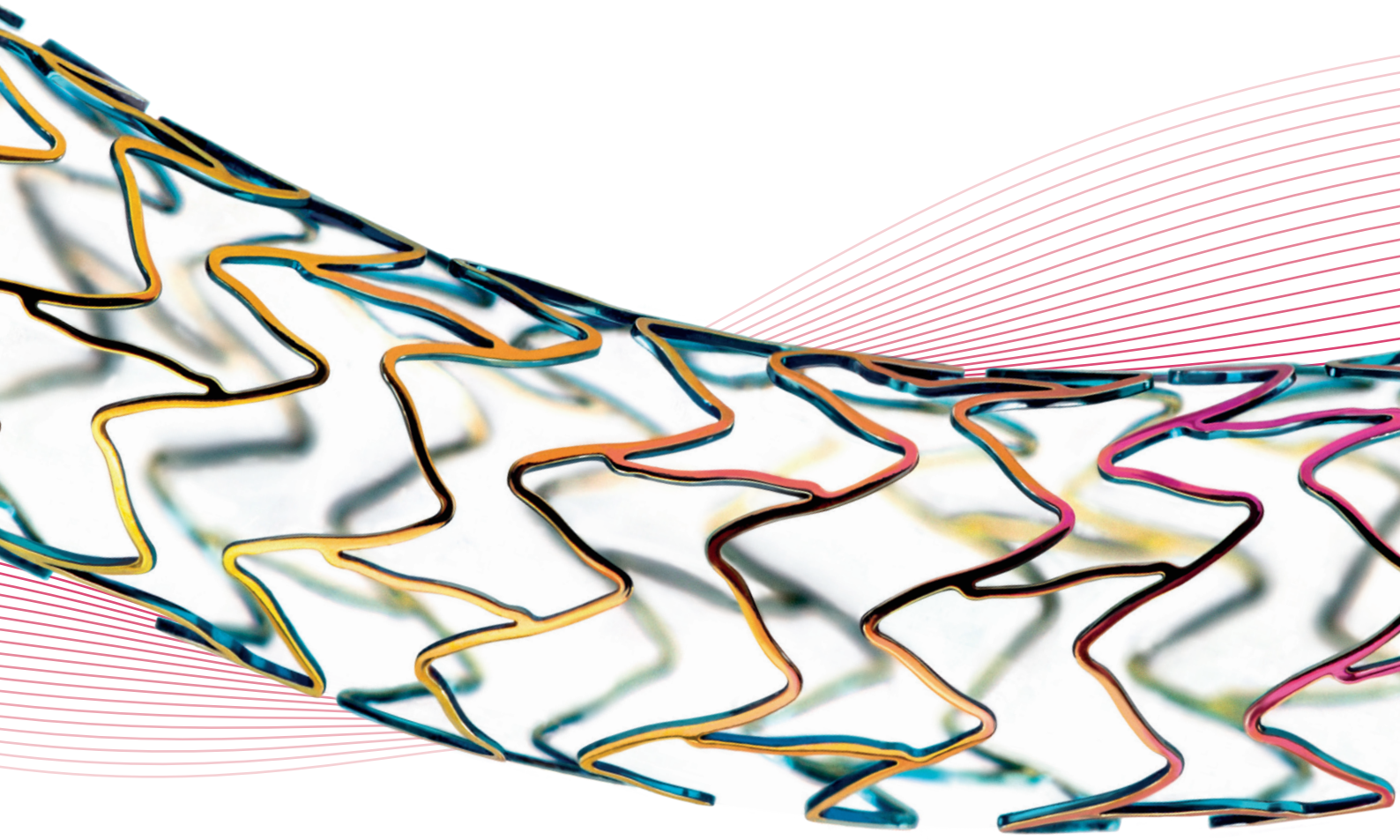
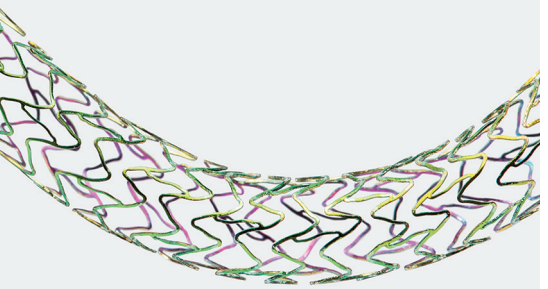
Vascular Intervention // Coronary
Drug-Eluting Stent System

