BIOLUX P-III
Passeo-18 Lux All-comers Registry: 12-month Results for the All-Comers Cohort

Prof. Dr. Gunnar TEPE,
Klinikum Rosenheim, Germany
CCI on behalf of the BIOLUX P-III Investigators

RoMed Klinikum Rosenheim

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Disclosure

Speaker name:**Prof. Dr. Gunnar TEPE**

I have the following potential conflicts of interest to report:

- ☐ Consulting : BIOTRONK
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☐ I do not have any potential conflict of interest

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Passeo-18 Lux Paclitaxel-Coated Balloon

Passeo-18 balloon Platform

- Controlled compliance
- Low profile
- Highly deliverable

Paclitaxel : 3 µg/mm2

Excipient: BTHC (Butyryl-tri-hexyl citrate)

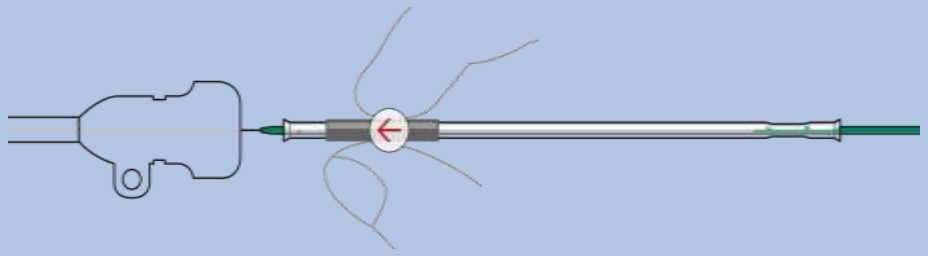
- Hydrophobic

Sizes available :

- 2.0 – 7.0 mm diameter
- 40-80-120 mm length

SAFE GUARD Insertion Aid

- Protects the user and coating from contact and damage
- Reduces drug loss due to friction within the introducer sheath
- Pre-mounted on the balloon and does not require any preparation prior to use



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Passeo-18 Lux Clinical Program

BIOLUX P-I		RCT Passeo-18 Lux vs PTA, femoro-popliteal artery (N= 60 pts)
BIOLUX P-II		RCT Passeo-18 Lux vs PTA, infra-popliteal artery (N= 72 pts)
BIOLUX P-IV		Prospective, single arm study, femoro-popliteal artery (N= 158 pts)
BIOLUX P-III		Global Prospective Registry, infra-inguinal artery (N= 882 pts)
BIOLUX P-III BENELUX		Prospective Registry, focus on isolated Popliteal Lesions (N= 100 pts)
BIOLUX P-III SPAIN		Prospective Registry, focus on Long Lesions (N= 150 pts)

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BIOLUX P-III Study Design

DESIGN:

- Prospective, global, multi-centre, Real-World All-Comers registry

STUDY GOALS:

- Further investigate Passeo-18 Lux DCB Efficacy and Safety in Infra-inguinal arteries, in a Real-World Environment

PRIMARY ENDPOINTS:

- Freedom from MAE[1] at 6 months
- Freedom from CD-TLR[2] at 12 months

(1) Major Adverse Event : Composite of device and procedure related mortality through 30 days, major target limb amputation and clinically driven target lesion revascularization (TLR). MAE are adjudicated by an independent Clinical Events Committee

(2) Clinically driven TLR is any re-intervention performed for ≥50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient

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BIOLUX P-III Study Incl./Excl. Criteria

Inclusion Criteria

- Lesion(s) in the **infra-inguinal arteries** suitable for endovascular intervention, treated with or scheduled to be treated with the Passeo-18 Lux drug coated balloon

Exclusion Criteria

- Failure to successfully cross the target lesion with a guide wire

BIOLUX P-III is **the only Real -World Registry in Infra-inguinal arteries :**

- ✓ No patient characteristic limitations
- ✓ No lesion characteristic limitations
- ✓ Use of additional devices allowed
- ✓ 47 sites, 16 countries (EU, Australia, Asia)

