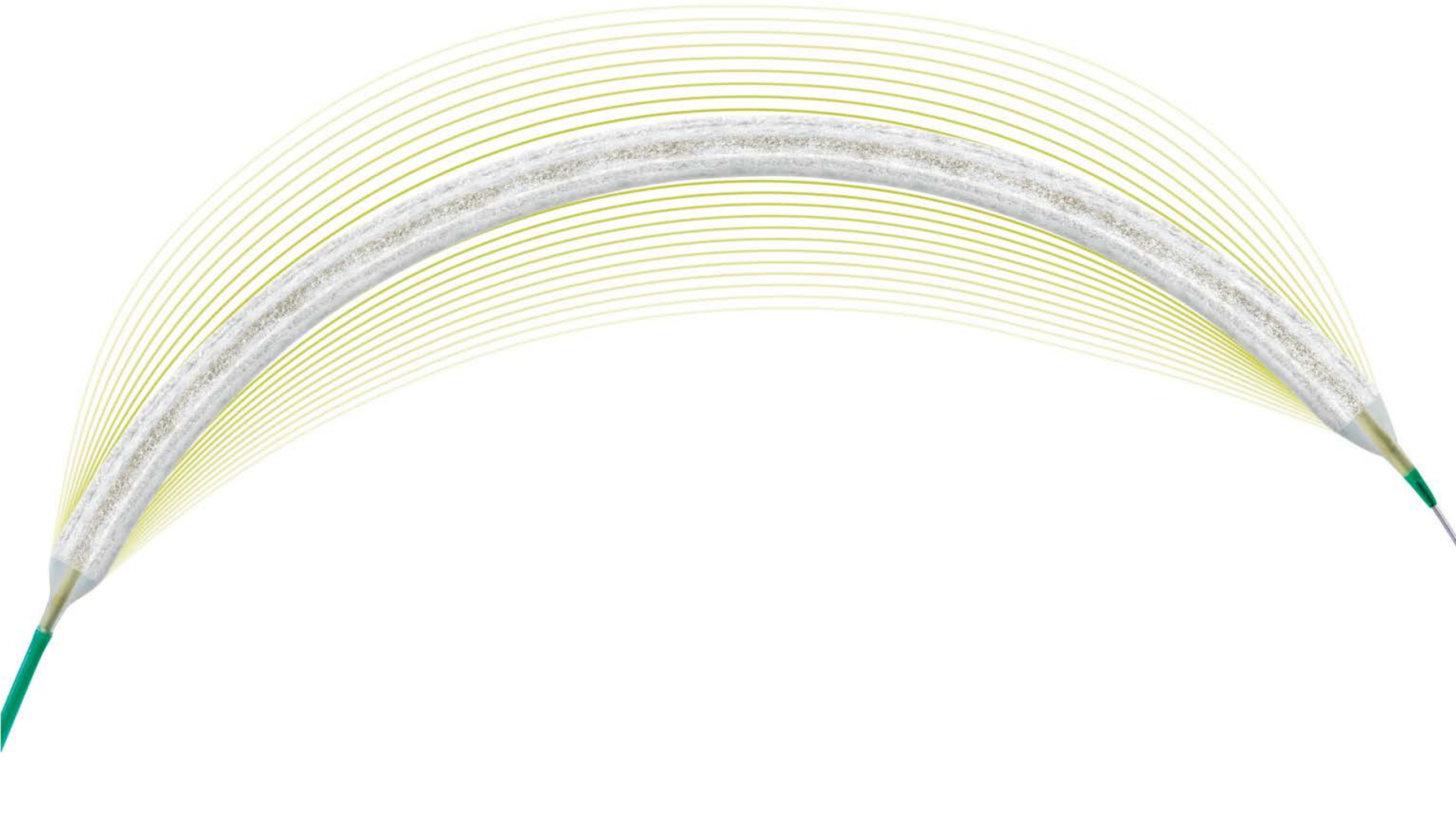
Clinically proven | Effective drug delivery | Prolonged drug presence | Technical data / ordering info

