Tri-axial system
with braided shaft

Low-profile
delivery system

Thin struts,
low COF

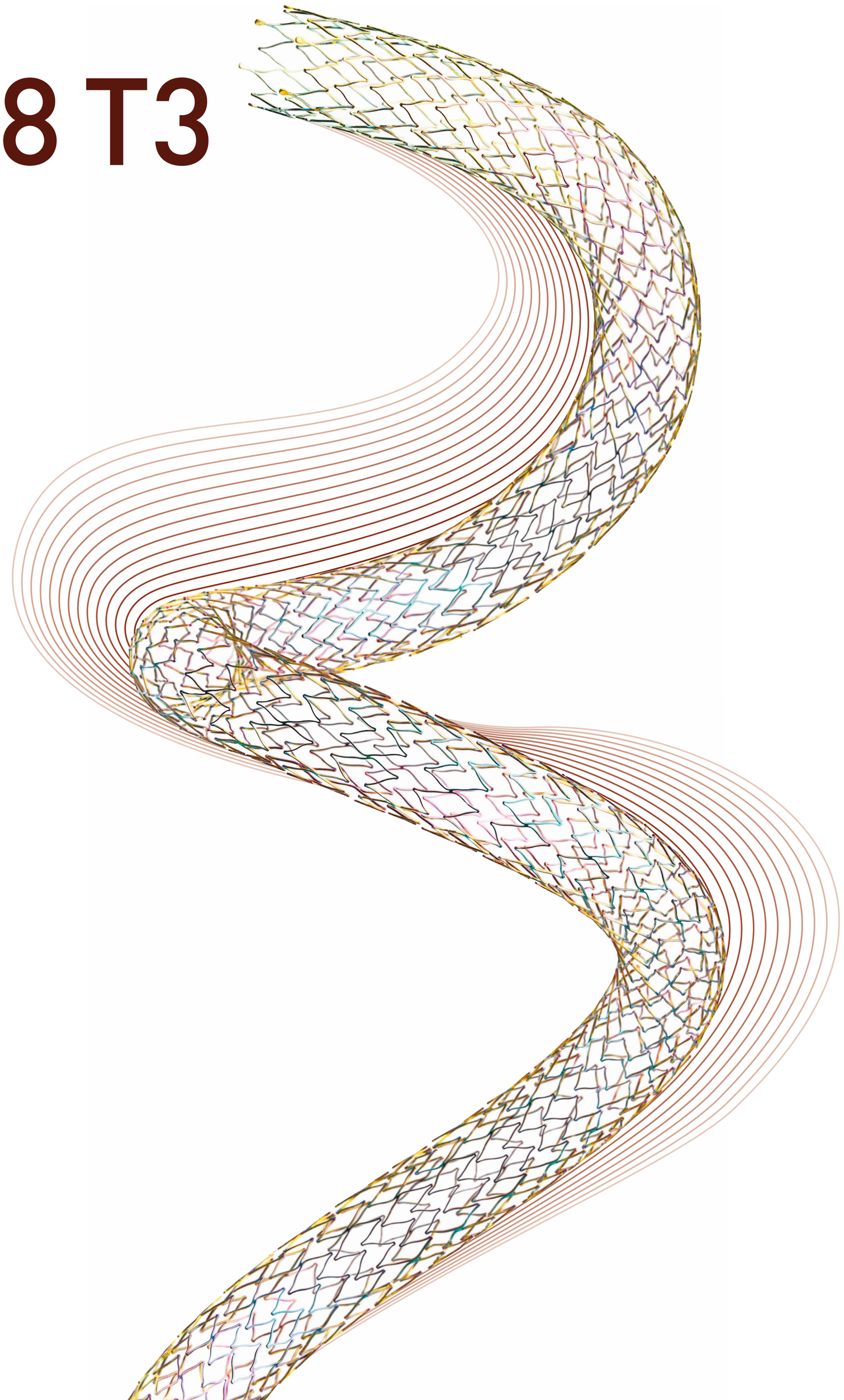
Technical data /
ordering info

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

BIOTRONIK
excellence for life

Pulsar®-18 T3

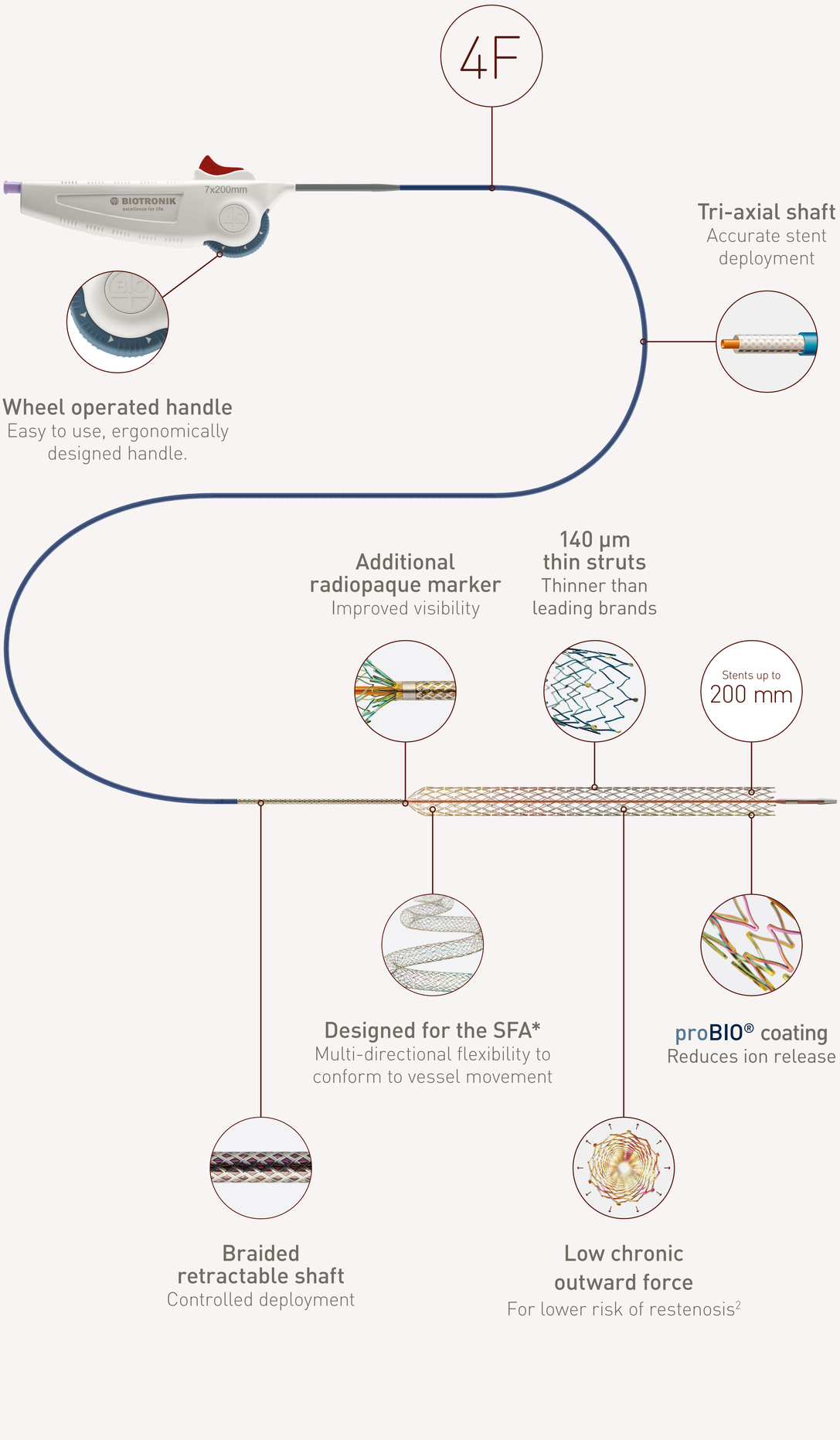
A unique combination
of 3 technologies



Pulsar-18 T3

Easy to use, intuitive wheel-operated handle and one-handed deployment

4F low profile
45% smaller puncture site vs. 6F[1]



Tri-axial shaft
Accurate stent deployment

Wheel operated handle
Easy to use, ergonomically designed handle.

Additional radiopaque marker
Improved visibility

140 µm thin struts
Thinner than leading brands

Stents up to 200 mm

Designed for the SFA*
Multi-directional flexibility to conform to vessel movement

proBIO® coating
Reduces ion release

Braided retractable shaft
Controlled deployment

Low chronic outward force
For lower risk of restenosis[2]

Unique tri-axial shaft design on a 4F lowprofile delivery system

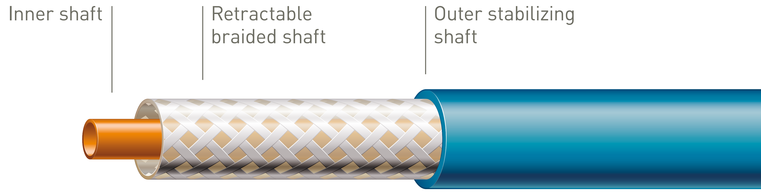
Wheel-operated handle ergonomically designed

Easy-to-use handle

Tri-axial system with braided retractable shaft

Accurate stent deployment

The outer stabilizing shaft isolates the retractable shaft from friction caused by the introducer valve to ensure accurate stent deployment.



