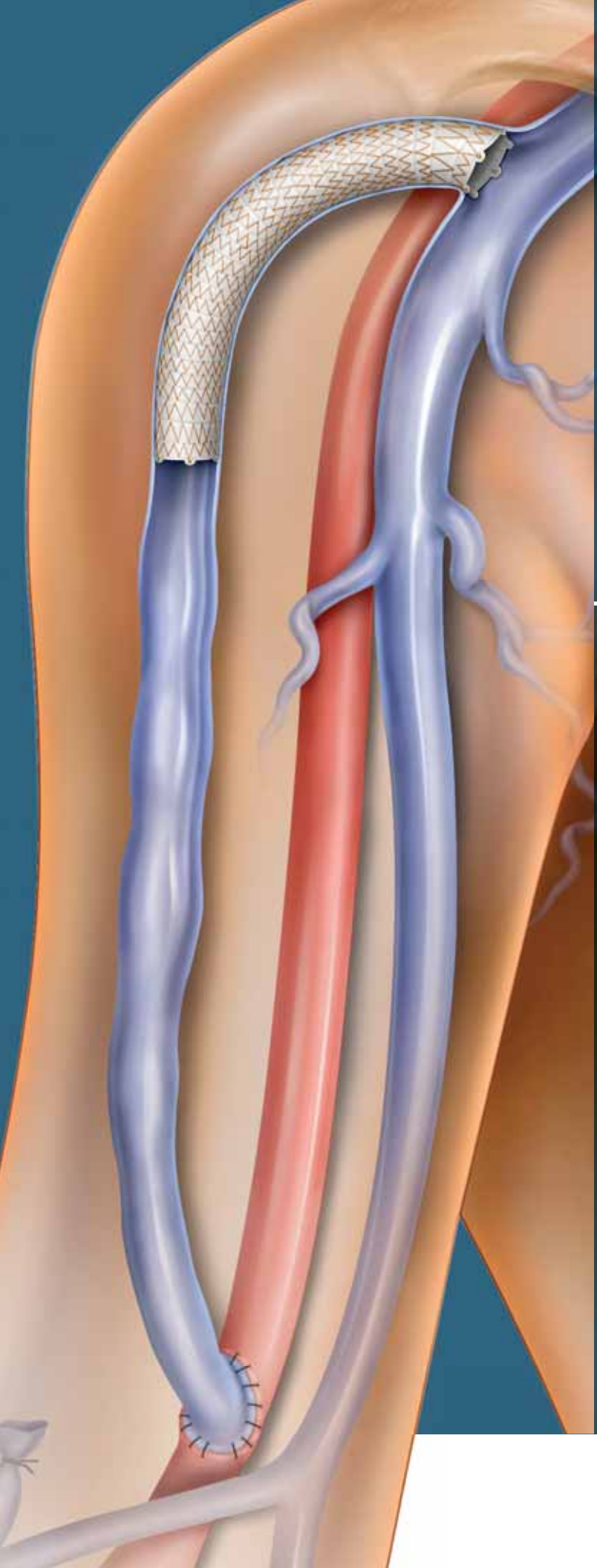


Proven Performance Through Innovative Design[1]

