

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

Orsiro[®] Mission_{DES}

Even better deliverability for
the outstanding Orsiro DES



The next level of deliverability¹



Ultrathin struts²



Outstanding patient outcomes³



BIOTRONIK
excellence for life

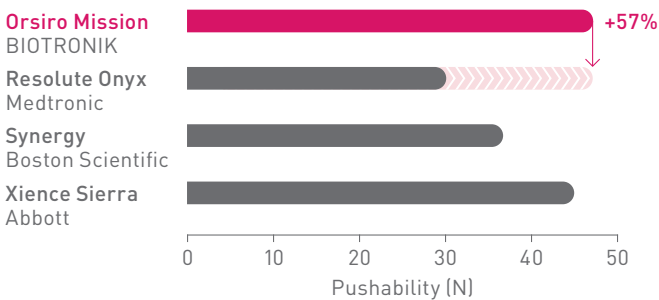
Orsiro Mission^{DES}

Even better deliverability
for the outstanding
Orsiro DES

The next level of deliverability¹

1st in Push⁴

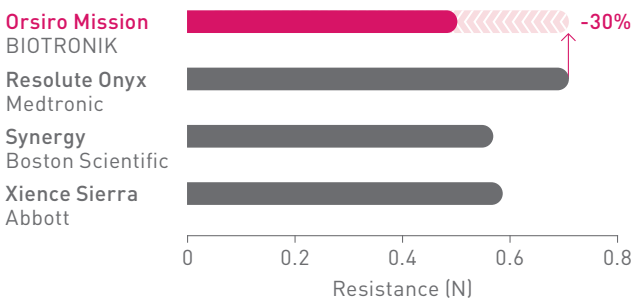
Transmitting up to 57% more force from hub to tip.



57%
better push

1st in Track⁴

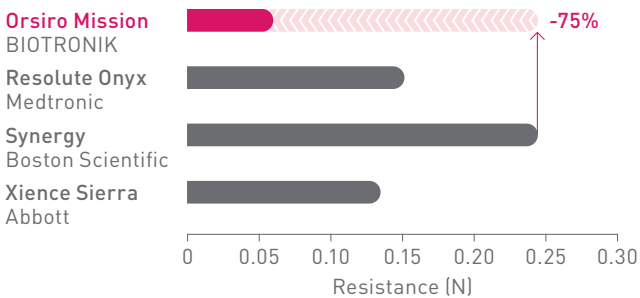
Up to 30% less force needed to follow the path to the lesion.



30%
better track

1st in Cross⁴

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



75%
better cross



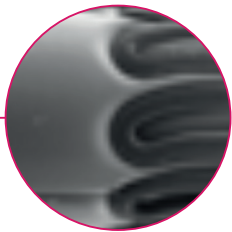


proBIO

Passive coating
for high
biocompatibility

BIOlute

Bioabsorbable
coating
with controlled
drug release and low⁵
thrombogenicity



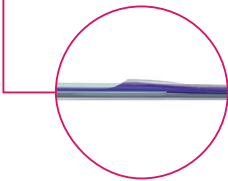
NEW
Deep embedding
for high cross



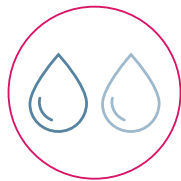
Ultrathin
60 µm* struts
for early
endothelialization



