Ordering information

LifeStent™ Vascular Stent System

80cm Catheter Length			130cm Catheter Length		
Order code	Stent Diameter (mm)	Stent Length (mm)	Order code	Stent Diameter (mm)	Stent Length (mm)
EX050201C	5	20	EX050203C	5	20
EX050301C		30	EX050303C		30
EX050401C		40	EX050403C		40
EX050601C		60	EX050603C		60
EX050801C		80	EX050803C		80
EX060201C	6	20	EX060203C	6	20
EX060301C		30	EX060303C		30
EX060401C		40	EX060403C		40
EX060601C		60	EX060603C		60
EX060801C		80	EX060803C		80
EX071001C	7	100	EX071003C	7	100
EX071201C		120	EX071203C		120
EX071501C		150	EX071503C		150
EX071701C		170	EX071703C		170
EX080201C	8	20	EX080203C	8	20
EX080301C		30	EX080303C		30
EX080401C		40	EX080403C		40
EX080601C		60	EX080603C		60
EX080801C		80	EX080803C		80
EX090201C	9	20	EX090203C	9	20
EX090301C		30	EX090303C		30
EX090401C		40	EX090403C		40
EX090601C		60	EX090603C		60
EX090801C		80	EX090803C		80
EX100201C	10	20	EX100203C	10	20
EX100301C		30	EX100303C		30
EX100401C		40	EX100403C		40
EX100601C		60	EX100603C		60
EX100801C		80	EX100803C		80

0.035” guidewire compatible

Units per case: 1

LifeStent™ XL Vascular Stent System

80cm Catheter Length			130cm Catheter Length		
Order code	Stent Diameter (mm)	Stent Length (mm)	Order code	Stent Diameter (mm)	Stent Length (mm)
EX051001C	5	100	EX051003C	5	100
EX051201C		120	EX051203C		120
EX051501C		150	EX051503C		150
EX051701C		170	EX051703C		170
EX061001C	6	100	EX061003C	6	100
EX061201C		120	EX061203C		120
EX061501C		150	EX061503C		150
EX061701C		170	EX061703C		170
EX071001C	7	100	EX071003C	7	100
EX071201C		120	EX071203C		120
EX071501C		150	EX071503C		150
EX071701C		170	EX071703C		170

LifeStent™ Solo™ Vascular Stent System

Order code	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
EX062001L	6	200	80
EX072001L	7	200	
EX062003L	6	200	135
EX072003L	7	200	

LifeStent™ Vascular Stent

Indication for Use: The LifeStent™ Vascular Stent is indicated for the treatment of atherosclerotic lesions in the superficial femoral artery (SFA) and popliteal artery.

Contraindication: The LifeStent™ Vascular Stent is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel, titanium) or tantalum.

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 temperature exposure indicator label should be grey and must be clearly visible on the pouch. • The LifeStent™ Vascular Stent 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 of patient or user infection, 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. • 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 with a target lesion with a large amount of adjacent acute or subacute thrombus. • DO NOT use in 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. • 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. • Persons with allergic reactions to nitinol (nickel, titanium) and/or tantalum 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 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 in-stent 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. • One or more components of this device contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: N-Methyl-2-pyrrolidinone (NMP; CAS 872-50-4) N-Methyl-2-pyrrolidinone (NMP) is a solvent used in the manufacturing process of certain components of the LifeStent™ Delivery System. NMP has been shown to have adverse effects in experimental animals, including reproductive and developmental effects. BD has not assessed any related adverse effects in relation to the exposure to NMP when this device is used with neonates, infants, pregnant or breast-feeding women. It is the responsibility of the physician to assess risks associated with the use of a device containing NMP.

LifeStent™ XL Vascular Stent

Indications for Use: The LifeStent™ XL Vascular Stent is indicated for the treatment of atherosclerotic lesions in the superficial femoral artery (SFA) and popliteal artery.

Contraindication: The LifeStent™ XL Vascular Stent is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel, titanium).

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 temperature exposure indicator label should be grey and must be clearly visible on the pouch. • The LifeStent™ XL Vascular Stent 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 of patient or user infection, 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. • 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 with a target lesion with a large amount of adjacent acute or subacute thrombus. • DO NOT use in 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. • 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. • Persons with allergic reactions to nitinol (nickel, titanium) 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 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 in-stent 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. • One or more components of this device contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: N-Methyl-2-pyrrolidinone (NMP; CAS 872-50-4) N-Methyl-2-pyrrolidinone (NMP) is a solvent used in the manufacturing process of certain components of the LifeStent™ Delivery System. NMP has been shown to have adverse effects in experimental animals, including reproductive and developmental effects. BD has not assessed any related adverse effects in relation to the exposure to NMP when this device is used with neonates, infants, pregnant or breast-feeding women. It is the responsibility of the physician to assess risks associated with the use of a device containing NMP.

LifeStent™ Solo™ Vascular Stent

Indications for Use: The LifeStent™ Solo™ Vascular Stent System is indicated for the treatment of atherosclerotic lesions in the superficial femoral artery (SFA) and popliteal artery.

Contraindication: The LifeStent™ Solo™ Vascular Stent System is contraindicated for use in: Patients with a known hypersensitivity to nitinol (nickel, titanium) or tantalum.

