Vascular Intervention // Coronary Drug-Eluting Stent System

Orsiro® Mission DES

Even better deliverability for the outstanding Orsiro DES
1st in Push:
Transmits more force from hub to tip.

1st in Track:
Less force needed to follow the path.

1st in Cross:
Less force needed to successfully cross demanding anatomies.

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

NEW
Deep embedding for high cross

NEW
Passive coating for high biocompatibility

NEW
Bioabsorbable coating with controlled drug release and low thrombogenicity

Enhanced force transmission for high push

Ultrathin 60 μm* struts for early endothelialization

Dual-coating on shaft for limited friction

NEW
Ergonomic hub with kink resistance

*Nominal strut thickness for size ø 2.25 - 3.0 mm, mean diameter 62 μm.
Orsiro Mission DES
Ultrathin struts — thinnest available in the US

Thinner struts make the difference

- Less disrupted flow
- Improved re-endothelialization

Strut thickness in perspective

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Strut Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orsiro Mission</td>
<td>BIOTRONIK</td>
<td>60 μm*</td>
</tr>
<tr>
<td>Synergy</td>
<td>Boston Scientific</td>
<td>74 μm</td>
</tr>
<tr>
<td>Resolute Onyx</td>
<td>Medtronic</td>
<td>81 μm</td>
</tr>
<tr>
<td>Xience Family</td>
<td>Abbott</td>
<td>81 μm</td>
</tr>
</tbody>
</table>

*Nominal strut thickness for size ø 2.25 - 3.0 mm, mean diameter 62 μm.
For early endothelialization

BIO-RESORT trial

Small vessels. Ultrathin struts. Big difference.

Small vessel subgroup analysis (n = 1,506) of a large scale all-comers BIO-RESORT (n = 3,514) trial.

Lower target lesion revascularization (TLR) rate compared to Resolute Integrity at 36 months.\(^{12}\)

Orsiro

<table>
<thead>
<tr>
<th>TLR rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>2.1</td>
</tr>
</tbody>
</table>

Synergy

<table>
<thead>
<tr>
<th>TLR rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>4.0</td>
</tr>
</tbody>
</table>

Resolute Integrity

<table>
<thead>
<tr>
<th>TLR rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>5.3</td>
</tr>
</tbody>
</table>

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


n = number of struts analyzed.
Orsiro Mission DES
Outstanding patient outcomes³

One of the most studied DES§

<table>
<thead>
<tr>
<th>STUDY NAME</th>
<th>STUDY TYPE</th>
<th>PATIENTS</th>
<th>STATUS</th>
<th>PRIMARY ENDPOINT</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIOSTEMI</td>
<td>RCT</td>
<td>1,300</td>
<td>24-month FU available</td>
<td>TLF at 12 months</td>
</tr>
<tr>
<td>TAGLIERI et al.</td>
<td>Network Meta-Analysis</td>
<td>99,039</td>
<td>-</td>
<td>TLF at 12 months and the longest FU available</td>
</tr>
<tr>
<td>BIOFLOW-Y</td>
<td>RCT</td>
<td>1,334</td>
<td>36-month FU available</td>
<td>TLF at 12 months</td>
</tr>
<tr>
<td>BIO-RESORT</td>
<td>RCT</td>
<td>3,514</td>
<td>36-month FU available</td>
<td>TVF at 12 months</td>
</tr>
<tr>
<td>BIONYX</td>
<td>RCT</td>
<td>2,488</td>
<td>36-month FU available</td>
<td>TVF at 12 months</td>
</tr>
<tr>
<td>BIOSCIENCE</td>
<td>RCT</td>
<td>2,119</td>
<td>Completed, 60-month FU available</td>
<td>TLF at 12 months</td>
</tr>
</tbody>
</table>

>55,000 patients enrolled
>71,500 patients enrolled or planned in total
>68 studies started

Taglieri et al. network meta-analysis

Orsiro – ranked as the best DES‡

99,039 patients in a network meta-analysis of 77 RCTs³

Orsiro is associated with a lower 1-year rate of TLF compared with Xience (OR (95% CI) 0.84 [0.71, 0.98], p = 0.03) and Resolute§ (OR (95% CI) 0.81 [0.68, 0.95], p = 0.01).

Orsiro – the highest probability (70.8%) to rank as the best stent.

SUCRA – Surface Under the Cumulative Ranking Curve.

