



The next level of
deliverability



Ultrathin struts



Outstanding patient
outcomes



Technical data /
ordering info

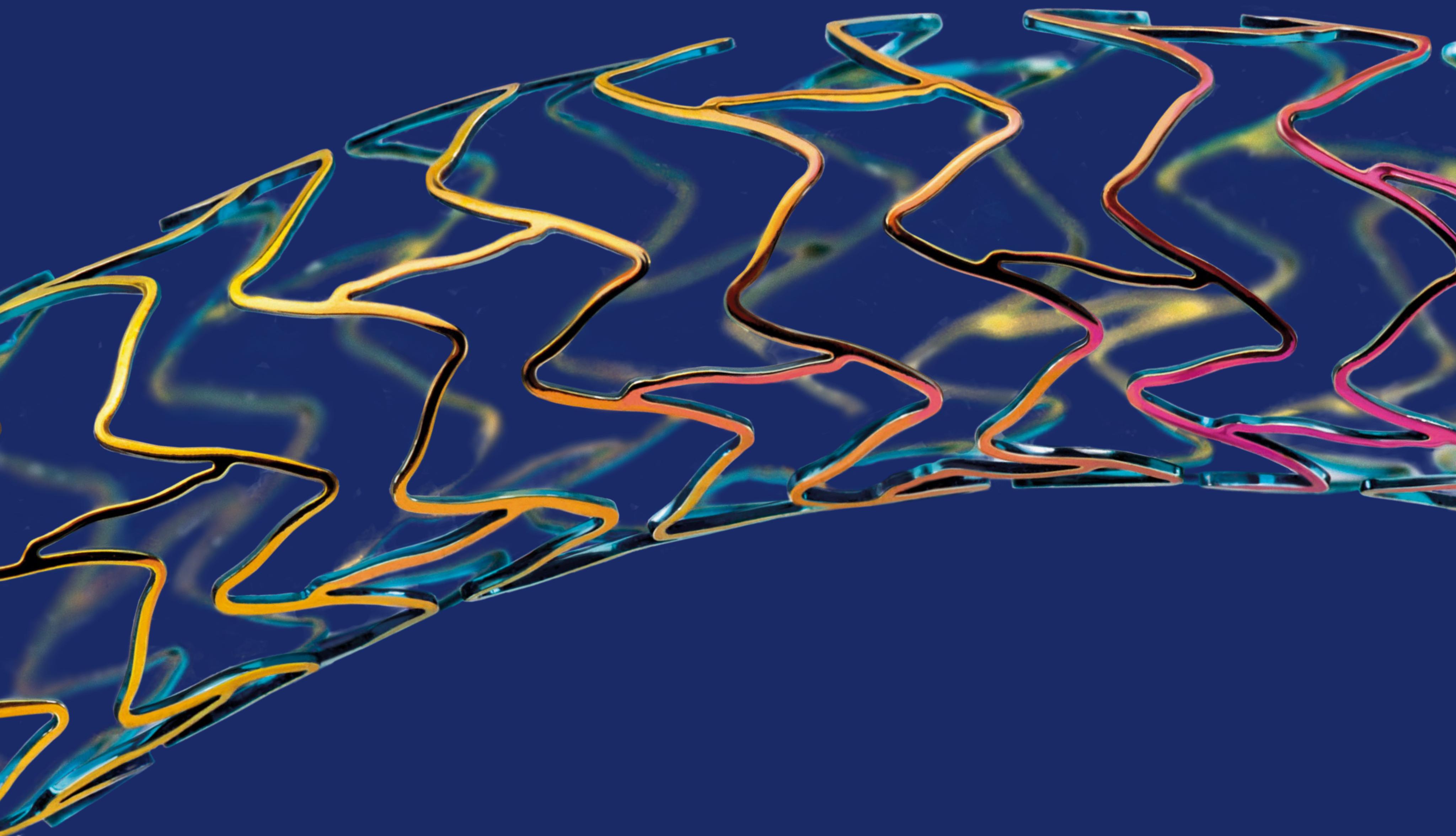
TeleflexTM

Empowering the future of healthcare

OrsiroTM MissionTM

Drug-Eluting Stent (DES)

