

E-TRYTON 150 & Benelux

A 'REAL-WORLD' ALL COMERS MULTICENTER REGISTRY
6 month Interim Analysis in 253 patients

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On Behalf of the e-Tryton Investigators

Disclosure Statement of Financial Interest

I, David Foley DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

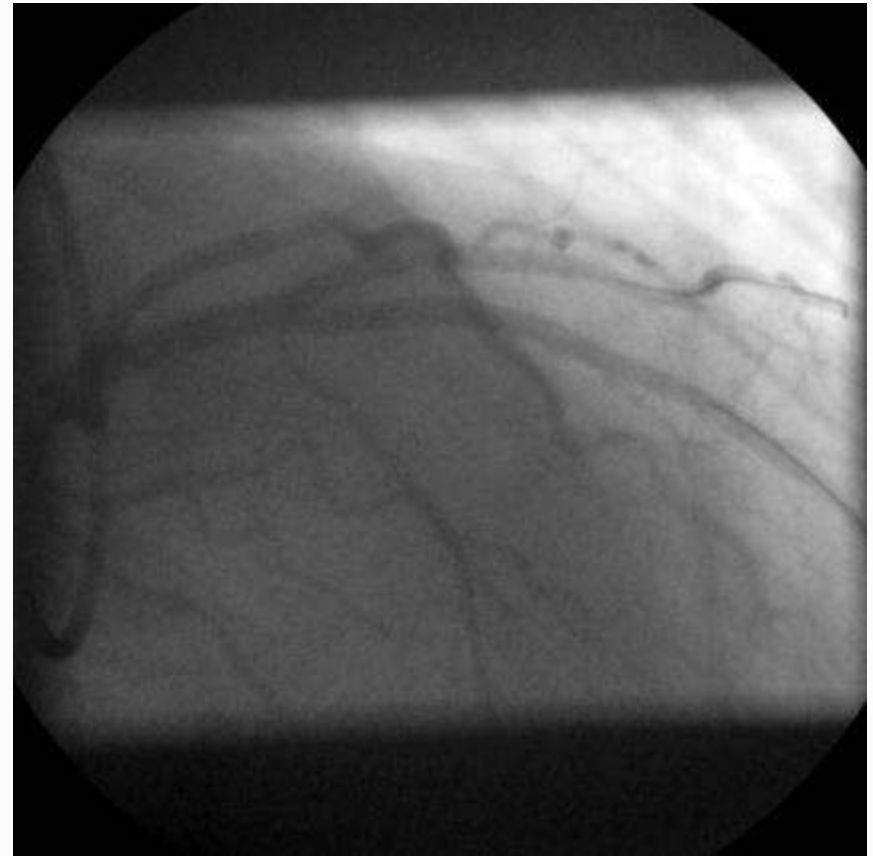
Complex LAD/D1 Bifurcation Lesion

Treated with Tryton + Promus Element

Pre



Post



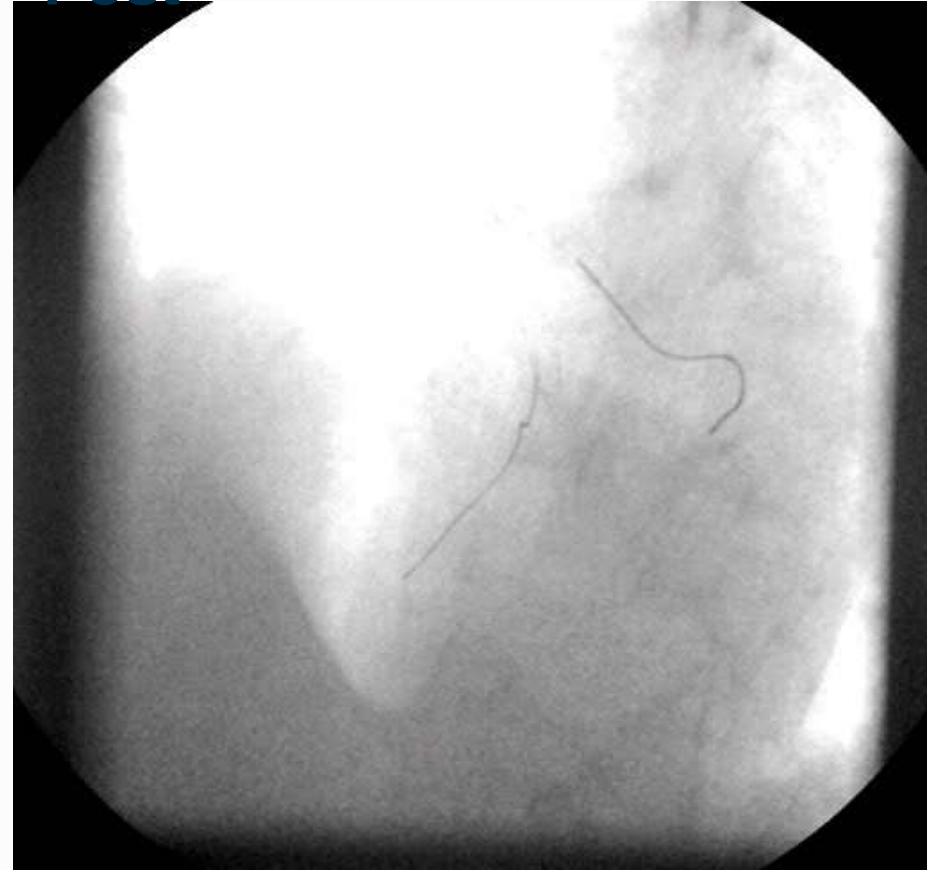
Complex LAD/D1 Bifurcation Lesion

Treated with Tryton + Biomatrix

Pre



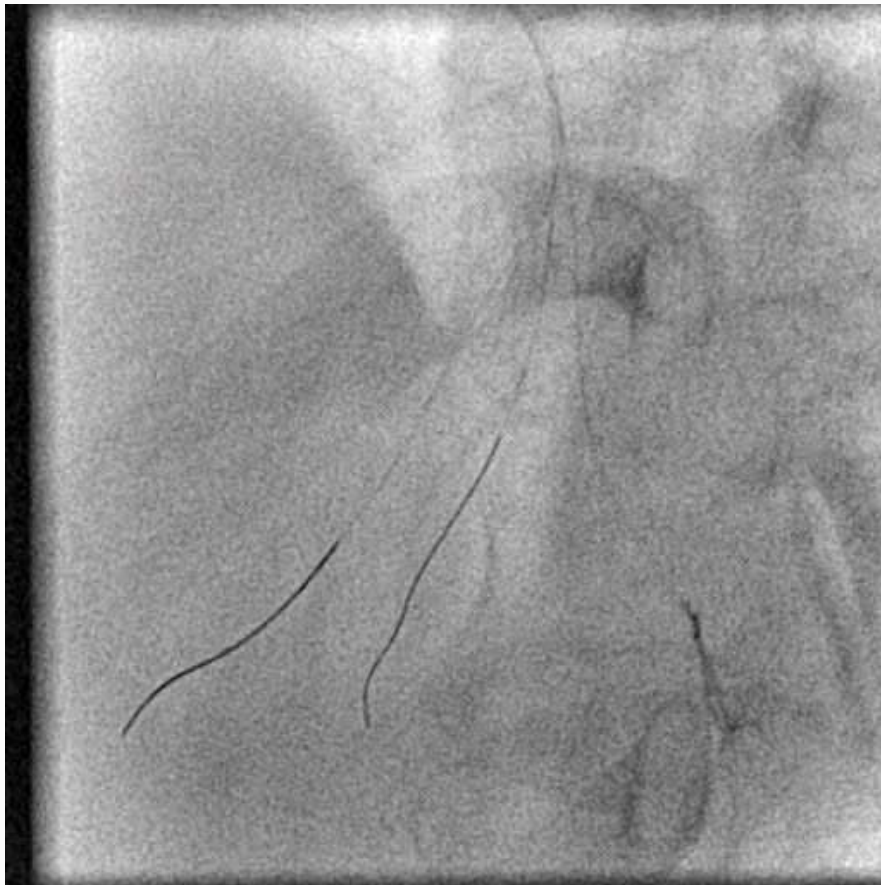
Post



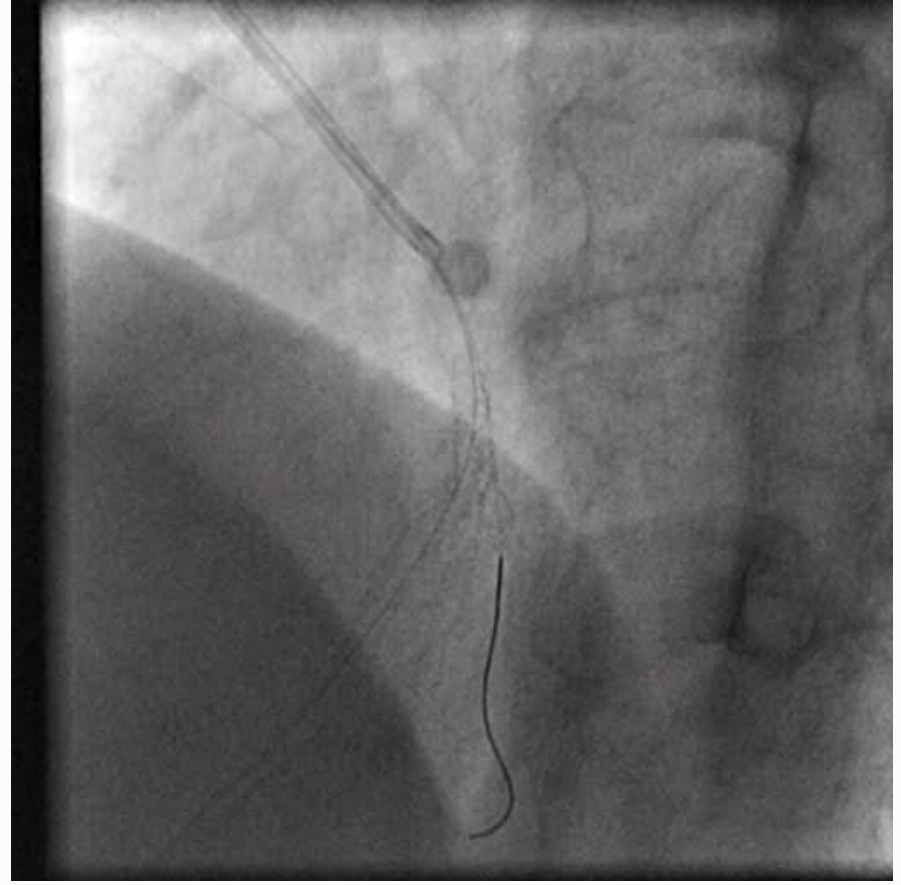
Complex LAD/D1 Trifurcation Lesion

Treated with Tryton + Xience V

Pre



Post



E-Tryton Registries

E-Tryton

E-Tryton 150
N=150
Enrollment Complete

E-Tryton Benelux
N=154
Enrollment Complete

E-Tryton Spain
(TRES) Enrollment
ongoing (60+)

