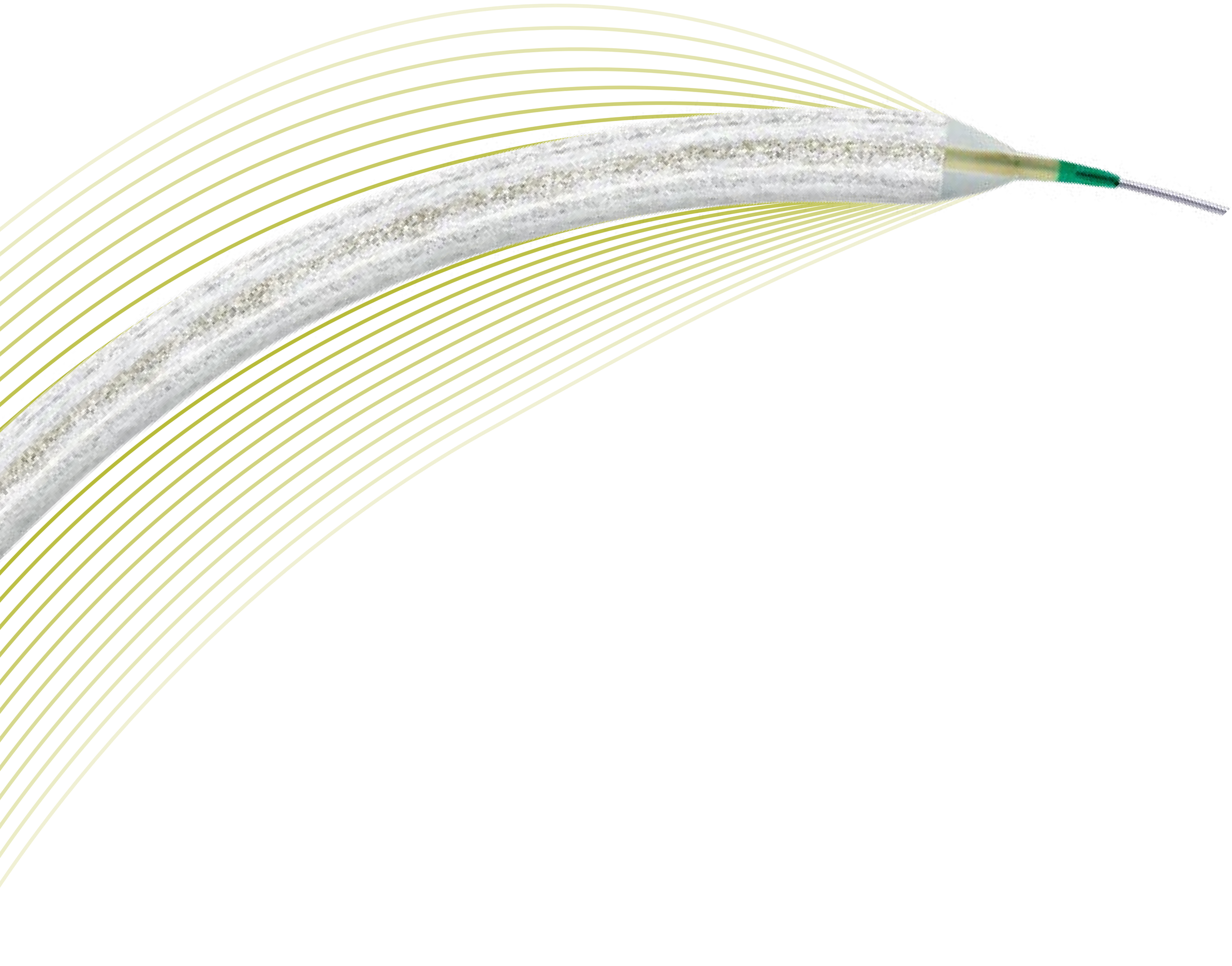
Vascular Intervention // Peripheral
Drug-Coated Balloon Catheter/0.018”/OTW

