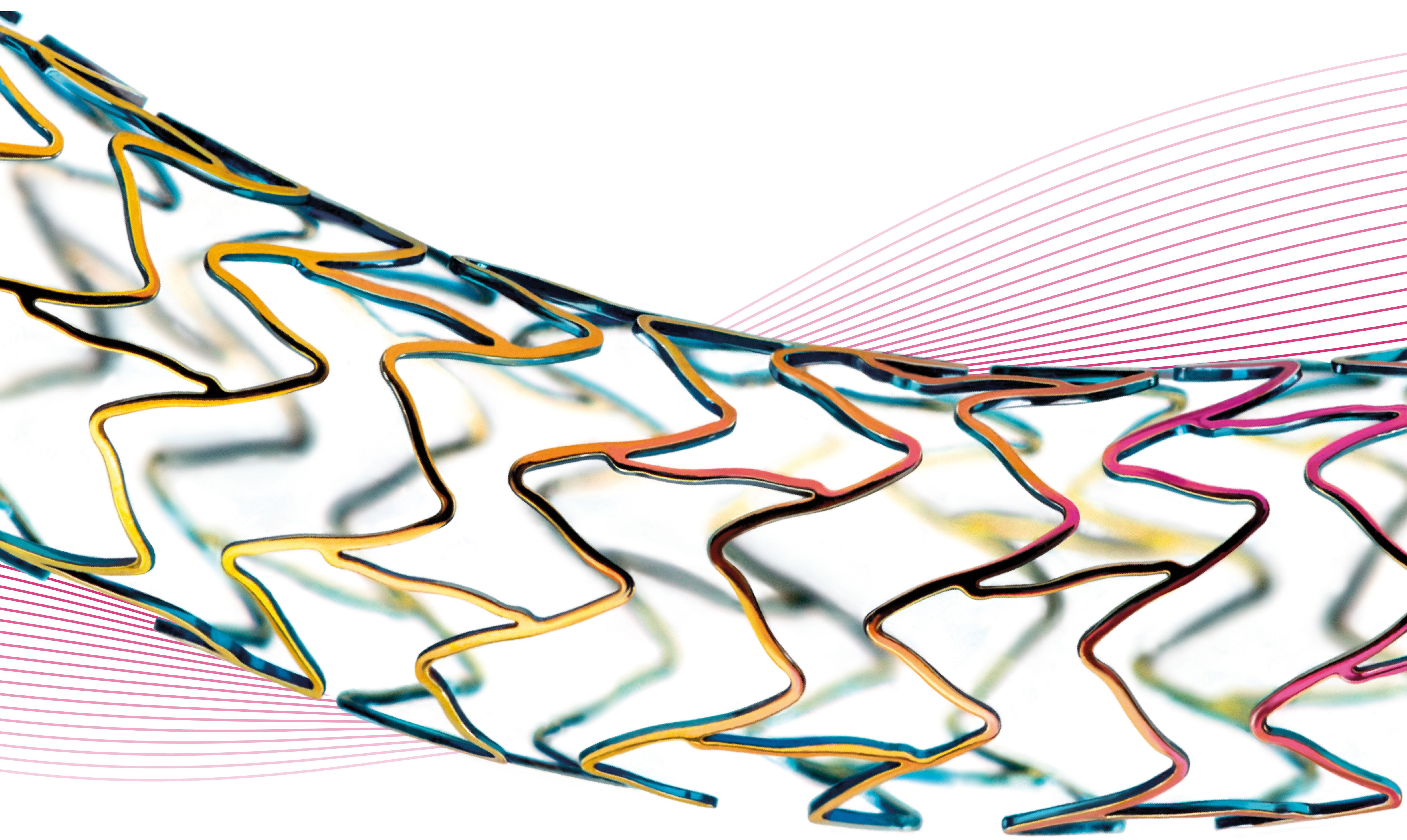
Outstanding patient outcomes | Highly deliverable | Ultrathin 60* µm struts | Technical data / ordering info

Vascular Intervention // Coronary
Drug-Eluting Stent System

BIOTRONIK
excellence for life

Orsiro®

Ultrathin struts. Outstanding patient outcomes.



*ø 2.25 – 3.0 mm

Orsiro
Ultrathin struts§. Outstanding patient outcomes◊.

