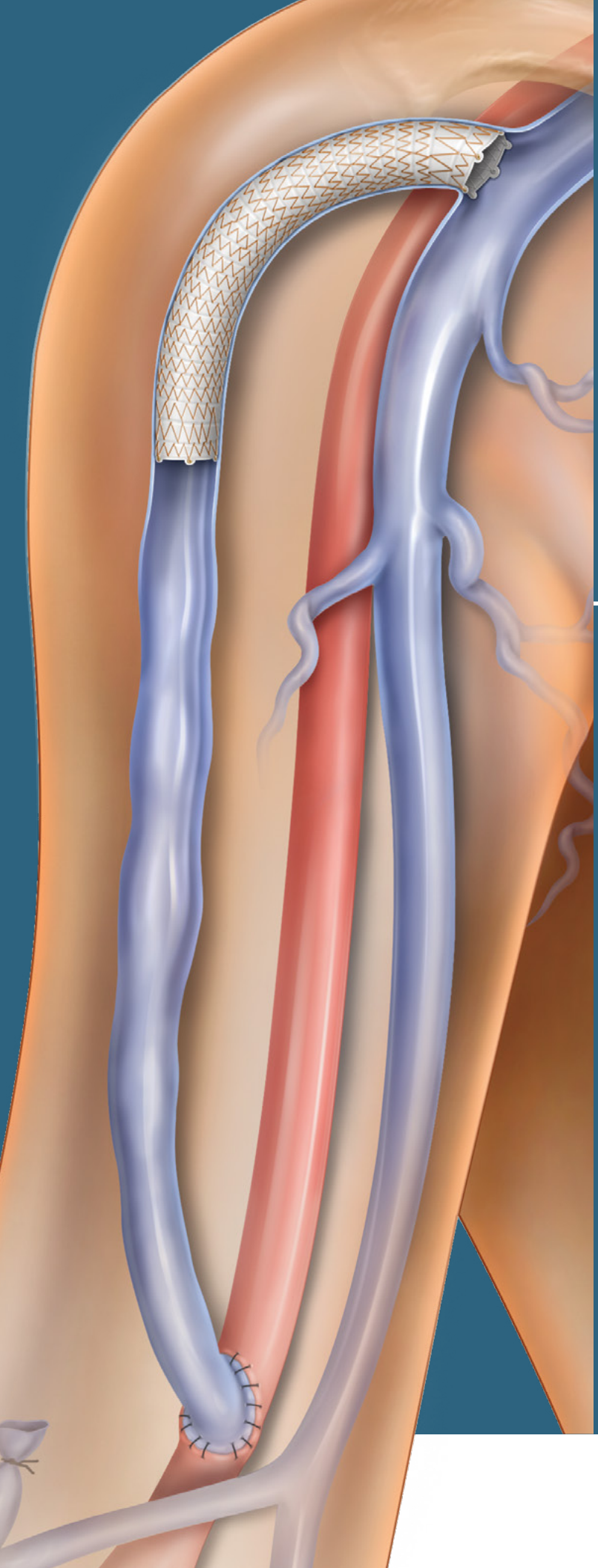


Proven Performance Through Innovative Design[1]

