Outstanding patient outcomes

Ultrathin struts

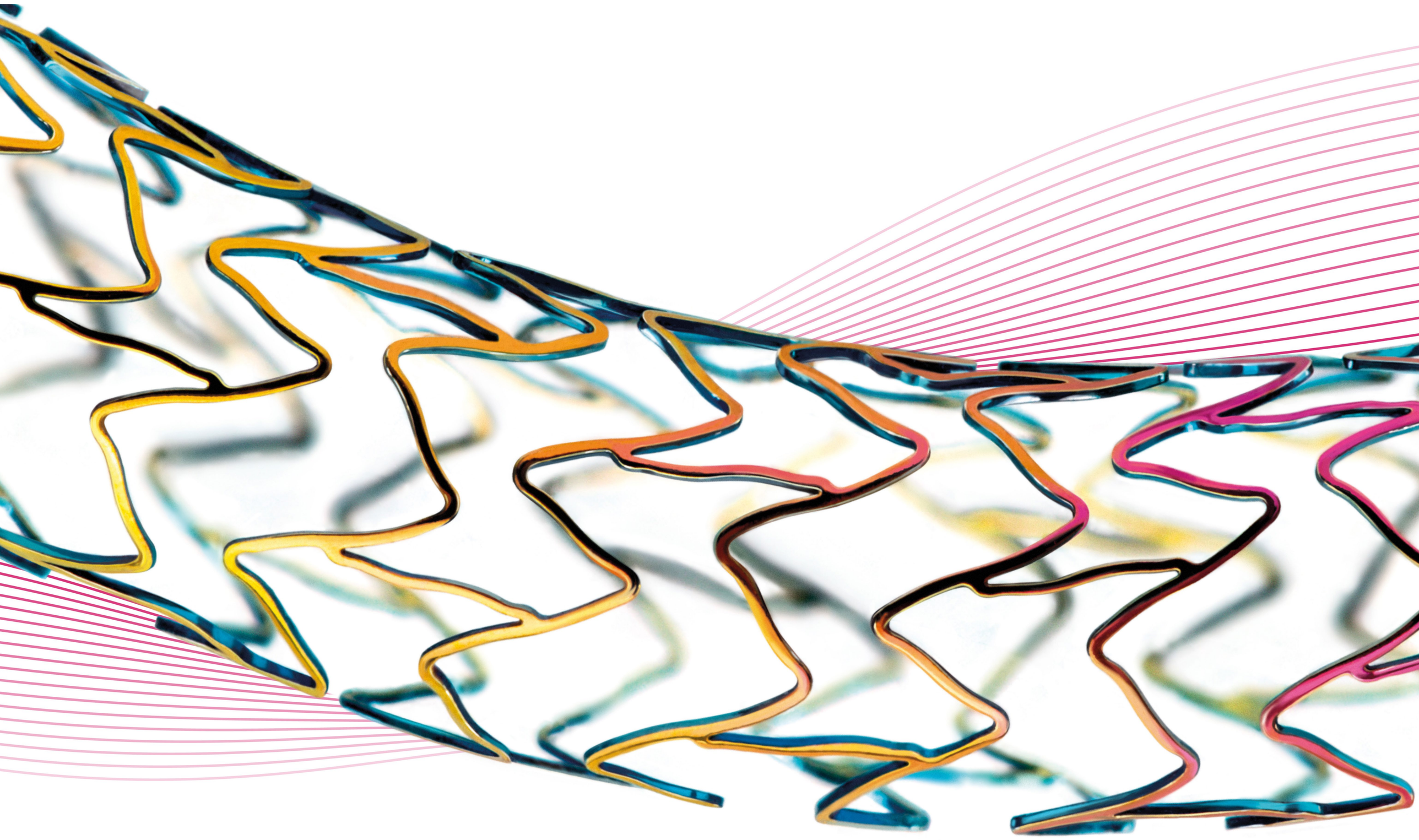
Excellent deliverability

Vascular Intervention // Coronary
Drug-Eluting Stent System

BIOTRONIK
excellence for life

Orsiro®

Ultrathin struts. Outstanding patient outcomes.



Orsiro
Ultrathin struts§. Outstanding patient outcomes◊.

