

Passeo[™]-18 Lux[™]

Drug-Coated
Balloon Catheter

Clinically proven results in challenging patient groups

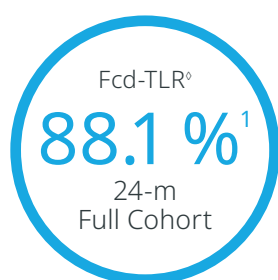


Passeo™-18 Lux™ DCB

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

Clinically proven

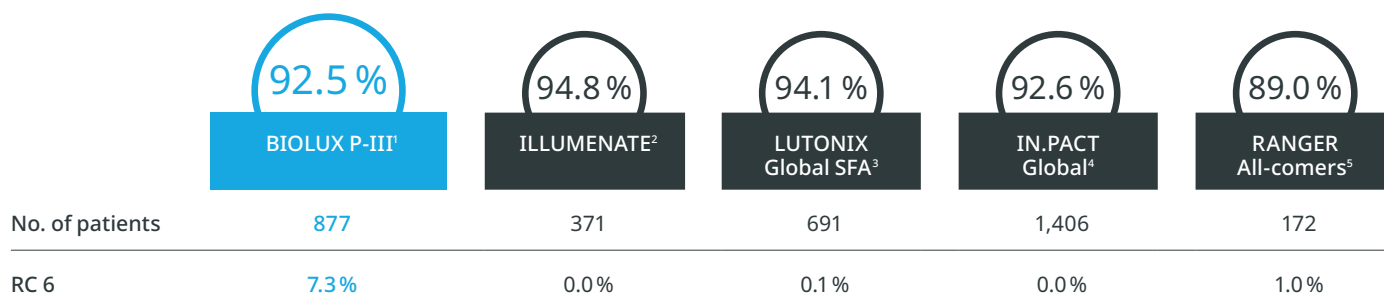
>1,900 patients studied in randomized controlled trials and all-comers registries.



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



Femoropopliteal artery

70 % relative risk reduction in 12-month TLR versus the control PTA balloon in the BIOLUX P-I RCT⁶

Infrapopliteal artery

No MAE at 30 days in the BIOLUX P-II RCT⁷

°Kaplan-Meier estimates






Fcd-TLR: Freedom from clinically driven Target Lesion Revascularization RC: Rutherford Classification 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

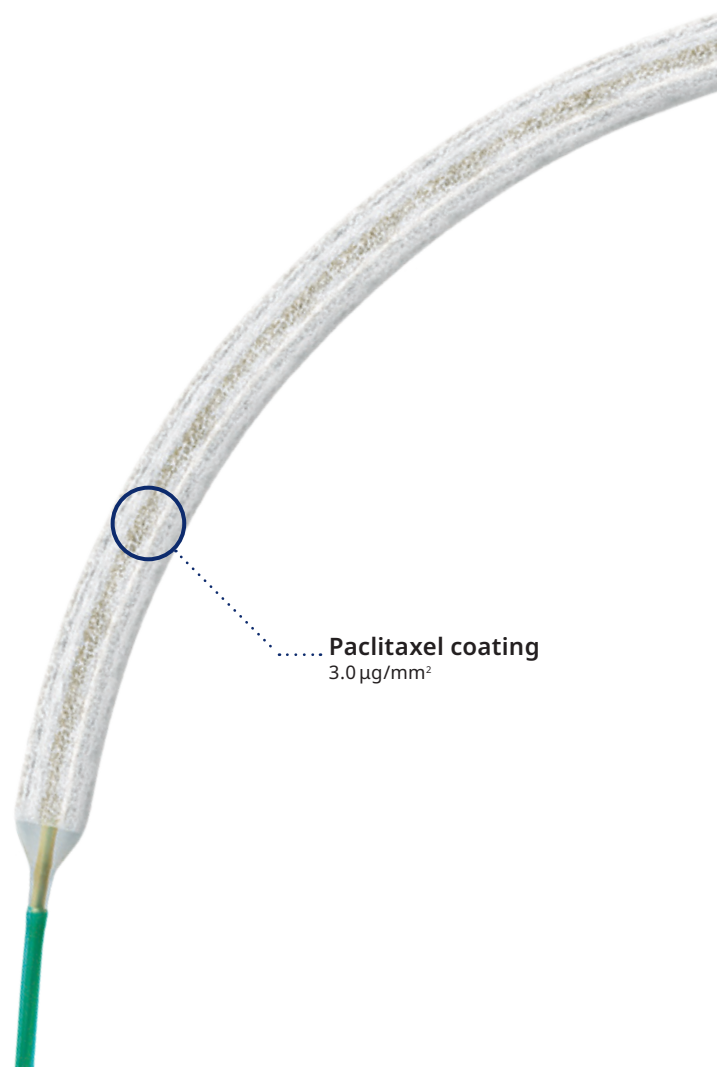
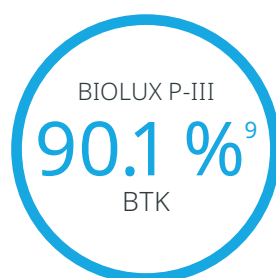
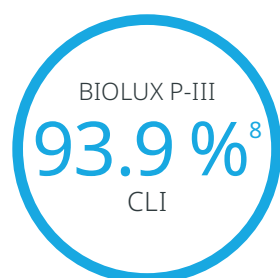