E-Tryton Italy
Enrollment starting in
Sept '10

Study Objectives

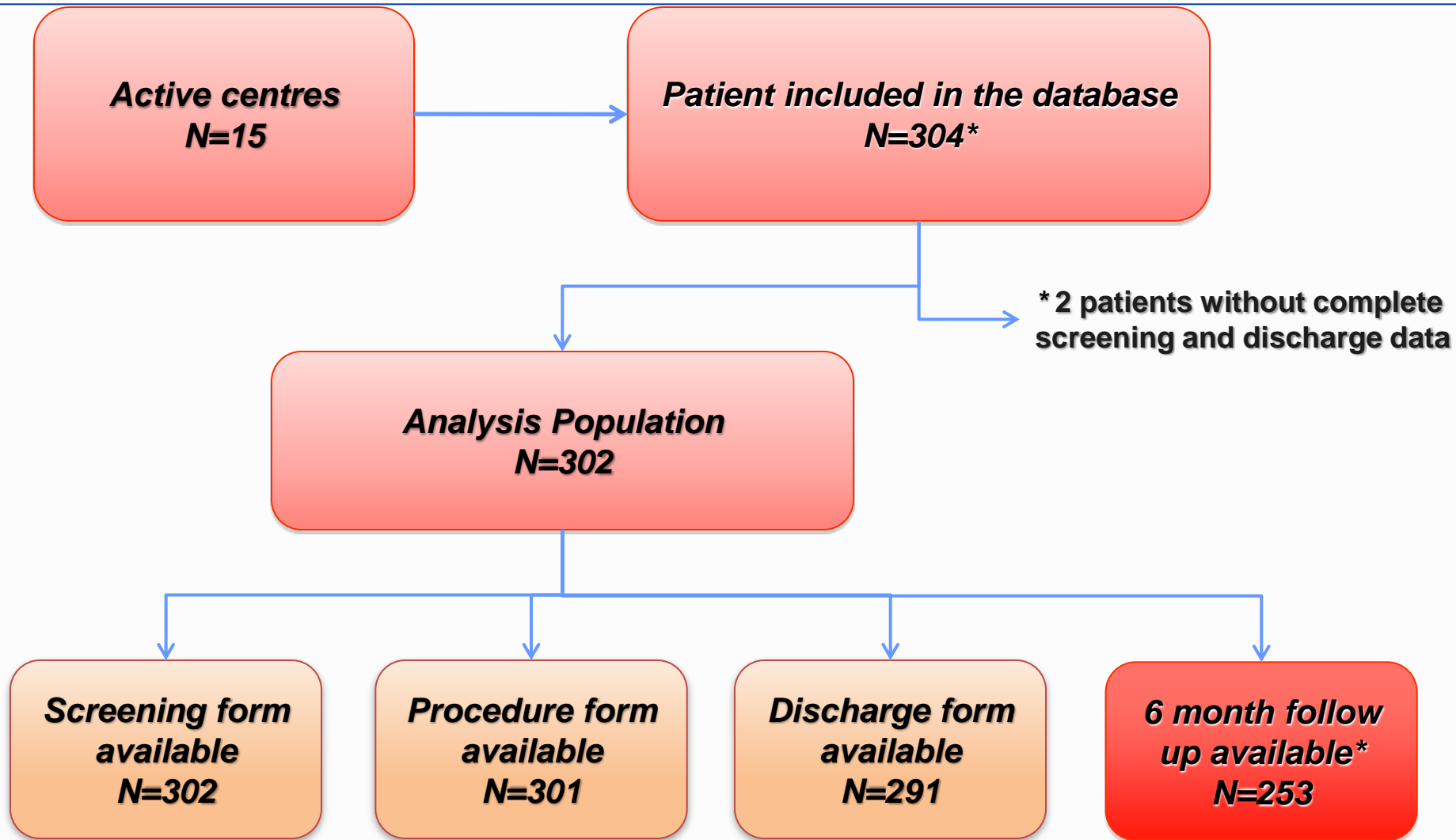
- **Primary Objective**

- **MACE (non-hierarchical) at six (6) months after the procedure.** MACE is defined as cardiac death, myocardial infarction, and target lesion revascularization (main and/or side branch).

- **Secondary Objectives**

- **Technical Success:** successful implantation of the side branch stent at the intended lesion.
- **Procedural Success:** successful implantation of the TRYTON Side Branch Stent™ and the main branch stent without in-hospital MACE.
 - 6 Month TLR
 - Hierarchical 6 Month MACE

