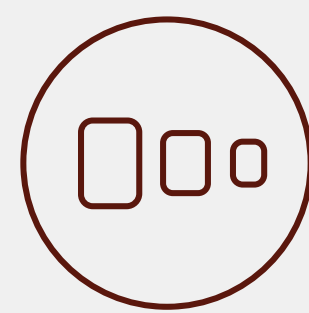


Tri-axial system  
with braided shaft



Low-profile  
delivery system



Thin struts,  
low COF



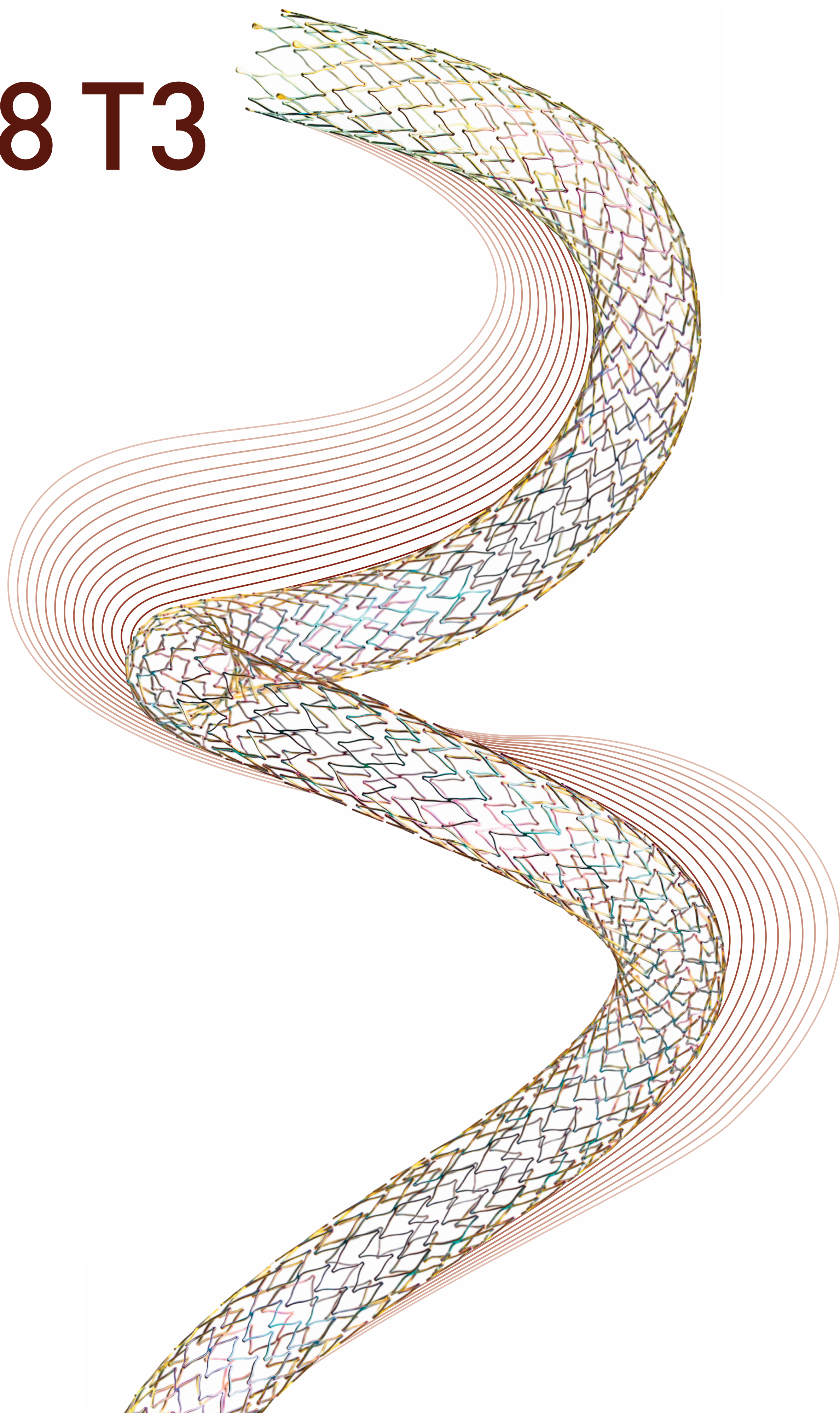
Technical data /  
