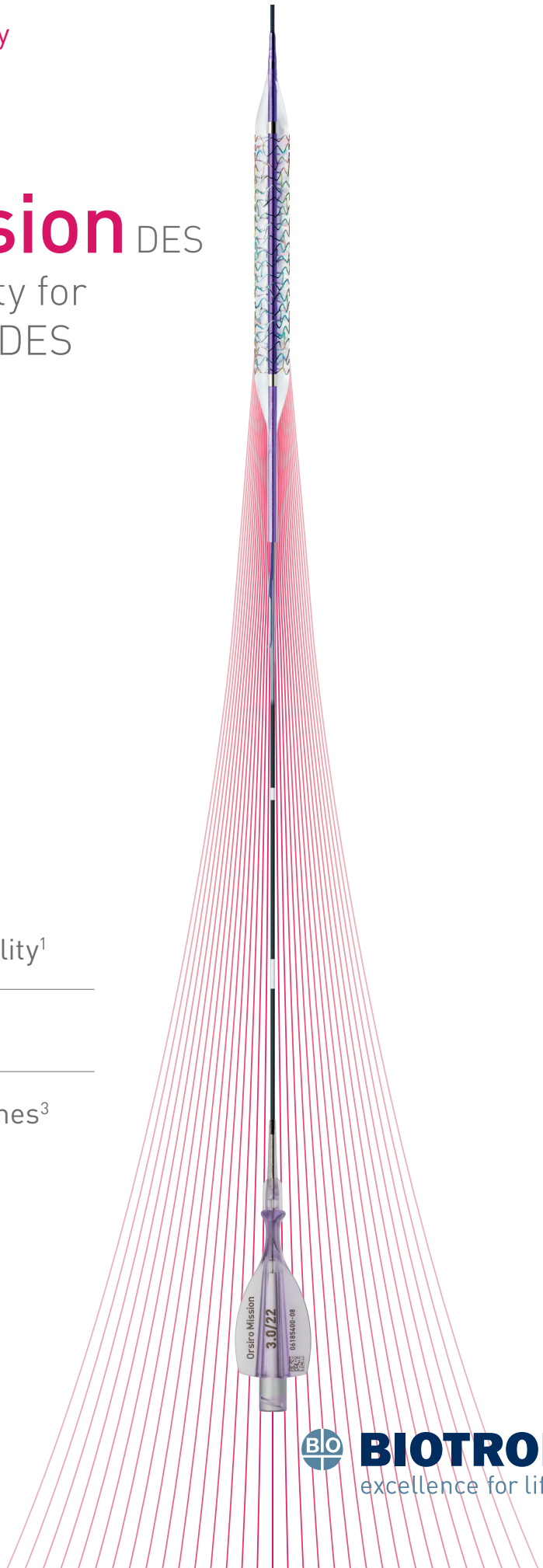
Vascular Intervention // Coronary
Drug-Eluting Stent System

Orsiro® Mission DES

Even better deliverability for the outstanding Orsiro DES

- The next level of deliverability[1]
- Ultrathin struts[2]
- Outstanding patient outcomes[3]



BIOTRONIK
excellence for life

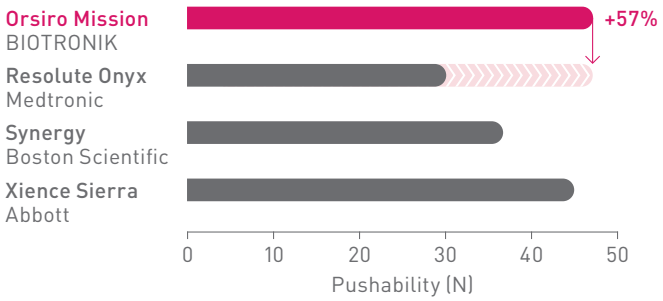
Orsiro Mission DES

Even better deliverability for the outstanding Orsiro DES

The next level of deliverability[1]

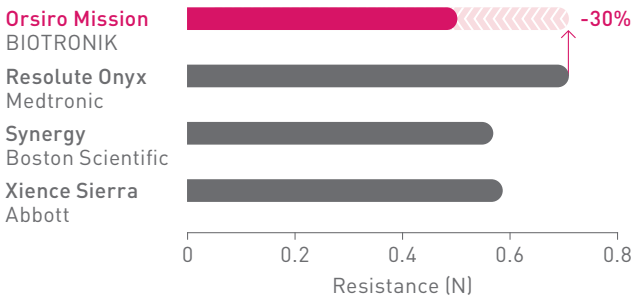
1st in Push[4]

Transmitting up to 57% more force from hub to tip.



