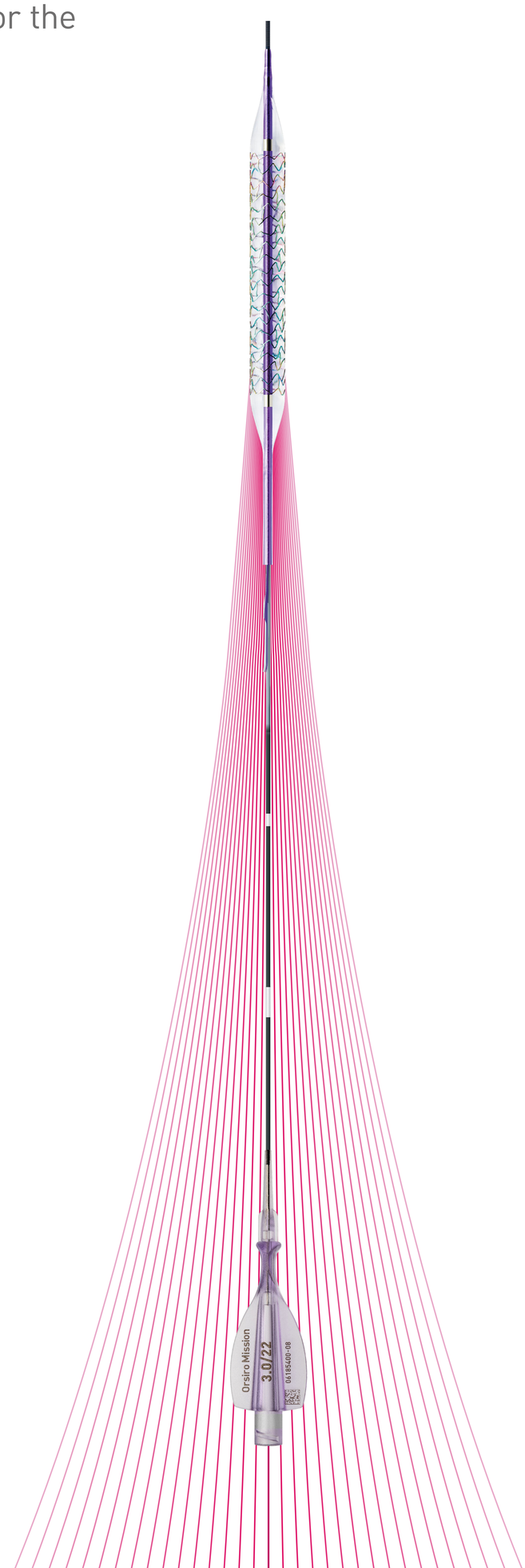
Vascular Intervention // Coronary
Drug-Eluting Stent System

BIOTRONIK
excellence for life

Orsiro® Mission DES

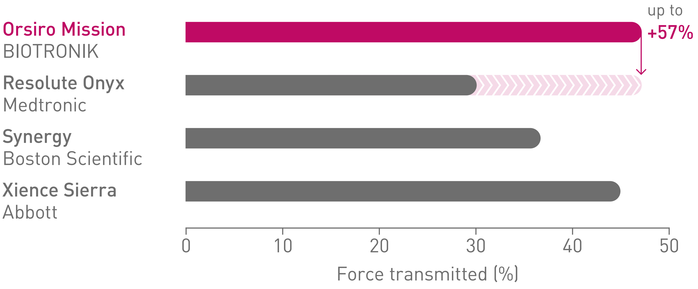
Even better deliverability for the outstanding Orsiro DES



Orsiro Mission DES
The next level of deliverability[1]

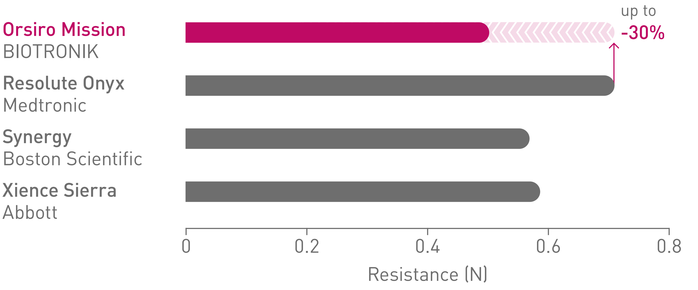
1st in Push[4]

Transmits more force from hub to tip.



