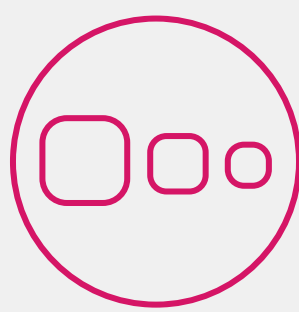




Outstanding patient
outcomes



Ultrathin struts

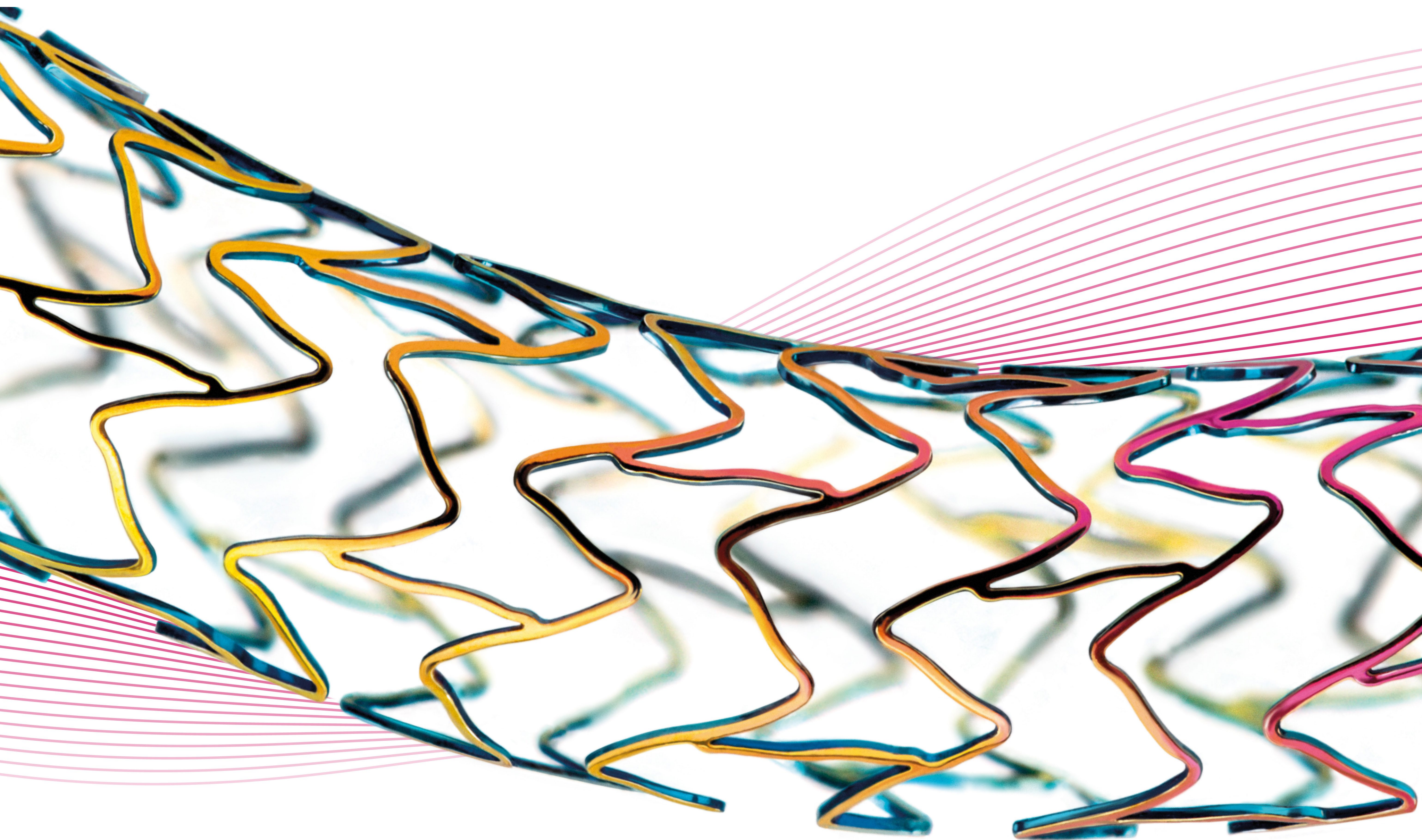


Excellent
deliverability

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

BIO **BIOTRONIK**
excellence for life

Orsiro[®]



Orsiro

Ultrathin struts[§]. Outstanding patient outcomes[◇].