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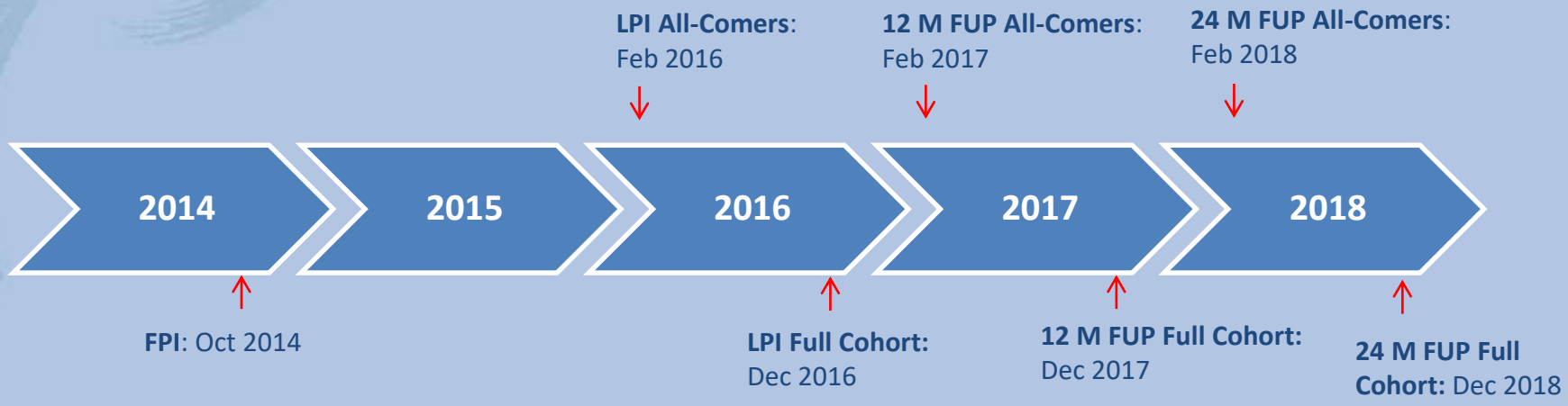
BIOLUX P-III Cohorts

All-Comers Cohort

- N= **700** Subjects
- Representative sample of consecutive subjects treated with Passeo-18 Lux DCB

Full Cohort

- N= **882** Subjects
- Enrolment was extended to complete some predefined subgroups



