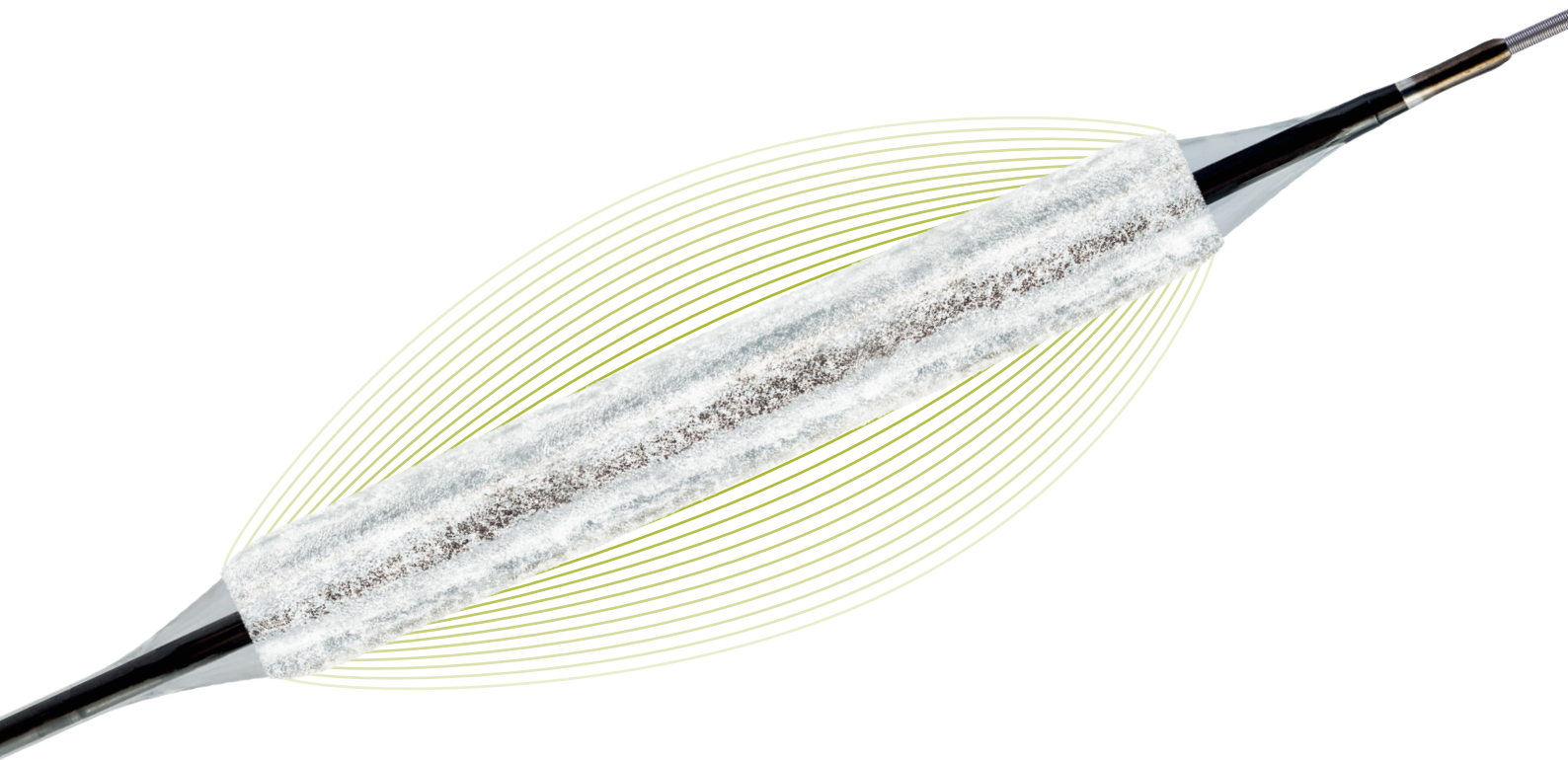


Vascular Intervention // **Coronary**
Drug-Coated Balloon Catheter

Pantera Lux



Clinically proven solution for in-stent restenosis and de novo lesions



Lux coating technology for rapid drug absorption



Advanced trackability

Pantera Lux

Clinically proven, rapid drug absorption and advanced trackability.

