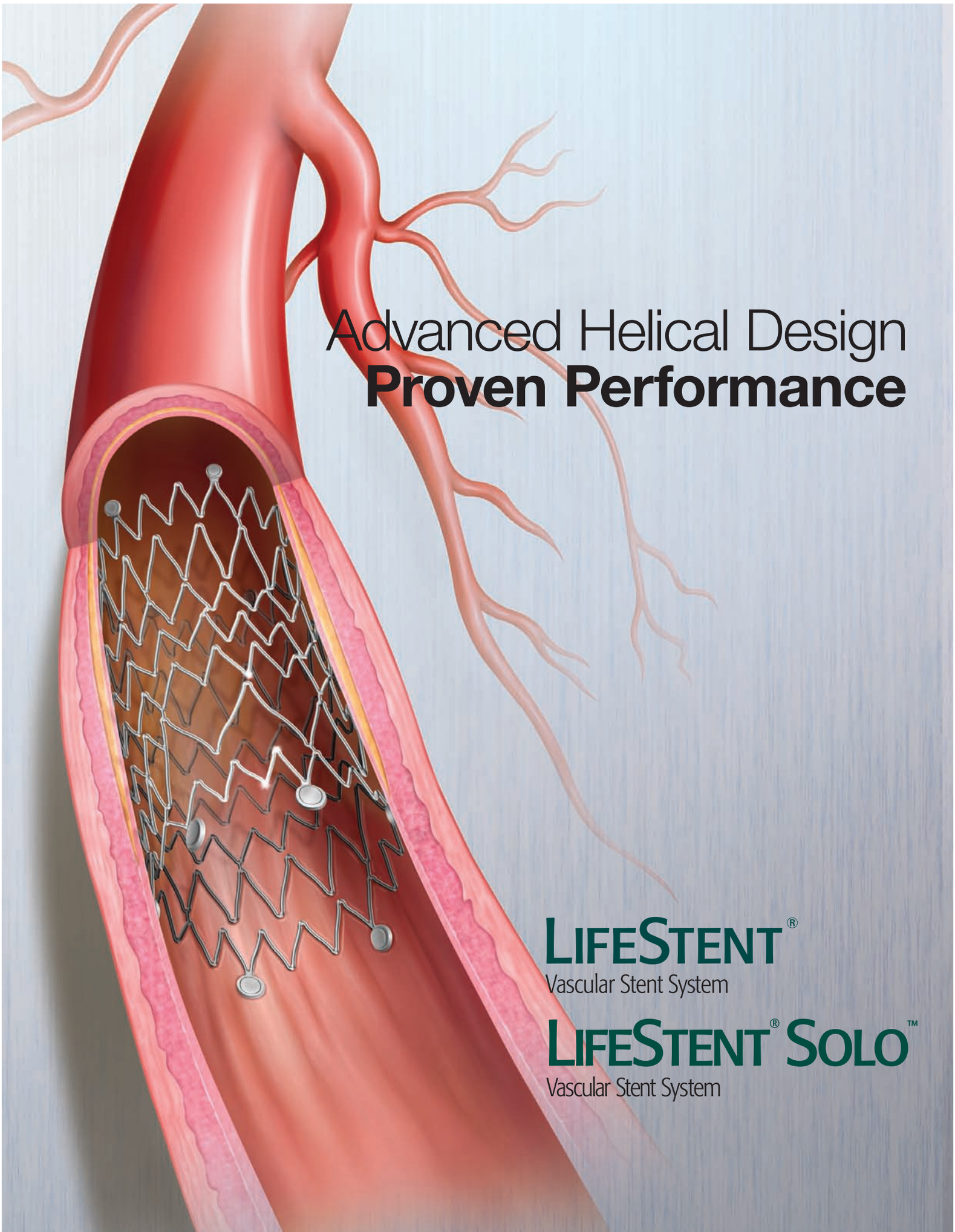


Advanced Helical Design
Proven Performance

LIFESTENT®
Vascular Stent System

LIFESTENT® SOLO™
Vascular Stent System

Advancing Lives and the Delivery of Health Care™

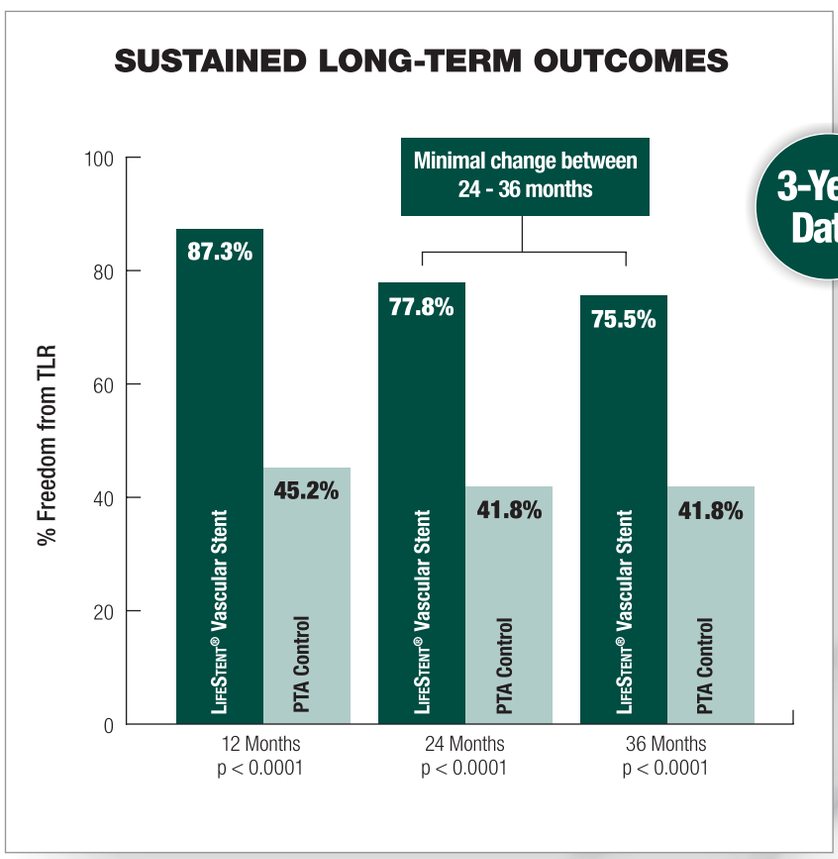
BD BARD has joined BD

LIFESTENT® Vascular Stent Systems & THE RESILIENT TRIAL

lasting RESULTS OVER THE LONG-TERM

Sustained **effectiveness up to 3 years**

Maintained primary stent treatment **superiority over PTA**



Data based on The RESILIENT Trial

These rates are estimated by Kaplan-Meier analysis. The p-values are based on the comparison of control vs. test of the randomized patients (stent group, n=134 and PTA control group, n=72). Target Lesion