BIOTRONIK
excellence for life

Passeo®-18 Lux®

Clinically proven results in challenging patient groups



Passeo-18 Lux

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

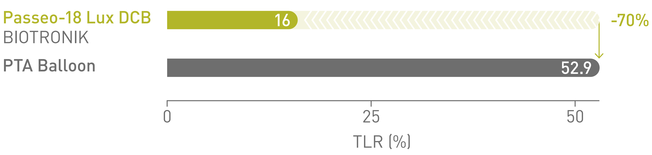
Clinically proven

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

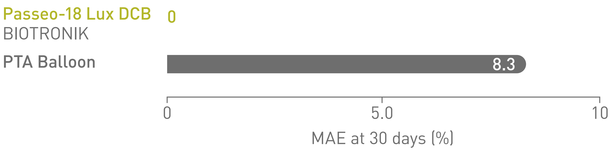
BIOLUX P-I RCT[1] Femoropopliteal Indication

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 RCT[2] Infrapopliteal Indication

Major Adverse Events (MAE)
MAE rate of the Passeo-18 Lux DCB was lower compared to the control PTA balloon.



BIOLUX P-III[3] All-Comers Registry

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

	Patients	RC 6 Enrollment	Freedom from cd-TLR◊ at 12-m (%)
BIOLUX P-III Full-cohort[3]	877	7.3%	92.5
ILLUMENATE[4]	371	0.0%	94.8
Lutonix Global SFA[5]	691	0.1%	94.1
IN.PACT Global[6]	1,406	0.0%	92.6
RANGER All-comers[7]	172	1.0%	89.0

Fcd-TLR◊
88.1%[3]
24-m
Full Cohort

◊ Kaplan-Meier estimates; PTA – Percutaneous Transluminal Angioplasty; RCT - Randomized Controlled Trial; RC - Rutherford Classification; cd-TLR - clinically driven Target Lesion Revascularization.