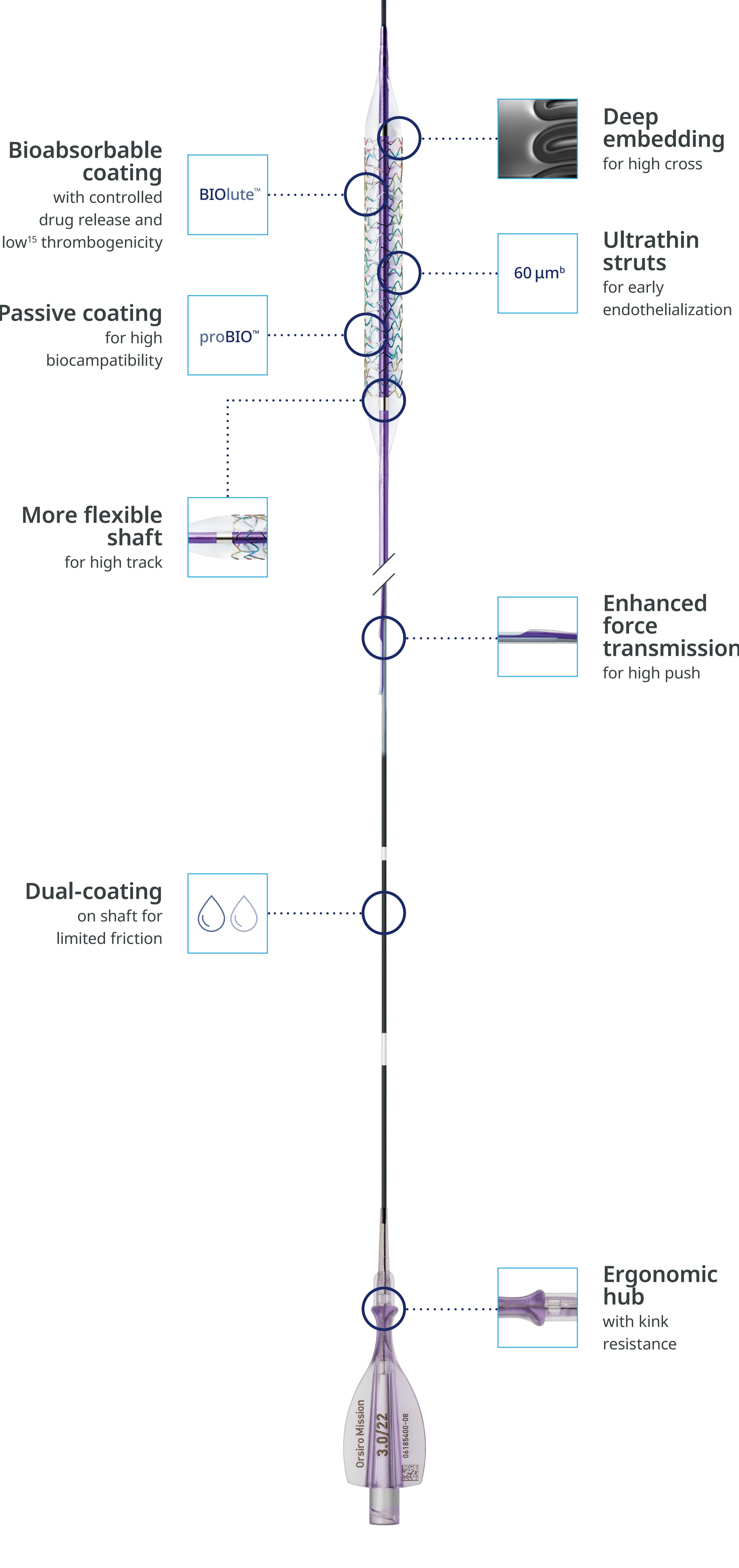
Delivering superiority^{1,a}



Orsiro™ Mission™ DES

Delivering superiority^{1,a}

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.