E-TRYTON_{150 & Benelux}

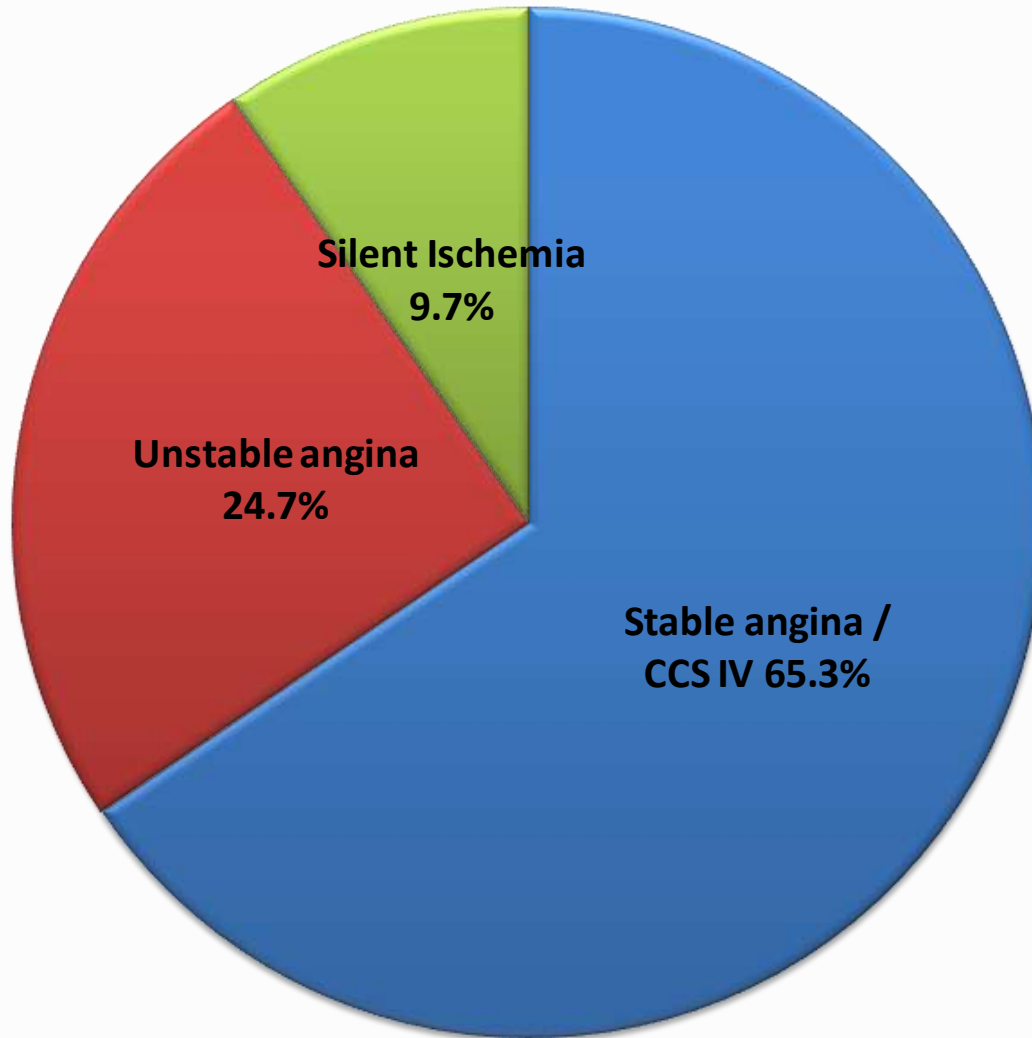


*: Follow-up still ongoing. Complete results to be presented at EBC 2010

Enrollment per Center

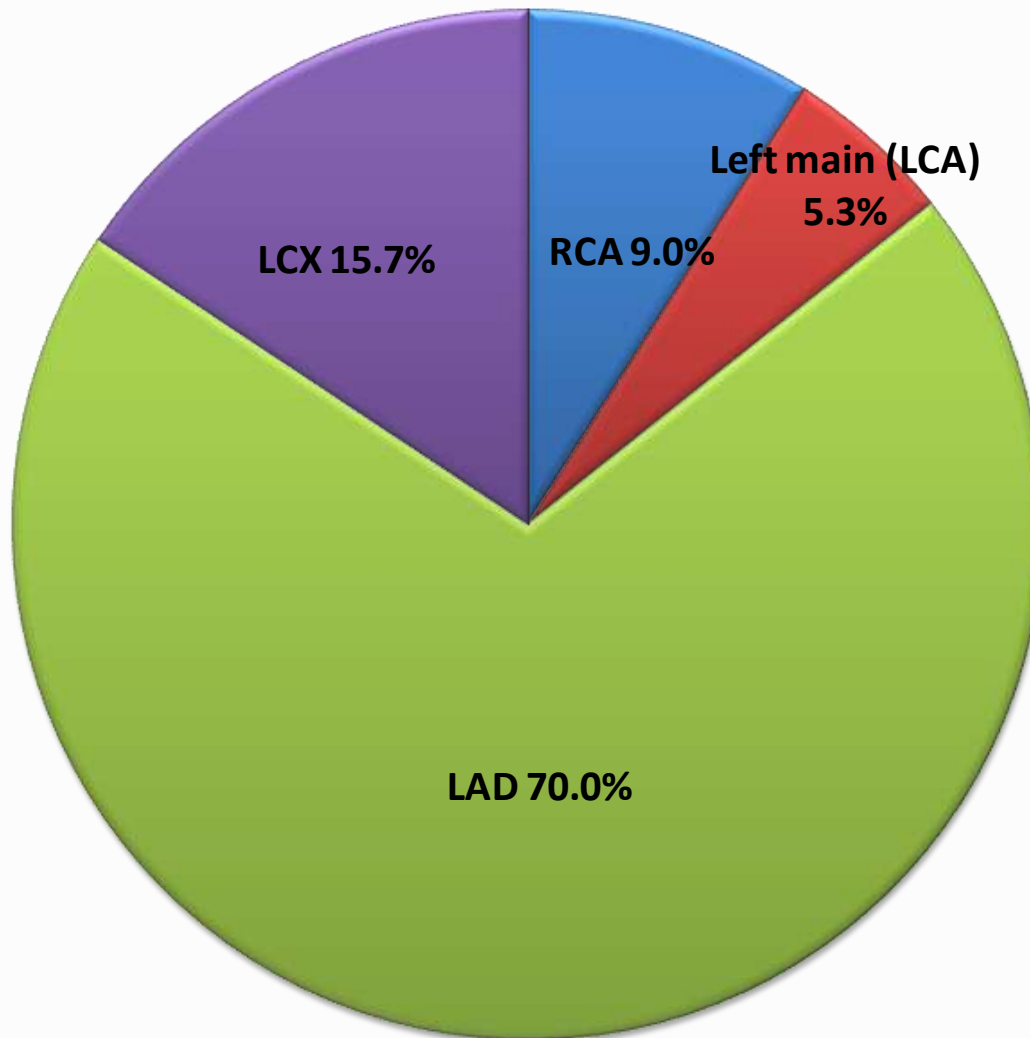
Center	Total N=302*
Utrecht – P. Stella	64 (21.2%)
Beaumont Hospital, Dublin – D. Foley	46 (15.2%)
Uni Hosp. Poznan – M. Lesiak	43 (14.2%)
ZOL Genk – J. Dens	24 (7.9%)
Riga – I. Kumsars	24 (7.9%)
UZ Brussels – B. Scott	22 (7.3%)
