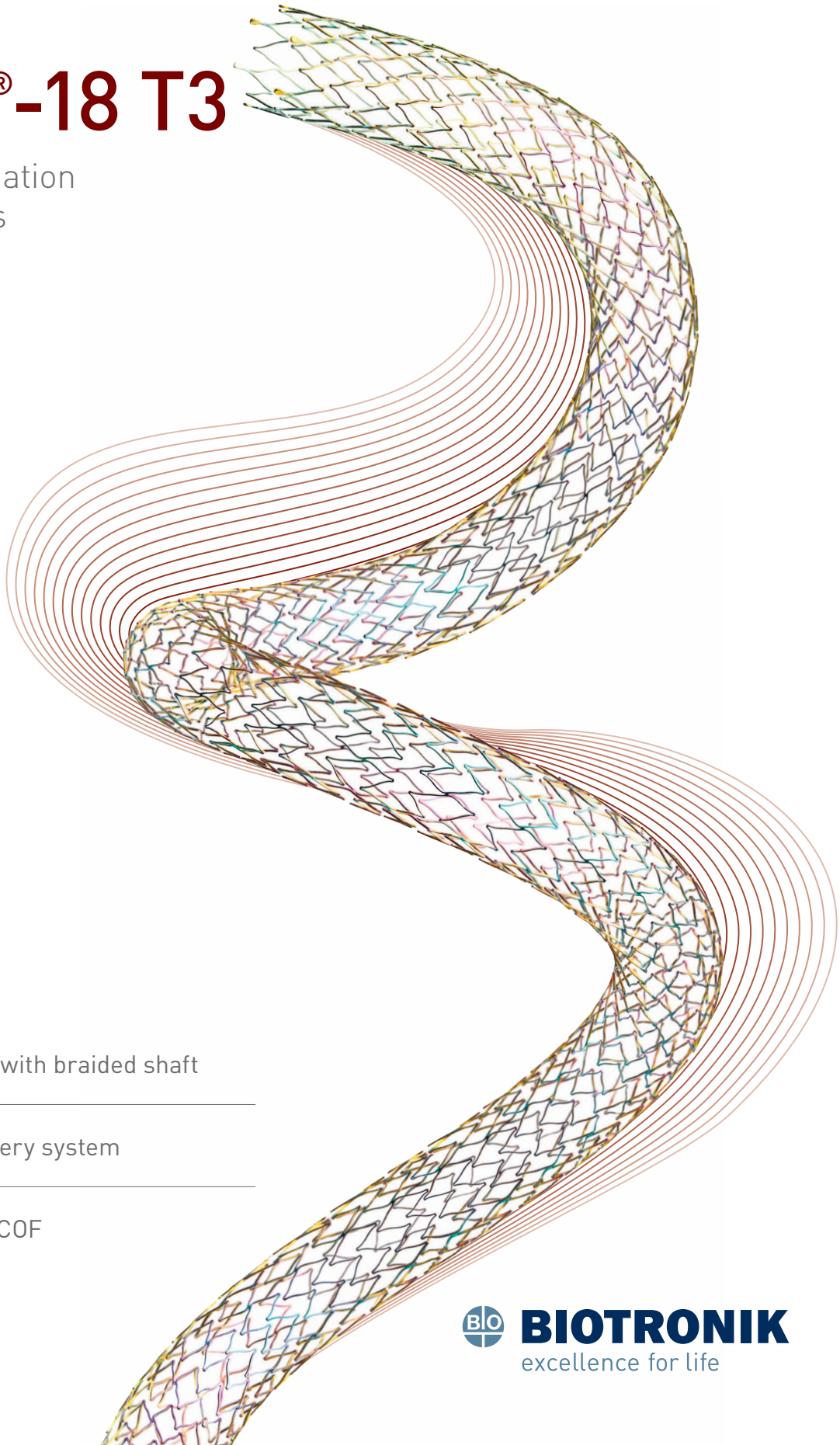
Vascular Intervention // Peripheral
Self-Expanding Stent System/0.018"/OTW

Pulsar®-18 T3

A unique combination
of 3 technologies



- Tri-axial system with braided shaft
- 4F Low profile delivery system
- Thin struts, low COF

