The nex level of deliverability

Ultrathin struts

Outstanding patient outcomes

Technical data / ordering info

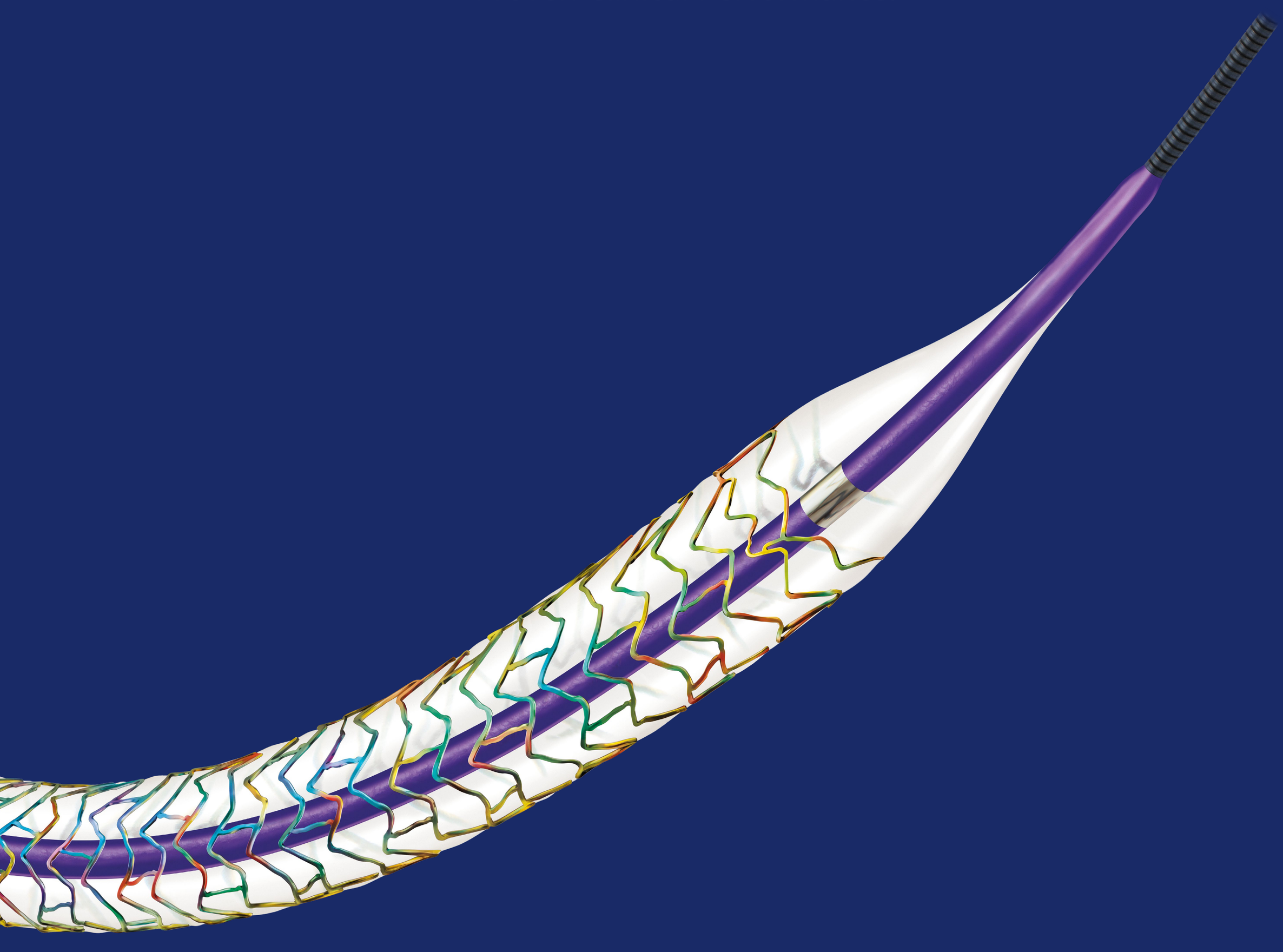
Teleflex™

Empowering the future of healthcare

Synsiro™ Pro

Drug-Eluting Stent (DES)