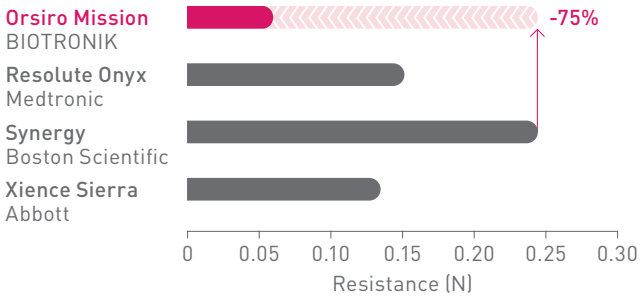
1st in Track[4]

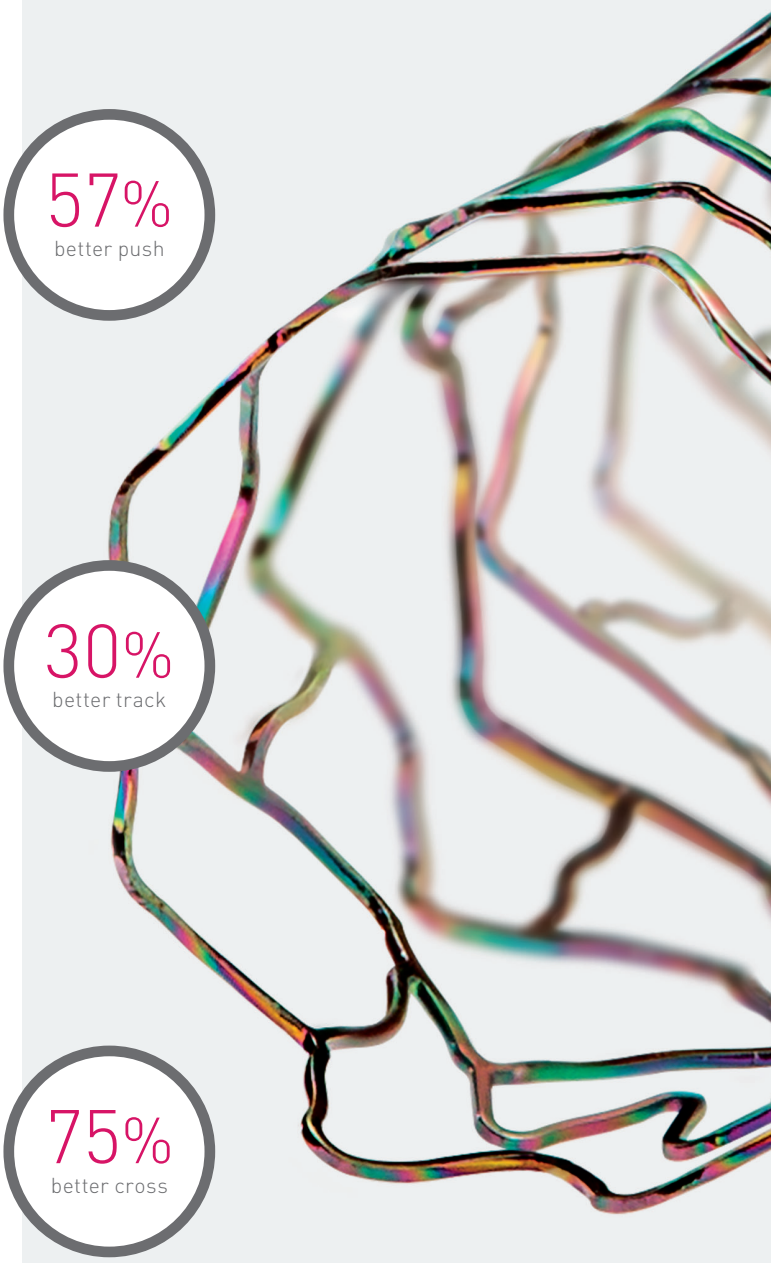
Up to 30% less force needed to follow the path to the lesion.



1st in Cross[4]

Up to 75% less force needed to successfully cross demanding anatomies.