COVERA™

Vascular Covered Stent

BD

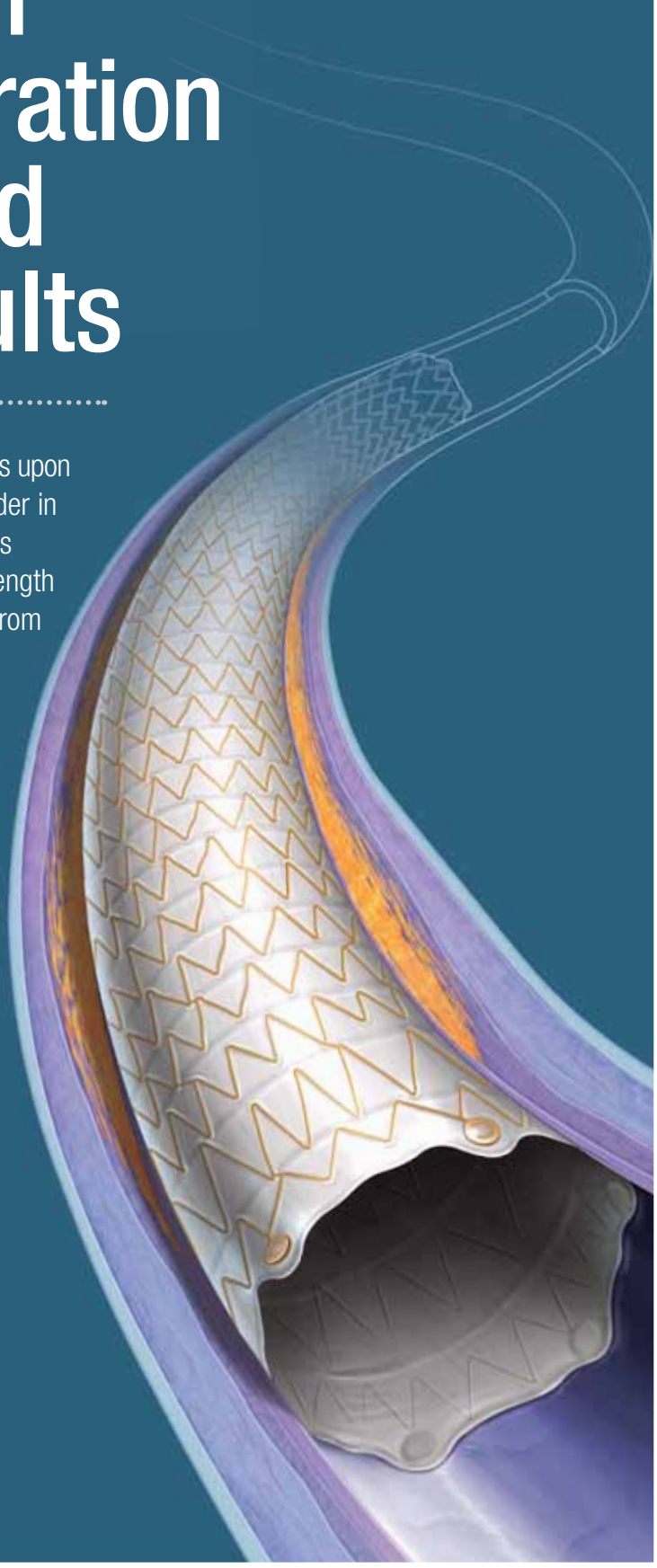
BARD

has joined BD

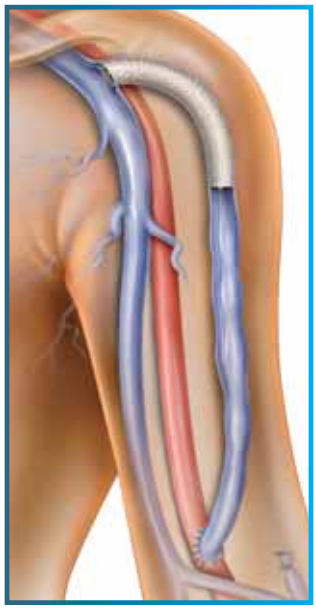
Deliver Our Next Generation AV Covered Stent Results

The COVERA™ Vascular Covered Stent builds upon proven technologies from the category leader in AV Access. This covered stent platform is designed to balance the flexibility and strength required to address challenging lesions from the terminal cephalic arch, to the basilic swingpoint segments, to the AV graft venous anastomosis. Flared and straight configurations allow for precise sizing and adaptation to the vessel wall, while an easy-to-use thumbwheel delivery system with two speed options provides placement control.

The COVERA™ Vascular Covered Stent delivered effective results in two separate clinical trials, one for patients dialyzing with AV grafts and one for patients dialyzing with AV fistulae, both of which demonstrated the benefits of this innovative design.



Improved Patency[1]

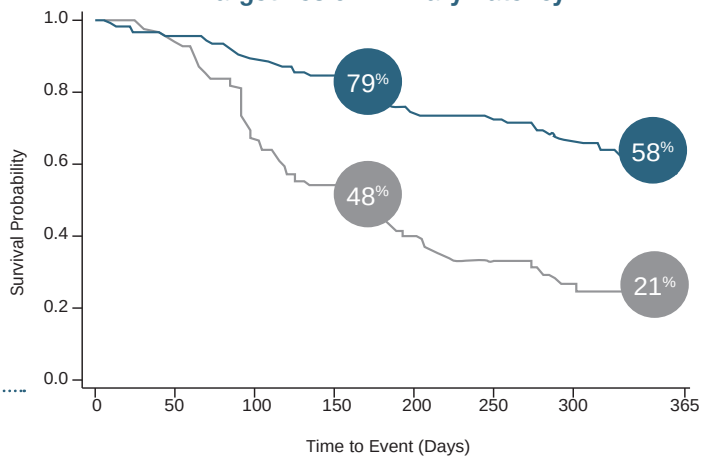


AVeNEW[1]

AVeNEW is a randomized study for the treatment of stenosis in the venous outflow of AV fistulae.

