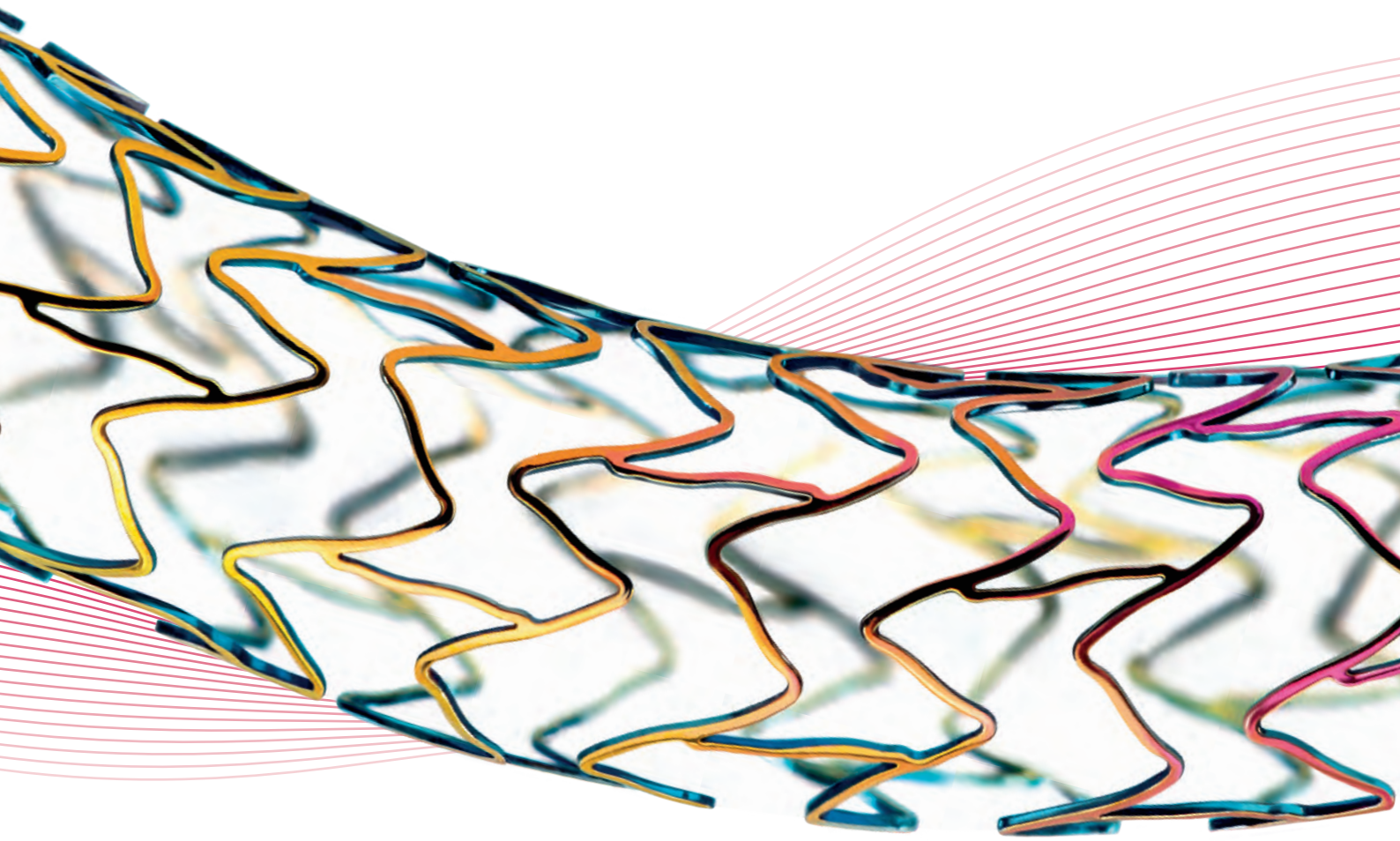
Vascular Intervention // Coronary
Drug-Eluting Stent System

