Six-Month and One-Year Clinical Outcomes after Placement of a Dedicated Bifurcation Device: A Patient-Level Pooled Analysis of Eight Registry Studies Confirms the Predictable Clinical Outcomes

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Objective of the Analysis:
• Confirm the clinical results from small size registries and studies in a larger sample size
• Evaluate clinical outcomes beyond 6 months

Evaluated Outcomes:
• Primary:
  – 6-month Target Vessel Failure (TVF), composite of cardiac death, any myocardial infarction (MI), clinically indicated target vessel revascularization (TVR)
• Secondary:
  – 1-year TVF
  – 6-month and 1-year cardiac death, any MI, clinically indicated TVR, clinically indicated TLR, Stent Thrombosis

Patient level data merged from 8 registries and studies included 905 patients with 929 bifurcations.

<table>
<thead>
<tr>
<th>Registry Cohorts</th>
<th>Initiated by</th>
<th>Number of Patients included in the Current Analysis</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-In-Man*</td>
<td>Sponsor</td>
<td>30</td>
<td>6 months</td>
</tr>
<tr>
<td>eTryton 150/ Benelux**</td>
<td>Sponsor</td>
<td>216†</td>
<td>6 months</td>
</tr>
<tr>
<td>eTryton Spain</td>
<td>Sponsor</td>
<td>142</td>
<td>6 months</td>
</tr>
<tr>
<td>IUVANT</td>
<td>Investigator</td>
<td>67</td>
<td>6 months</td>
</tr>
<tr>
<td>Amsterdam+</td>
<td>Investigator</td>
<td>91‡</td>
<td>6 months‡</td>
</tr>
<tr>
<td>Poznan††</td>
<td>Investigator</td>
<td>91‡</td>
<td>9 months†</td>
</tr>
<tr>
<td>Wolverhampton</td>
<td>Investigator</td>
<td>79‡</td>
<td>18 months‡</td>
</tr>
<tr>
<td>Dublin</td>
<td>Investigator</td>
<td>189</td>
<td>16 months‡</td>
</tr>
</tbody>
</table>

1. Data presented at EuroPCR 2012
** Agostoni P, Foley D, Lesiak M, et al. A prospective multicentre registry, evaluating real-world usage of the Tryton side branch stent: results of the E-Tryton 150/Benelux registry. EuroIntervention 2012. ¥ In the original publication 302 patients were included; duplicates are removed and reported as part of the Poznan and Dublin cohorts.
† Median follow-up.

Acute Coronary Syndrome: 42%

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>N=905</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>65±10</td>
</tr>
<tr>
<td>Male gender</td>
<td>76%</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>23%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>63%</td>
</tr>
<tr>
<td>Current smoker</td>
<td>20%</td>
</tr>
<tr>
<td>Previous MI</td>
<td>30%</td>
</tr>
<tr>
<td>Prior revascularization</td>
<td>40%</td>
</tr>
<tr>
<td>Indication for PCI</td>
<td></td>
</tr>
<tr>
<td>Stable Angina</td>
<td>52%</td>
</tr>
<tr>
<td>Unstable Angina</td>
<td>23%</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>13%</td>
</tr>
<tr>
<td>STEMI</td>
<td>6%</td>
</tr>
</tbody>
</table>

Complex Bifurcations: 85%

<table>
<thead>
<tr>
<th>Lesion Characteristics (visual estimate)</th>
<th>N=929</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bifurcation Location</td>
<td></td>
</tr>
<tr>
<td>Left main</td>
<td>5%</td>
</tr>
<tr>
<td>LAD / diagonal branch</td>
<td>67%</td>
</tr>
<tr>
<td>Cx / obtuse marginal</td>
<td>16%</td>
</tr>
<tr>
<td>Posterior lateral / posterior descending</td>
<td>10%</td>
</tr>
<tr>
<td>True bifurcation (Medina 1,1,1; 1,0,1; 0,1,1)</td>
<td>85%</td>
</tr>
<tr>
<td>Side branch angles</td>
<td></td>
</tr>
<tr>
<td>Narrow (&lt;30°)</td>
<td>22%</td>
</tr>
<tr>
<td>Large (&gt;30°)</td>
<td>10%</td>
</tr>
<tr>
<td>Reference vessel diameter</td>
<td></td>
</tr>
<tr>
<td>Main branch</td>
<td>3.0 [3.0-3.5]</td>
</tr>
<tr>
<td>Side branch</td>
<td>2.5 [2.5-2.7]</td>
</tr>
<tr>
<td>Lesion length</td>
<td></td>
</tr>
<tr>
<td>Main branch</td>
<td>20 [13-33]</td>
</tr>
<tr>
<td>Side branch</td>
<td>7 [4-12]</td>
</tr>
</tbody>
</table>

Device Not Approved for Sale in the US and Japan.
www.trytonmedical.com
Tryton Clinical TVF Rates Compare Favorably with Historical Data

1. Romagnoli et al. Real-world outcome of coronary bifurcation lesions in the drug-eluting stent era - Results from the SIIC-GISE I-BIGISAm Heart J. 2010  
2. Brindie et al. Outcomes and Complications With Off-Label Use of Drug-Eluting Stents: Title and Results From the STENT (Strategic Transcatheter Evaluation of New Therapies) Group JACC int. 2008  
4. Garg et al. Implantation of the SES in patients with high SYNTAX score is associated with decreased cardiac mortality compared to a permanent polymer SES: two year follow-up results from the “all-comers” LEADERS trial - Eurointervention 2011

TLR Rates of 2.9% at 6 Months and 4% at 12 Months

Tryton Clinical Results Challenge the Paradigm of Provisional Strategy

Low Thrombosis Rate of 0.5% at 6 and 12 Months

Tryton Thrombosis Rates Demonstrate its Safety Profile

Device Not Approved for Sale in the US and Japan.

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Tryton Stent Thrombosis Rates1  
Tryton Stent TLR Rates1