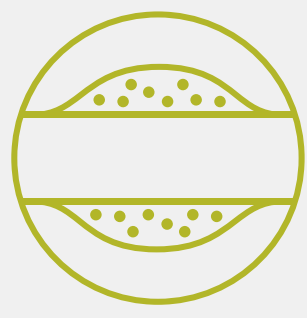




Clinically proven solution for in-stent -restenosis and further indications



Lux[®] coating technology for rapid drug absorption



Excellent deliverability



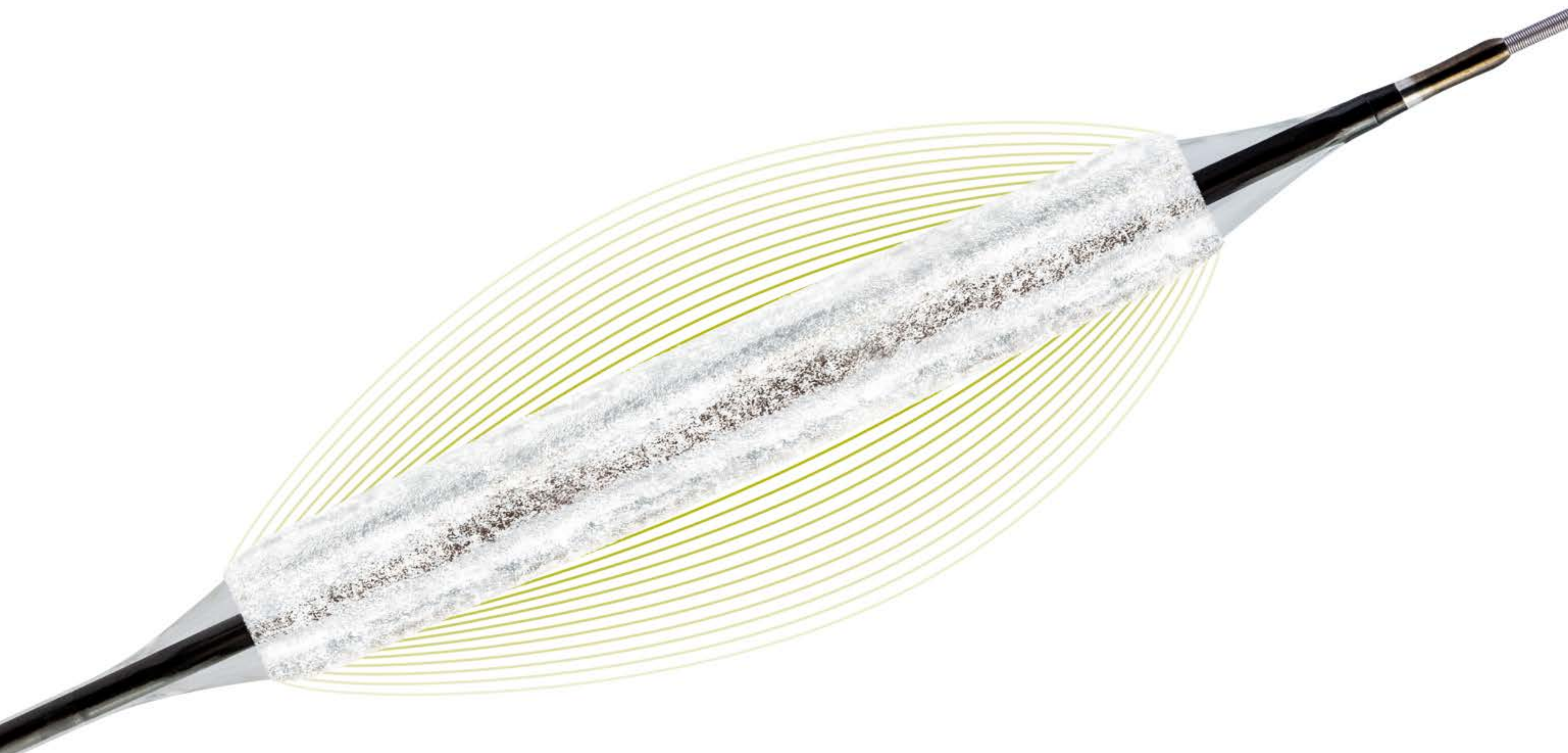
Technical data / ordering info

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



Pantera[®] Lux[®] DCB

Clinically proven. Best in class crossability.



