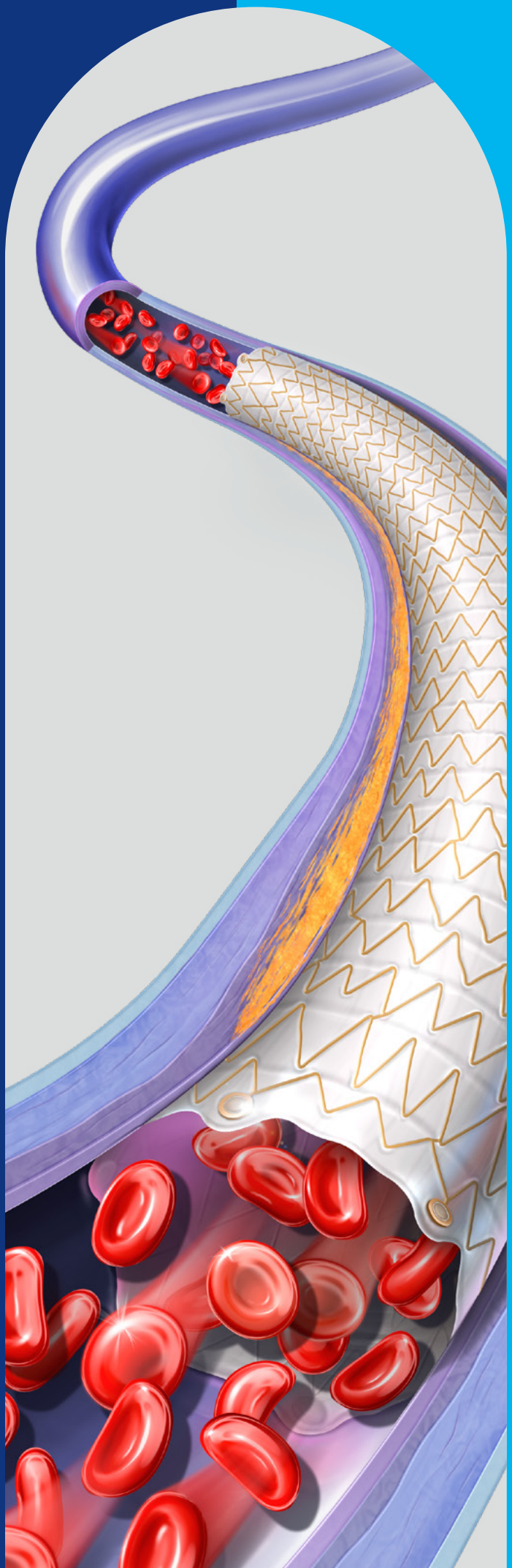
A wide range of ePTFE covered stents designed to enhance your treatment options

Expand your treatment options with the Covera™ Vascular Covered Stent & Covera™ Plus Vascular Covered Stent Family to include stenosis in the arteriovenous outflow and atherosclerotic lesions in iliac and femoral arteries, with a single ePTFE Covered Stent design.

Covera™ Vascular Covered Stent

Covera™ Plus Vascular Covered Stent

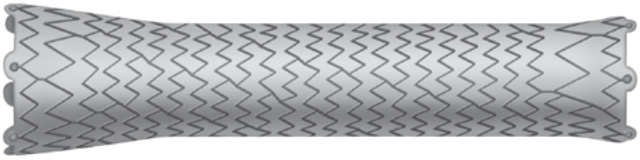


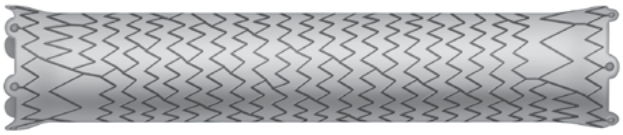
BD

Covera™ Vascular Covered Stent
Covera™ Plus Vascular Covered Stent

The Covera™ Vascular Covered Stent and Covera™ Plus Vascular Covered Stent family builds upon proven, highly flexible stent architecture designed for tortuous anatomy, challenging fatigue conditions, and adaptation to the venous vessel wall with a flared configuration.