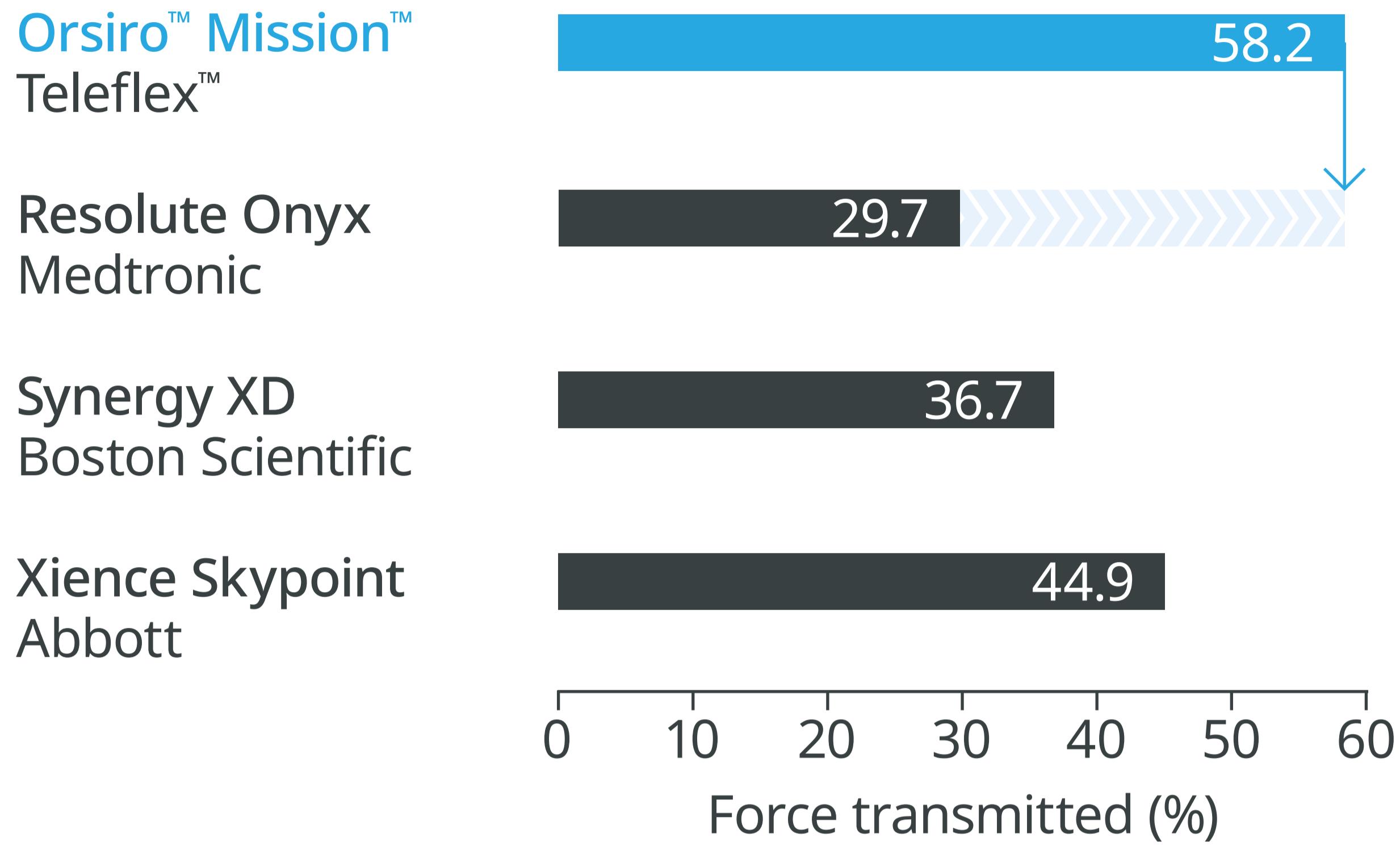




The next level of deliverability²

Better pushability³

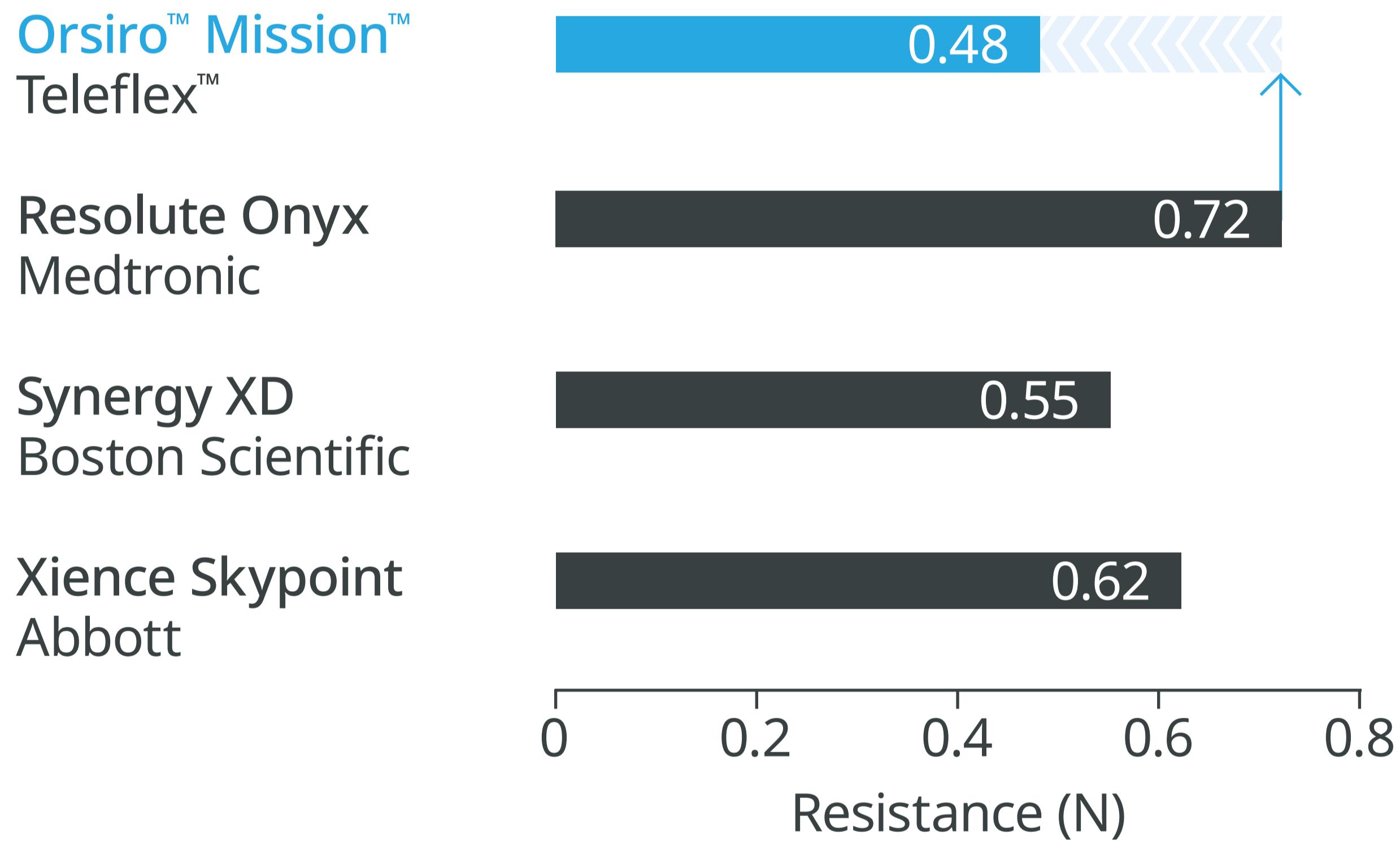
Transmitting up to 96 % more force from hub to tip.