Den Haag – P. Oemrawsinghe & Schotborgh	19 (6.3%)
UZ Leuven – C. Dubois	17 (5.6%)
Clinico San Carlos, Madrid – E. Garcia	13 (4.3%)
Amphia Breda – P. den Heijer	11 (3.6%)
OLVZ Aalst – W. Wijns & E. Barbato	6 (2.0%)
Luxembourg – D. Wagner & P. Frambach	5 (1.7%)
Krakow – D. Dudek	4 (1.3%)
Eindhoven – J. Koolen	2 (0.7%)
Massy – T. Lefèvre	2 (0.7%)

Presentation (Ischemic Status)



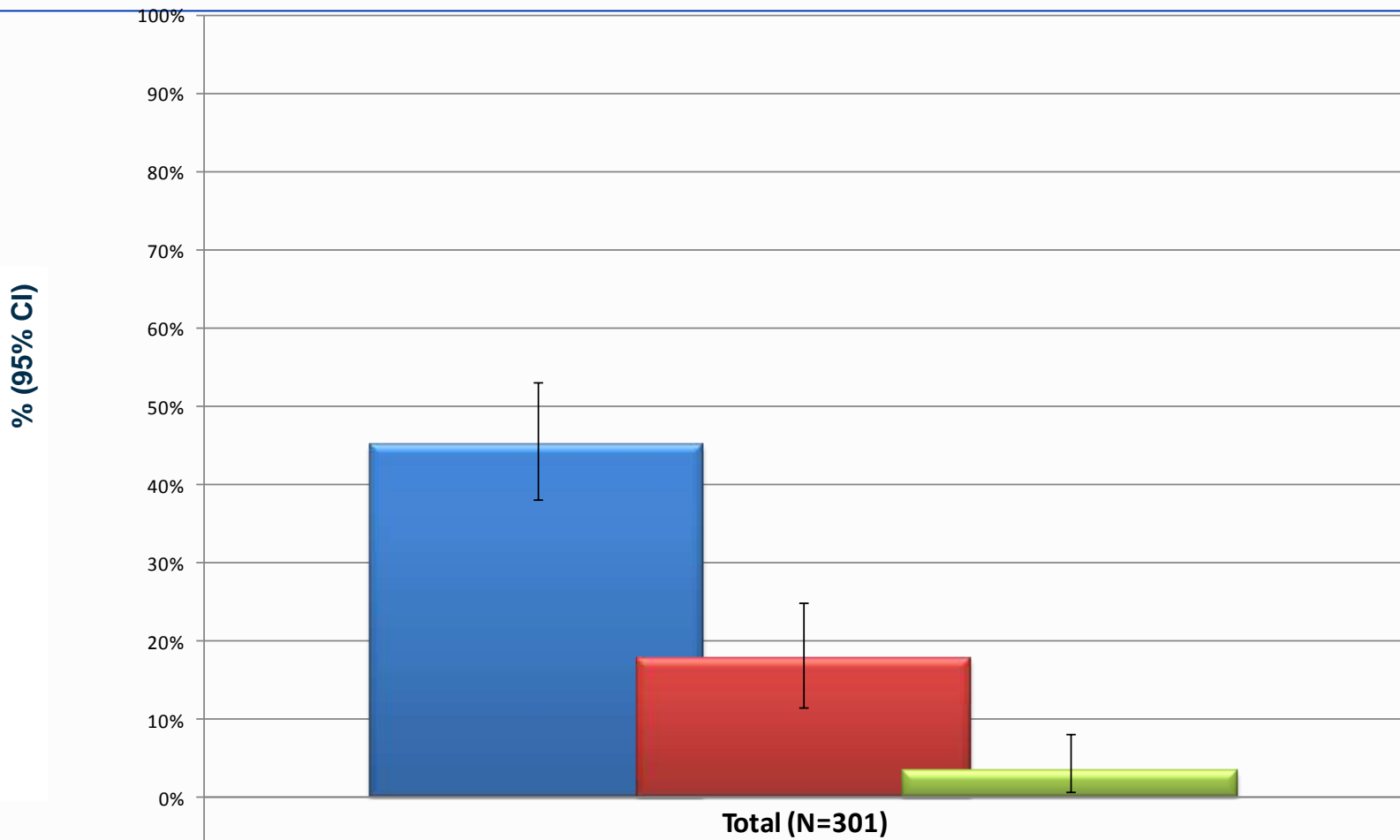
■ Stable angina / CCS IV ■ Unstable angina ■ Silent Ischemia