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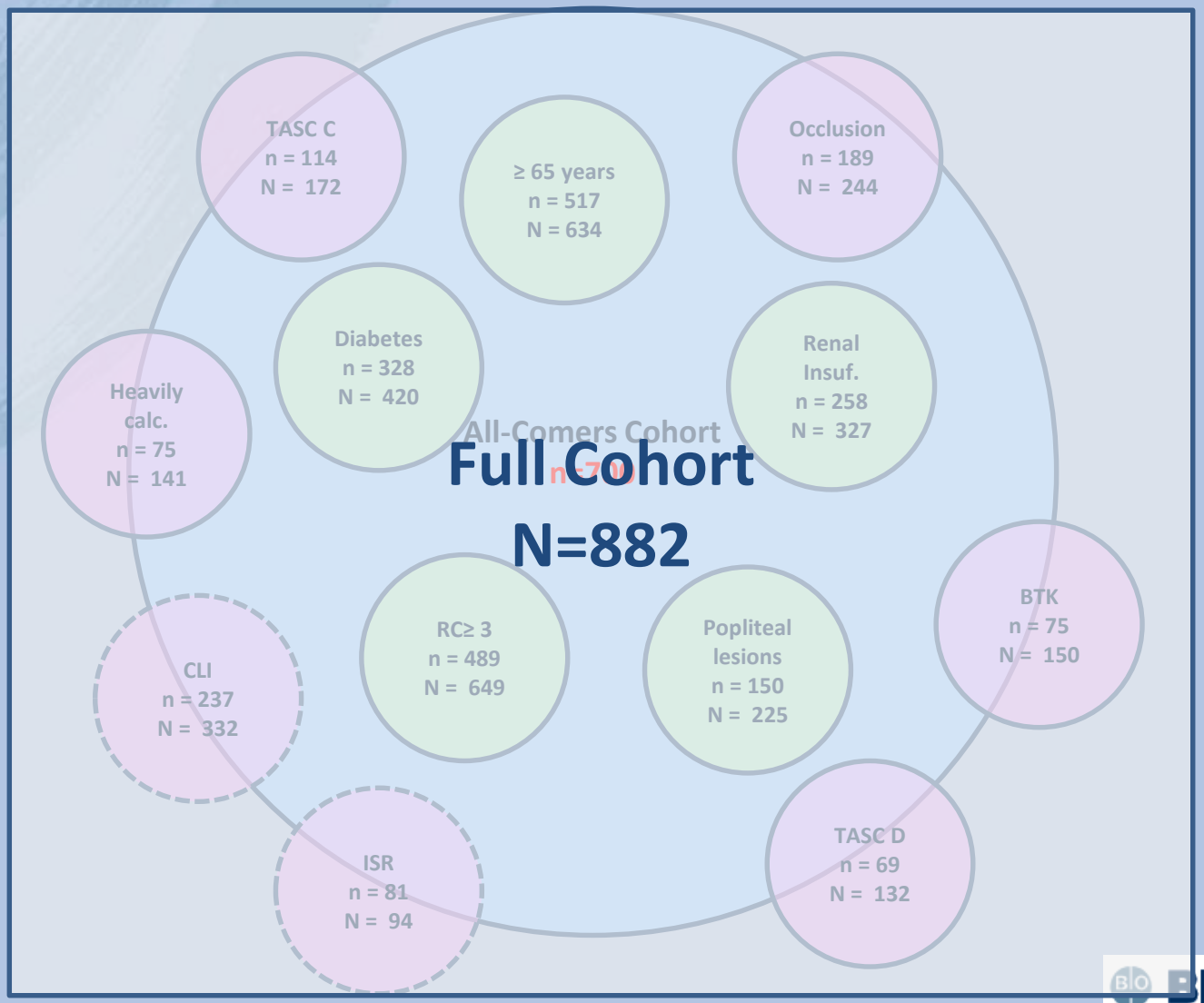
BIOLUX P-III Cohorts and Subgroups



n = # subjects from the subgroup in the All-Comers population

N = # subjects from the subgroup in the Full Cohort population

Not pre defined subgroup

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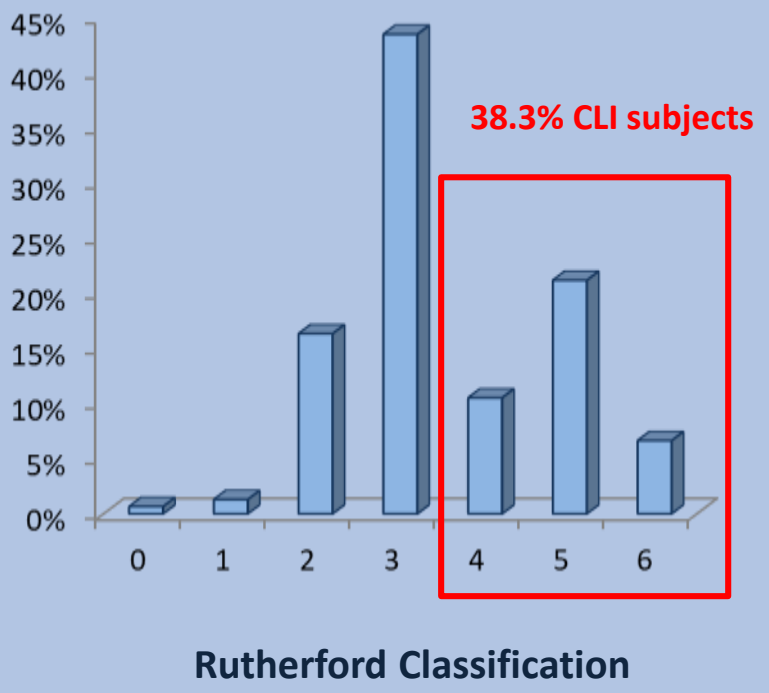
Baseline Characteristics All-Comers