Clinically proven solution for in-stent restenosis and de novo lesions

Clinical outcomes from multiple studies¹⁻⁸ including randomized controlled trials like BIOLUX RCT, ISAR-DESIRE 4 and PEBSI show high efficacy and safety for both in-stent restenosis and de novo lesions.

Lux coating technology for rapid drug absorption

Drug Paclitaxel

- 3.0 µg Paclitaxel/mm² balloon surface
- Anti-proliferative

Excipient Butyryl-tri-hexyl citrate (BTHC)

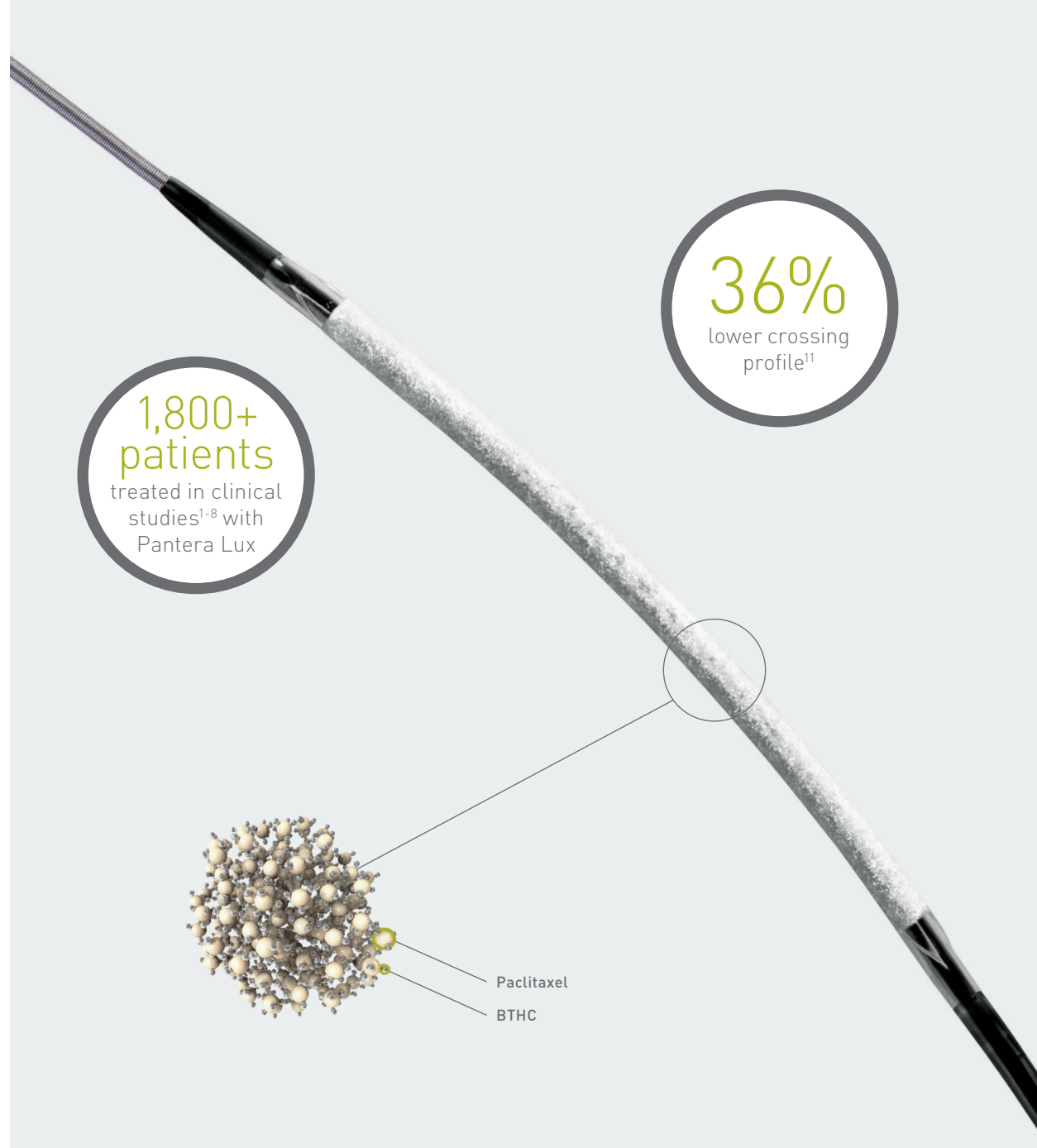
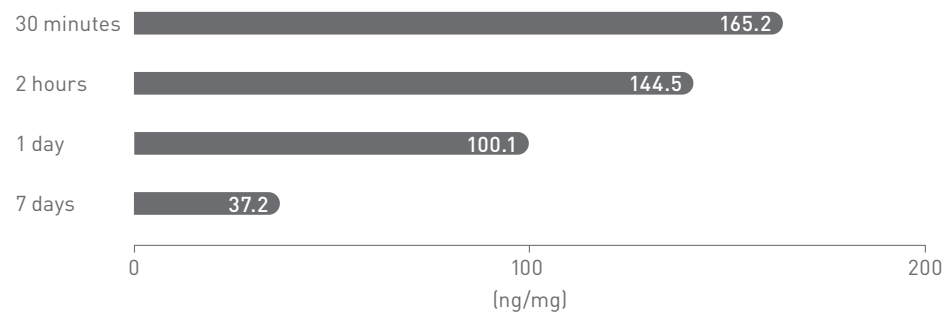
- Degrades to citric acid and alcohol, rapidly metabolized
- Keeps Paclitaxel in microcrystalline structure

