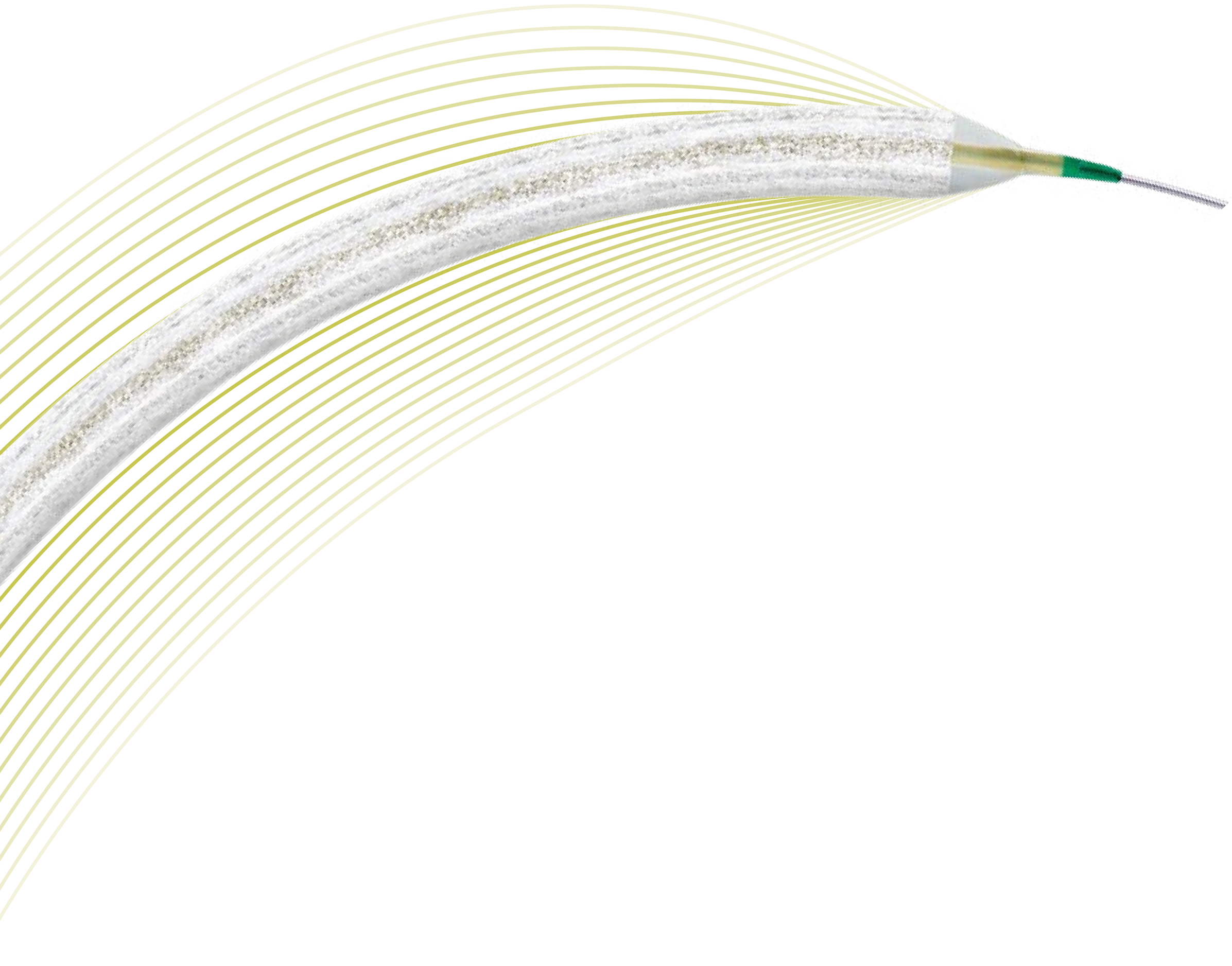
Vascular Intervention // Peripheral
Drug-Coated Balloon Catheter/0.018”/OTW

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

>1,900 patients

studied in randomized controlled trials and all-comers registries.