# Subjects	N = 700
Age, yrs (mean ± SD)	70.0 ± 10.2
Male (n, %)	439 (62.7%)
Hypertension (n, %)	595 (85.0%)
Hyperlipidemia (n, %)	472 (67.4%)
Smoking (n, %)	483 (69.0%)
Current Smokers	*191 (39.5%)*
History of PAOD (n, %)	411 (58.7%)
Previous PVI /Surgeries (n, %)	373 (53.3%)
Diabetes (n, %)	330 (47.1%)
Coronary Artery Disease (n, %)	295 (42.1%)
Cerebrovascular Disease (n, %)	145 (20.7%)
Renal Disease (n, %)	255 (36.4%)
ABI target limb (mean± SD)	0.7 ± 0.2



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Lesion Characteristics All-Comers

Lesion Characteristics	N=864
Lesion Length, mm (mean ± SD)	84.6+/-73.3
Reference Vessel Diameter, mm (mean ± SD)	4.8+/-1.0
Diameter Stenosis (%)	86.4+/-12.9
De novo Lesion (n, %)	466 (53.9%)
Occlusion (n, %)	205 (23.7%)
In Stent Restenosis (n, %)	97 (11.2%)
Re-Stenosis (n, %)	96 (11.1%)
Calcification (n,%)	
None	216 (25.1%)
Mild	283 (32.8%)
Moderate	260 (30.2%)
Heavy	103 (11.9%)
TASC Classification (n,%)	
A	361 (42.2%)
B	269 (31.4%)
C	143 (16.7%)
D	83 (9.7%)

Lesion Location	N (%)
Common femoral	9 (1.0%)
SFA	492 (56.9%)
Popliteal artery	194 (22.5%)
ATA	37 (4.3%)
PTA	20 (2.3%)
Tibioperoneal trunc	28 (3.2%)
Peroneal artery	19 (2.2%)
Dorsalis Pedis	1 (0.1%)
Other	64 (7.4%)

- **74.9% of lesions calcified**
- **42.1% moderate to heavy calcified lesions**
- **26.4% lesions are TASC C/D**
- **12.2% BTK lesions**

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Procedure Details All-Comers

Vessel Preparation	72.5% (626/864)
Pre-dilation	64.7% (559/864)
Cutting/scoring balloon	4.2% (36/864)
Rotational thrombectomy	3.2% (28/864)
Atherectomy	1.9% (16/864)

Technical success[1]	98.6% (852/864)
Bailout Stenting	16.7% (144/864)

(1) Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation)

