



The next level of deliverability



Ultrathin struts



Outstanding patient outcomes



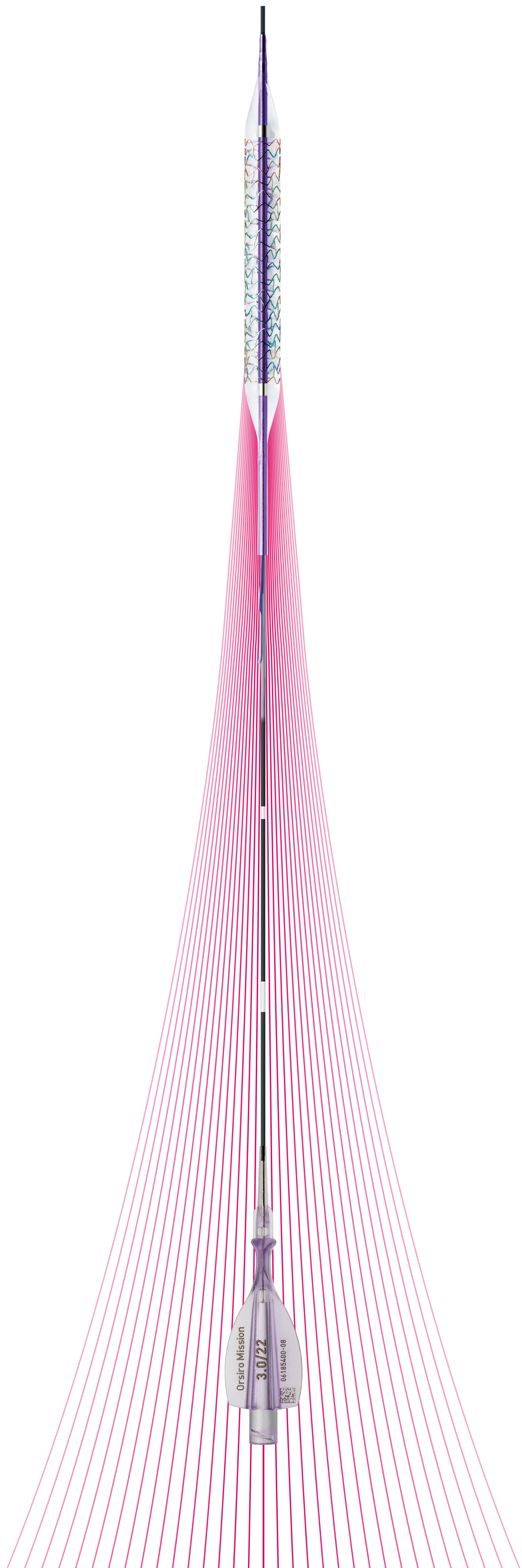
Technical data / ordering info

Vascular Intervention // **Coronary**  
Drug-Eluting Stent System



# Orsiro<sup>®</sup> Mission DES

Delivering superiority