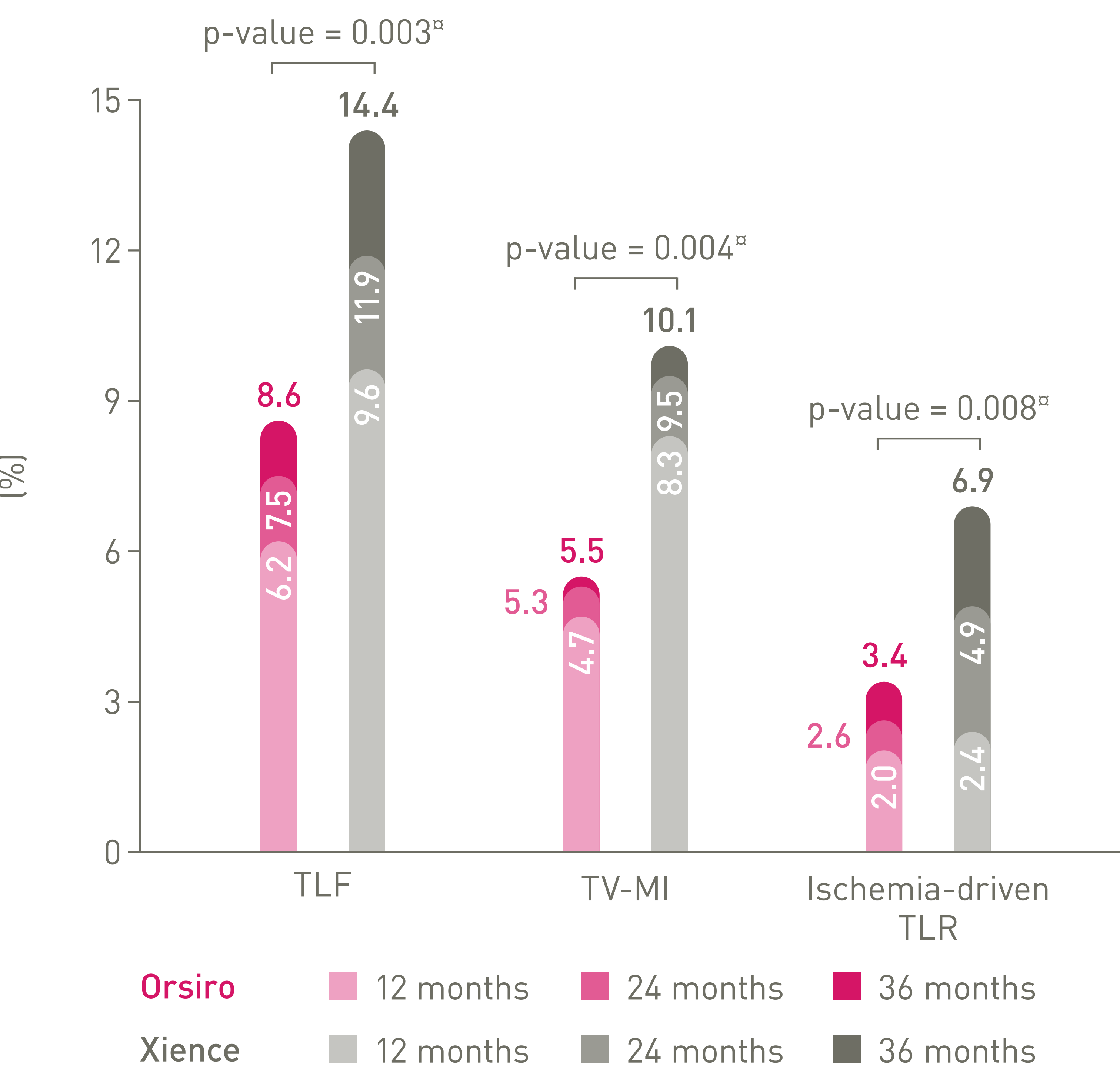
Outstanding patient outcomes

Improving patient outcomes, year after year*

BIOFLOW-V (n = 1,334) FDA pivotal trial

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.^{1,2,3}

TLF and components at 12, 24 and 36 Months



40%

lower
TLF rate³ ^ϕ

(p=0.003)

46%

lower
TV-MI rate³ ^ϕ

(p=0.004)

52%

lower
Ischemia-driven
TLR rate³ ^ϕ

(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.