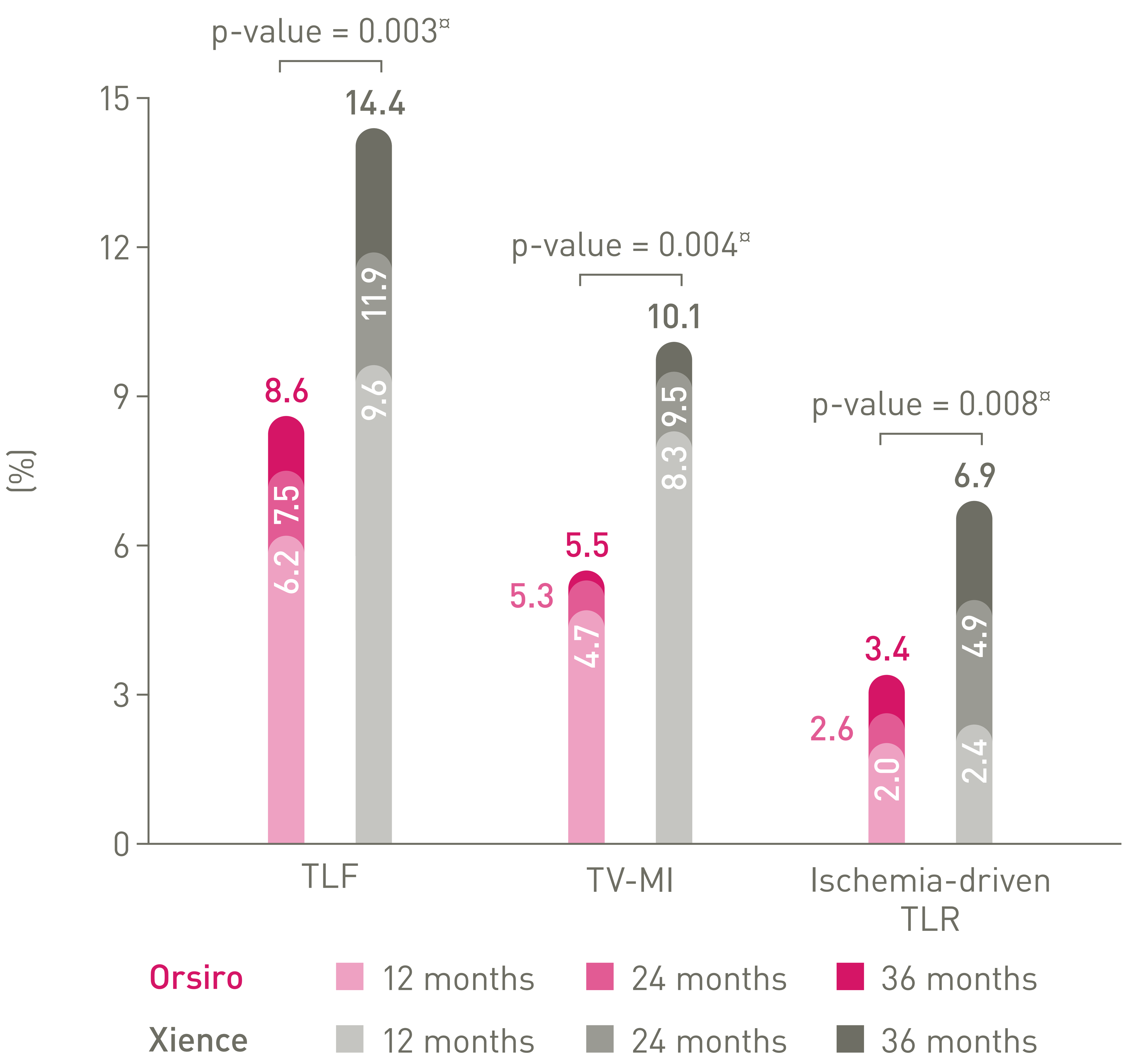
Outstanding patient outcomes

Improving patient outcomes, year after year*

BIOFLOW-V (n = 1,334) the FDA pivotal trial[1,2,3,4,5]

Significant differences in TLF observed at year 1 and 2 were maintained and further increased at year 3 (8.6% vs. 14.4%, p = 0.003), driven by significant differences in TV-MI (5.5% vs. 10.1%, p = 0.004) and Ischemia-driven TLR (3.4% vs. 6.9%, p = 0.008) that favor Orsiro over Xience.

TLF and components at 12, 24 and 36 Months



40%	46%	52%
lower TLF rate[5 ɸ]	lower TV-MI rate[5 ɸ]	lower Ischemia-driven TLR rate[5 ɸ]
(p=0.003)	(p=0.004)	(p= 0.008)

TLF – Target Lesion Failure; TV-MI – Target Vessel Myocardial Infarction; TLR – Target Lesion Revascularization.