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

BIOTRONIK
excellence for life

Passeo-18 Lux



Clinically proven

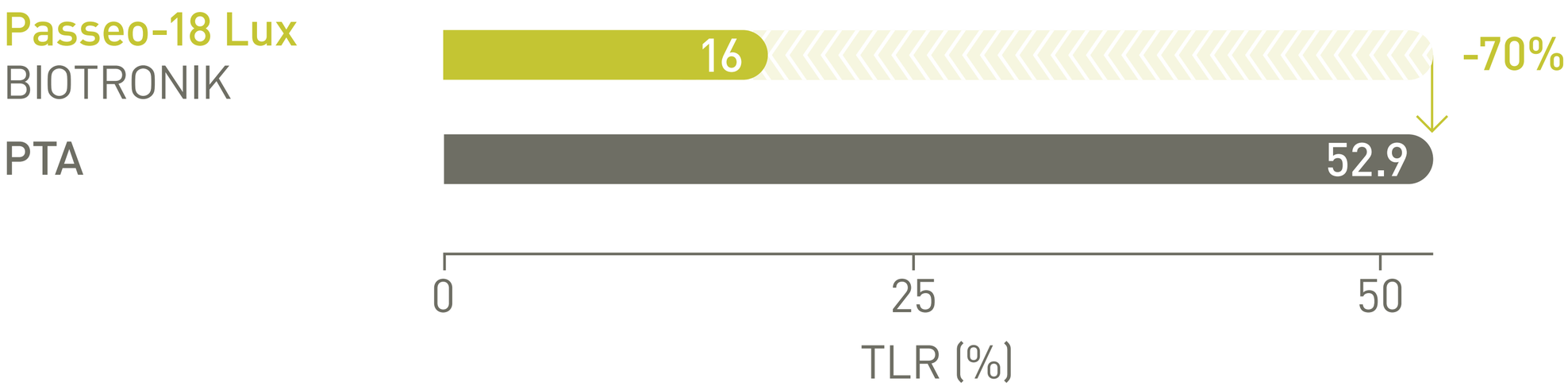
Randomized controlled and all-comers registry clinical data investigated safety and efficacy in the treatment of femoropopliteal and infrapopliteal arteries.

Safe and effective

BIOLUX P-I[1] Femoropopliteal Indication

12-month Target Lesion Revascularization (TLR)

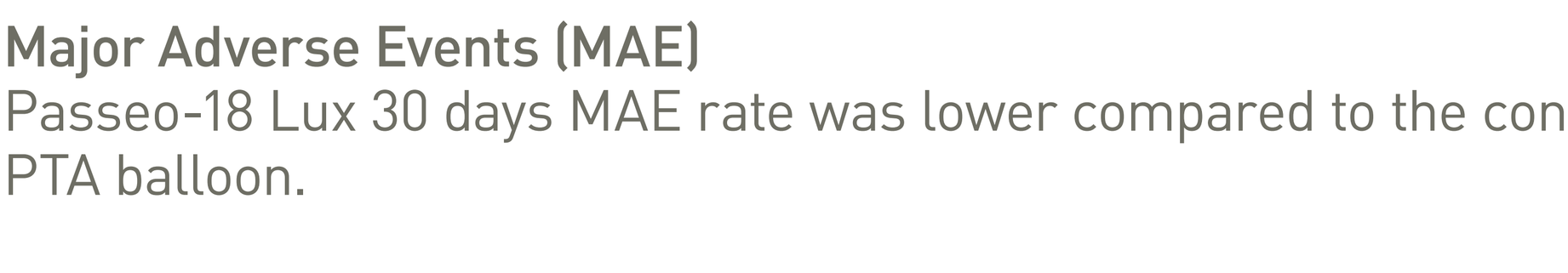
Passeo-18 Lux significantly reduced TLR rates compared to the control PTA* balloon in the as-treated population.



BIOLUX P-II[2] Infrapopliteal Indication

Major Adverse Events (MAE)

Passeo-18 Lux 30 days MAE rate was lower compared to the control PTA balloon.