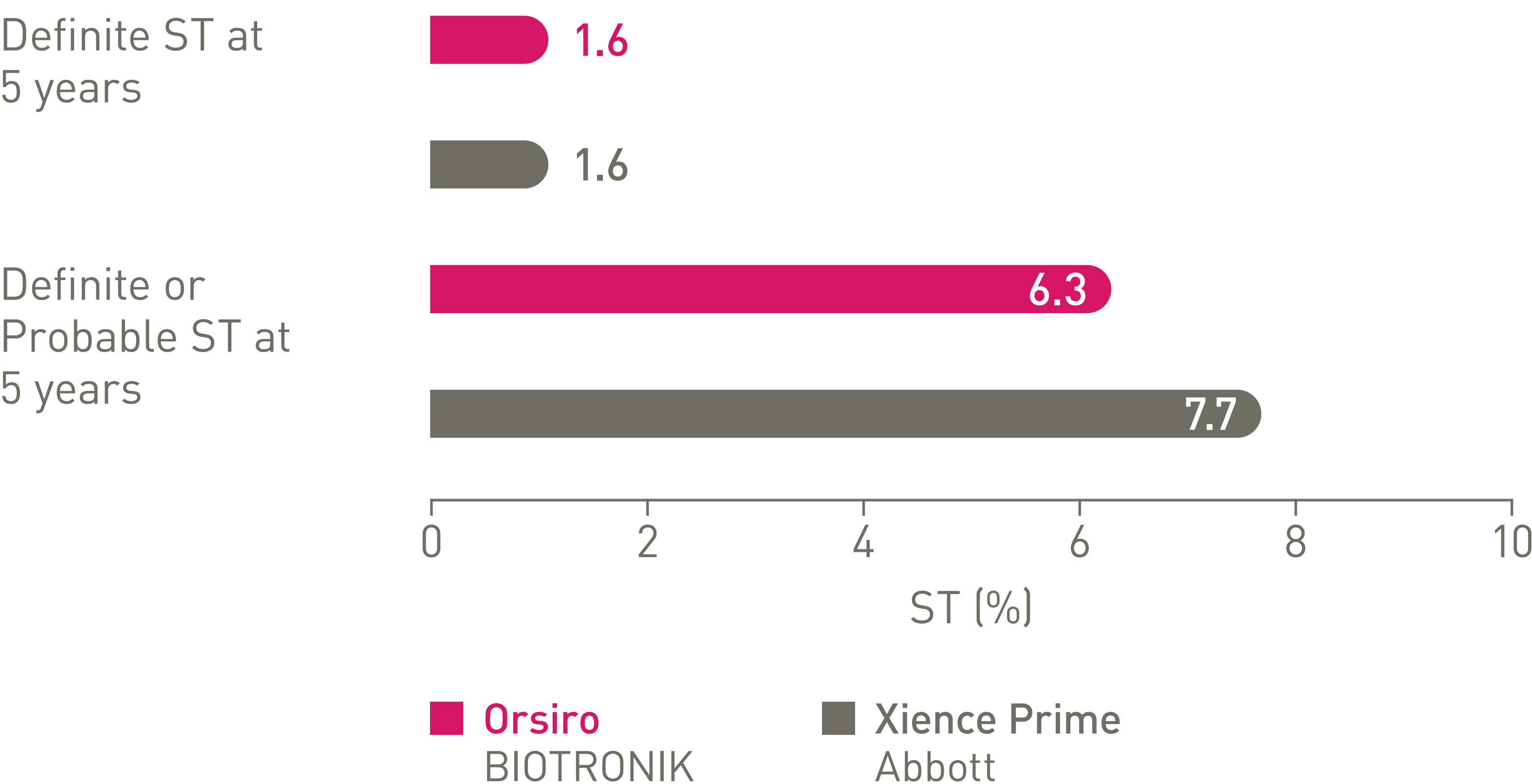
[▮]p-values for 36-m frequentist analysis.