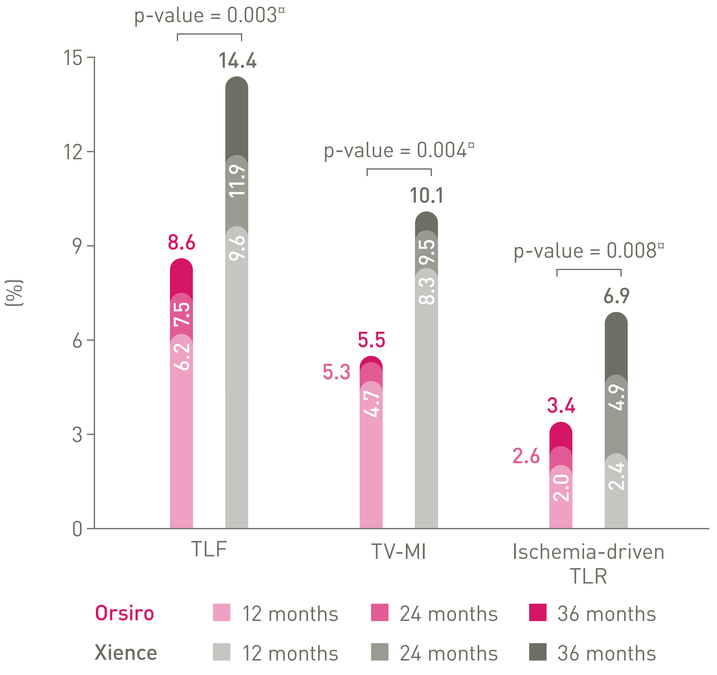
Outstanding patient outcomes

Improving patient outcomes, year after year*

BIOFLOW-V (n = 1,334) 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%
lower TLF rate[5 ϕ]
(p=0.003)

46%
lower TV-MI rate[5 ϕ]
(p=0.004)

52%
lower Ischemia-driven TLR rate[5 ϕ]
(p= 0.008)

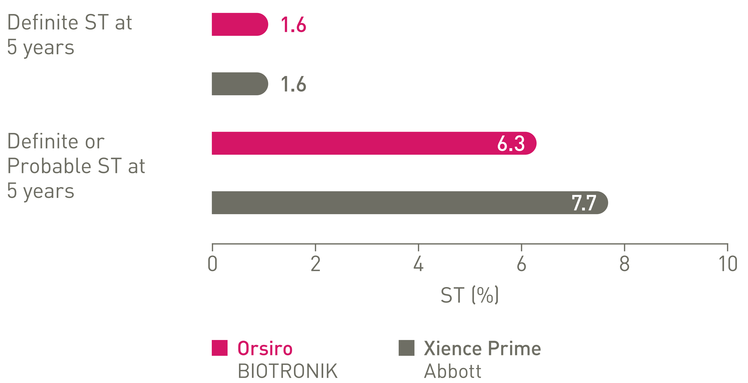
TLF – Target Lesion Failure; TV-MI – Target Vessel Myocardial Infarction; TLR – Target Lesion Revascularization.

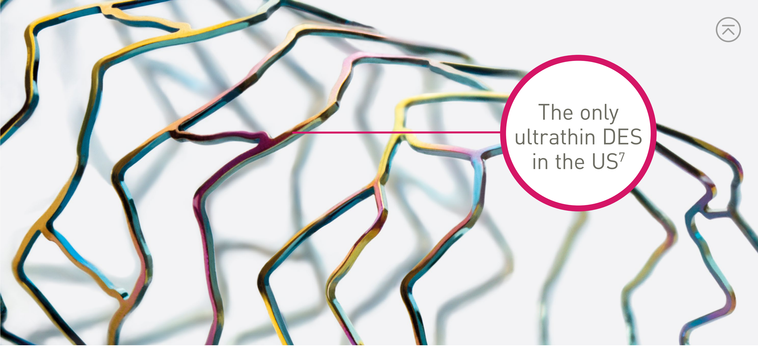
§As characterized with respect to strut thickness in the Bangalore et al. meta-analysis.[11]
◊Based on investigator's interpretation of BIOFLOW-V primary endpoint results.
*Compared to Xience in BIOFLOW-V, based on three consecutive years.
¤p-values for 36-m frequentist analysis of BIOFLOW-V.[5]
ϕvs. Xience, based on 36-m frequentist analysis of BIOFLOW-V.[5]

Long-term performance

In the randomized, all-comers BIOSCIENCE trial (n= 2,119)[6]

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





Ultrathin Struts – thinnest available in the US[7]

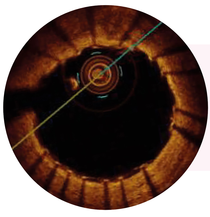
Thinner struts, faster endothelialization[8]