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



* ø 2.25 – 3.0 mm

Strut thickness in perspective⁶

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



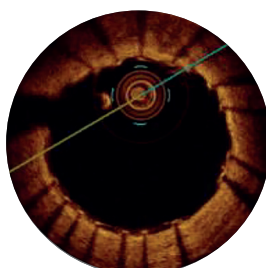
120 µm

* ø 2.25 – 3.0 mm

Ultrathin struts²

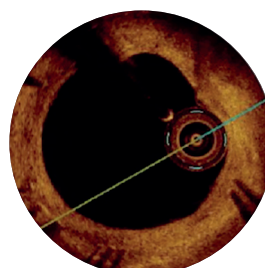
For early endothelialization

Strut coverage⁹
30 days^Δ



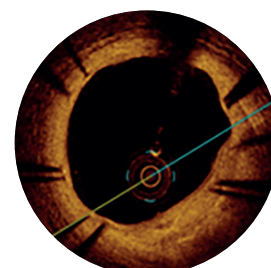
>80%
n = 589a

Strut coverage⁹
90 days^Δ



>97%
n = 874a

Strut coverage⁹
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

Orsiro
BIOTRONIK

1.6

6.3

Xience
Abbott

1.6

7.7

Stent thrombosis (%)

DST

D/PST

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.

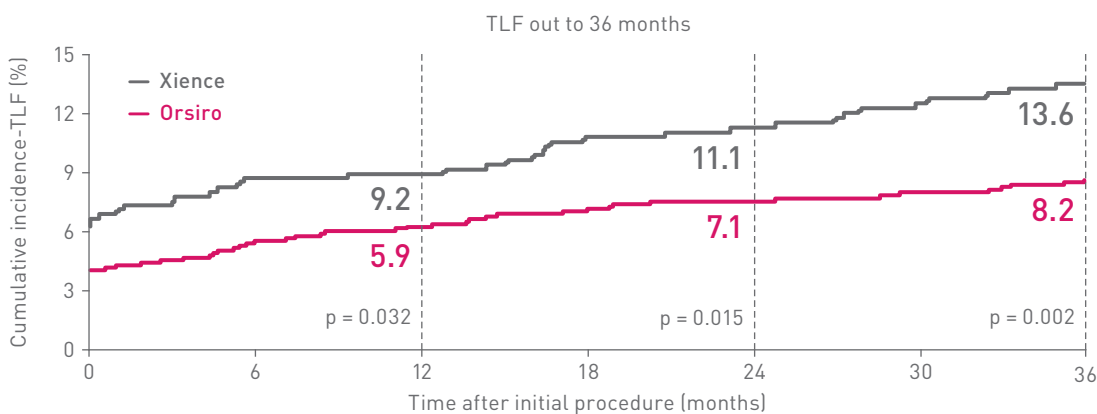
Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

Outstanding patient outcomes³

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

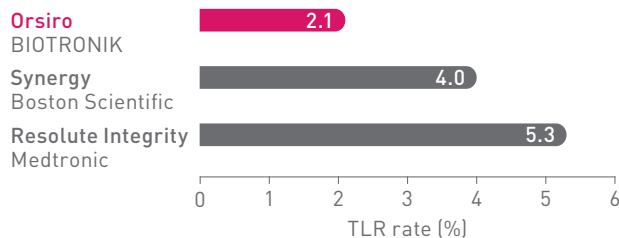
6%
Xience

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	$\varnothing$ 2.25 – 3.0 mm: 60 μ m (0.0024"); $\varnothing$ 3.50 – 4.0 mm: 80 μ m (0.0031")
Passive coating	proBIO (Amorphous Silicon Carbide)
Active coating	BIOlute bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug
Drug dose	1.4 μ g/mm ²

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: $\varnothing$ 2.25 – 3.0 mm; 2.9F: $\varnothing$ 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 $\varnothing$ (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](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 ESC 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/10.1016/j.jacc.2018.09.019>; 13. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interv. 2020. doi: 10.1016/j.jcin.2020.02.019; 14. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interv. 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 (BIOTEMI): 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. Orsiro, Orsiro Mission, proBIO and BIOlute are trademarks or registered trademarks of the BIOTRONIK Group of Companies. Synergy and Promus are trademarks or registered trademarks of the Boston Scientific group of companies. Resolute, Resolute Onyx and Integrity are trademarks or registered trademarks of the Medtronic group of companies. Xience and Xience Sierra are trademarks or registered trademarks of the Abbott group of companies. Ultimaster is a trademark or registered trademark of the Terumo group of companies. BioMatrix is a trademark or registered trademark of the Biosensors International Group.

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