^ϕvs. Xience, based on 36-m frequentist analysis.

Long-term performance

In the randomized, all-comers BIOSCIENCE trial (n= 2,119)⁴

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





The only
ultrathin DES
in the US⁵

Ultrathin Struts – thinnest available in the US⁵

Thinner struts, faster endothelialization⁶

Improved outcomes start in the early phase

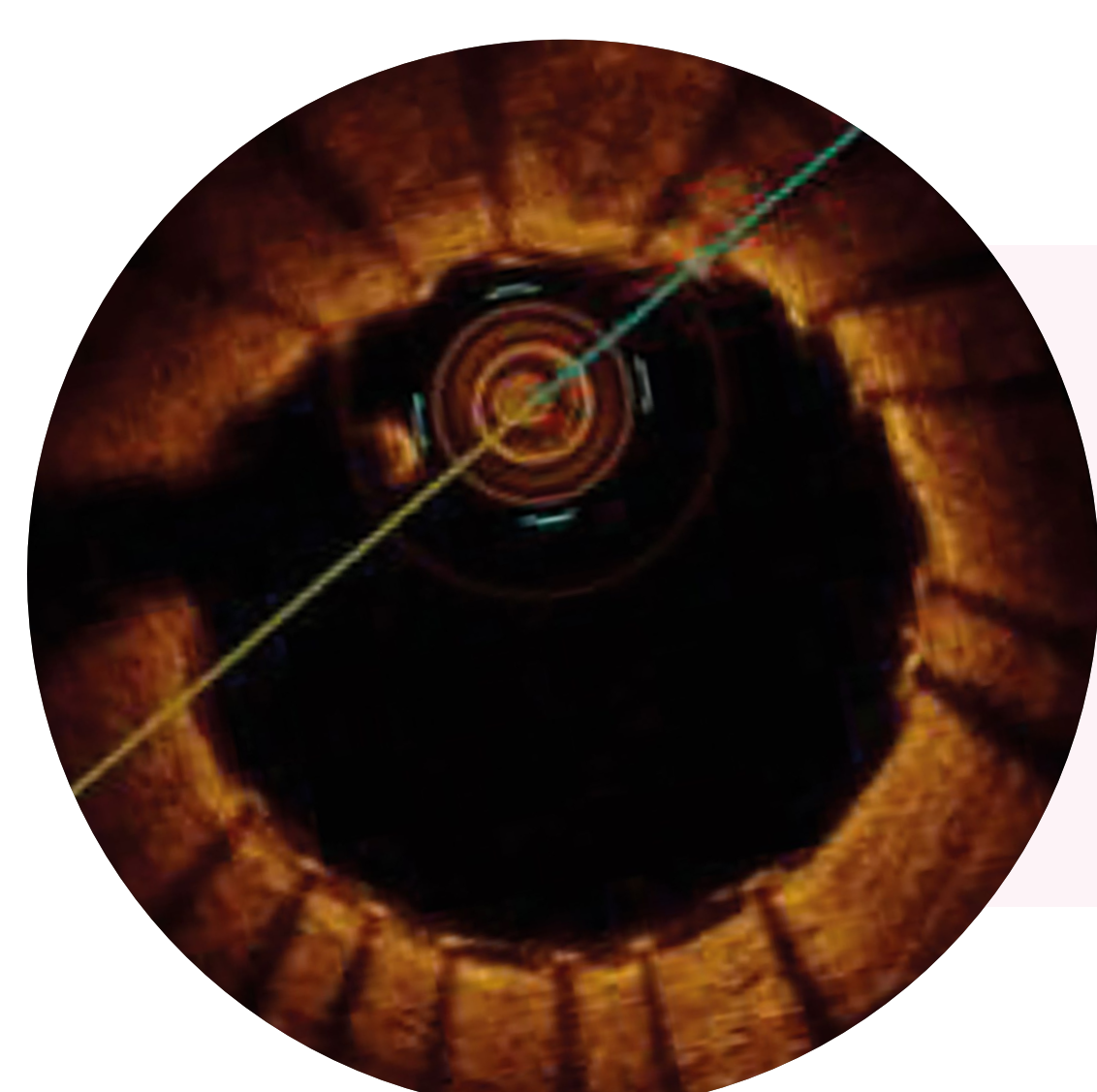
43%

lower in-hospital
MI rate[‡]
vs. Xience¹

48 hours

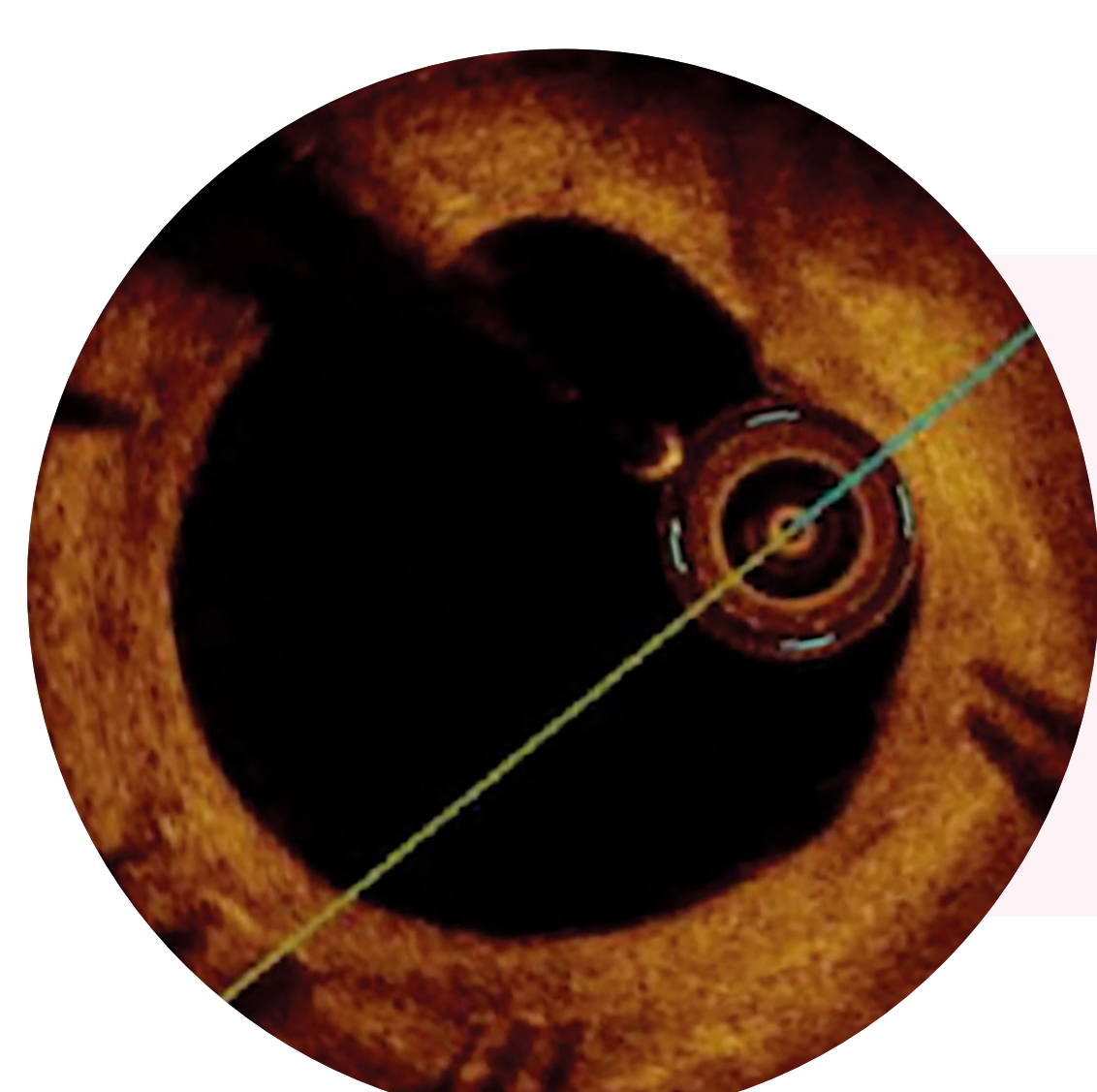
