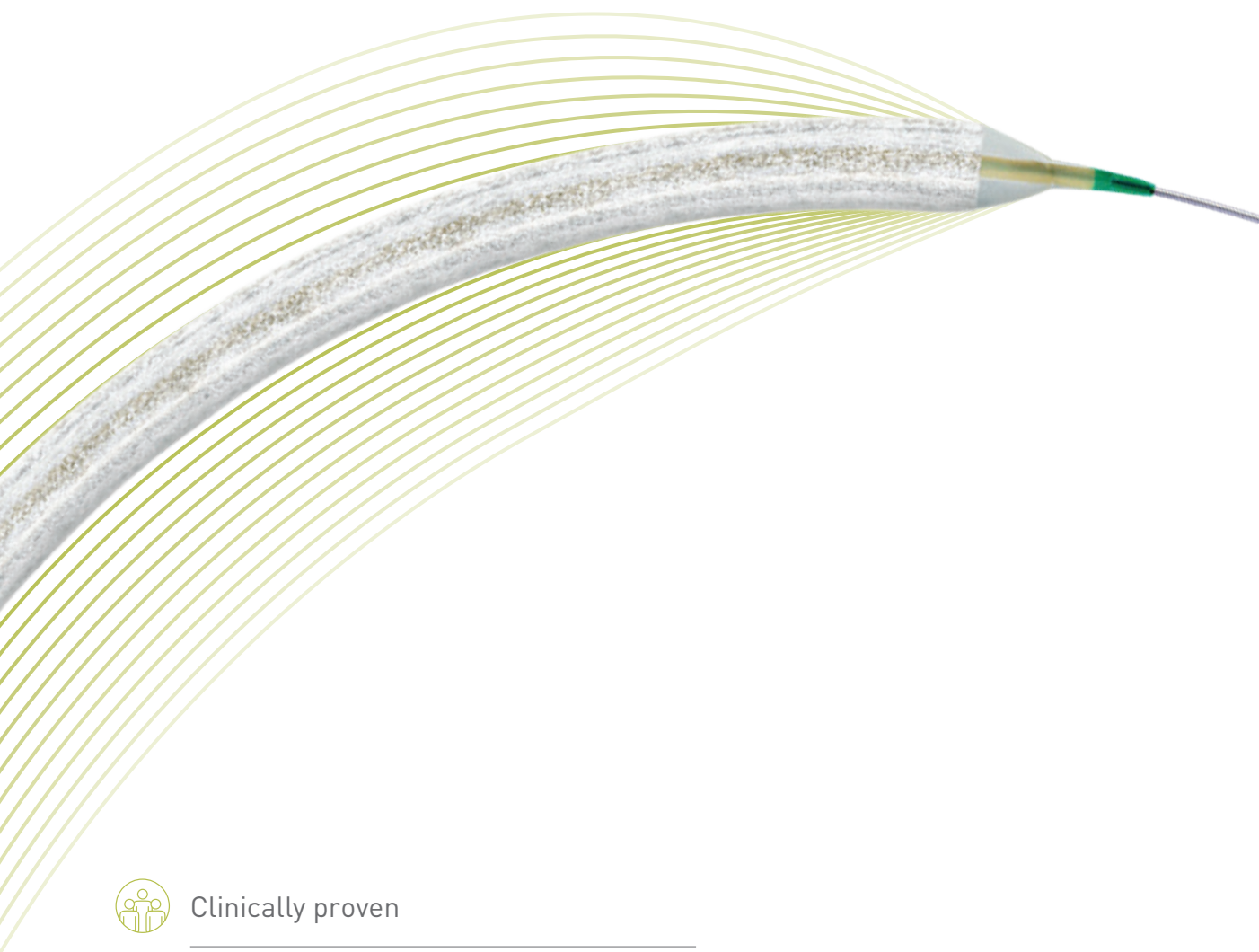


Vascular Intervention // **Peripheral**
Drug-Coated Balloon Catheter /0.018"/OTW

Passeo[®]-18 Lux[®]

Clinically proven results in challenging patient groups



Clinically proven



For challenging patient groups



Effective drug delivery



BIOTRONIK
excellence for life

Passeo-18 Lux

Clinically proven drug-coated balloon (DCB) in challenging patient groups with effective drug delivery.