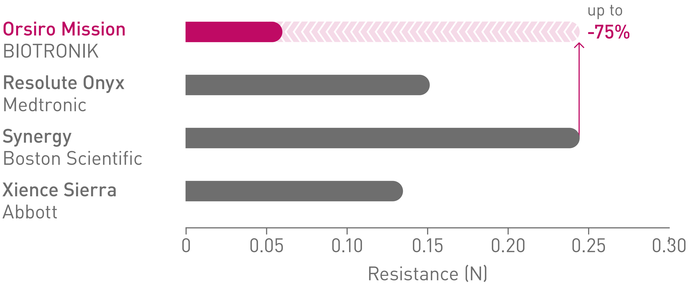
1st in Track[4]

Less force needed to follow the path.



1st in Cross[4]

Less force needed to successfully cross demanding anatomies.



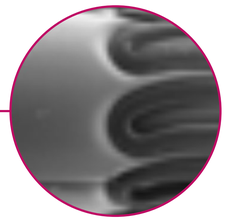
57%
better push

30%
better track

75%
better cross

proBIO

Passive coating
for high biocompatibility



NEW
Deep embedding
for high cross

BIOlute

Bioabsorbable coating
with controlled drug release and low thrombogenicity[5]

Ultrathin 60 µm* struts
for early endothelialization

NEW
More flexible shaft
for high track

Enhanced force transmission
for high push

Dual-coating
on shaft for limited friction

NEW
Ergonomic hub
with kink resistance

*Nominal strut thickness for size ø 2.25 - 3.0 mm, mean diameter 62 µm.

Orsiro Mission DES
Ultrathin struts[2] – thinnest available in the US[6]

Thinner struts make the difference[7]

- Less disrupted flow
- Improved re-endothelialization

Strut thickness in perspective[8]

Orsiro
BIOTRONIK
CoCr-SES

60 µm*

Synergy
Boston Scientific
PtCr-EES

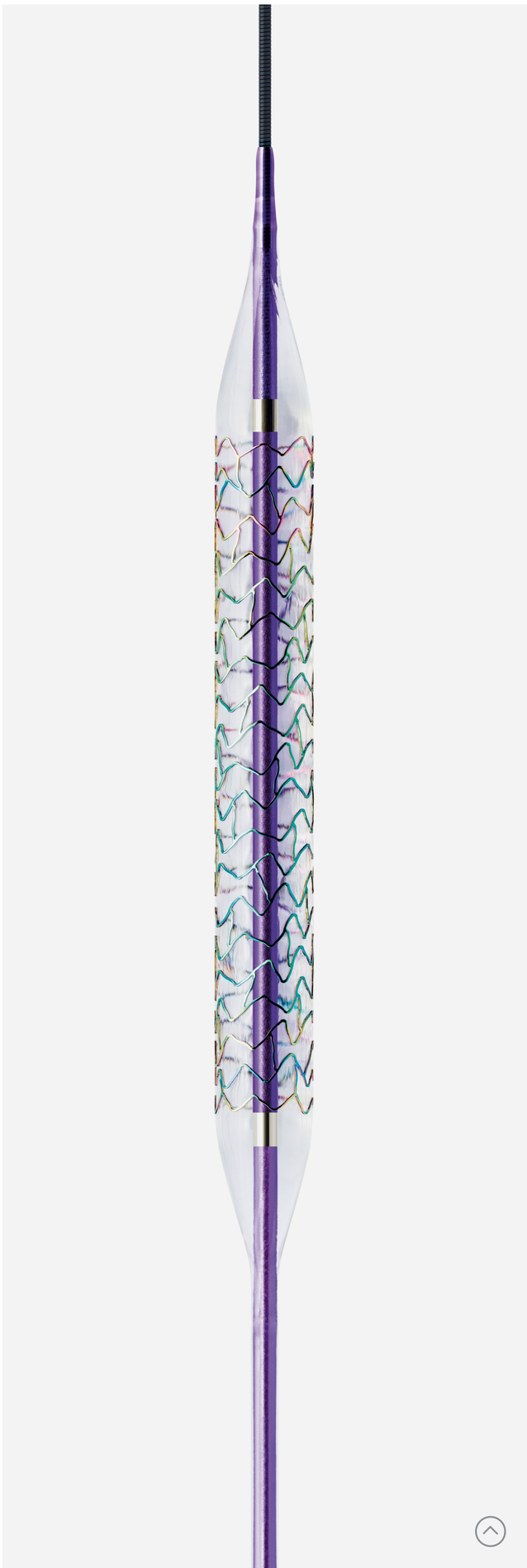
74 µm

Resolute Onyx[9,10]
Medtronic
CoNi-ZES

81 µm

Xience Family
Abbott
CoCr-EES

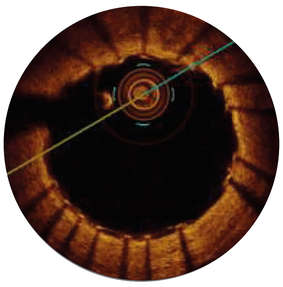
81 µm



*Nominal strut thickness for size ø 2.25 - 3.0 mm, mean diameter 62 µm.

