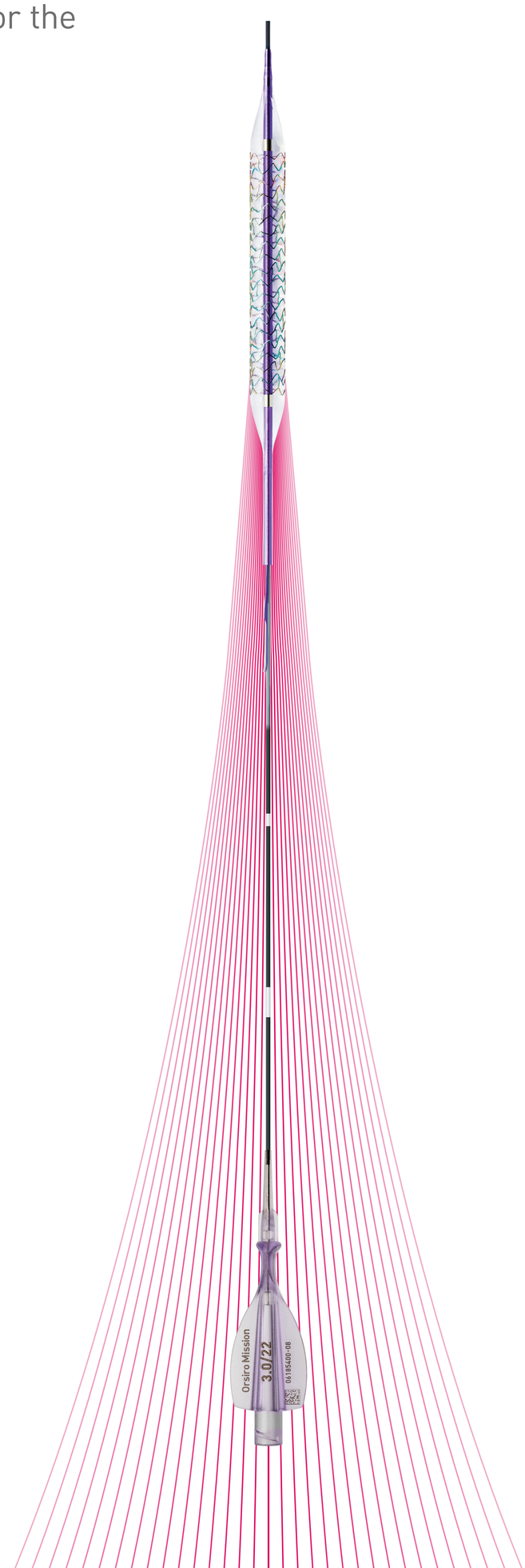
Vascular Intervention // Coronary
Drug-Eluting Stent System

BIOTRONIK
excellence for life

Orsiro® Mission DES

Even better deliverability for the outstanding Orsiro DES



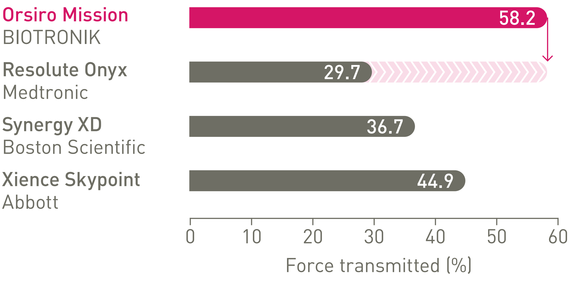
Orsiro Mission DES

Even better deliverability for the outstanding Orsiro DES

The next level of deliverability[1]

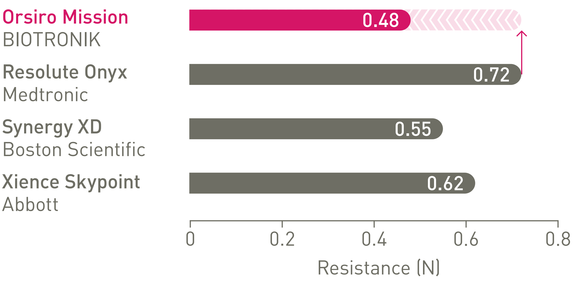
1st in Push[4]

Transmitting up to **96% more** force from hub to tip.