Clinically proven

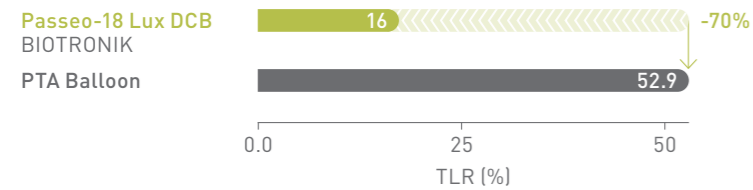
Randomized controlled trials and all-comers registries have investigated safety and efficacy in the treatment of over 1,900 patients with peripheral artery disease (PAD) in the femoropopliteal and infrapopliteal arteries.

Safe and effective

BIOLUX P-I RCT¹ Femoropopliteal Indication

12-month Target Lesion Revascularization (TLR)

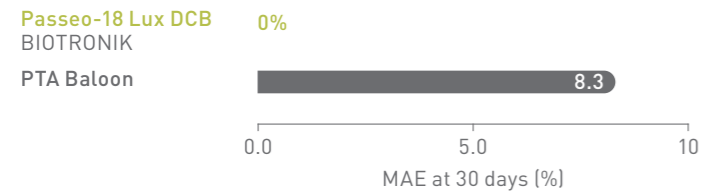
Passeo-18 Lux DCB significantly reduced TLR rates compared to the control PTA* balloon in the as-treated population.



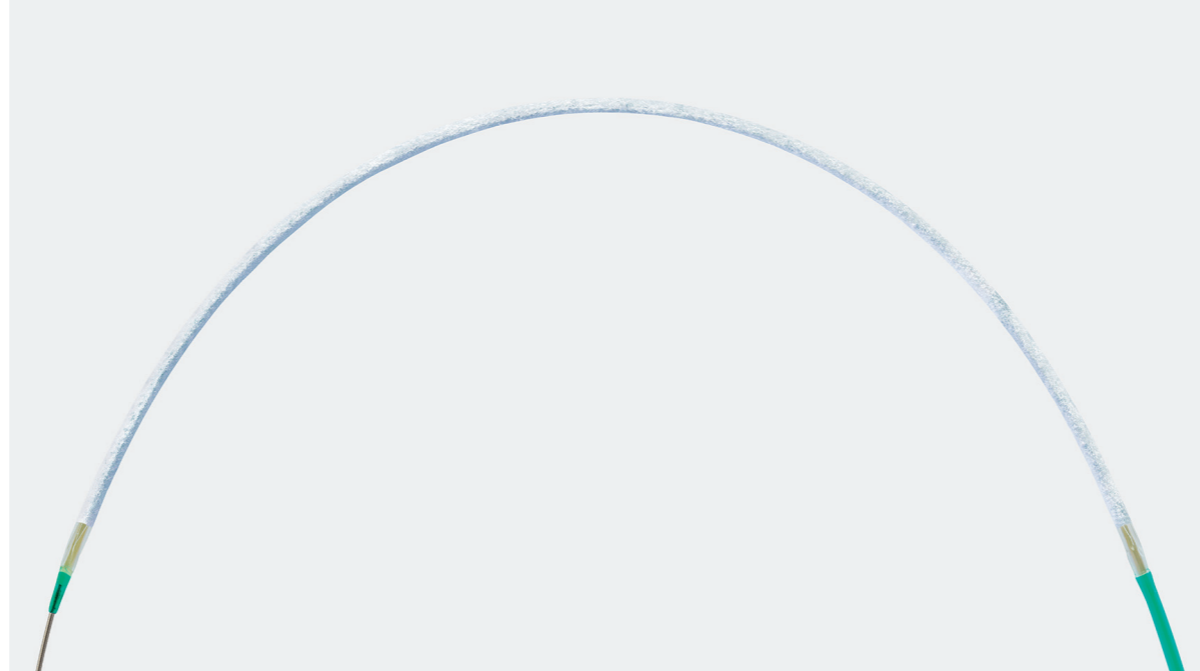
BIOLUX P-II RCT² Infrapopliteal Indication

Major Adverse Events (MAE)

MAE rate of the Passeo-18 Lux DCB was lower compared to the control PTA balloon.



