Orsiro® Mission DES

Even better deliverability for the outstanding Orsiro DES

Vascular Intervention // Coronary Drug-Eluting Stent System
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.

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

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

Orsiro Mission
BIOTRONIK
Resolute Onyx
Medtronic
Synergy
Boston Scientific
Xience Sierra
Abbott

### Graphs

**Pushability (N):**
- Orsiro Mission: +57%
- Resolute Onyx
- Medtronic
- Synergy
- Boston Scientific
- Xience Sierra
- Abbott

**Resistance (N):**
- Orsiro Mission: -30%
- Resolute Onyx
- Medtronic
- Synergy
- Boston Scientific
- Xience Sierra
- Abbott

**Resistance (N):**
- Orsiro Mission: -75%
- Resolute Onyx
- Medtronic
- Synergy
- Boston Scientific
- Xience Sierra
- Abbott

57% better push
30% better track
75% better cross
NEW More flexible shaft for high track

Passive coating for high biocompatibility

Bioabsorbable coating with controlled drug release and low thrombogenicity

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
Ultrathin struts²

For early endothelialization

Strut coverage<sup>9</sup>
- 30 days<sup>Δ</sup>
- 90 days<sup>Δ</sup>
- 180 days<sup>Δ</sup>

>80%  
\( n = 589a \)

>97%  
\( n = 874a \)

>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

BIOSCIENCES, all-comers RCT (n= 2,119)<sup>10</sup>

<table>
<thead>
<tr>
<th>Device</th>
<th>Definite ST (%)</th>
<th>Probable ST (%)</th>
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</thead>
<tbody>
<tr>
<td>Orsiro</td>
<td>1.6</td>
<td>6.3</td>
</tr>
<tr>
<td>Xience</td>
<td>1.6</td>
<td>7.7</td>
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</tbody>
</table>

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

1.6% Definite ST at 5 years


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

Clinically proven Orsiro DES\textsuperscript{11,12,13,14}
BIOFLOW-V, FDA pivotal trial (n = 1,334)

Cumulative incidence-TLF [%]

\begin{center}
\begin{tabular}{c|c|c|c|c|c|c|c|c|c|c}
Time after initial procedure (months) & 0 & 6 & 12 & 18 & 24 & 30 & 36 \\
\hline
Xience & 0 & 3 & 6 & 9 & 12 & 15 & 18 \\
Orsiro & 5.9 & 7.1 & 8.2 & 11.1 & 13.6 & & \\
\hline
\end{tabular}
\end{center}

p = 0.032
p = 0.015
p = 0.002

55,000 patients enrolled

Orsiro Mission is indicated for complex patients and lesions, including:*
Orsiro Mission DES
The Orsiro Mission Sirolimus-Elongating Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.

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 (≤4.0 mm) in the 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 (B2/C)
- High Bleeding Risk (HBR)

Technical Data

Stent
- Stent material: Cobalt chromium, L-695
- Strut thickness: ø 2.25 – 3.0 mm: 60 µm (0.0024”), ø 3.5 – 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 (mm. 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
- Rated burst pressure (RBP): 16 atm
- Storage
- 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

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<thead>
<tr>
<th>Stent a (mm)</th>
<th>Stent Length (mm)</th>
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<td>4.0</td>
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</table>

8. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: International Cardiovascular Nurse/Technologist Symposium, June 17, 2016, New York, USA; 9. Secco G et al. Biodegradable polymer sirolimus-eluting stents: 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, proBIO and BIOlute are trademarks or registered trademarks of the BIOTRONIK Group of Companies. Synergy and Premus are trademarks or registered trademarks of the Boston Scientific group of companies. Resolute, Resolute Dnyx 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.

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