The COVERA™ Vascular Covered Stent was superior to the PTA control with respect to TLPP at 6 & 12 months

Target Lesion Primary Patency[3]



TLPP at 6 Months – Subgroup Analysis

Cephalic Vein Arch

38%

75%

55% of patients treated with the COVERA™ Vascular Covered Stent had a lesion located in the Cephalic Vein Arch.

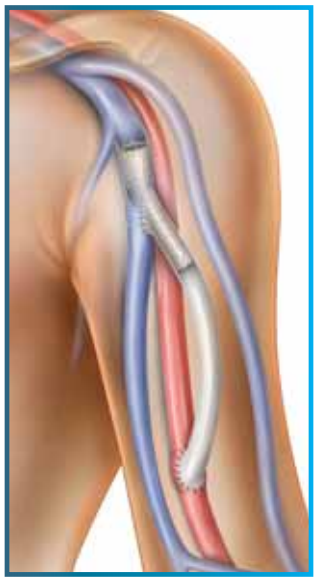
Restenotic Lesions

40%

78%

75% of lesions treated with the COVERA™ Vascular Covered Stent were restenotic.

Key: COVERA™ Vascular Covered Stent PTA



AVeVA[1]

AVeVA studied the treatment of stenoses at the venous anastomosis of AV grafts.

The AVeVA Clinical Study demonstrated that covered stents are effective in the treatment of stenosis at the vein-graft anastomosis.[1]

71% **Target Lesion Primary Patency** through 6 Months[1]

TLPP Summary of BD AV Graft Clinical Trials at 6 Months

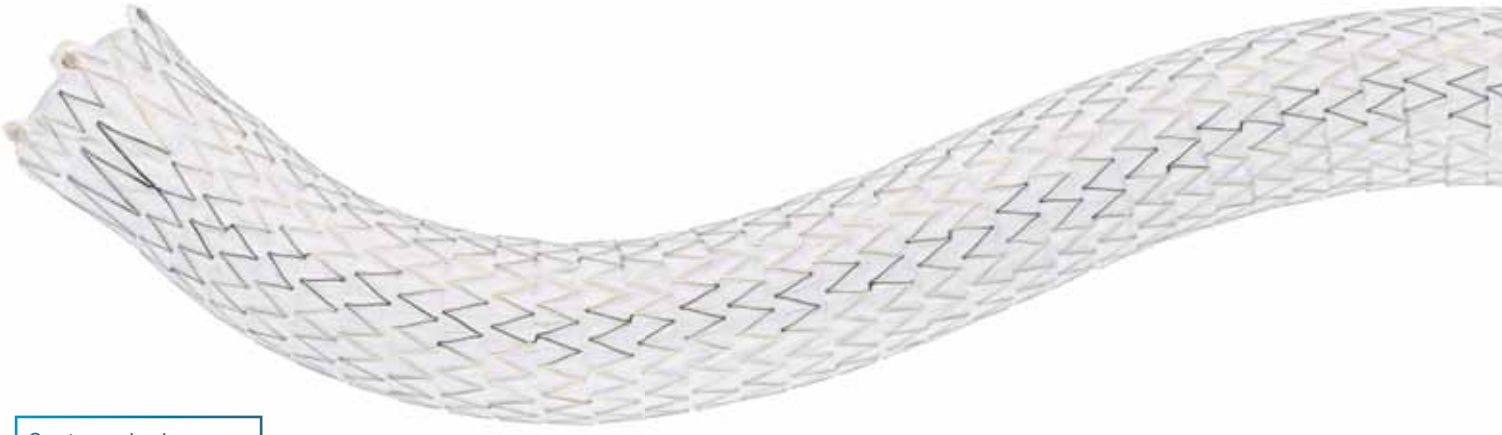
		Study Device		Randomized PTA	
Study	**Device**	**TLPP**	**N**	**TLPP**	**N**
FLAIR[4]	FLAIR® Endovascular Stent Graft	51%	91	23%	86
RENOVA[5]	FLAIR® Endovascular Stent Graft	66%	138	40%	132
AVeVA[1]	**COVERA™ Vascular Covered Stent**	**71%**	**100**	-	-

Note: This chart is for educational purposes only and not for comparison. Differences in study design may impact results.