>1900
patients studied



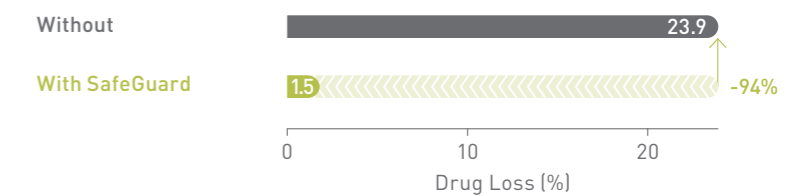
Effective drug delivery

Insertion and handling

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

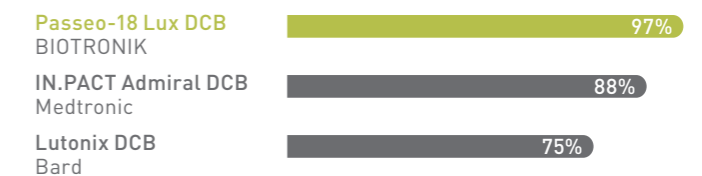


Reduction of drug loss in the introducer sheath valve¹¹



High drug retention¹¹

BIOTRONIK's Lux® coating provides a hydrophobic butyryl-tri-hexyl citrate (BTHC) excipient, which is less soluble than hydrophilic alternatives, ensuring more drug is available at the lesion site.



Drug coating integrity: % of drug load remaining on balloon after being submerged for ~90 seconds in physiological solution.

PTA - Percutaneous Transluminal Angioplasty; RCT - Randomized Controlled Trial.

Passeo-18 Lux

Clinically proven drug-coated balloon (DCB) in challenging patient groups with effective drug delivery.

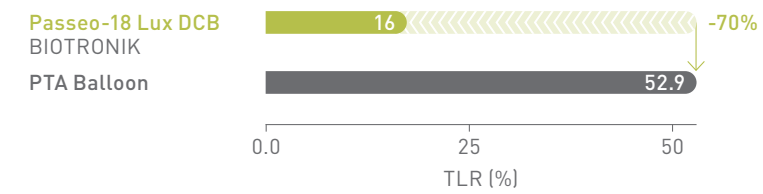
Clinically proven

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Safe and effective

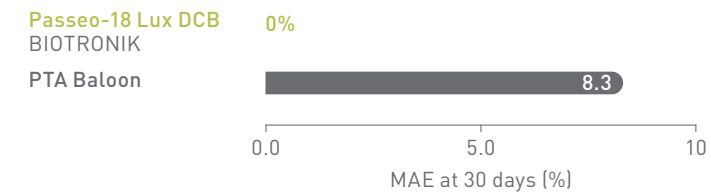
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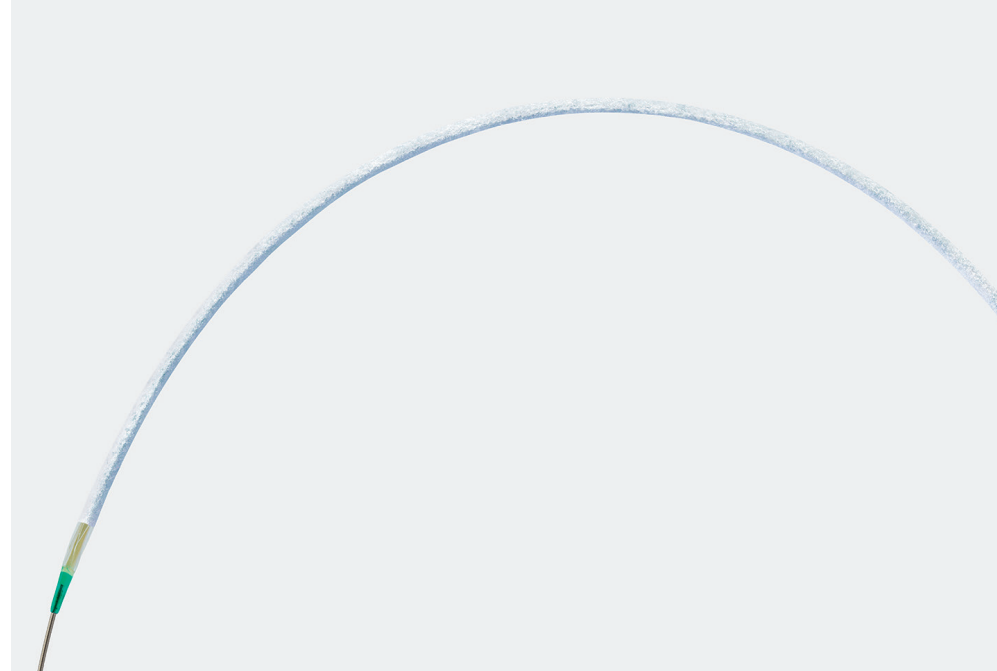
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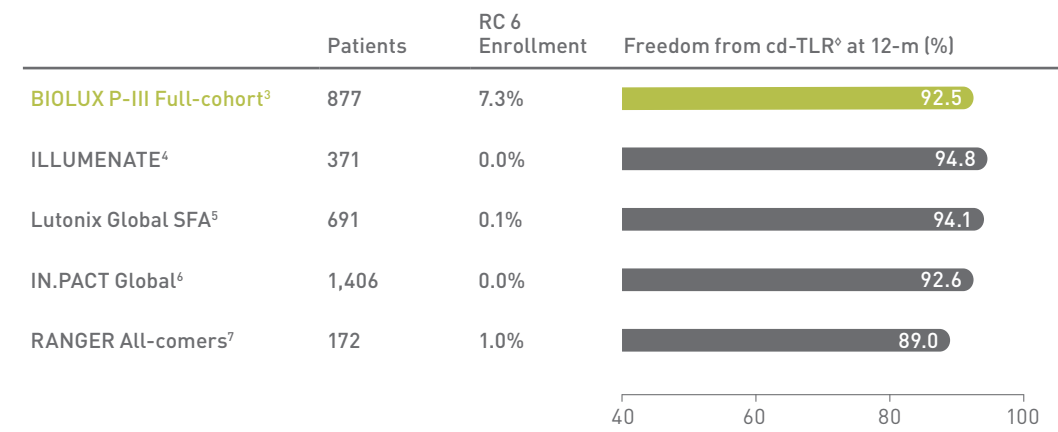
PTA - Percutaneous Transluminal Angioplasty; RCT - Randomized Controlled Trial.