Lesion Distribution



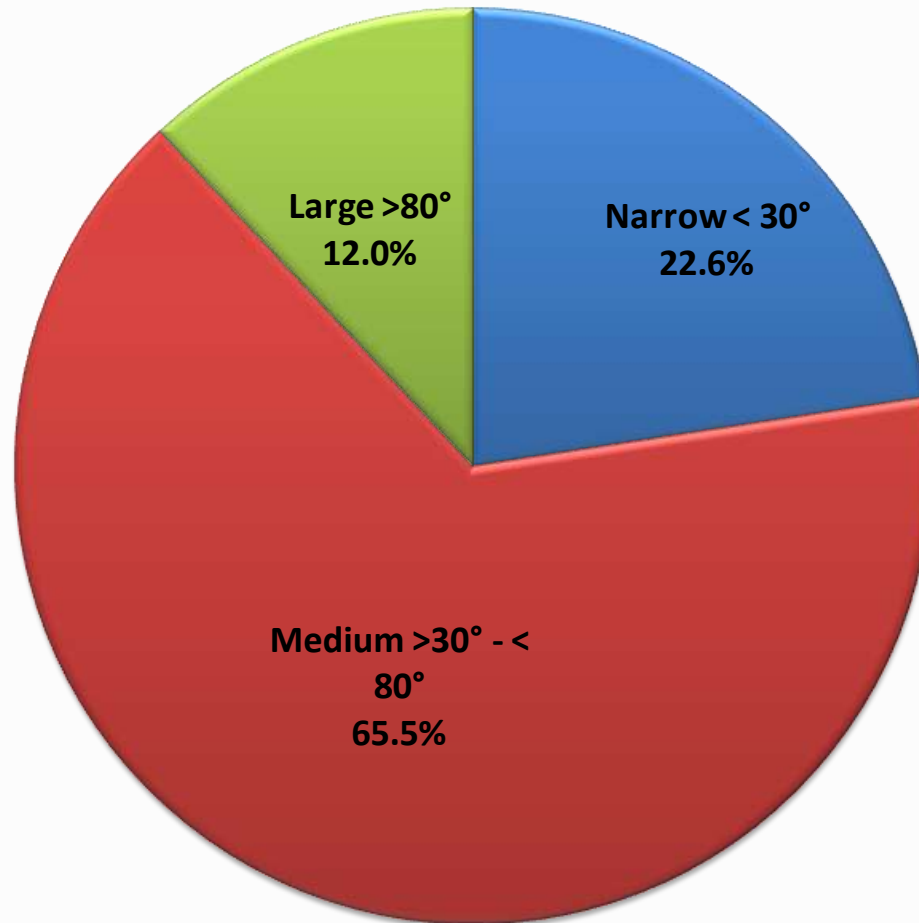
■ RCA ■ Left main (LCA) ■ LAD ■ LCX

Procedural Information: Angiographic



■ Calcification	45.2%
■ Vessel tortuosity	17.6%
■ Thrombus present	3.3%

Lesion Characteristics: Angle*



**by visual estimate*

■ Narrow < 30° ■ Medium > 30° - < 80° ■ Large > 80°

Lesion Characteristics*

Criteria		Total, N=301 mean (\pm STD)
Main vessel	Length of target lesion (mm)	18.8 (\pm 13.6)
	Reference vessel diameter (mm)	3.2 (\pm 0.4)
	Diameter stenosis pre-procedure (%)	74.0 (\pm 19.5)
Side branch	Length of target lesion (mm)	8.0 (\pm 6.8)
	Reference vessel diameter (mm)	2.6 (\pm 0.3)
	Diameter stenosis pre-procedure (%)	70.7 (\pm 24.6)

