# BIOLUX P-III

## Interim 12-month results for Superficial Femoral Artery (SFA)

## Conclusions

- BIOLUX P-III is a real all-comers registry evaluating the safety and the performance of Passeo-18 Lux Drug-Coated Balloon (DCB) in daily practice
- At 12 months the results of the first 131 SFA subjects demonstrate safety and performance comparable to the results reported in competitor global registries[1]
  - 91.8 % Freedom from Major Adverse Events (MAE)[2]
  - 94.0 % Freedom from clinically-driven Target Lesion Revascularization (cd-TLR)[3]
  - 82.1 % Primary Patency (PP)[4]
- High risk population and complex lesions subgroup analysis will reveal further insights on Passeo-18 Lux benefits in daily routine practice

## Study Design

Prospective, international, multi-center, all-comers registry investigating safety and efficacy data on the Passeo-18 Lux DCB in a real world population of subjects with atherosclerotic disease of the infrainguinal arteries in at least 700 patients

**Principal investigator**

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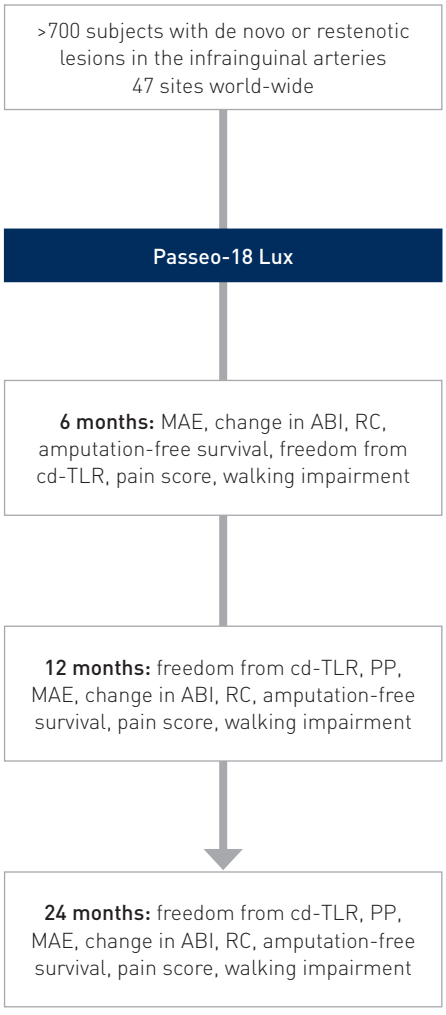


## Endpoints

**Primary endpoint**

- Clinical: Freedom from MAE at 6 months
- Performance: Freedom from cd-TLR at 12 months

**Secondary clinical endpoints (selected)**

- Technical success
- Procedural success
- Device success
- Amputation-free survival at 6, 12 and 24 months
- PP rate at 12 and 24 months
- Freedom from cd-TLR at 6 and 24 months post index procedure
- Freedom from MAE at 12 and 24 months
- Clinical success defined as an improvement of Rutherford Classification (RC) at 6, 12 and 24 months follow-up of one class or more
- Changes in Ankle Brachial Index (ABI) measurements at 6, 12 and 24 months follow-up
- Patient-reported outcomes assessment: pain score, walking impairment questionnaire at 6, 12 and 24 months compared to the pre-procedure score

## Dedicated Subgroups

Diabetes; renal insufficiency; TASC II C&D lesions; heavily calcified lesions; RC 3+; 65 yrs+; Below-The-Knee (BTK); popliteal lesions, occlusions

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## Baseline Characteristics

| | |
|---|---|
| Age, yrs (mean ± SD), [Min; Max] | 69.2 ± 10.3 [67.4 ; 70.9] |
| Male (n, %) | 82 (62.6 %) |

| Medical history | n = 131 | % |
|---|---|---|
| Hypertension | 110 | 84.0 % |
| Hyperlipidemia | 90 | 68.7 % |
| Smoking | 103 | 78.6 % |
| Current smokers | 43 | 41.7 % |
| History of PAOD | 80 | 61.1 % |
| Previous PVI / surgeries | 78 | 59.5 % |
| Diabetes | 54 | 41.2 % |
| Coronary Artery Disease (CAD) | 51 | 38.9 % |
| Cerebrovascular disease | 34 | 26.0 % |

