RESTORE® DEB

Paclitaxel Releasing PTCA Balloon Catheter
Specifically designed for ease of handling, high safety and precise drug delivery

Powered by SAFEPAX® Technology
The 3rd generation, unique, virtually loss-less matrix. For improved homogeneity of drug transfer and highest coating stability on the market
Controlled trials confirm the excellent safety profile of RESTORE®

- Procedural success rates >98% in both ISR and SVD patients\(^1\text{-}^3\)

- No procedure-related complications with RESTORE in two ISR trials and 160 patients: <1% complication rates\(^1\text{-}^3\)

- Similar complication rates to DES in vulnerable SVD patients (\(p=0.19\) for comparison)\(^2\)

- Only DCB with demonstrated low complication rates (~3%) in patients with very small vessels\(^2\)
**RESTORE SVD China:** RESTORE is a proven equal alternative to zotarolimus-eluting stent in patients with coronary small vessel lesions.

- Multi-centre, randomised, controlled clinical trial in 262 subjects at 12 sites in China. The primary end point was in-segment diameter stenosis after 9 months follow-up. Major adverse events were evaluated at 1, 6, 9 and 12 months and will be collected up to 5 years.

**Percent diameter restenosis at 9 months**

- Non-inferiority proven at $p<0.001$

- No difference in 12-months rates of target lesion failure between RESTORE and zotarolimus-eluting stent ($p=0.47$)

**Results:**

- Non-inferiority threshold
- 97.5% confidence interval for difference

**RESTORE ISR China:** RESTORE is a proven equal alternative to the best-in-class DCB in the treatment of patients with coronary in-stent restenosis.

- Multi-centre, randomised, controlled clinical trial in 240 subjects at 12 sites in China. Patients had in-stent restenosis $\geq 70\%$ diameter on visual assessment, or $\geq 50\%$ diameter stenosis and with ischaemic symptoms on coronary angiography. The primary endpoint was in-segment late lumen loss of the target lesion at 9 months after the procedure. Major adverse events were evaluated at 1, 6, 9 and 12 months.

**Primary end point: statistically similar rates of in-segment late loss at 9 months**

- $p=0.63$ for difference

**Results were valid for both in-segment and in-device late loss at one year**

**RESTORE matches best-in-class DCB on rates of target lesion failure (TLF) over 12 months**

- $p=0.86$

- TLF rates with RESTORE and the best-in-class DCB

- 13.4% vs 12.9%
RESTORE® is indicated for the treatment of:

- Coronary in-stent restenosis
- Small vessel lesions Ø < 2.5 mm
- Side branch dilation of bifurcated coronary artery lesions
- De-novo lesion dilation

### Technical specifications

<table>
<thead>
<tr>
<th>Drug releasing balloon</th>
<th></th>
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<tbody>
<tr>
<td>Shaft material</td>
<td>Plastic tube and a stainless steel hypotube</td>
</tr>
<tr>
<td>Balloon material</td>
<td>Polyamide blend / Nylon 12</td>
</tr>
<tr>
<td>Usable catheter length</td>
<td>140 cm</td>
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<tr>
<td>Max. recommended guidewire</td>
<td>0.014&quot;</td>
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<tr>
<td>Length of guide wire lumen</td>
<td>25 cm</td>
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<tr>
<td>Entry profile</td>
<td>0.016&quot;</td>
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<tr>
<td>Guiding catheter compatibility</td>
<td>5F</td>
</tr>
<tr>
<td>Rated Burst Pressure</td>
<td>16 bar (14 bar for balloons &gt; 4.0-20)</td>
</tr>
<tr>
<td>Paclitaxel coating</td>
<td>3.0 μg/mm² balloon surface</td>
</tr>
</tbody>
</table>

### Ordering Information

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<thead>
<tr>
<th>Balloon diameter (mm)</th>
<th>15 mm</th>
<th>20 mm</th>
<th>25 mm</th>
<th>30 mm</th>
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</thead>
<tbody>
<tr>
<td>2.00 mm</td>
<td>R 2.00-15</td>
<td>R 2.00-20</td>
<td>R 2.00-25</td>
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<tr>
<td>2.25 mm</td>
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<tr>
<td>2.50 mm</td>
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<tr>
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<tr>
<td>3.00 mm</td>
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<td>R 3.00-20</td>
<td>R 3.00-25</td>
<td>R 3.00-30</td>
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<tr>
<td>4.00 mm</td>
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</tbody>
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The 3rd generation, unique, virtually loss-less matrix. For improved homogeneity of drug transfer and highest coating stability on the market
RESTORE: Leveraging all the benefits from SAFEPAX

With RESTORE I am in control of drug delivery to the target site with minimal risk for embolisation

Dr. YunDai Chen

- Locally delivered 3 μg/mm² paclitaxel dose
- Virtually loss-less matrix
- Proprietary ammonium salt solution excipient
- Highly stable coating, with low surface friction
  - Excellent manoeuvrability for maximal control: smooth pushability and optimised tensile resistance
  - Enhanced crossability and trackability
  - No need for a loading tool
- Designed for maximal procedural safety
  - No major adverse procedural complications reported in two clinical trials of in-stent restenosis¹,³ - the lowest rates reported to date
  - Low mass-related risk of distal embolisation

Stable vs Unstable

Comparison between the virtually loss-less SAFEPAX® DCB PTX Balloon Coating (top) and a first-generation DCB coating (bottom)
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References