§As characterized with respect to strut thickness in Bangalore et al. Meta-analysis.
◊Based on investigator's interpretation of BIOFLOW-V primary endpoint results.
*Compared to Xience, based on three consecutive years.
¤p-values for 36-m frequentist analysis (see supplemental material).
ɸvs. Xience, based on 36-m frequentist analysis (see supplemental material).

Superiority in STEMI[6]

BIOSTEMI (n=1,300) is the first RCT demonstrating superiority between two contemporary DES

Orsiro is superior to Xience in STEMI patients undergoing primary PCI with respect to Target Lesion Failure (TLF) rate at 12 months.

4%	6%
Orsiro	Xience

41%
Lower risk* of TLF with Orsiro in STEMI

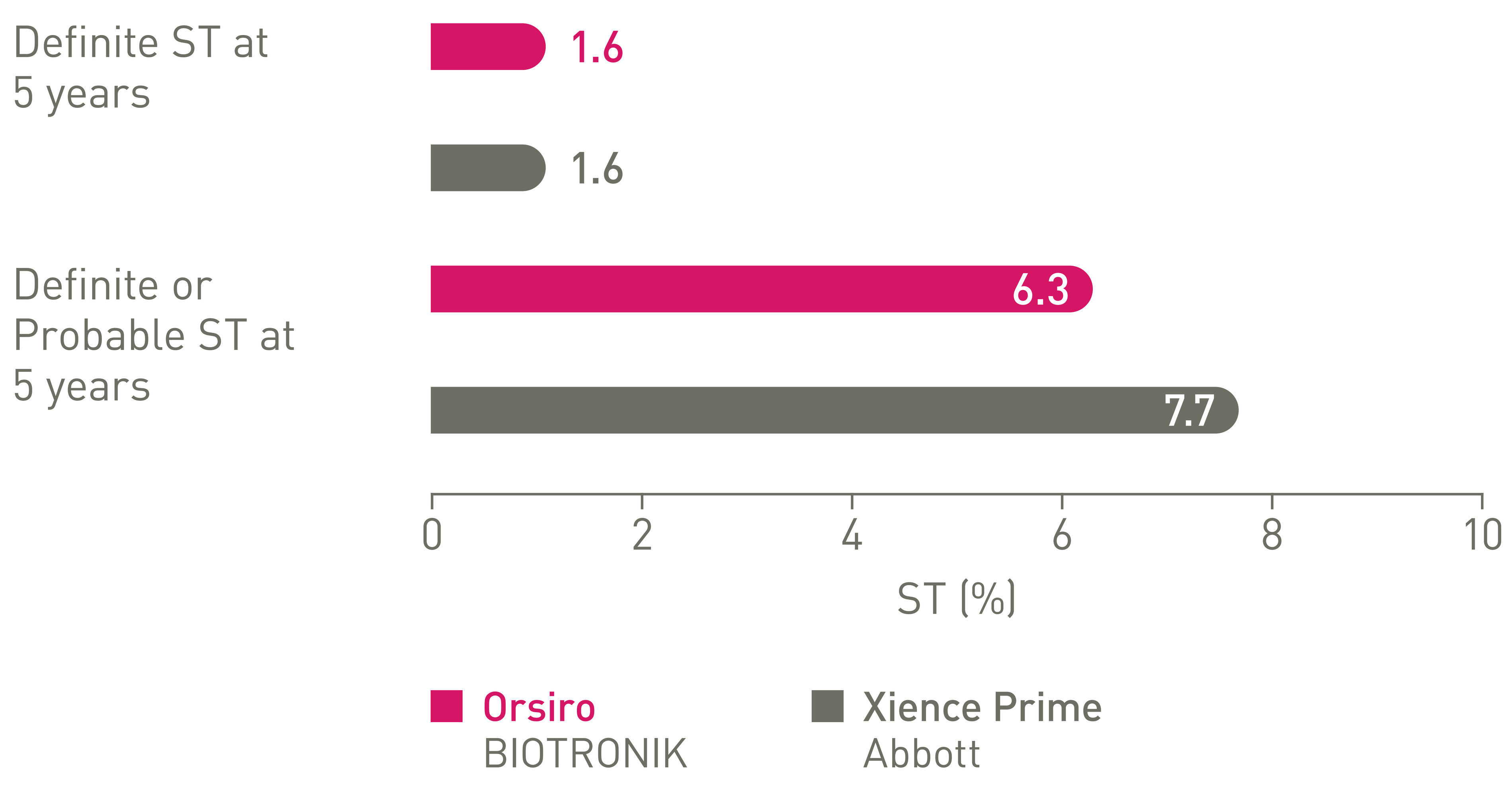
Rate Ratio (95% BCI**): 0.59, (0.37-0.94),
Posterior Probability of Superiority: 98.6%

Bayesian ITT Population¤

Long-term safety

In the randomized, all-comers BIOSCIENCE trial (n= 2,119)[7]

Orsiro shows numerically equal or lower Stent Thrombosis (ST) in complex patients in comparison to Xience.