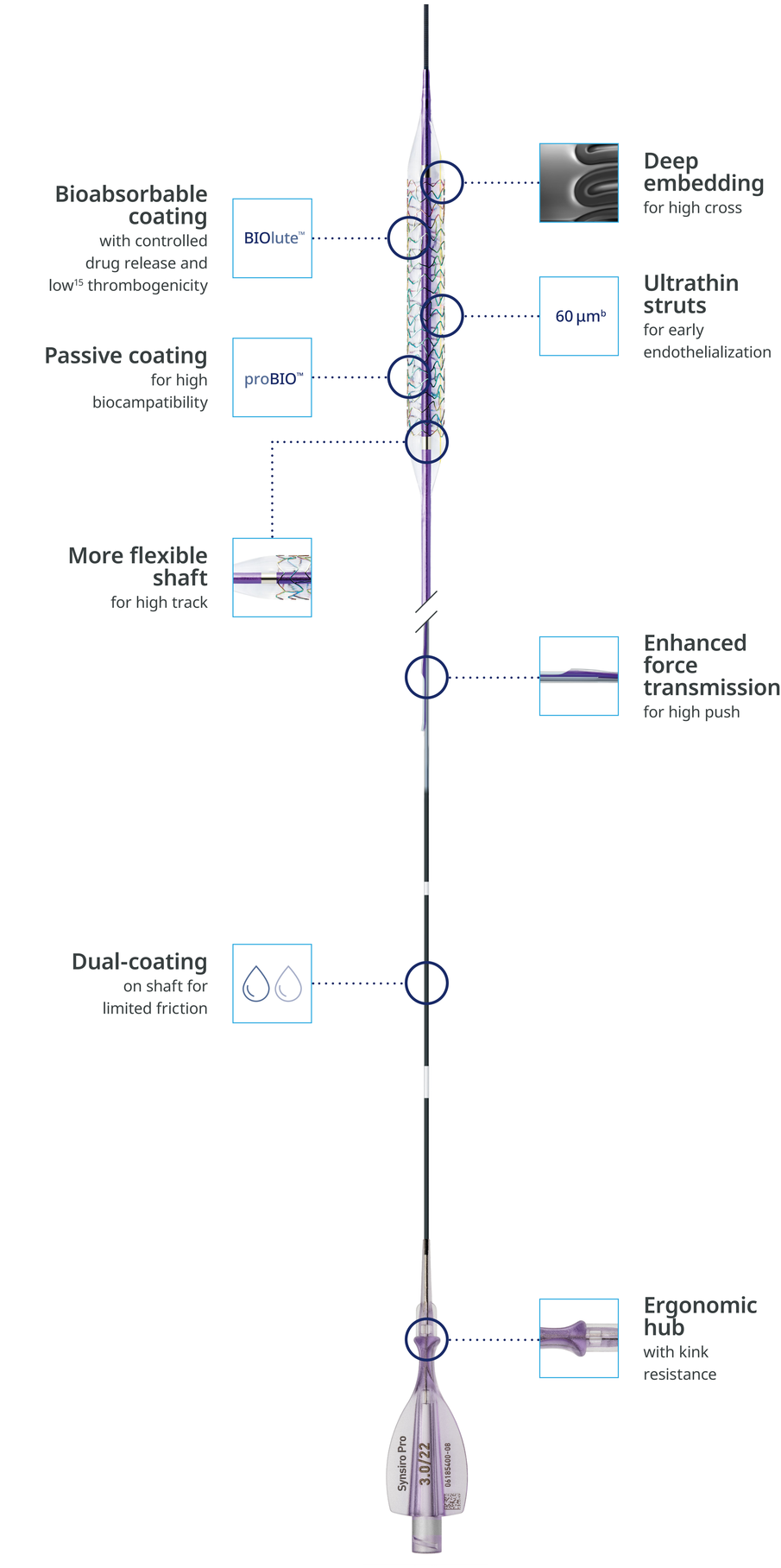
The Next Level of Deliverability.
Proven Clinical Performance.[1,a]



Synsiro™ Pro DES

The Next Level of Deliverability. Proven Clinical Performance.[1,a]

