# BIOLUX 4EVER
## 12-month results

## Conclusions

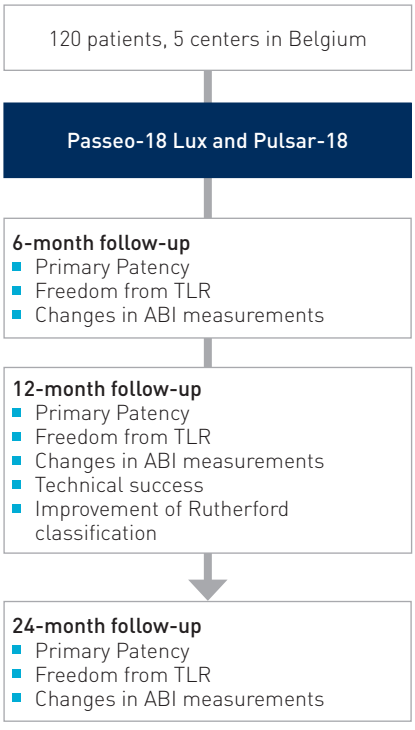
- At 12 months, results on 120 patients show Primary Patency[1] (PP) of 89.9% and Freedom from Target Lesion Revascularization (FTLR) of 93.6%
- BIOLUX 4EVER results confirms safety and efficacy of combined use of Passeo-18 Lux and Pulsar-18, offering similar outcomes compared to available drug-eluting stent data
- Combining Passeo-18 Lux DCB with low profile and low Chronic Outward Force (COF) Pulsar-18 BMS creates a win-win situation as shown in the 12 months data of BIOLUX 4EVER and confirmed in longer term DEBAS[2] results, even up to 2 years
- Results showed an increase of a PP of 8% when compared to the 4EVER[3] trial, where BMS was used on its own, confirming that there is a Paclitaxel effect by adding a DCB to a BMS

## Study Design

Investigator-initiated, prospective, multi-center, trial investigating the efficacy of endovascular treatment of femoropopliteal arterial stenotic or occlusive disease with a combination of Passeo-18 Lux DCB and the Pulsar-18 stent comparing with the 4EVER[3] trial results (stent only).

### Principal Investigator

- Dr. Marc Bosiers, A.Z. Sint-Blasius, Dendermonde, Belgium




## Endpoints

### Primary endpoint

- Primary Patency at 12 months

### Secondary clinical endpoints (selected)

- Primary Patency at 1, 6 and 24 months follow-up
- Freedom from TLR at 1, 6, 12 and 24 months follow-up
- Changes in ABI measurements at 12 and 24 months follow-up
- Technical success[4]
- Clinical success at follow-up[5]

## Patient Demographics

| | n = 120 |
|---|---|
| Male [%] | 79 (65.83%) |
| Age [min. - max.; ± SD] years | 70.87 (43.73-92.41 ± 10.52) |
| Nicotine abuse [%] | 73 (60.83%) |
| Hypertension [%] | 76 (63.34%) |
| Diabetes mellitus [%] | 23 (19.17%) |
| Renal insufficiency [%] | 15 (12.50%) |
| Hypercholesterolemia [%] | 66 (55.00%) |
| Obesity [%] | 28 (23.33%) |

## Lesion Characteristics

| | n = 120 |
|---|---|
| Left/right limb [%] | 41 (48.2%) / 44 (51.8%) |
| Lesion length [min. - max.; ± SD] mm | 83.33 mm (6.0-190; ± 49.49) |
| Reference vessel diameter [min-max; ±SD] mm | 5.26 mm (4.0-6.0; ± 0.59) |
| Occlusion [%] | 40 (33.33%) |
| Calcified lesion [%] | 60 (50.00%) |

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## Indications and Procedural Characteristics

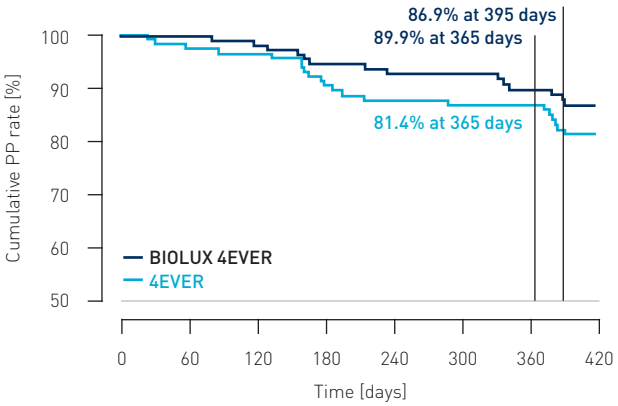
| | n = 120 |
|---|---|
| Rutherford 2 [%] | 38 [31.67%] |
| Rutherford 3 [%] | 62 [51.67%] |
| Rutherford 4 [%] | 20 [16.67%] |
| Procedure time [min-max ±SD] (min) | 48.32 [6.0-120; ± 18.57]* |
| Access side | Common femoral artery [100%] |
| Cross-over performed [%] | 100 [83.33%] |
| Scopy time [min-max ±SD] (min) | 11.37 [2.00-45.00; ± 7.08]** |
| Amount of contrast used [min-max ±SD] (cc) | 92.62 [17.00-150.00; ± 35.68][1] |

