‘Supraflex Cruz was designed to have twice the flexibility of the Supraflex, with all other safety and efficacy parameters being same.’

*LDZ = Long Dual Z - link
## From Supraflex to Supraflex Cruz

<table>
<thead>
<tr>
<th></th>
<th>Supraflex SES</th>
<th>Supraflex Cruz SES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug</strong></td>
<td>Sirolimus (1.4 µg/mm²)</td>
<td>Sirolimus (1.4 µg/mm²)</td>
</tr>
<tr>
<td><strong>Polymer type</strong></td>
<td>Biodegradable polymers</td>
<td>Biodegradable polymers</td>
</tr>
<tr>
<td><strong>Stent design</strong></td>
<td>Open-cell design</td>
<td>Open-cell design</td>
</tr>
<tr>
<td><strong>Stent material</strong></td>
<td>L605 Co-Cr alloy</td>
<td>L605 Co-Cr alloy</td>
</tr>
<tr>
<td><strong>Stent strut thickness</strong></td>
<td>60 µm</td>
<td>60 µm</td>
</tr>
<tr>
<td><strong>No. of crown</strong></td>
<td>4, 6 and 8 crown</td>
<td>4, 6 and 8 crown</td>
</tr>
<tr>
<td><strong>No. of interconnectors</strong></td>
<td>Two</td>
<td>Two</td>
</tr>
<tr>
<td><strong>Link type</strong></td>
<td>S-link</td>
<td>LDZ link</td>
</tr>
<tr>
<td><strong>Stent drawing</strong></td>
<td><img src="image1" alt="Supraflex SES drawing" /></td>
<td><img src="image2" alt="Supraflex Cruz SES drawing" /></td>
</tr>
</tbody>
</table>

LDZ = Long Dual Z link
Long Dual 'Z' Link

LDZ LINK

- Long connectors enhance the overall radial strength
- Improves flexibility of the stent
- Transmit ‘Push force’ with higher efficiency
- Resists longitudinal compression

It is more suitable for PCI in tortuous lesions and distal segments
In Phase Design

Diameter

- 2.0 & 2.25
- 2.5, 2.75, 3.0 & 3.5
- 4.0 & 4.5

4 Crowns
6 Crowns
8 Crowns

Open cell design
2 connectors between the ringlets
In-phase design
Unique LDZ link

*LDZ = Long Dual Z link
Open-Cell design with two connectors between the ringlets

Open-cell design aids in:
- Flexibility
- Better side-branch access.

- Open cell provide increased flexibility, deliverability, and side branch access
- Open cell designs tend to conform better on bends
- Open cell design is best suited for Bifurcations, Tortuous bends, Distal Lesions
Low strut thickness helps in flexibility
Lower strut thickness is associated with lower restenosis rates¹


* Orsiro: 60 µm for ≤3 mm, 80 µm for >3 mm
** Synergy: 74 µm for 2.25 to 2.75 mm, 79 µm for 3.00 to 3.5 mm, 81 µm for > 3.5 mm diameter
Thinner strut leads to **less vessel wall trauma during implantation**

Yellow zone represents the area of trauma on vessel wall during implantation

Higher the trauma more aggressive inflammatory response & healing process, which will lead to more late loss and restenosis
Thin Strut minimizes flow disturbances

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**Thin Strut**

- Minimizes flow disturbances
- Thinner struts → Less disrupted flow
- Re-establish regular flow dynamics sooner
- Improved endothelialization
- Reduced risk of restenosis and thrombosis

---

**Thicker Strut**

- High shear rate
- Pro-thrombotic state
- Platelet activation
- Formation of microthrombi
- Low endothelial shear stress

---

**Physiologic shear rate**

- Physiologic endothelial shear stress
- Anti-thrombotic state
- Quiescent platelets
- Platelet aggregation ↓
- Less flow disturbance

---

**Reference**

- Figure adapted from Circ Res. 2017;120(8):1341-1352.
Impact of strut thickness on Coronary Arterial Healing