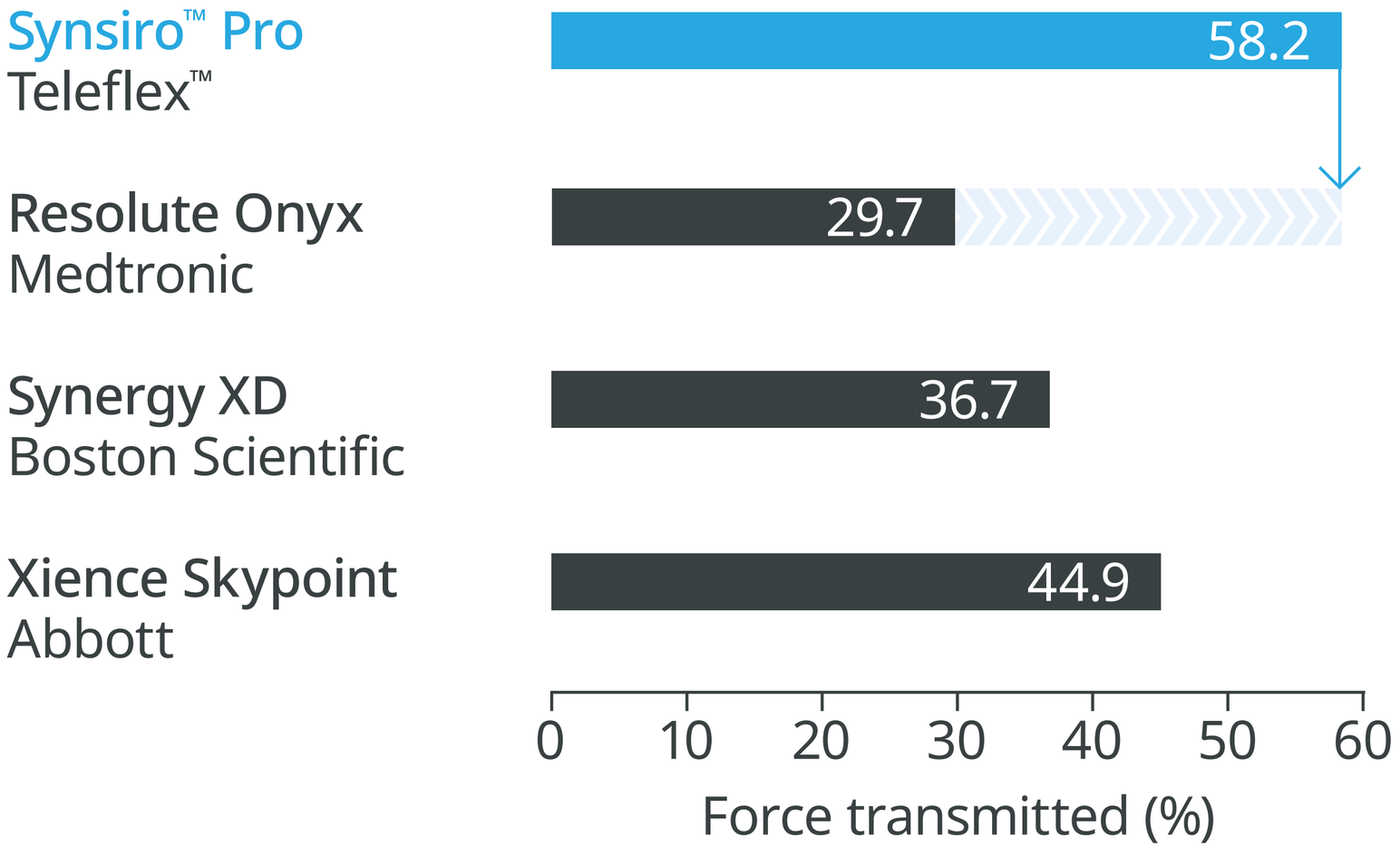
The Synsiro™ Pro Sirolimus-Eluting Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.



