140 µm thin struts

Clinically proven

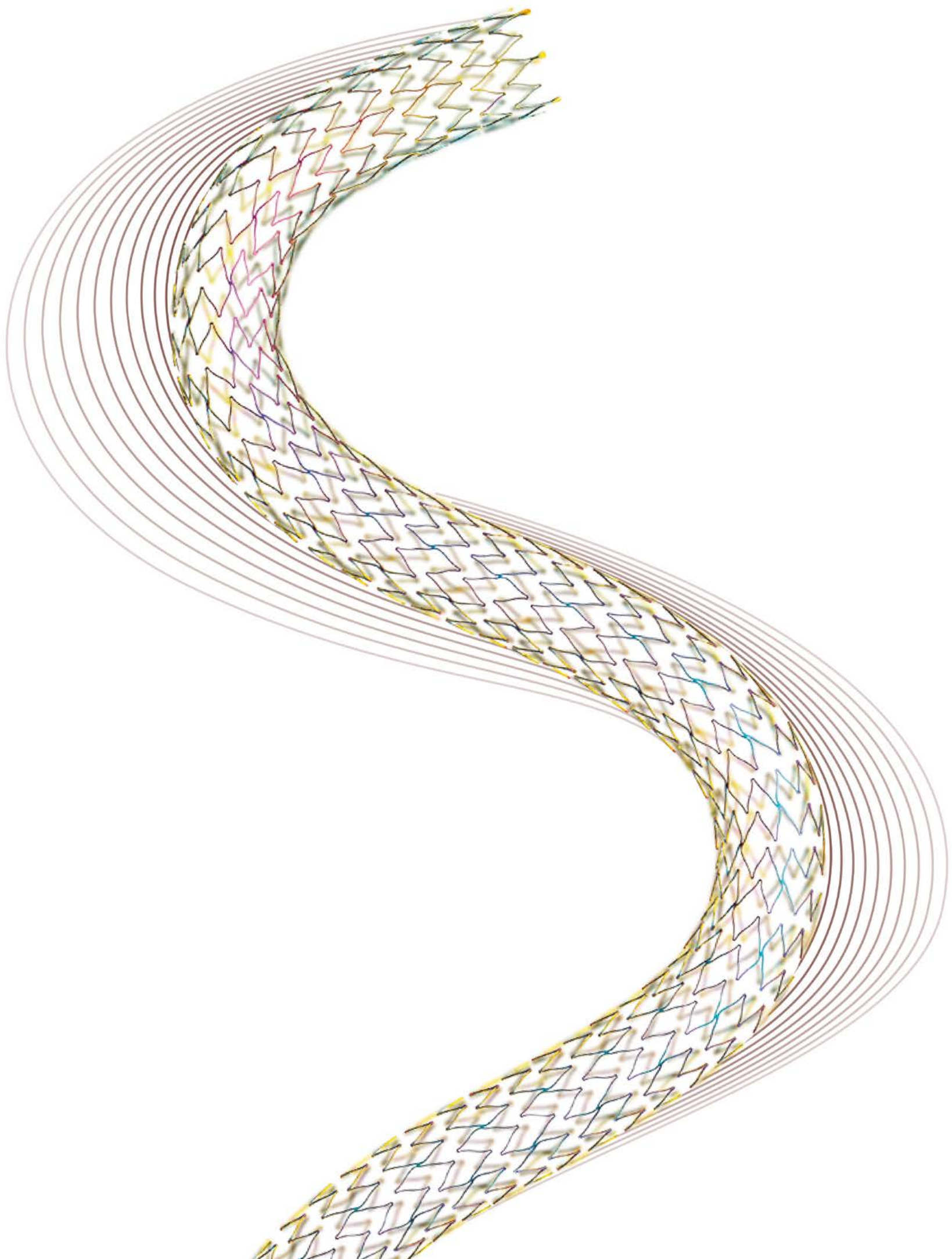
4F low profile

Technical data / ordering info

Vascular Intervention // Peripheral
Self-Expanding Stent System/0.018”/OTW

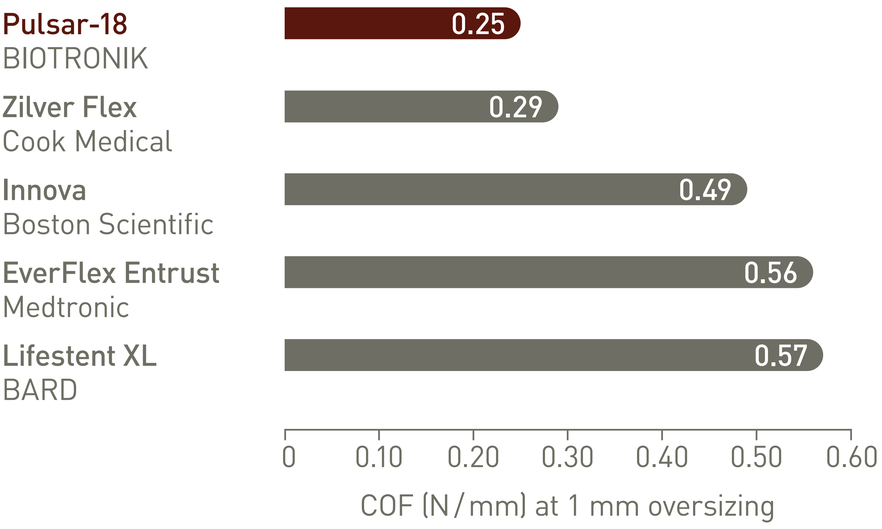
BIOTRONIK
excellence for life

Pulsar-18



140 µm thin struts - thinner than the leading brands[1]

Thinner struts for low Chronic Outward Force (COF)[2]

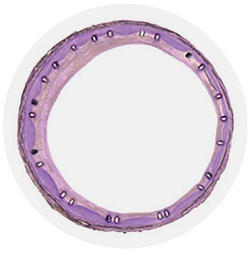


Thinner struts and lower COF make a difference:*

- Lower risk of restenosis[3]
- Reduced vessel injury and inflammation[4]
- Faster endothelialization[5]

*As demonstrated in pre-clinical studies

1 mm stent oversizing at 90 days[6]



Pulsar Stent
BIOTRONIK
Low COF

Lifestent XL
BARD
High COF

Stent strut thickness in perspective[1]

Pulsar-18
BIOTRONIK

140 µm[1]