Orsiro



- Clinically proven
- Highly deliverable
- Ultrathin 60 µm struts

BIOTRONIK
excellence for life

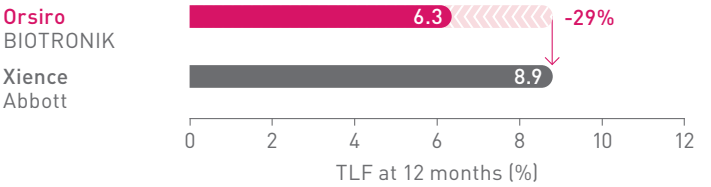


The new benchmark for DES

BIOFLOW-V 12-month clinical outcomes compared to Xience

In a post-hoc analysis of pooled patient-level data from three RCTs, Orsiro achieved a 96.9% probability of superiority* on TLF rate versus Xience.[10]

BIOFLOW-V / -IV / -II Bayesian Population (n=2,208)

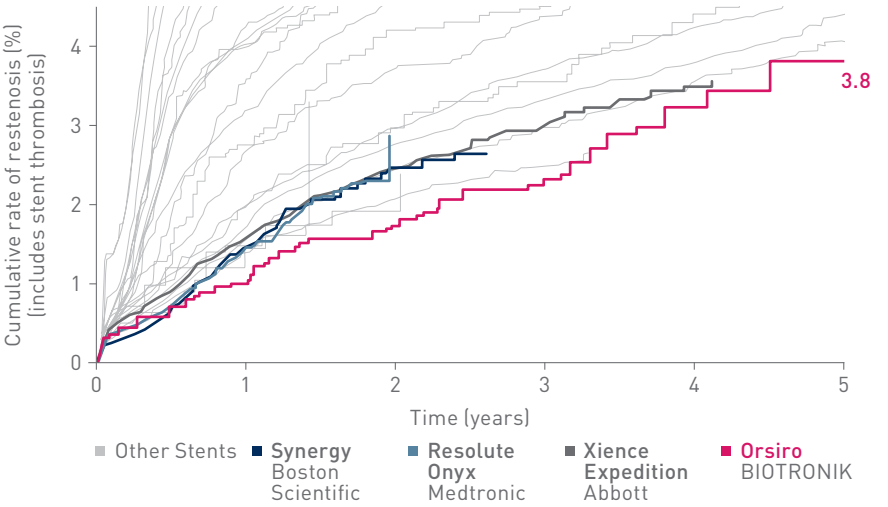


*Posterior probability, Bayesian analytical methods were applied

Proven long term clinical outcomes

All stents implanted from 2007 until January 11, 2017 unadjusted (SCAAR)[11,12]

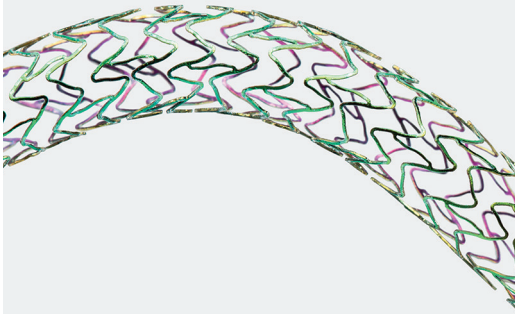
Orsiro showed a lower restenosis rate than all DES out to five years.



3.8%
restenosis rate at five years

Orsiro

Clinically proven, highly deliverable with ultrathin 60 µm* struts.



Clinically proven

Extensive clinical program**

>32,500 patients enrolled
>50,500 patients planned in total

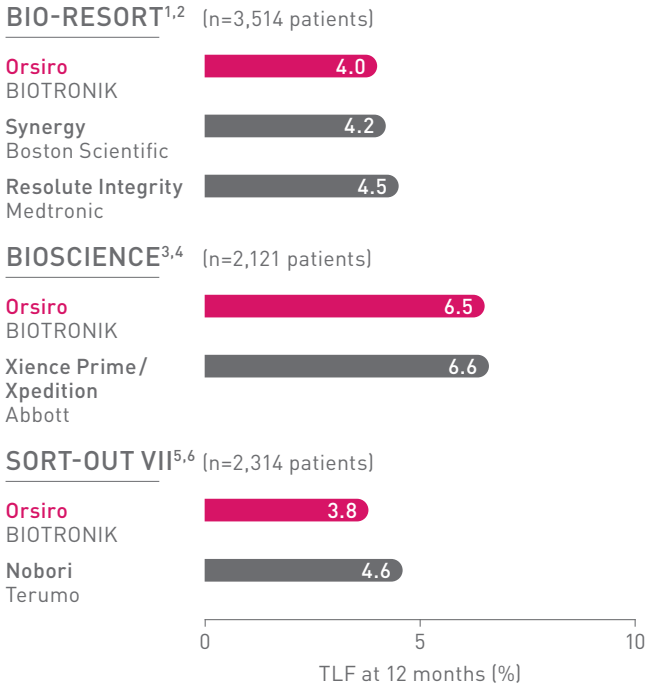
>44 studies ongoing
>55 studies planned in total