# Orsiro



- Clinically proven
- Highly deliverable
- Ultrathin 60 µm struts

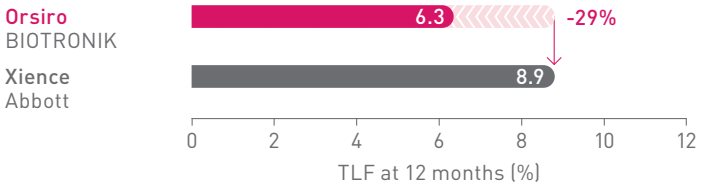
BIOTRONIK
excellence for life

## The new benchmark for DES

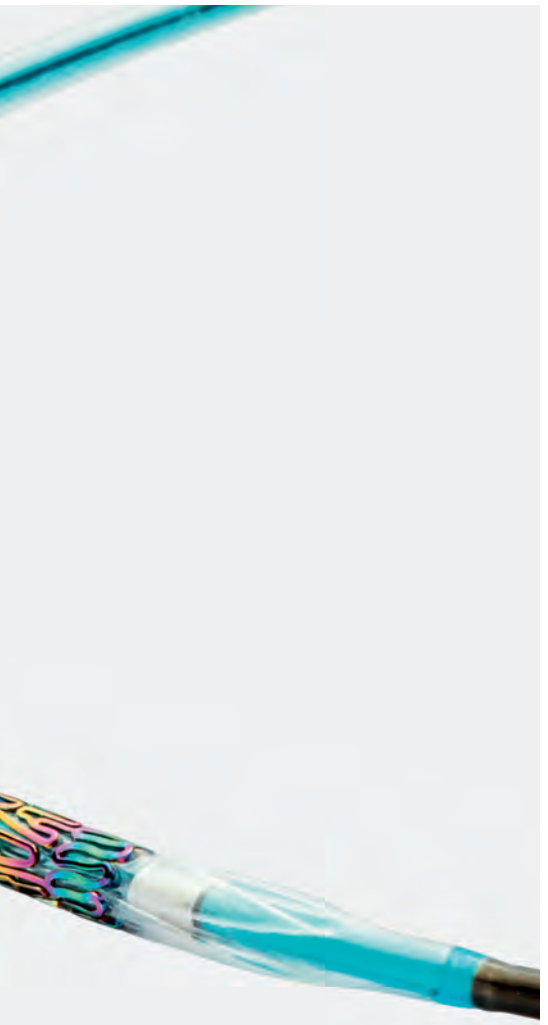
### BIOFLOW-V 12-month clinical outcomes compared to Xience

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)



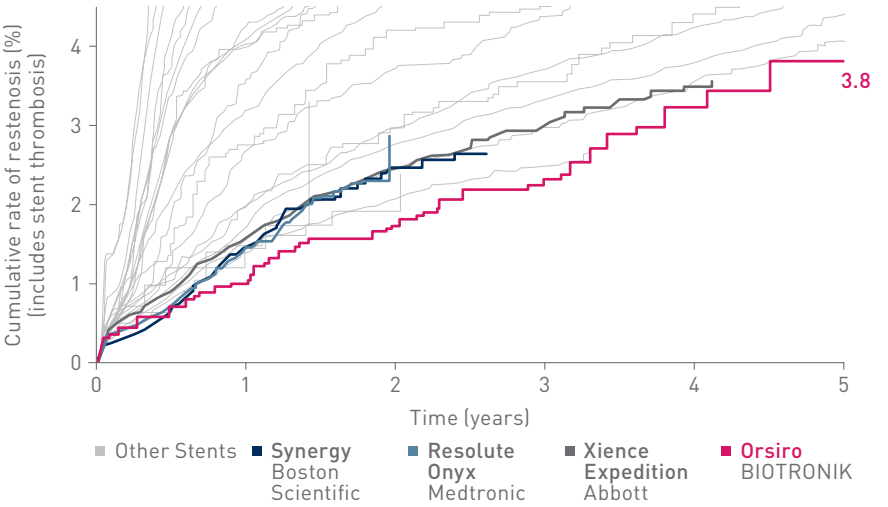

*Posterior probability, Bayesian analytical methods were applied



## Proven long term clinical outcomes

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

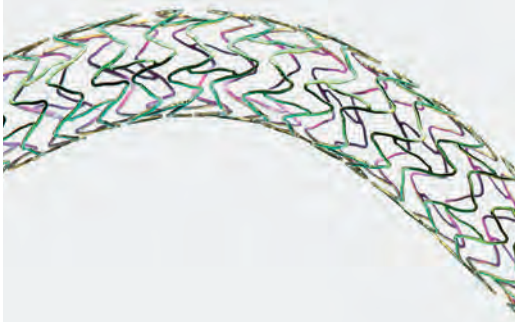
Orsiro showed a lower restenosis rate than all DES out to five years.