Thinner struts mean less
vessel injury⁶

Vascular Healing



30 days^Δ

80.4% strut coverage⁷



90 days^Δ

98.7% strut coverage⁷

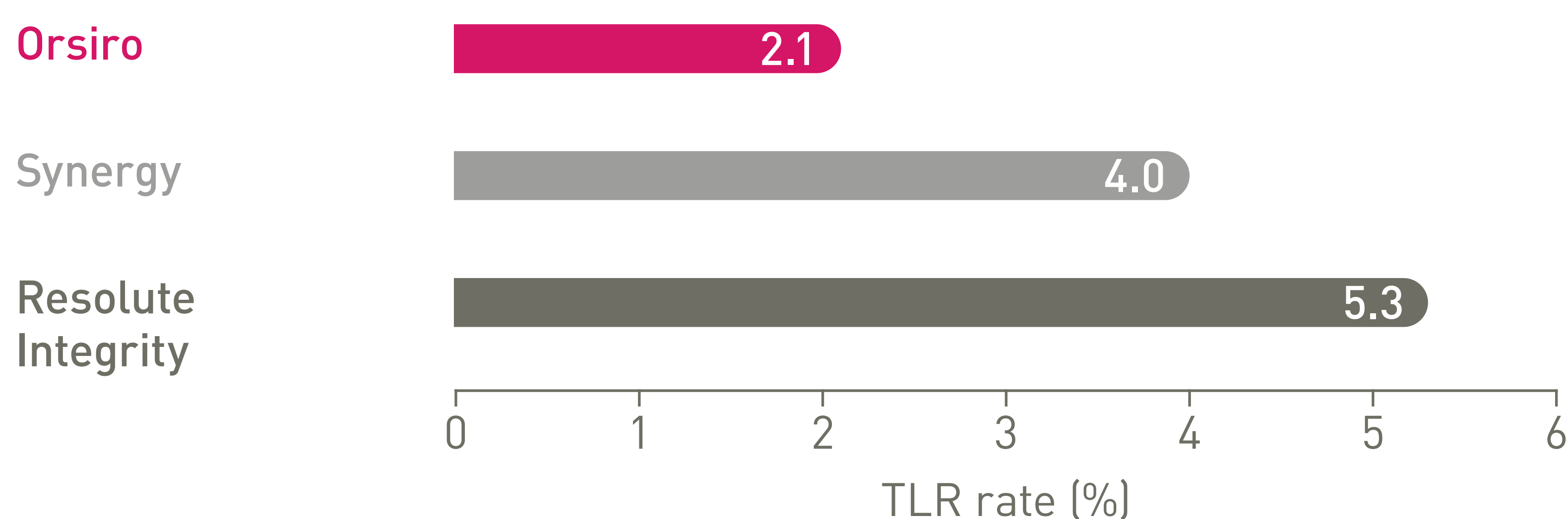
[‡] Driven by peri-procedural MI events (<48 hours). In-hospital rate may include events > 48 hours.

^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: EuroPCR, May 20, 2014; Paris, France.

Small Vessels. Ultrathin Struts. Big Difference.

Small vessel subgroup analysis (n = 1,506) of a large scale all-comers BIO-RESORT (n = 3,514) trial.

Fewer repeat target lesion revascularizations (TLR) compared to Resolute Integrity at 36 months.⁸



Lower revascularization rates in the 3rd year

BIO-RESORT⁸
small vessel sub-group

60%

lower TLR rate vs.
Resolute Integrity

(p = 0.009)

BIOFLOW-V³

52%

lower TLR rate vs.
Xience

(p = 0.008^a)

Ultrathin, ultra effective

Ultrathin vs. thin strut DES in a large scale meta-analysis including more than 11,000 patients⁹

16%

reduction in TLF
rate at 12m
(RR=0.84; 95%
CI 0.72-0.99)