Supera
Abbott

178 µm

Zilver Flex
Cook Medical

192 µm

Lifestent XL
Bard

192 µm

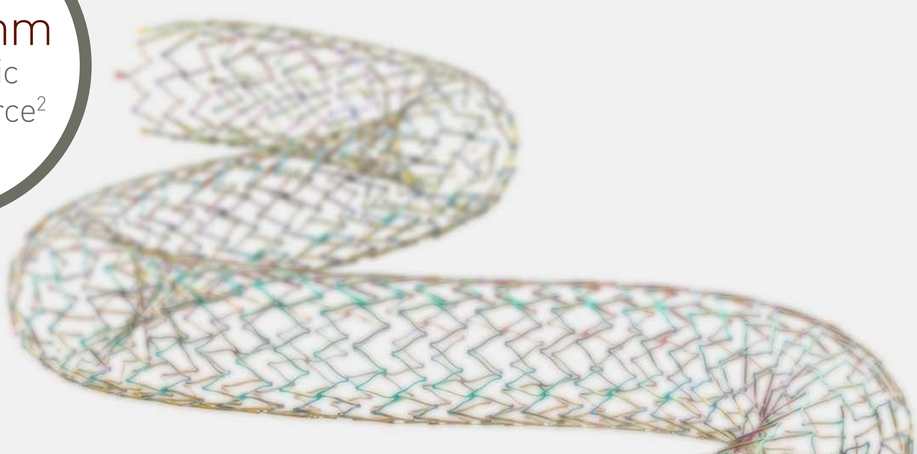
Innova
Boston Scientific

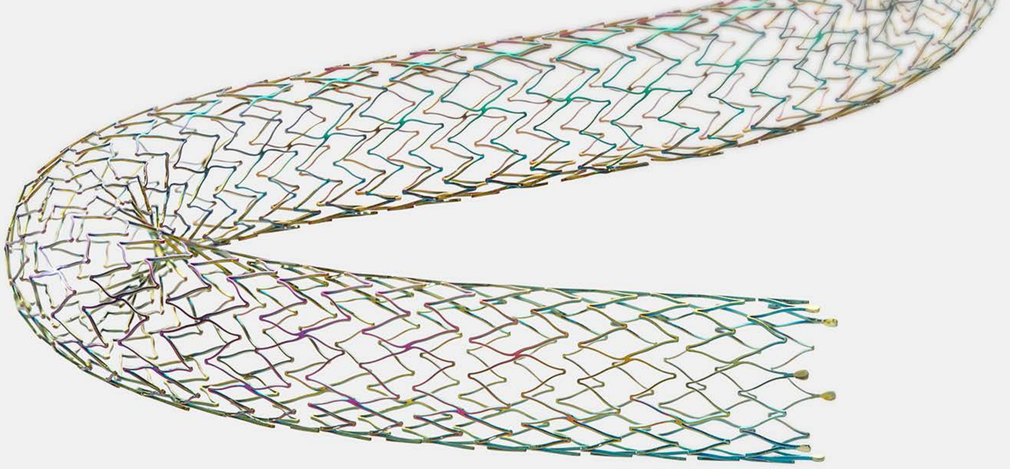
213 µm

EverFlex Entrust
Medtronic

228 µm

0.25 N/mm
low Chronic Outward Force[2]





Clinically proven

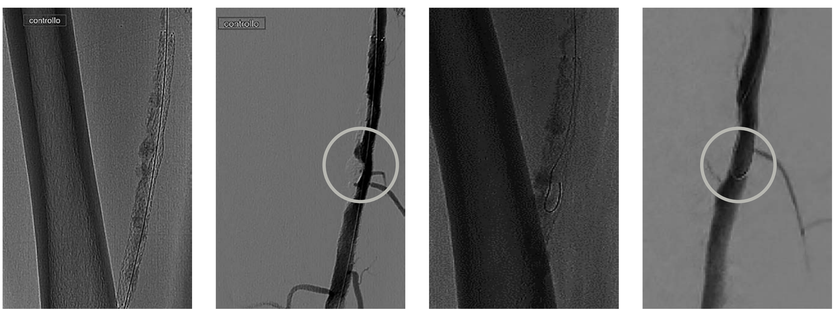
97.1%
12 month
FTLR BIOFLEX
PEACE

Long term safety and efficacy (12 month data)

4F INTERVENTIONS 4EVER[7]		LONG & OCCLUDED TASC D[8]		ALL-COMERS BIOFLEX PEACE[9]	
FTLR:** **89.3%**		FTLR:** **86%**		FTLR:** **97.1%**	
PP:† **81.4%**	A.L.L.:†† **7.1 cm**	PP:† **77%**	A.L.L.:†† **24.5 cm**	PP:† **86.2%**	A.L.L.:†† **11.6 cm**

**FTLR - Freedom from Target Lesion Revascularization;
†PP - Primary Patency; ††A.L.L. - Average Lesion Length

Sufficient radial force for a long term vessel support, even in calcified lesions



After the treatment 2011 2016

(Courtesy of Prof. van den Berg)

Exceptional clinical outcomes (12 month data)

	FTLR	PP
BIOFLEX PEACE Pulsar-18 (BIOTRONIK)[10]	97.1%	86.2%
RESILIENT Lifestent (Bard)[11]	87.3%	81.3%
SUPERB Supera (Abbott)[12]	88.9%	80.3%
SuperNOVA Innova (Boston Scientific)[13]	85.8%	66.4%
Zilver PTX Zilver Flex Arm* (Cook Medical)[14]	n/a	73.0%
Durability Protege EverFlex (Medtronic)[15]	79.1%	72.2%

Results from different trials are not directly comparable. Differences in outcomes may be the result of differences in protocol design, patient populations or other factors.