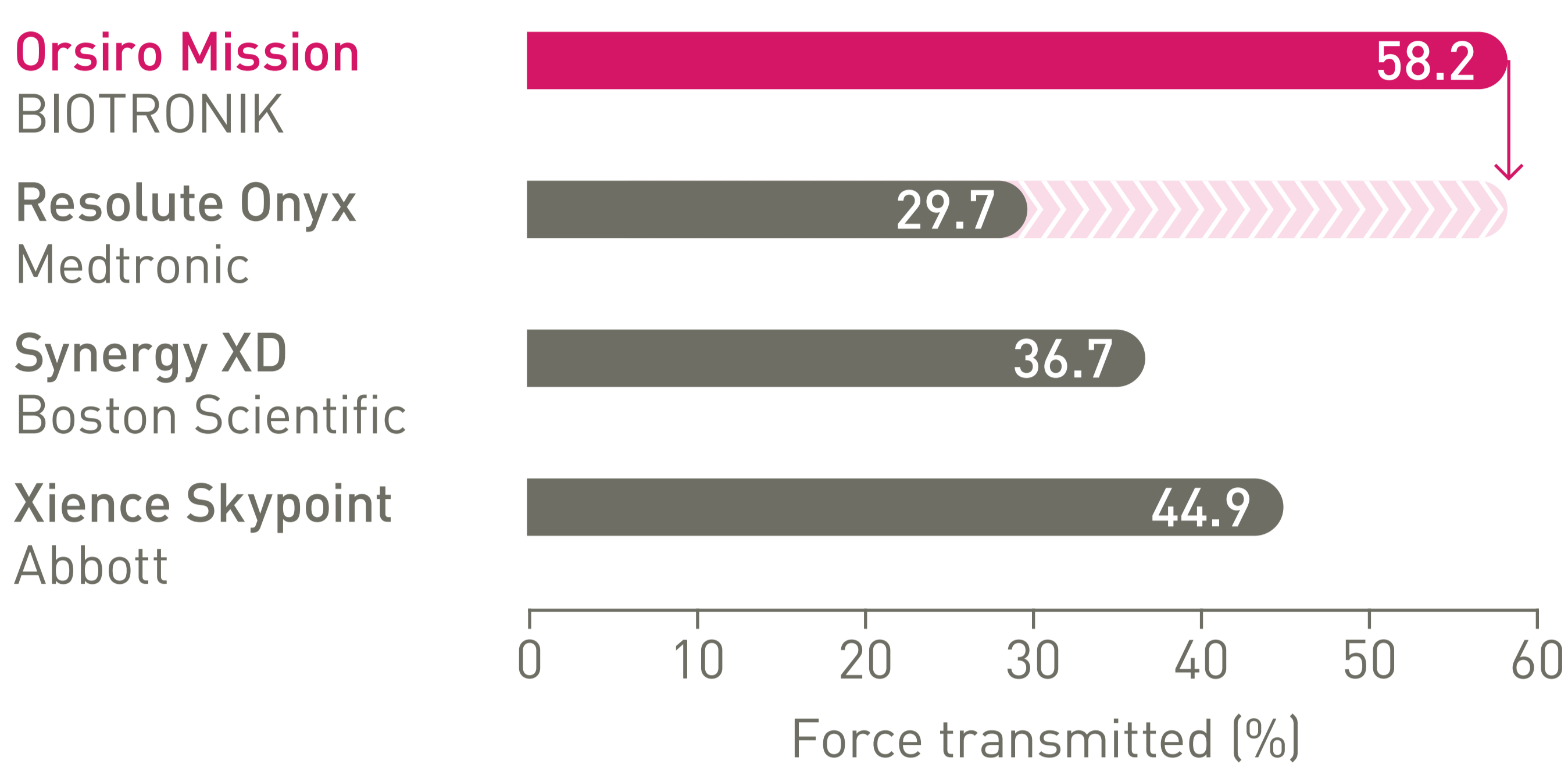
# Orsiro Mission<sup>DES</sup>

## Delivering superiority<sup>1,a</sup>

### The next level of deliverability<sup>2</sup>

#### Better pushability<sup>3</sup>

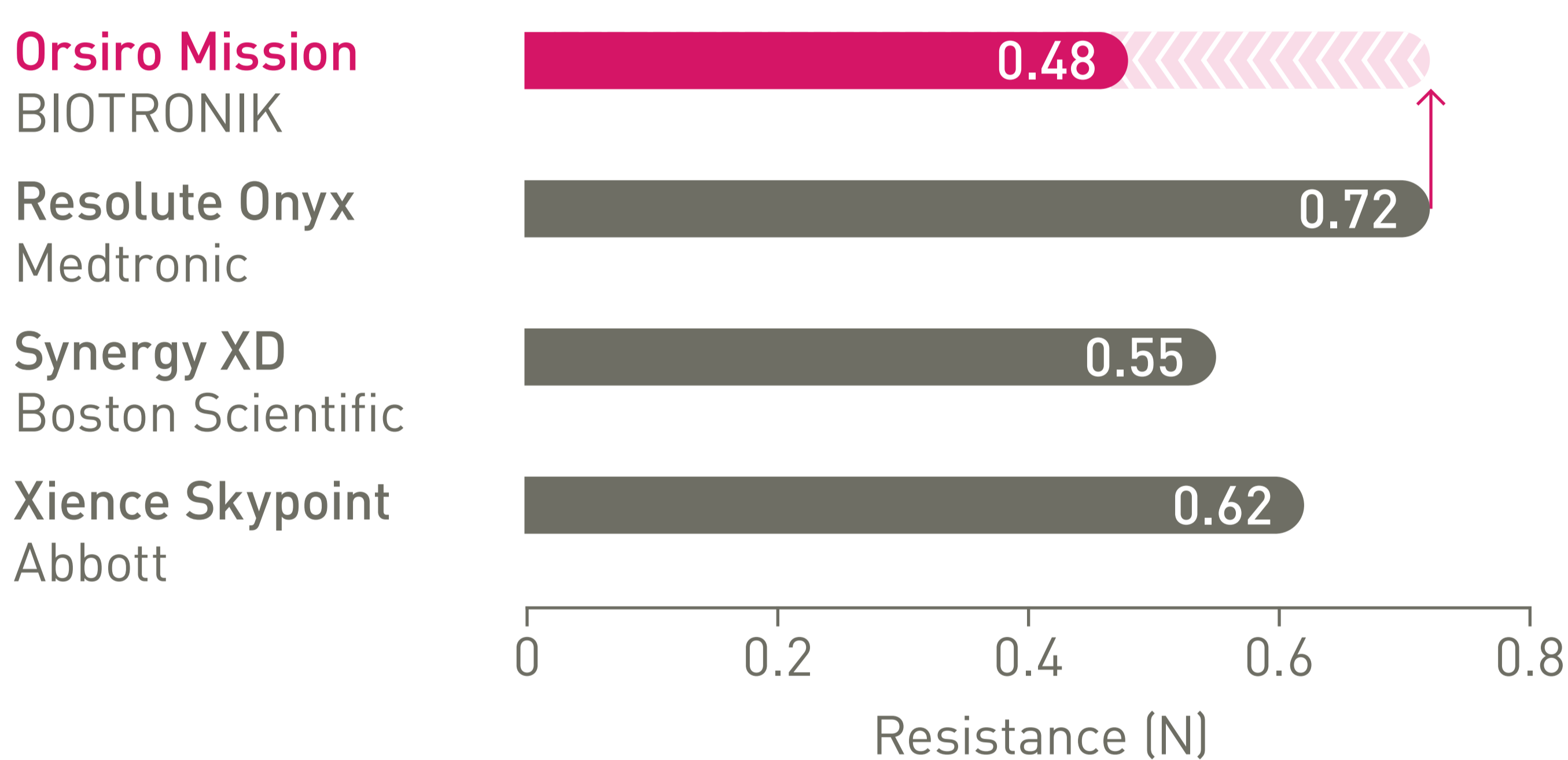
Transmitting up to **96% more** force from hub to tip.