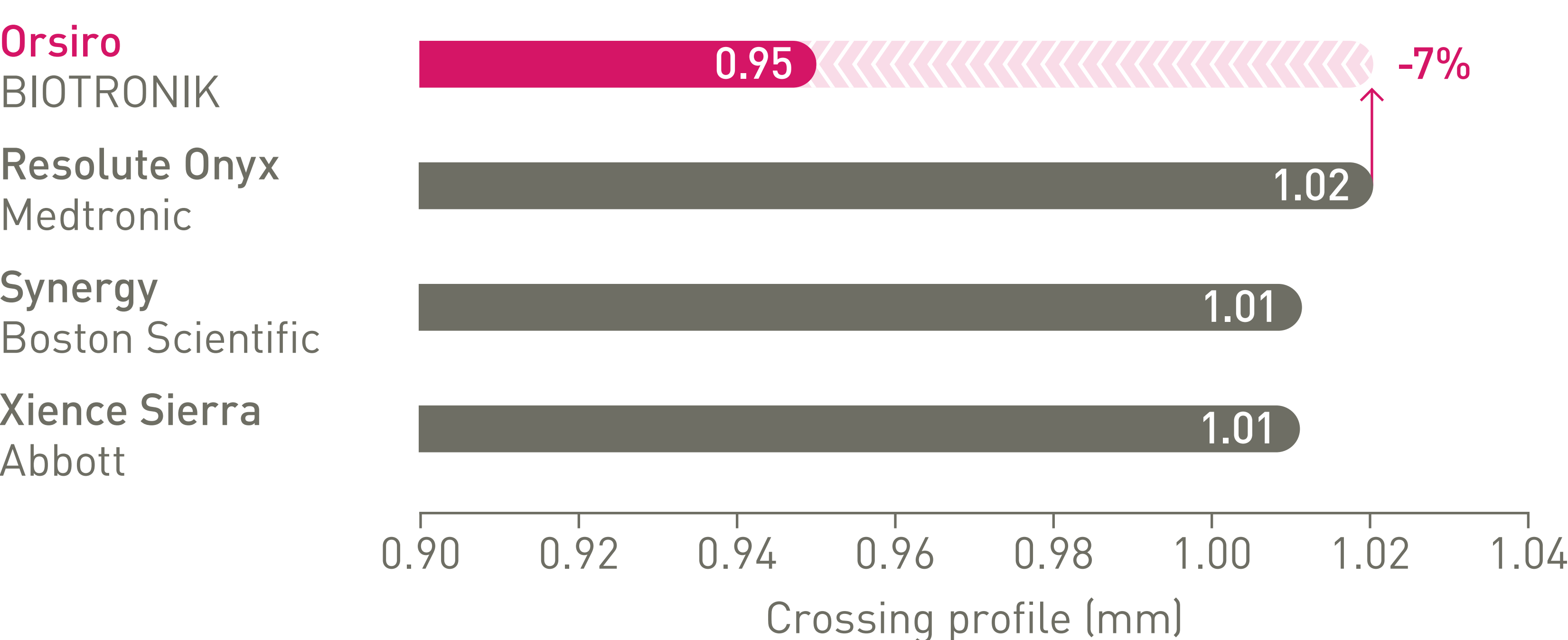
Excellent deliverability



79%
easier to cross
vs. Synergy¹⁰

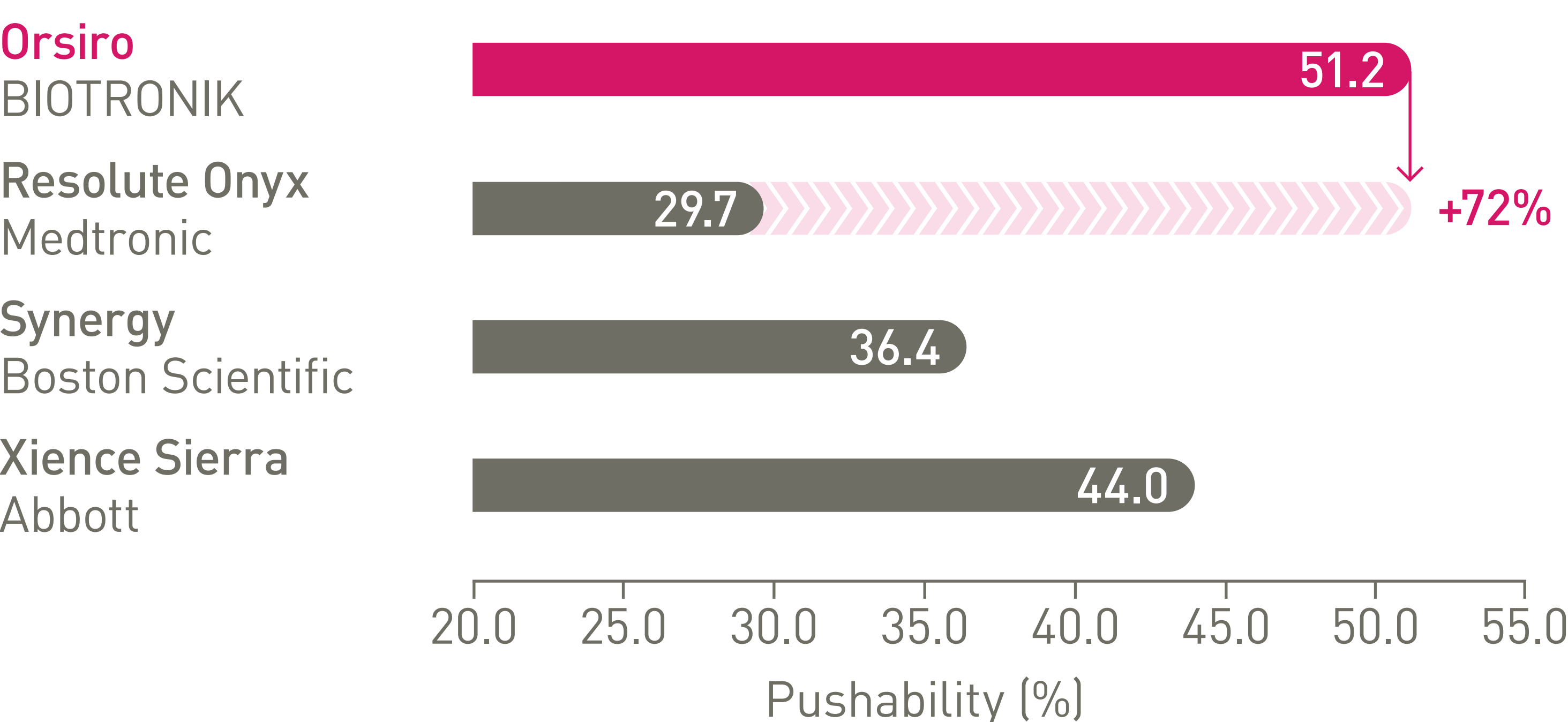
Lower crossing profile

Improved acute performance – up to 7% lower crossing profile¹⁰



Better push

Transmits up to 72% more force from hub to tip¹⁰



“Low profile and great deliverability coupled with superb clinical outcomes is a game-changer. In the current era of coronary stents, thinner struts are better and thinnest might be best.”

Dr. Dean Kereiakes
BIOFLOW-V Site Principal Investigator

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. October, 2017; 2. Kandzari D et al. Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents versus Thin Durable Polymer Everolimus-Eluting Stents: Journal of American College of Cardiology. 2018, doi: <https://doi.org/10.1016/j.jacc.2018.09.019>; 3. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020, doi: [10.1016/j.jcin.2020.02.019](https://doi.org/10.1016/j.jcin.2020.02.019); 4. Pilgrim T et al. 5-year outcomes of the BIOSCIENCE randomised trial. Supplementary appendix. Lancet, August, 2018; 5. When compared to FDA approved Drug Eluting Stents. BIOTRONIK data on file; 6. Foin N et al. Int J of Cardiol. 2014, 177(3); 7. 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; 8. Buiten R et al. Outcomes in patients treated with thin-strut, very thin-strut, or ultrathin-strut drug-eluting stents in small coronary vessels - A prespecified analysis of the randomized BIO-RESORT trial; JAMA Cardiol. Published online May 21, 2019. doi:10.1001/jamacardio.2019.1776; Clinical Trials. gov: NCT01674803; 9. Bangalore S et al. Circulation. 2018, 138; 10. BIOTRONIK data on file; IIB(P)24/2018.

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BIOTRONIK
excellence for life

