Vascular Intervention // Coronary
Drug-Eluting Stent System

Synsiro® Pro DES

The Next Level of Deliverability.
Proven Clinical Performance.[Δ]

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

BIOTRONIK
excellence for life

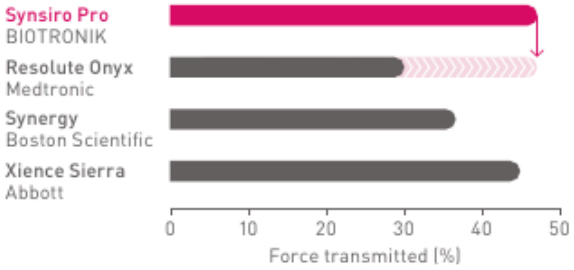
Synsiro Pro DES

The Next Level of Deliverability.
Proven Clinical Performance.[Δ]

The next level of deliverability[1]

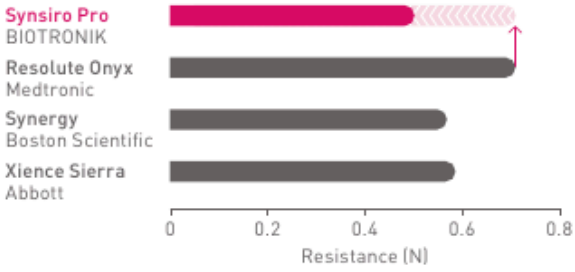
1st in Push[4]

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



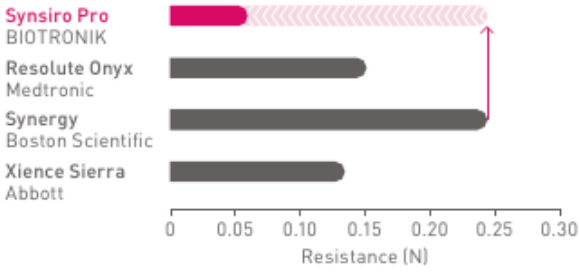
1st in Track[4]

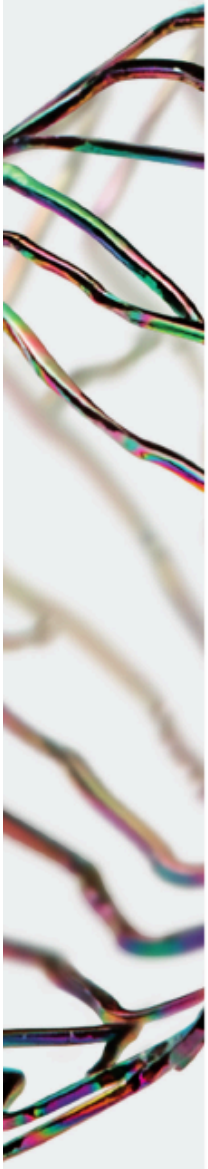
Up to **30% less** force needed to follow the path to the lesion.



1st in Cross[4]

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





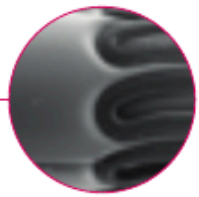
proBIO

Passive coating
for high biocompatibility

BIOlute

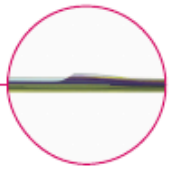
Bioabsorbable coating
with controlled drug release and low[5] thrombogenicity

NEW
More flexible shaft
for high track



NEW
Deep embedding
for high cross

Ultrathin 60 µm* struts
for early endothelialization

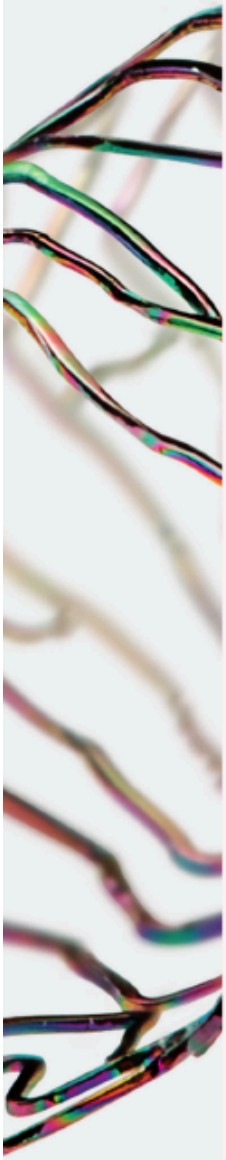


Enhanced force transmission
for high push

Dual-coating
on shaft for limited friction

NEW
Ergonomic hub
with kink resistance

* ø 2.25 – 3.0 mm



Strut thickness in perspective[6]

Synsiro Pro
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

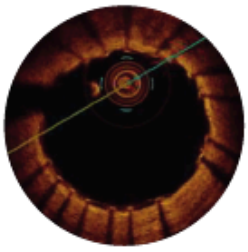
BioMatrix
Biosensors
316L-BES
120 µm

* ø 2.25 – 3.0 mm

Ultrathin struts[2]