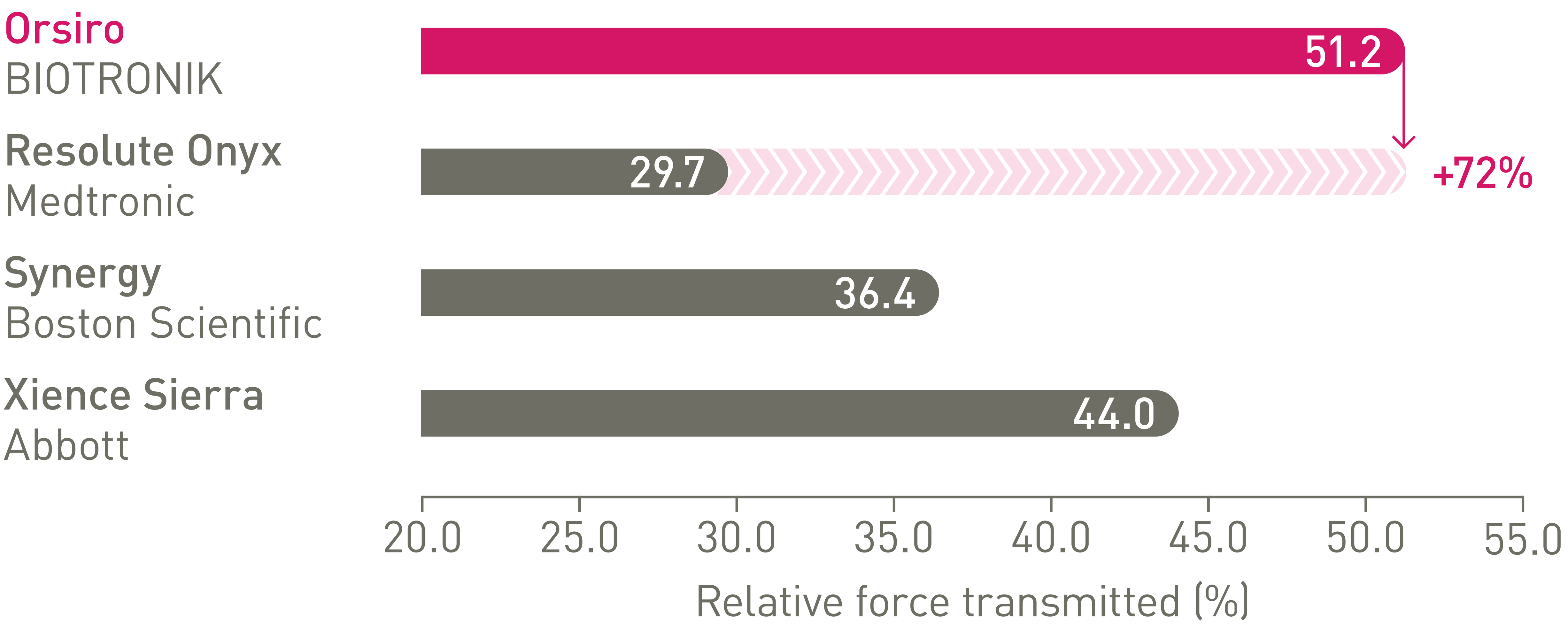


*Compared to Xience, BIOTRONIK data on file based on the Rate Ratio of 0.59.
**BCI: Bayesian Credibility Interval.
¤n= 1,300 newly enrolled STEMI patients including 407 patients from the BIOSCIENCE STEMI subgroup used as prior information.