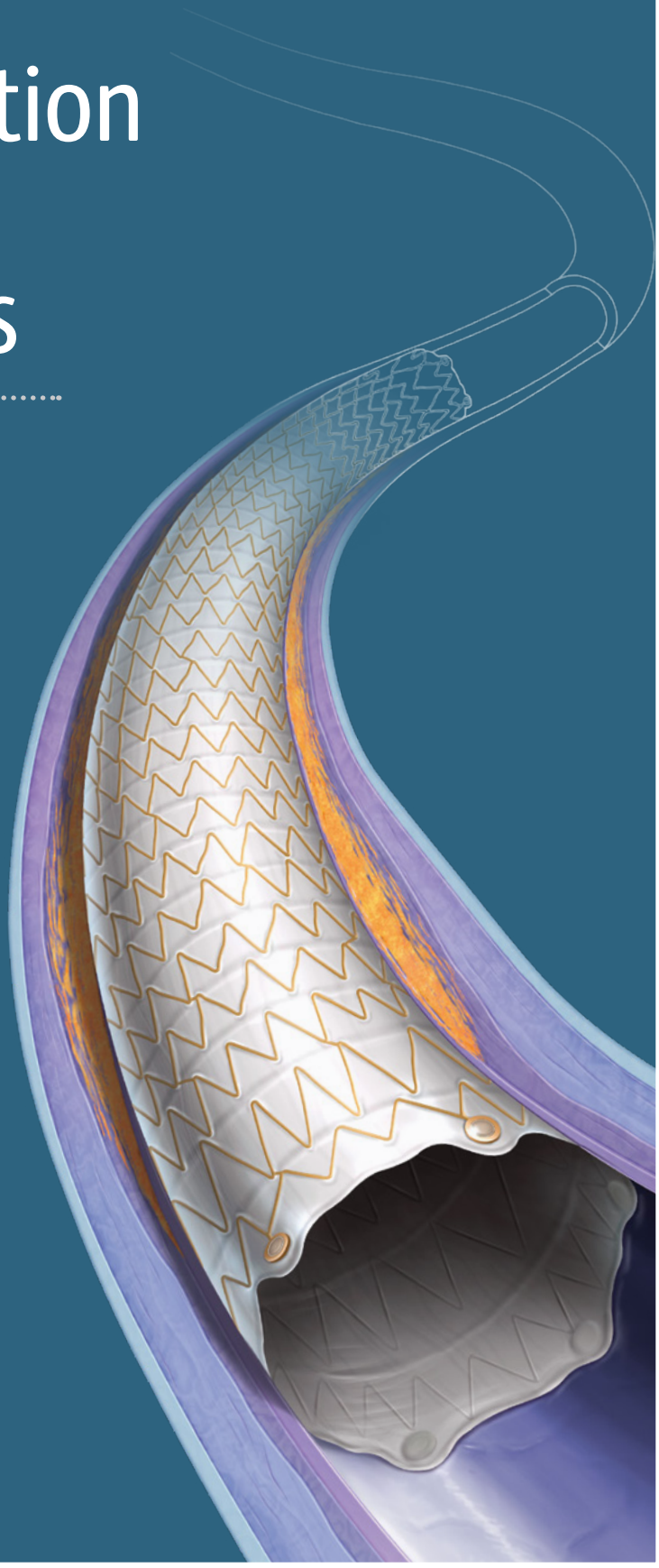
Covera™ Vascular Covered Stent

BD

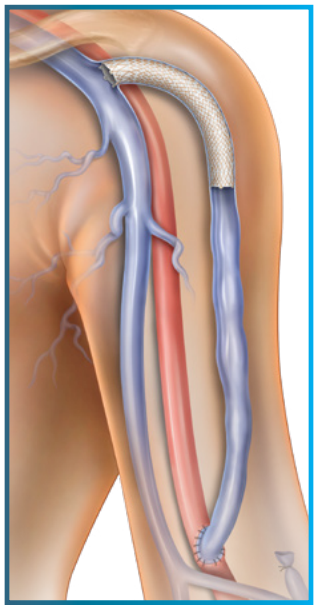
Deliver Our Next Generation AV Covered Stent Results

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]