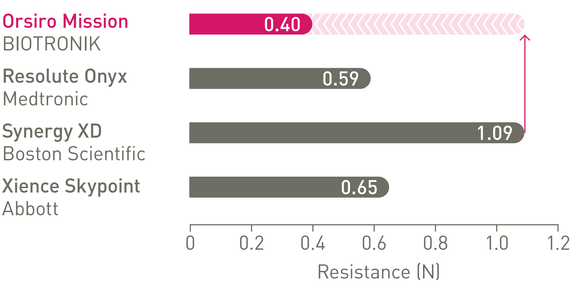
1st in Track[4]

Up to **33% less** force needed to follow the path to the lesion.



1st in Cross[4]

Up to **64% less** force needed to successfully cross demanding anatomies.

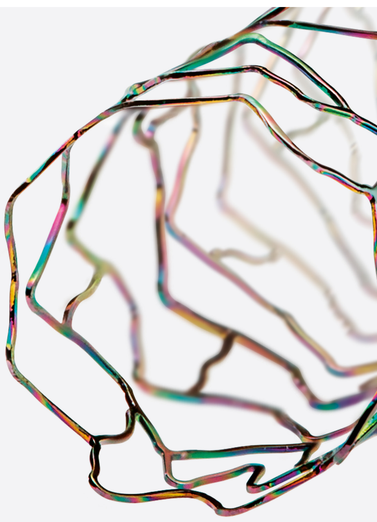


Proven deliverability on the bench and in a **real-world** user evaluation of over 1,000 implantations[5]:

98%
Proven very good / good pushability

97%
Proven very good / good trackability

97%
Proven very good / good crossability



"Lesion crossing with low friction, reliable performance"

Dr. Mathias Brandt,
Paracelsus Medical University,
Salzburg, Austria

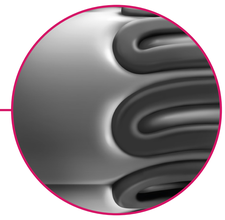
proBIO®

Passive coating
for high biocompatibility

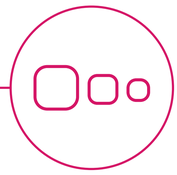
BIOlute®

Bioabsorbable coating
with controlled drug release and low thrombogenicity[6]

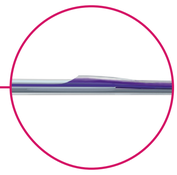
NEW
More flexible shaft
for high track



NEW
Deep embedding
for high cross



Ultrathin 60 µm[b] struts
for early endothelialization



Enhanced force transmission
for high push

Dual-coating
on shaft for limited friction

NEW
Ergonomic hub
with kink resistance

[b] ø 2.25 – 3.0 mm

Ultrathin struts[2]

For early endothelialization

Strut thickness in perspective[7]

Orsiro
BIOTRONIK
CoCr-SES
60 µm[b]