ordering info

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



# Pulsar<sup>®</sup>-18 T3

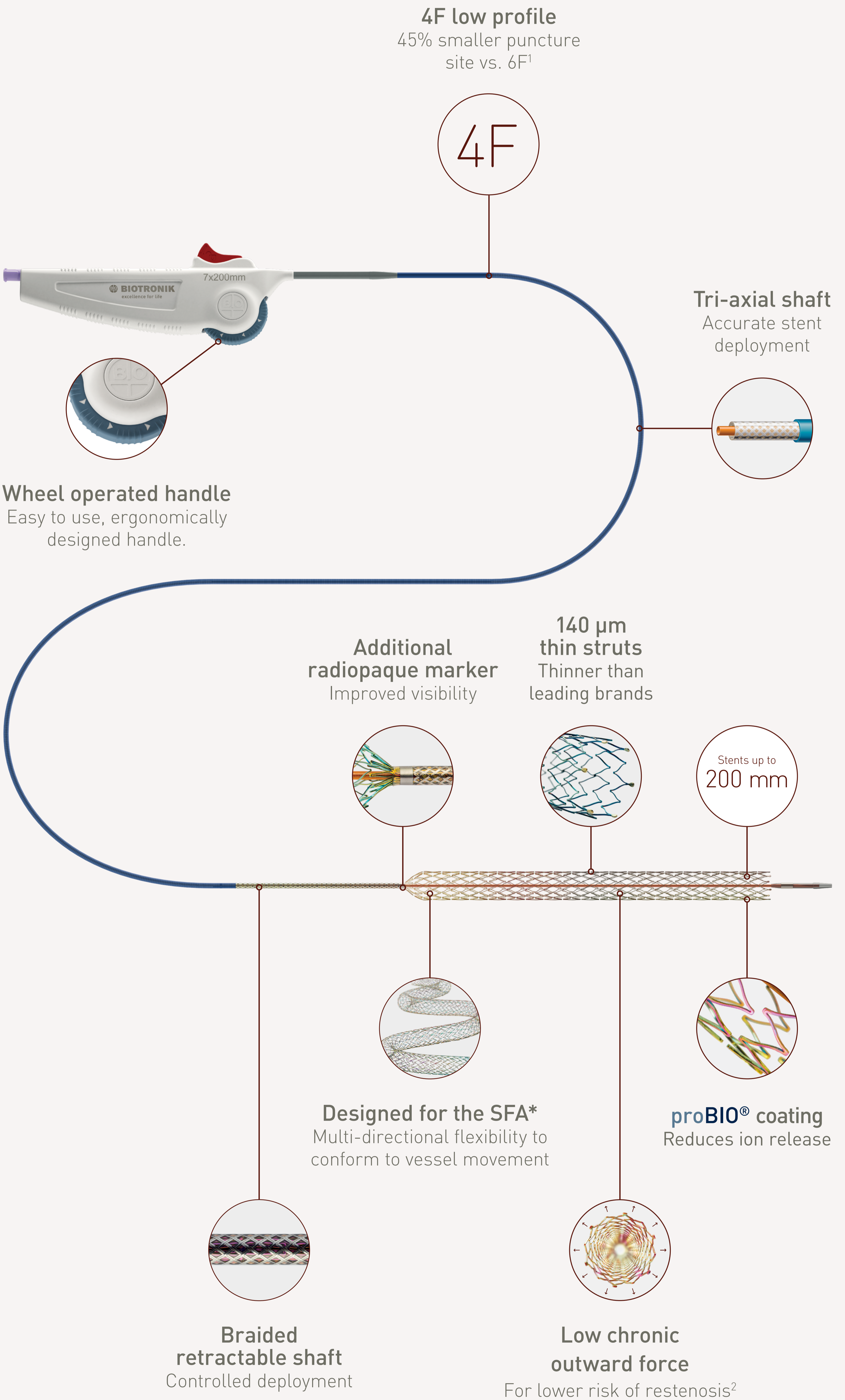
A unique combination  
of 3 technologies