Fcd-TLR◊ **88.1%**[1] 24-m Full Cohort

Excellent outcomes in BIOLUX P-III, one of the largest real-world DCB registries with few exclusion criteria.

Challenging patients, comparable outcomes

Freedom from clinically driven TLR at 12 months

	BIOLUX P-III[1]	ILLUMENATE[2]	LUTONIX Global SFA[3]	IN.PACT Global[4]	RANGER All-comers[5]
	92.5%	94.8%	94.1%	92.6%	89.0%
No. of pts	877	371	691	1,406	172
RC 6	7.3%	0.0%	0.1%	0.0%	1.0%

pts = patients; RC = Rutherford Classification

Femoropopliteal artery

70% relative risk reduction in 12-month TLR versus the control PTA balloon in the BIOLUX P-I RCT[6]

Infrapopliteal artery

NO MAE at 30 days in the BIOLUX P-II RCT[7]

◊ Kaplan-Meier estimates; Fcd-TLR – Freedom from clinically driven Target Lesion Revascularization; TLR - Target Lesion Revascularization; PTA – Percutaneous Transluminal Angioplasty; MAE – Major Adverse Event defined as a composite of all-cause mortality, target extremity major amputation, target lesion thrombosis, and target vessel 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	Freedom from cd-TLR[◊] at 24 months (%)
Femoro-popliteal[1]	592	46.6%	22.0%	88.9
Critical limb ischemia[8]	328	45.0%	68.6%	87.9
Below the knee[9]	151	36.4%	63.6%	90.9
Diabetes mellitus[10]	418	48.3%	40.9%	87.1
In-stent restenosis[1]	103	27.6%	21.2%	78.4

Freedom from major target limb amputation at 24 months

BIOLUX P-III
93.9%[8]
CLI

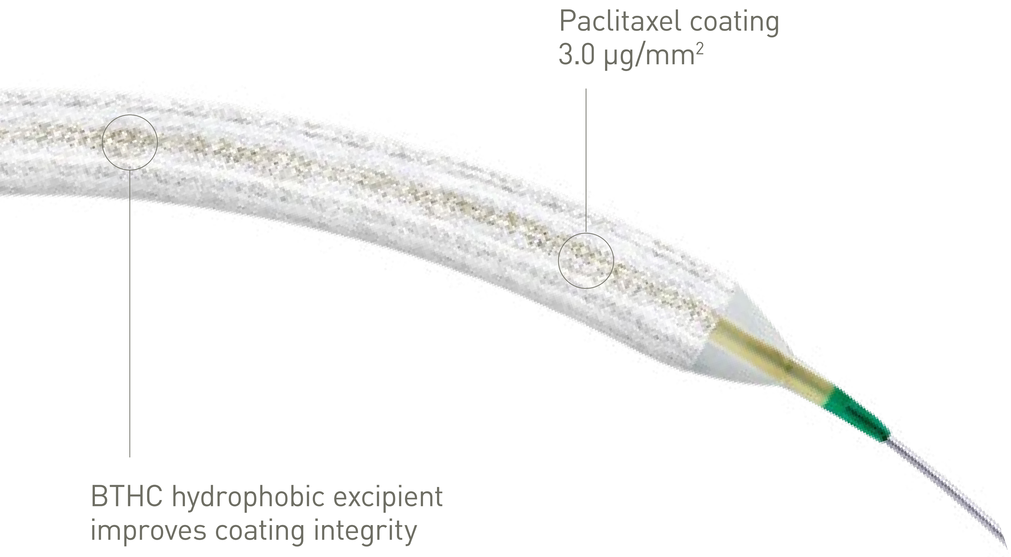
BIOLUX P-III
90.1%[9]
BTK

[Δ] Moderate/Severe Calcified Lesions; [◊] Kaplan-Meier estimates; cd-TLR - clinically driven Target Lesion Revascularization; RC – Rutherford Classification; CLI – Critical Limb Ischemia; BTK – Below The Knee

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.



