflow of an arteriovenous fistula, development of new access circuit lesions has been reported at a higher rate for Covera™ treated subjects compared to PTA treated subjects. Sixty (60) subjects treated with Covera™ Vascular Covered Stent required reinterventions involving new lesions compared to 40 subjects who were treated with PTA alone.

Potential complications may include, but are not limited to: New lesions in the access circuit requiring reintervention, Thrombotic occlusion, restenosis of the target lesion requiring reintervention, pseudoaneurysm, vessel rupture, dissection, extravasation, perforation, pain, infection, hemorrhage, hematoma, arm or hand edema, steal syndrome, congestive heart failure, cerebrovascular accident, allergic reaction, rash, reaction to contrast, fever, sepsis, prolonged bleeding, ventricular fibrillation, face or neck edema, bleeding at access site, numbness, venous spasm, hemoptysis and death.
Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

BD