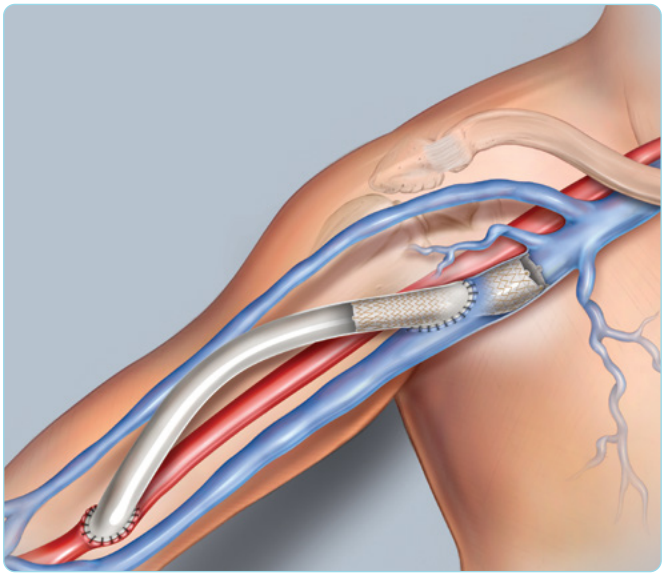
Covera™ Vascular Covered Stent + Covera™ Plus Vascular Covered Stent

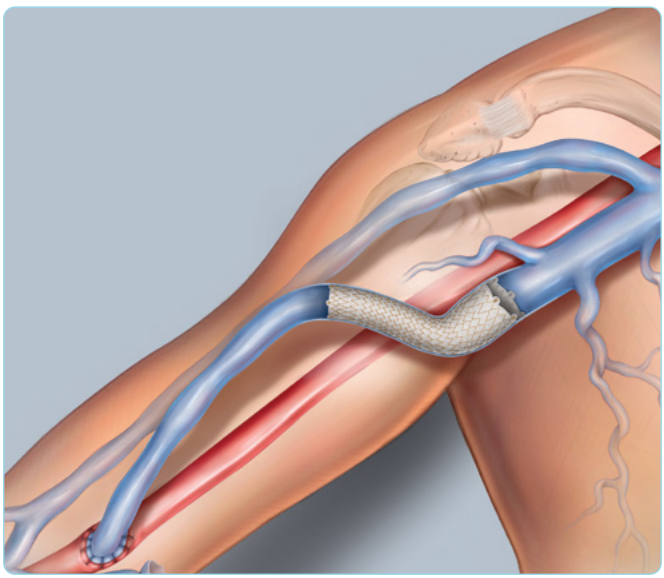


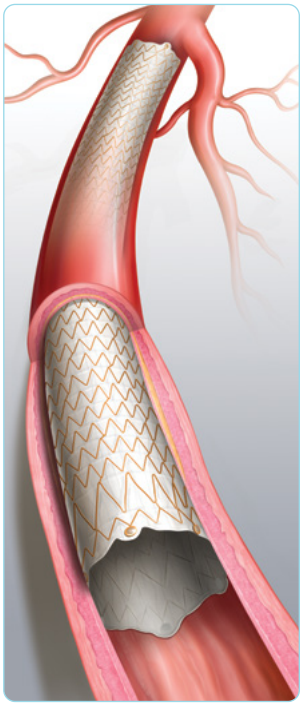


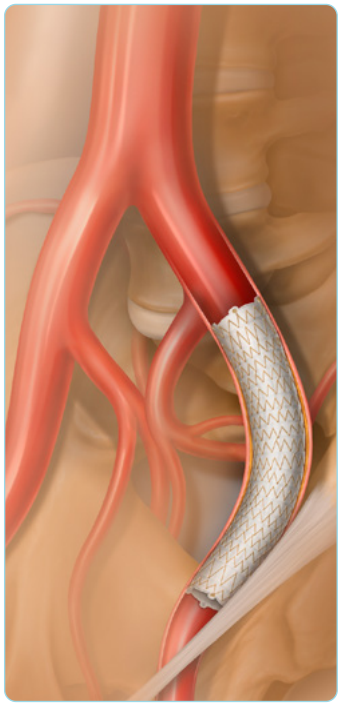
Flared covered stent design for optimal adaptation to diameter differences in the outflow vein of patients dialyzing with a synthetic AV graft or a native arteriovenous fistula.