Lux coating technology

- For rapid drug absorption into the vessel wall⁹
- Improving bioavailability at the target site⁹

Prolonged tissue retention at the target site^{9,10}

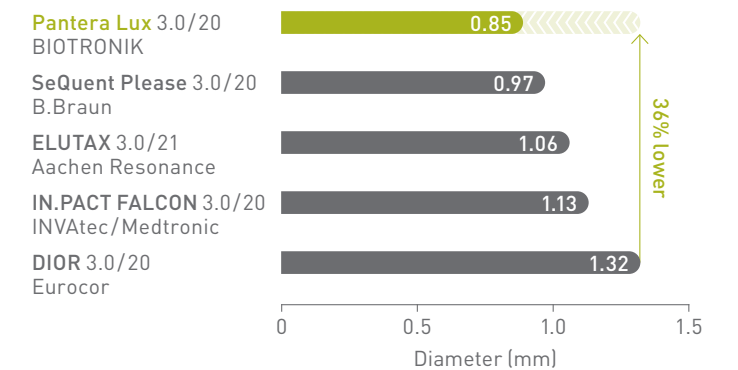
Pig coronary artery Paclitaxel tissue concentrations



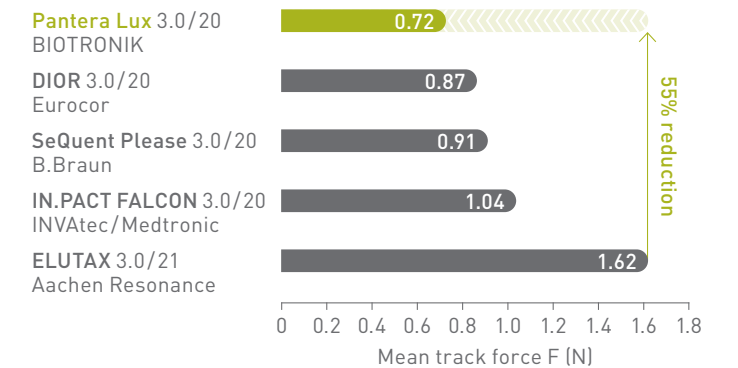
Advanced trackability

Pantera Lux, with its low crossing profile, provides advanced trackability to successfully reach and treat most cases in daily practice.