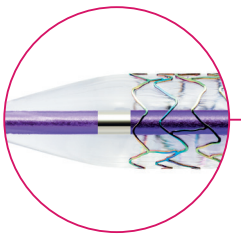


proBIO

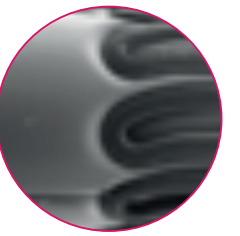
Passive coating
for high biocompatibility

BIOlute

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



NEW
More flexible shaft
for high track

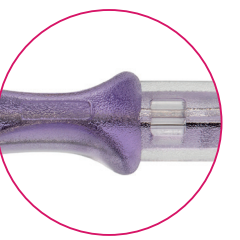


NEW
Deep embedding
for high cross

Ultrathin 60 µm* struts
for early endothelialization

Enhanced force transmission
for high push

Dual-coating
on shaft for limited friction



NEW
Ergonomic hub
with kink resistance

* ø 2.25 – 3.0 mm

Strut thickness in perspective[6]

Orsiro
BIOTRONIK
CoCr-SES
60 µm*

Synergy
Boston Scientific
PtCr-EES
74 µm

Ultimaster
Terumo
CoCr-SES
80 µm

Resolute Onyx[7,8]
Medtronic
CoNi-ZES
81 µm

Xience Family
Abbott
CoCr-EES
81 µm

Promus
Boston Scientific
PtCr-EES
81 µm

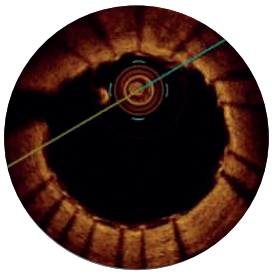
BioMatrix
Biosensors
316L-BES
120 µm

* ø 2.25 – 3.0 mm

Ultrathin struts[2]

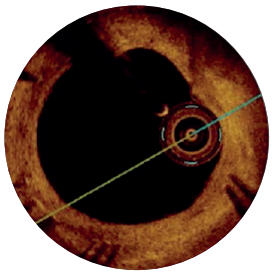
For early endothelialization

Strut coverage[9]
30 days[Δ]



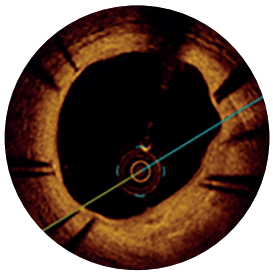
>80%
n = 589a

Strut coverage[9]
90 days[Δ]



>97%
n = 874a

Strut coverage[9]
180 days[Δ]



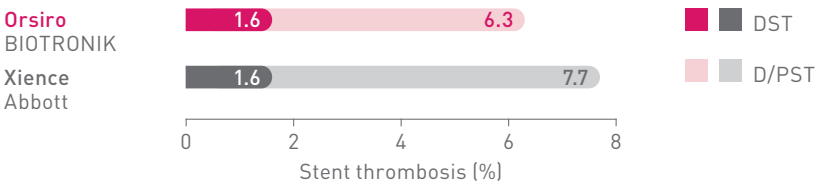
>98%
n = 1,130a

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

Long-term safety

Low definite Stent Thrombosis (ST) out to 5 years

BIOSCIENCE, all-comers RCT (n= 2,119)[10]



DST – Definite Stent Thrombosis
D/PST – Definite/Probable Stent Thrombosis

1.6%
Definite ST
at 5 years

[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.

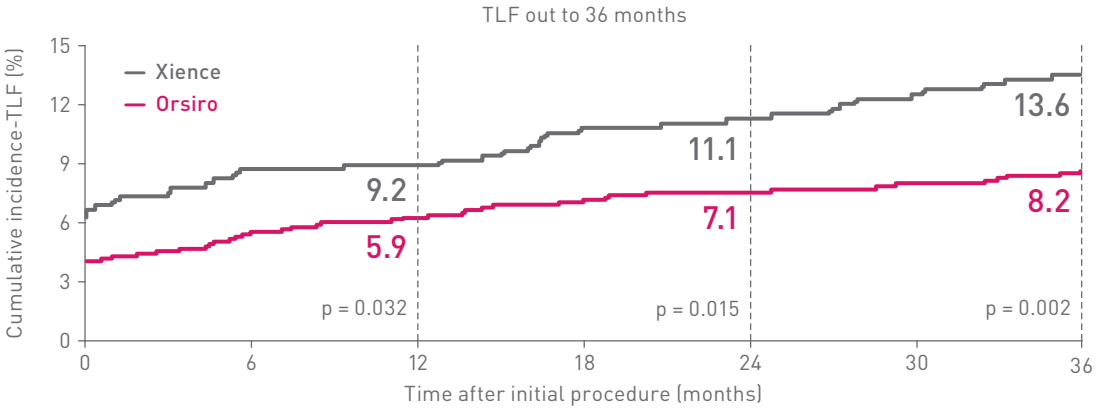
Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