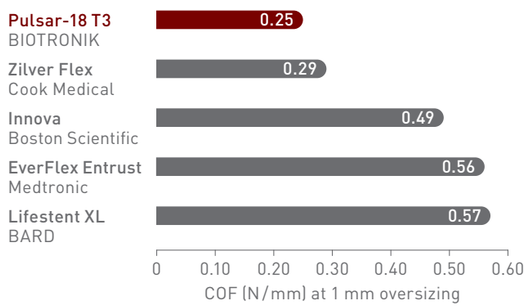
BIOTRONIK
excellence for life

Pulsar-18 T3

Clinically proven thin struts stent, with tri-axial shaft on a 4F low profile

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

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

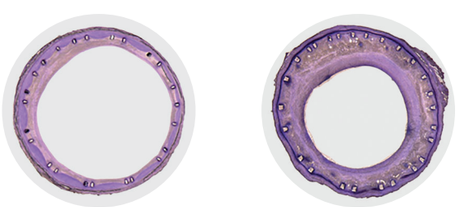


0.25 N/mm
low Chronic Outward Force[2]

Thinner struts and lower COF make a difference:*

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

Vessel response on SE stent 1 mm oversizing showing neointimal hyperplasia at 90 days[6*]

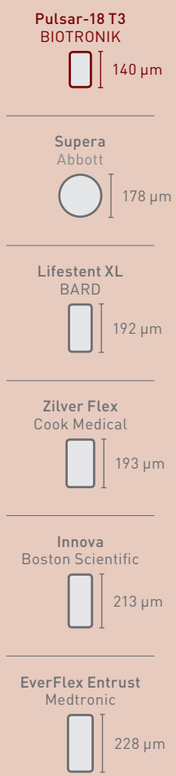


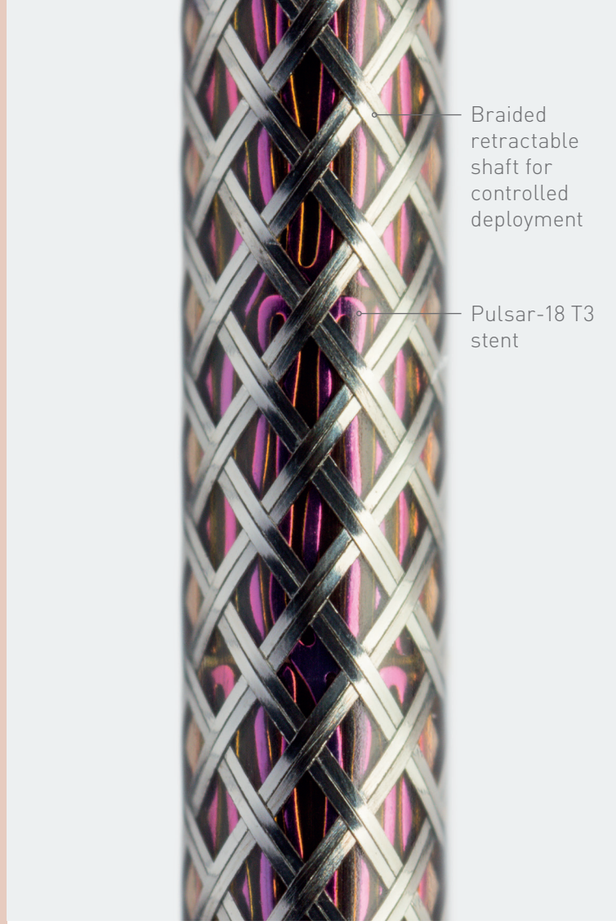
Pulsar Stent
BIOTRONIK
Low COF

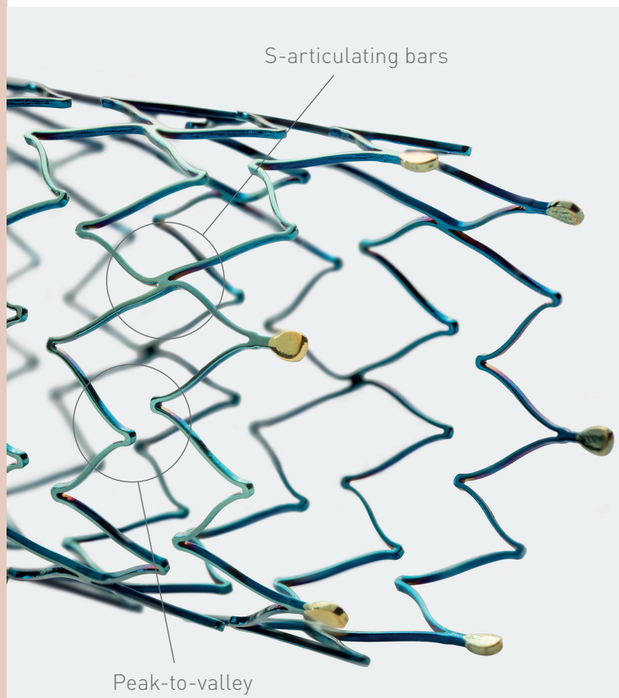
Lifestent XL
BARD
High COF

*As demonstrated in pre-clinical studies

Stent strut thickness in perspective[1]





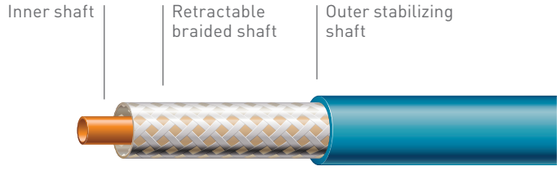


Unique tri-axial shaft design on 4F low profile

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[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 than 6F[8]
- No need for a closure device[7]
- Potential for ambulatory treatment

45%
smaller puncture site than 6F[8]