Low crossing profile¹¹



Low track force¹¹



Pantera Lux

Vascular
Intervention
Coronary



Indicated for balloon dilatation for in-stent restenosis, de-novo lesions, acute or impending vascular occlusion and treatment of small vessel disease.*

Technical Data		Drug-coated balloon catheter
Catheter type	Fast-exchange PTCA balloon catheter	
Recommended guide catheter	5F (min. I.D. 0.056")	
Lesion entry profile	0.017"	
Guide wire diameter	0.014"	
Usable catheter length	140 cm	
Balloon folding	3-fold	
Balloon markers	Two embedded platinum-iridium markers	
Brachial shaft marker	92 cm from tip	
Femoral shaft marker	102 cm from tip	
Proximal shaft diameter	2.0F	
Distal shaft diameter	2.5F (ø 2.0 - 3.5 mm), 2.6F (ø 4.0 mm)	
Nominal Pressure (NP)	7 atm	
Rated Burst Pressure (RBP)	13 atm (ø 2.0 - 3.5 mm); 12 atm (ø 4.0 mm)	
Coating		
Drug	Paclitaxel	
Drug dose	3.0 µg/mm ²	
Delivery 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 10-30	ø 2.5 x 10-30	ø 3.0 x 10-30	ø 3.5 x 10-30	ø 4.0 x 10-30
Nominal Pressure (NP)	atm**	7	7	7	7	7
	ø (mm)	2.00	2.50	3.00	3.50	4.00
Rated Burst Pressure (RBP)	atm**	13	13	13	13	12
	ø (mm)	2.26	2.82	3.48	4.11	4.59

**1 atm = 1.013 bar

Ordering Information	Balloon ø (mm)	Catheter length 140cm Balloon length (mm)				
		10	15	20	25	30
	2.0	365110	365111	365112	365113	365114
	2.5	365120	365121	365122	365123	365124
	3.0	365125	365126	365127	365128	365129
	3.5	365130	365131	365132	365133	365134
	4.0	365135	365136	365137	365138	365139

1. Hehrlein C. et al. Cardiovasc. Revasc. Med. 2012 Sep; 13(5): 260-4; 2. Toelg R. et al. EuroIntervention 2014 Sep; 10(5): 591-9; 3. Naber C.K. EuroPCR 2016, oral presentation. BIOLUX RCT Clinical performance of the Pantera Lux Paclitaxel coated balloon vs. drug-eluting Orsiro hybrid stent system in patients with in-stent restenosis: a randomized controlled trial; 4. Kufner et al. J Am Coll Cardiol Intv 2017;10: 1332 -40, Clinical trials.gov, NCT01632371; 5. Garcia-Touchard et al. EuroIntervention. 2017 Jan 20;12(13):1587-1594. NCT01839890; 6. Vos N. S. et al. EuroIntervention 2014;10:584-590; 7. Jim M. H. AsiaPCR 2014, oral presentation, Six-month Angiographic Restudy of Paclitaxel-Eluting balloon kissing in Dealing with side branch Ostial Narrowing (SARPEDON); 8. Worthley S. et al. Cardiovasc. Revasc. Med. 2015; 16: 413-417; 9. Radke P. et al. EuroIntervention. 2011 Oct; 7(6): 730-7; 10. BIOTRONIK data on file; 11. BIOTRONIK data on file, compared to main competitors.

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*Indication as per IFU (may differ in countries not accepting CE mark).