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[1]

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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.**

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

1. Data presented at EuroPCR 2012
* Onuma Y, Muller R, Ramcharitar S, et al. Tryton I, First-In-Man (FIM) study: six month clinical and angiographic outcome, analysis with new quantitative coronary angiography dedicated for bifurcation lesions. EuroIntervention 2008.
**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.
†† Magro M, Wykrzykowska J, Serruys PW, et al. Six-month clinical follow-up of the Tryton side branch stent for the treatment of bifurcation lesions: A two center registry analysis. Catheter Cardiovasc Interv 2011.
+M. Grundeken et al. Six-month clinical outcomes of the Tryton Side Branch Stent for the treatment of bifurcation lesions. Neth Heart J 2012 Jul 5. [Epub ahead of print]

Acute Coronary Syndrome: 42%

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

Complex Bifurcations: 85%

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

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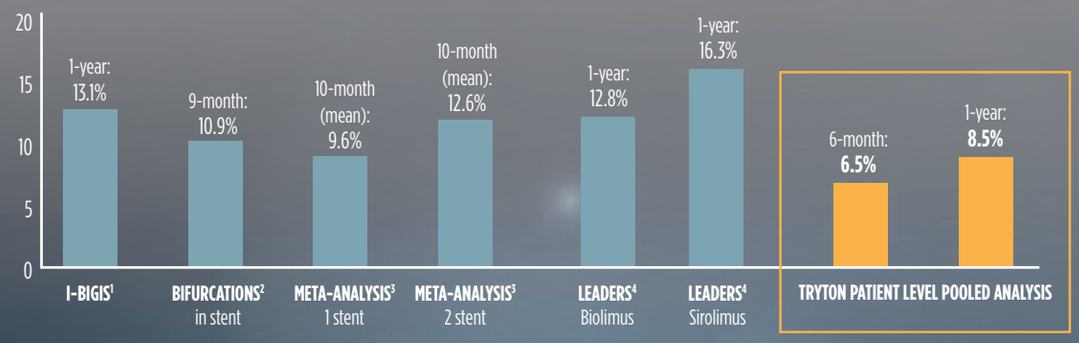
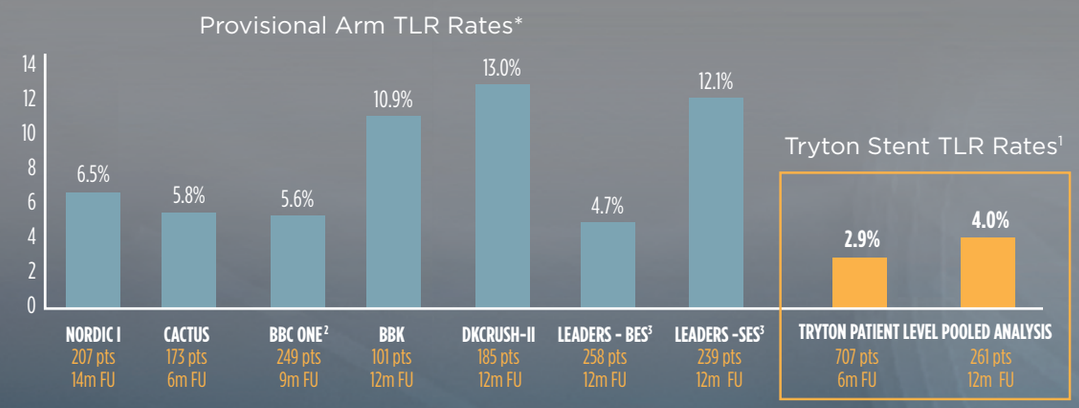
Tryton Clinical TVF Rates Compare Favorably with Historical Data



1. Romagnoli,et al. Real-world outcome of coronary bifurcation lesions in the drug-eluting stent era - Results from the SICI-GISE I-BIGISAm Heart J. 2010
2. Brodie 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
3. Hakeemet al. Provisional vs. Complex Stenting Strategy for Coronary Bifurcation Lesions: Meta-Analysis of Randomized Trials J INVASIVE CARDIOL 2009
4. Garg et al. Implantation of the BES 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

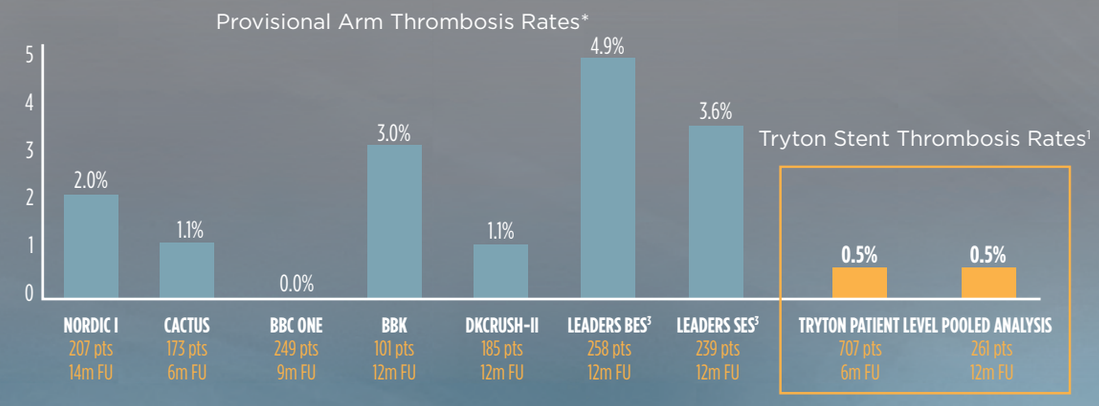
TLR Rates of 2.9% at 6 Months and 4% at 12 Months

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



1. Data presented at EuroPCR 2012. 2. TVF rate indicated. 3. Combined 1 and 2 stent strategy. *Data on File at Tryton Medical.

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