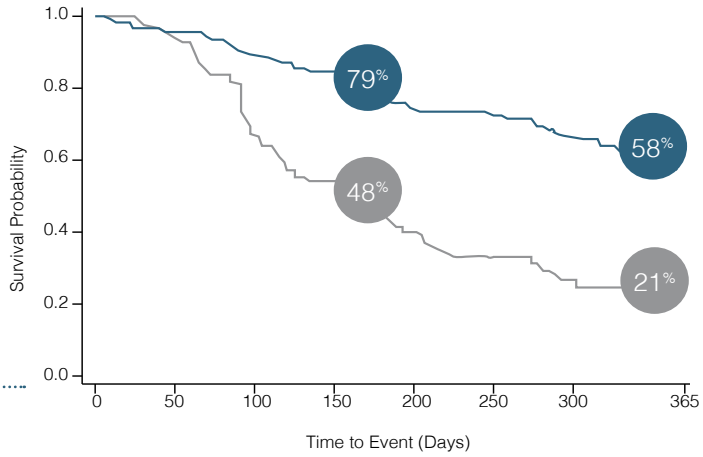


AVeNEW[1]

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.

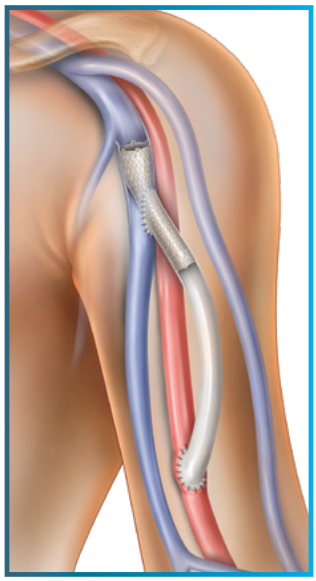
Restenotic Lesions

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

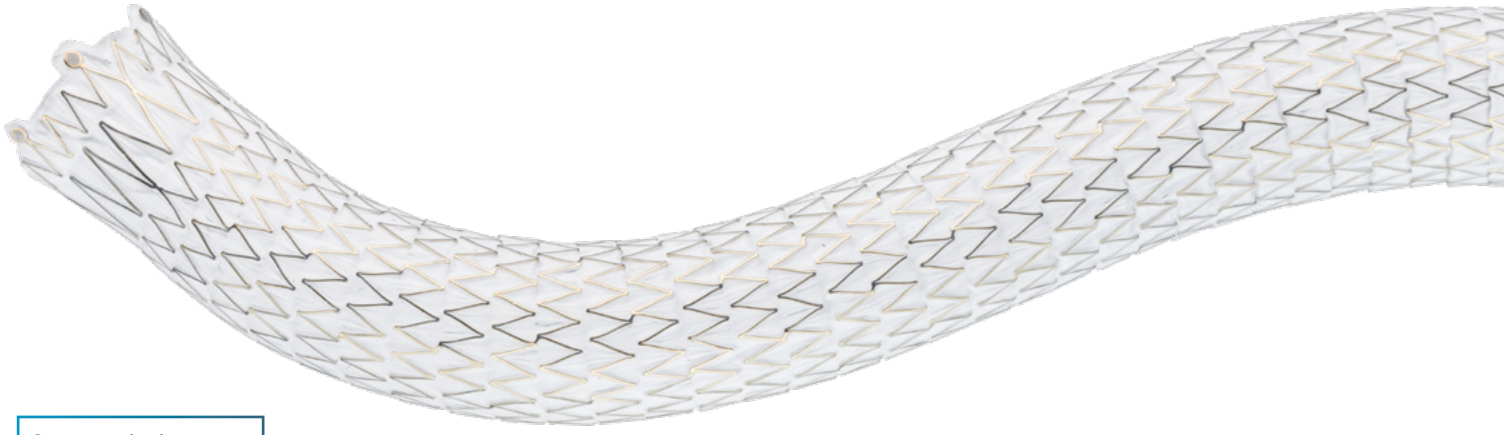
		Study Device		Randomized PTA	
Study	**Device**	**TLPP**	**N**	**TLPP**	**N**
FLAIR[4]	FLAIR® Endovascular Stent Graft	51%	91	23%	86
RENOVA[5]	FLAIR® Endovascular Stent Graft	66%	138	40%	132
AVeVA[1]	**Covera™ Vascular Covered Stent**	**71%**	**100**	-	-