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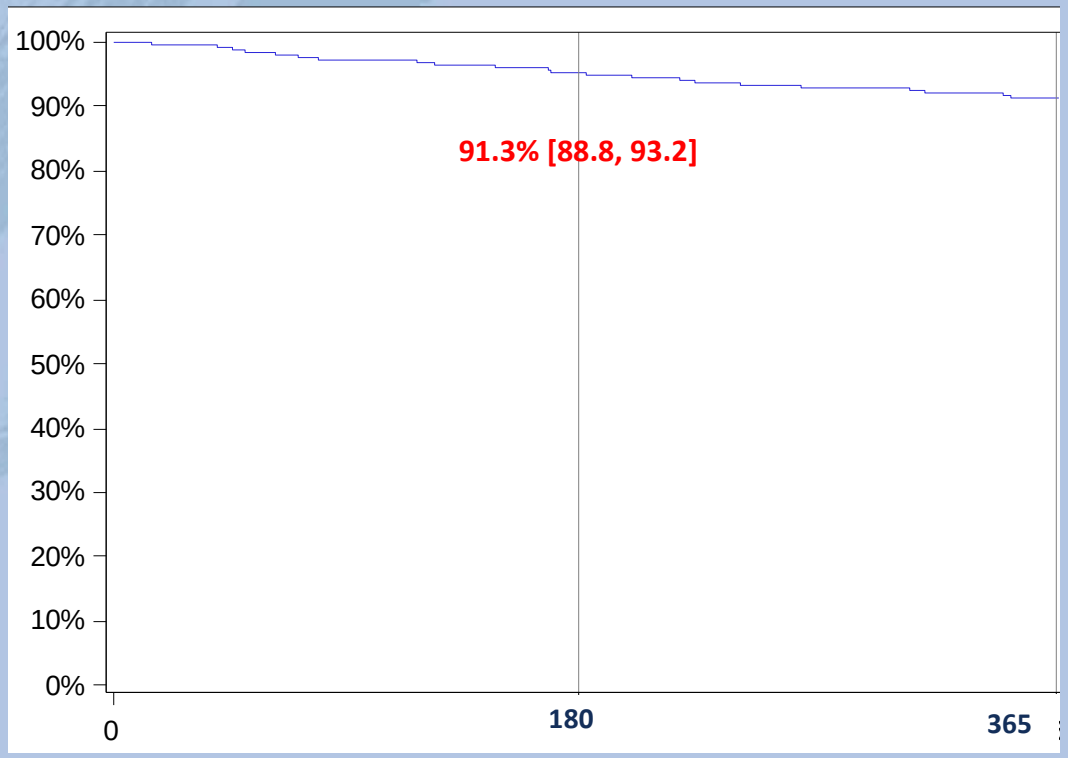
Major Adverse Events[1] All-Comers



95.3 %[93.4, 96.6]

Key Baseline Characteristics	
TASC C/D	26.4%
Calcification	74.9% (42.1% moderate/heavy)

Description	180 days	365 days
Left at risk (baseline:700)	629	526
# Events	32	57

(1) Major Adverse Event : Composite of device and procedure related mortality through 30 days, major target limb amputation and clinically driven target lesion revascularization (TLR). MAE are adjudicated by an independent Clinical Events Committee

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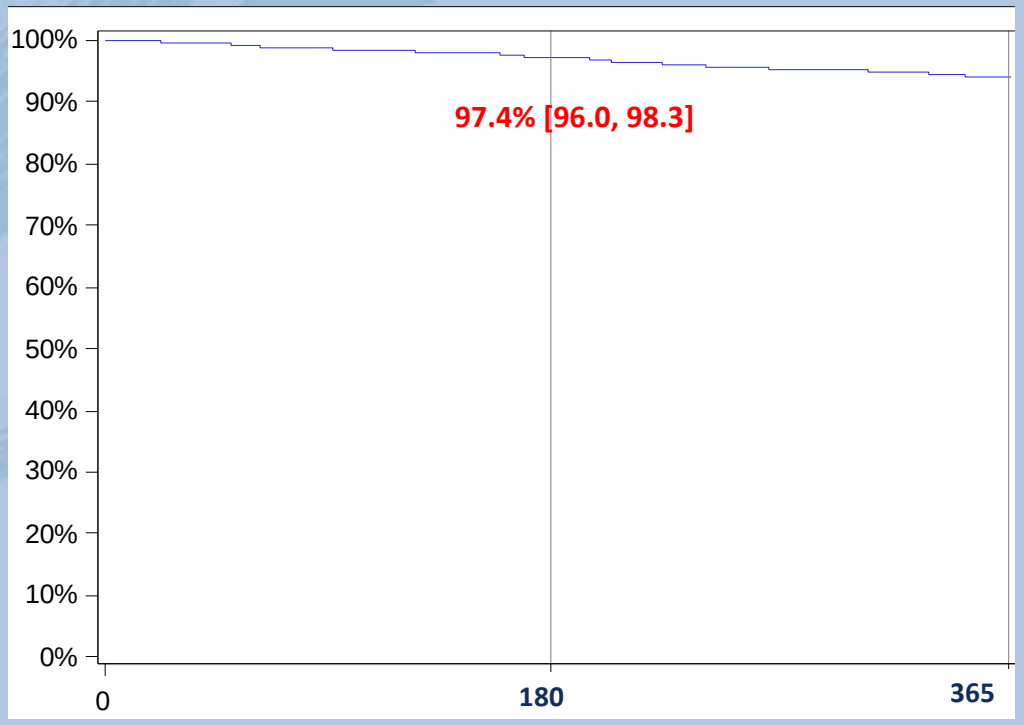
Freedom From Clinically Driven Target Lesion Revascularization[1] All-Comers