Fcd-TLR^o
88.1%³
24-m
Full Cohort

BIOLUX P-III³ All-Comers Registry

Passeo-18 Lux DCB demonstrates excellent outcomes in one of the largest real-world DCB registries with few exclusion criteria.



^o Kaplan-Meier estimates; RC - Rutherford Classification; cd-TLR - clinically driven Target Lesion Revascularization.

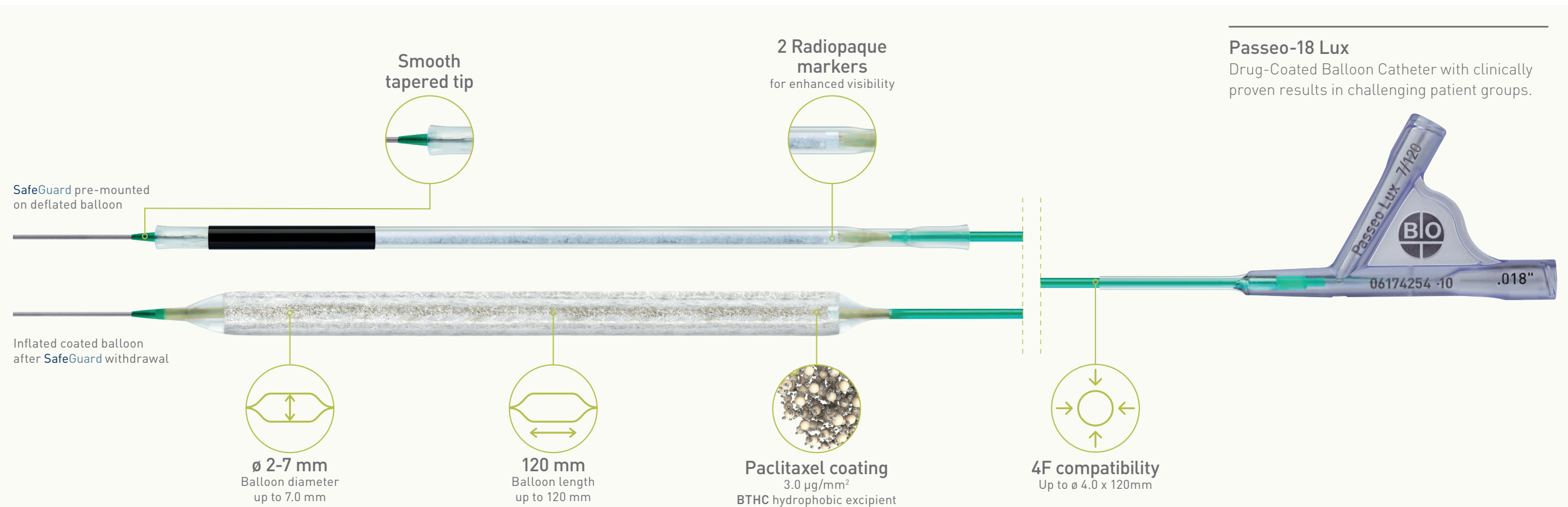
For challenging patient groups

Safety and efficacy clinically proven across challenging subgroups in BIOLUX P-III all-comers registry.

