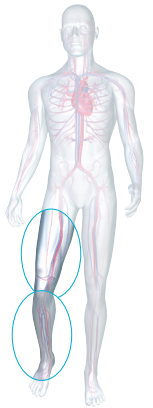


Vascular Intervention // Peripheral

# Passeo-18 Lux

Drug-Coated Balloon/0.018"/OTW  
Indicated for lower limb arteries



- Clinically proven to reduce restenosis and the need for reinterventions<sup>1</sup>
- Lux coating technology optimizes drug transfer for maximized efficacy
- Low profile, highly deliverable Passeo-18 balloon platform
- Innovative SafeGuard insertion aid for unrivaled safety and ease of handling

<sup>1</sup> BIOLUX P-I and BIOLUX P-II Randomized Clinical Trials

# Passeo-18 Lux

Passeo-18 Lux drug-coated balloon – an advanced therapy to expand conventional PAD treatment options – **proven to inhibit restenosis while maintaining a high safety profile.**

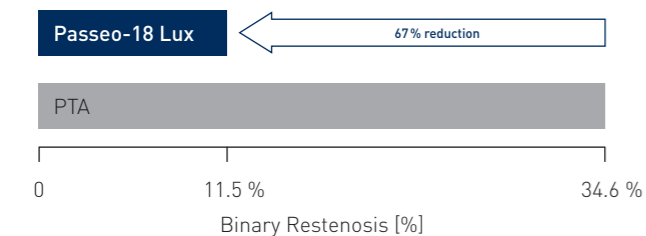
## Safe and effective

Robust, high quality clinical data demonstrate Passeo-18 Lux safety and efficacy in the treatment of femoropopliteal and infrapopliteal arteries.

### BIOLUX P-II<sup>2,3</sup> Femoropopliteal Indication

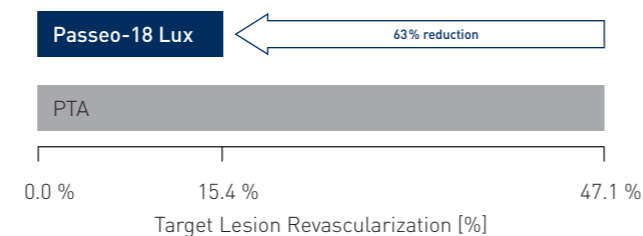
#### 6-month Binary Restenosis

Passeo-18 Lux significantly reduced Binary Restenosis compared to the control PTA balloon (p = 0.048<sup>3</sup>).



#### 12-month Target Lesion Revascularization<sup>4</sup>

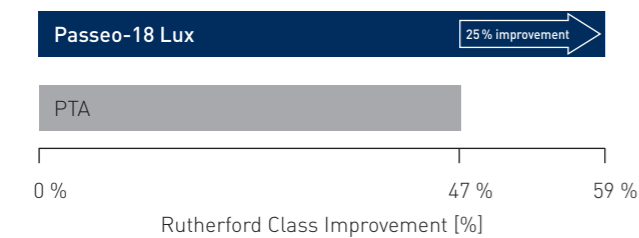
Passeo-18 Lux significantly reduced Target Lesion Revascularization rates compared to the control PTA balloon (p = 0.020<sup>3</sup>).



### BIOLUX P-II<sup>3,5</sup> Infrapopliteal Indication

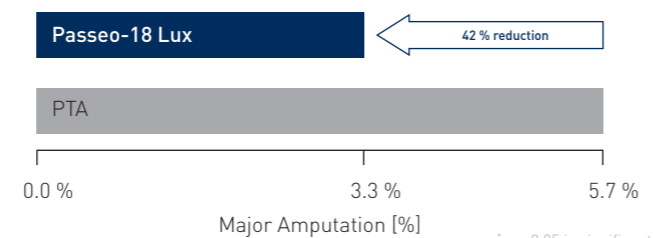
#### 6-month change in Rutherford Class

Passeo-18 Lux improved Rutherford Class compared to the control PTA balloon.



#### 12-month Major Amputation

Passeo-18 Lux Major Amputation rate was lower compared to the control PTA balloon. In the DCB group, it was 3.3% at 6 months and no additional amputation occurred after 180 days.



\* p < 0.05 is significant

<sup>2</sup> Scheinert D, et al. BIOLUX P-I. JEVT. 2015; 22(1): 14-21.

<sup>3</sup> Selected endpoints

<sup>4</sup> As-Treated population

<sup>5</sup> Zeller et al. BIOLUX P-II. J Am Coll Cardiol Intv. 2015; 8: 1614-22.

# Proven technologies combined

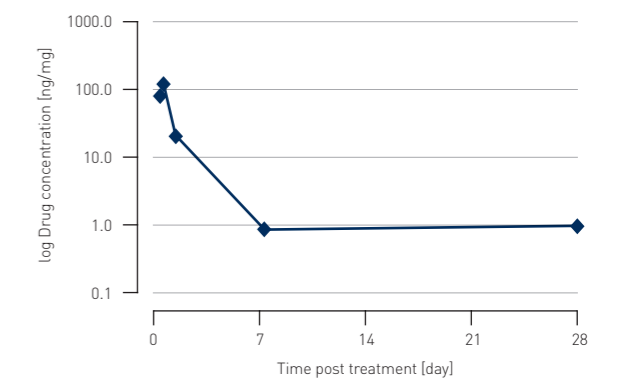
## Optimized coating formulation

The Lux coating technology provides an optimal delivery mechanism, ensuring minimal drug loss during tracking and inflation, rapid drug transfer to the vessel wall and a sustained therapeutic effect.<sup>6</sup>