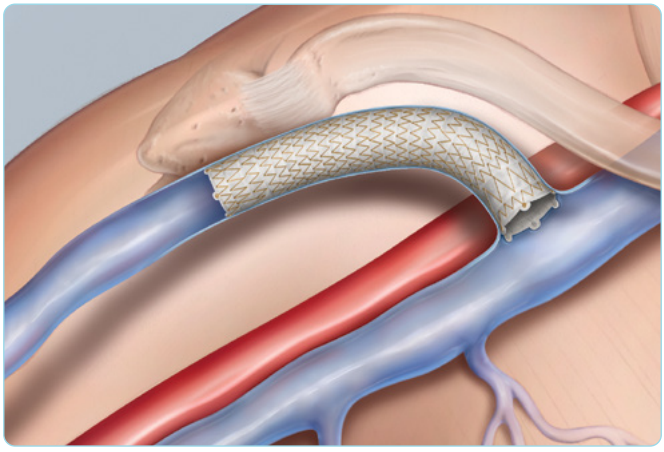
Straight covered stent design indicated for the treatment of stenosis in uniform outflow veins of hemodialysis patients as well as in atherosclerotic lesions in iliac and femoral arteries.









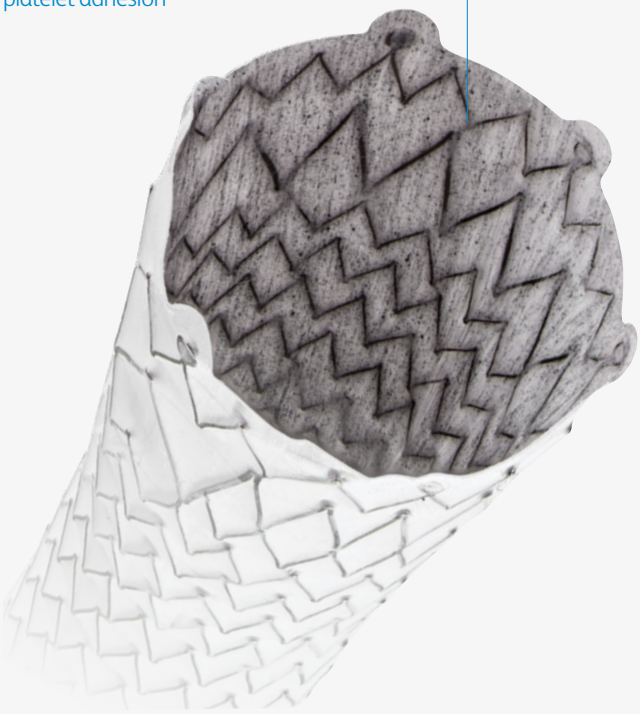


Protection

A proprietary dual-layer ePTFE encapsulation with Carbon impregnation on the luminal surface.