4F low profile - improved acute outcomes* vs. 6F[3]

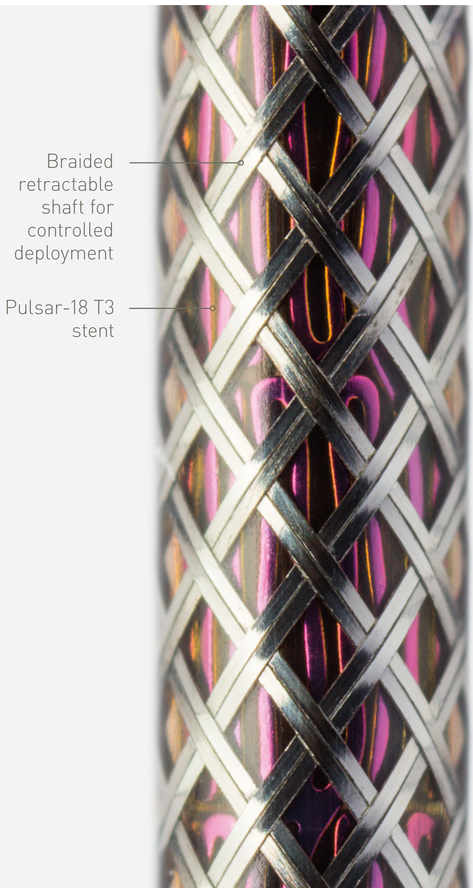
Potential for safer, faster and simpler procedures than 6F

- Clinically proven lower access site complication rates[3]
- Shorter compression time[3]
- 45% smaller puncture site than 6F[1]
- No need for a closure device[3]
- Potential for ambulatory treatment

100%
Technical success 4F intervention 4EVER[3]

45%
smaller puncture site than 6F[1]

* Less access site complications



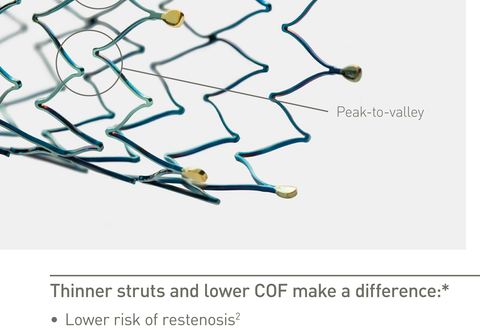
Pulsar-18 T3

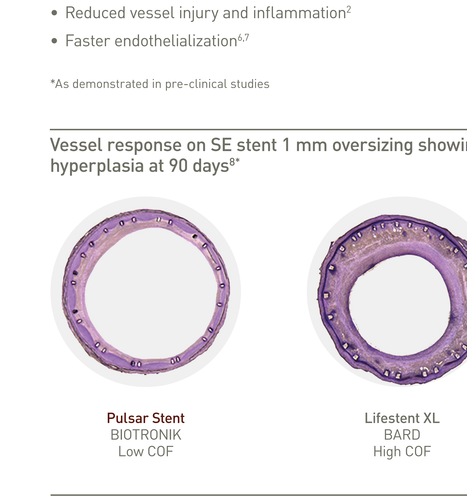
Thin struts and low chronic outward force

140 µm thin struts - thinner than leading brands[4]

Thinner struts for lower chronic outward force (COF)[5]

0.25 N/mm
low chronic outward force[2]





140 µm thin struts – thinner than other US brands[4,5]

Pulsar-18 T3
BIOTRONIK
140 µm

Supera
Abbott
178 µm

Lifestent XL
BARD
192 µm

Zilver Flex
Cook Medical
193 µm

Innova
Boston Scientific
213 µm

EverFlex Entrust
Medtronic
228 µm

Thinner struts and lower COF make a difference:*

- Lower risk of restenosis[2]
- Reduced vessel injury and inflammation[2]
- Faster endothelialization[6,7]

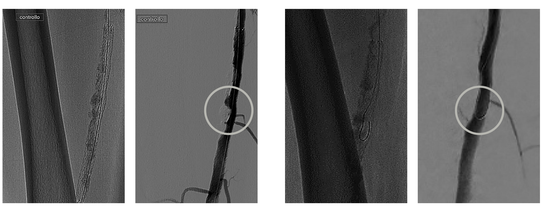
*As demonstrated in pre-clinical studies