**1<sup>st</sup>**  
in Push<sup>3</sup>

#### Better trackability<sup>3</sup>

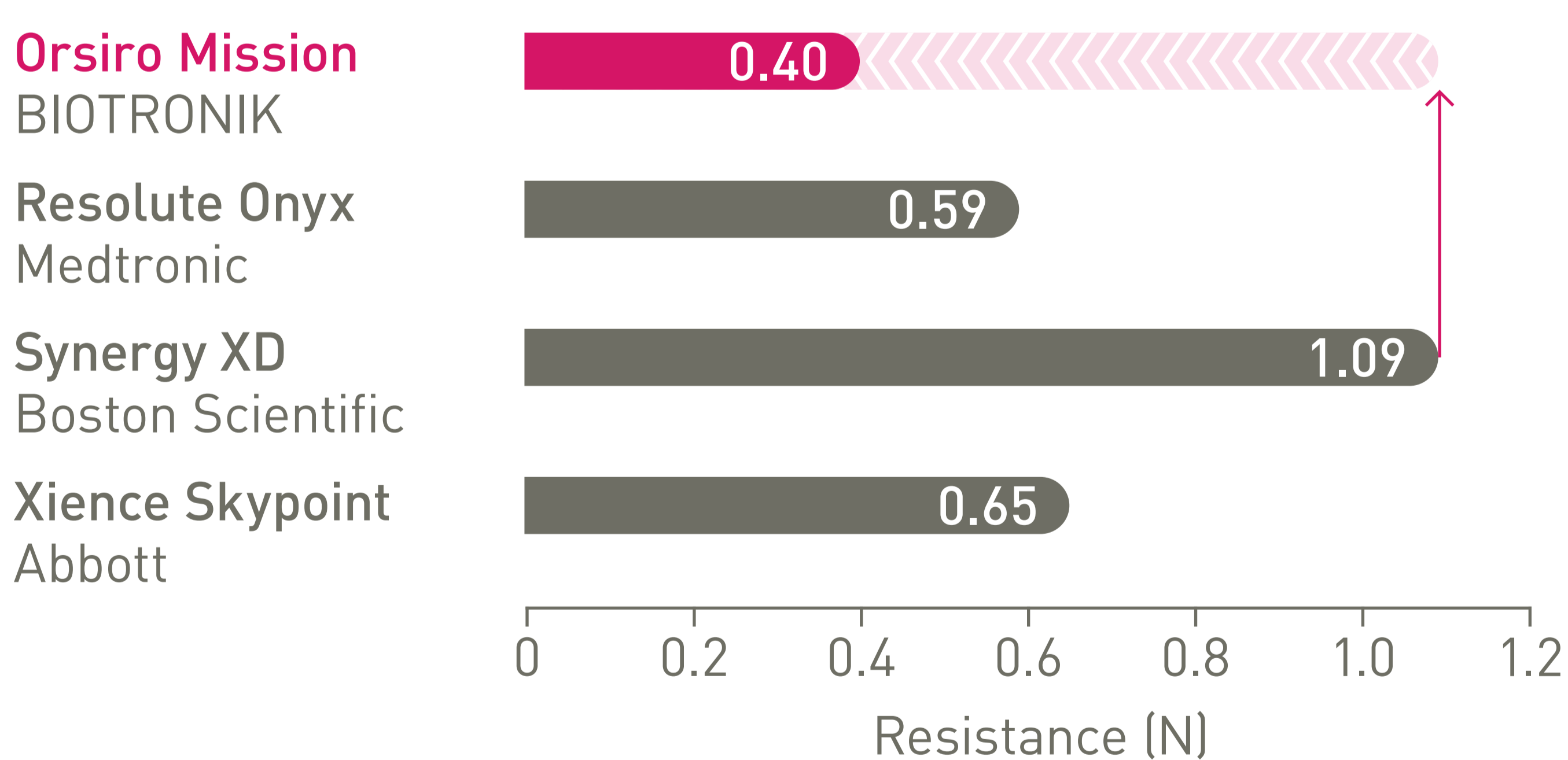
Up to **33% less** force needed to follow the path to the lesion.



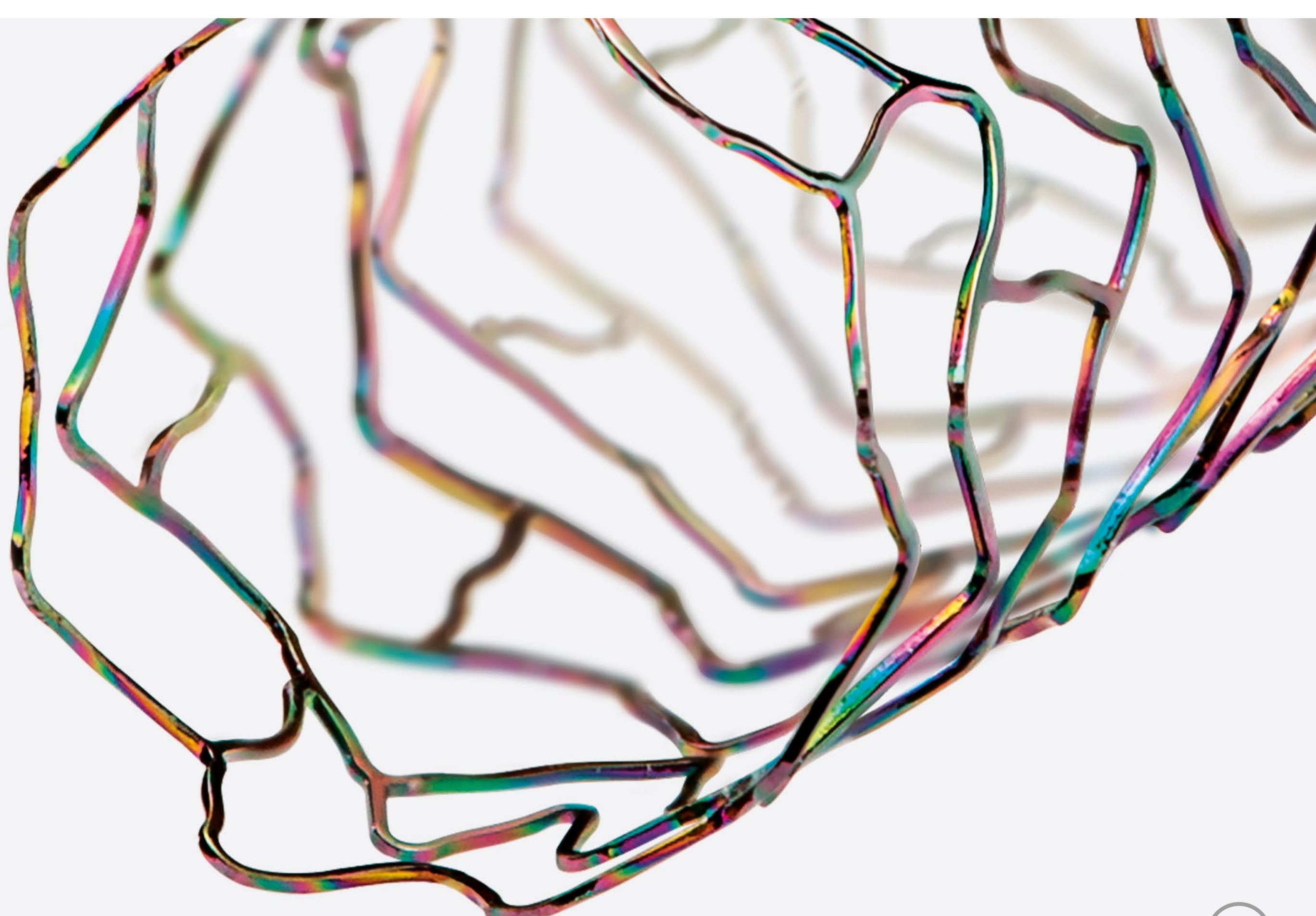
**1<sup>st</sup>**  
in Track<sup>3</sup>

#### Better crossability<sup>3</sup>

Up to **64% less** force needed to successfully cross demanding anatomies.