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

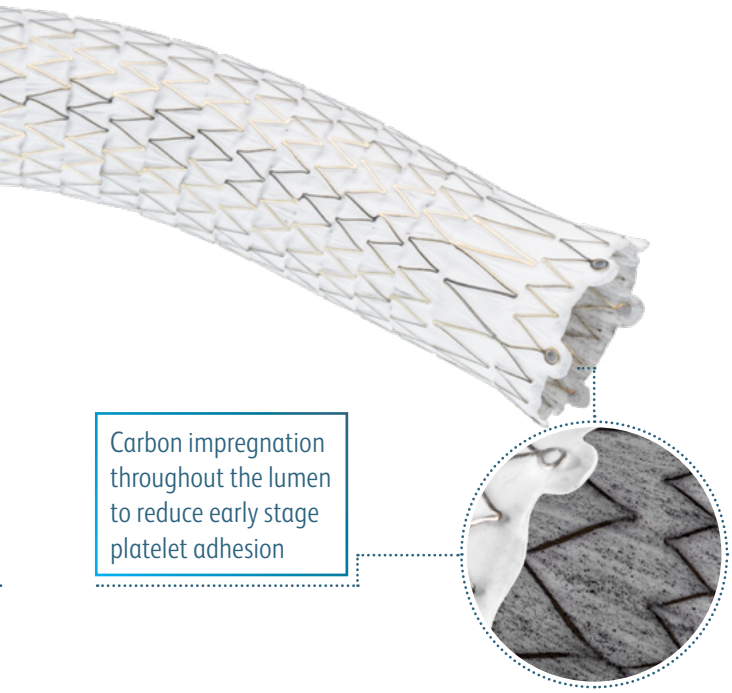
Straight and flared configurations for optimized hemodynamic flow at the venous anastomosis

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



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

Length (mm)†

Diameter (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

Ordering information

Order Code						Implant Diameter (mm)	Implant Length (mm)	Recommended Introducer
Straight System Working Length				Flared System Working Length				
80cm	Alternative Codes 80cm	120cm	Alternative Codes 120cm	80cm	120cm			
AASME06030	AVSME06040		AVSLE06040				30mm	8F
AASME06040	AVSME06040	AASLE06040	AVSLE06040	AVFME06040	AVFLE06040		40mm	8F
AASME06060	AVSME06060	AASLE06060	AVSLE06060	AVFME06060	AVFLE06060	6	60mm	8F
AASME06080	AVSME06080	AASLE06080	AVSLE06080	AVFME06080	AVFLE06080		80mm	8F
AASME06100	AVSME06100	AASLE06100	AVSLE06100	AVFME06100	AVFLE06100		100mm	8F
AASME07030	AVSME07040		AVSLE07040				30mm	8F
AASME07040	AVSME07040	AASLE07040	AVSLE07040	AVFME07040	AVFLE07040		40mm	8F
AASME07060	AVSME07060	AASLE07060	AVSLE07060	AVFME07060	AVFLE07060	7	60mm	8F
AASME07080	AVSME07080	AASLE07080	AVSLE07080	AVFME07080	AVFLE07080		80mm	8F
AASME07100	AVSME07100	AASLE07100	AVSLE07100	AVFME07100	AVFLE07100		100mm	8F
AASME08030	AVSME08040		AVSLE08040				30mm	8F
AASME08040	AVSME08040	AASLE08040	AVSLE08040	AVFME08040	AVFLE08040		40mm	8F
AASME08060	AVSME08060	AASLE08060	AVSLE08060	AVFME08060	AVFLE08060	8	60mm	8F
AASME08080	AVSME08080	AASLE08080	AVSLE08080	AVFME08080	AVFLE08080		80mm	8F
AASME08100	AVSME08100	AASLE08100	AVSLE08100	AVFME08100	AVFLE08100		100mm	9F
AASME09030	AVSME09040		AVSLE09040				30mm	8F
AASME09040	AVSME09040	AASLE09040	AVSLE09040	AVFME09040	AVFLE09040		40mm	8F
AASME09060	AVSME09060	AASLE09060	AVSLE09060	AVFME09060	AVFLE09060	9	60mm	8F
AASME09080	AVSME09080	AASLE09080	AVSLE09080	AVFME09080	AVFLE09080		80mm	8F
AASME09100	AVSME09100	AASLE09100	AVSLE09100	AVFME09100	AVFLE09100		100mm	9F
AASME10030	AVSME10040		AVSLE10040				30mm	8F
AASME10040	AVSME10040	AASLE10040	AVSLE10040	AVFME10040	AVFLE10040		40mm	8F
AASME10060	AVSME10060	AASLE10060	AVSLE10060	AVFME10060	AVFLE10060	10	60mm	8F
AASME10080	AVSME10080	AASLE10080	AVSLE10080	AVFME10080	AVFLE10080		80mm	9F
AASME10100	AVSME10100	AASLE10100	AVSLE10100	AVFME10100	AVFLE10100		100mm	9F