*Bail out group

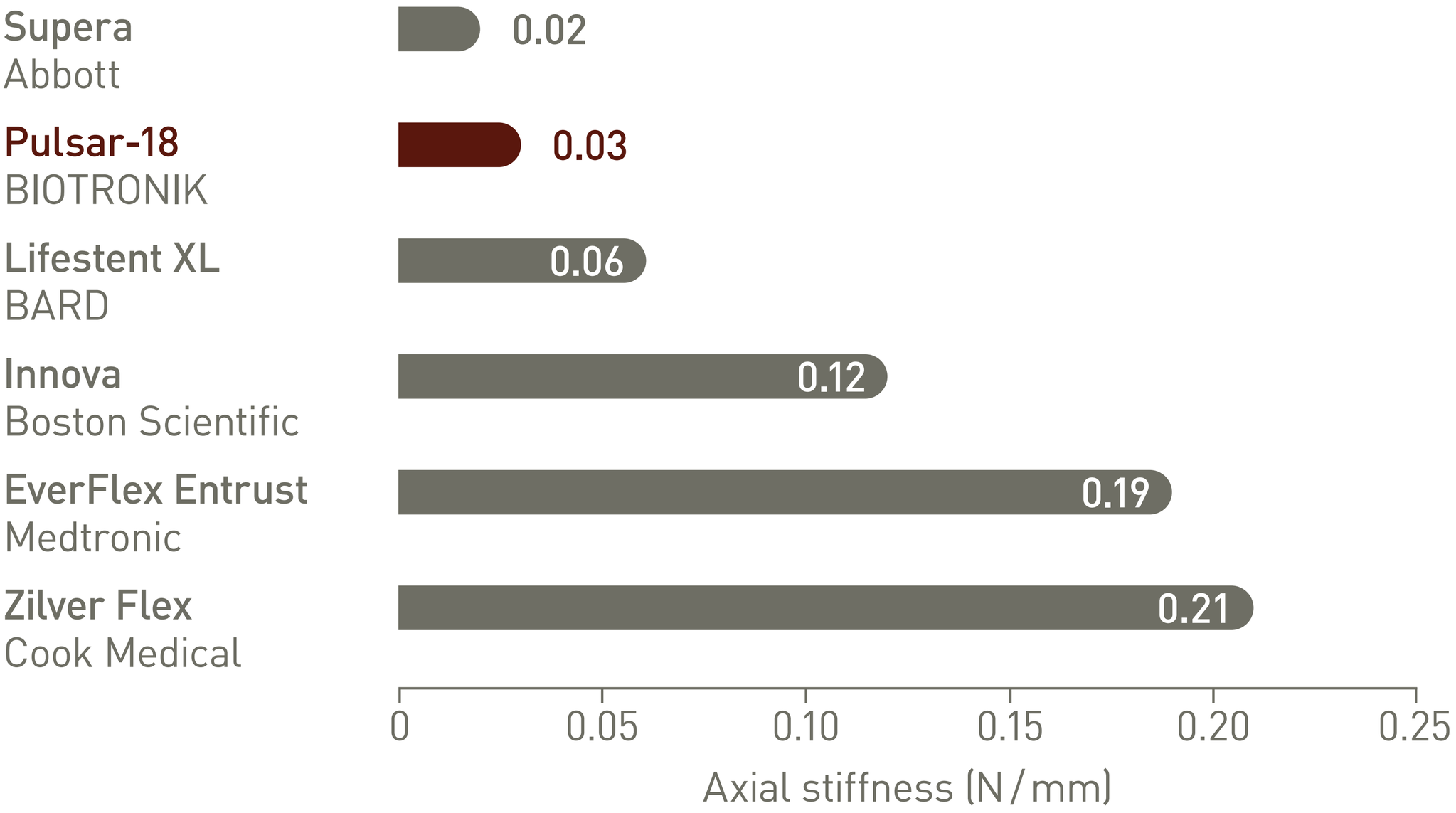
Stent designed for SFA*

Multi-directional flexibility to conform to the natural vessel movement.