Outstanding patient outcomes[3]

55,000
patients enrolled

Clinically proven Orsiro DES[11, 12, 13, 14]

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



40%
lower TLF◊ vs. Xience
(p = 0.003)

52%
lower ischemia-driven TLR◊
(p = 0.008)

Orsiro Mission is indicated for complex patients and lesions, including:*

ACS | STEMI | DM | HBR | B2C | SV | MVD

BIOSTEMI (n=1,300)

Superiority in STEMI. The first RCT demonstrating superiority between two contemporary DES.[15]
Orsiro is superior to Xience in STEMI patients undergoing primary PCI with respect to Target Lesion Failure (TLF) rate at 12 months

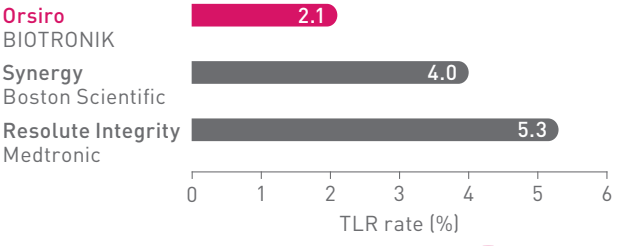
4% Orsiro | **6%** Xience

Rate Ratio (95% BCI**): 0.59, (0.37-0.94)
Posterior probability of Superiority: 98.6%
Bayesian ITT Population

41%
lower risk‡ of TLF vs. Xience

BIO-RESORT Small Vessels (n=1,506)

Target Lesion Revascularization (TLR) rate at 3 yrs.[16]



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

◊ Based on 36-m frequentist analysis.
* As per IFU: ACS – Acute Coronary Syndrome; STEMI – ST-Elevation Myocardial Infarction; DM – Diabetes Mellitus. HBR – High Bleeding Risk; B2C – Complex Lesions; SV – Small Vessels; MVD – Multi-Vessel Disease.
** BCI: Bayesian Credibility Interval.
‡ Based on a Rate Ratio 0.59.

Orsiro® Mission DES

Vascular Intervention Coronary

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

Indication

Orsiro Mission 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)	Long Lesions (LL) (e.g. ⩾ 20 mm)
ST-Elevation Myocardial Infarction (STEMI)	Small Vessels (SV) (e.g. ⩽ 2.75 mm)
Diabetes Mellitus (DM)	Multi-Vessel Disease (MVD)
Complex Lesions (B2/C)	Male/Female
High Bleeding Risk (HBR)	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	**BIO**lute bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug
Drug dose	1.4 µg/mm²

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 material
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

Storage

Use Before Date (UBD)	24 months
Temperature	Between 15°C (59°F) and 25°C (77°F), short term excursions between 10°C (50°F) and 40°C (104°F) are allowed

Ordering Information

Stent ø (mm)	Stent Length (mm) 9	13	15	18	22	26	30	35	40
2.25	419101	419107	419113	419119	419125	419131	419137	419143	419149
2.5	419102	419108	419114	419120	419126	419132	419138	419144	419150
2.75	419103	419109	419115	419121	419127	419133	419139	419145	419151
3.0	419104	419110	419116	419122	419128	419134	419140	419146	419152
3.5	419105	419111	419117	419123	419129	419135	419141	419147	419153
4.0	419106	419112	419118	419124	419130	419136	419142	419148	419154

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. Stefanini GG et al. Coronary stents: novel developments. Heart. 2014 Jul 1;100(13):1051-61; 7. Low AF. Stent platform for procedural success: Introducing the Continuous Sinusoidal & Core Wire Technologies. Presented at: AsiaPCR; 22-24 January, 2015; Singapore, Singapore; 8. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: Cardiovascular Nurse/Technologist Symposium; June 17, 2016; New York, USA; 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. 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; 11. 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 E SC 2017; 12. 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/10.1 016/j.jac c.2018. 09.019; 13. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020, doi: 10.1016/ j.jcin.2020.02.019; 14. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020. Supplemental Material; 15. 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; 16. 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; ClinicalTrials.gov: NCT01674803.

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