Vessel response on SE stent 1 mm oversizing showing neointimal hyperplasia at 90 days[8]*

Pulsar Stent
BIOTRONIK
Low COF

Lifestent XL
BARD
High COF

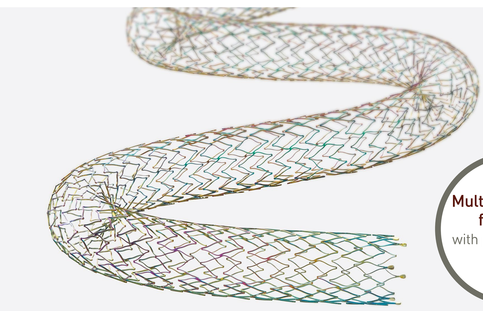
Sufficient radial force for long term vessel support, even in calcified lesions



After the treatment 2011
(Courtesy of Prof. van den Berg[8])

2016

With a constant low chronic outward force applied to the vessel, patency can be achieved and maintained over a long term follow up even in calcified lesions.



Multi-directional flexibility
with peak-to-valley design

Pulsar-18 T3

Clinically proven thin struts stent design

12-month PP
81.4%
4EVER study[3]

24-month FTLR
89.3%
BIOFLEX PEACE[9]

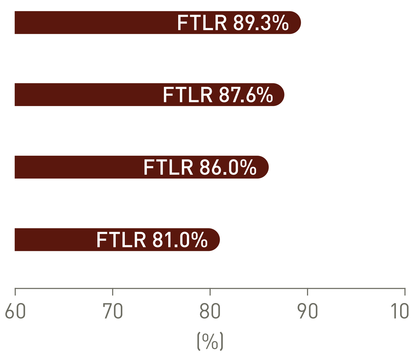
Average lesion length
24.5 cm
TASC D[10]

Pulsar stent outcomes at 12 months

>1200
patients enrolled

Safety and efficacy at 12 months

Study	A.L.L.†	PP††	FTLR*
4EVER[3] 4F Intervention	7.1 cm	81.4%	89.3%
BIOFLEX-I[11] US IDE trial	8.2 cm	70.6%	87.6%
TASC D[10] Long & occluded	24.5 cm	77.0%	86.0%
PEACE[12] All-comers	11.2 cm	79.5%	81.0%



Long-term outcomes in perspective

Pulsar stent outcomes at 24 and 36 months, highlighting long-term safety and efficacy.

Study, Product	Manufacturer	A.L.L.	PP 24m	PP 36m	FTLR 24m	FTLR 36m
BIOFLEX PEACE[9] Pulsar (stent only)	**BIOTRONIK**	8.2 cm	78.4%	N/A	89.3%	N/A
SUPERB[13] Supera	Abbott	7.8 cm	N/A	N/A	84.0%	82.0%
4EVER[14] Pulsar	**BIOTRONIK**	7.1 cm	72.3%	N/A	82.7%	N/A
BIOLFLEX-I[11] Pulsar	**BIOTRONIK**	8.2 cm	N/A	N/A	81.0%	78.2%
Complete SE[15] Complete SE	Medtronic	6.1 cm	N/A	N/A	79.3%	73.6%
STROLL[16] SMART Control	Cardinal Health/Cordis	7.7 cm	74.9%	N/A	79.0%	75.8%
OSPREY[17] Misago	Terumo	8.4 cm	N/A	N/A	78.5%	75.4%
RESILIENT[18] LifeStent	BD/Bard	7.1 cm	N/A	N/A	77.8%	75.5%
DURABILITY II[19] EverFlex	Medtronic	8.9 cm	66.0%	60.0%	75.0%	70.0%
SuperNOVA[20] Innova	Boston Scientific	9.3 cm	N/A	39.0%	N/A	N/A

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

Pulsar-18 T3

Indicated for use to improve luminal diameter in patients with symptomatic de novo, restenotic, or occlusive lesions located in the superficial femoral or proximal popliteal arteries, with reference vessel diameters from 3.0 to 6.0 mm and total lesion lengths up to 190 mm.*