**by visual estimate*

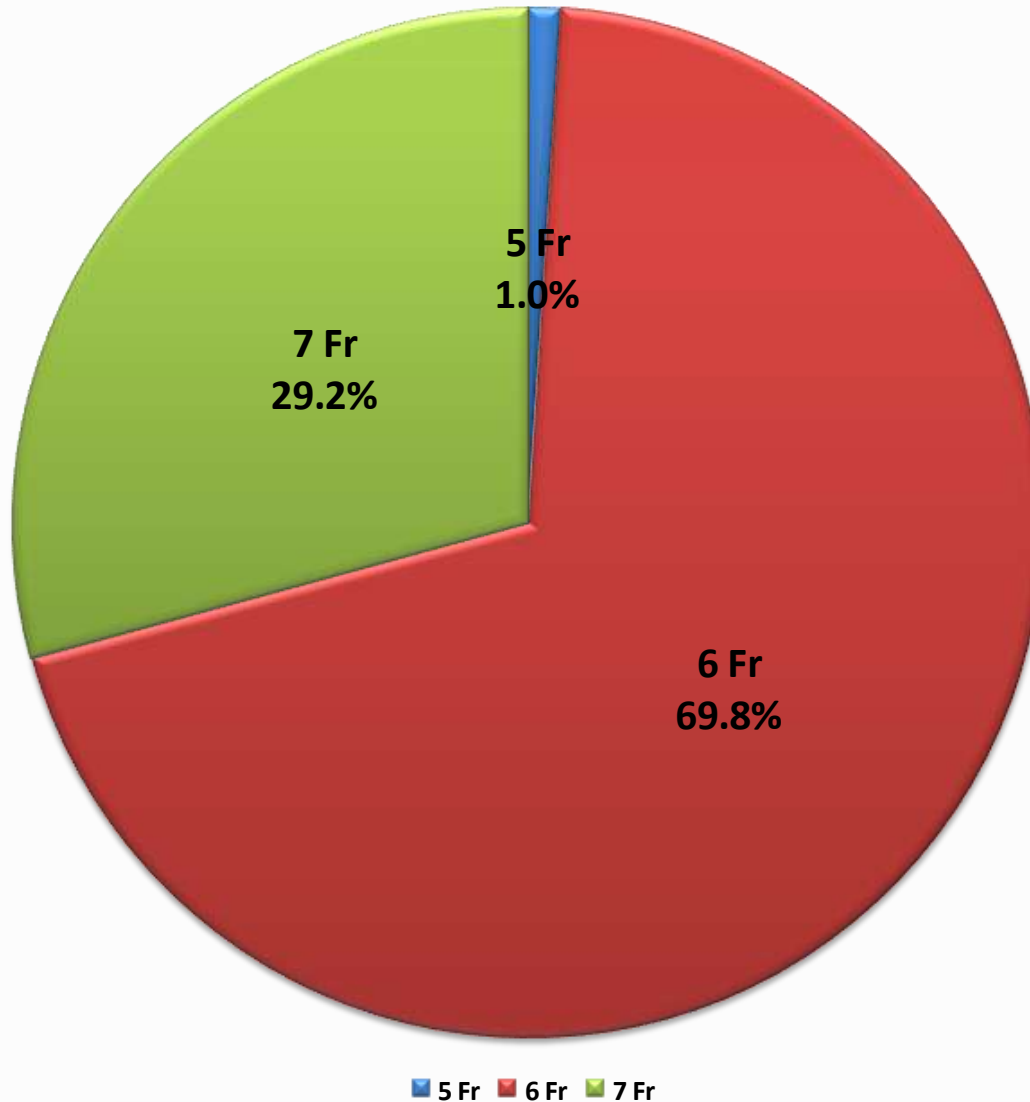
Lesion Characteristics: *Medina Classification*

Criteria	Total, N=301 N (% - 95%CI)
<i>MEDINA classification</i>	
1,1,1	191 (63%)
0,1,1	28 (9%)
1,0,1	18 (6%)
0,0,1	25 (8%)
1,1,0	18 (6%)
0,1,0	13 (4%)
1,0,0	8 (3%)