# Pulsar-18 T3

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



# 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.

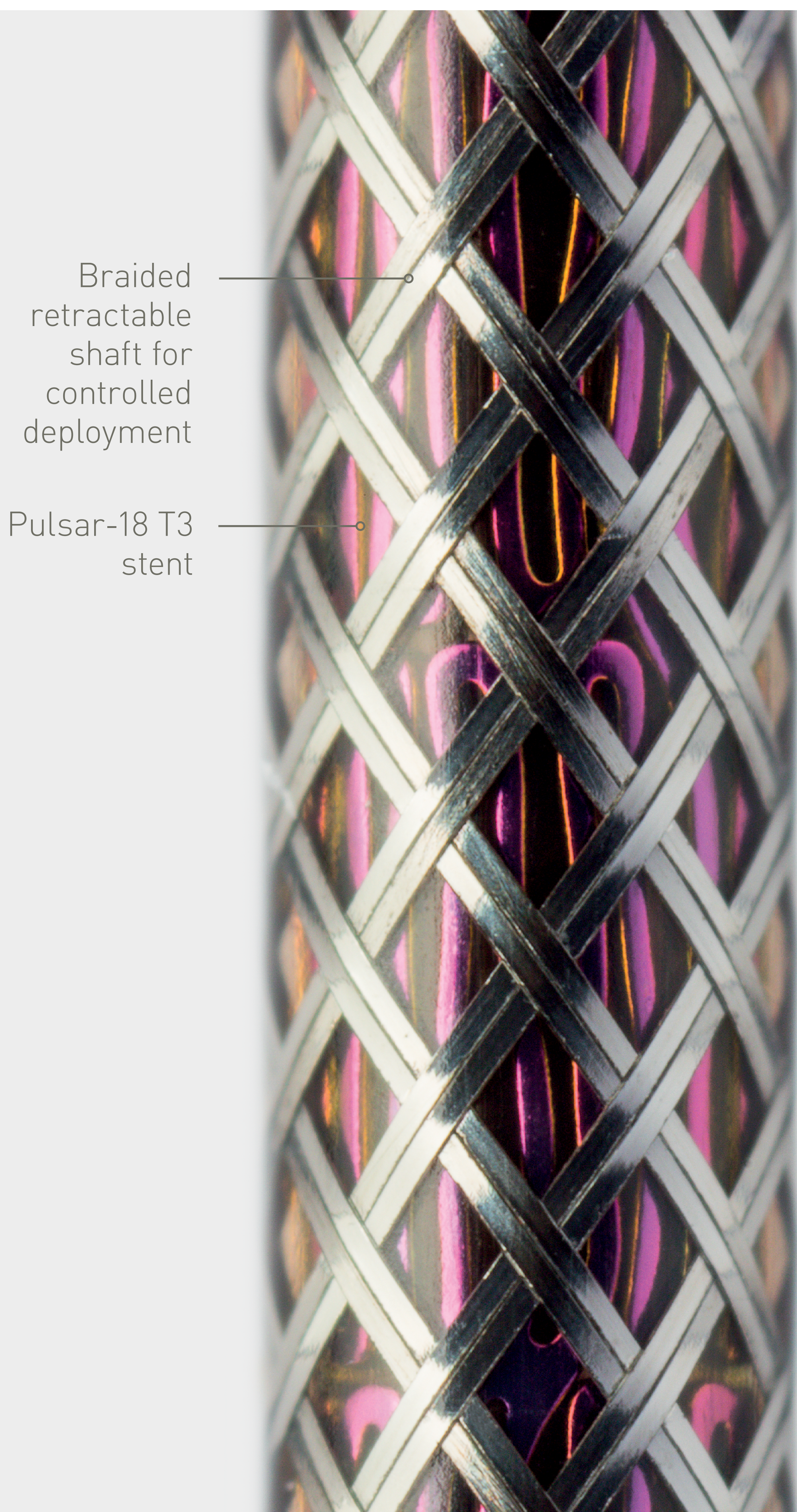
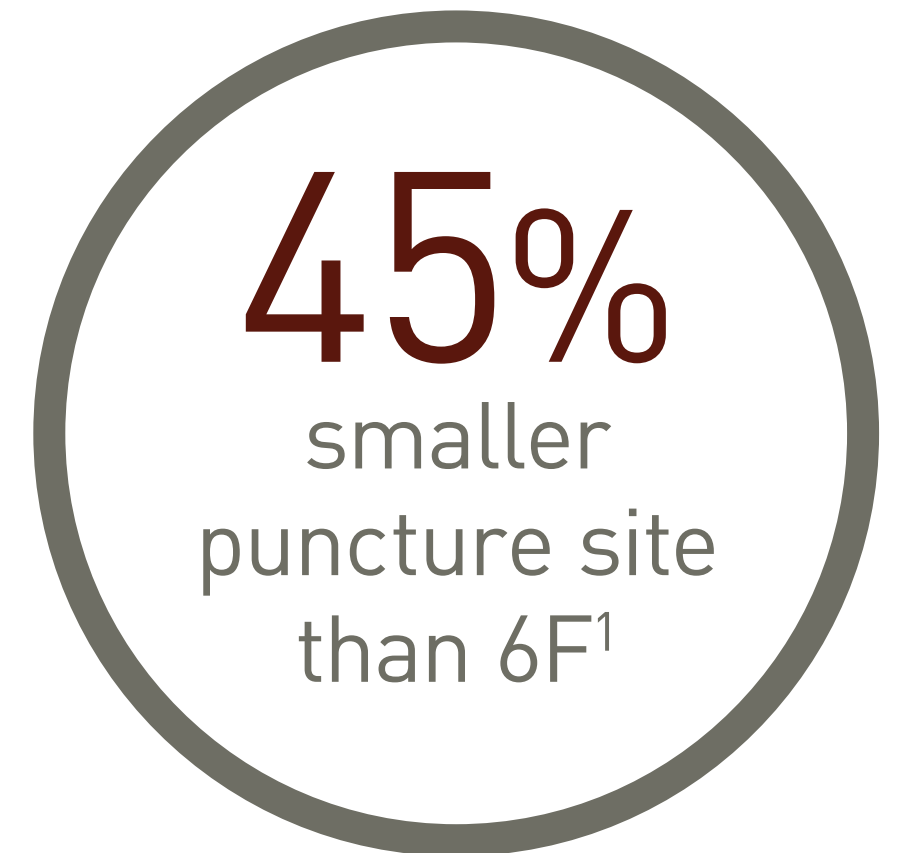