1st
in Push³

Better trackability³

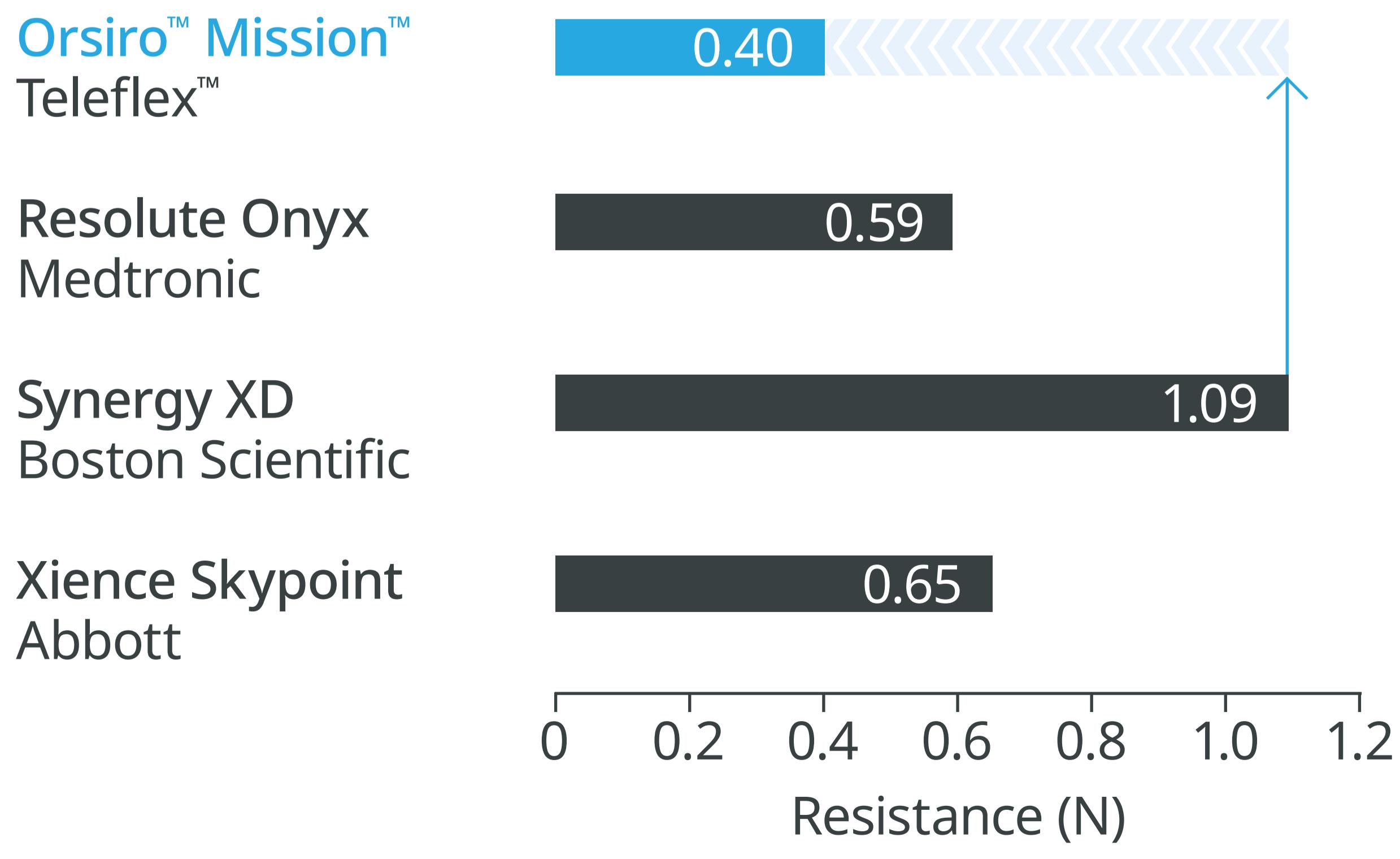
Up to 33 % less force needed to follow the path to the lesion.