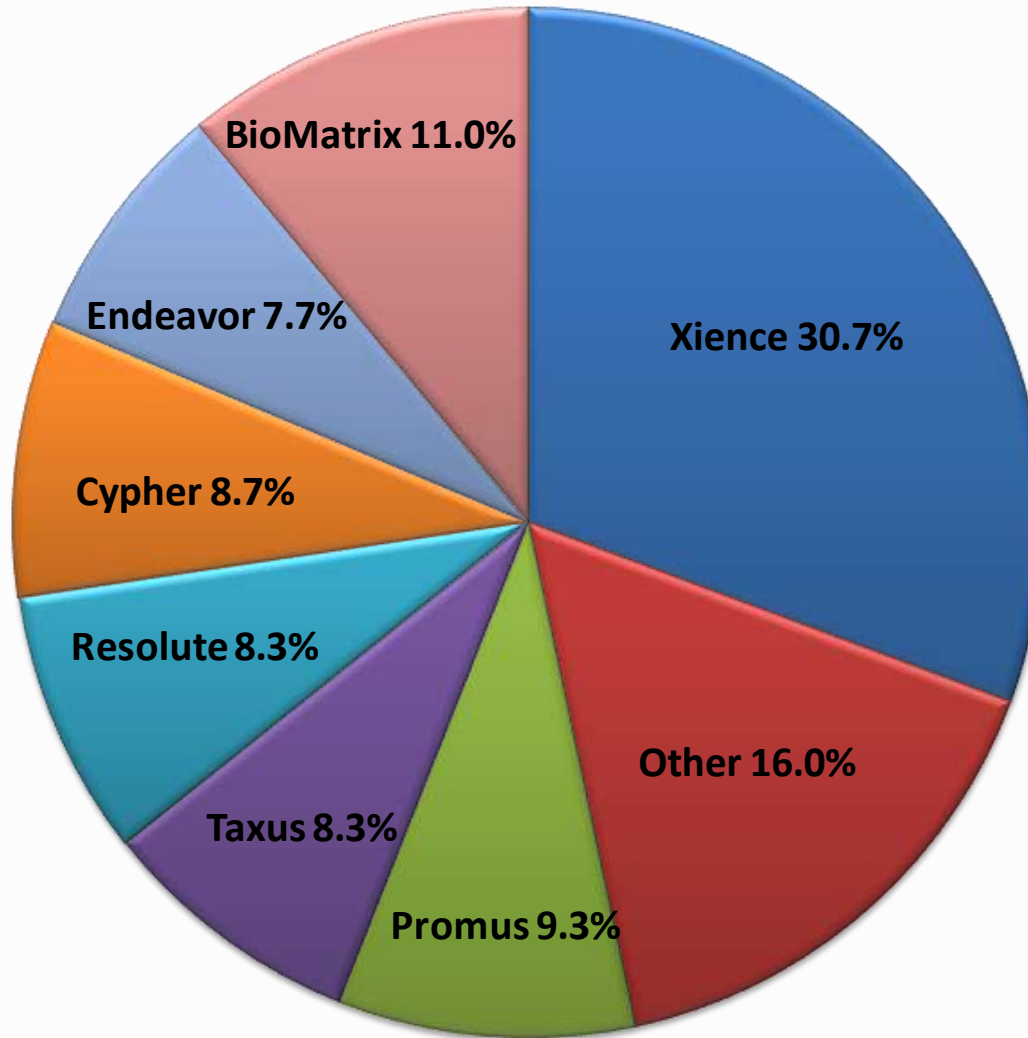
**86% with
SB disease**

Procedural Data

Guide Catheter Size



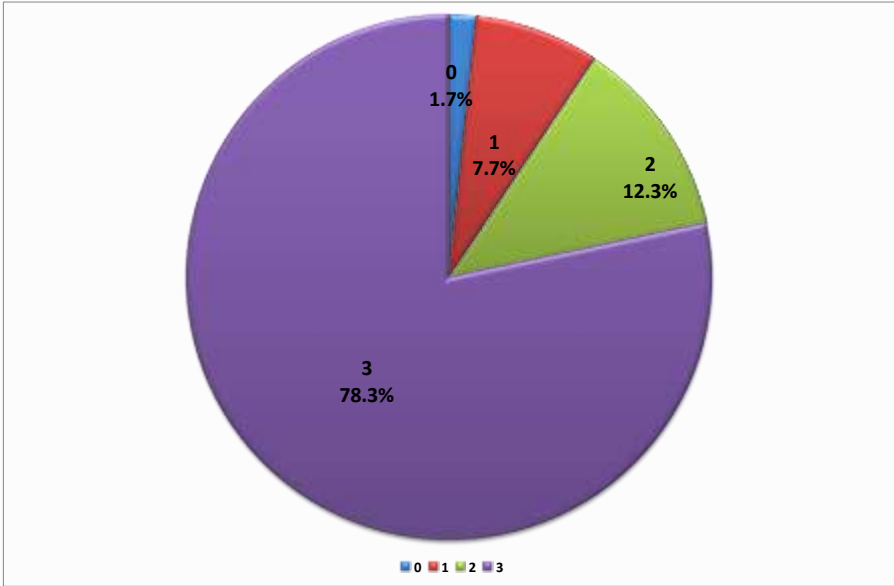
Main Branch Stents Used



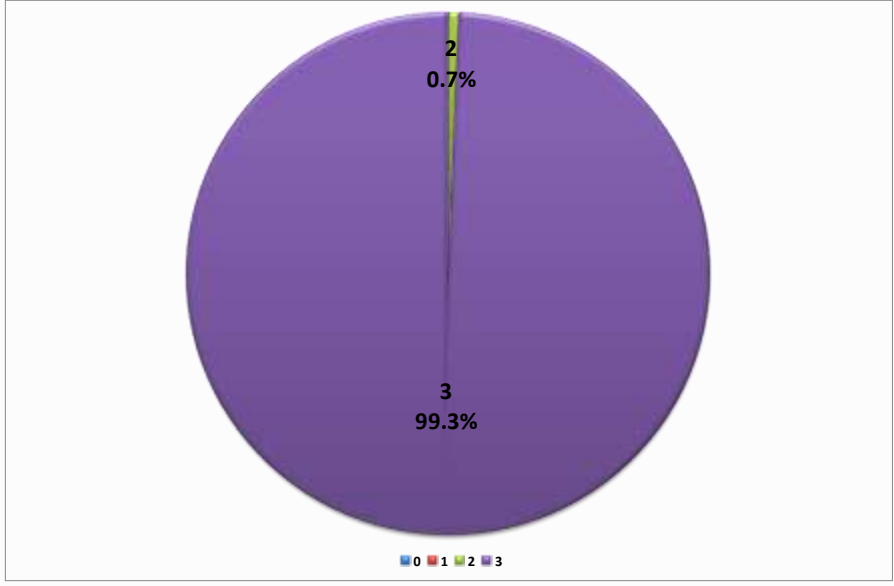
■ Xience ■ Other ■ Promus ■ Taxus ■ Resolute ■ Cypher ■ Endeavor ■ BioMatrix