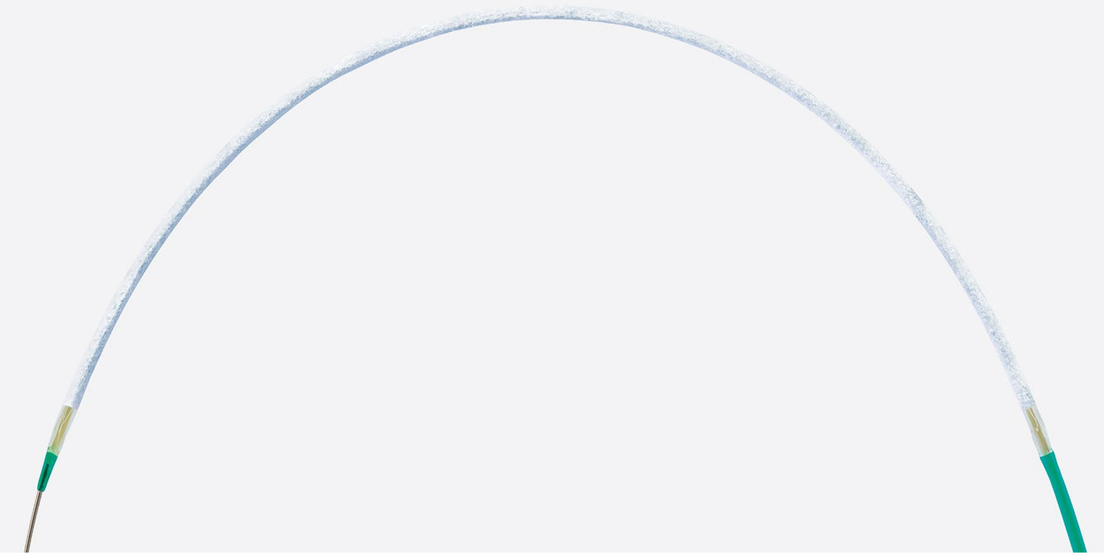
For challenging patient groups

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

BIOLUX P-III Subgroup	Patients	Calcified lesions[Δ]	RC 5+6 Enrollment	Freedom from MAE[◊,ϕ] (%)	Freedom from cd-TLR[◊] (%)	Freedom from MA (%)
FEMPOP[3]	592	46.6%	28.9%	90.5 / 84.9	93.6 / 88.9	98.0 / 97.6
CLI[8]	328	45.0%	68.6%	85.1 / 80.6	91.5 / 87.9	94.8 / 93.9
BTK[9]	151	36.4%	63.6%	80.8 / 79.0	90.9 / 90.9	91.0 / 90.1
DM[10]	418	48.3%	40.9%	85.4 / 80.0	91.6 / 87.1	94.6 / 93.9
ISR[3]	103	27.6%	21.2%	87.8 / 72.5	89.2 / 78.4	100.0 / 100.0

12 months 24 months

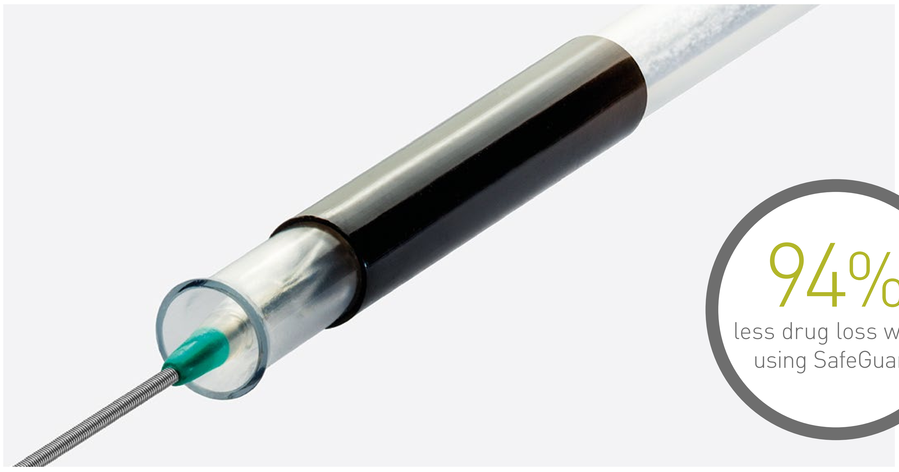
Δ Moderate/Severe Calcified Lesions; ◊ Kaplan-Meier estimates; ϕ Defined as composite of device - and procedure-related mortality through 30 days, and major target limb amputation and clinically driven target lesion revascularization; FEMPOP - Femoropopliteal; CLI - Critical Limb Ischemia; BTK - Below The Knee; DM - Diabetes Mellitus; ISR - In Stent Restenosis; RC - Rutherford Classification; MAE -Major Adverse Events; cd-TLR - clinically driven Target Lesion Revascularization; MA - Major target limb Amputations.



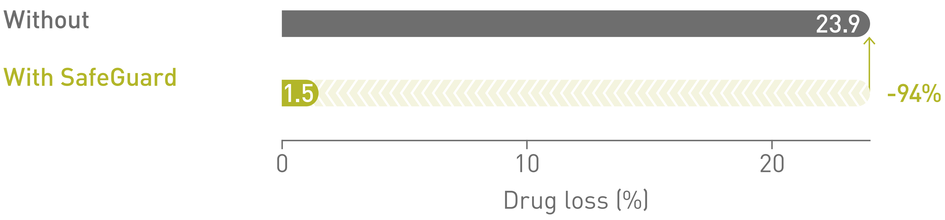
Effective drug delivery

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.

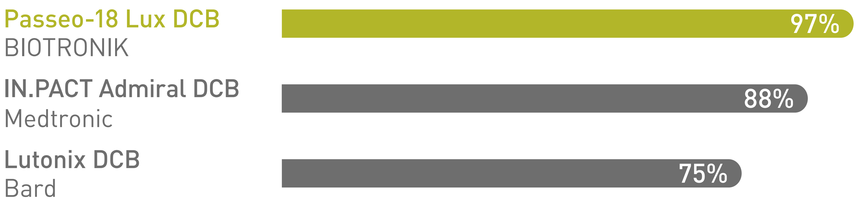


Reduction of drug loss in the introducer sheath valve[11]



High drug retention[11]