1st
in Track³

Better crossability³

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



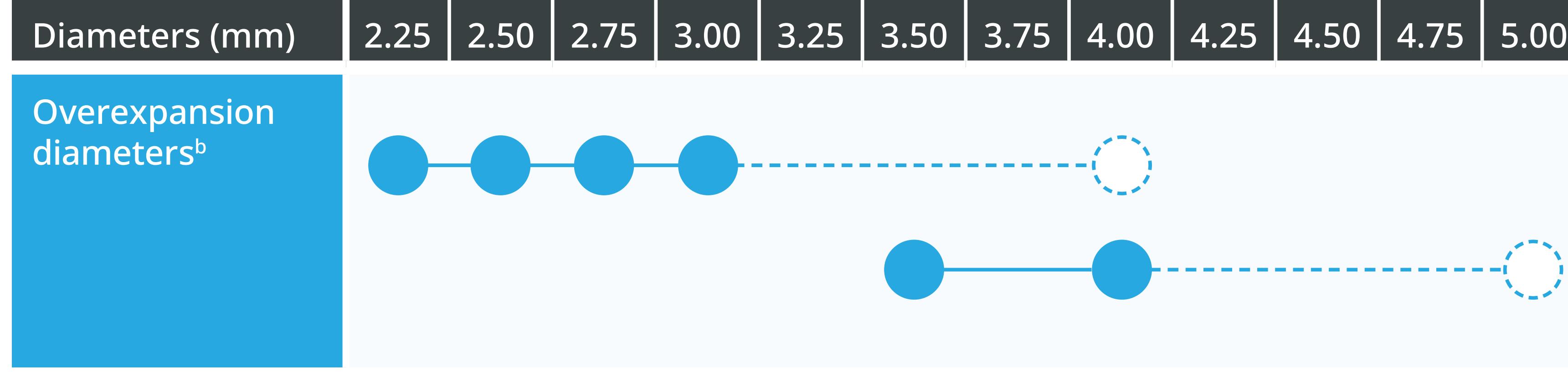
1st
in Cross³





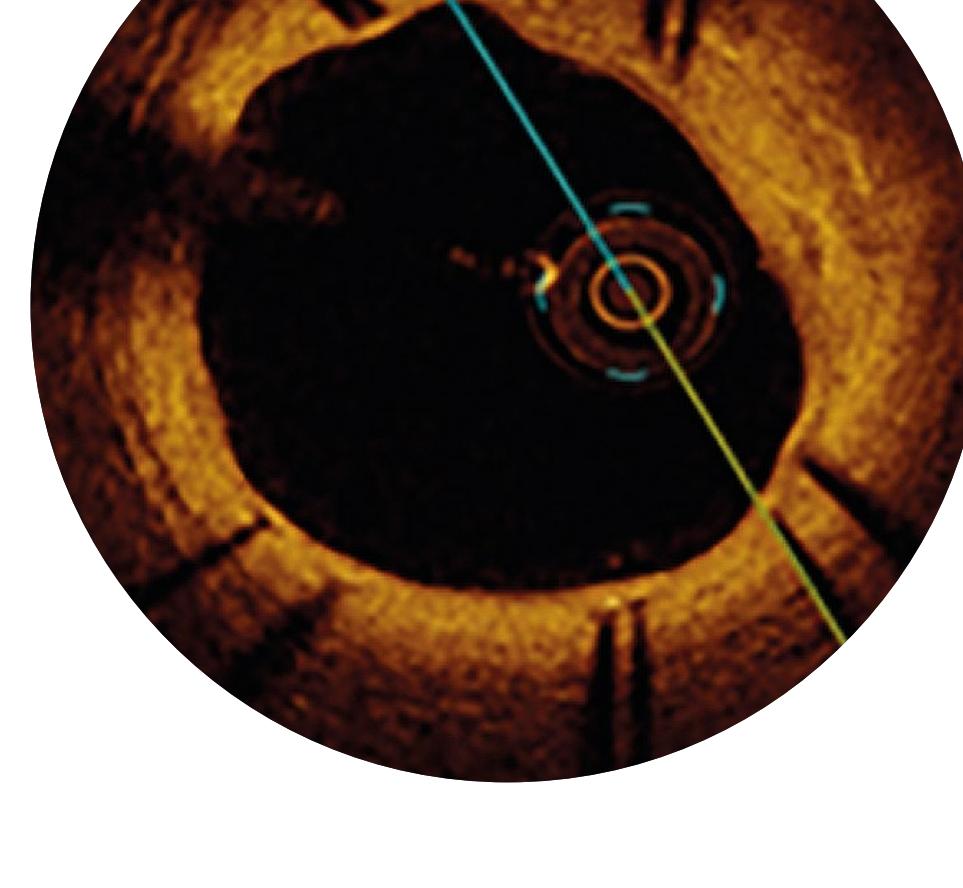
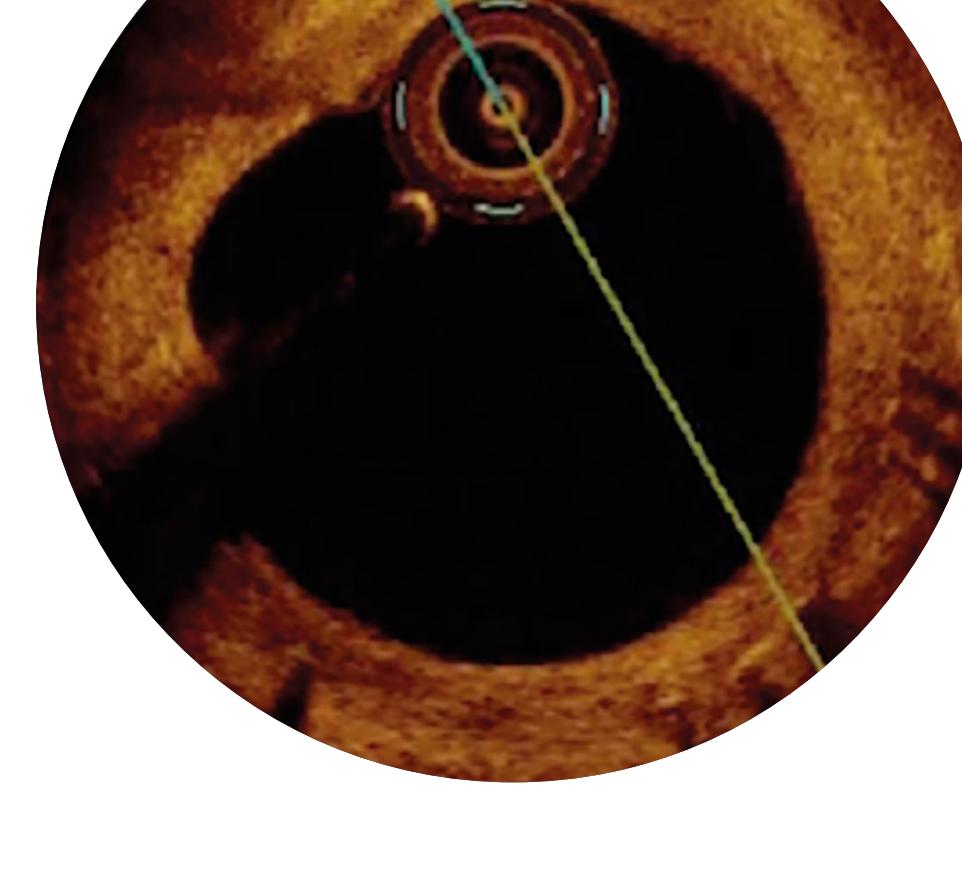
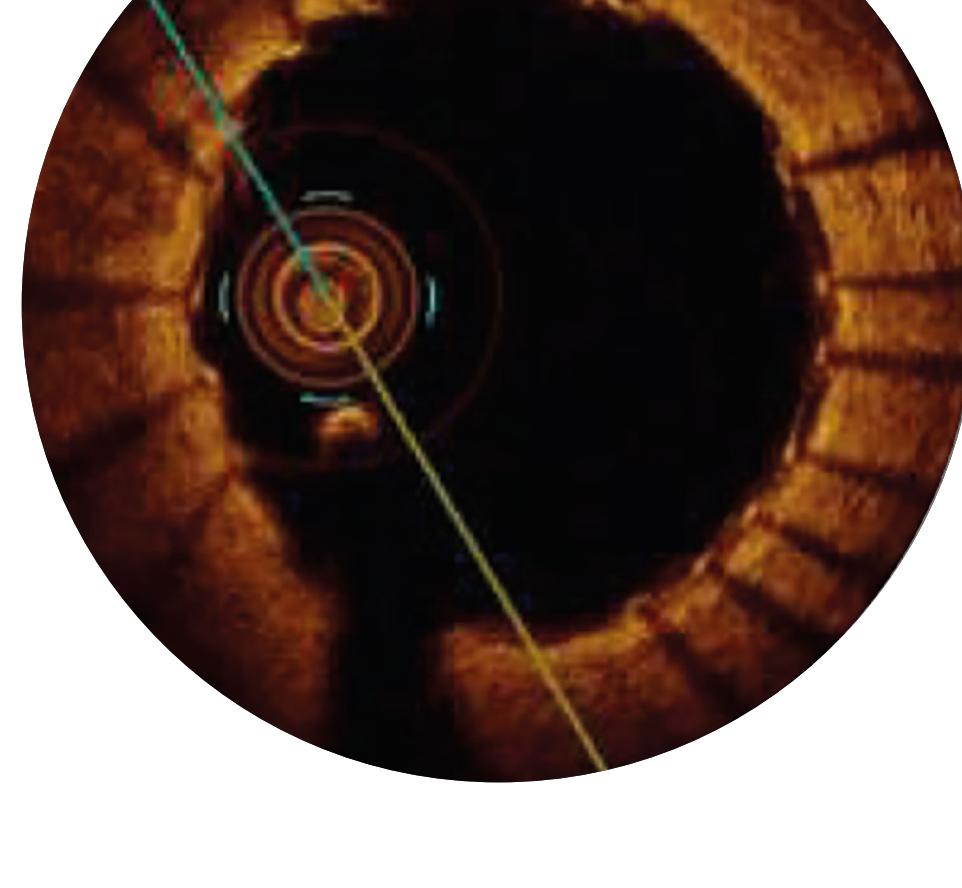
Ultrathin struts⁷

Conforming to a wider range of vessels^{8,c}



● Labeled nominal diameter ○ Labeled max. diameter for post-dilatation

Early endothelialization



Strut coverage⁹

30 days^d

>80 %

n = 589

Strut coverage⁹

90 days^d

>97 %

n = 874

Strut coverage⁹

180 days^d

>98 %

n = 1,130

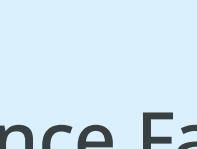
Immature tissue coverage

→ HEALING PROGRESS →

Tissue maturation and full coverage

Strut thickness in perspective⁴

Orsiro™ Mission™
Teleflex™
CoCr-SES



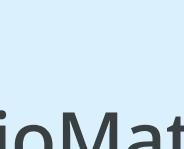
60 µm^b

Synergy XD
Boston Scientific
PtCr-EES



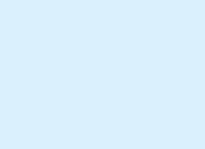
74 µm

Ultimaster
Terumo
CoCr-SES



80 µm

Resolute Onyx^{5,6}
Medtronic
CoNi-ZES



81 µm

Xience Family
Abbott
CoCr-EES



81 µm

Promus
Boston Scientific
PtCr-EES



81 µm

BioMatrix
Biosensors
316L-BES



120 µm

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

a. 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.