Highly deliverable

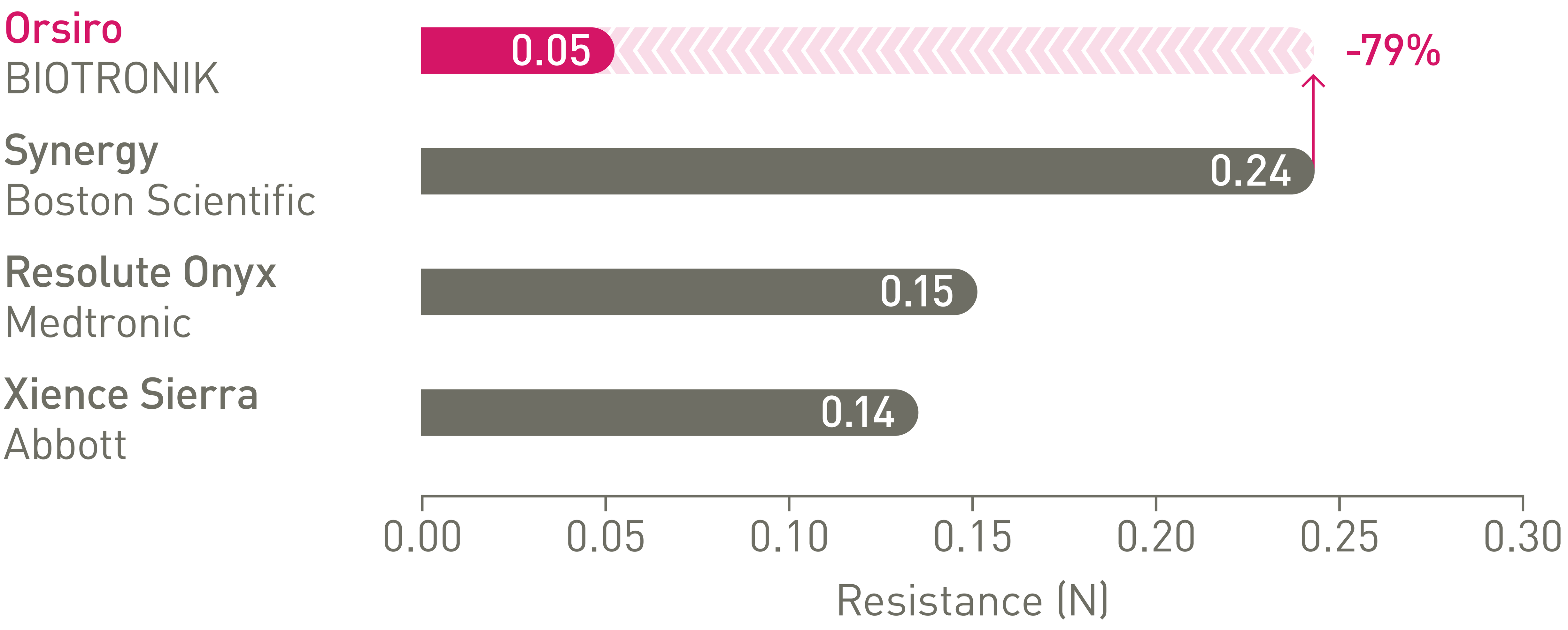
Better push

Transmits up to 72% more force from hub to tip.[15]