*PTA - Percutaneous Transluminal Angioplasty

Proven in a real-world setting

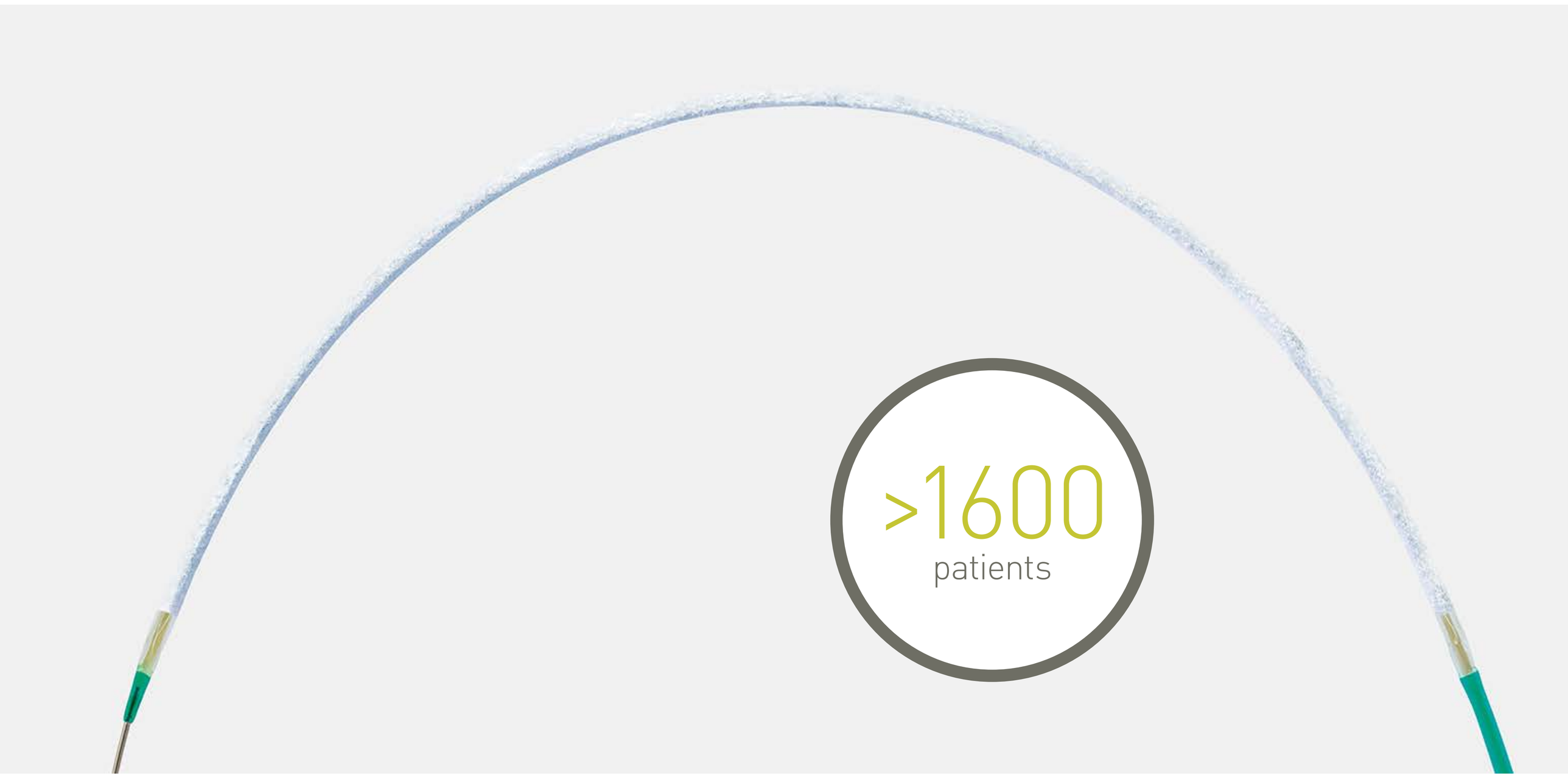
BIOLUX P-III[3] all-comers Superficial Femoral Artery (SFA) 12-month results in 441 patients.