For challenging patient groups

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 (%)
 Femoropopliteal 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



^ΔModerate/Severe Calcified Lesions

[°]Kaplan-Meier estimates

cd-TLR: clinically driven Target Lesion Revascularization

RC: Rutherford Classification

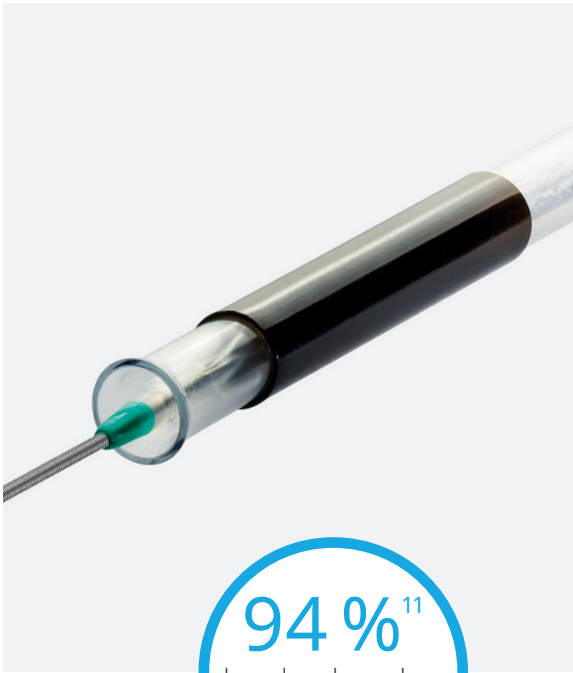
CLI: Critical Limb Ischemia

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.



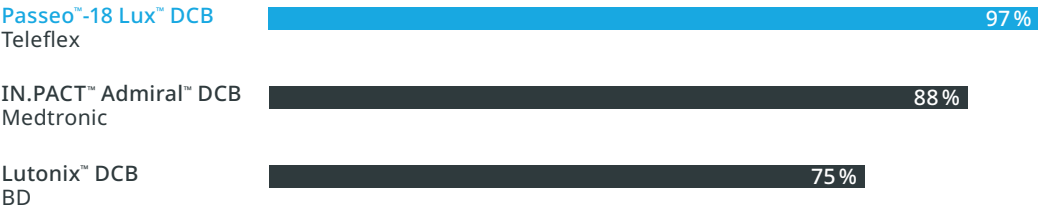
94 %¹¹
less drug loss when
using SafeGuard™
Insertion Aid

BTHC hydrophobic
excipient improves
coating integrity
BTHC- butyryl-tri-hexyl citrate



High drug retention¹¹

Lux™ Coating provides a hydrophobic excipient, which is less soluble than hydrophilic alternatives, ensuring more drug is available at the lesion site.

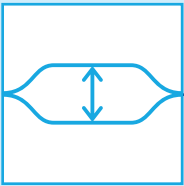


Drug coating integrity: % of drug load remaining on balloon after being submerged for ~90 seconds in physiological solution.

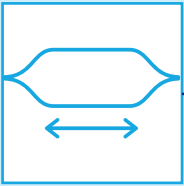
Inflated coated balloon after
SafeGuard™ Insertion Aid withdrawal

SafeGuard™ Insertion Aid pre-mounted
on deflated balloon

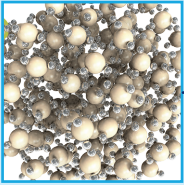
Ø 2-7 mm
Balloon diameter
up to 7.0 mm



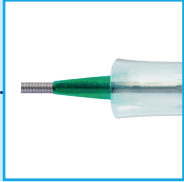
Ø 200 mm
Balloon length
up to 200 mm



Paclitaxel coating
3.0 µg/mm²
BTHC hydrophobic excipient



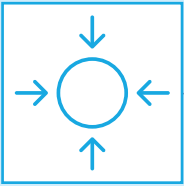
Smooth
tapered tip



2 Radiopaque
markers
for enhanced
visibility



4F compatibility
Up to Ø 4.0 x 200 mm



Passeo™-18 Lux™ DCB

Vascular
Intervention
Peripheral



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

*Indication as per IFU.

References

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- 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 Paseo-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 Data on file.

Refer to IFU

Refer to QR code for a copy of the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.



About Teleflex

As a global provider of medical technologies, Teleflex is driven by our purpose to improve the health and quality of people's lives. Through our vision to become the most trusted partner in healthcare, we offer a diverse portfolio with solutions in the therapy areas of anesthesia, emergency medicine, interventional cardiology and radiology, surgical, vascular access, and urology. We believe that the potential of great people, purpose driven innovation, and world-class products can shape the future direction of healthcare.

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The Paseo™-18 Lux™ DCB with its Lux™ coating is part of the Lux™ family of Paclitaxel-coated balloons.

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