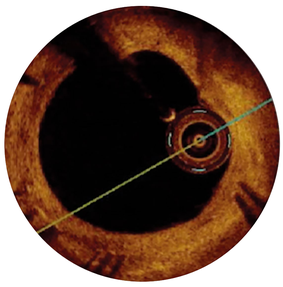
For early endothelialization

Strut coverage[11]
30 days[Δ]



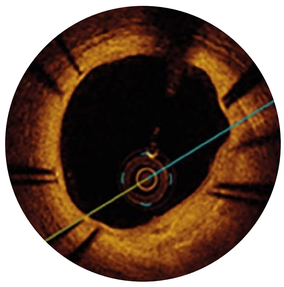
>80%
n = 589

Strut coverage[11]
90 days[Δ]



>97%
n = 874

Strut coverage[11]
180 days[Δ]



>98%
n = 1,130

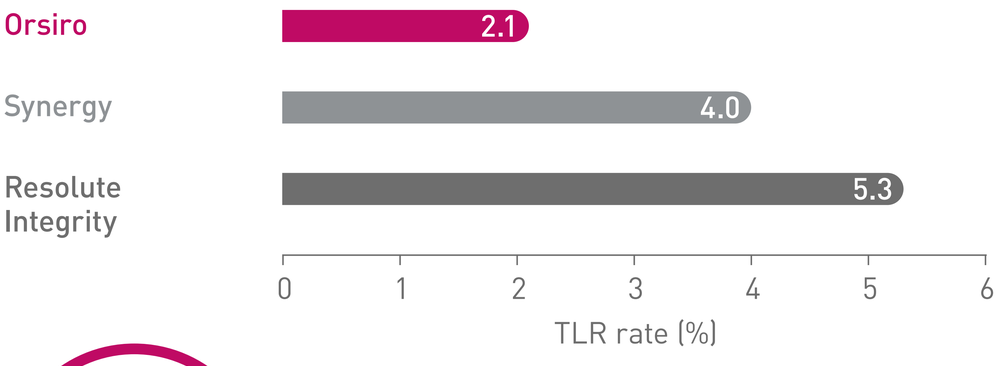
Immature tissue coverage → HEALING PROGRESS → Tissue maturation and full coverage

BIO-RESORT trial

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.

Lower target lesion revascularization (TLR) rate compared to Resolute Integrity at 36 months.[12]



60%
lower rate TLR vs. Resolute Integrity (p = 0.009)

n = number of struts analyzed.

[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.

Orsiro Mission DES
Outstanding patient outcomes[3]

One of the most studied DES◊

STUDY NAME	STUDY TYPE	PATIENTS	STATUS	PRIMARY ENDPOINT
BIOSTEMI	RCT	1,300	24-month FU available	TLF at 12 months
TAGLIERI et al.	Network Meta-Analysis	99,039	-	TLF at 12 months and the longest FU available
BIOFLOW-V	RCT	1,334	36-month FU available	TLF at 12 months
BIO-RESORT	RCT	3,514	36-month FU available	TVF at 12 months
BIONYX	RCT	2,488	36-month FU available	TVF at 12 months
BIOSCIENCE	RCT	2,119	Completed, 60-month FU available	TLF at 12 months

>55,000 patients enrolled[13]

>71,500 patients enrolled or planned in total [13]

>68 studies started[13]