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 temperature exposure indicator label should be grey and must be clearly visible on the pouch. The LifeStent™ Solo™ Vascular Stent System 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 that cannot be adequately pre-medicated. • DO NOT use in patients with a target lesion with a large amount of adjacent acute or subacute thrombus. • DO NOT use in 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. • 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. • Persons with allergic reactions to nitinol (nickel, titanium) and/or tantalum 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 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. • It is recommended to use the 100 cm working length device for ipsilateral procedures. The longer working length of the 135 cm device may potentially be challenging for the user to keep straight for ipsilateral procedures. Failure to keep the device straight may impede the optimal deployment of the implant, potentially resulting in an elongated or foreshortened implant. • DO NOT continue triggering the device following complete deployment of the implant. • Operator deployment techniques other than those indicated by the Instructions for Use are advised against. Stent elongation or stent foreshortening are potential consequences as a result of not following the deployment Instructions for Use.

Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions.

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Advanced helical design Proven performance

LifeStent™ Vascular Stent

LifeStent™ XL Vascular Stent

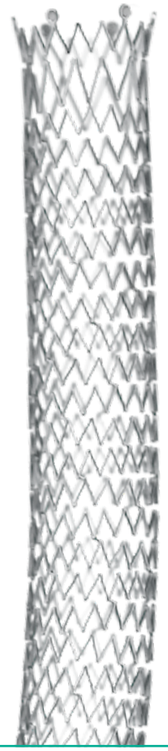
LifeStent™ Solo™ Vascular Stent System

LifeStent™ & THE RESILIENT TRIAL

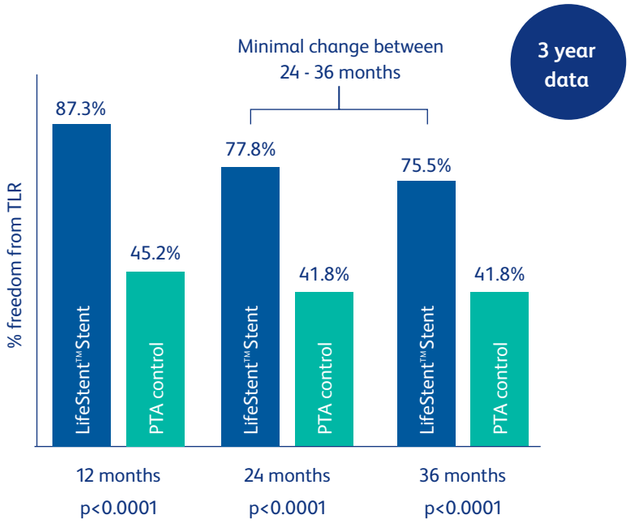
Vascular Stent

Lasting results over the long-term

- Sustained effectiveness up to 3 years
- Maintained primary stent treatment superiority over PTA



Sustained long-term outcomes



Resilient

A prospective, randomised, controlled, multi-center study comparing LifeStent™ Vascular Stent vs. Angioplasty alone in lesions of the SFA and/or proximal popliteal artery.

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 randomised patients (stent group, n= 134 and PTA control group, n=72). Target Lesion Revascularisation (TLR) occurred in subjects who underwent revascularisation (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.

Trial overview

- 206 patients enrolled: 72 in PTA group,134 in PTA and LifeStent™ Vascular Stent group
- 24 study sites in United States and Europe
- Symptomic *de novo* or restenosed lesions
- Average lesion length of 71 mm

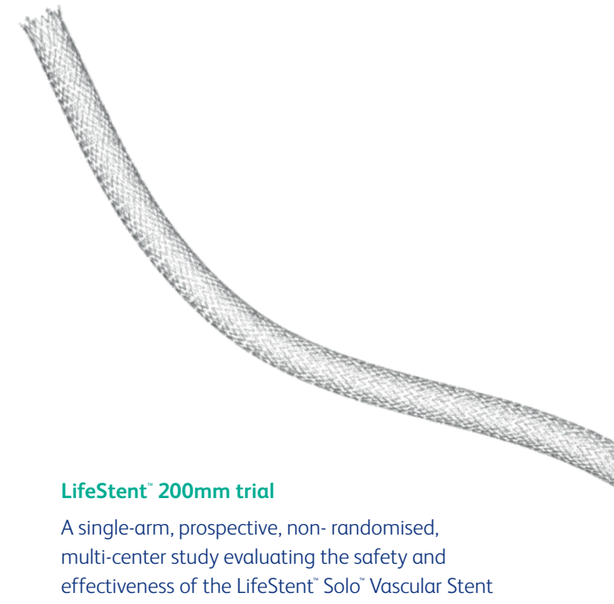
LifeStent™ Solo™ & LifeStent™ 200mm trial

Vascular Stent System

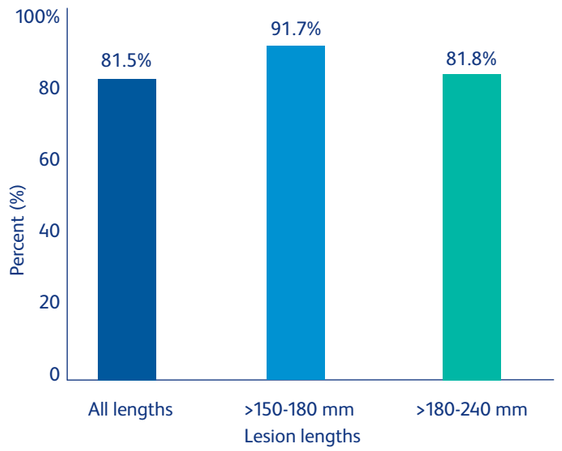
LifeStent™ Delivery System Study

Stent lengths up to 200mm**

- Designed to allow for treatment of longer lesions with one stent*
- Patency rates remained high at 12 months for all lesion lengths



Primary stent patency at 12 months



n=53 of 65 available subjects

LifeStent™ 200mm trial

A single-arm, prospective, non- randomised, multi-center study evaluating the safety and effectiveness of the LifeStent™ Solo™ Vascular Stent 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-nova 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.