Revascularization (TLR) occurred in subjects who underwent revascularization (surgical or endovascular) of the segment treated by the stent (test) or PTA (control). The LIFESTENT® 5 mm and 8-10 mm stent diameters were not included in the RESILIENT Trial.

RESILIENT

A prospective, randomized, controlled, multi-center study comparing LIFESTENT® Vascular Stent vs. angioplasty alone in lesions of the SFA and/or proximal popliteal artery.

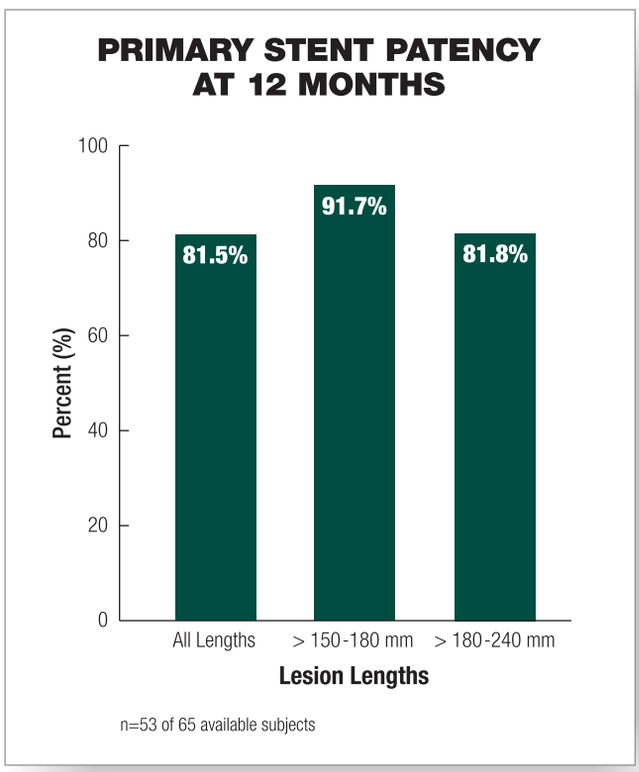
TRIAL OVERVIEW

- 206 patients enrolled: 72 in PTA group, 134 in PTA and LIFESTENT® Vascular Stent group
- 24 study sites in the United States and Europe
- Symptomatic de-novo or restenosed lesions
- Average lesion length of 71 mm