BTHC - butyryl-tri-hexyl citrate

High drug retention[11]

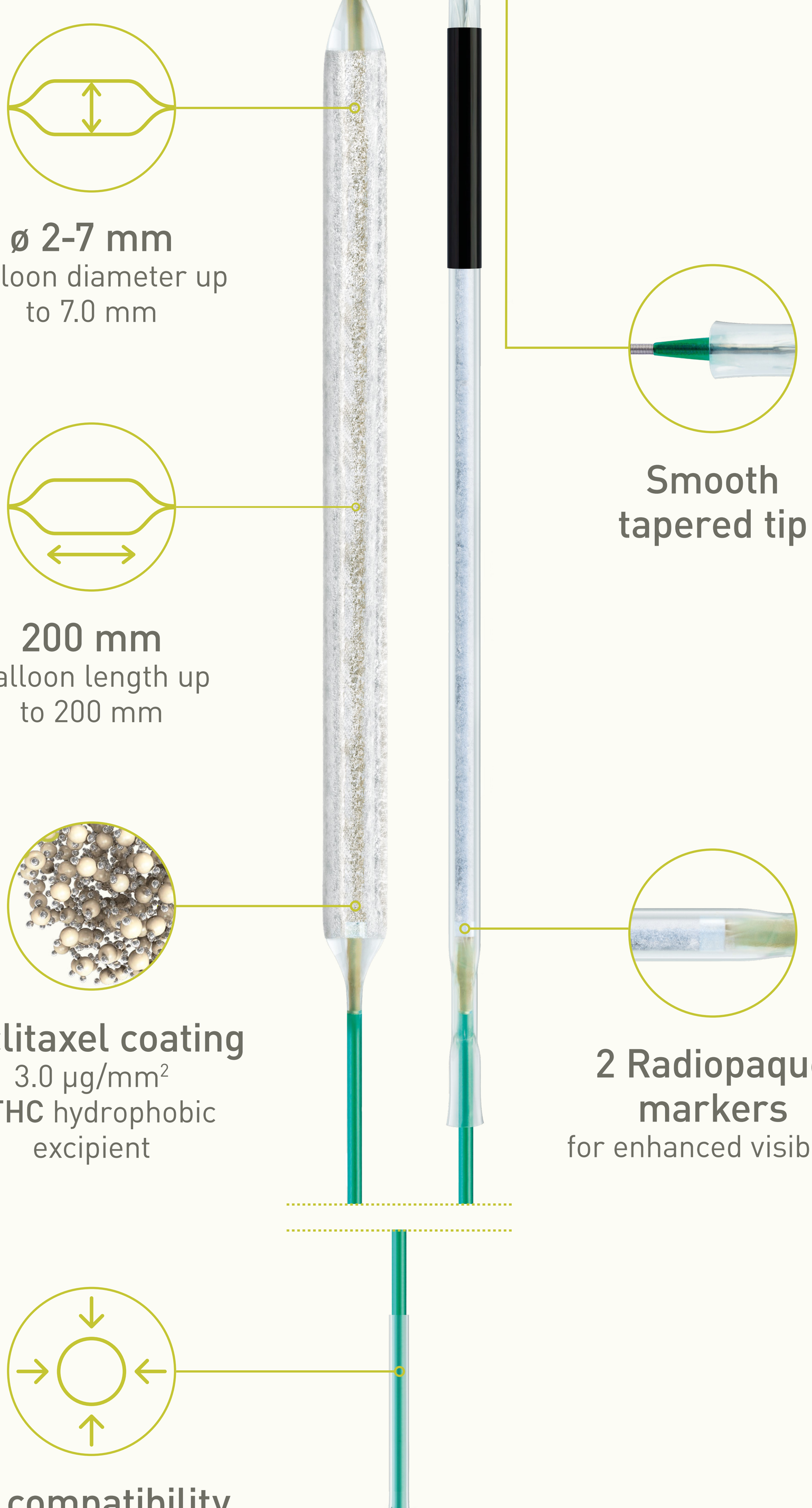
BIOTRONIK's Lux® coating provides a hydrophobic excipient, which is less soluble than hydrophilic alternatives, ensuring more drug is available at the lesion site.