Fcd-TLR
94.5%
including

76.5%
calcified lesions

30.6%
CLI patients

9
multi-center clinical trials



>1600
patients

Proven in more calcified lesions and more challenging patients (12-month SFA data)

	Passeo-18 Lux BIOLUX P-III	Stellarex Illumenate[4]	Lutonix Global SFA[5]	IN.PACT Admiral IN.PACT Global[6]
Fcd-TLR	**94.5%**	94.8%	94.1%**	92.6%
PP	**84.9%**	81.4%	85.4%	n/a
Calcification	**76.5%**	40.8%*	50.2%	68.7%
CLI	**30.6%**	8.6%	9.0%	11.0%

*Severe calcification only **FTLR as Kaplan Meier estimate

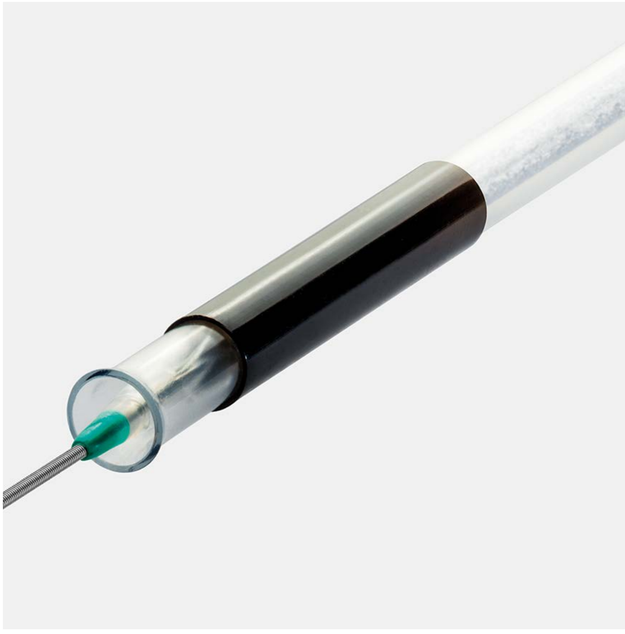
Fcd-TLR - Freedom from clinically driven Target Lesion Revascularization as Kaplan Meier estimate; PP - Primary Patency as Kaplan Meier estimate; CLI- Critical Limb Ischemia

Effective drug delivery to the lesion

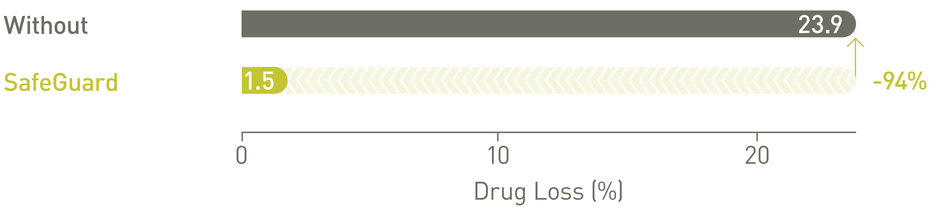
Insertion and handling

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.

-94%
drug loss when using SafeGuard



Reduction of the drug loss in the introducer sheath valve[7]



Tracking

Passeo-18 Lux hydrophobic Butyryl-tri-hexyl citrate (BTHC) excipient is less soluble than hydrophilic alternatives, ensuring more drug is available at the lesion site.

High drug retention[8]