Synergy XD
Boston Scientific
PtCr-EES
74 µm

Ultimaster
Terumo
CoCr-SES
80 µm

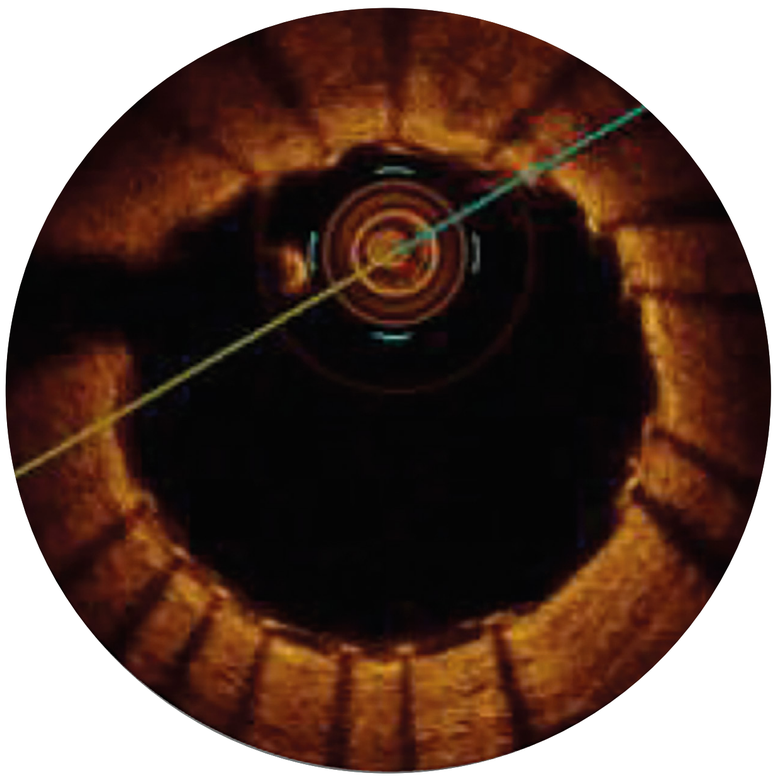
Resolute Onyx[8,9]
Medtronic
CoNi-ZES
81 µm

