Devoir Sirolimus Coated Balloon Catheter

Description and technical features
CONTENTS

1. Overview
2. CE mark indications
3. Bio-sphere technology
4. Coating process
5. Platform
6. Specifications
7. Range
OVERVIEW

SIROLIMUS
1.27µg/mm²

BIO-SPHERE TECHNOLOGY
Phospholipid carrier

5Fr COMPATIBLE
From 1.5 - 4.0mm diameter
CE MARK INDICATIONS

The Devoir Sirolimus coated balloon is indicated to dilate the diseased segment(s) and deliver drug in a coronary artery to improve myocardial perfusion with lesion lengths ranging from 8 to 38 mm and diameters ranging from 1.50 mm to 4.00 mm. Usage of one Devoir is recommended, beyond 38 mm length there should be use of two devices in summation of the lesion.

The device is intended for use in following conditions:

- Patients with in-stent restenosis of previous stent implantation

- Patients with disease in small vessels where drug eluting stent implantation is either not feasible or involving higher risk of restenosis

- Patients with bifurcation lesions, where side branch treatment increases risks of dissection and a balloon dilation treatment is more advised.

- Stenotic portions also including total occlusions, it can be used also for the post dilatation of stents
BIO-SPHERE TECHNOLOGY

Sirolimus:
• 1.27 µg/mm²
• Cytostatic effect
• Drug most widely used for drug eluting stents
BIO-SPHERE TECHNOLOGY

Features:

- Cell membrane bio-mimicking carrier for reduced drug rejection
  - Better compatibility and acceptance in tissue
  - Promotes healing and assists in endothelialisation

- Small size for higher uptake
  - Easier and faster transfer in to arterial tissue

- Bio-sphere drug encapsulation
  - Stabilisation and protection

- Two-steps release
  - First: bio-spheres transfer in to tissue
  - Second: drug release from bio-spheres

Homogeneous Drug Repartition within 7 days
COATING PROCESS

Balloon surface application

- Effective adhesion to balloon surface
  - No coating delamination
  - Low ‘particulate’ generation

- Uniform surface coating
  - Homogenous drug distribution
  - Protection during transit (between the folds)

10% in-transit loss
RELIABLE DRUG DELIVERY PLATFORM

- Guiding catheter 5Fr compatible
- Distal shaft hydrophilic coating
- Entry profile 0.016”
- Semi-compliant balloon material

Yangtze µ catheter system physicians feedback: 642 cases (data on file)
## TECHNICAL SPECIFICATION

<table>
<thead>
<tr>
<th><strong>Drug</strong></th>
<th><strong>Sirolimus</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug dose</strong></td>
<td>1.27 μg / mm²</td>
</tr>
<tr>
<td><strong>Drug carrier</strong></td>
<td>Phospholipid based excipient</td>
</tr>
<tr>
<td><strong>Balloon material</strong></td>
<td>Polyamide blend (semi-compliant)</td>
</tr>
<tr>
<td><strong>Catheter design</strong></td>
<td>Rapid exchange</td>
</tr>
<tr>
<td><strong>Shaft diameter - prox.</strong></td>
<td>1.7F</td>
</tr>
<tr>
<td><strong>Shaft diameter - dist.</strong></td>
<td>2.5F</td>
</tr>
<tr>
<td><strong>Usable catheter length</strong></td>
<td>140cm</td>
</tr>
<tr>
<td><strong>Tip profile</strong></td>
<td>0.016”</td>
</tr>
<tr>
<td><strong>Nominal Pressure (NP)</strong></td>
<td>6 bar</td>
</tr>
<tr>
<td><strong>Rated Burst Pressure (RBP)</strong></td>
<td>16 bar (14 bar for 4.00 / 25 to 40mm)</td>
</tr>
<tr>
<td><strong>Guide catheter compatibility</strong></td>
<td>5Fr (0.056” ID) for all sizes</td>
</tr>
<tr>
<td><strong>Guidewire compatibility</strong></td>
<td>0.014” maximum recommended</td>
</tr>
</tbody>
</table>
### SIZE RANGE & CODES

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 15 20 25 30 35 40</td>
</tr>
<tr>
<td>1.50</td>
<td>CDE15010 CDE15015 CDE15020 CDE15025 CDE15030 CDE15035 CDE15040</td>
</tr>
<tr>
<td>2.00</td>
<td>CDE20010 CDE20015 CDE20020 CDE20025 CDE20030 CDE20035 CDE20040</td>
</tr>
<tr>
<td>2.25</td>
<td>CDE22510 CDE22515 CDE22520 CDE22525 CDE22530 CDE22535 CDE22540</td>
</tr>
<tr>
<td>2.50</td>
<td>CDE25010 CDE25015 CDE25020 CDE25025 CDE25030 CDE25035 CDE25040</td>
</tr>
<tr>
<td>2.75</td>
<td>CDE27510 CDE27515 CDE27520 CDE27525 CDE27530 CDE27535 CDE27540</td>
</tr>
<tr>
<td>3.00</td>
<td>CDE30010 CDE30015 CDE30020 CDE30025 CDE30030 CDE30035 CDE30040</td>
</tr>
<tr>
<td>3.50</td>
<td>CDE35010 CDE35015 CDE35020 CDE35025 CDE35030 CDE35035 CDE35040</td>
</tr>
<tr>
<td>4.00</td>
<td>CDE40010 CDE40015 CDE40020 CDE40025 CDE40030 CDE40035 CDE40040</td>
</tr>
</tbody>
</table>