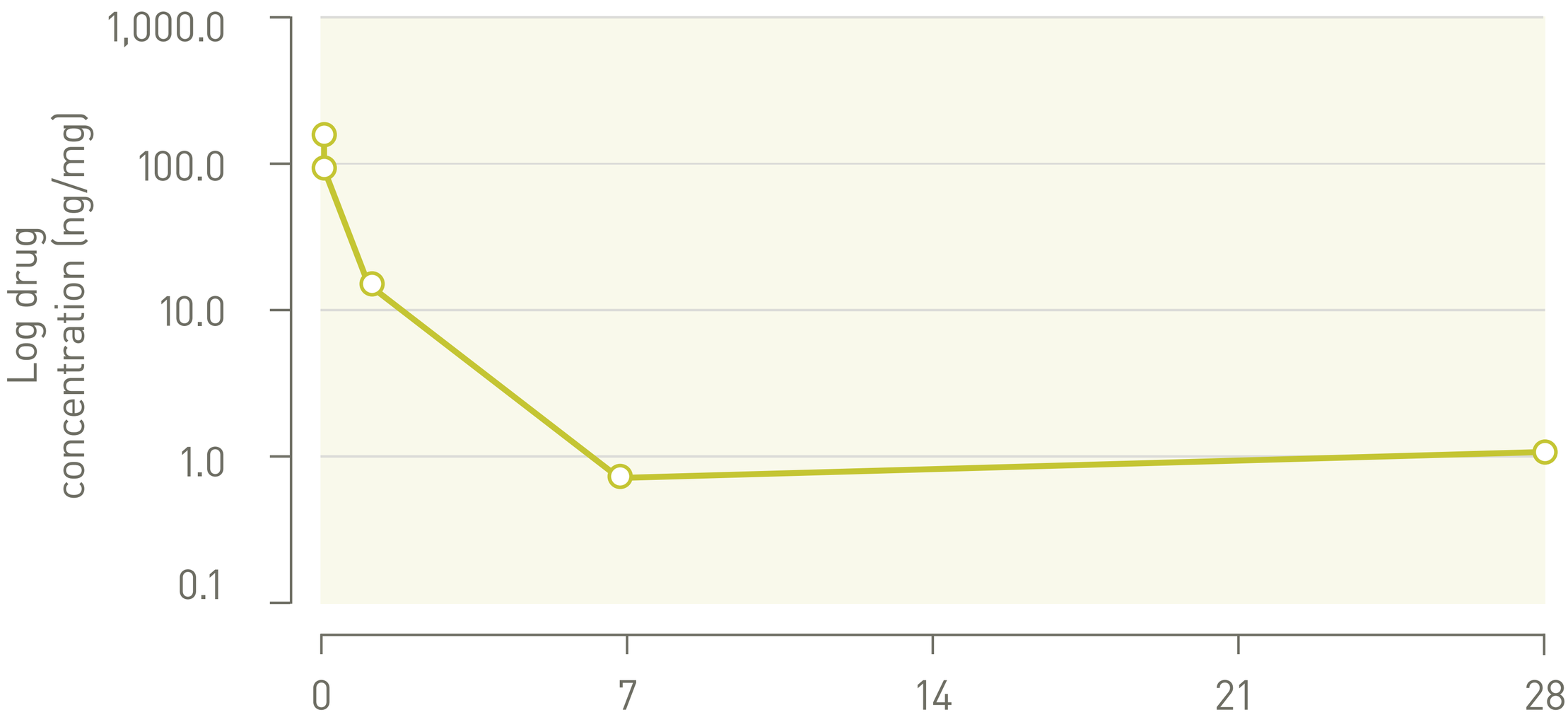
Drug coating integrity: % of drug load remaining on balloon after being submerged for ~90 seconds in physiological solution.