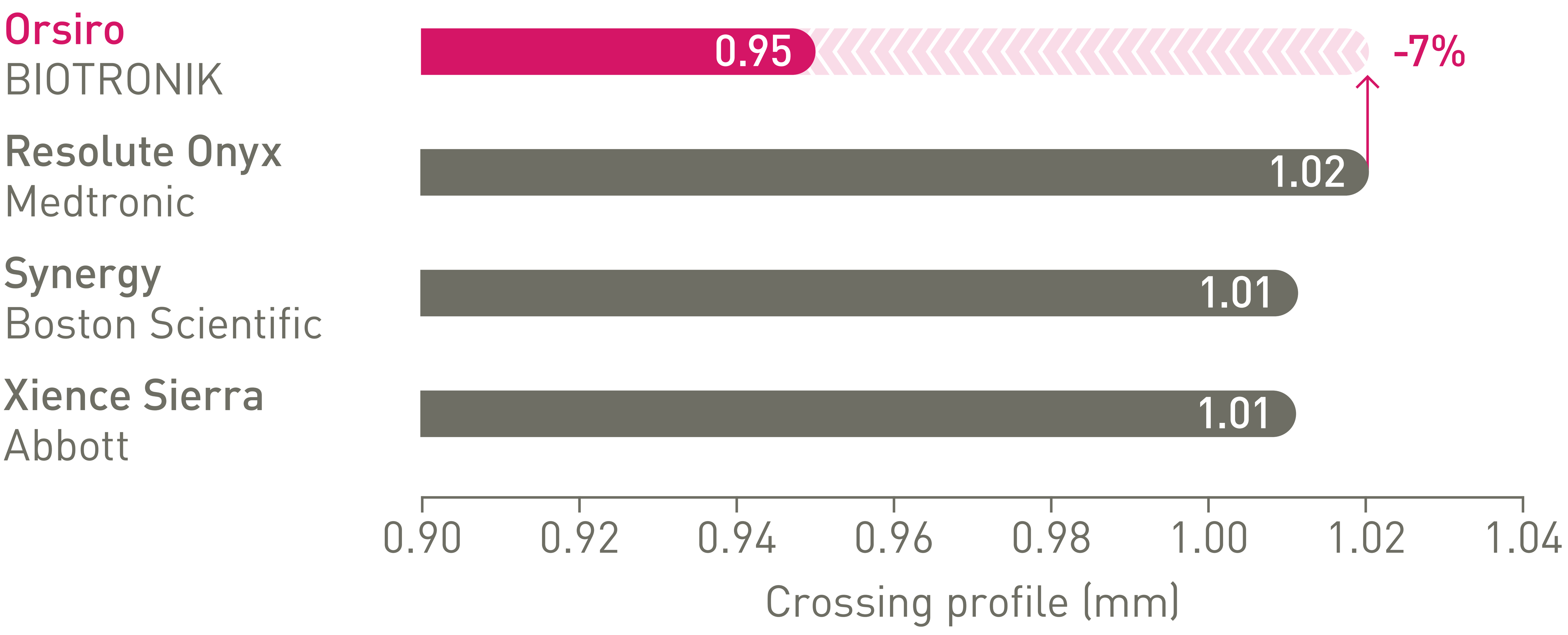
Easier cross

Up to 79% less force needed to successfully cross demanding anatomies.[15]



Lower crossing profile

Improved acute performance – up to 7% lower crossing profile.[15]



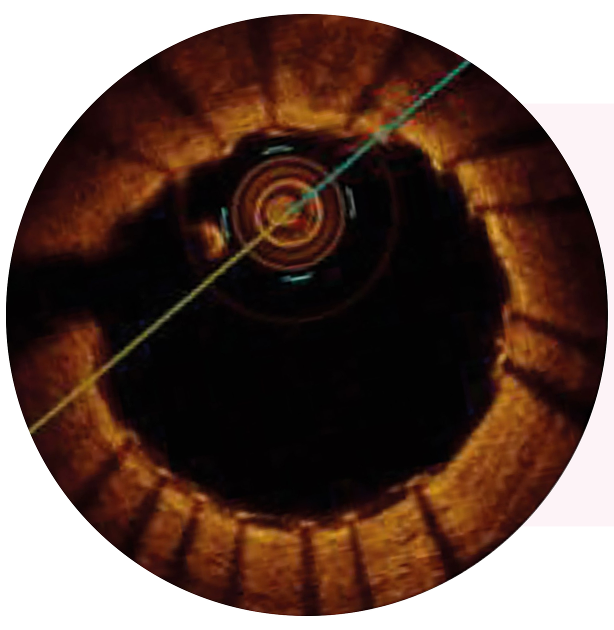
79%
easier to cross
vs. Synergy[15]

Ultrathin 60 µm struts

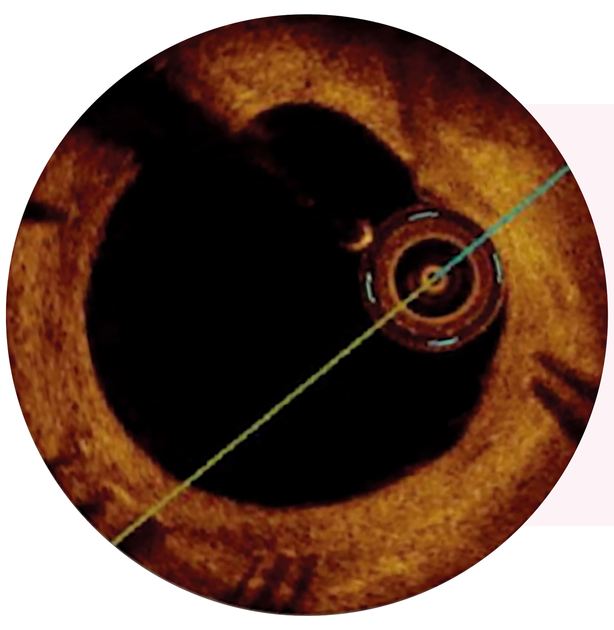
Improved outcomes start in the early phase

43%
lower in-hospital MI rate‡ vs. Xience[1]

48 hours
Thinner struts mean less vessel injury[8]



30 daysΔ
80.4% strut coverage[9]



90 daysΔ
98.7% strut coverage[9]

Thinner struts make the difference

Ultrathin vs. second generation DES in a large scale meta-analysis including more than 11,000 patients[10,11]

16%

Relative risk reduction in TLF at 12 months
RR (95% CI) 0.84 (0.72, 0.99)

‡ Driven by peri-procedural MI events (<48 hours). In-hospital rate may include events > 48 hours.
Δ Images: Secco G et al. Time-related changes in neointimal tissue coverage following a new generation SES implantation: an OCT observational study. Presented at: euro PCR, May 20, 2014; Paris, France.