BIOLUX P-III Subgroup	Patients	Calcified lesions ^a	RC 5+6 Enrollment	Freedom from MAE ^{a*} (%)	Freedom from cd-TLR ^o (%)	Freedom from MA (%)
Femoropopliteal ³	592	46.6%	28.9%	90.5 84.9	93.6 88.9	98.0 97.6
Critical limb ischemia ⁸	328	45.0%	68.6%	85.1 80.6	91.5 87.9	94.8 93.9
Below the knee ⁹	151	36.4%	63.6%	80.8 79.0	90.9 90.9	91.0 90.1
Diabetes mellitus ¹⁰	418	48.3%	40.9%	85.4 80.0	91.6 87.1	94.6 93.9
In-stent restenosis ³	103	27.6%	21.2%	87.8 72.5	89.2 78.4	100.0 100.0

Legend: ■ 12 months ■ 24 months

MA - Major target limb Amputations; ^aModerate/Severe Calcified Lesions; ^{*}Defined as composite of device - and procedure-related mortality through 30 days, and major target limb amputation and clinically driven target lesion revascularization.



Passeo[®]-18 Lux[®]

Vascular
Intervention
Peripheral



Indicated to dilate de novo or restenotic lesions in the infrainguinal arteries.*

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 ²	
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	3.2	4.3	5.3	6.2	7.3

**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	
			379866	379867	379868	
			370843	370848	370853	
			370844	370849	370854	
5F	90	5.0	370845	370850	370855	
			370846	370851	370856	
			370847	370852	370857	
4F	150	2.0	379863	379864	379865	
			379869	379870	379871	
			370858	370863	370868	
			370859	370864	370869	
5F	130	5.0	370860	370865	370870	
			370861	370866	370871	
			370862	370867	370872	

1. Scheinert D, et al. Paclitaxel Releasing Balloon in Femoropopliteal lesions using a BTHC excipient: 12-month results from the BIOLUX P-I randomized trial. J EVT. 2015; 22(1): 14-21; 2. Zeller et al. Paclitaxel-Coated Balloon in Infrapopliteal arteries 12-month results from the BIOLUX P-II randomized trial. J Am Coll Cardiol Interv. 2015; 8: 1614-22; 3. Tepe G. Paclitaxel-Coated Balloon Angioplasty for the Treatment of Infrainguinal Arteries: 24-Month Outcomes in the Full Cohort of BIOLUX P-III Global Registry. Cardiovasc Intervent Radiol. 2021;44:207-217; 4. Schró, Herman, et al. Stellarex drug-coated balloon for treatment of femoropopliteal arterial disease—The ILLUMINATE Global Study: 12-Month results from a prospective, multicenter, single-arm study. Catheterization and Cardiovascular Interventions 91.3; 5. Thieme M et al. The 24-month results of the Lutonix Global SFA Registry: worldwide experience with Lutonix drug-coated balloon. JACC: Cardiovasc Interv. 2017;10:1682-1690; 6. Zeller T. Drug-coated balloon treatment of femoropopliteal lesions for patients with intermittent claudication and ischemic rest pain. Circulation: Cardiovasc Interv. 2019;12:e007730; 7. Lichtenberg M, von Bilderling P, Ranft J et al. Treatment of Femoropopliteal Atherosclerotic Lesions using the Ranger PTX - 12m results, All-Comers. JCV 2017. doi: 10.23736/S0031-9509.17.10261-2; 8. Brodmann B et al. Real-World Experience With a Paclitaxel-Coated Balloon in Critical Limb Ischemia 24-Month Subgroup Outcomes of BIOLUX P-III. JACC Cardiovasc Interv. 2020;13:2289-2299; 9. Tepe G et al. BIOLUX P-III Passeo-18 Lux All-Comers Registry: 24-Month Results in Below-the-Knee Arteries. Cardiovasc Intervent Radiol. 2021;44:10-18; 10. Mwapatayi P, Barry I, Brodmann M, et al. Twenty-Four-Month Outcomes of Drug-Coated Balloon in Diabetic Patients in the BIOLUX P-III Registry: A Subgroup Analysis. Annals of Vascular Surgery [2021]; https://doi.org/10.1016/j.avsg.2021.02.050; 11. BIOTRONIK data on file.

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