Outstanding patient outcomes^{10,e}

Orsiro™ family of DES – One of the most studied DES^{11,e,f}

>100,000

patients enrolled or planned in total^{12,e,f}

>71,000

patients enrolled^{12,e,f}

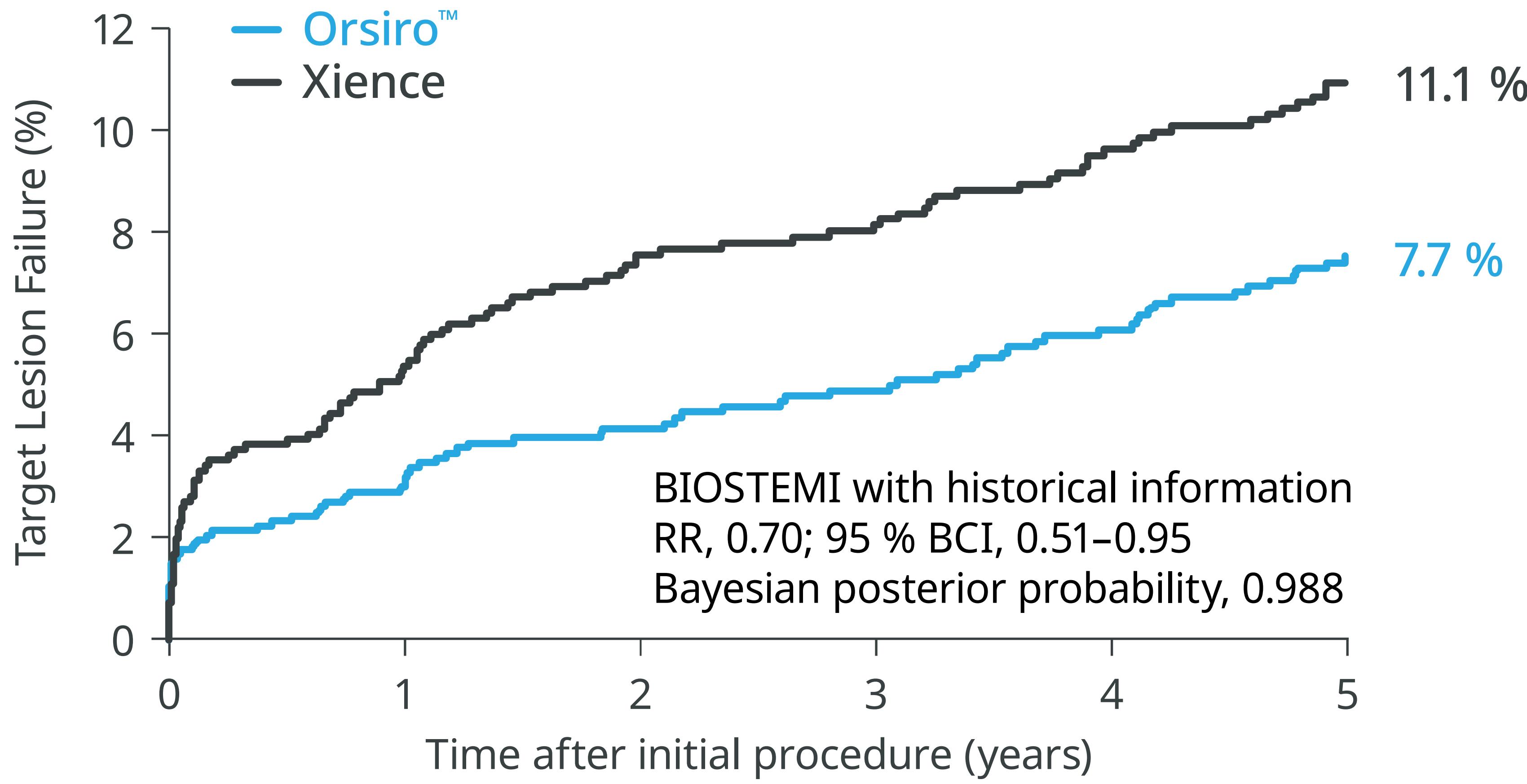
>86

studies started^{12,e,f}

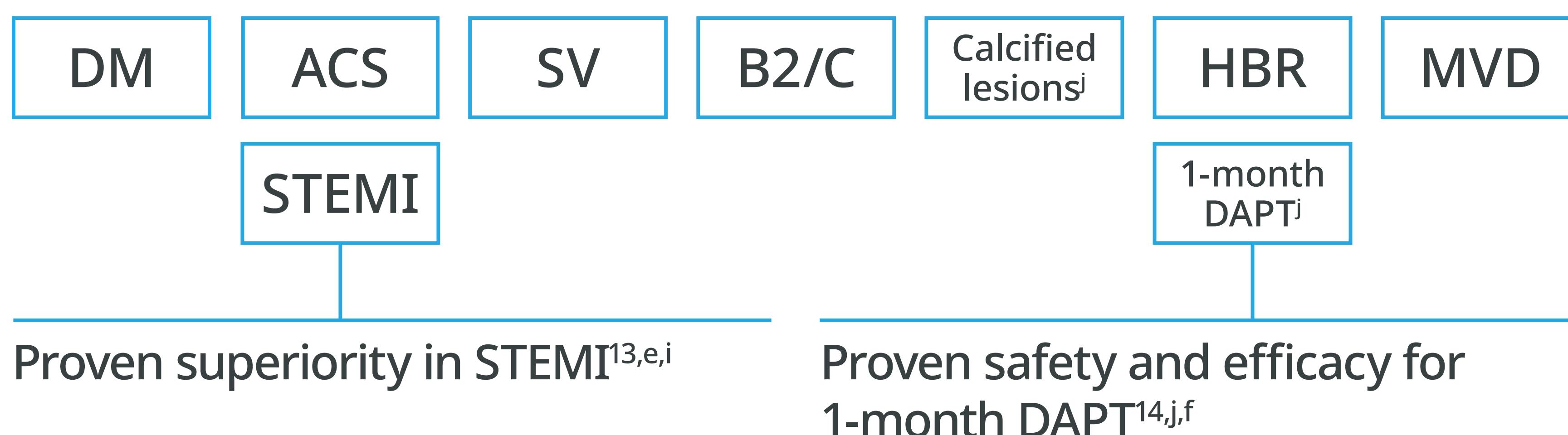
31 %
significantly
lower TLF^{13,e,g}

BIOSTEMI

TLF at 5 years – continued superiority in STEMI^{13,e}



Orsiro™ Mission™ DES is indicated for complex patients and lesions^h





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:

| | |
|---|--|
| <ul style="list-style-type: none"> • Acute Coronary Syndrome (ACS) • ST-Elevation Myocardial Infarction (STEMI) • Diabetes Mellitus (DM) • High Bleeding Risk (HBR) • One month of Dual Antiplatelet Therapy (DAPT) in HBR patients • Calcified lesions (moderate/severe calcification) | <ul style="list-style-type: none"> • Complex Lesions (B2/C) • Long Lesions (LL) (e.g. ≥ 20 mm) • Small Vessels (SV) (e.g. ≤ 2.75 mm) • Multi-Vessel Disease (MVD) • Male/Female • Old Patients (e.g. > 65 y) |
|---|--|

Technical Data

STENT

| | |
|-----------------|---|
| Stent material | Cobalt chromium, L-605 |
| Strut thickness | \varnothing 2.25–3.0 mm: 60 μm (0.0024"); \varnothing 3.50–4.0 mm: 80 μm (0.0031") |
| Passive coating | proBIO™ (Amorphous Silicon Carbide) |
| Active coating | BIOlute™ bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug |
| Drug dose | 1.4 $\mu\text{g}/\text{mm}^2$ |

Delivery System

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 |
| 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: \varnothing 2.25–3.0 mm; 2.9F: \varnothing 3.5–4.0 mm |
| Proximal shaft diameter | 2.0F |
| Nominal pressure (NP) | 10 atm |
| Rated burst pressure (RBP) | 16 atm |

Ordering Information

| SCAFFOLD Ø | SCAFFOLD LENGTH | | | | |