## 4F low profile - improved acute outcomes\* vs. 6F<sup>3</sup>

### Potential for safer, faster and simpler procedures than 6F

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

\* Less access site complications



Braided retractable shaft for controlled deployment

Pulsar-18 T3 stent

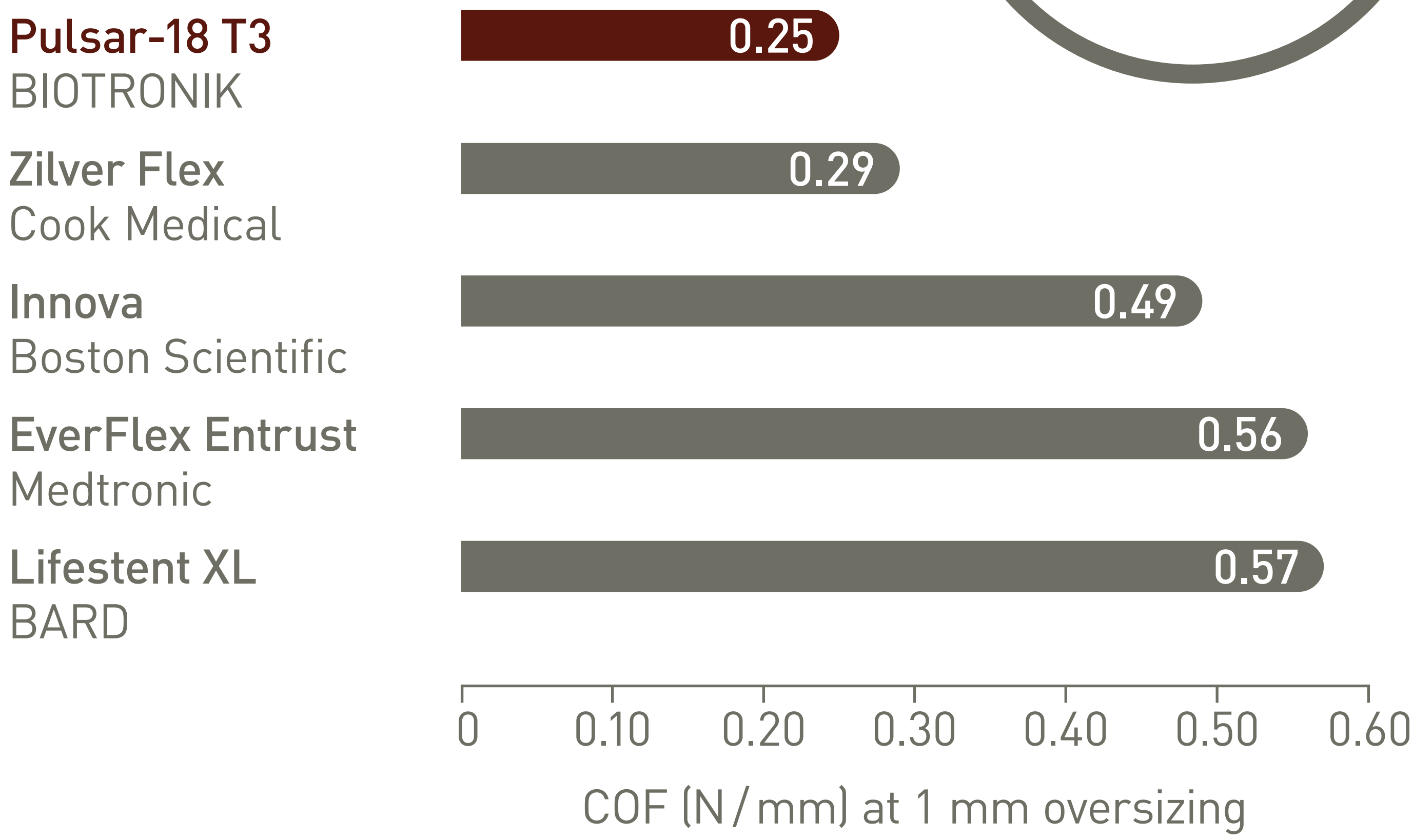
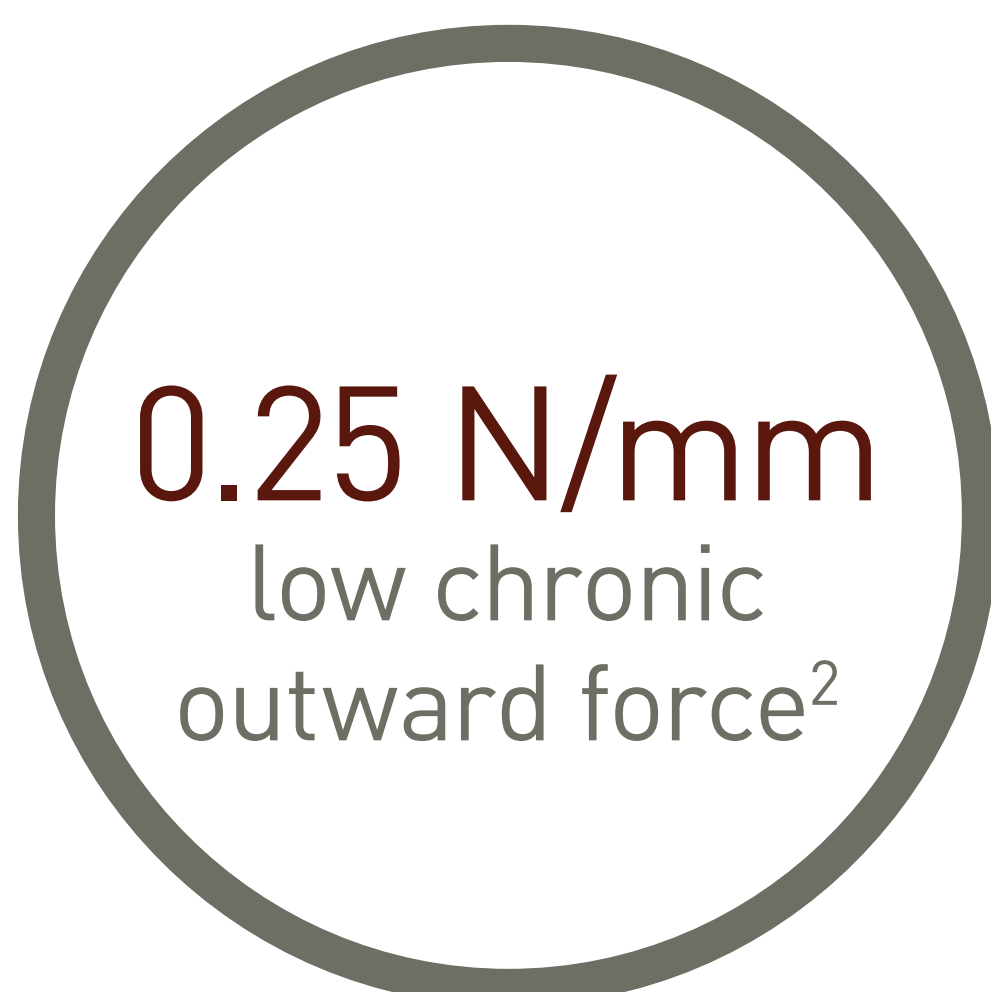