Strut thickness in perspective[12]

Orsiro
BIOTRONIK
CoCr-SES
60 µm*

Synergy
Boston Scientific
PtCr-EES
74 µm

Ultimaster
Terumo
CoCr-SES
80 µm

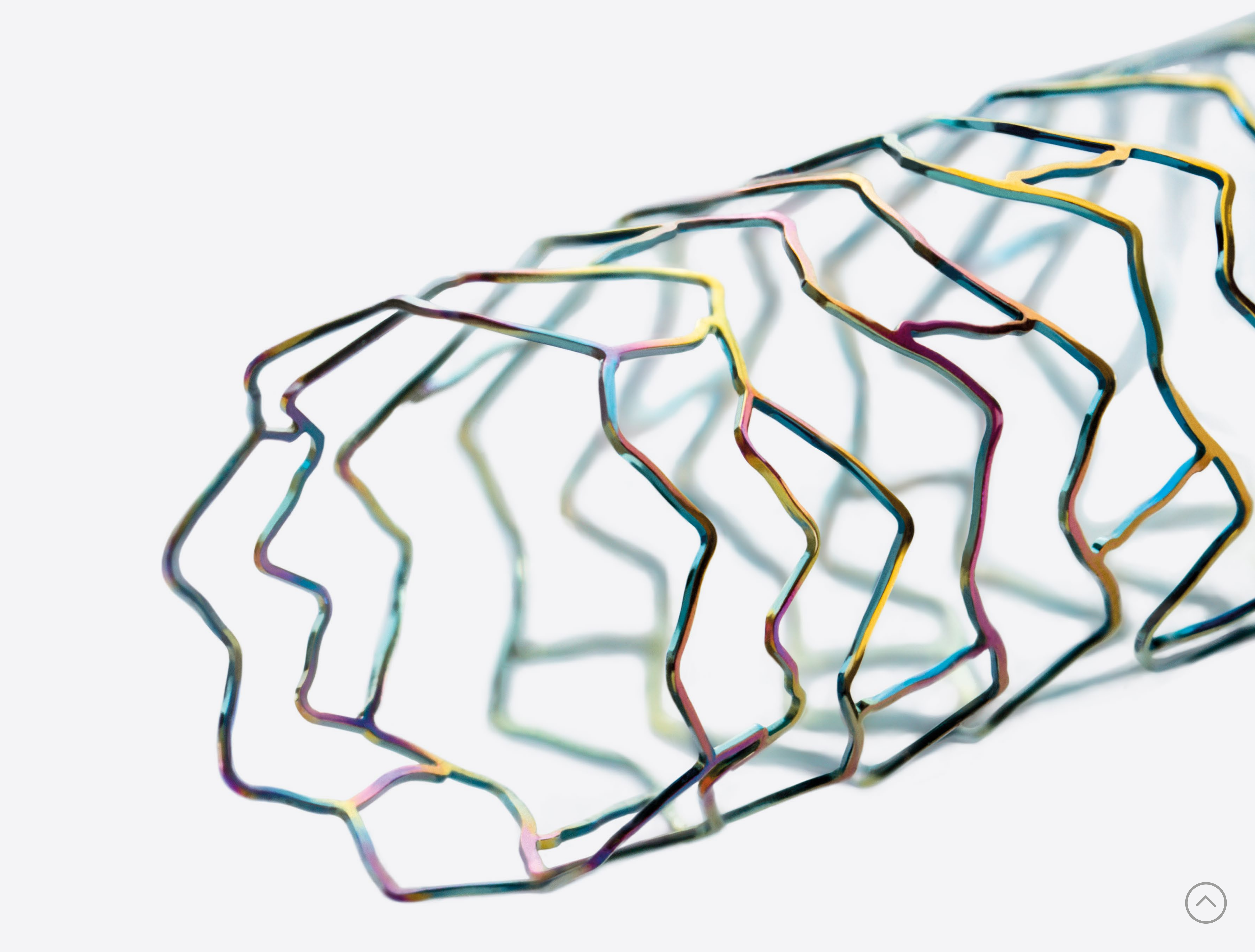
Resolute Onyx[13,14]
Medtronic
CoNi-ZES
81 µm

Xience Family
Abbott
CoCr-EES
81 µm

Promus
Boston Scientific
PtCr-EES
81 µm

BioMatrix
Biosensors
316L-BES
120 µm

* ø 2.25 – 3.0 mm



Orsiro®

Indicated for discrete de novo stenotic lesions and in-stent restenotic lesions.*