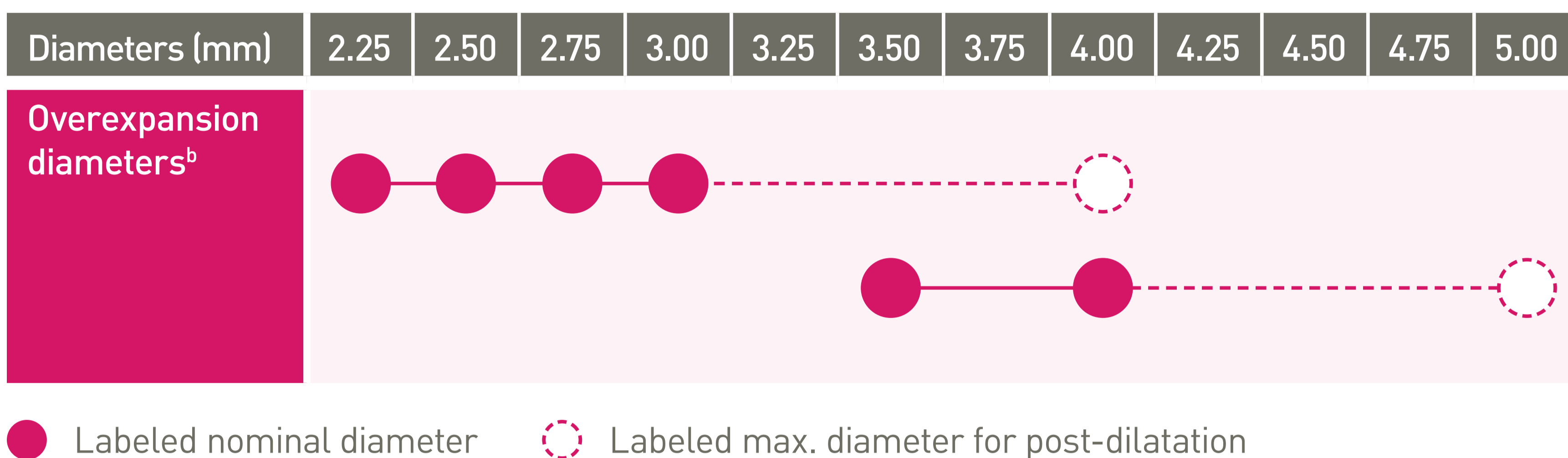
**1<sup>st</sup>**  
in Cross<sup>3</sup>



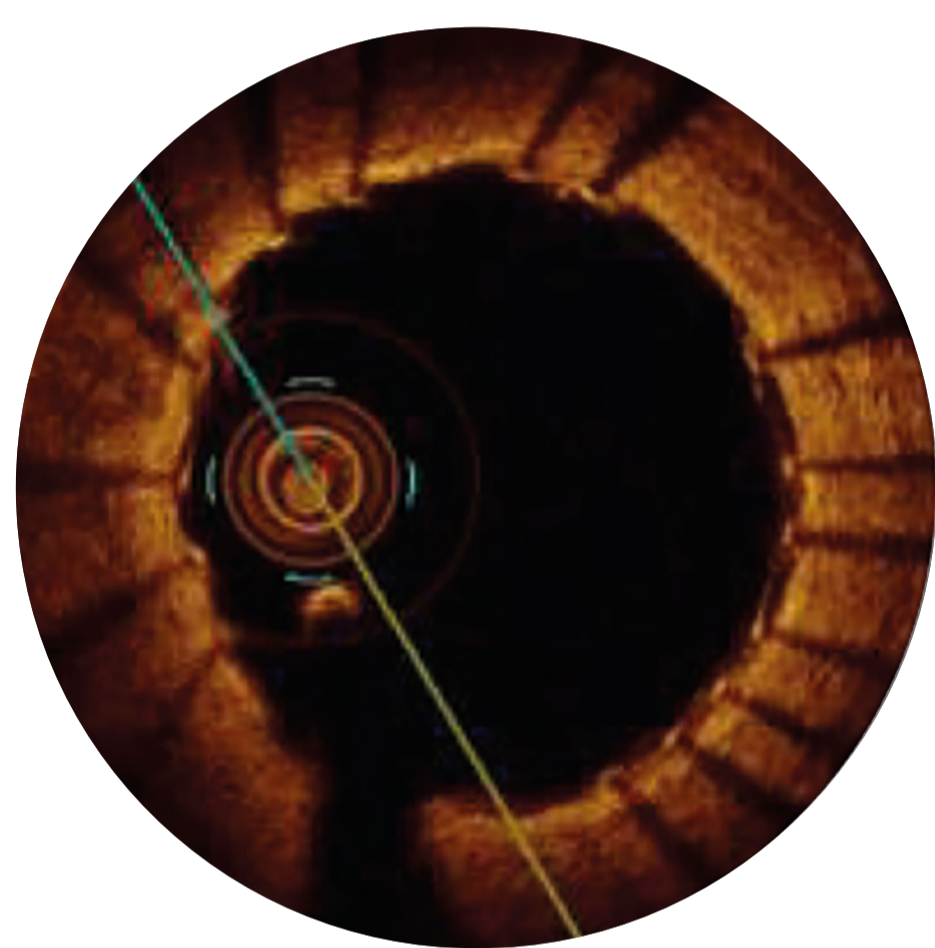


# Ultrathin struts<sup>7</sup>

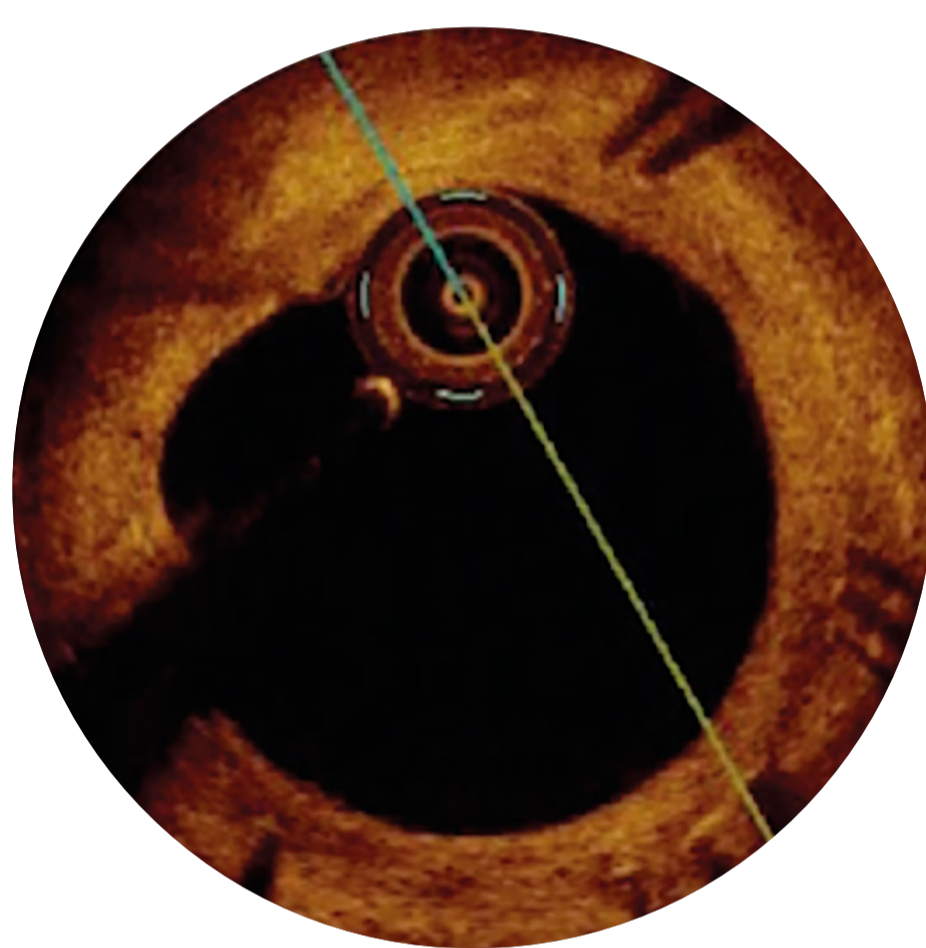
## Conforming to a wider range of vessels<sup>8,c</sup>