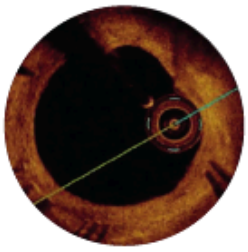
For early endothelialization

Strut coverage[9]
30 days*



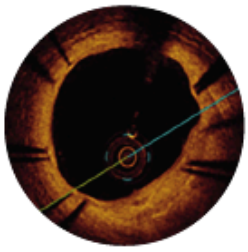
>80%
n = 589a

Strut coverage[9]
90 days*



>97%
n = 874a

Strut coverage[9]
180 days*



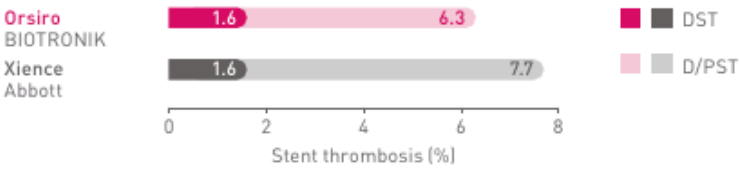
>98%
n = 1,130a

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

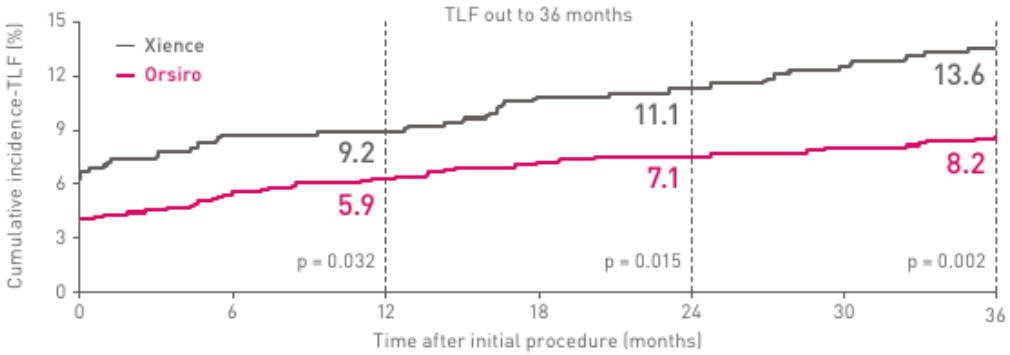
*Images: Secco G et al. Time-related changes in neointimal tissue coverage following a new generation SES implantation: an OCT observational study. Presented at: euro PCR, May 20, 2014; Paris, France.

Outstanding patient outcomes[3]

One of the most studied DES§

More than 55,000 patients enrolled and more than 68 Studies started♦

BIOFLOW-V, FDA pivotal trial (n = 1,334)[11, 12, 13, 14]



40% lower TLF° vs. Xience (p = 0.003)

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

Synsiro Pro DES is indicated for complex patients and lesions, including:*

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

BIOSTEMI (n=1,300)

Continued Superiority in STEMI at 2 years.¶[15]

5.1% Orsiro | **8.1%** Xience

Target Lesion Failure (TLF) rate at 2 years.

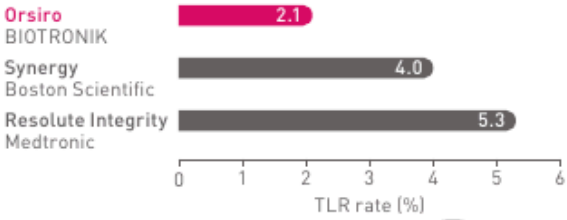
Rate Ratio (95% BCI**): 0.58 (0.40-0.84)
Posterior probability of Superiority: 99.8%

Bayesian ITT Population°

42% lower risk of TLF‡ vs. Xience

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

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



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

§ in large RCTs, based on Taglieri et al. Meta-analysis, against currently used DES
♦ BIOTRONIK data on file, status January 2020
¶ vs. Xience, based on TLF, in the BIOSTEMI trial
° p-values for 36-m frequentist analysis (see supplemental material).
* 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.
° n= 1,300 newly enrolled STEMI patients including 407 patients from the BIOSCIENCE STEMI subgroup used as prior information.
‡ Based on a Rate Ratio of 0.58.

Synsiro® Pro DES

Vascular Intervention Coronary

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

Indication

Synsiro Pro DES 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	**pro**BIO (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
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	419155	419161	419167	419173	419179	419185	419191	419197	419203
2.5	419156	419162	419168	419174	419180	419186	419192	419198	419204
2.75	419157	419163	419169	419175	419181	419187	419193	419199	419205
3.0	419158	419164	419170	419176	419182	419188	419194	419200	419206
3.5	419159	419165	419171	419177	419183	419189	419195	419201	419207
4.0	419160	419166	419172	419178	419184	419190	419196	419202	419208

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. 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. 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, Synsiro, **pro**BIO and **BIO**lute 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.

Δ Clinical data collected with Orsiro and Orsiro Mission bench performance testing can be used to illustrate Synsiro Pro clinical safety and performance.

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