Vascular
Intervention
Coronary

Technical Data

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

Delivery system	
Catheter type	Rapid exchange
Recommended guide catheter	5F (min. I.D. 0.056")
Lesion entry profile	0.017"
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi crystalline polymer material
Coating (distal shaft)	Hydrophilic coating
Marker bands	Two swaged platinum-iridium markers
Proximal shaft diameter	2.0F
Distal shaft diameter	2.6F: ø 2.25 - 3.5 mm; 2.8F: ø 4.0 mm
Nominal pressure (NP)	8 atm
Rated burst pressure (RBP)	16 atm

Compliance Chart

Balloon diameter x length (mm)		ø 2.25 × 9-40	ø 2.50 × 9-40	ø 2.75 × 9-40	ø 3.00 × 9-40	ø 3.50 × 9-40	ø 4.00 × 9-40
Nominal Pressure (NP)	atm**	8	8	8	8	8	8
	ø (mm)	2.25	2.50	2.75	3.00	3.50	4.00
Rated Burst Pressure (RBP)	atm**	16	16	16	16	16	16
	ø (mm)	2.50	2.77	3.05	3.33	3.88	4.44

**1 atm = 1.013 bar

Ordering Information

Stent ø (mm)	Catheter length 140 cm, Stent length (mm): 9	13	15	18	22	26	30	35	40
2.25	364469	364475	364481	364487	364499	364505	364511	391234	391238
2.50	364470	364476	364482	364488	364500	364506	364512	391235	391239
2.75	364471	364477	364483	364489	364501	364507	364513	391236	391240
3.00	364472	364478	364484	364490	364502	364508	364514	391237	391241
3.50	364473	364479	364485	364491	364503	364509	364515	391018	391020
4.00	364474	364480	364486	364492	364504	364510	364516	391019	391021

1. Kandzari D et al. Ultrathin, bioresorbable polymer sirolimus-eluting stents versus thin, durable polymer everolimus-eluting stents in patients undergoing coronary revascularisation (BIOFLOW V): a randomised trial. Lancet. 2017 Oct 21; 390(10105):1843-1852; 2. Kandzari D, et al. BIOFLOW-V: A Prospective Randomized Multicenter Study to Assess the Safety and Effectiveness of the Orsiro Sirolimus Eluting Coronary Stent System in the Treatment Of Subjects With up to Three De Novo or Restenotic Coronary Artery Lesions Science. Presentation at ESC 2017; 3. Kandzari D et al. Ultrathin bioresorbable polymer sirolimus-eluting stents versus thin durable polymer everolimus-eluting stents. Journal of the American College of Cardiology. 2018 Dec 17;72(25):3287-97; 4. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020, doi: 10.1016/j. jcin.2020.02.019; 5. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020 Supplemental Material; 6. Iglesias JF et al. Biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents in patients with ST-segment elevation myocardial infarction (BIOSTEMI): a single-blind, prospective, randomised superiority trial; Lancet, September, 2019; 7. Pilgrim T et al. 5-year outcomes of the BIOSCIENCE randomised trial. Supplementary appendix; Lancet 2018; published online Aug 28. http://dx.doi.org/10.1016/S0140-6736(18)31715-X; 8. Foin et al. Impact of stent strut design in metallic stents and biodegradable scaffolds. Int J Cardiol.2014 Dec 20;177(3):800-8; 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. Bangalore S et al. Newer-generation ultrathin strut drug-eluting stents versus older second-generation thicker strut drug-eluting stents for coronary artery disease: meta-analysis of randomized trials. Circulation. 2018 Nov 13;138(20):2216-26; 11. Bangalore S, et al. Newer-generation ultrathin strut drug-eluting stents versus older second-generation thicker strut drug-eluting stents for coronary artery disease: meta-analysis of randomized trials. Circulation. 2018 Jul. 24: 2216-2226; 12. Stefanini GG et al. Coronary stents: novel developments. Heart. 2014 Jul 1;100(13):1051-61; 13. Low AF. Stent platform for procedural success: Introducing the Continuous Sinusoidal & Core Wire Technologies. Presented at: AsiaPCR; 22-24 January, 2015; Singapore, Singapore; 14. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: Cardiovascular Nurse/TechnologistSymposium; June 17, 2016; New York, USA; 15. BIOTRONIK data on file.

Target Lesion Failure (TLF), Target Lesion Revascularization (TLR), Target Vessel Myocardial Infarction (TV-MI), Stent Thrombosis (ST).

*Indication as per IFU.

380085/K/Jul_2020

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