Innovative Design

Helical Design for Radial Strength and Flexibility

Unique, flexible base stent architecture designed to conform to native vessel in challenging AV anatomy



Contoured edges designed to optimize wall apposition and promote laminar flow

Tantalum markers for enhanced visibility under fluoroscopy

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

Full encapsulation between two ePTFE layers designed to resist neointimal hyperplasia in the treatment area

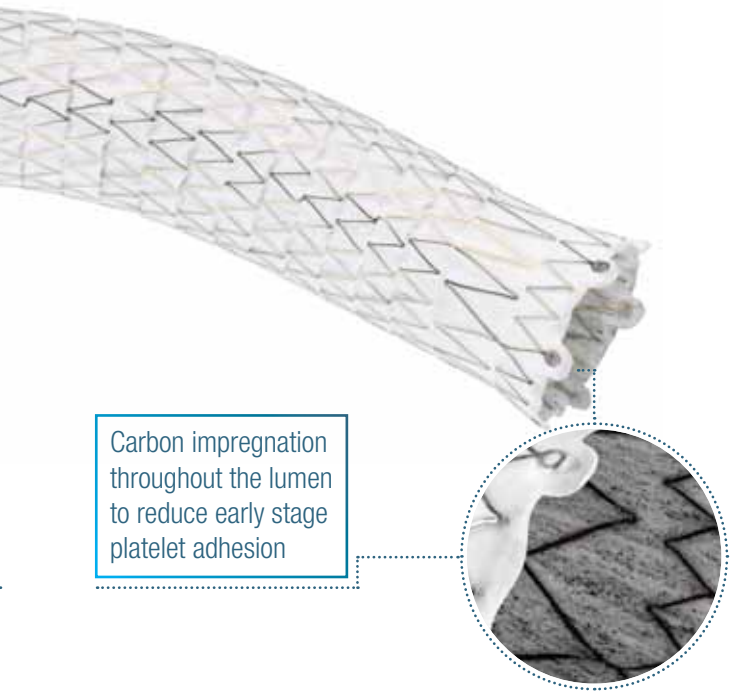
Straight and flared configurations for optimized hemodynamic flow at the venous anastomosis

Atraumatic tip designed to facilitate smooth insertion and removal at the access site

Thumbwheel Delivery

facilitates Accurate Placement Control

Intuitive triaxial delivery system designed for precise placement and to facilitate optimal lesion coverage



Carbon impregnation throughout the lumen to reduce early stage platelet adhesion

Stability sheath for smooth and precise delivery

Dual-speed thumbwheels for operator control

Ergonomic grip for one-handed deployment

Demonstrated effective pushability, trackability, and visibility under fluoroscopy on a low profile delivery system platform in a pre-clinical model[6]

Diameter (mm) \ Length (mm)†	30†	40	60	80	100
6					
7					
8					
9					
10					
				8F	9F

†30 mm lengths available in straight configurations only

COVERA™

Vascular Covered Stent

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

1 AVeVA and AVeNEW Clinical Studies data on file. At 6 months in AVeVA (N=110), target lesion primary patency (TLPP) was 71.4%. 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 AVeVA, primary safety event rate of 96.4% and 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.

2 As of March 2019

3 Based on a Kaplan-Meier analysis of Target Lesion Primary Patency (mITT subjects). Data on File. Bard Peripheral Vascular

4 Haskal et al., N Engl J Med 2010; 362: 494-503

5 Haskal et al., J Vasc Interv Radiol 2016 Aug; 27(8):1105-1114

6 Results based on pre-clinical testing. Pre-clinical testing may not be indicative of clinical performance. Data on File. Bard Peripheral Vascular Inc., Tempe AZ Inc, Tempe AZ.

Differences in study design may impact results.

Reference full manuscript for complete study design details.

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** use in patients with known hypersensitivity to nickel-titanium or tantalum. · Placing a covered stent across a vessel side branch may impede blood flow and hinder or prevent future procedures. · **DO NOT** place a flared covered stent with the flared end in a straight vessel segment since this may lead to flow turbulences. · Covered stent placement beyond the ostium of the cephalic vein into the axillary/subclavian vein may hinder or prevent future access.

Precautions: Prior to covered stent implantation refer to the sizing table and read the Instructions for Use.
· 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. · 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. · 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 effects of direct cannulation of the covered stent have not been evaluated. 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.

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.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

Bard Peripheral Vascular, Inc. | www.bardpv.com |
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BPV/SGF2/0518/0103(1)

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