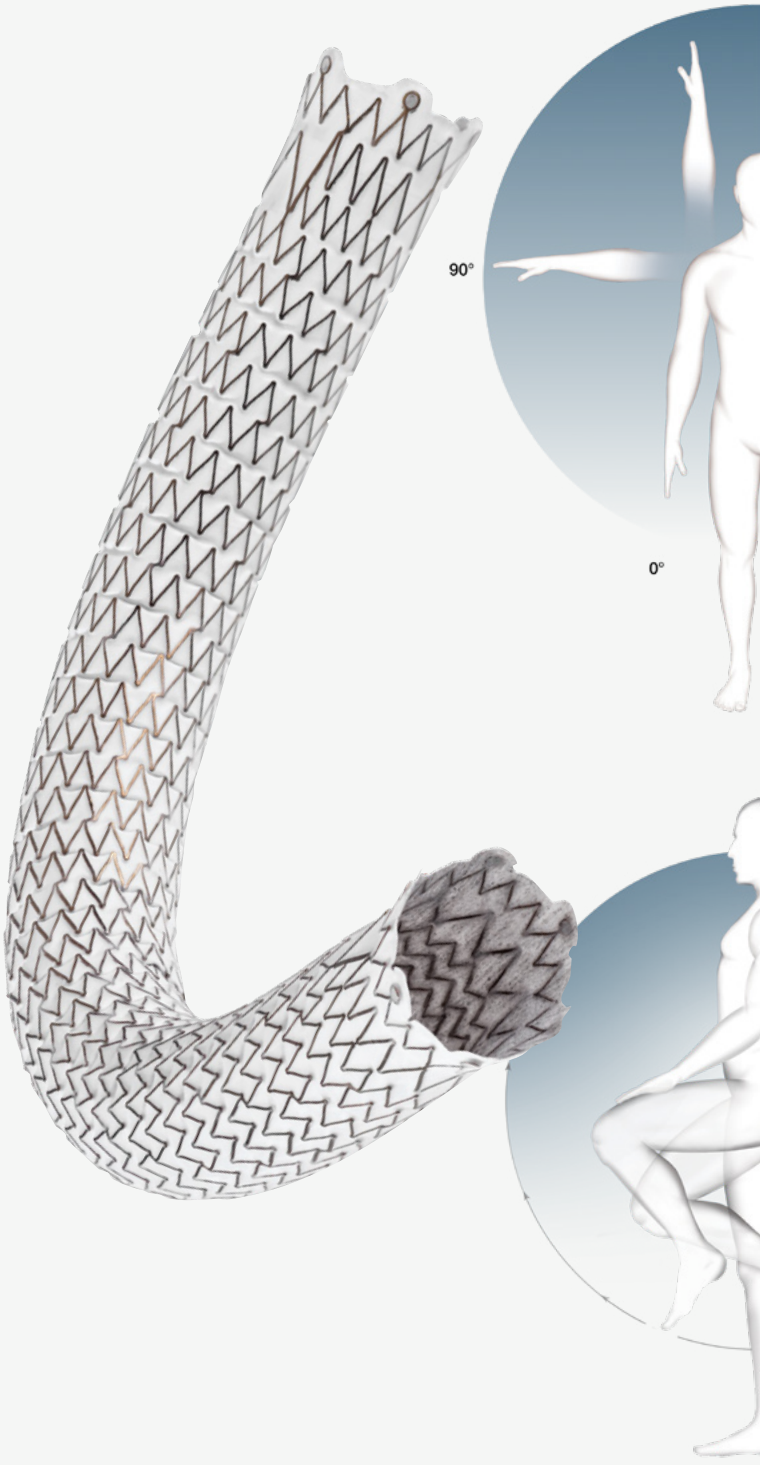
A proven ePTFE design and manufacturing process provides a barrier between bloodstream and endothelial lining to reduce the risk of intimal hyperplasia

Proprietary bioactive carbon impregnation designed to decrease early stage platelet adhesion