Description	180 days	365 days
Left at risk (baseline:864)	788	660
# Events	22	48

Key Baseline Characteristics	
TASC C/D	26.4%
Calcification	74.9% (42.1% moderate/heavy)

(1) Any re-intervention performed for ≥ 50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient adjudicated by an independent CEC

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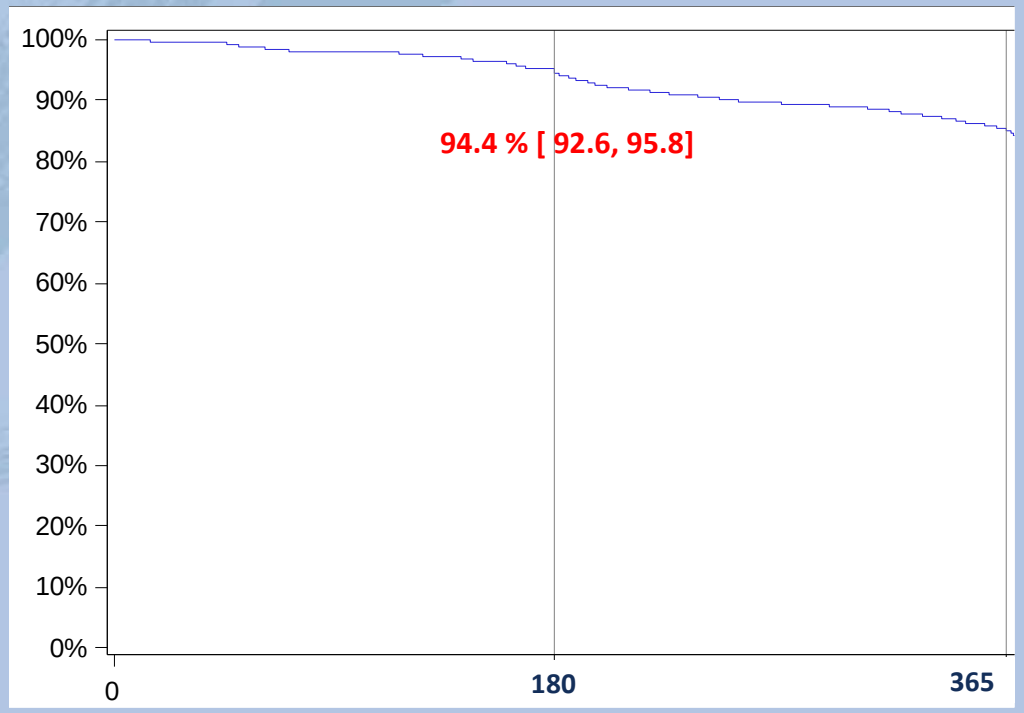
Primary Patency[1] All-Comers



Key Baseline Characteristics	
TASC C/D	26.4%
Calcification	74.9% (42.1% moderate/heavy)

Description	180 days	365 days
Left at risk (baseline:864)	764	600
# Events	46	117

(1) Defined as freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual assessment of an angiogram with no clinically driven reintervention