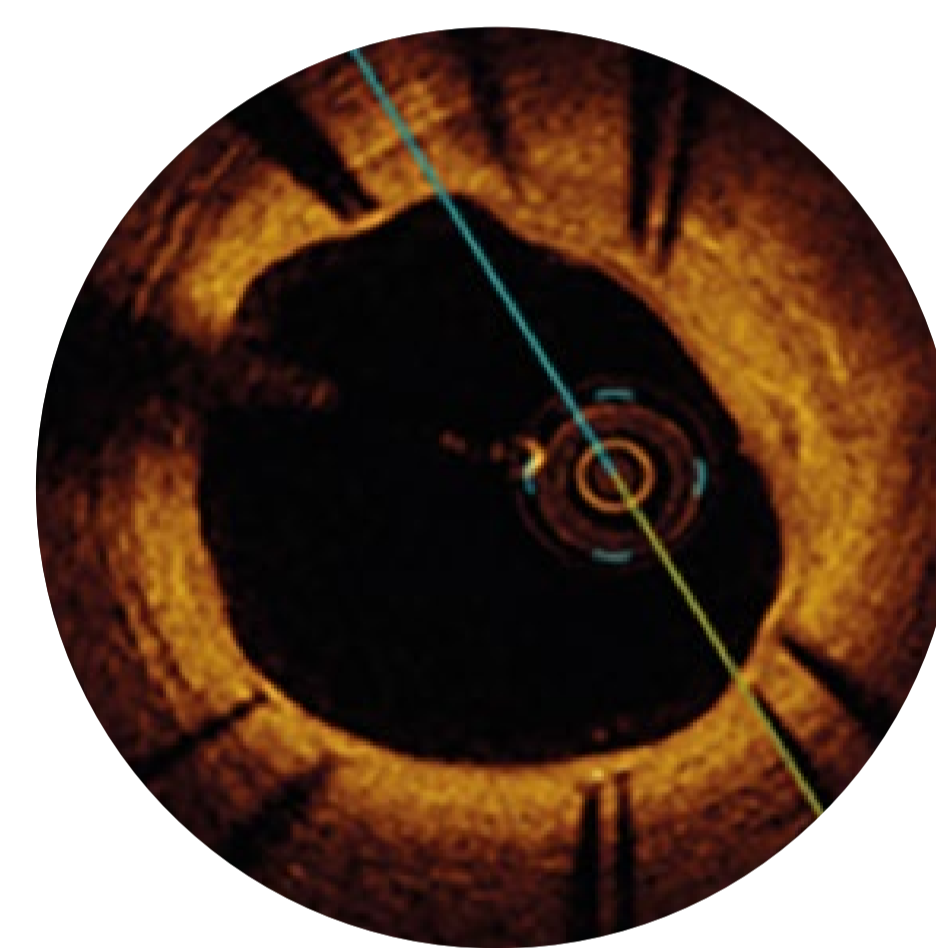
## Early endothelialization



Strut coverage<sup>9</sup>  
**30 days<sup>d</sup>**  
 >80%  
 n = 589



Strut coverage<sup>9</sup>  
**90 days<sup>d</sup>**  
 >97%  
 n = 874



Strut coverage<sup>9</sup>  
**180 days<sup>d</sup>**  
 >98%  
 n = 1,130



## Strut thickness in perspective<sup>4</sup>

**Orsiro Mission**  
 BIOTRONIK  
 CoCr-SES

60  $\mu\text{m}^b$

**Synergy XD**  
 Boston Scientific  
 PtCr-EES

74  $\mu\text{m}$

**Ultimaster**  
 Terumo  
 CoCr-SES

80  $\mu\text{m}$

**Resolute Onyx<sup>5,6</sup>**  
 Medtronic  
 CoNi-ZES

81  $\mu\text{m}$

**Xience Family**  
 Abbott  
 CoCr-EES

81  $\mu\text{m}$