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

94%[11]
less drug loss when using SafeGuard

Inflated coated balloon after SafeGuard withdrawal

SafeGuard pre-mounted on deflated balloon



ø 2-7 mm
Balloon diameter up to 7.0 mm

200 mm
Balloon length up to 200 mm

Paclitaxel coating
3.0 µg/mm²
BTHC hydrophobic excipient

Smooth tapered tip

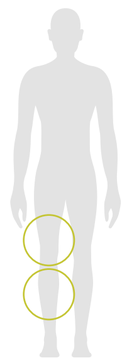
2 Radiopaque markers
for enhanced visibility

4F compatibility
Up to ø 4.0 x 200 mm

Passeo®-18 Lux®

DCB 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
Ballon 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)

Coating

Drug	Paclitaxel
Drug concentration	3.0 µg/mm^2
Lux® 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 40-150	ø 2.0 x 200	ø 2.5 x 40-150	ø 2.5 x 200	ø 3.0 x 40-150	ø 3.0 x 200	ø 4.0 x 40-150	ø 4.0 x 200	ø 5.0 x 40-120	ø 5.0 x 150	ø 5.0 x 200	ø 6.0 x 40-200	ø 7.0 x 40-200
Nominal Pressure (NP)	atm**	6	6	6	6	6	6	6	6	6	6	6	6	6
	ø (mm)	2.0	2.0	2.5	2.5	3.0	3.0	4.0	4.0	5.0	5.0	5.0	6.0	7.0
Rate Burst Pressure (RBP)	atm**	15	14	15	14	15	14	15	13	15	12	13	12	12
	ø (mm)	2.1	2.1	2.6	2.6	3.2	3.2	4.3	4.2	5.3	5.2	5.2	6.2	7.3

**1 atm = 1.013 bar

Ordering Information

	Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 40	60	80	100	120	150	200
4F	90	2.0	379860	-	379861	-	379862	449970	449977
4F	90	2.5	379866	-	379867	-	379868	449971	449978
4F	90	3.0	370843	484199	370848	484206	370853	449972	449979
4F	90	4.0	370844	484200	370849	484207	370854	449973	449980
4F	90	5.0	370845	484201	370850	484208	370855	449974	449981
5F	90	6.0	370846	484202	370851	484209	370856	449975	449982
5F	90	7.0	370847	484203	370852	484210	370857	449976	449983
4F	150	2.0	379863	484211	379864	484218	379865	449984	449991
4F	130	2.5	379869	484212	379870	484219	379871	449985	449992
4F	130	3.0	370858	484213	370863	484220	370868	449986	449993
4F	130	4.0	370859	484214	370864	484221	370869	449987	449994
5F	130	5.0	370860	484215	370865	484222	370870	449988	449995
5F	130	6.0	370861	484216	370866	484223	370871	449989	449996
5F	130	7.0	370862	484217	370867	484224	370872	449990	449997

1. Tepe G. Paclitaxel-coated balloon angioplasty for the treatment of infrainguinal arteries: 24-month outcomes in the full cohort of the BIOLUX P-III global registry. Cardiovasc Intervent Radiol. 2021;44:207–217; 2. Schroë, H, 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. Catheter Cardiovasc Interv. 2018;91:497-504; 3. 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; 4. Zeller T, et al. Drug-coated balloon treatment of femoropopliteal lesions for patients with intermittent claudication and ischemic rest pain. Circ Cardiovasc Interv. 2019;12:e007730; 5. Lichtenberg M, et al. Treatment of femoropopliteal atherosclerotic lesions using the ranger paclitaxel-coated balloon catheter: 12-month results from an all-comers registry. J Cardiovasc Surg (Torino). 2018;59:45-50; 6. 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 Endovasc Ther. 2015;22:14–21; 7. Zeller T, et al. Paclitaxel-coated balloon in infrapopliteal arteries 12-month results from the BIOLUX P-II randomized trial. JACC Cardiovasc Interv. 2015;8:1614-22; 8. Brodmann M, 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, 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.

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