0.035" guidewire compatible

Units per case: 1

Covera™ Plus Vascular Covered Stent

INDICATION FOR USE: The Covera™ Plus Vascular Covered Stent is indicated for the treatment of stenoses in the upper extremity venous outflow of patients dialyzing with an arterio-venous (AV) access graft or fistula and for the treatment of atherosclerotic lesions in iliac and femoral arteries with a reference vessel diameter of 4.5 mm to 9 mm.

CONTRAINDICATIONS: There are no known contraindications for the Covera™ Plus 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 680 °F (360 °C). ePTFE decomposes at elevated temperatures, producing highly toxic decomposition byproducts. • DO NOT use the device if packaging/pouch is damaged. • DO NOT use the device after the "Use By" date specified on the label. • The Covera™ Plus Vascular Covered Stent device is supplied STERILE and is intended for SINGLE USE ONLY. DO NOT RESTERILIZE AND/OR REUSE the device. Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death. • DO NOT use in patients with uncorrectable coagulation disorders. • DO NOT use in patients that cannot be adequately pre-medicated. • DO NOT use in patients who 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 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. • DO NOT use in patients who cannot receive recommended antiplatelet and/or anticoagulation therapy. • DO NOT use in patients with functionally relevant arterial obstruction of the inflow path, poor outflow or no distal runoff. • DO NOT place in patients with a target lesion with a large amount of adjacent acute or subacute thrombus. • Placing a covered stent across a vessel side branch may impede blood flow and hinder or prevent future procedures. • DO NOT use for the treatment of lesions that would prevent a surgical salvage bypass procedure. • DO NOT track and deploy the 9F endovascular system across the aorto-iliac bifurcation in crossover fashion since this may result in failure to deploy the covered stent. • The long-term outcomes following repeat dilatation of endothelialized covered stents are unknown. Specific AV Access related warnings • The device has not been tested for tracking and deployment around an AV loop graft. • DO NOT use in patients whose AV access grafts have been implanted for less than 30 days or in an immature fistula. • Covered stent placement beyond the ostium of the cephalic vein into the axillary/subclavian vein may hinder or prevent future access. • DO NOT use in patients with bacteremia or septicaemia and/or evidence of fistula or graft infection.

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: • 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 the sterile packaging has been damaged or unintentionally opened prior to use. • DO NOT use the device after the "Use By" date specified on the label. The Covera™ Vascular Covered Stent device is supplied STERILE (by ethylene oxide) and is intended for SINGLE USE ONLY. • DO NOT RESTERILIZE AND/OR REUSE the device. Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death. • DO NOT use in patients with uncorrectable coagulation disorders. • DO NOT use in patients with bacteremia or septicemia and/or evidence of fistula or graft infection. • DO NOT use in patients that cannot be adequately pre-medicated. • DO NOT use in patients who 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 patients whose AV access grafts have been implanted less than 30 days or in an immature fistula. • 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 device has not been tested for tracking and deployment around an AV loop graft.

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