**status as of Feb 2017

>50,500
patients planned
in total

Outstanding clinical results even in challenging subgroups

Orsiro has demonstrated consistently low target lesion failure (TLF) in all-comers trials compared to major modern drug-eluting stents (DES).

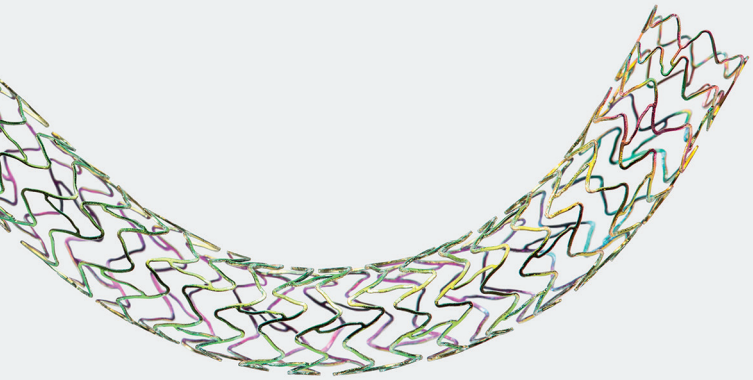


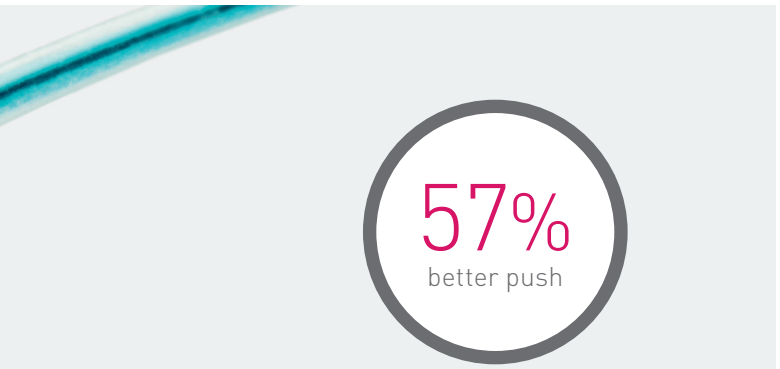
0.0%
ST[8] at 5 years
BIOFLOW-II[9]

STEMI	Diabetics	Small vessels
5.4%	0.0%	0.0%
10.8% Xience TLF[4] 24 months BIOSCIENCE[7]	ST[8] 60 months BIOFLOW-II[9]	ST[8] 60 months BIOFLOW-II[9]

ST - Stent Thrombosis

*ø 2.25 – 3.0 mm





57%
better push

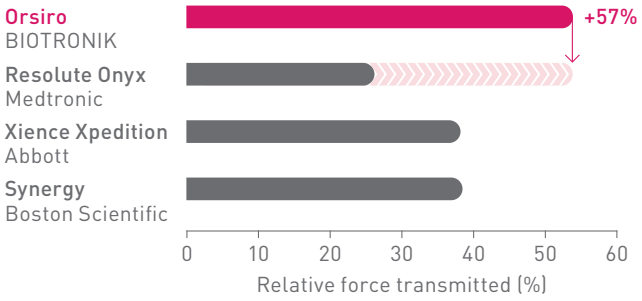
13%
lower crossing profile

Highly deliverable

Designed for challenging cases, the Orsiro stent system provides better push and easier cross with a lower crossing profile.