## Lesion Characteristics

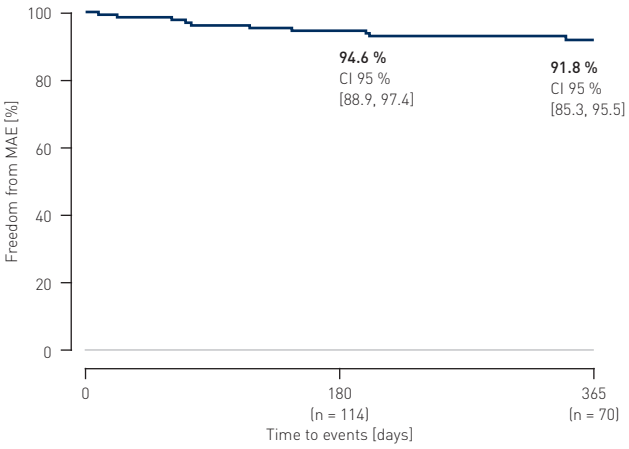
| | n = 145 | % |
|---|---|---|
| Lesion length, mm (mean ± SD) | 80.4 ± 70.7 | |
| Reference vessel diameter, mm (mean ± SD) | 5.0 ± 0.8 | |
| Diameter stenosis (%) | 86.2 ± 13.4 | |
| De novo lesion (n, %) | 73 | 50.3 % |
| Occlusion (n, %) | 32 | 22.1 % |
| In-stent restenosis (n, %) | 21 | 14.5 % |
| Restenosis (n, %) | 19 | 13.1 % |

## Procedural Details

| | n = 145 | % |
|---|---|---|
| Lesions treated with DCB only | 124 | 85.5 % |
| Lesions treated with DCB and a stent | 21 | 14.5 % |

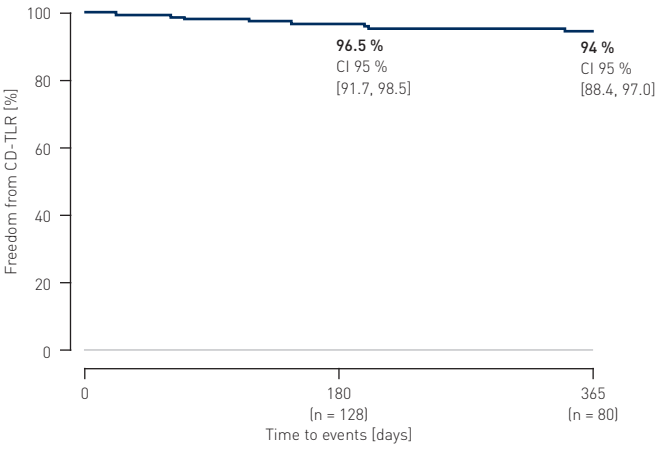
## Freedom from MAE – SFA[2, *]

(adjudicated by an independent CEC)



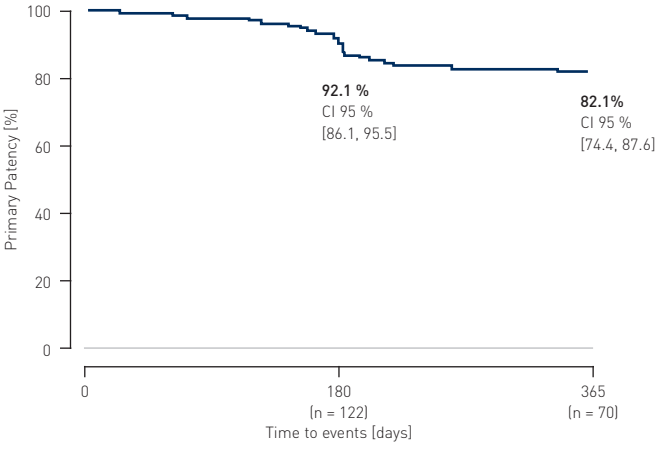

## Freedom from cd-TLR – SFA[3, **]

(adjudicated by an independent CEC)




| MAE[2, *] | n = 10 |
|---|---|
| Death (procedure or device related death within 30 days post index procedure) | 1 |
| cd-TLR | 8 |
| Target limb major amputation | 1 |

## PP – SFA[4, **]




[1] ILLUMENATE Global Registry, INPACT Global, Lutonix Global SFA Real Word Registry
[2] Major Adverse Event: Composite of device and procedure related mortality through 30 days post index procedure, major target limb amputation and clinically-driven Target Lesion Revascularization (cd-TLR). MAE are adjudicated by an independent Clinical Events Committee (CEC)
[3] Clinically-driven Target Lesion Revascularization (cd-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
[4] Primary Patency (PP) is 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
[*] Data presented by Prof. M. Brodmann at CIRSE 2016
[**] Data presented by Dr. K. Keirse at LINC 2017



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