**Promus**  
 Boston Scientific  
 PtCr-EES

81  $\mu\text{m}$

**BioMatrix**  
 Biosensors  
 316L-BES

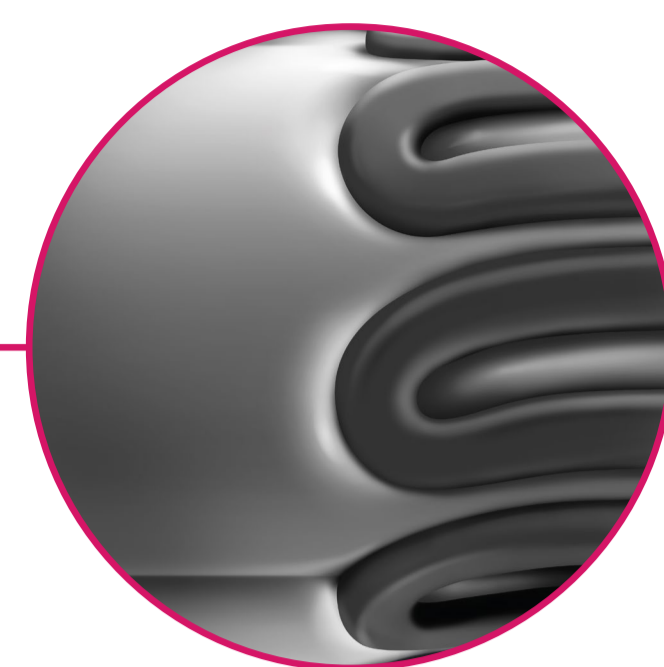
120  $\mu\text{m}$





**BIOlute<sup>®</sup>**

**Bioabsorbable coating**  
with controlled drug release and low<sup>15</sup> thrombogenicity



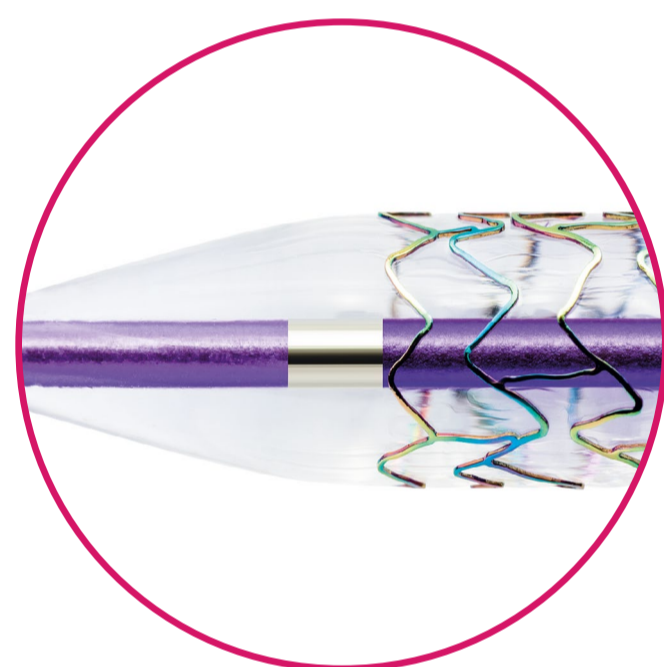
**Deep embedding**  
for high cross

**proBIO<sup>®</sup>**

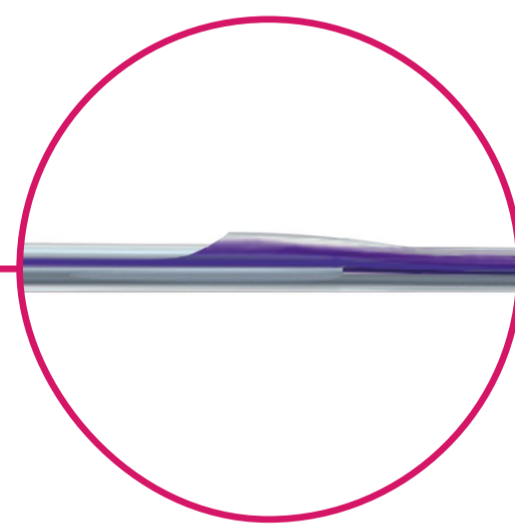
**Passive coating**  
for high biocompatibility

**60  $\mu\text{m}^b$**

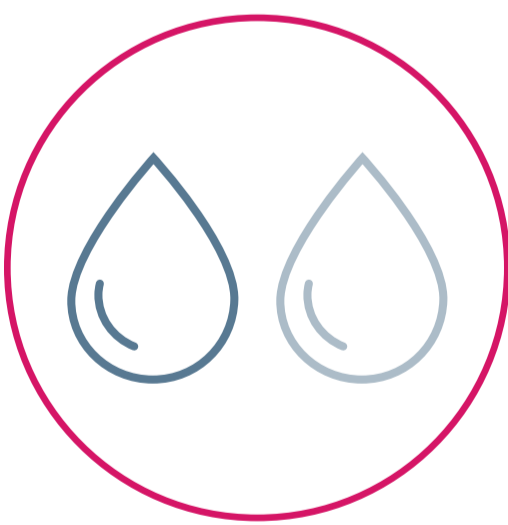
**Ultrathin struts**  
for early endothelialization



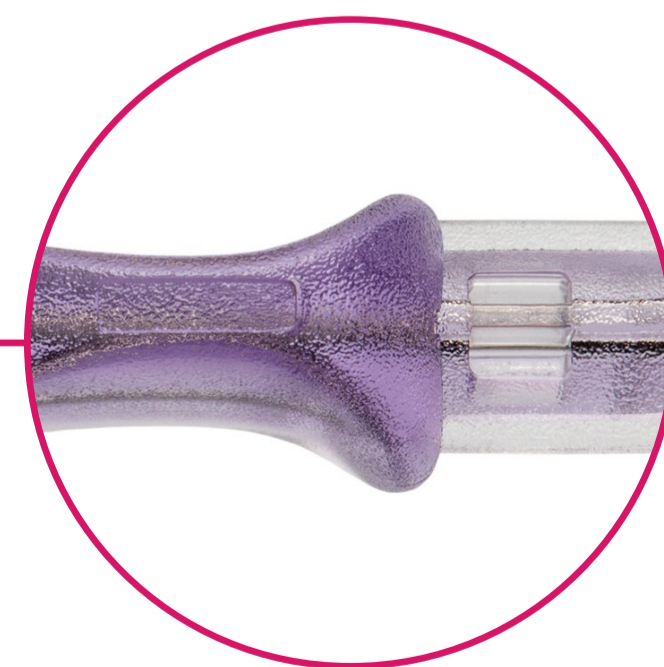
**More flexible shaft**  
for high track