**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

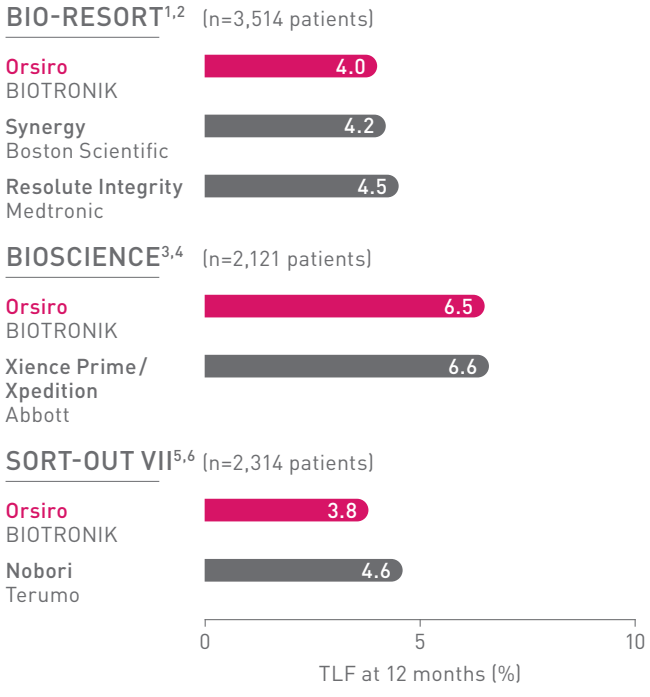
**>44** studies ongoing
**>55** studies planned in total

**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).

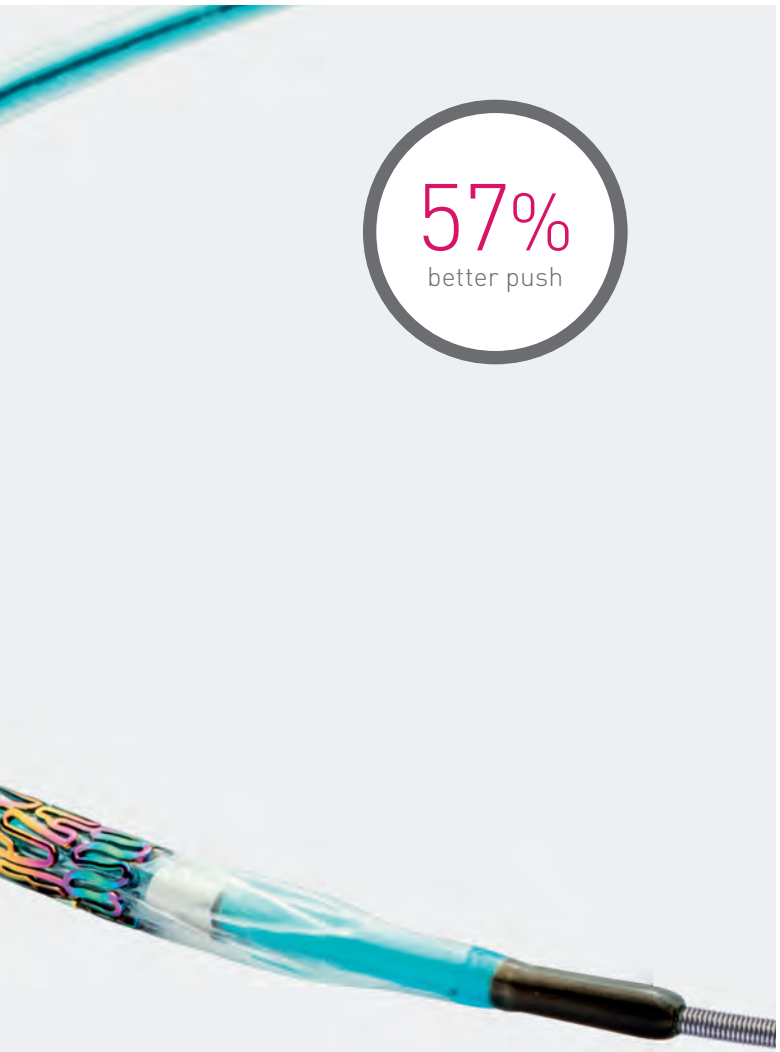



0.0%
ST[8] at 5 years
BIOFLOW-II[9]