*Superficial Femoral Artery

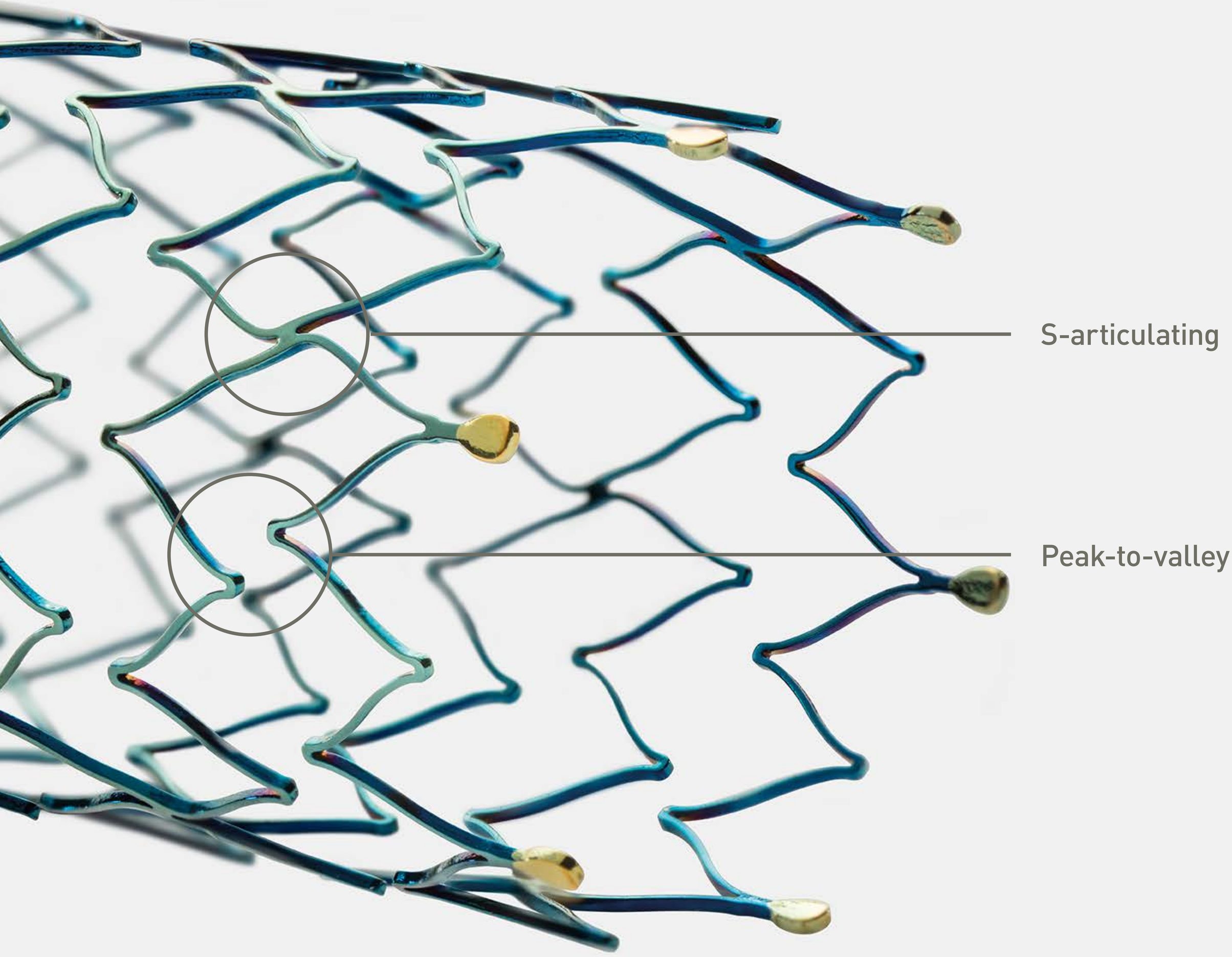
Elongation

Low axial stiffness for high flexibility[16]



Bending

Peak-to-valley design and S-articulating connecting bars provide multi-directional flexibility and avoid fish scaling in mobile vessel architecture.[17]



45%
smaller
puncture site
area than 6F[18]

4F Low Profile - Improved acute outcomes vs. 6F[7]