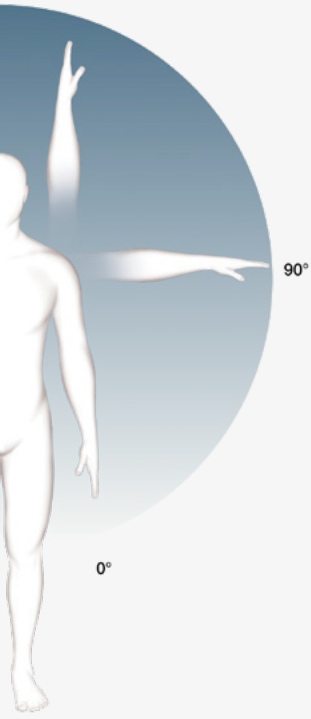
Flexibility

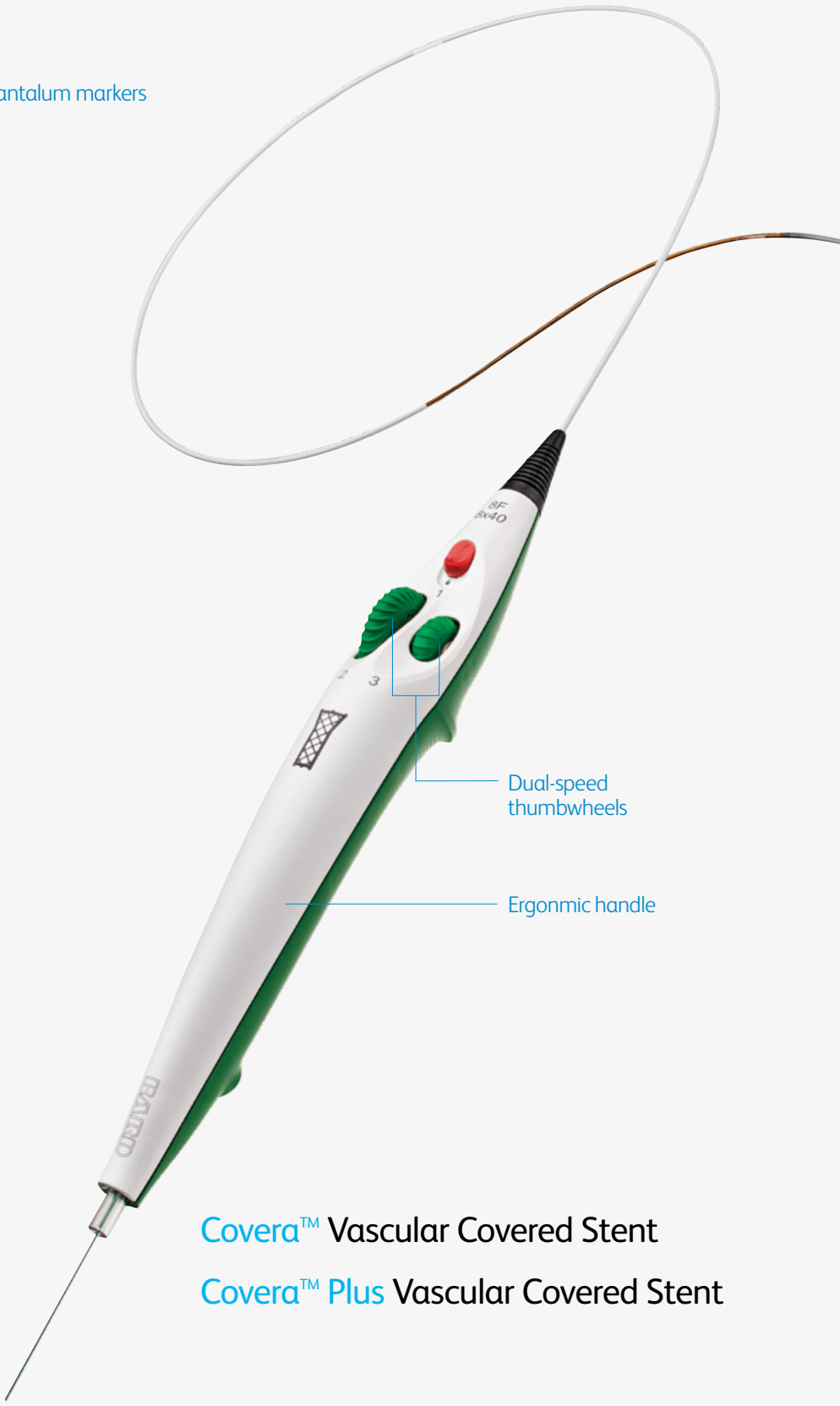
The highly flexible and fracture resistant base stent architecture is designed for tortous anatomical segments like the cephalic arch and the SFA.



Placement Control

A triaxial delivery system with two speed options, in combination with minimal implant foreshortening during deployment and highly radiopaque Tantalum markers at the covered stent ends contribute to placement control and accuracy.



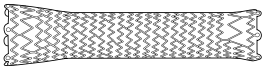


Covera™ Vascular Covered Stent

Covera™ Plus Vascular Covered Stent

Covera™ Vascular Covered Stent + Covera™ Plus Vascular Covered Stent

Indicated for peripheral AV outflow and iliac and femoral arteries



Indicated for peripheral AV outflow

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

Note: Covera™ Vascular Covered Stent and Covera™ Plus Vascular Covered Stent Systems are compatible with 0.035 inch guidewires

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.

BD Switzerland Sarl, Route de Crassier 17, Business Park Terre Bonne, Batiment A4, 1262 Eysins Switzerland, Tel: +41 21 556 30 00. Fax: +41 44 722 5370

bd.com