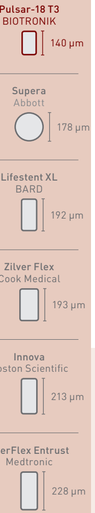
*Less access site complications

Pulsar-18 T3

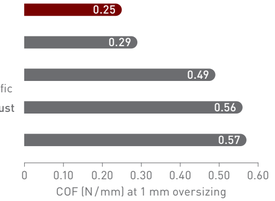
Clinically proven thin struts stent, with tri-axial shaft on a 4F low profile

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

Stent strut thickness in perspective[1]



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



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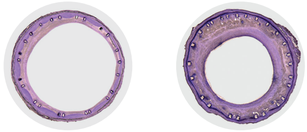


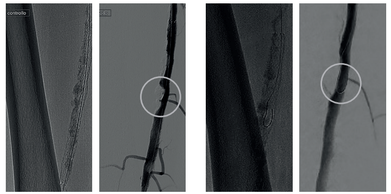
Pulsar Stent
BIOTRONIK
Low COF

Lifestent XL
BARD
High COF

*As demonstrated in pre-clinical studies

>1200
patients enrolled

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.

Clinically proven

Safety and efficacy at 12 months

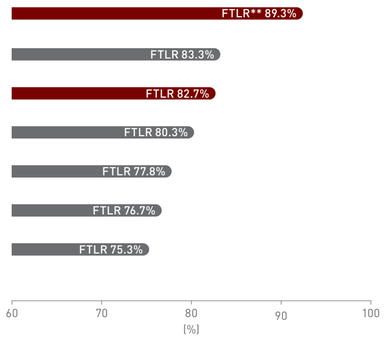
4F INTERVENTIONS 4EVER[7]		
FTLR:** **89.3%**	PP:† **81.4%**	A.L.L.:†† **7.1 cm**
LONG & OCCLUDED TASC D[9]		
FTLR: **86%**	PP: **77%**	A.L.L.: **24.5 cm**
ALL-COMERS BIOFLEX PEACE[10] (stent only)		
FTLR: **89.3%**	PP: **84.7%**	A.L.L.: **8.2 cm**

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

89.3%
24-month FTLR
BIOFLEX PEACE[10]