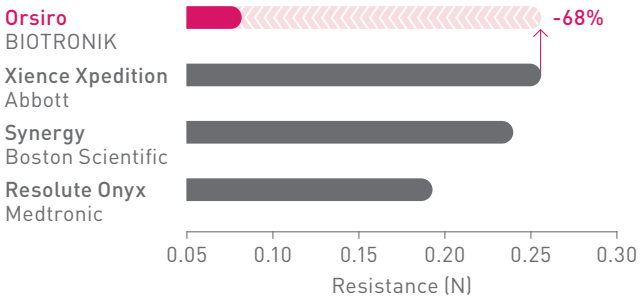
Better push

Transmitting up to 57%[13] more force from hub to tip.[14]



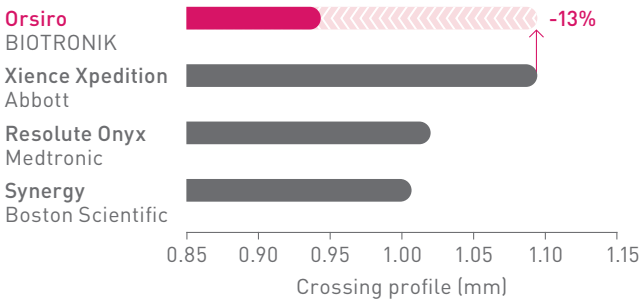
Easier cross

Up to 68% less force[15,16] needed to successfully cross demanding anatomies.



Lower crossing profile

Improved acute performance - up to 13% lower crossing profile.[15]



Strut thickness in perspective[17]

Orsiro
BIOTRONIK
CoCr-SES
60 µm*

Synergy
Boston Scientific
PtCr-EES
74 µm

Ultimaster
Terumo
CoCr-SES
80 µm

Resolute Onyx
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 60 µm struts

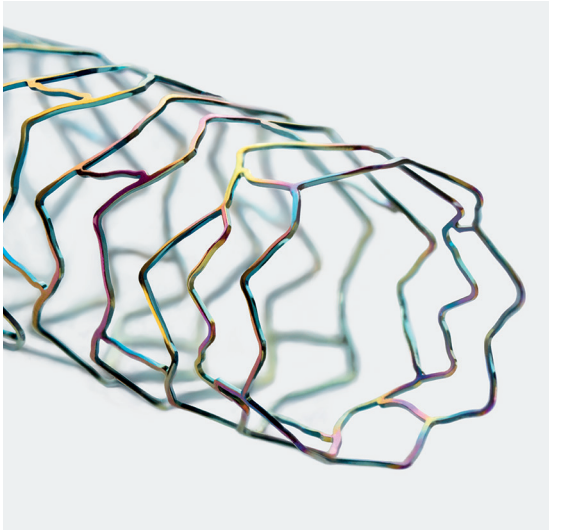
Thinner struts make the difference

Thinner struts create:

- **Less disrupted flow[18]**
- **Less arterial injury[18]**

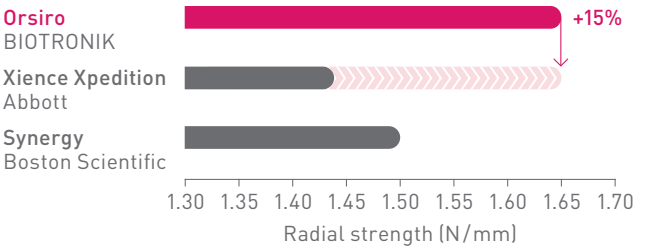
Which leads to:

- **Improved re-endothelialization[18]**
- **Reduced risk of restenosis and thrombosis[18]**



The thinner the better, as long as the radial force can be maintained[18]

Up to 15% more radial strength[19,20] for stronger scaffolding once implanted.



15%
more radial strength

Orsiro

Indicated for discrete de novo stenotic lesions and in-stent restenotic lesions.*

Vascular Intervention Coronary

Technical Data

Stent	
Stent material	Cobalt chromium, L-605
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
Strut thickness	ø 2.25 - 3.0 mm: 60 µm (0.0024"); ø 3.50 - 4.0 mm: 80 µm (0.0031")

Delivery system	
Catheter type	Rapid exchange
Recommended guide catheter	5F (min. I.D. 0.056")
Lesion entry profile	0.017"
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi crystalline polymer material
Coating (distal shaft)	Hydrophilic coating
Marker bands	Two swaged platinum-iridium markers
Proximal shaft diameter	2.0F
Distal shaft diameter	2.6F: ø 2.25 - 3.5 mm; 2.8F: ø 4.0 mm
Nominal pressure (NP)	8 atm
Rated burst pressure (RBP)	16 atm