Xience Family
Abbott
CoCr-EES
81 µm

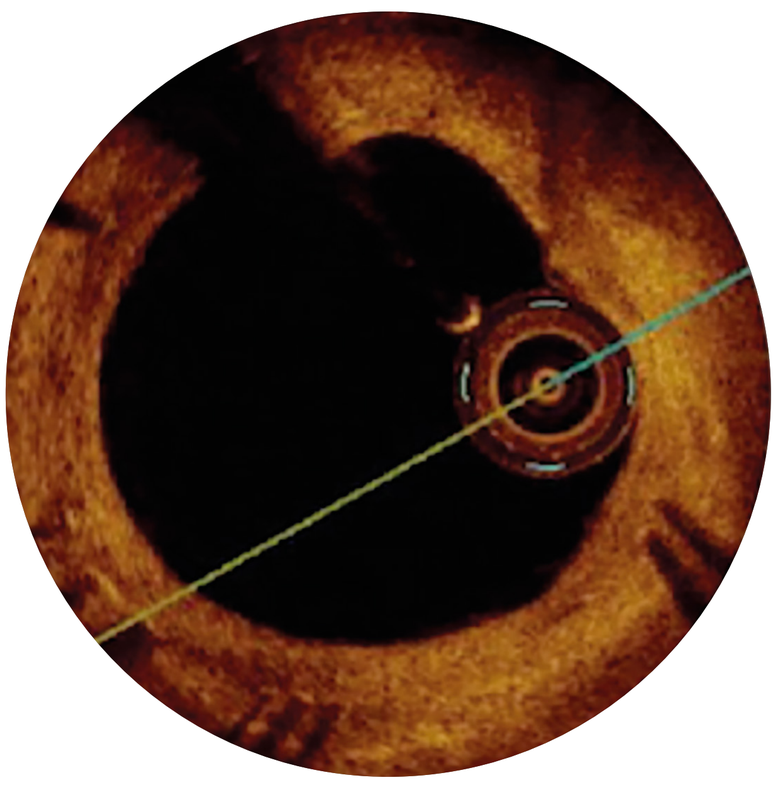
Promus
Boston Scientific
PtCr-EES
81 µm

BioMatrix
Biosensors
316L-BES
120 µm

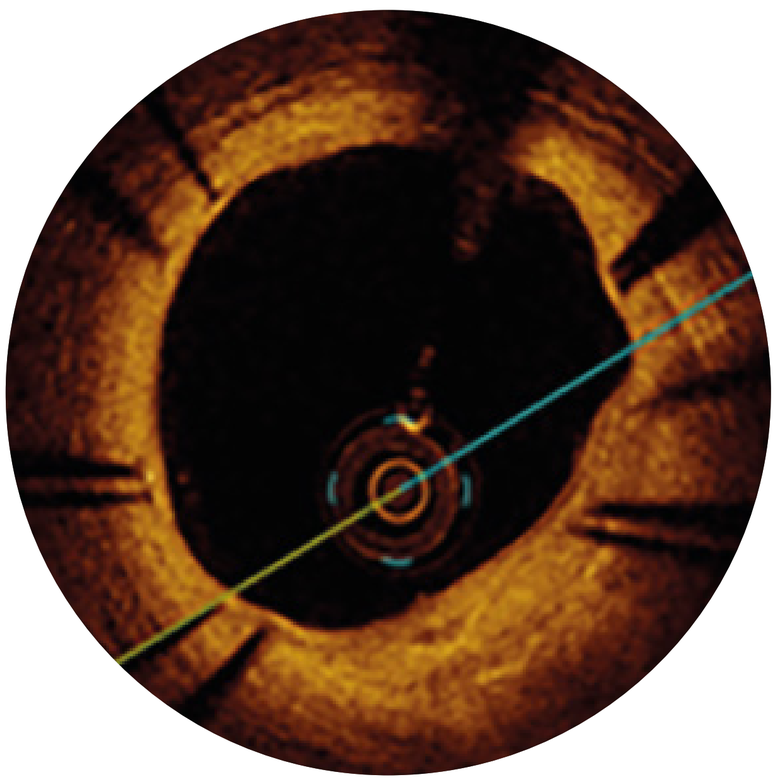
[b] ø 2.25 – 3.0 mm



Strut coverage[10]
30 days[c]
>80%
n = 589



Strut coverage[10]
90 days[c]
>97%
n = 874



Strut coverage[10]
180 days[c]
>98%
n = 1,130

Immature tissue coverage

HEALING PROGRESS

Tissue maturation and full coverage

n = number of struts analyzed

[c] 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.

Outstanding patient outcomes[3,a]

Orsiro – One of the most studied DES[11,a]

>55,000 patients enrolled[12]

>71,500 patients enrolled or planned in total[12]

>68 studies started[12]

Orsiro – the highest probability (70.8%) to rank as the best stent[a,d]

Taglieri et al. network meta-analysis (n = 99,039 patients, 77 RCTs)[13]

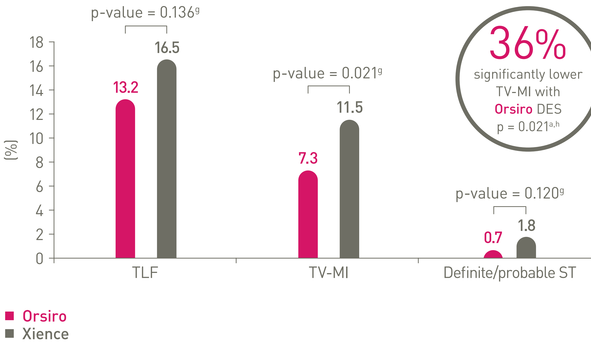
TLF at 1 year – Orsiro vs.	Odds Ratio (95% CI)
Xience	**0.84 (0.71 - 0.98)**
Resolute[e]	**0.81 (0.68 - 0.95)**
Promus	0.86 (0.68 - 1.10)
Synergy	0.89 (0.69 - 1.15)
Cre8	0.67 (0.43 - 1.05)
Biofreedom	**0.79 (0.63 - 0.99)**
Nobori/BioMatrix	**0.81 (0.67 - 0.98)**

"If we want to inform our clinical practice on the best evidence available, we have to acknowledge that at 1-year the best stent, is the Orsiro stent."