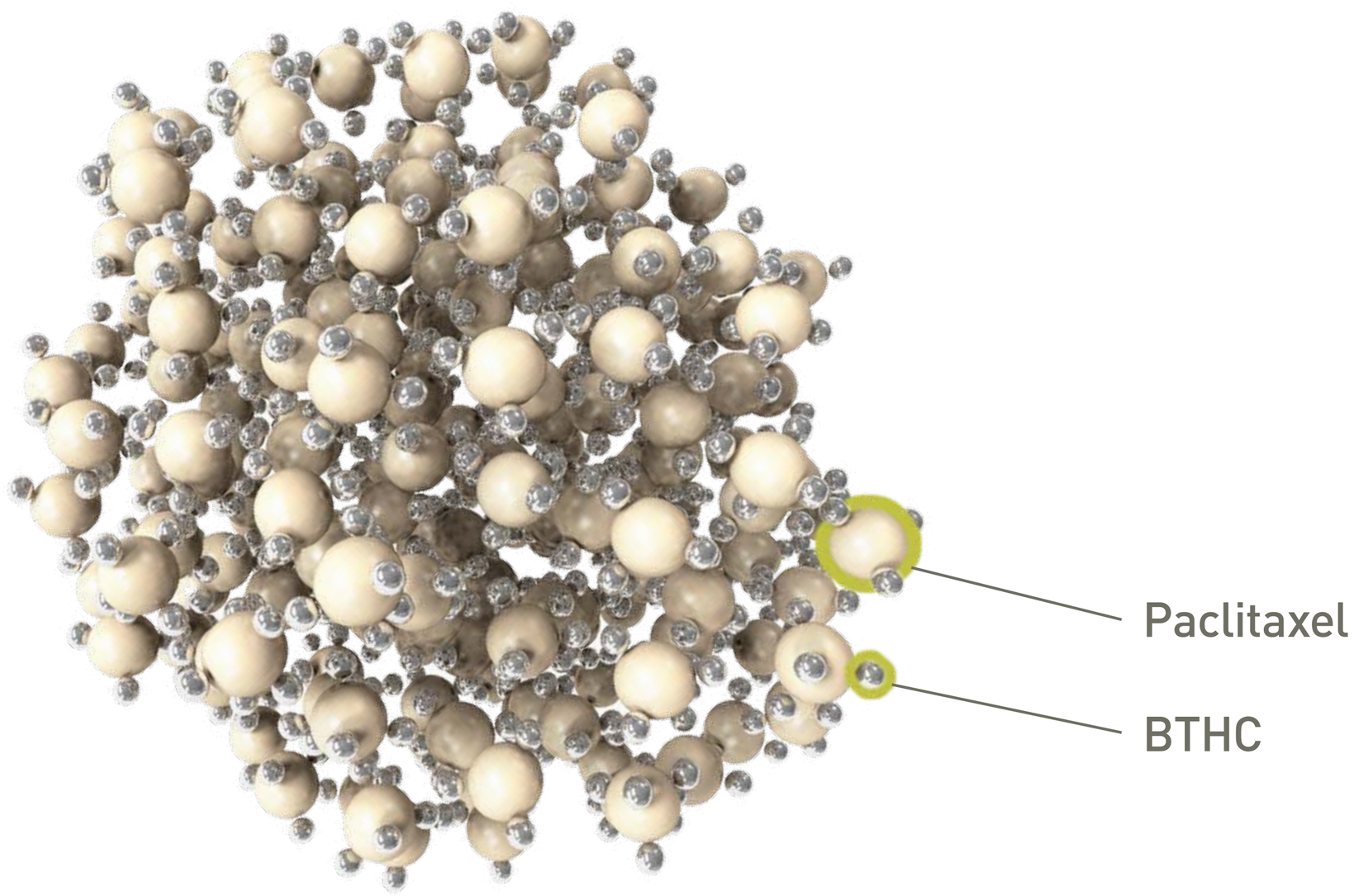
Effective tissue absorption and prolonged drug presence

At the lesion site

BTHC excipient keeps paclitaxel in microcrystalline structure, ensuring efficient drug transfer and prolonged bioavailability at the lesion site.[9]

Paclitaxel Vessel Concentration[9]

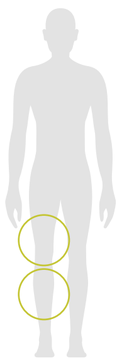




Paclitaxel and BTHC microcrystalline structure

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
4F	90	2.5	379866	379867	379868
4F	90	3.0	370843	370848	370853
4F	90	4.0	370844	370849	370854
5F	90	5.0	370845	370850	370855
5F	90	6.0	370846	370851	370856
5F	90	7.0	370847	370852	370857
4F	150	2.0	379863	379864	379865
4F	130	2.5	379869	379870	379871
4F	130	3.0	370858	370863	370868
4F	130	4.0	370859	370864	370869
5F	130	5.0	370860	370865	370870
5F	130	6.0	370861	370866	370871
5F	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. BIOLUX P-III 12-month results, SFA subgroup analysis. Presented at CIRSE 2017; 4. Schroe H. 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. 2017; 1-8; 5. Thieme M. The 24-month Results of the Lutonix global SFA registry worldwide experience with Lutonix Drug-Coated Balloon. JACC: Cardiovascular Interventions. 2017:10:16:1691-1693 6. IN.PACT global full clinical cohort. Presented by M. R. Jaff at VIVA 2016; 7, 8, 9. BIOTRONIK data on file.

*Indication as per IFU.

376041/C/Jan_2018_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

BIOTRONIK
excellence for life