* Missing data of one patient; ** Missing data of 18 patients

### Technical success

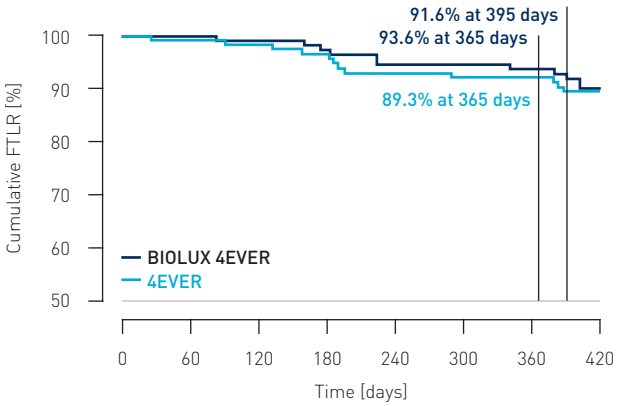
Technical success is 100%.

## 12-month Primary Patency



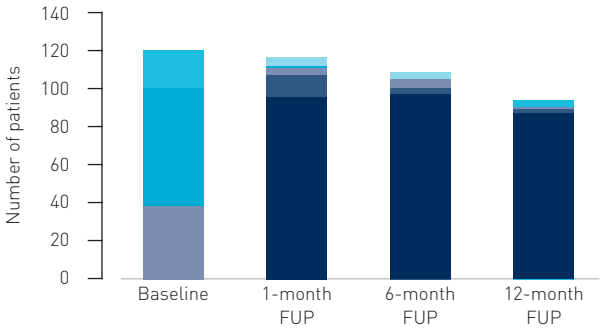

| Time [days] | Baseline | 30 | 180 | 365 | 395 |
|---|---|---|---|---|---|
| At risk | 120 | 119 | 108 | 90 | 89 |
| % | 100 | 100 | 94.7 | 89.9 | 86.9 |

## 12-month Freedom from TLR




| Time [days] | Baseline | 30 | 180 | 365 | 395 |
|---|---|---|---|---|---|
| At risk | 120 | 119 | 111 | 94 | 92 |
| % | 100 | 100 | 97.4 | 93.6 | 91.6 |

## Improvement of Rutherford Classification




| | Baseline | 1-month FUP | 6-month FUP | 12-month FUP |
|---|---|---|---|---|
| Rutherford 5 | 0 | 5 | 3 | 0 |
| Rutherford 4 | 20 | 0 | 0 | 0 |
| Rutherford 3 | 62 | 1 | 1 | 4 |
| Rutherford 2 | 38 | 4 | 3 | 1 |
| Rutherford 1 | 0 | 11 | 4 | 2 |
| Rutherford 0 | 0 | 96 | 97 | 87 |

* Source: BIOLUX 4EVER. Deloose K. DCB + Stent in the SFA: Full 12-month data of the BIOLUX 4EVER trial (365 days). Presented at Charing Cross 2017.

** 4EVER, Bosiers M, J Endovasc Ther. 2013; 20: 746–756


1 Bosiers M. 4-French–Compatible Endovascular Material Is Safe and Effective in the Treatment of Femoropopliteal Occlusive Disease: Results of the 4-EVER Trial. J Endovasc Ther. 2013; 20: 746 -756.

2 Mwipatayi P. First-in-man experience of self-expanding nitinol stents combined with drug-coated balloonin the treatment of femoropopliteal occlusive disease. Sage Journals. 2017; 0(0) 1 -9, 24-month data.

3 Defined as Freedom from >50% restenosis as indicated by an Peak Systolic Velocity Ratio (PSVR) <2.5 in the target vessel with no re-intervention

4 Defined as the ability to cross and stent the lesion to achieve residual angiographic stenosis no greater than 30% and residual stenosis less than 50% by duplex imaging

5 Defined as an improvement of Rutherford classification at 1, 6, 12 and 24 months follow-up of one class or more as compared to the pre-procedure Rutherford classification





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