STENTYS SES Sirolimus Eluting Self-Apposing® Coronary Stent

Complete and Continuous Apposition
Faster Healing
Low Late Loss
Complete and Continuous Apposition

Stent Malapposition has been demonstrated as a contributor to clinical events1

STENTYS’ unique Self-Apposing technology overcomes the challenges that balloon expandable stents face in
- Gaining full apposition when stent sizing is unclear such as thrombus laden, tapering or ectatic vessels.
- Maintaining full apposition in situations such as STEMI when there is significant changes to the vessel after the initial procedure.

Stents with >5% Malapposed Struts (OCT Analysis)

Faster Healing

The combination of STENTYS unique Self-Apposing technology and biostable polymer allows for a more rapid re-endothelisation and healing of the vessel.

Total Stent Coverage 4 Month Cohort3
Strut coverage at least ≥20µm at 4 months OCT Analysis

Values between measured data points are based on linear extrapolation and are not necessarily indicative.
**Low Late Lumen Loss**

Complete apposition allows effective elution of the drug into the vessel wall minimising late lumen loss without compromising healing.

**Late Lumen Loss at 9 Months**

![Graph showing late lumen loss at 9 months](image)

P=0.23

![Graph showing late lumen loss at 9 months](image)

**Combining Sirolimus Elution with Self-Apposition**

Upon implantation the polymer forms a smooth non thrombogenic surface and remains biostable which combined with complete apposition allows rapid strut coverage.

Polysulfone, a well proven hemocompatible, non inflammatory, and non thrombogenic biostable polymer, also used in dialysis and bone replacement indications, is combined with Sirolimus (1.4µg/mm²) and Polyvinylpyrrolidone (PVP), an excipient, originally used as blood plasma substitute.

**% Strut Area Occupied by Thrombus After 24 Hours**

![Graph showing strut area occupied by thrombus](image)

P=0.05

**Sirolimus Elution Profile**

*(Based on STENTYS SES 2.5-3.0mm x 25mm)*

![Graph showing sirolimus elution profile](image)

**References**


3. Van Geuns, Apposition IV final Results, Oral presentation at PCR 2014

4. Michael Joner, CV Path Oral presentation at PCR 2014

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1. Position the guidewire into the side-branch through the stent cell closest to the carina.

2. Inflate a regular PTCA balloon at low pressure (8atm) at the side-branch opening to disconnect the struts.

3. Stent interconnectors separate due to the combined effect of flexion and torsion created by the balloon.

4. Deflate and withdraw the balloon allowing the stent to expand fully. This creates an opening to the side-branch. Final kissing balloon is not required.

The STENTYS System Platform Includes

<table>
<thead>
<tr>
<th>Indicated Reference Vessel Diameter (mm)</th>
<th>STENTYS SES</th>
<th>STENTYS BMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 – 3.0</td>
<td>STY02-2530-17 STY02-2530-22 STY02-2530-27</td>
<td>STY00-2530-17 STY00-2530-22 STY00-2530-27 ≥ 2.20</td>
</tr>
<tr>
<td>3.0 – 3.5</td>
<td>STY02-3035-17 STY02-3035-22 STY02-3035-27</td>
<td>STY00-3035-17 STY00-3035-22 STY00-3035-27 ≥ 2.25</td>
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<tr>
<td>3.5 – 4.5</td>
<td>STY02-3545-17 STY02-3545-22 STY02-3545-27</td>
<td>STY00-3545-17 STY00-3545-22 STY00-3545-27 ≥ 2.50</td>
</tr>
</tbody>
</table>

Guidewire compatibility: 0.014” (0.35mm). Guiding catheter compatibility: 6F (2.0mm). Useable Catheter Length 145cm.

* BMS: STENTYS BMS bare metal stent; SES: STENTYS SES Sirolimus-eluting stent.
† Maximum Vessel Diameter for vessels with diameter variations (e.g. tapered, ectatic).
‡ Foreshortening can be over 10% outside the recommended reference vessel diameter range.
§ For lesions in vessels involving a side branch (bifurcation); side branch & main branch having a 30-70° angle

Size Selection Based on Distal Vessel Diameter

At the stent size boundaries (3.0 & 3.5mm), use the smaller size as the vessel normally tapers.