Vascular Intervention Peripheral

Technical Data

Stent	
Catheter type	OTW
Recommended guide wire	0.018"
Stent material	Nitinol
Strut thickness	140 µm
Strut width	85 µm - 90 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
Shaft	4F, hydrophobic coating, tri-axial
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	430437	430438	430439	430440	430441	430442	430443	430444	430445	430446
5.0	430447	430448	430449	430450	430451	430452	430453	430454	430455	430456
6.0	430457	430458	430459	430460	430461	430462	430463	430464	430465	430466
7.0	430467	430468	430469	430470	430471	430472	430473	430474	430475	430476

4F

Stent ø (mm)	Catheter length 135 cm (Stent length mm)									
	20	30	40	60	80	100	120	150	170	200
4.0	430477	430478	430479	430480	430481	430482	430483	430484	430485	430486
5.0	430487	430488	430489	430490	430491	430492	430493	430494	430495	430496
6.0	430497	430498	430499	430500	430501	430502	430503	430504	430505	430506
7.0	430507	430508	430509	430510	430511	430512	430513	430514	430515	430516

4F

1. BIOTRONIK data on file; 2. Zhao HQ Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc. Interv. Radiol. 2009; 32(4); 720-6; 3. 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; 4. BIOTRONIK data on file. 6.0 mm diameters; 5. BIOTRONIK data on file. 6.0 mm diameters. Supera stent not possible to test due to its design and applied test method; 6. Koskinas C. Role of endothelial shear stress in stent restenosis and thrombosis: pathophysiologic mechanisms and implications for clinical translation. JACC 2012 10;59(15):1337-49; 7. Koppara T. Thrombogenicity and early vascular healing response in metallic biodegradable polymer-based and fully bioabsorbable drug-eluting stents. Circ Cardiovasc Interv. 2015 8(6):e002427; 8. Funovics M. Correlation between chronic outward force (COF) and neointimal hyperplasia in self-expanding nitinol stents in swine in clinically relevant oversizing ranges. Presented at: LINC, Jan 26, 2017; Leipzig, Germany; 9. Lichtenberg et al. Effectiveness of the Pulsar-18 self-expanding stent with optional drug-coated balloon angioplasty in the treatment of femoropopliteal lesions - the BIOFLEX PEACE All-Comers Registry. Vasa (2019), 1-9. doi_10.1024/0301-1526/a000785; 10. 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 ; 54(4):433-9; 11. BIOFLEX-I Pulsar 2018 Post Approval Clinical Report_Final_36m; 12. Lichtenberg M. et al PEACE I All-Comers Registry: Patency Evaluation After Implantation of the 4-French Pulsar-18 Self-Expanding Nitinol Stent in Femoropopliteal Lesions. J ENDOVASC THER. 2014;21:373–380, doi:10.1583/13-4637R.1; 13. Garcia LA et al. SUPERB Final 3-Year Outcomes Using Interwoven Nitinol Biometric Supera Stent. Catherization and Cardiovascular Interventions 2017; 89: 1259-1267; 14. Bosiers M. 4EVER 24 month results: long-term results of 4F Pulsar stent in femoropopliteal lesions. Presented at: CIRSE 2013; Barcelona, Spain; 15. Medtronic Complete SE SSED P110040 (September 19, 2013); 16. Bunte M et al. in STROLL Catheterization and Cardiovascular Interventions 2018; 92:106-114; 17. Osprey Misago P140002 (May 22, 2015); 18. Laird J et al. RESILIENT SFA nitinol stenting. JET 2012;19:1-9; 19. Rocha-Singh et al. DURABILITY II Three-Year Follow-up. Catheterization and Cardiovascular Interventions 2015; 86:164-170; 20. SuperNOVA. US Food and Drug Administration, Center for Devices and Radiological Health, Innova™ Vascular Self-Expanding Stent System P140028.

Leading competitors have been selected based on the PV Stent Revenue Market Shares EU, 2017 and PV Revenue Market Shares APAC 2015; (Source: Millennium Research Group Inc.). Latest SFA self expanding stents for each manufacturer; Zilver and Zilver Flex are trademarks or registered trademarks of Cook Medical Technologies or its affiliates. Innova is a trademark or registered trademark of Boston Scientific or its affiliates. Everflex and Entrust are trademarks or registered trademarks of Medtronic or its affiliates. Lifestent is a trademark or registered trademark of C. R. Bard or its affiliates. Supera is a trademark or registered trademark of the Abbott Group of Companies. S.M.A.R.T. Control is a trademark or registered trademark of Cardinal Health or its affiliates.

*Indication as per IFU.

Manufacturer:
BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

Distributed in the US by:
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
Tel (800) 547-0394 (24-hour)
Fax (800) 291-0470
www.biotronik.com

℞ ONLY

BR433/Apr_2022_DV

BIOTRONIK
excellence for life