The SYNERGY Stent: Complete Revascularisation Solutions in Complex PCI

Sponsored by Boston Scientific

Chairpersons: Adrian Banning and Franz-Josef Neumann
Potential conflicts of interest

Speaker's name: Franz-Josef Neumann

☑️ I do not have any personal conflict of interest to report.

Institutional Conflicts:

Speaker honoraria, consultancy fees and research grants from

Daiichi Sankyo, Astra Zeneca, Sanofi-Aventis, Bayer, Medicines, Bristol, Novartis, Roche, Boston Scientific, Biotronik, Medtronic, Edwards
Two-stage evaluation:

- Objective performance criteria benchmarking
- Large-scale randomized trial with clinical endpoint evaluation

Byrne R et al., Eur Heart J 2015
The SYNERGY Stent

**Platinum Chromium Platform**
- 74μm (0.0029in) strut thickness
  - Visibility
  - Strength
  - Flexibility
  - Conformability
  - Recoil

**Everolimus-Eluting**
- 100μg/cm²
- 3 month release time

**Bioabsorbable Polymer Coating (PLGA)**
- Abluminal
- 4μm thick
- 85:15 ratio
- <4 month absorption time

Ultrathin Abluminal Coating
Extended length SYNERGY stent

New Features

• 48 mm length
  – Small vessel diameter: 2.50, 2.75mm
  – Workhorse diameter: 3.00, 3.50mm
  – Large vessel diameter: 4.00mm

• Adjustments to accommodate longer balloon and stent
  – Markerband to markerband spacing
  – Balloon body length
  – Crimped stent length
Diversity of bioresorbable-polymer DES

- BioMime (PLLA+PLGA)
- Ultimaster (PLLA-CL)
- MiStent (PLGA)
- ABLUMINUS (PLA)
- ELIXIR DESyne BD (PLA)
- FIREHAWK (PLA)
- BIOMATRIX (PLA)
- NOBORI (PLA)
- SVELTE (Amino Acid)
- ORSIRO (PLLA)

Drug Release and Bioabsorbable Polymer Levels Over Time (Months)
**Diversity of bioresorbable-polymer DES**

<table>
<thead>
<tr>
<th>Durable Polymer Coated</th>
<th>Bioabsorbable Polymer Coated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Xience CoCr-EES</strong></td>
<td><strong>SYNERGY</strong></td>
</tr>
<tr>
<td><strong>Promus PtCr-EES</strong></td>
<td><strong>MiStent</strong></td>
</tr>
<tr>
<td><strong>Resolute CoNi-ZES</strong></td>
<td><strong>Orsiro</strong></td>
</tr>
</tbody>
</table>

- **Strut thickness**
  - Xience CoCr-EES: 81 µm (0.0032”) 89 µm (0.0035”)
  - Resolute CoNi-ZES: 120 µm (0.0046”) 125 µm (0.0047”)
  - Biomatrix 316L-BES: 80 µm (0.0031”)
  - Nobori 316L-BES: 74 µm (0.0029”)
  - Ultimaster CoCr-SES: 64 µm (0.0025”)
  - SYNERGY PtCr-EES: 61 µm (0.0024”)

- **Polymer**
  - PVDF: Conformal 7-8µm / side
  - BioLinx: Conformal 6µm / side
  - PLA: Abluminal 10 µm
  - PLA: Abluminal 20 µm
  - PLGA + PCL: Abluminal 15 µm
  - PLGA: Conformal 5 µm / 15 µm
  - PLGA Probio*: Conformal 3.5 µm / 7.5 µm

- **Distribution / thickness**
  - Conformal 7-8µm / side
  - Conformal 6µm / side
  - Abluminal 10 µm
  - Abluminal 20 µm
  - Abluminal 15 µm
  - Abluminal 4 µm
Performance criteria benchmarking: EVOLVE - Late lumen loss

SYNERGY: $0.10 \pm 0.25 \text{ mm}$

PROMUS Element: $0.15 \pm 0.34 \text{ mm}$

Meredith IT et al., J Am Coll Cardiol 2012
Large-scale randomized trial: EVOLVE II:

Randomized Cohort (RCT)
- 125 global sites

PROMUS Element Plus
N=838

SYNERGY
N=846

RCT Design
- Multicenter noninferiority trial
- Pivotal, single-blind, 1:1 randomization

Primary Endpoint: TLF (CD, TV-MI, or TLR) at 12 mo
- Follow-up through 5 years

Kereiakis DJ et al., Circ Cardiovasc Interv J 2015
EVOLVE II: Favourable 3-year results

**PROMUS Element Plus vs. SYNERGY**

1° Endpoint: 12 months ITT

\[ P_{\text{noninferiority}} < 0.001 \]

- TLF (\%): 6.5% for SYNERGY and 6.7% for PE+

3 years

- HR 1.10 [0.82, 1.49]
- \( P = 0.53 \)

**No. at risk**

<table>
<thead>
<tr>
<th>0</th>
<th>12</th>
<th>24</th>
<th>36</th>
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<tbody>
<tr>
<td>PE+</td>
<td>838</td>
<td>772</td>
<td>734</td>
</tr>
<tr>
<td>SYNERGY</td>
<td>846</td>
<td>794</td>
<td>757</td>
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</table>

**Mo**

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<tbody>
<tr>
<td>520</td>
<td>539</td>
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EVOLVE II: Low risk of stent thrombosis

<table>
<thead>
<tr>
<th></th>
<th>Acute (≤1 d)</th>
<th>Subacute (2-30 d)</th>
<th>Late (30 d – 1 y)</th>
<th>Very Late (1 – 3 y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMUS Element Plus</td>
<td>N=5 (2 Definite/3 Probable)</td>
<td>N=1 (Def)</td>
<td>0.8% (N=6)</td>
<td></td>
</tr>
<tr>
<td>SYNERGY</td>
<td>N=2 (Definite)</td>
<td>N=1 (Prob)</td>
<td>N=1 (Def)</td>
<td>0.5% (N=4)</td>
</tr>
</tbody>
</table>

$P=0.54$
EVOLVE II: Low risk of very late stent thrombosis

PROMUS Element Plus vs SYNERGY

>24 h Landmark HR 0.33 [0.07, 1.61]

$P=0.15$
The SYNERGY Stent: Complete Revascularisation Solutions in Complex PCI

Session objectives:

• To discuss the potential benefits of bioabsorbable polymer DES in high-bleeding risk patients
• To understand how PCI guidance can optimise coronary procedures
• To learn how the Synergy stent is being used in complex patient subsets