The next level of deliverability[2]

Better pushability[3]

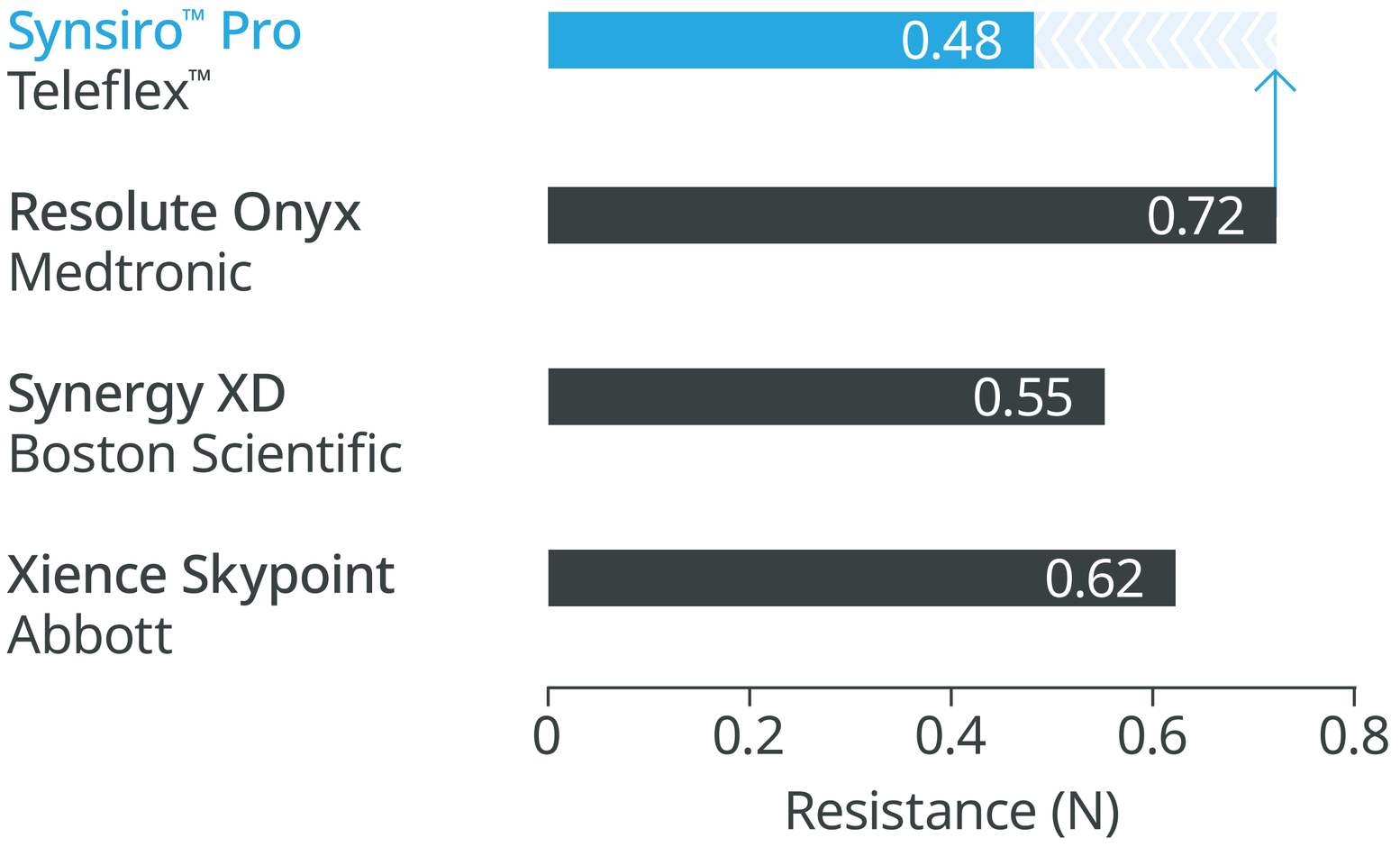
Transmitting up to **96 % more force** from hub to tip.