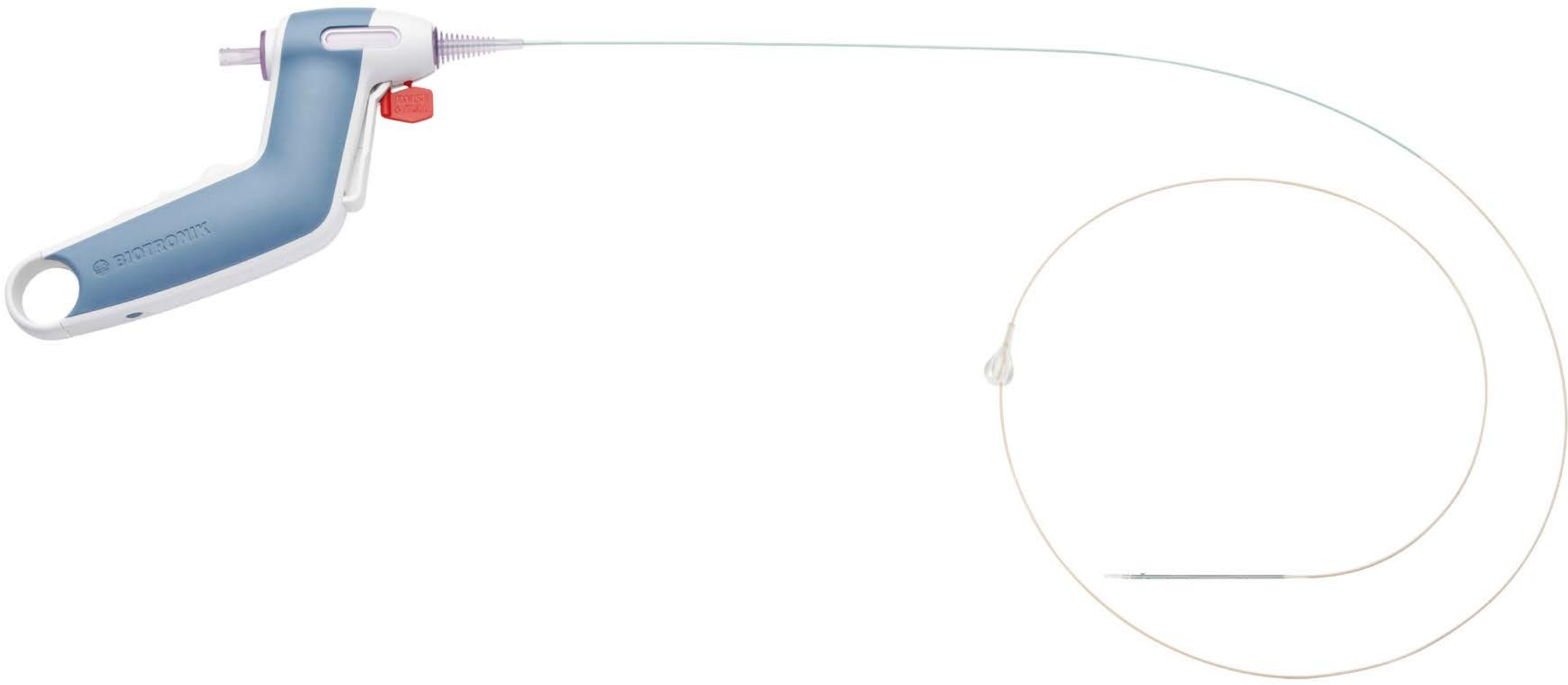
Potential for safer, faster and simpler procedures than 6F

- Clinically proven lower access site complication rates[7]
- Shorter compression time[7]
- 45% smaller puncture site area than 6F[18]
- No need for a closure device

100%
technical success
4EVER study[7]

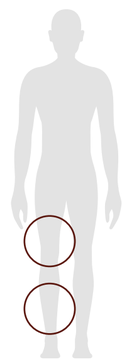
Stent deployment

One-handed stent release handle, ergonomically designed for a comfortable and stable handling.