**Healing index** is used to quantify the degree of vessel healing. This score combines the following parameters:\(^1\)

- Presence of intraluminal defect
- Presence of both malapposed and uncovered struts
- Presence of uncovered struts alone
- Presence of malapposition alone
- Presence of neointimal volume obstruction of >30%

Stents with **thinner strut designs** have shown more rapid healing process compared to stents with thicker strut design.\(^2\)

---

Comparison of Healing Index for Different DES

<table>
<thead>
<tr>
<th>Polymer Type</th>
<th>Strut Thickness</th>
<th>n*</th>
<th>Time Point</th>
<th>Healing Index [median (range)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cypher Sirolimus-eluting Stent</td>
<td>Durable</td>
<td>29</td>
<td>9 months</td>
<td>26.1 (4.6-127.4)</td>
</tr>
<tr>
<td>BioMatrix Biolimus A9-eluting stent</td>
<td>Biodegradable</td>
<td>22</td>
<td>9 months</td>
<td>36.7 (1.1-79.6)</td>
</tr>
<tr>
<td>Resolute Zotarolimus-eluting Stent</td>
<td>Durable</td>
<td>17</td>
<td>13 months</td>
<td>15.2 (0.0-79.0)</td>
</tr>
<tr>
<td>Supraflex Sirolimus-eluting Stent</td>
<td>Biodegradable</td>
<td>47</td>
<td>6 months</td>
<td>4.8 (1.0–22.9)</td>
</tr>
</tbody>
</table>

Low healing index indicates a favourable healing process without intraluminal defect, malapposition or uncovered struts.³

High healing index reflects a poor healing process with remnant thrombus, uncovered and/or malapposed struts.³

*In stable patients

Clinical advantages of ultra-thin strut thickness

- Lower crimped profile
- Improved flexibility; better stent deliverability
- Reduce disturbance to blood flow & abnormal shear parameters
- Lesser injury to arterial wall
- Lower risk of acute/chronic inflammation following stent implantation
- Faster healing; Better healing quality; Lower late lumen loss
- Lower rates of restenosis and improved clinical outcomes

Optimal Crossing Profile (mm)

Lower is better

0.956
0.965
0.992
1.005
1.012
1.12
1.135

Orsiro
Resolute Onyx
Synergy
Xience Sierra
Suprareflex Cruz
Xience Xpedition
Ultimaster

Crimped Profile (mm)

*Data on File
Helps in side branch access

Cell Opening (mm)

Cell opening is equivalent to side branch access.

*Data on File*
Recoil (%)

Lower is better

Less than 4%

Foreshortening (%)

Percent Foreshortening = 100 x (Change in Length + Loaded Length).

Supraflex Cruz

-1.116

*Data on File*
Post-Dilatation Limits

Drug Release Profile

Programed to address the entire wound healing cascade in real-world patients.

- Nearly 80% of drug is released within one month (Initial burst).
- Remaining drug is programmed to get released for 3 months.
- Designed to cover the entire period of arterial wound healing in real-world patients.

*After 90 days of drug release, the amount of residual drug in the stent is so low that it goes beyond the detection/quantitation limit.

Sirolimus drug dose: 1.4 µg/mm²

Time Course For Dissolution (Months)

* Drug

* Polymer

*Data on file

Available Sizes

Diameters (mm): 2, 2.25, 2.5, 2.75, 3.0, 3.5, 4, 4.5

Lengths (mm): 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48

88 SKUs
Supraflex Cruz in distal LAD tortuous lesion

LAD proximal two bend and distal lesion

Supraflex Cruz 2.50mm x 32mm negotiated in distal LAD
Summary

• Cruz is an evolution in design and manufacture that enhances the deliverability of the Supraflex stent

• whilst maintaining the class leading clinical efficacy seen with the low strut thickness, biodegradable polymer and sirolimus drug coating