1st in Push[3]

Better trackability[3]

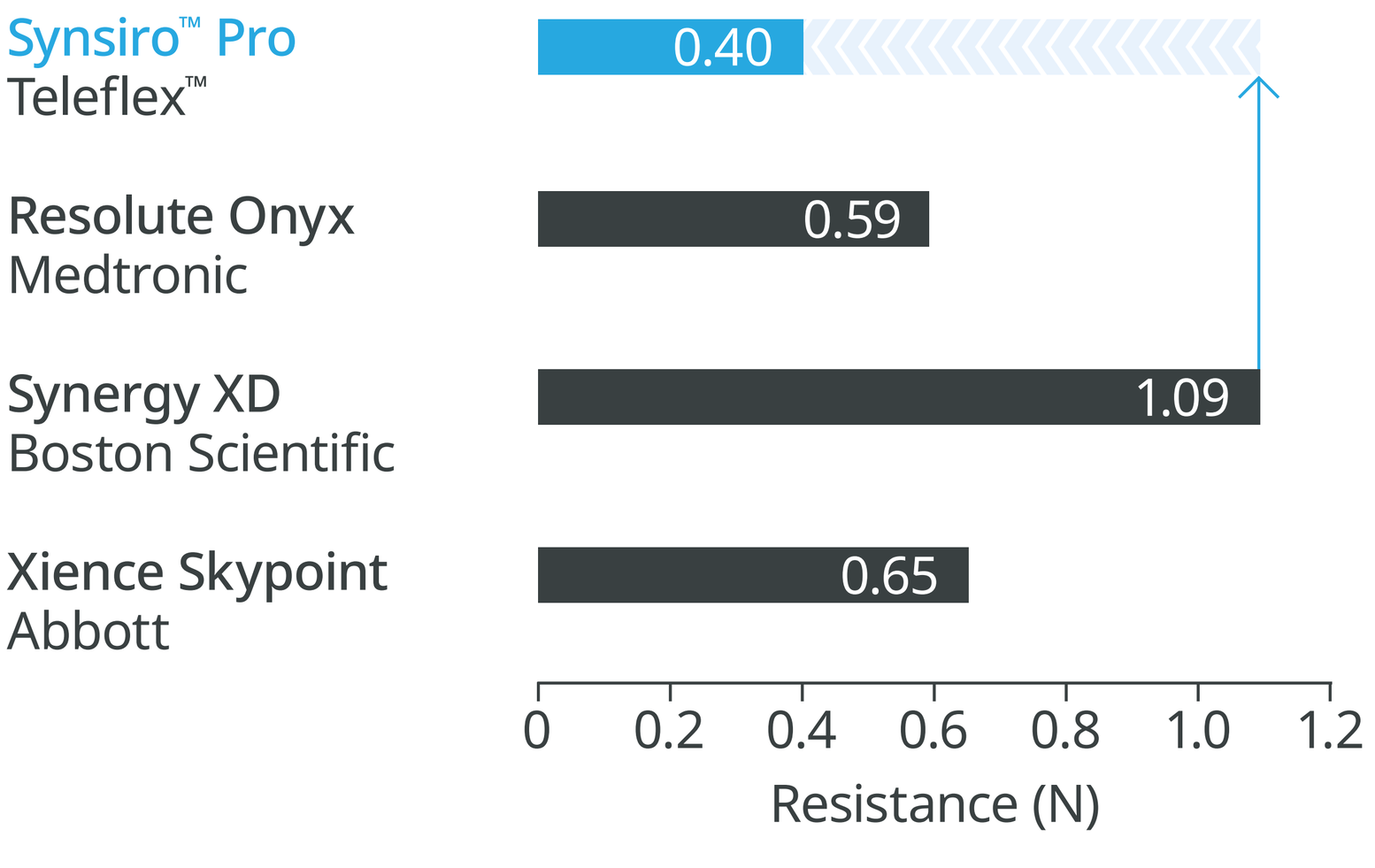
Up to **33 % less force needed** to follow the path to the lesion.



1st in Track[3]

Better crossability[3]

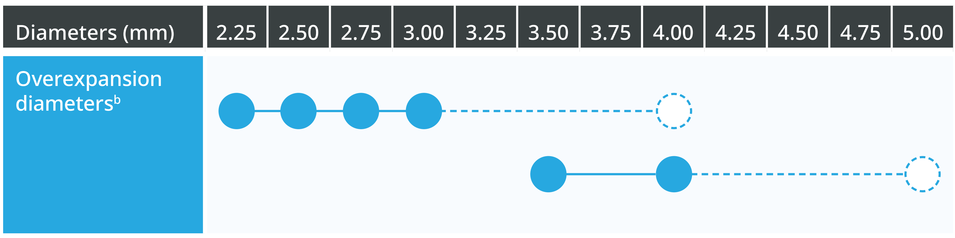
Up to **64 % less force needed** to successfully cross demanding anatomies.



