The tailored solution for your bifurcation therapy
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Dedicated self-expanding platform that conforms to the specific bifurcation anatomy

Full bifurcation lesion coverage without creating a false carina

Bifurcation DES technology
Complete reconstruction possible
**Proven safety** of a dedicated bifurcation DES with an abluminal biodegradable polymer

**Confirmed safety in DIVERGE**
- The use of Axxess™ for the treatment of complex bifurcation lesions resulted in low 3-year event rates, with a cumulative MACE rate of 16.0%

**Proven efficacy** of the Biolimus A9™ drug
- Very low restenosis rate in bifurcation lesions
- Low in-stent late loss in DIVERGE at 9 months

**Restenosis in DIVERGE at 9 months**
- Proximal edge: 2.8%
- Axxess: 0.7%
- SB Cypher: 4.8%
- Distal PV Cypher: 2.1%
- Any in-segment bifurcation restenosis: 6.4%

**In-stent late loss (prox. main branch)**
- DIVERGE 9 months: 0.18
- Axxess: 0.21
- Sideward 1-2: 0.24
- Tryton 1: 0.83

**Dedicated self-expanding platform**

**Dedicated bifurcation stent**
- Self-expanding nitinol stent that conforms to the specific bifurcation anatomy
  - Excellent wall apposition
  - Spans both vessels at the same time
- No false carina
  - Does not cover the flow divider even in a full bifurcation reconstruction

**MACE (Death, MI, id-TLR) at 3 years**
- Primary endpoint MACE 9 months: 7.7%
- 9.3%
- 14.0%
- 16.0%

Cumulative incidence (%) vs Months of follow-up

n=302

*For descriptive purposes only - Clinical trials with different protocols should not be compared.*
Very low definite VLST not resulting in any death\(^1\)

- Only one definite VLST attributed to the Axxess\(^\text{TM}\) stent whereas all events occurred in relation to Cypher\(^\text{TM}\) stents

Definite stent thrombosis at 3 years\(^{1,3}\)

<table>
<thead>
<tr>
<th>Cumulative Incidence (%)</th>
<th>Months of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0%</td>
<td>0</td>
</tr>
<tr>
<td>1.3%</td>
<td>6</td>
</tr>
<tr>
<td>1.7%</td>
<td>12</td>
</tr>
<tr>
<td>2.4%</td>
<td>36</td>
</tr>
</tbody>
</table>

\(n=302\)

Abluminal\(^*\) biodegradable coating

No drug carrier or drug inside the stent leads to:
- Early BMS-like endothelial coverage\(^8\)
- More targeted drug release
- Reduced systemic exposure

BA9\(^\text{TM}\) drug 10 times more lipophilic than Sirolimus\(^8\)

Highest lipophilicity of the common limus drugs\(^8\)

- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

Conical shape

Two models

- Reference vessel diameter 3.0 ± 0.25 mm
  - Max. proximal stent diameter = 3.75 mm
  - Max. distal stent diameter = 6.00 mm
- Reference vessel diameter 3.5 ± 0.25 mm
  - Max. proximal stent diameter = 4.25 mm
  - Max. distal stent diameter = 6.50 mm

Maximum diameter without constraint
### AXXESS
**FRANCE, GERMANY**
- **n = 43**
- 6-month follow-up available
- Study completed
- Pilot study using bare metal stent Axxess™ platform
- In-segment restenosis at 6 months

### AXXESS PLUS
**EUROPE, BRAZIL, NEW ZEALAND**
- **n = 139**
- 5-year follow-up available
- Study completed
- To evaluate the acute and long term safety and performance of the Axxess™ DES
- Main vessel in-stent late loss at 6 months

### DIVERGE
**EUROPE, AUSTRALIA, NEW ZEALAND**
- **n = 302**
- 3-year follow-up available
- Follow-up planned up to 5 years
- To evaluate the safety and performance of the Axxess™ DES for the treatment of de novo bifurcation lesions
- MACE (Death, MI and id-TLR) at 9 months

### AXXENT
**EUROPE**
- **n = 33**
- 12-month follow-up available
- Study completed
- Pilot study for Axxess™ Left Main DES
- MACE (Death, MI or CABG/PCI TLR) at 6 months
Axxess™ Drug Eluting Coronary Bifurcation Stent System is CE approved.

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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