◊ In large RCTs, based on Taglieri et al. Meta-analysis, against currently used DES.
‡ Based on 1-year TLF SUCRA score, in comparison to Xience, Resolute and Nobori/BioMatrix, after a median follow-up period of 50 months.
§ Resolute Integrity and Resolute Onyx.
ψ The Nobori, BioMatrix, Cre8, Biofreedom and Cypher drug eluting stents are not available in the US.
BIOFLOW-V trial

Improving patient outcomes, year after year\textsuperscript{15}

BIOFLOW-V (n = 1,334) FDA pivotal trial\textsuperscript{16,17,18,19,20}

Significant differences in TLF observed at year 1 and 2 were maintained and further increased at year 3 (8.6\% vs. 14.4\%, \( p = 0.003 \)), driven by significant differences in TV-MI (5.5\% vs. 10.1\%, \( p = 0.004 \)) and ischemia-driven TLR (3.4\% vs. 6.9\%, \( p = 0.008 \)) that favor Orsiro over Xience.

**TLF and components at 12, 24 and 36 Months**

\[\begin{array}{|c|c|c|c|}
\hline
& 12 months & 24 months & 36 months \\
\hline
Orsiro & 6.2 \% & 5.3 \% & 2.6 \% \\
Xience & 8.6 \% & 4.7 \% & 2.8 \% \\
\hline
\end{array}\]

\( p = 0.003 \)  
\( p = 0.004 \)  
\( p = 0.008 \)

**Ischemia-driven TLR Landmark Analysis**\textsuperscript{19}

\[\begin{array}{|c|c|c|}
\hline
& 0-360 days & 361 days -36 months \\
\hline
Orsiro & 2.0 \% & 4.7 \% \\
Xience & 2.3 \% & 1.5 \% \\
\hline
\end{array}\]

**ST at 36 Months**\textsuperscript{19}

\[\begin{array}{|c|}
\hline
& 0.1 \% \text{ Def/ prob late/ very late ST} & 1.2 \% \text{ Def/ prob late/ very late ST} \\
\hline
Orsiro & & \\
Xience & & \\
\hline
\end{array}\]

TLF – Target Lesion Failure; TV-MI – Target Vessel Myocardial Infarction;  
TLR – Target Lesion Revascularization; ST – Stent Thrombosis.  
\( \text{p-values for } 36-\text{m frequentist analysis of BIOFLOW-V.} \textsuperscript{17} \)  
\( \text{vs. Xience, based on } 36-\text{m frequentist analysis of BIOFLOW-V.} \textsuperscript{18} \)
# Orsiro® Mission DES

## Sirolimus-Eluting Coronary Stent System

**Indication**

Orsiro Mission is indicated for improving coronary luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST-elevation myocardial infarction or documented silent ischemia due to atherosclerotic lesions in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of ≤ 36 mm.

## Technical Data

### Stent

- **Stent material**: Cobalt chromium, L-605
- **Passive coating**: proBIO™ amorphous silicon carbide
- **Active coating**: BioLute™ biodegradable drug matrix consisting of sirolimus and polymer poly-l-lactide (PLLA)
- **Nominal drug content**: 1.4 µg/mm²

### Delivery system

- **Catheter type**: Fast-exchange
- **Recommended guide catheter**: 5 F (min. I.D. = 0.056")
- **Guide wire diameter**: 0.034" (0.36 mm)
- **Usable catheter length**: 140 cm
- **Balloon material**: Semi-crystalline polymer
- **Coating (distal shaft)**: Hydrophilic
- **Coating (proximal shaft)**: Hydrophobic
- **Proximal shaft diameter**: 2.0 F
- **Distal shaft diameter**: 2.7 F, ø 2.25 – 3.0 mm; 2.9 F, ø 3.5 – 4.0 mm
- **Nominal pressure (NP)**: 10 atm
- **Rated burst pressure (RBP)**: 16 atm

## Ordering Information

**Stent length** (mm)

<table>
<thead>
<tr>
<th>Stent a (mm)</th>
<th>9</th>
<th>13</th>
<th>15</th>
<th>18</th>
<th>22</th>
<th>26</th>
<th>30</th>
<th>40</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.25</td>
<td>453925</td>
<td>453931</td>
<td>453937</td>
<td>453943</td>
<td>453949</td>
<td>453955</td>
<td>453961</td>
<td>453967</td>
</tr>
<tr>
<td>2.75</td>
<td>453928</td>
<td>453934</td>
<td>453940</td>
<td>453946</td>
<td>453952</td>
<td>453958</td>
<td>453964</td>
<td>453970</td>
</tr>
<tr>
<td>3.00</td>
<td>453928</td>
<td>453934</td>
<td>453940</td>
<td>453946</td>
<td>453952</td>
<td>453958</td>
<td>453964</td>
<td>453970</td>
</tr>
<tr>
<td>3.50</td>
<td>453928</td>
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<td>453952</td>
<td>453958</td>
<td>453964</td>
<td>453970</td>
</tr>
</tbody>
</table>

**Stent diameter**

- **I.D. = Inner Diameter**

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