TIMI Flow

Baseline



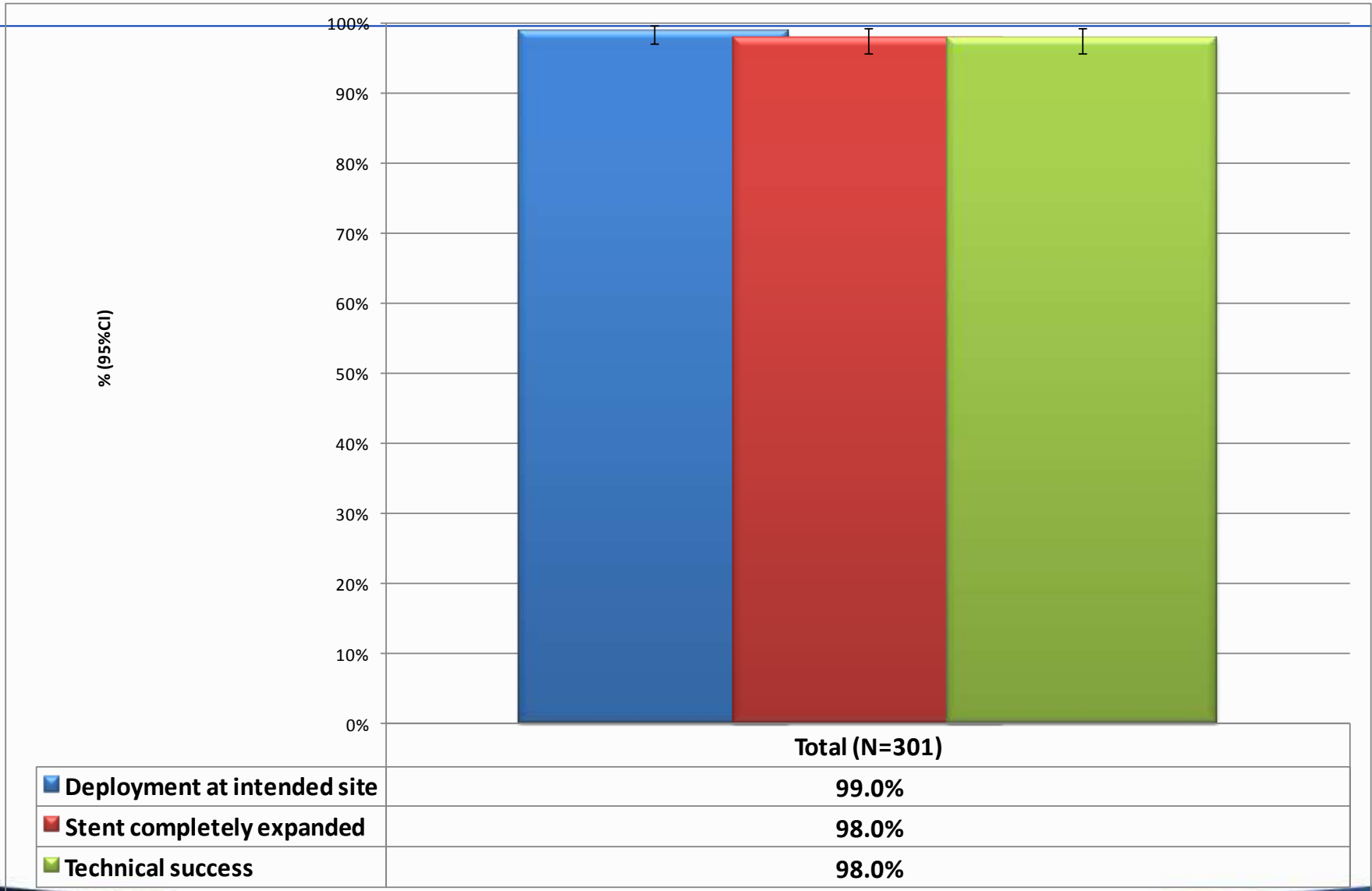
Completion



Procedural Information

Criteria	Total N=301 N (%)
Delivery Success: TRYTON stent at the intended site	298 (99.0%)
Main branch stent unable to cross and remove	0 (0.0%)
Dissection requiring additional treatment	9 (3.0%)

Procedural Success



Hospital Course

In-Hospital Complications

Criteria	Total, N=291
	N (%)
Death	0 (0.0%)
Stroke	0 (0.0%)
Myocardial infarction	4 (1.4%)
Repeat revascularization	2 (0.7%)
Bleeding	2 (0.7%)

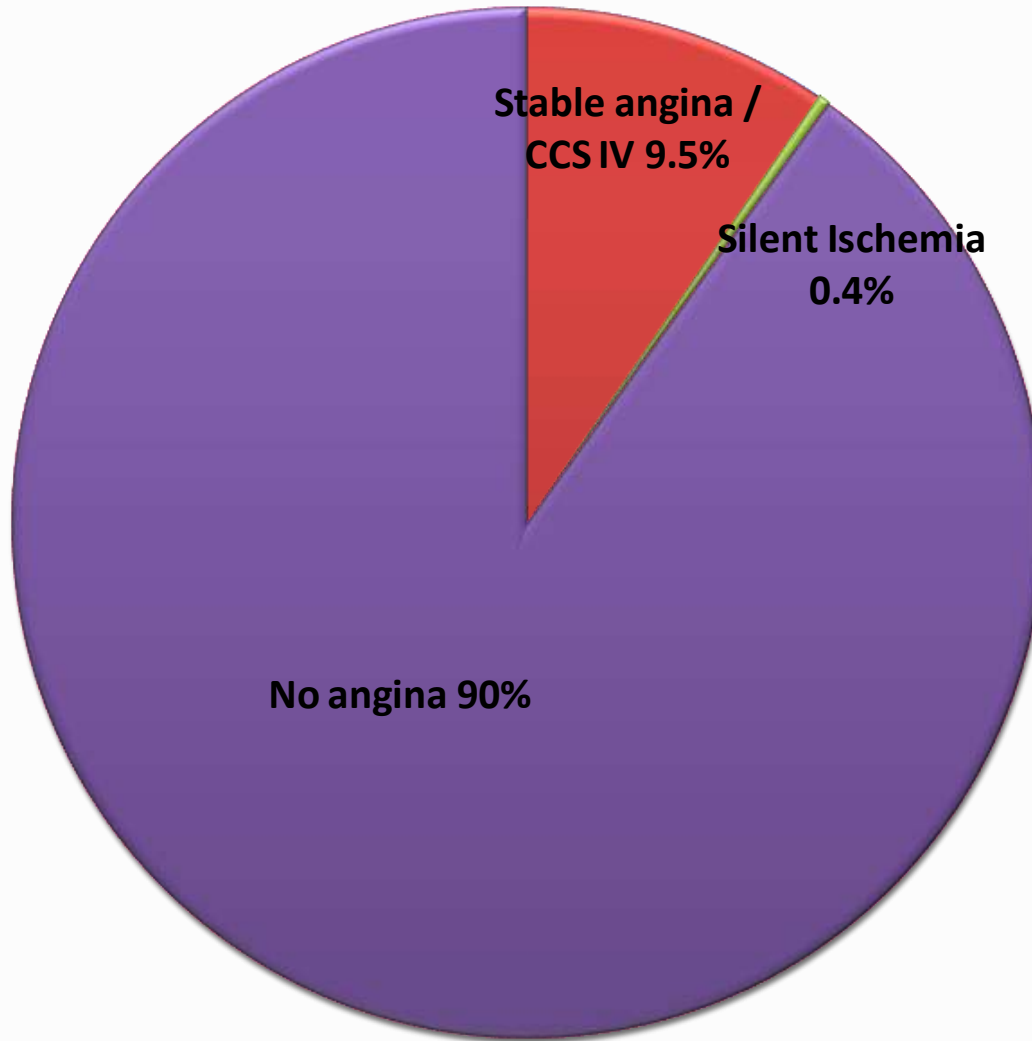
In-hospital MACE

Criteria		Total, N=283 N (%)
Hierarchical in-hospital MACE	•Cardiac death	0 (0.0%)
	•Myocardial infarction	4* (1.4%)
	•Repeat revascularization	1 (0.3%)
Procedural Success		274 (98.3%)

**All MI's occurred during the index procedure*

6 month Follow-up

6 month follow-up: Ischemic Status



■ Stable angina / CCS IV ■ Unstable angina ■ Silent Ischemia ■ No angina

MACE: Discharge to 6 month follow-up

Criteria		Total, N=253 N (%)
Hierarchical MACE	•Cardiac death	0 (0.0%)
	•Myocardial infarction (without cardiac death)	2* (0.8%)
	•Repeat revascularization on target lesion (without cardiac death and MI)	7 (2.8%)

Total TLR = 9 (3.6%) Angiographic Analysis

MB Stenosis >50% = 6 (2.4%)

SB Stenosis >50% = 3 (1.2%)

Pt #1: CPK elevation (no q wave) associated with target lesion without evidence of stent thrombosis
Pt #2: CPK elevation (no q wave) not associated with target lesion without evidence of stent thrombosis

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6 month Interim Analysis in 253 patients

Conclusions: The Tryton Side Branch Stent when used in conjunction with standard stents to treat high risk bifurcation lesions:

- **Procedure**

- Easily Integrated into Routine Practice
- High Procedural Success
- Low Complications

- **6 month Outcomes**

- No Stent Thrombosis
- Low TLR (3.6%), Low SB Failure (1.2%)
- Comparable to DES Treated Lesions

The End

THANK YOU