Orsiro

Vascular Intervention // Coronary Drug-Eluting Stent System
Extensive clinical program*

>32,500 patients enrolled  >44 studies ongoing
>50,500 patients planned in total  >55 studies planned in total

*status as of Feb 2017

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).

**Bio-Resort**[^1][^2] (n=3,514 patients)
- Orsiro: 4.8%
- Synergy: 4.2%
- Resolute Integrity: 4.5%

**BioScience**[^3][^4] (n=2,121 patients)
- Orsiro: 6.5%
- Xience Prime/Xpedition: 6.6%

**Sort-Out VII**[^5][^6] (n=2,314 patients)
- Orsiro: 3.8%
- Nobori: 4.6%

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<table>
<thead>
<tr>
<th>TLF at 12 months (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

- **STEMI**: 5.4%
  - 10.8% Xience TLF[^7] 24months BIO-SCIEN[^7]
- **Diabetics**: 0.0%
  - ST[^8] 60months BIOFLOW-II[^9]
- **Small vessels**: 0.0%
  - ST[^8] 60months BIOFLOW-II[^9]

**ST** - Stent Thrombosis

[^1]: BIO-RESORT[^1][^2] (n=3,514 patients)
[^2]: Orsiro: 4.8%
[^3]: BioScience[^3][^4] (n=2,121 patients)
[^4]: Orsiro: 6.5%
[^5]: Sort-Out VII[^5][^6] (n=2,314 patients)
[^6]: Orsiro: 3.8%
[^7]: STEMI[^7] 5.4%
[^8]: Diabetics[^8] 0.0%
[^9]: Small vessels[^9] 0.0%
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)

<table>
<thead>
<tr>
<th>Stent</th>
<th>TLF at 12 months [%]</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orsiro BIOTRONIK</td>
<td>6.3</td>
<td>-29%</td>
</tr>
<tr>
<td>Xience Abbott</td>
<td>8.9</td>
<td></td>
</tr>
</tbody>
</table>

*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
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% more force from hub to tip.14

Easier cross

Up to 68% less force needed to successfully cross demanding anatomies.

Lower crossing profile

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

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**Graph:**

- **Orsiro**
  - BIONTRONIK
  - 60 μm

- **Synergy**
  - Boston Scientific
  - 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

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**Legend:**

- 1.30
- 1.35
- 1.40
- 1.45
- 1.50
- 1.55
- 1.60
- 1.65
- 1.70

**Radial strength (N/mm) +15%**

15% more radial strength
Orsiro

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

Technical Data

<table>
<thead>
<tr>
<th>Stent</th>
<th>Stent material</th>
<th>Passive coating</th>
<th>Active coating</th>
<th>Drug dose</th>
<th>Strut thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cobalt chromium, L-405</td>
<td>proBIO (Amorphous Silicon Carbide)</td>
<td>BiOulse biodegradable Polylactic-Coated PLLA eluting a limus drug</td>
<td>1.4 µg/mm²</td>
<td>ø 2.25 - 3.0 mm: 60 µm [0.0024&quot;]; ø 3.50 - 4.0 mm: 80 µm [0.0031&quot;]</td>
</tr>
</tbody>
</table>

Delivery system

<table>
<thead>
<tr>
<th>Catheter type</th>
<th>Rapid exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended guide catheter</td>
<td>5F (min. I.D. 0.056&quot;)</td>
</tr>
<tr>
<td>Guide wire diameter</td>
<td>0.014&quot;</td>
</tr>
<tr>
<td>Usable catheter length</td>
<td>140 cm</td>
</tr>
<tr>
<td>Balloon material</td>
<td>Semi-crystalline polyethylene material</td>
</tr>
<tr>
<td>Coating (distal shaft)</td>
<td>Hydrophilic coating</td>
</tr>
<tr>
<td>Marker bands</td>
<td>Two swaged platinum-iridium markers</td>
</tr>
<tr>
<td>Proximal shaft diameter</td>
<td>2.0F</td>
</tr>
<tr>
<td>Distal shaft diameter</td>
<td>ø 2.25 - 3.5 mm; 2.8F - ø 4.0 mm</td>
</tr>
<tr>
<td>Nominal pressure (NP)</td>
<td>8 atm</td>
</tr>
<tr>
<td>Rated burst pressure (RBP)</td>
<td>16 atm</td>
</tr>
</tbody>
</table>

Compliance Chart

<table>
<thead>
<tr>
<th>Balloon diameter x length (mm)</th>
<th>Nominal Pressure (NP) atm**</th>
<th>Rated Burst Pressure (RBP) atm**</th>
</tr>
</thead>
<tbody>
<tr>
<td>ø 2.25 x 9 - 40</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>ø 2.50 x 9 - 40</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>ø 2.75 x 9 - 40</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>ø 3.00 x 9 - 40</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>ø 3.50 x 9 - 40</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>ø 4.00 x 9 - 40</td>
<td>8</td>
<td>16</td>
</tr>
</tbody>
</table>

Ordering Information

<table>
<thead>
<tr>
<th>Stent ø (mm)</th>
<th>Catheter length 140 cm (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ø 2.25</td>
<td>22 26 30 35 40</td>
</tr>
<tr>
<td>ø 2.50</td>
<td>25 30 35 40</td>
</tr>
<tr>
<td>ø 2.75</td>
<td>27 32 37 42</td>
</tr>
<tr>
<td>ø 3.00</td>
<td>30 35 40</td>
</tr>
<tr>
<td>ø 3.50</td>
<td>35 40</td>
</tr>
<tr>
<td>ø 4.00</td>
<td>40</td>
</tr>
</tbody>
</table>