LIFESTENT® SOLO™ & LIFESTENT® 200MM TRIAL

Vascular Stent System

LIFESTENT® SOLO™ Delivery System Study

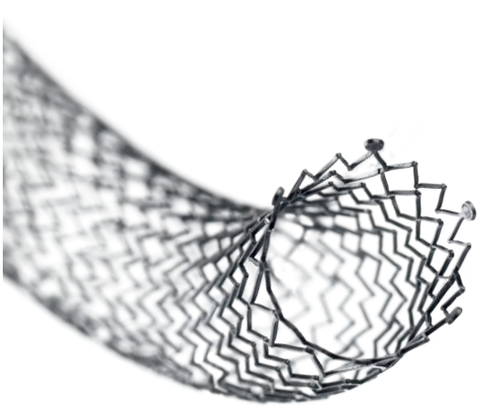


STENT LENGTHS UP TO

200 mm**

Designed to allow for treatment of **longer lesions with one stent***

Patency rates remained high at 12 months for all lesion lengths



LIFESTENT® 200 MM TRIAL**

A single-arm, prospective, non-randomized, multi-center study evaluating the safety and effectiveness of the LIFESTENT® SOLO™ in the treatment of symptomatic vascular disease of the SFA and/or proximal popliteal artery. Subjects were treated with conventional PTA followed by implantation of the Bard LIFESTENT® Vascular Stent.

TRIAL OVERVIEW

- 76 patients
- 7 study sites in Germany
- Symptomatic de-novo or restenosed lesions
- Average lesion length of 91 mm

	LIFESTENT® RESILIENT TRIAL**	LIFESTENT® 200 MM TRIAL**
Mean Lesion Length	71 mm	91 mm
Stents per Patient	1.6	1.1
Primary Patency at 12 months	81.5%	81.5%
Freedom from TLR at 12 months	87%	91.2%

*The LIFESTENT® Vascular Stent is intended for primary stenting of de-novo or restenotic lesions of the peripheral arteries. The LIFESTENT® SOLO™ Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and proximal popliteal artery.

**The LIFESTENT® 5 mm and 8-10 mm stent diameters were not included in the LIFESTENT® 200 mm or the RESILIENT Trial.

LIFESTENT® SOLO™
Vascular Stent System

Stent Diameter	Catheter Length	Stent Length
		200 mm
6 mm	100 cm	EX062001L
	135 cm	EX062003L
7 mm	100 cm	EX072001L
	135 cm	EX072003L

LIFESTENT®
Vascular Stent System

80cm Catheter Length									
Stent Diameter	Stent Length								
	20 mm	30 mm	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm	170 mm
5 mm	EX050201C	EX050301C	EX050401C	EX050601C	EX050801C	EX051001C	EX051201C	EX051501C	EX051701C
6 mm	EX060201C	EX060301C	EX060401C	EX060601C	EX060801C	EX061001C	EX061201C	EX061501C	EX061701C
7 mm	EX070201C	EX070301C	EX070401C	EX070601C	EX070801C	EX071001C	EX071201C	EX071501C	EX071701C
8 mm	EX080201C	EX080301C	EX080401C	EX080601C	EX080801C				
9 mm	EX090201C	EX090301C	EX090401C	EX090601C	EX090801C				
10 mm	EX100201C	EX100301C	EX100401C	EX100601C	EX100801C				

130cm Catheter Length									
Stent Diameter	Stent Length								
	20 mm	30 mm	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm	170 mm
5 mm	EX050203C	EX050303C	EX050403C	EX050603C	EX050803C	EX051003C	EX0512013C	EX051503C	EX051703C
6 mm	EX060203C	EX060303C	EX060403C	EX060603C	EX060803C	EX061003C	EX061203C	EX061503C	EX061703C
7 mm	EX070203C	EX070303C	EX070403C	EX070603C	EX070803C	EX071003C	EX071203C	EX071503C	EX071703C
8 mm	EX080203C	EX080303C	EX080403C	EX080603C	EX080803C				
9 mm	EX090203C	EX090303C	EX090403C	EX090603C	EX090803C				
10 mm	EX100203C	EX100303C	EX100403C	EX100603C	EX100803C				

LIFESTENT® Vascular Stent
Indication for Use: The LIFESTENT® Vascular Stent is intended for primary stenting of de-novo or restenotic lesions of the peripheral arteries.