Pantera Lux^{DCB}

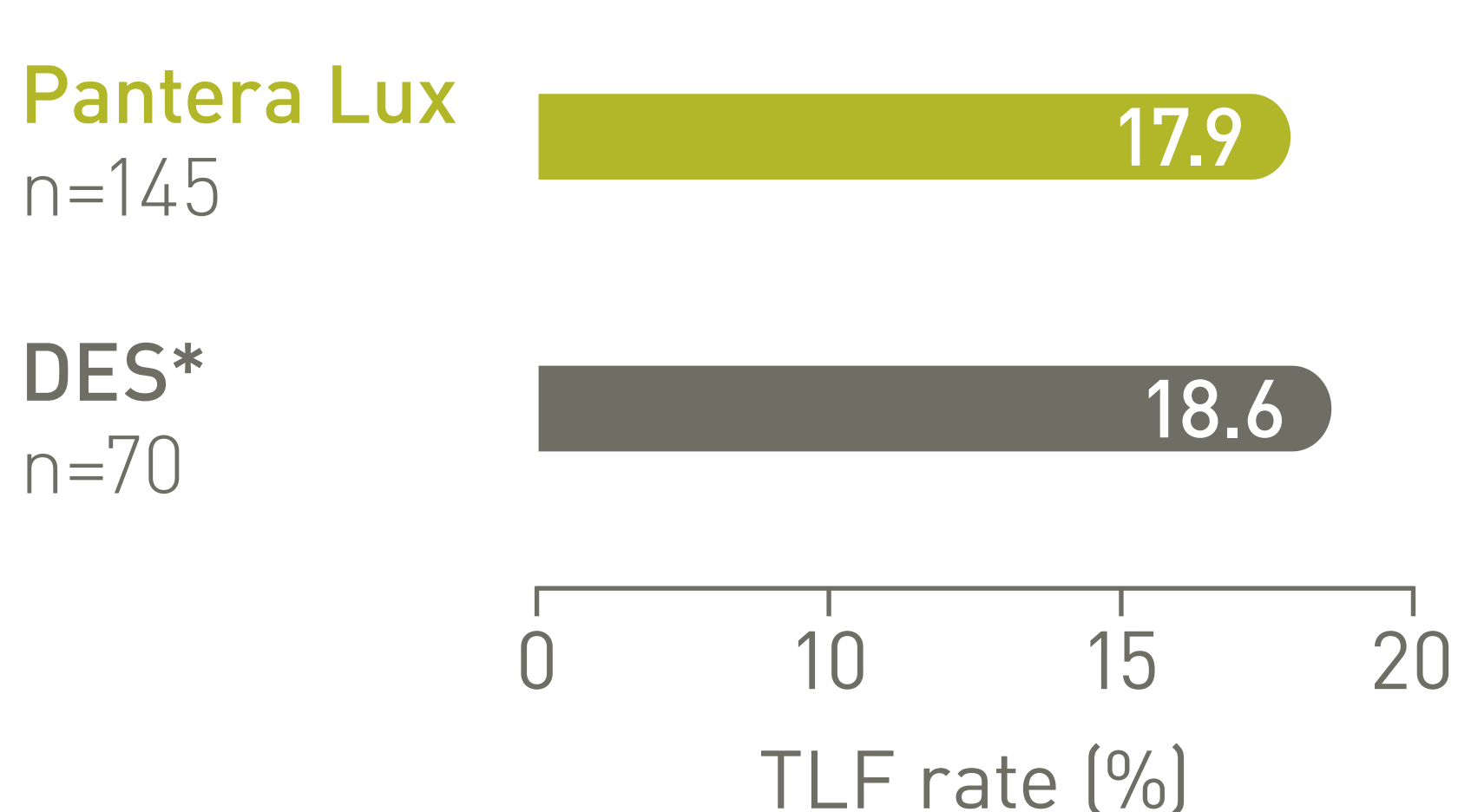
Clinically proven.
Best in class crossability.