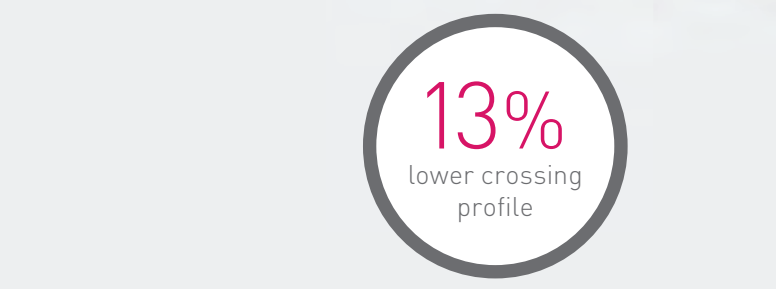
| STEMI | Diabetics | Small vessels |
|---|---|---|
| 5.4% | 0.0% | 0.0% |
| 10.8% Xience TLF[4] 24 months BIOSCIENCE[7] | ST[8] 60 months BIOFLOW-II[9] | ST[8] 60 months BIOFLOW-II[9] |

ST - Stent Thrombosis

*ø 2.25 – 3.0 mm





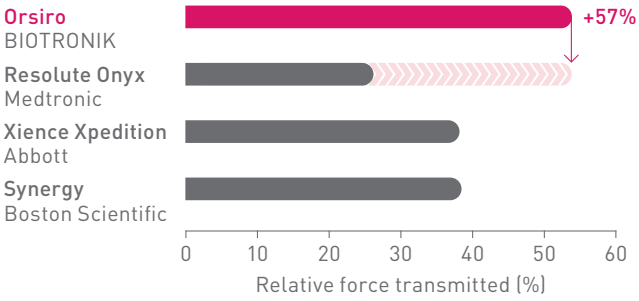




## Highly deliverable

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

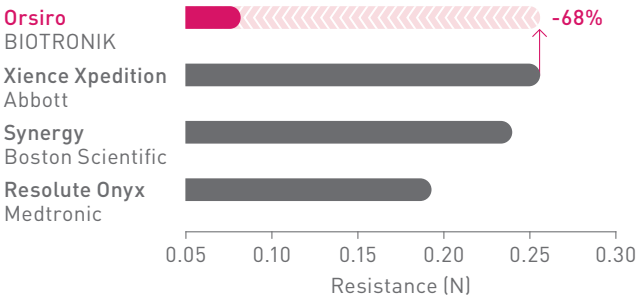
### Better push

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



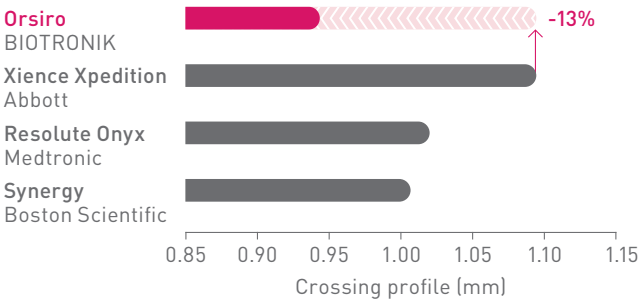

### Easier cross

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

# Ultrathin 60 µm struts

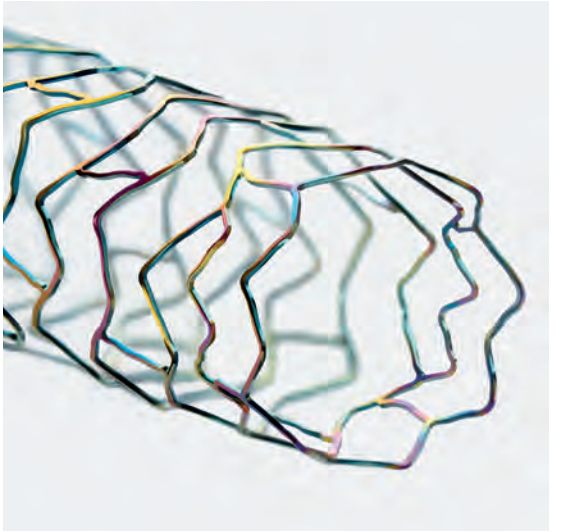
## Thinner struts make the difference

Thinner struts create:

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

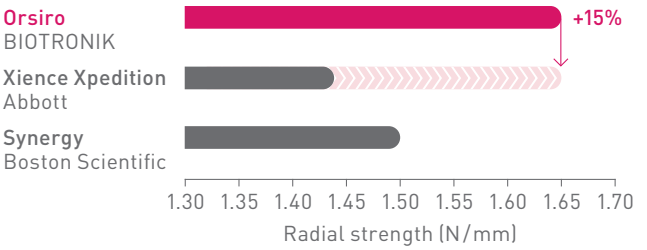
Which leads to:

- **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

* ø 2.25 – 3.0 mm

# 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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