**Enhanced force transmission**  
for high push



**Dual-coating**  
on shaft for limited friction



**Ergonomic hub**  
with kink resistance



Orsiro Mission  
3.0/22  
06185400-08



# Outstanding patient outcomes<sup>10,e</sup>

Orsiro family of DES – One of the most studied DES<sup>11,e,f</sup>

>100,000

patients enrolled or planned in total<sup>12,e,f</sup>

>71,500

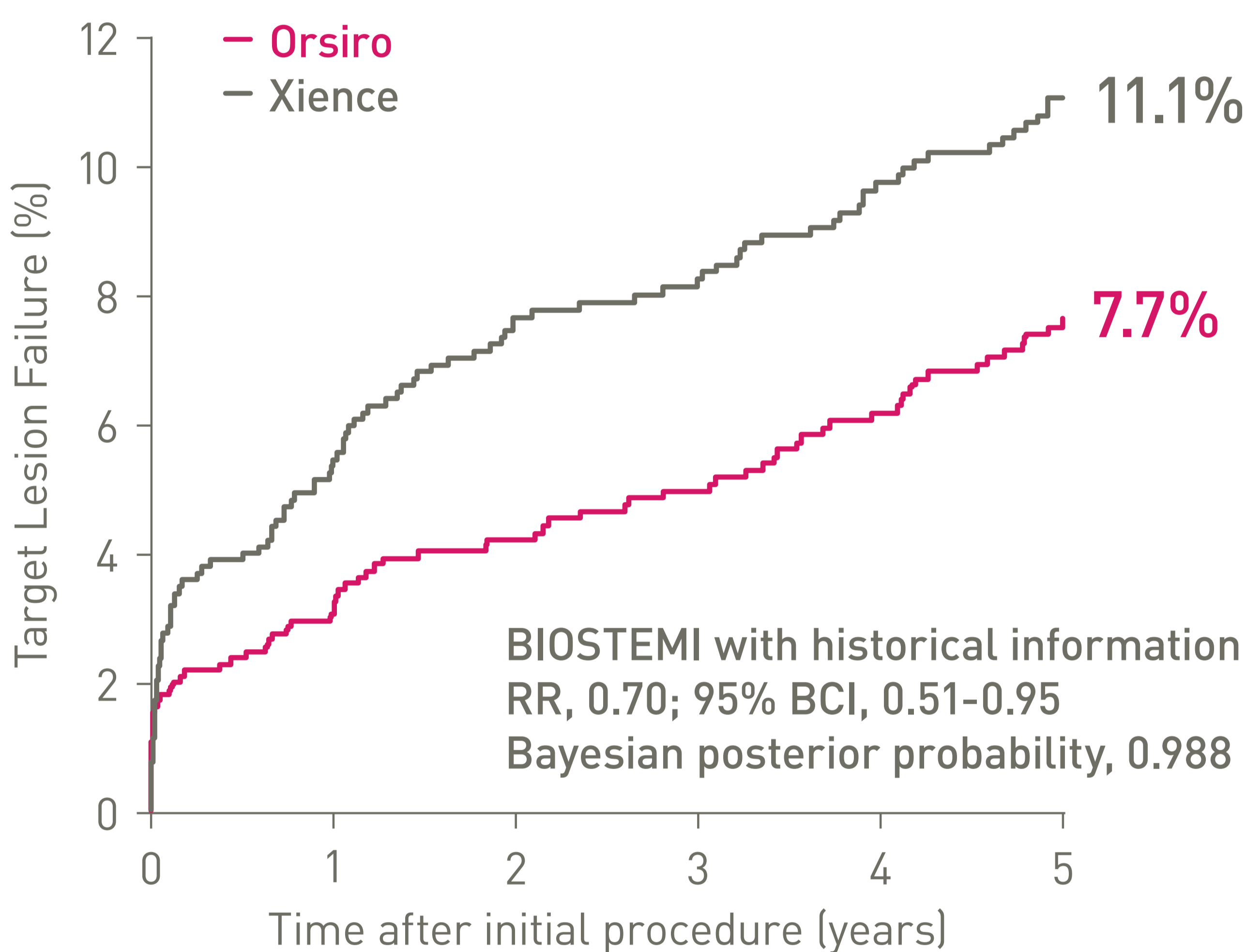
patients enrolled<sup>12,e,f</sup>

>86

studies started<sup>12,e,f</sup>

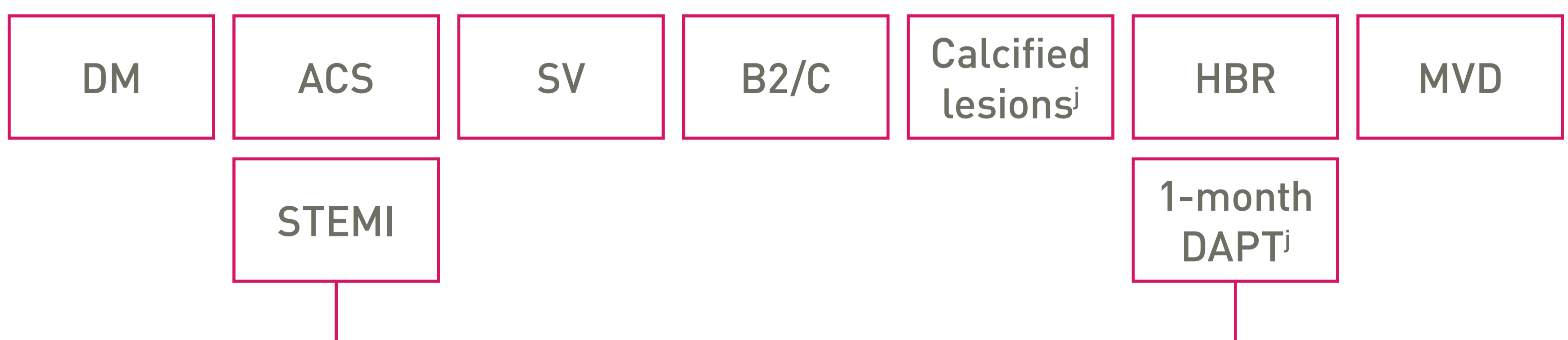
## BIOSTEMI

TLF at 5 years - continued superiority in STEMI<sup>13,e</sup>



**31%**  
significantly lower TLF<sup>13,e,g</sup>

## Orsiro Mission DES is indicated for complex patients and lesions<sup>h</sup>



Proven superiority in STEMI<sup>13,e,i</sup>

Proven safety and efficacy for 1-month DAPT<sup>14,j,f</sup>

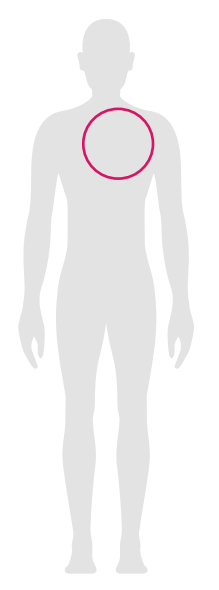




# Orsiro<sup>®</sup> Mission DES

The Orsiro Mission Sirolimus-Eluting Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.