Clinically proven solution for in-stent -restenosis and further indications¹⁻¹²

Pantera Lux has proven efficacy and safety in multiple clinical trials investigating coronary drug-coated balloons for various implant-free treatment options:¹⁻¹⁰



BIOLUX RCT (n=229)⁴
Target Lesion Failure (TLF) rate at 18 months (p>0.99)



REVELATION (n=120)⁸
Mean Fractional Flow Reserve (FFR) rate at 9 months (p=0.27)



The treatment with Pantera Lux DCB may represent a valuable alternative strategy in selected STEMI patients undergoing primary PCI.

DCB is confirmed as a viable treatment option for ISR with the advantage of avoiding an additional stent layer.

*Orsiro (BIOTRONIK)

**Orsiro (BIOTRONIK) or Xience (Abbott)

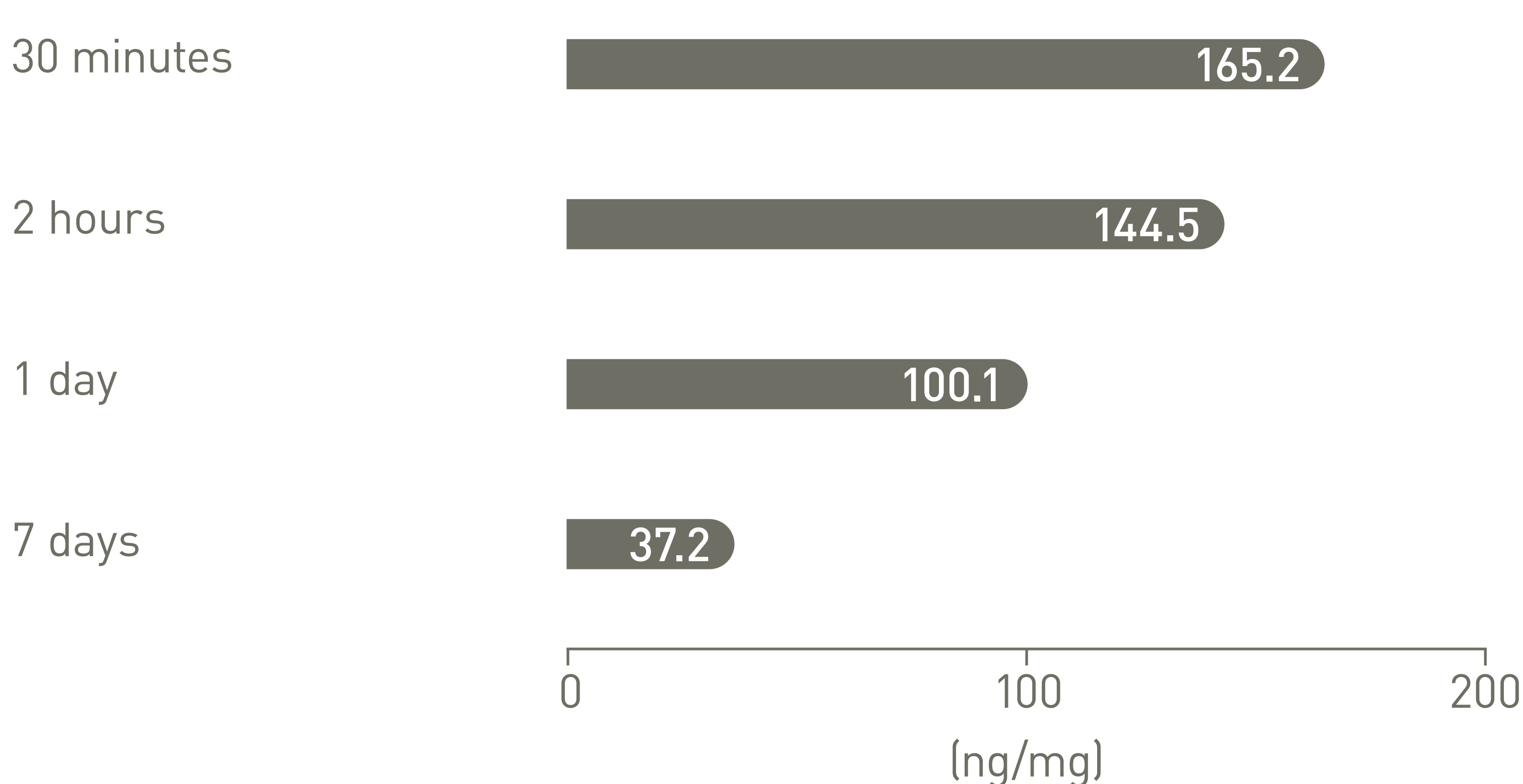


Lux coating technology for rapid drug absorption

The Lux coating technology blends paclitaxel with BTHC, a rapidly metabolized, safe and biocompatible excipient, thus improving bioavailability at the target site.¹⁴