1st in Cross[3]

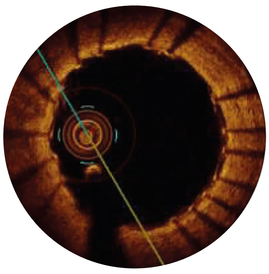
Ultrathin struts[7]

Conforming to a wider range of vessels[8,c]

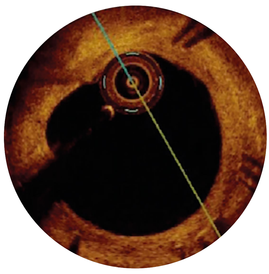


Labeled nominal diameter *Labeled max. diameter for post-dilatation*

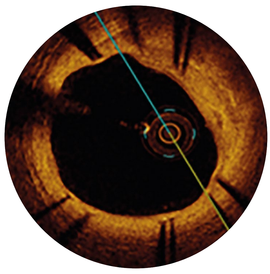
Early endothelialization



Strut coverage[9]
30 days[d]
>80 %
n = 589



Strut coverage[9]
90 days[d]
>97 %
n = 874



Strut coverage[9]
180 days[d]
>98 %
n = 1,130

Immature tissue coverage → HEALING PROGRESS → Tissue maturation and full coverage

Strut thickness in perspective[4]

Synsiro™ Pro
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. Clinical data collected with the Orsiro DES device within the Orsiro DES family clinical program. The predecessor device of the Orsiro Mission DES can be used to illustrate Synsiro Pro DES clinical outcomes; 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 Mission DES device within the Orsiro DES family clinical program. The Orsiro Mission DES can be used to illustrate Synsiro Pro DES clinical outcomes; f. At 5-year in STEMI patients; g. As per IFU: ACS - Acute Coronary Syndrome; B2C - 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; h. 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; i. Please refer to the IFU for indications and post-procedure antiplatelet therapy recommendations.

Outstanding patient outcomes[10,a]

Orsiro™ family of DES – One of the most studied DES[11,a,e]

>100,000
patients enrolled or planned in total[12,a,e]