# Pulsar-18 T3

## Thin struts and low chronic outward force

### 140 µm thin struts - thinner than leading brands<sup>4</sup>

Thinner struts for lower chronic outward force (COF)<sup>5</sup>

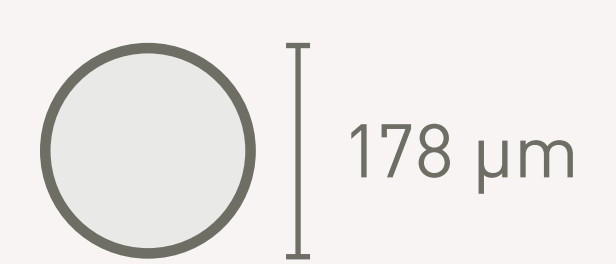


140 µm thin struts – thinner than other US brands<sup>4,5</sup>

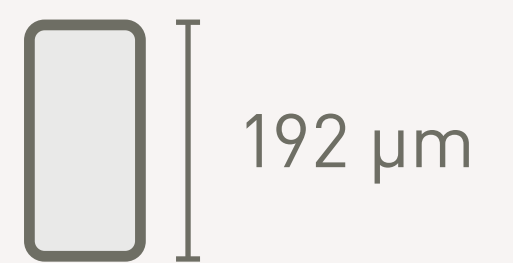
Pulsar-18 T3 BIOTRONIK



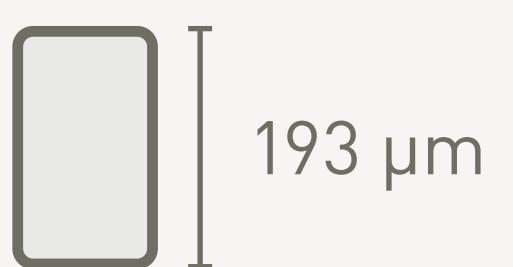
Supera Abbott



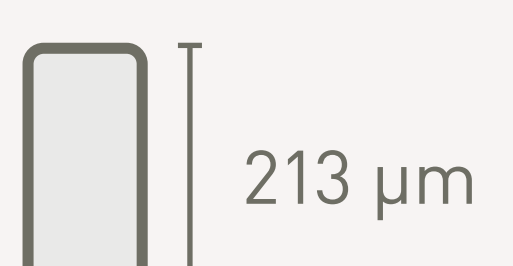
Lifestent XL BARD



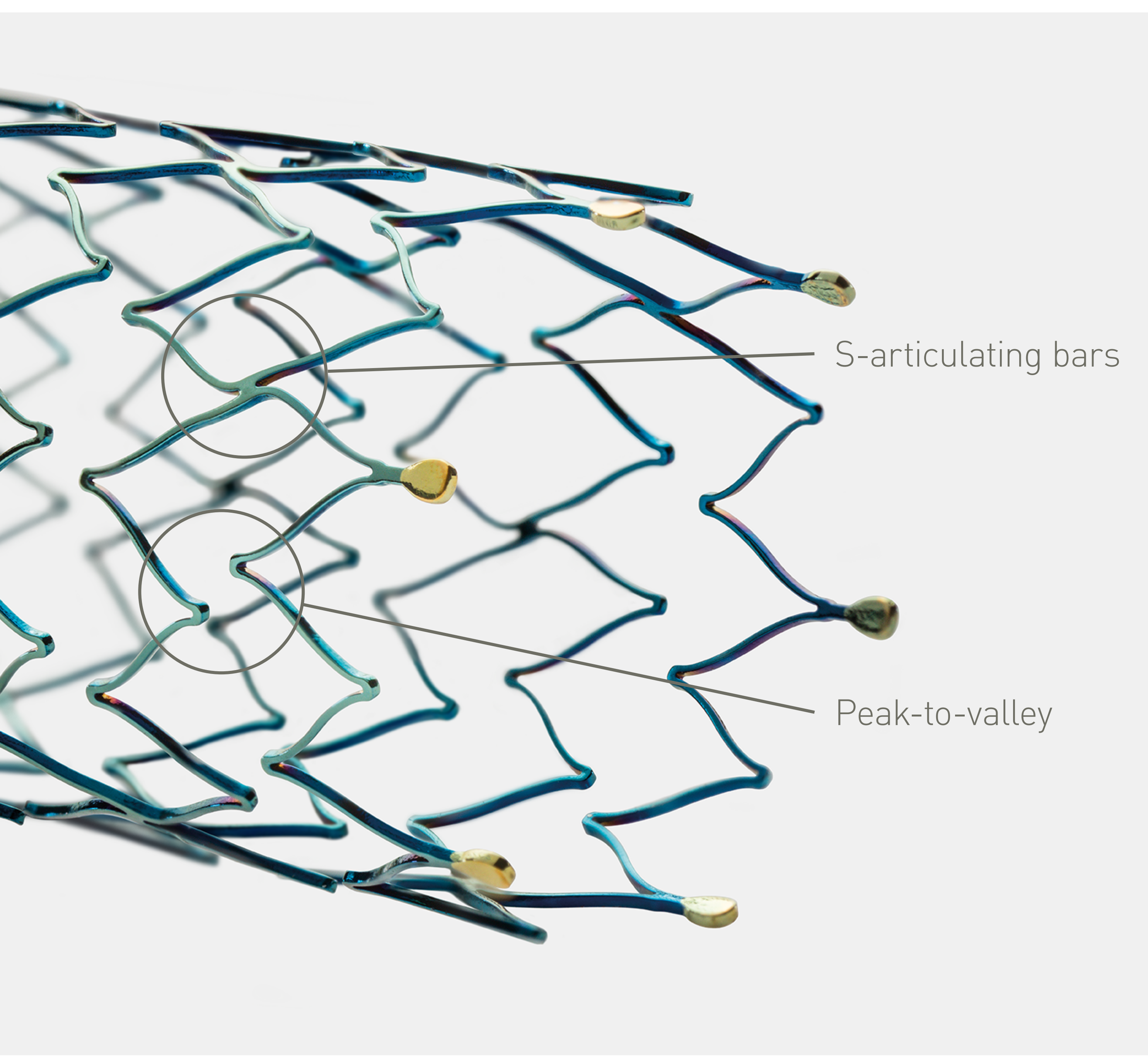
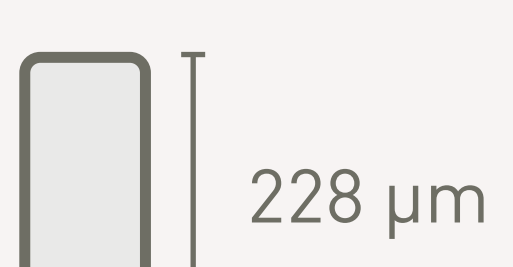
Zilver Flex Cook Medical