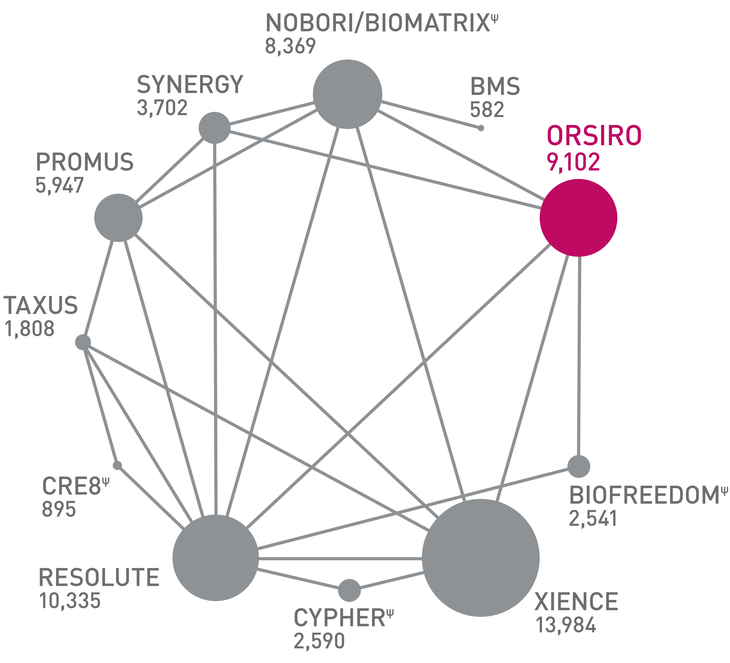
Taglieri et al. network meta-analysis

Orsiro – ranked as the best DES‡

99,039 patients in a network meta-analysis of 77 RCTs[14]

Orsiro is associated with a lower 1-year rate of TLF compared with Xience (OR (95% CI) 0.84 [0.71, 0.98], p = 0.03) and Resolute§ (OR (95% CI) 0.81 [0.68, 0.95], p = 0.01).

Orsiro – the highest probability (70.8%) to rank as the best stent.‡



SUCRA – Surface Under the Cumulative Ranking Curve.

◊ In large RCTs, based on Taglieri et al. Meta-analysis, against currently used DES.
‡ Based on 1-year TLF SUCRA score, in comparison to Xience, Resolute and Nobori/BioMatrix, after a median follow-up period of 50 months.
§ Resolute Integrity and Resolute Onyx.
ψ The Nobori, BioMatrix, Cre8, Biofreedom and Cypher drug eluting stents are not available in the US.

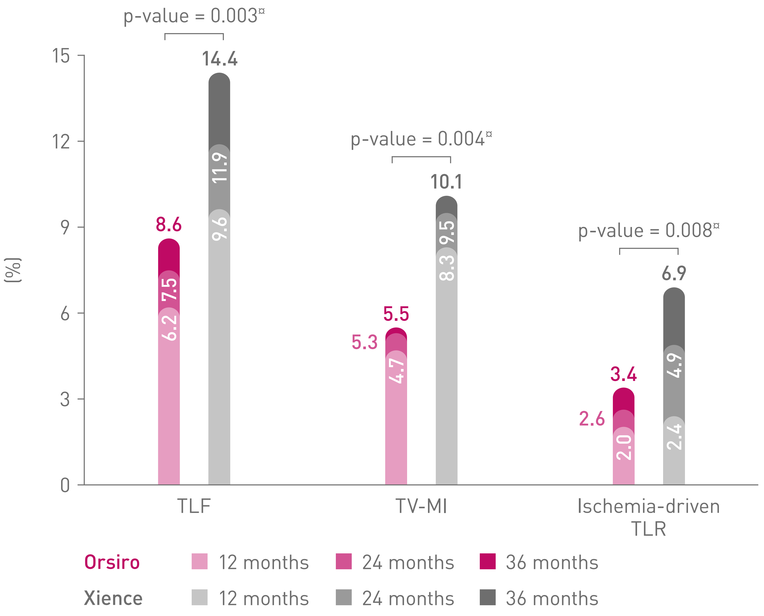
BIOFLOW-V trial

Improving patient outcomes, year after year[15]

BIOFLOW-V (n = 1,334) FDA pivotal trial[16,17,18,19,20]

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

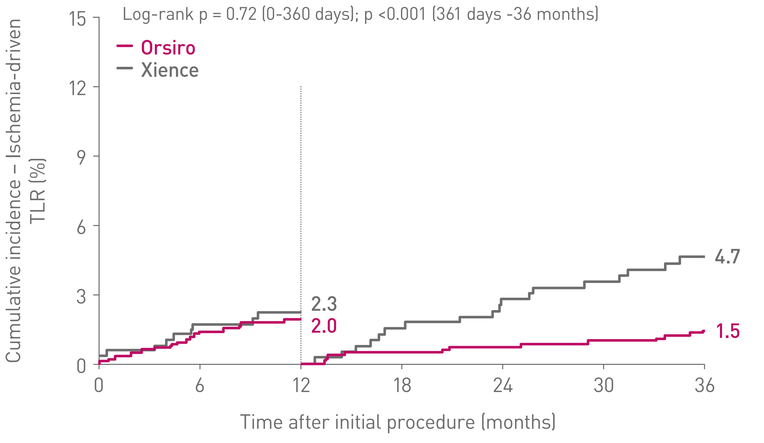


40% lower TLF rate[20 ϕ] (p = 0.003)