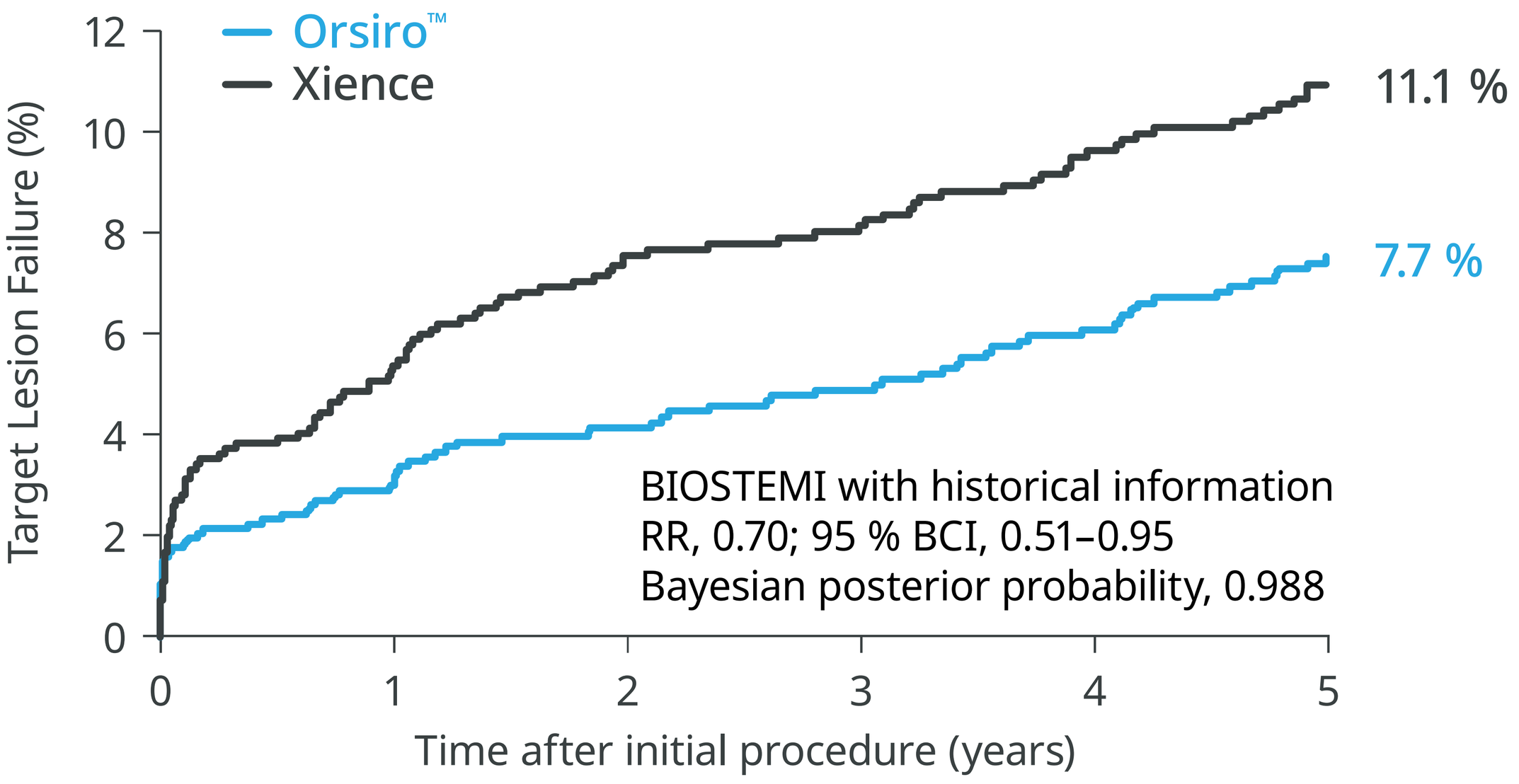
>71,000
patients enrolled[12,a,e]

>86
studies started[12,a,e]

31 %
significantly lower TLF[13,a,f]

BIOSTEMI

TLF at 5 years – continued superiority in STEMI[13,a]



Synsiro™ Pro DES is indicated for complex patients and lesions[g]

DM | ACS | SV | B2/C | Calcified lesions[i] | HBR | MVD

STEMI

1-month DAPT[i]

Proven superiority in STEMI[13,a,h]

Proven safety and efficacy for 1-month DAPT[14,e,i]

Synsiro™ Pro DES

Vascular Intervention Coronary

Indication

Synsiro™ Pro 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)
- 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)
- 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	ø 2.25–3.0 mm: 60 µm (0.0024″); ø 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 µg/mm²

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: 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

SCAFFOLD Ø	SCAFFOLD LENGTH				
	9 mm	**13 mm**	**15 mm**	**18 mm**	**22 mm**
2.25 mm	419155	419161	419167	419173	419179
2.50 mm	419156	419162	419168	419174	419180
2.75 mm	419157	419163	419169	419175	419181
3.00 mm	419158	419164	419170	419176	419182
3.50 mm	419159	419165	419171	419177	419183
4.00 mm	419160	419166	419172	419178	419184

SCAFFOLD Ø	SCAFFOLD LENGTH			
	26 mm	**30 mm**	**35 mm**	**40 mm**
2.25 mm	419185	419191	419197	419203
2.50 mm	419186	419192	419198	419204
2.75 mm	419187	419193	419199	419205
3.00 mm	419188	419194	419200	419206
3.50 mm	419189	419195	419201	419207
4.00 mm	419190	419196	419202	419208

References:

1 2018 ESC/EACTS Guidelines on myocardial revascularization Supplementary Table 6.
2 In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, data on file.
3 In comparison to Resolute Onyx, Xience Sierra and Synergy, 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, 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 randomised 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(2):688-692.

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