Innova Boston Scientific



EverFlex Entrust Medtronic



### Thinner struts and lower COF make a difference:\*

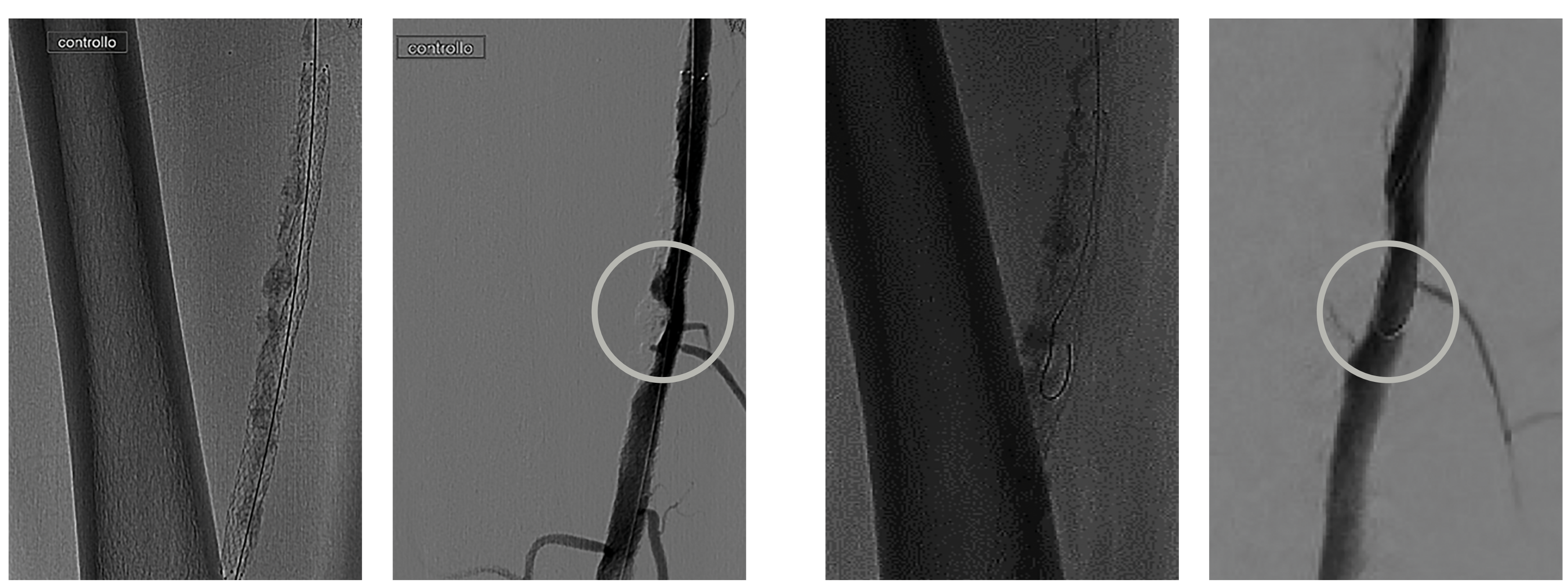
- Lower risk of restenosis<sup>2</sup>
- Reduced vessel injury and inflammation<sup>2</sup>
- Faster endothelialization<sup>6,7</sup>

\*As demonstrated in pre-clinical studies

### Vessel response on SE stent 1 mm oversizing showing neointimal hyperplasia at 90 days<sup>8\*</sup>



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



After the treatment 2011 [Courtesy of Prof. van den Berg<sup>8</sup>]

2016

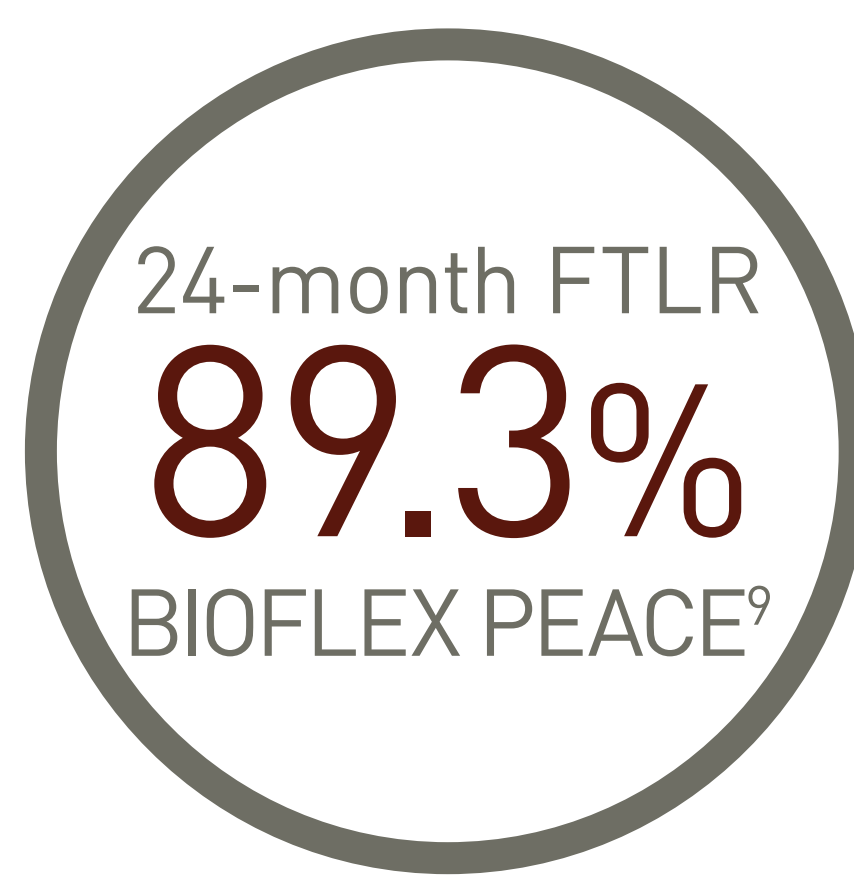
With a constant low chronic outward force applied to the vessel, patency can be achieved and maintained over a long term follow up even in calcified lesions.