Compliance Chart

Balloon diameter x length (mm)		ø 2.25 x 9-40	ø 2.50 × 9-40	ø 2.75 × 9-40	ø 3.00 × 9-40	ø 3.50 × 9-40	ø 4.00 × 9-40
Nominal Pressure (NP)	atm**	8	8	8	8	8	8
	ø (mm)	2.25	2.50	2.75	3.00	3.50	4.00
Rated Burst Pressure (RBP)	atm**	16	16	16	16	16	16
	ø (mm)	2.50	2.77	3.05	3.33	3.88	4.44

**1 atm = 1.013 bar

Ordering Information

Stent ø (mm)	Catheter length 140 cm Stent length (mm)								
	9	13	15	18	22	26	30	35	40
2.25	364469	364475	364481	364487	364499	364505	364511	391234	391238
2.50	364470	364476	364482	364488	364500	364506	364512	391235	391239
2.75	364471	364477	364483	364489	364501	364507	364513	391236	391240
3.00	364472	364478	364484	364490	364502	364508	364514	391237	391241
3.50	364473	364479	364485	364491	364503	364509	364515	391018	391020
4.00	364474	364480	364486	364492	364504	364510	364516	391019	391021

1. von Birgelen et al. Very thin strut biodegradable polymer everolimus-eluting stents versus durable polymer zotarolimus-eluting stents in all-comers with coronary artery disease (BIO-RESORT): a three-arm, randomised, non-inferiority trial. The Lancet 2016. 10.1016.S0140-6736(16)31920-1 and presentation at TCT 2016; 2. TLF as a composite of cardiac death, target vessel-related myocardial infarction, or clinically indicated target lesion revascularization; 3. Pilgrim et al. Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularization (BIOSCIENCE): a randomised, single-blind, non-inferiority trial. The Lancet 2014.10.1016/S0140-6736(14)61038-2; 4. TLF as a composite of cardiac death, target vessel myocardial infarction, and clinically indicated target lesion revascularization; 5. Jensen et al. Randomized comparison of a sirolimus-eluting Orsiro stent with a biolimus-eluting Nobori stent in patients treated with percutaneous coronary intervention: Rationale and study design of the Scandinavian Organization of Randomized Trials with Clinical Outcome VII trial. 10.1016/j.ahj.2015.05.009; 6. Target Lesion Failure as a composite of cardiac death, myocardial infarction (not related to other than index lesion), or taret lesion revascularization; 7. Piccolo R. Biodegradable polymer Sirolimus-eluting stents vs. Durable polymer Everolimus- eluting stents in patients with STEMI: Two-year follow-up of the BIOSCIENCE oral presentation, EuroPCR 2016; 8. Definite or probable stent thrombosis per ARC definition; 9. Preliminary analysis based on non locked data – Ton Slagboom, poster presentation, presented at TCT, November 2016; 10. Kandzari et al. Ultrathin Bioresobable Polymer Sirolimus-Eluting Stents versus thin durable Polymer Everolimus-eluting stents in patients Undergoing Coronary Revascularization (BIOFLOW-V): a randomized trial, The Lancet 2017; 11. Adapted from SCAAR data (January 11, 2017) http://www.ucr.uu.se/swedeheart/99-scaar/forskning-scaar; 12. Compared to other DES included in SCAAR at five years; 13. Compared to Resolute Onyx; 14. The stent system is advanced through a model, to a point of blockage (simulating a total occlusion). The force at the proximal hub and the blockage is measured. Pushability is the force transmitted along the length of the catheter. IIB(P)31/2015 – IIB(P)85/2014-2; 15(16). Compared to Xience Xpedition; 16. The stent system is advanced through a stenosis model. Crossability is the mean resistance (mean force) registered by the stenosis during the complete passage of the stent delivery system. IIB(P)31/2015 – IIB(P)85/2014-2; 17. Stefanini GG, Taniwaki M, Windecker S. Coronary stents: novel development, Heart doi:10.1136/heartjnl-2012-303522; 18. Foin et al. Impact of stent strut design in metallic stents and biodegradable scaffolds. Int J Cardiol.2014 Dec 20;177(3):800-8; 19. Compared to Xience Expedition; 20. Expanded 3.0 mm diameter stents are radially compressed (15% of ø) along full length. The force required to compress the stent is radial strength. BIOTRONIK data on file.

*Indication as per IFU.

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380085/G/Apr_2018