Orsiro® Mission DES

Even better deliverability for the outstanding Orsiro DES
The next level of deliverability

1st in Push
Transmitting up to 57% more force from hub to tip.

<table>
<thead>
<tr>
<th>Orsiro Mission</th>
<th>BIOTRONIK</th>
<th>Resolute Onyx</th>
<th>Medtronic</th>
<th>Synergy</th>
<th>Boston Scientific</th>
<th>Xience Sierra</th>
<th>Abbott</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force transmitted (%)</td>
<td>0</td>
<td>10</td>
<td>20</td>
<td>30</td>
<td>40</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

1st in Track
Up to 30% less force needed to follow the path to the lesion.

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<th>Boston Scientific</th>
<th>Xience Sierra</th>
<th>Abbott</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance (N)</td>
<td>0</td>
<td>0.2</td>
<td>0.6</td>
<td>0.4</td>
<td>0.10</td>
<td>0.20</td>
<td>0.25</td>
</tr>
</tbody>
</table>

1st in Cross
Up to 75% less force needed to successfully cross demanding anatomies.

<table>
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<th>Xience Sierra</th>
<th>Abbott</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance (N)</td>
<td>0</td>
<td>0.05</td>
<td>0.15</td>
<td>0.25</td>
<td>0.15</td>
<td>0.30</td>
<td>0.80</td>
</tr>
</tbody>
</table>

Proven deliverability on the bench and in a real-world user evaluation of over 1,000 implantations.

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
NEW
More flexible shaft for high track

NEW
Deep embedding for high cross

NEW
Enhanced force transmission for high push

Passive coating for high biocompatibility

Bioabsorbable coating with controlled drug release and low thrombogenicity

Ultrathin 60 μm* struts for early endothelialization

NEW
Ergonomic hub with kink resistance

Dual-coating on shaft for limited friction

3 out of 4 cases show Orsiro Mission DES to have better deliverability in complex lesionsΔ5

* ø 2.25 – 3.0 mm
Δ ‘Complex lesions’ are defined by lesions where both calcification and tortuosity were individually reported as ‘Moderate or Severe’. In comparison to Xience Sierra and Synergy.
Ultrathin struts$^2$

For early endothelialization

Strut coverage$^{10}$
30 days$^\Delta$

>80%
n = 589a

90 days$^\Delta$

>97%
n = 874a

180 days$^\Delta$

>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)$^{11}$

Orsiro
BIOTRONIK

Definite ST
at 5 years

1.6%

DST – Definite Stent Thrombosis
D/PST – Definite/Probable Stent Thrombosis

Outstanding patient outcomes

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)

Orsiro Mission DES is indicated for complex patients and lesions, including:

0 12 24 36
0 3 6 9 12 15
Cumulative incidence—TLF [%]

Time after initial procedure (months)

Xience
Orsiro

p = 0.032
p = 0.005
p = 0.002

40% lower TLF vs. Xience (p = 0.003)
52% lower ischemia-driven TLR (p = 0.008)

ACS STEMI DM HBR B2C SV MVD

BIOSTEMI (n=1,300)
Continued Superiority in STEMI at 2 years

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

BIO-RESORT Small Vessels
(n=1,506)
Target Lesion Revascularization (TLR) rate at 3 yrs

Orsiro
BIOFRONIK
Synergy
Boston Scientific
Resolute Integrity
Medtronic

2.1
4.0
5.3

42% lower risk of TLF vs. Xience
60% lower TLR vs. Resolute Integrity (p = 0.009)


* 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.

§ in large RCTs, based on Taglieri et al. Meta-analysis, against currently used DES

φ 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.

** BCI: Bayesian Credibility Interval.
Orsiro® Mission DES

The Orsiro Mission Sirolimus-Eulting Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.

Indication

Orsiro Mission 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)
- ST-Elevation Myocardial Infarction (STEMI)
- Diabetes Mellitus (DM)
- Complex Lesions (BC/C)
- High Blood Risk (HBR)

Long Lesions (LL) (e.g. > 20 mm)

Small Vessels (SV) (e.g. < 2.75 mm)

Multi-Vessel Disease (MVD)

Male/Female

Old Patients (e.g. > 65 y)

Technical Data

Stent

Stent material: Cobalt chromium, L-605

Shunt thickness: ø 2.25 – 3.00 mm: 60 µm (0.0024”); ø 3.50 – 4.00 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. 0.054”)

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: Ø 1.0 mm

Distal shaft diameter: 2.25 – 3.5 mm; 3.5 mm – 4.0 mm

Proximal shaft diameter: 2.0 mm

Nominal pressure (NPM): 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)

Use excursions between 10°C (50°F) and 40°C (104°F) are allowed

Ordering Information

Stent ø (mm) Stent Length (mm)

13 15 18 22 26 30 35 40

2.25 419101 419107 419113 419119 419125 419131 419137 419143 419149

2.50 419102 419108 419114 419120 419126 419132 419138 419144 419150

2.75 419103 419109 419115 419121 419127 419133 419139 419145 419151

3.00 419104 419110 419116 419122 419128 419134 419140 419146 419152

3.50 419105 419111 419117 419123 419129 419135 419141 419147 419153

4.00 419112 419118 419124 419130 419136 419142 419148 419154


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

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