Prolonged tissue retention at the target site^{14,15}

Pig coronary artery Paclitaxel tissue concentrations



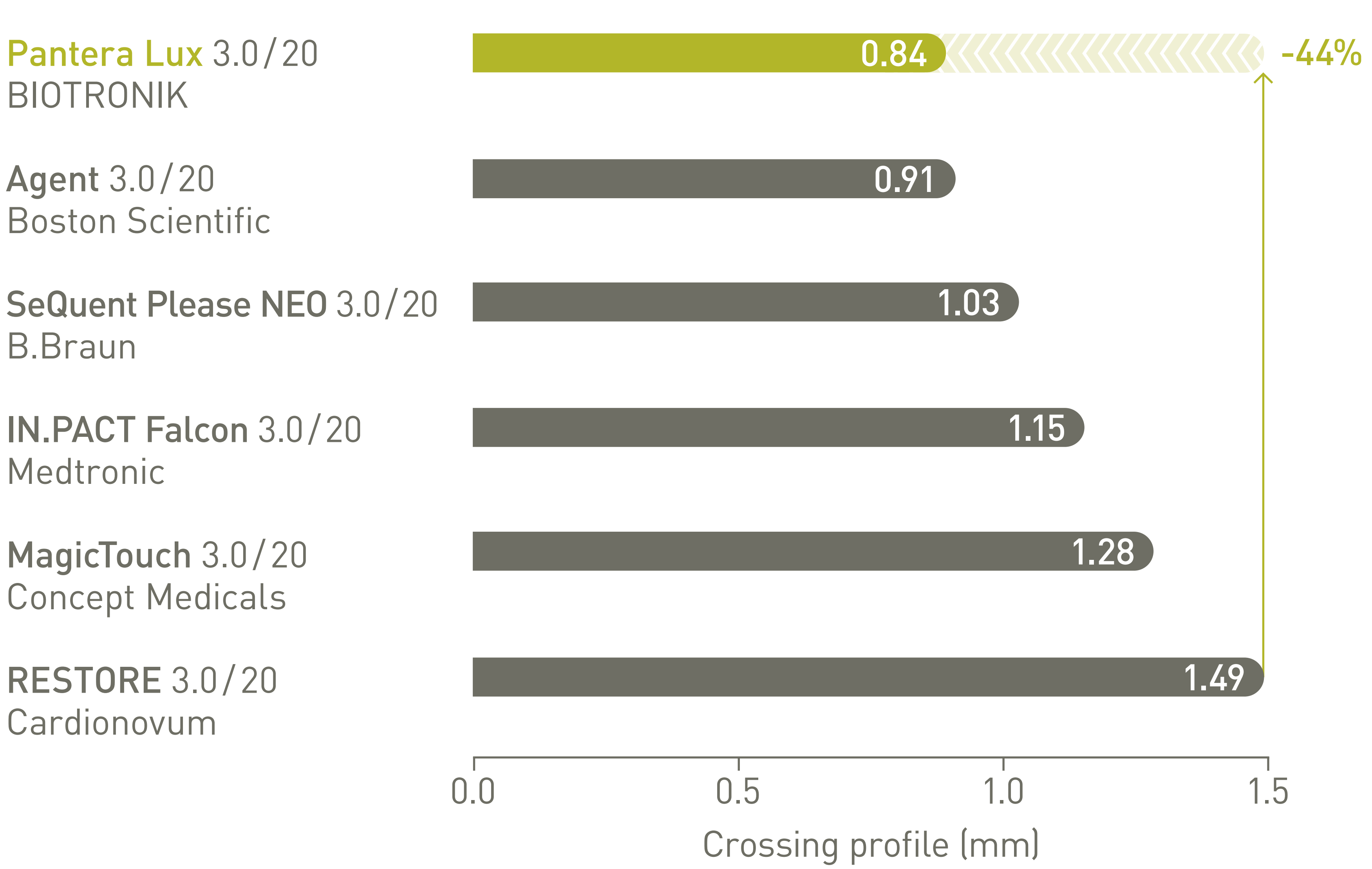


Excellent deliverability

Pantera Lux, with its lowest crossing profile, provides better pushability and easier crossability.¹⁵