(2) DUS not mandated _ KM curve based on last contact date

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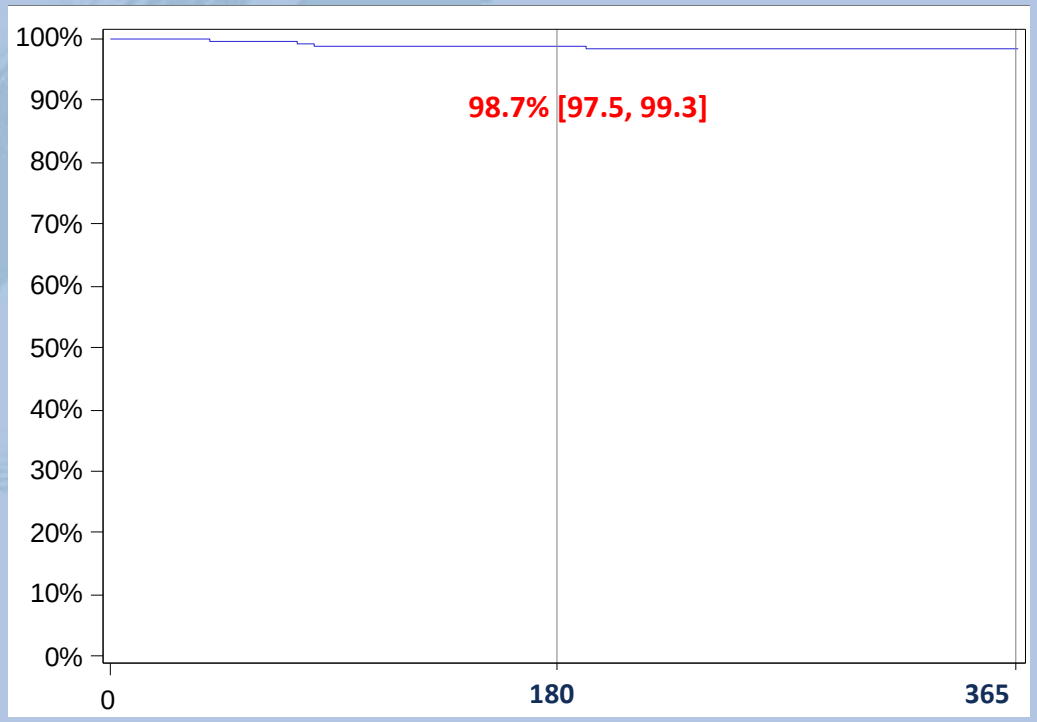
Major Amputations All-Comers



98.4% [97.1, 99.1]

Key Baseline Characteristics	
TASC C/D	26.4%
Calcification	74.9% (42.1% moderate/heavy)

Description	180 days	365 days
Left at risk (baseline:705)	655	570
# Events	9	11

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BIOLUX P-III All-Comers

Consistent Results Through Subgroups

	12-month Kaplan Meier Estimates		
BIOLUX P-III	**Freedom from cd TLR**	**Primary Patency**	**Freedom from Major target limb amputation**
All-comers	94.0% [92.1-95.4]	85.2% [82.5-87.5]	98.4% [97.1-99.1]
SFA	94.4% [91.8-96.1]	85.3% [81.6-88.2]	98.5% [96.7-99.3]
CLI	91.2% [87.1-94.1]	84.7% [79.7-88.5]	95.9% [92.3-97.9]

Illumenate Global : Schroë H. et al, Catheter Cardiovasc Interv 2017
Lutonix Global: Thieme M. et al, JACC: Cardiovascular Interventions 2017
In.Pact Global: Jaff MR, VIVA 2016