Dr. Tullio Palmerini,
Policlinico S. Orsola, Malpighi,
Bologna, Italy

Pushing the boundaries of safety performance with Orsiro[a,f]

BIOFLOW-V (n = 1,334), 5-Year results of the FDA pivotal trial[14]



■ Orsiro
■ Xience

Orsiro Mission DES is indicated for complex patients and lesions[a,i]

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

Continued Superiority in STEMI at 2 years[15,a,j]

BIOSTEMI (n = 1,300)

5.1% Orsiro

8.1% Xience

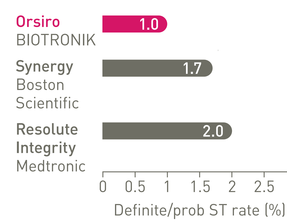
Target Lesion Failure (TLF) rate at 2 years.

Rate Ratio (95% BCI[k]): 0.58 (0.40-0.84)
Posterior probability of Superiority: 99.8%
Bayesian ITT Population[l]

42% lower risk of TLF with Orsiro[a,m]

Low stent thrombosis (ST) at 5 years[16,a]

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



50% lower ST with Orsiro p = 0.22[a,n]

[a] Clinical data collected with the Orsiro DES device within the Orsiro family clinical program; [d] Based on 1-year TLF SUCRA score, in comparison to Xience, Resolute and Nobori/BioMatrix, after a median follow-up period of 50 months; [e] Resolute Integrity and Resolute Onyx; [f] In comparison to Xience, based on statistically significant lower TV-MI and late/very late definite/probable ST rates from the BIOFLOW-V trial through 5 years; [g] p-values for 60-month frequentist analysis; [h] In comparison to Xience, based on BIOFLOW-V 5-year results; [i] 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; [j] In comparison to Xience, based on TLF, in the BIOSTEMI trial at 2 years; [k] BCI: Bayesian Credibility Interval; [l] n= 1,300 newly enrolled STEMI patients including 407 patients from the BIOSCIENCE STEMI subgroup used as prior information; [m] In comparison to Xience, based on a Rate Ratio of 0.58, in the BIOSTEMI trial at 2 years; [n] In comparison to Resolute Integrity, based on 5-year results of the BIO-Resort trial SV subgroup.

Orsiro® Mission DES

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.

Vascular Intervention Coronary

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	BIOlute® 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. Evaluation of Market Acceptance, BIOTRONIK data on file; 6. Per investigators' interpretation of preclinical studies with Orsiro as mentioned in Cassese et al. J Thorac Dis 2018;10(2):688-692; 7. Stefanini GG et al. Coronary stents: novel developments. Heart. 2014 Jul 1;100(13):1051-61; 8. Low AF. Stent platform for procedural success: Introducing the Continuous Sinusoidal & Core Wire Technologies. Presented at: AsiaPCR; 22-24 January, 2015; Singapore, Singapore; 9. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: Cardiovascular Nurse/Technologist Symposium; June 17, 2016; New York, USA; 10. 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; 11.Based on Taglieri et al. Meta-analysis, against currently used DES; 12. Including Orsiro DES and Orsiro Mission DES, BIOTRONIK data on file, as of January 2020; 13. 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; 14. Kandzari D et al. Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents versus Thin Durable Polymer Everolimus-Eluting Stents for Coronary Revascularization: Final 5-year Outcomes from the Randomized BIOFLOW V Trial, Submitted manuscript to JACC, 2022: NCT02389946; 15. Pilgrim et al. Biodegradable – versus durable-polymer drug-eluting stents for STEMI. Final 2-year outcomes of the BIOSTEMI trial. J Am Coll Cardiol. Cardiovasc Interven. 2021, doi: 10.1016/j.jcin.2020.12.011; 16. Ploumen etal. BIO-RESORT Small Vessels 5Y-EuroPCR2022.

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