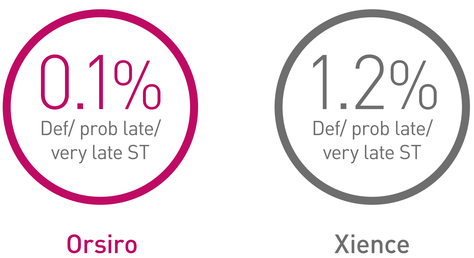
46% lower TV-MI rate[20 ϕ] (p = 0.004)

52% lower Ischemia-driven TLR rate[20 ϕ] (p = 0.008)

Ischemia-driven TLR Landmark Analysis[19]



ST at 36 Months[19]



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

¤ p-values for 36-m frequentist analysis of BIOFLOW-V.[20]
ϕ vs. Xience, based on 36-m frequentist analysis of BIOFLOW-V.[20]

Orsiro® Mission DES

Sirolimus-Eluting Coronary Stent System

Vascular
Intervention
Coronary

Indication

Orsiro Mission is indicated for improving coronary luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST-elevation myocardial infarction or documented silent ischemia due to atherosclerotic lesions in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of ⩽ 36 mm.

Technical Data

Stent

Stent material	Cobalt chromium, L-605
Passive coating	**pro**BIO™ amorphous silicon carbide
Active coating	**BIO**lute™ bioabsorbable drug matrix consisting of sirolimus and polymer poly-l-lactide (PLLA)
Nominal drug content	1.4 µg/mm²

Delivery system

Catheter type	Fast-exchange
Recommended guide catheter	5 F (min. I.D.* ⩾ 0.056")
Guide wire diameter	0.014" (0.36 mm)
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
Proximal shaft diameter	2.0 F
Distal shaft diameter	2.7 F: ø 2.25 – 3.0 mm; 2.9 F: ø 3.5 – 4.0 mm
Nominal pressure (NP)	10 atm
Rated burst pressure (RBP)	16 atm

*I.D. = Inner Diameter

Ordering Information

Stent ø (mm)	Stent length (mm)								
	9	13	15	18	22	26	30	35	40
2.25	453925	453931	453937	453943	453949	453955	453961		
2.50	453926	453932	453938	453944	453950	453956	453962	453968	453974
2.75	453927	453933	453939	453945	453951	453957	453963	453969	453975
3.00	453928	453934	453940	453946	453952	453958	453964	453970	453976
3.50	453929	453935	453941	453947	453953	453959	453965	453971	453977
4.00	453930	453936	453942	453948	453954	453960	453966	453972	453978

1. In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, BIOTRONIK data on file; 2. As characterized with respect to strut thickness in Bangalore et al. Meta-analysis; 3. Based on investigator's interpretation of BIOFLOW-V primary endpoint result; 4. BIOTRONIK data on file; 5. Per investigators' interpretation of preclinical studies with Orsiro as mentioned in Cassese et al. J Thorac Dis 2018;10(2):688-692; 6. When compared to FDA approved Drug Eluting Stents. BIOTRONIK data on file; 7. Foin N et al. International journal of cardiology. 2014 Dec 20;177(3):800-8; 8. Stefanini GG et al. Coronary stents: novel developments. Heart. 2014 Jul 1;100(13):1051-61; 9. Low AF. Stent platform for procedural success: Introducing the Continuous Sinusoidal & Core Wire Technologies. Presented at: AsiaPCR; 22-24 January, 2015; Singapore, Singapore; 10. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: Cardiovascular Nurse/Technologist Symposium; June 17, 2016; New York, USA; 11. 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; 12. 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; 13. BIOTRONIK data on file, as of January 2020; 14. Taglieri N et al. Target lesion failure with current drug-eluting stents: Evidence from a comprehensive network meta-analysis. JACC 2020 13(24):2868-78; 15. Compared to Xience in BIOFLOW-V, based on three consecutive years; 16. 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; 17. 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; 18. Kandzari D et al. Ultrathin bioresorbable polymer sirolimus-eluting stents versus thin, durable polymer everolimus-eluting stents. JACC. 2018. 72(25):3287-97; 19. 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; 20. 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.

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