Pulsar-18

Vascular
Intervention
Peripheral



Indicated for use in patients with atherosclerotic disease of the femoral and infrapopliteal arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty.*

Technical Data

Stent	
Catheter type	OTW
Recommended guide wire	0.018”
Stent material	Nitinol
Strut thickness	140 µm
Strut width	85 µm
Stent coating	proBIO (Amorphous Silicon Carbide)
Stent Markers	6 gold markers each end
Sizes	ø 4.0 - 7.0 mm: L:20 - 200 mm
Proximal shaft	3.6F, hydrophobic coating
Usable length	90 cm and 135 cm

Ordering Information

Stent ø (mm)	Catheter length 90 cm (Stent length mm)									
	20**	30	40	60	80	100	120	150	170	200
4.0	377456	377457	377458	377459	377460	366808	366809	366810	366811	366812
5.0	377461	377462	377463	377464	377465	366813	366814	366815	366816	366817
6.0	377466	377467	377468	377469	377470	366818	366819	366820	366821	366822
7.0	377471	377472	377473	377474	377475	366823	366824	366825	366826	366827

4F

Stent ø (mm)	Catheter length 135 cm (Stent length mm)									
	20**	30	40	60	80	100	120	150	170	200
4.0	377476	377477	377478	377479	377480	366828	366829	366830	366831	366832
5.0	377481	377482	377483	377484	377485	366833	366834	366835	366836	366837
6.0	377486	377487	377488	377489	377490	366838	366839	366840	366841	366842
7.0	377491	377492	377493	377494	377495	366843	366844	366845	366846	366847

4F

**8 weeks pre-order only

1. 6.0 mm diameters. BIOTRONIK data on file; 2. 6.0 mm diameters. Supera stent not possible to test due to its design and applied test method. BIOTRONIK data on file; 3, 4. As demonstrated in pre-clinical studies: Zhao HQ Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc. Interv. Radiol. 2009 Jul; 32(4); 720-6; 5. As demonstrated in pre-clinical studies: Konstantinos C. Role of endothelial shear stress in stent restenosis and thrombosis. JACC 2012; Koppara et al. Circ Cardiovasc. Interv 2015; 8: e002427; Soucy N. Strut tissue coverage and endothelial cell coverage: a comparison between bare metal stent platforms and platinum chromium stents with and without everolimus-eluting coating. EuroIntervention 2010;6:630-637; 6. Funovic M. Presented at LINC 2017; Astron Pulsar results can be used to illustrate the impact of over sizing on the vessel for Pulsar-18 stent due to the similarity in the Astron Pulsar and Pulsar-18 stent materials and designs; 7. Bosiers M, et al. 4-French -compatible endovascular material is safe & effective in the treatment of femoropopliteal occlusive disease: Results of the 4EVER Trial. ENDOVASC THER 2013; 20: 746-756; 8. Lichtenberg M. Superficial Femoral Artery TASC D registry: 12-month effectiveness analysis of the Pulsar-18 SE nitinol stent in patients with critical limb ischemia. J Cardiovasc Surg (Torino). 2013 Aug; 54(4):433-9; 9, 10. Nolte-Ernsting C. BIOFLEX Peace 12-month results. Presented at CIRSE 2017; 11. Laird JR. Nitinol stent implantation versus balloon angioplasty for lesions in the Superficial Femoral Artery and Proximal Popliteal Artery. 12-month Results From the RESILIENT randomized trial (stent group). Circ Cardiovasc Interv. 2010; 3(3):267-76; 12. Supera SSED. US Food and Drug Administration, Center for Devices and Radiological Health. Supera® Peripheral Stent System P120020. 13. SuperNOVA. US Food and Drug Administration, Center for Devices and Radiological Health, Innova™ Vascular Self-Expanding Stent System P140028; 14. Dake M. Paclitaxel-Eluting Stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease. 12-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011; 4:495-504; 15. Bosiers M. Nitinol stent implantation in long Superficial Femoral Artery Lesions: 12-month results of the DURABILITY I Study. J ENDOVASC THER 2009; 16:261–269; 16-18. BIOTRONIK data on file.

Leading competitors have been selected based on the PV Stent Revenue Market Shares EU, 2017 and PV Revenue Market Shares APAC 2015; (Source: Milennium Research Group Inc.). Latest SFA self expanding stents for each manufacturer; Supera is a registered trademark of the Abbott Group of Companies; Lifestent is a registered trademark of C.R. Bard; Zilver is a registered trademark of Cook Medical; EverFlex and Entrust are registered trademarks of the Medtronic Group of Companies; Innova is a registered trademark of Boston Scientific.

*Indication as per IFU.

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