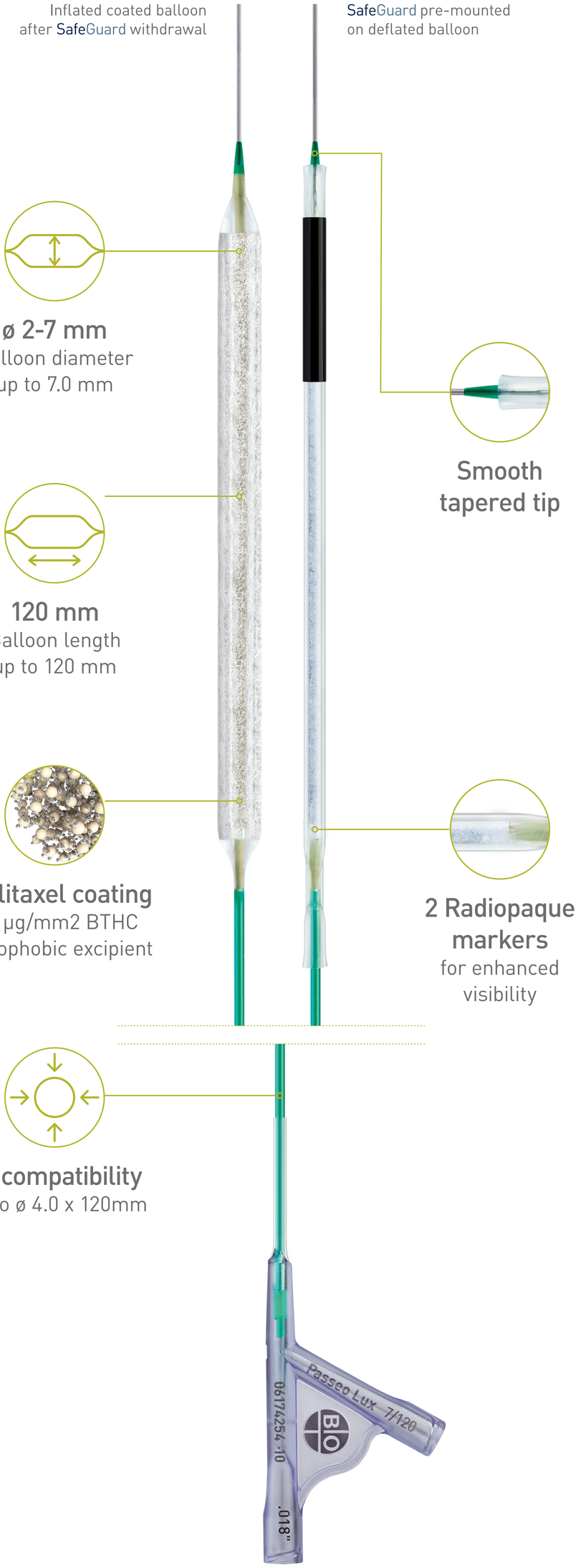
BIOTRONIK's Lux® coating provides a hydrophobic butyryl-tri-hexyl citrate (BTHC) excipient, which is less soluble than hydrophilic alternatives, ensuring more drug is available at the lesion site.



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

Passeo-18 Lux

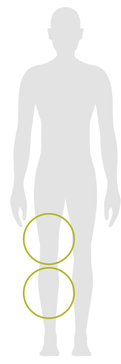
Drug-Coated Balloon Catheter with clinically proven results in challenging patient groups.



Passeo®-18 Lux®

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

Vascular
Intervention
Peripheral



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
	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

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. JEVT. 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 Intv. 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. Schroë, Herman, et al. Stellarex drug-coated balloon for treatment of femoropopliteal arterial disease—The ILLUMENATE 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. Mwipatayi 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.

*Indication as per IFU. Passeo, Lux and SafeGuard are trademarks or registered trademarks of the BIOTRONIK Group of Companies. All other trademarks are the property of their respective owners.

376041/D/Apr_2022_DV

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

© 2022 BIOTRONIK AG – All rights reserved.
Specifications are subject to modification, revision and improvement.

BIOTRONIK
excellence for life