|----------------|-----------------|--------|--------|--------|--------|
| | 9 mm | 13 mm | 15 mm | 18 mm | 22 mm |
| 2.25 mm | 419101 | 419107 | 419113 | 419119 | 419125 |
| 2.50 mm | 419102 | 419108 | 419114 | 419120 | 419126 |
| 2.75 mm | 419103 | 419109 | 419115 | 419121 | 419127 |
| 3.00 mm | 419104 | 419110 | 419116 | 419122 | 419128 |
| 3.50 mm | 419105 | 419111 | 419117 | 419123 | 419129 |
| 4.00 mm | 419106 | 419112 | 419118 | 419124 | 419130 |

| SCAFFOLD Ø | SCAFFOLD LENGTH | | | |
|----------------|-----------------|--------|--------|--------|
| | 26 mm | 30 mm | 35 mm | 40 mm |
| 2.25 mm | 419131 | 419137 | 419143 | 419149 |
| 2.50 mm | 419132 | 419138 | 419144 | 419150 |
| 2.75 mm | 419133 | 419139 | 419145 | 419151 |
| 3.00 mm | 419134 | 419140 | 419146 | 419152 |
| 3.50 mm | 419135 | 419141 | 419147 | 419153 |
| 4.00 mm | 419136 | 419142 | 419148 | 419154 |

References:

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- In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, data on file.
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- Secco G, et al. Time-re-lated 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.
- Based on investigatory's interpretation of BIOTEST-V primary endpoint result.
- In large RCTs based on Tagliari et al. Meta-analysis, against currently used DES.
- Including Orsiro DES and Orsiro Mission DES, data on file, as of February 2023.
- Based on polymer sirolimus-eluting stents, in ST-segment elevation myocardial infarction: 5-year follow-up of the BIOTESTMI randomized superiority trial presented at TCT 2023.
- Based on primary and secondary outcomes Valgimigli M, et al BIOTEST DAPT Circulation 2023.
- 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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