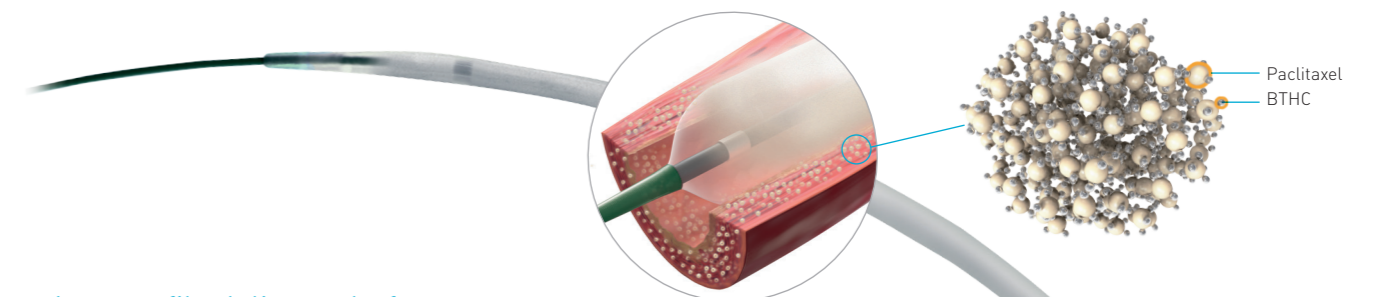
- **Drug:** 3 µg/mm<sup>2</sup> paclitaxel anti-proliferative agent
- **Excipient:** butyryl-tri-hexyl citrate (BTHC) hydrophobic carrier improves coating integrity so that more drug is available at the lesion site. Safe and biocompatible.
- **Coating process:** homogeneous balloon coating shelters drug within the balloon folds and ensures drug transfer to the entire region treated.

Pharmacokinetics (PK) measurements demonstrate high tissue concentration of paclitaxel and sustained therapeutic effect<sup>6</sup>

Paclitaxel vessel concentrations



Structure of paclitaxel and BTHC matrix



## Low profile delivery platform

Passeo-18 Lux is part of BIOTRONIK 4F solutions. It is based on the Passeo-18 low profile balloon platform, thus minimizing the risk of access site complications<sup>7</sup> and improving lesion crossing performance.

## SafeGuard – Improved and safer handling

SafeGuard insertion aid improves ease of handling and protects the user and balloon coating from contact and damage. It is pre-mounted on the balloon and after use, it can simply be peeled away.



<sup>6</sup> Pre-clinical data on file at BIOTRONIK AG

<sup>7</sup> Bosiers M, et al. 4-French-Compatible Endovascular Material Is Safe and Effective in the Treatment of Femoropopliteal Occlusive Disease. Results of the 4EVER Trial. J Endovasc Ther. 2013; 20(6): 746-756.

# Passeo-18 Lux – Drug-Coated Balloon

Technical Data		Drug-coated balloon	
Catheter type		OTW	
Recommended guide wire		0.018"	
Tip		Short, tapered	
Balloon markers		2 swaged markers (zero profile)	
Shaft		3.8F, hydrophobic coated	
Usable length		90, 130 cm; 150 cm (only ø 2.0 mm)	
Introducer size		4F (ø 2.0 - 4.0 mm); 5F (ø 5.0 - 7.0 mm)	
Nominal Pressure (NP)		6 atm	
Rated Burst Pressure (RBP)		15 atm (ø 2.0 - 5.0 mm); 12 atm (ø 6.0 - 7.0 mm)	
		Coating	
Drug		Paclitaxel	
Drug concentration		3.0 µg/mm <sup>2</sup>	
Coating matrix		Paclitaxel and butyryl-tri-hexyl citrate (BTHC)	
Coated area		Cylindrical section of the balloon, exceeding the proximal and distal markers	

Compliance Chart		Balloon diameter x length (mm)						
		ø 2.0 x 40-120	ø 2.5 x 40-120	ø 3.0 x 40-120	ø 4.0 x 40-120	ø 5.0 x 40-120	ø 6.0 x 40-120	ø 7.0 x 40-120
Nominal Pressure (NP)	atm*	6	6	6	6	6	6	6
	ø (mm)	2.0	2.5	3.0	4.0	5.0	6.0	7.0
Rated Burst Pressure (RBP)	atm*	15	15	15	15	15	12	12
	ø (mm)	2.1	2.6	3.3	4.3	5.2	6.3	7.2

\* 1 atm = 1.013 bar

Ordering Information		Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm)		
				40	80	120
4F	90	2.0	379860	379861	379862	
	90	2.5	379866	379867	379868	
	90	3.0	370843	370848	370853	
	90	4.0	370844	370849	370854	
	90	5.0	370845	370850	370855	
5F	90	6.0	370846	370851	370856	
	90	7.0	370847	370852	370857	
	150	2.0	379863	379864	379865	
4F	130	2.5	379869	379870	379871	
	130	3.0	370858	370863	370868	
	130	4.0	370859	370864	370869	
	130	5.0	370860	370865	370870	
5F	130	6.0	370861	370866	370871	
	130	7.0	370862	370867	370872	

Passeo-18 Lux is part of the BIOTRONIK  Solutions portfolio, including:

- Introducer Sheath: **Fortress** ■ Guide Wires: **Cruiser, Cruiser-18** ■ Balloons: **Passeo-14, Passeo-18**
- Stents: **Pulsar-18, PRO-Kinetic Energy Explorer**

For ordering please contact your local sales representative

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