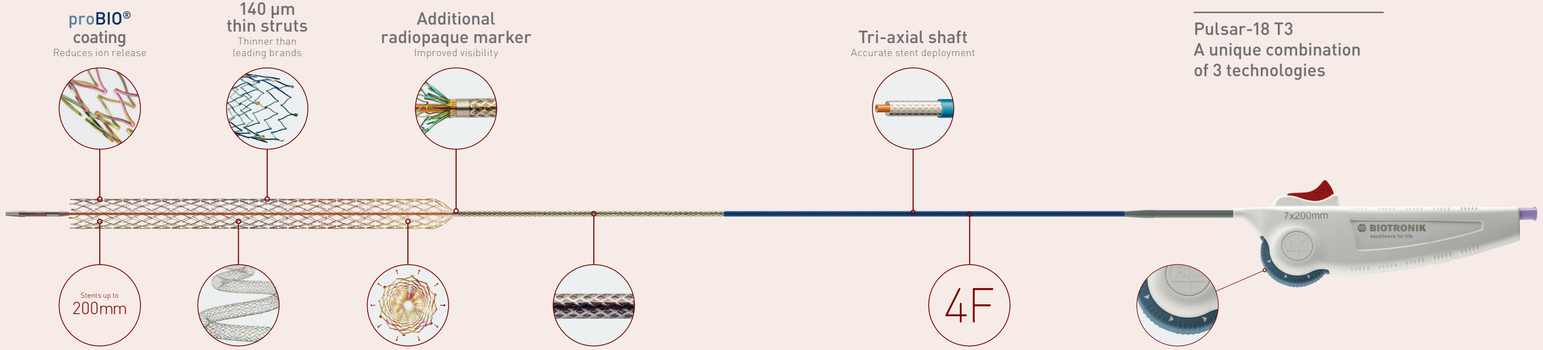
24-month outcomes of Pulsar stent, highlighting the long term safety and efficacy

Study, Product	Manufacturer	A.L.L.††	PP†
BIOFLEX PEACE[10] Pulsar (stent only)	**BIOTRONIK**	8.2 cm	78.4%
SUPERB[11] Supera	Abbott	7.8 cm	N/A
4EVER[12] Pulsar	**BIOTRONIK**	7.1 cm	72.3%
STROLL[13] S.M.A.R.T Control	Cardinal Health/Cordis	7.7 cm	74.9%
RESILIENT[14] Lifestent	BD/Bard	7.0 cm	N/A
ZILVER PTX[15] Zilver BMS provisional	Cook Medical	6.3 cm	65.8%
DURABILITY II[16] EverFlex	Medtronic	10.9 cm	66.1%



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. Astron Pulsar, Pulsar-18, Pulsar-18 T3 and Pulsar-35 have equivalent stent platforms, therefore the clinical results are valid for the Pulsar range.

Pulsar-18 T3
A unique combination of 3 technologies



*Superficial Femoral Artery

Pulsar-18 T3

Vascular
Intervention
Peripheral

Indicated for use in patients with atherosclerotic disease of the superficial femoral, proximal popliteal and infrapopliteal arteries and for the treatment of insufficient results after Percutaneous Transluminal Angioplasty (PTA), e.g. residual stenosis and dissection.*

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
Shaft	4F, hydrophobic coating, tri-axial
Usable length	90 cm and 135 cm

Ordering Information

4F

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

**8 weeks pre-order only

1. BIOTRONIK data on file. 6.0 mm diameters; 2. BIOTRONIK data on file. 6.0 mm diameters. Supera stent not possible to test due to its design and applied test method ; 3. Zhao HQ Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc. Interv. Radiol. 2009; 32(4); 720-6; 4. 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; 5. 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; 6. 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; 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. BIOTRONIK data on file; 9. 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; 10. 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_10.10240301-1526a000785; 11. Supera IFU, EL2100430 (2016-03-23); 12. Bosiers M. 4EVER 24 month results: long-term results of 4F Pulsar stent in femoropopliteal lesions. Presented at: CIRSE 2013; Barcelona, Spain; 13. Bunte M et al. in STROLL Catheterization and Cardiovascular Interventions 2018; 92:106-114; 14. Laird J et al. RESILIENT SFA nitinol stenting. JET 2012;19:1-9; 15. Dake M et al. Durable clinical effectiveness with paclitaxel-eluting stents in the femoropopliteal artery: 5-year results of the Zilver PTX randomized trial. Am Heart Assoc 133.15 (2016): 1472-1483. doi: 10.1161/CIRCULATIONAHA.115.016900; 16. Rocha-Singh et al. DURABILITY II Three-Year Follow-up. Catheterization and Cardiovascular Interventions 2015; 86:164-170.

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.

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