# Pulsar-18 T3

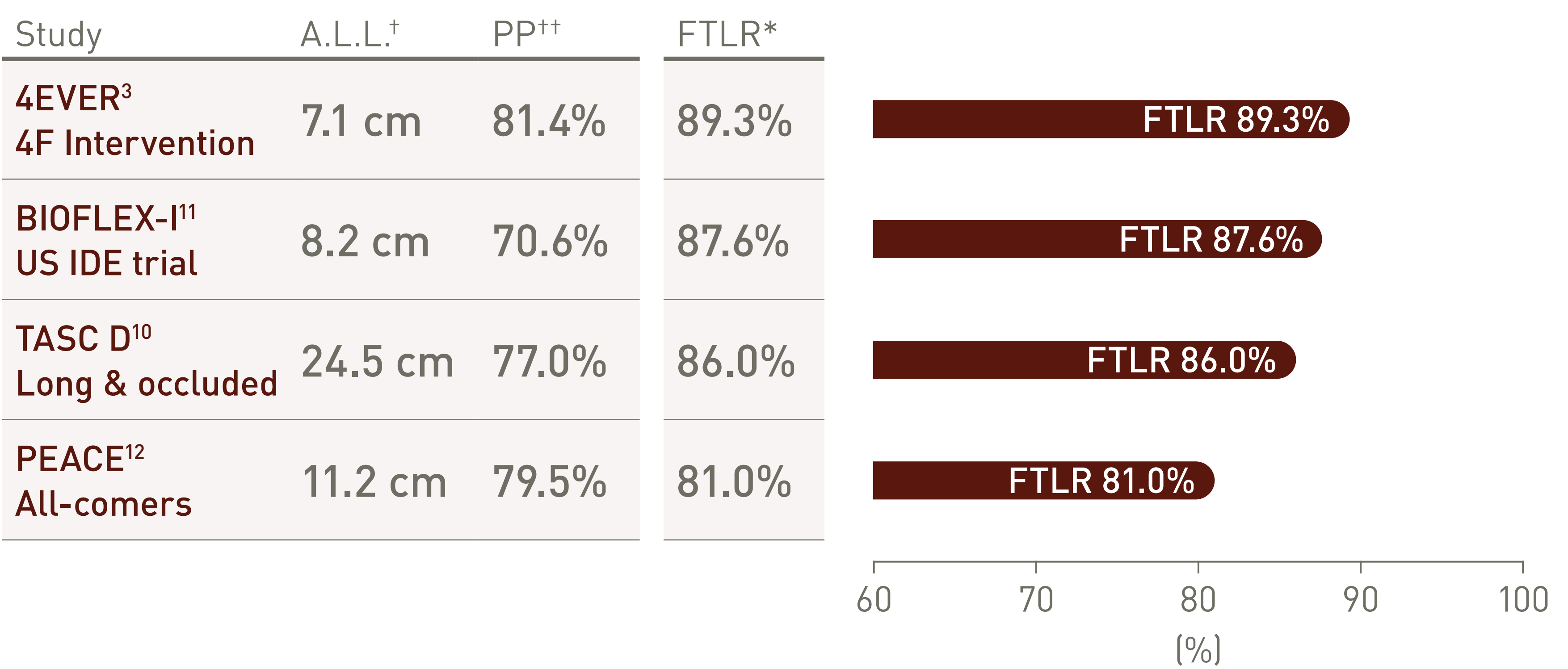
Clinically proven  
thin struts stent design



## Pulsar stent outcomes at 12 months



Safety and efficacy at 12 months



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

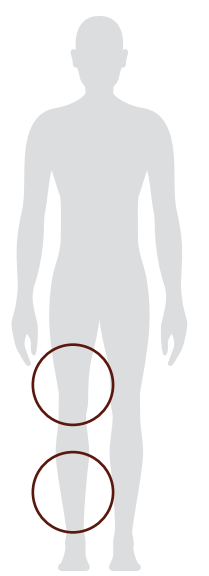
<sup>†</sup>A.L.L. - Average Lesion Length; <sup>††</sup>PP - Primary Patency;  
<sup>\*</sup>FTLR - Freedom from Target Lesion Revascularization





# Pulsar-18 T3

Vascular  
Intervention  
Peripheral



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.\*

## 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 Catheter length 90 cm ø (mm) (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 Catheter length 135 cm ø (mm) (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. *ENDOASC 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. Koppala 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 ENDOASC 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 *Catherization 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. *Catherization and Cardiovascular Interventions* 2015; 86:164-170; 20. SuperNOVA. US Food and Drug Administration, Center for Devices and Radiological Health, Inova™ 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. Inova 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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