Vascular  
Intervention  
Coronary



## Indication

Orsiro Mission DES is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions (length ≤ 40 mm) in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm including the following patient and lesion subsets:

|   |                                     |
|---|-------------------------------------|
| Acute Coronary Syndrome (ACS)                                 | Complex Lesions (B2/C)              |
| ST-Elevation Myocardial Infarction (STEMI)                    | Long Lesions (LL) (e.g. ≥ 20 mm)    |
| Diabetes Mellitus (DM)  | Small Vessels (SV) (e.g. ≤ 2.75 mm) |
| High Bleeding Risk (HBR)                                      | Multi-Vessel Disease (MVD)          |
| One month of dual antiplatelet therapy (DAPT) in HBR patients | Male/Female                         |
| Calcified lesions (moderate/severe calcification)             | Old Patients (e.g. > 65 y)          |

## Technical Data

### Stent

|                 |   |
|-----------------|---|
| Stent material  | Cobalt chromium, L-605  |
| Strut thickness | ø 2.25 – 3.0 mm: 60 µm (0.0024");<br>ø 3.50 – 4.0 mm: 80 µm (0.0031")         |
| Passive coating | proBIO <sup>®</sup> (Amorphous Silicon Carbide)                               |
| Active coating  | BIOLute <sup>®</sup> bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug |
| Drug dose       | 1.4 µg/mm <sup>2</sup>  |

### Delivery system

|                            |   |
|----------------------------|---|
| Catheter type              | Rapid exchange                              |
| Recommended guide catheter | 5F (min. I.D. 0.056")                       |
| Guide wire diameter        | 0.014"                                      |
| Usable catheter length     | 140 cm                                      |
| Balloon material           | Semi crystalline polymer material           |
| Coating (Distal shaft)     | Hydrophilic                                 |
| Coating (Proximal shaft)   | Hydrophobic                                 |
| Marker bands               | Two swaged platinum-iridium markers         |
| Lesion entry profile       | 0.017"                                      |
| Distal shaft diameter      | 2.7F: ø 2.25 – 3.0 mm; 2.9F: ø 3.5 – 4.0 mm |
| Proximal shaft diameter    | 2.0F  |
| Nominal pressure (NP)      | 10 atm                                      |
| Rated burst pressure (RBP) | 16 atm                                      |

## Ordering Information

| Stent<br>ø (mm) | Stent Length<br>(mm) |        |        |        |        |        |        |        |        |
|-----------------|----------------------|--------|--------|--------|--------|--------|--------|--------|--------|
|                 | 9                    | 13     | 15     | 18     | 22     | 26     | 30     | 35     | 40     |
| 2.25            | 419101               | 419107 | 419113 | 419119 | 419125 | 419131 | 419137 | 419143 | 419149 |
| 2.5             | 419102               | 419108 | 419114 | 419120 | 419126 | 419132 | 419138 | 419144 | 419150 |
| 2.75            | 419103               | 419109 | 419115 | 419121 | 419127 | 419133 | 419139 | 419145 | 419151 |
| 3.0             | 419104               | 419110 | 419116 | 419122 | 419128 | 419134 | 419140 | 419146 | 419152 |
| 3.5             | 419105               | 419111 | 419117 | 419123 | 419129 | 419135 | 419141 | 419147 | 419153 |
| 4.0             | 419106               | 419112 | 419118 | 419124 | 419130 | 419136 | 419142 | 419148 | 419154 |

n = number of struts analyzed. TLF = target lesion failure.

a. BIOTRONIK data on file (n = 5), based on statistically significant differences on the bench for Pushability, Trackability, and Crossability compared to Xience Skypoint, superior to Xience in STEMI patients; b. ø 2.25 – 3.0 mm strut thickness 60 µm, ø 3.5-4.0 mm strut thickness 80 µm; c. Always refer to the Instruction for Use (IFU) for the maximum diameter for post-dilatation applying in your country; d. Images: Secco G et al. Time-related changes in neointimal tissue coverage following a new generation SES implantation: an OCT observational study. Presented at: EuroPCR, May 20, 2014; Paris, France; e. Clinical data collected with the Orsiro DES device within the Orsiro DES family clinical program; f. Clinical data collected with the Orsiro Mission DES device within the Orsiro DES family clinical program; g. at 5-year in STEMI patients; h. As per IFU: ACS - Acute Coronary Syndrome; B2/C - Complex Lesions; DAPT - Dual Antiplatelet Therapy; DM - Diabetes Mellitus; HBR - High Bleeding Risk; MVD - Multi-Vessel Disease; STEMI - ST-Elevation Myocardial Infarction; SV - Small Vessels; i. Compared to Xience, up to 5 years. Orsiro DES: 7.7%, Xience DES: 11.1%, BIOSTEMI with historical information RR, 0.70; 95% BCI, 0.51-0.95, Bayesian posterior probability, 0.988; j. Please refer to the IFU for indications and post-procedure antiplatelet therapy recommendations.

1. Iglesias JF. et al, Long-term outcomes with biodegradable polymer sirolimus eluting stents versus durable polymer everolimus-eluting stents in ST-segment elevation myocardial infarction: 5-year follow-up of the BIOSTEMI randomized superiority trial, The Lancet, 2024; 2. In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, BIOTRONIK data on file; 3. In comparison to Resolute Onyx, Xience Sierra and Synergy. BIOTRONIK data on file; 4. Stefanini GG et al. Coronary stents: novel developments. Heart. 2014 Jul 1;100(13):1051-61; 5. Low AF. Stent platform for procedural success: Introducing the Continuous Sinusoidal & Core Wire Technologies. Presented at: AsiaPCR; 22-24 January, 2015; Singapore, Singapore; 6. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: Cardiovascular Nurse/Technologist Symposium; June 17, 2016; New York, USA; 7. As characterized with respect to strut thickness in Bangalore et al. Meta-analysis; 8. Kapoor A. et al., The road to the ideal stent: A review of stent design optimization methods, findings, and opportunities, Materials&Design, 2024; 9. Secco G. et al. Time-related changes in neointimal tissue coverage of a novel Sirolimus eluting stent: Serial observations with optical coherence tomography. Cardiovascular Revascularization Medicine 17.1 (2016): 38-43; 10. Based on investigator's interpretation of BIOFLOW-V primary endpoint result; 11. Based on Taglieri et al. Meta-analysis, against currently used DES; 12. Including Orsiro DES and Orsiro Mission DES, BIOTRONIK data on file, as of February 2023; 13. Based on TLF primary endpoint. Iglesias, JF. et al. Long-term outcomes with biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stents in ST-segment elevation myocardial infarction: 5-year follow-up of the BIOSTEMI randomized superiority trial, presented at TCT 2023; 14. Based on primary and secondary outcomes, Valgimigli M. et al BIOFLOW DAPT Circulation 2023; 15. Per investigators' interpretation of pre-clinical studies with Orsiro as mentioned in Cassese et al. J Thorac Dis 2018;10(02):688-692.

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excellence for life