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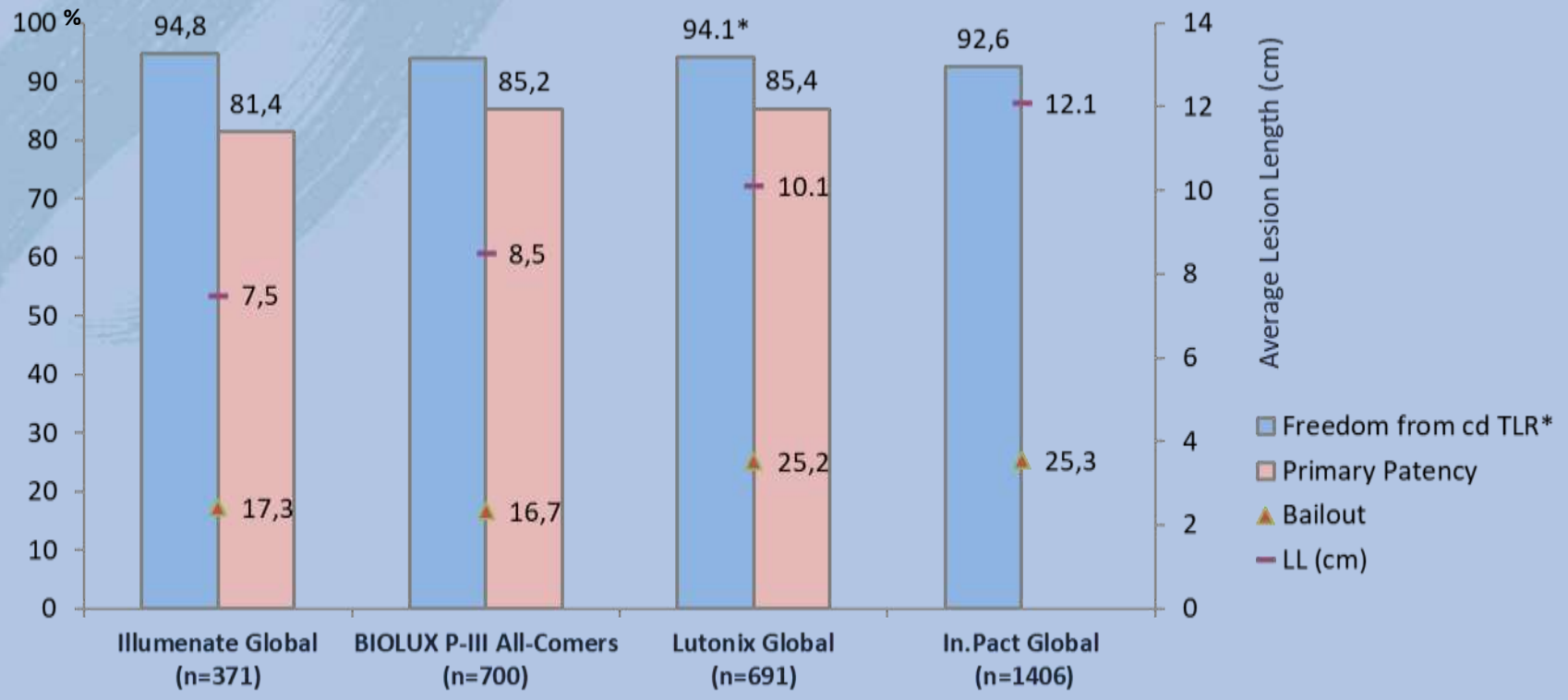
BIOLUX P-III All-Comers

Passeo-18 Lux shows comparable 12-m Outcomes in complex lesions



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Lutonix Global: Thieme M. et al, JACC: Cardiovascular Interventions 2017
In.Pact Global: Jaff MR, VIVA 2016

*Freedom from TLR
Chart for illustration purpose only

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Conclusion

- Despite almost 75% of calcified lesions, **only 16.7 % of the treated lesions required a stent**
- BIOLUX P-III 12-month outcomes confirm Passeo-18 Lux DCB safety and effectiveness in **infra-inguinal arteries** of a **700 patients** all-comers cohort:
  - **85.2% Primary Patency**
  - **94.0% Freedom from Clinically-Driven TLR**
  - **8.7% MAE**
  - **1.6% Major target limb amputations**
- The results are comparable to other global DCB registries investigating femoropopliteal arteries only
- Benefit is consistently shown in a high risk population such as CLI

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