Contraindication: Generally, contraindications to PTA are also contraindications for stent placement. Contraindications include, but are not limited to patients with highly calcified lesions resistant to PTA and patients with a target lesion with a large amount of adjacent acute or subacute thrombus.

Warnings: Do not use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The LIFESTENT® Vascular Stent is supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device. Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant. DO NOT use with Ethiodol® or Lipiodol contrast media. DO NOT expose the delivery system to organic solvents (e.g., alcohol). The stent is not designed for repositioning or recapturing. Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). The safety and effectiveness of stent overlapping in the middle (P2) and distal popliteal artery (P3) has not yet been established. The long-term outcomes following repeat dilatation of endothelialized stents are unknown.

Precautions: The delivery system is not designed for use with power injection systems. Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. Prior to stent deployment, remove slack from the delivery system catheter outside the patient. If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. Do not attempt to break, damage, or disrupt the stent after placement. The safety and effectiveness of this device for use in treatment of instent restenosis has not been established. Cases of fracture have been reported in clinical use of the LIFESTENT® Vascular Stent. Cases of stent fracture occurred in lesions that were moderate to severely calcified, proximal or distal to an area of stent overlap and in cases where stents experienced >10% elongation at deployment. Therefore, care should be taken when deploying the stent as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent stent fracture. The long-term clinical implications of these stent fractures have not yet been established.

Potential Adverse Reactions: Potential complications associated with the use of peripheral stents may include, but are not limited to: Allergic/anaphylactoid reaction; Amputation; Aneurysm; Angina/coronary ischemia; Arterial occlusion/thrombus; Arteriovenous fistula; Arrhythmia; Bypass Surgery; Death related/unrelated to procedure; Embolization; Fever; Hematoma bleed; Hypotension/hypertension; Intimal injury/dissection; Ischemia/infarction of tissue/organ; Local infection; Malposition (failure to deliver the stent to the intended site); Pulmonary embolism; Pseudoaneurysm; Renal failure; Restenosis; Septicemia/bacteremia; Stroke; Vasospasm; Venous occlusion/thrombosis; Sepsis / infection; Stent migration; Stent misplacement.

LIFESTENT® SOLO™ Vascular Stent
Indications for Use: The LIFESTENT® SOLO™ Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and proximal popliteal artery.

Contraindication: The LIFESTENT®SOLO™ Vascular Stent System is contraindicated for use in patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum; patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy; patients with a target lesion with a large amount of adjacent acute or subacute thrombus; or patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

Warnings: DO NOT use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The LIFESTENT®SOLO™ Vascular Stent System is supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device. Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant. DO NOT expose the delivery system to organic solvents, e.g., alcohol. The stent is not designed for repositioning or recapturing. Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). The long-term outcomes following repeat dilatation of endothelialized stents are unknown.

Precautions: The device is intended for use by physicians who have received appropriate training. During system flushing, observe that saline exits at the catheter tip. The delivery system is not designed for use with power injection systems. Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. Prior to stent deployment, remove slack from the delivery system catheter outside the patient. If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. Store in a cool, dark, dry place. Do not attempt to break, damage, or disrupt the stent after placement. Cases of fracture have been reported in clinical use of the LIFESTENT®SOLO™ Vascular Stent. Cases of stent fracture occurred in lesions that were moderate to severely calcified, proximal or distal to an area of stent overlap and in cases where stents experienced >10% elongation at deployment. Therefore, care should be taken when deploying the stent as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent stent fracture. The long-term clinical implications of these stent fractures have not yet been established.

Potential Adverse Reactions: Allergic/anaphylactoid reaction; Amputation; Aneurysm; Angina/coronary ischemia; Arterial occlusion/thrombus; Arteriovenous fistula; Arrhythmia; Bypass Surgery; Death related/unrelated to procedure; Embolization; Fever; Hemorrhage/bleeding requiring a blood transfusion; Hematoma bleed; Hypotension/hypertension; Incorrect positioning of the stent requiring further stenting or surgery; Intimal injury/dissection; Ischemia/infarction of tissue/organ; Liver failure; Local infection; Malposition (failure to deliver the stent to the intended site); Open surgical repair; Pain; Pancreatitis Pulmonary embolism/edema; Pneumothorax; Pseudoaneurysm; Renal failure; Respiratory arrest; Restenosis; Septicemia/bacteremia; Stent Fracture; Stent Migration; Stroke; Vasospasm; Venous occlusion/thrombosis

Please consult package insert for more detailed safety information and instructions for use.

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