Improved outcomes start in the early phase

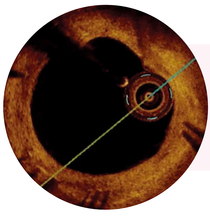
43%
lower in-hospital MI rate‡ vs. Xience[1]

48 hours
Thinner struts mean less vessel injury[8]

Vascular Healing



30 daysΔ
80.4% strut coverage[9]



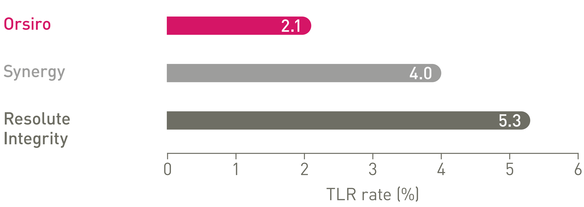
90 daysΔ
98.7% strut coverage[9]

‡ 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.[10]



Lower revascularization rates in the 3rd year

BIO-RESORT[10] small vessel sub-group

60%
lower TLR rate vs. Resolute Integrity

(p = 0.009)

BIOFLOW-V[3]

52%
lower TLR rate vs. Xience

(p = 0.008ª)

Ultrathin, ultra effective

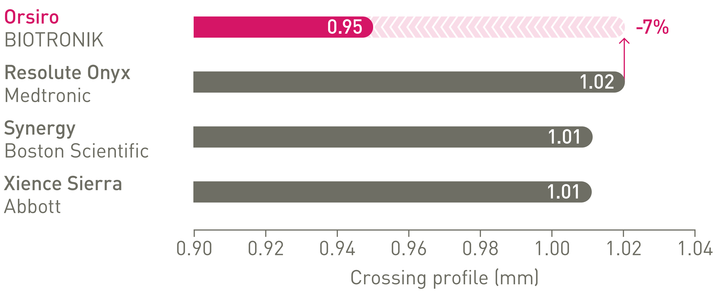
Ultrathin vs. thin strut DES in a large scale meta-analysis including more than 11,000 patients[11]

16%
reduction in TLF rate at 12m (RR=0.84; 95% CI 0.72-0.99)

Excellent deliverability

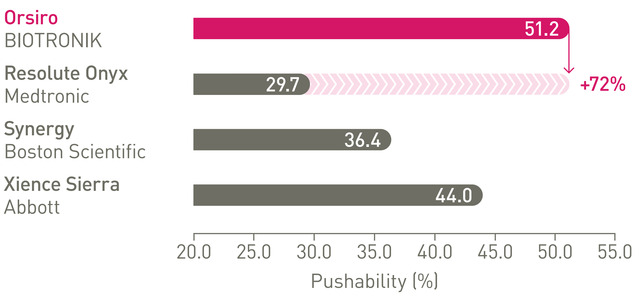
Lower crossing profile

Improved acute performance – up to 7% lower crossing profile[12]



Better push

Transmits up to 72% more force from hub to tip[12]



"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. 2017. 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. JACC. 2018. 72(25):3287-97; 4. Kandzari, D et al. Ultrathin bioresorbable-polymer sirolimus-eluting stents versus thin durable-polymer everolimus-eluting stents for coronary revascularization: 3-year outcomes from the randomized BIOFLOW V trial. JACC: Cardiovascular Interventions. 2020, doi: 10.1016/j. jcin.2020.02.019; 5. Kandzari D et al. D et al. Ultrathin bioresorbable-polymer sirolimus-eluting stents versus thin durable-polymer everolimus-eluting stents for coronary revascularization: 3-year outcomes from the randomized BIOFLOW V trial. JACC: Cardiovascular Interventions. 2020. Supplementary material; 6. Pilgrim T et al. Ultrathin-strut, biodegradable-polymer, sirolimus-eluting stents versus thin-strut, durable-polymer, everolimus-eluting stents for percutaneous coronary revascularisation: 5-year outcomes of the BIOSCIENCE randomised trial. Lancet. 2018. 392.10149, 737-746. Supplementary appendix; 7. When compared to FDA approved Drug Eluting Stents. BIOTRONIK data on file; 8. Foin N et al. Impact of stent strut design in metallic stents and biodegradable scaffolds. International journal of cardiology. 2014. 177.3, 800-808; 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. 2016. 17.1, 38-43; 10. 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. 2019. doi:10.1001/jamacardio.2019.1776: Clinical Trials. gov: NCT01674803; 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. 138.20: 2216-2226. BIOTRONIK data on file; 12. IIB(P)24/2018.

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