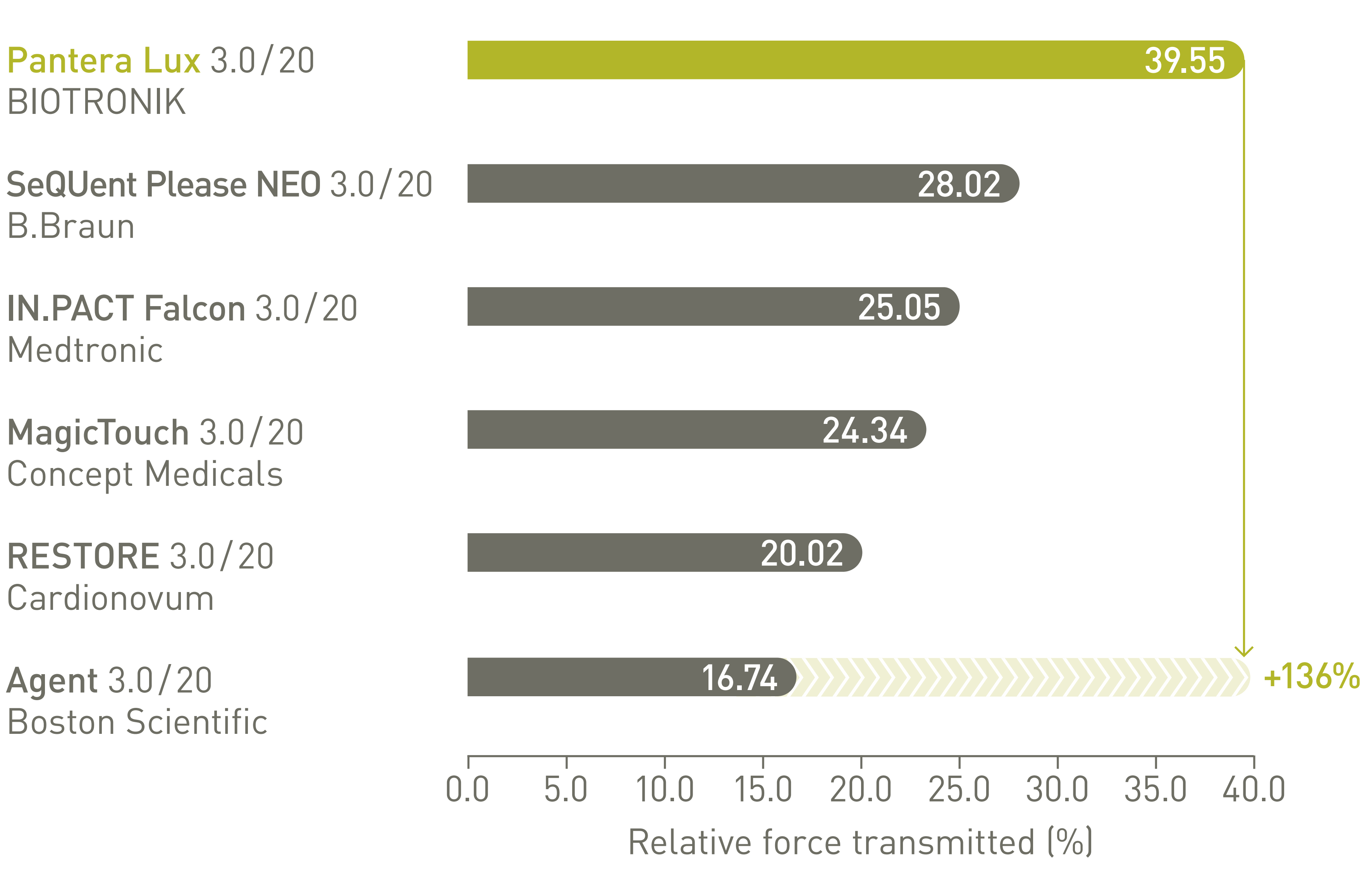
Lowest crossing profile¹⁵

Pantera Lux has a **44% smaller** crossing profile.



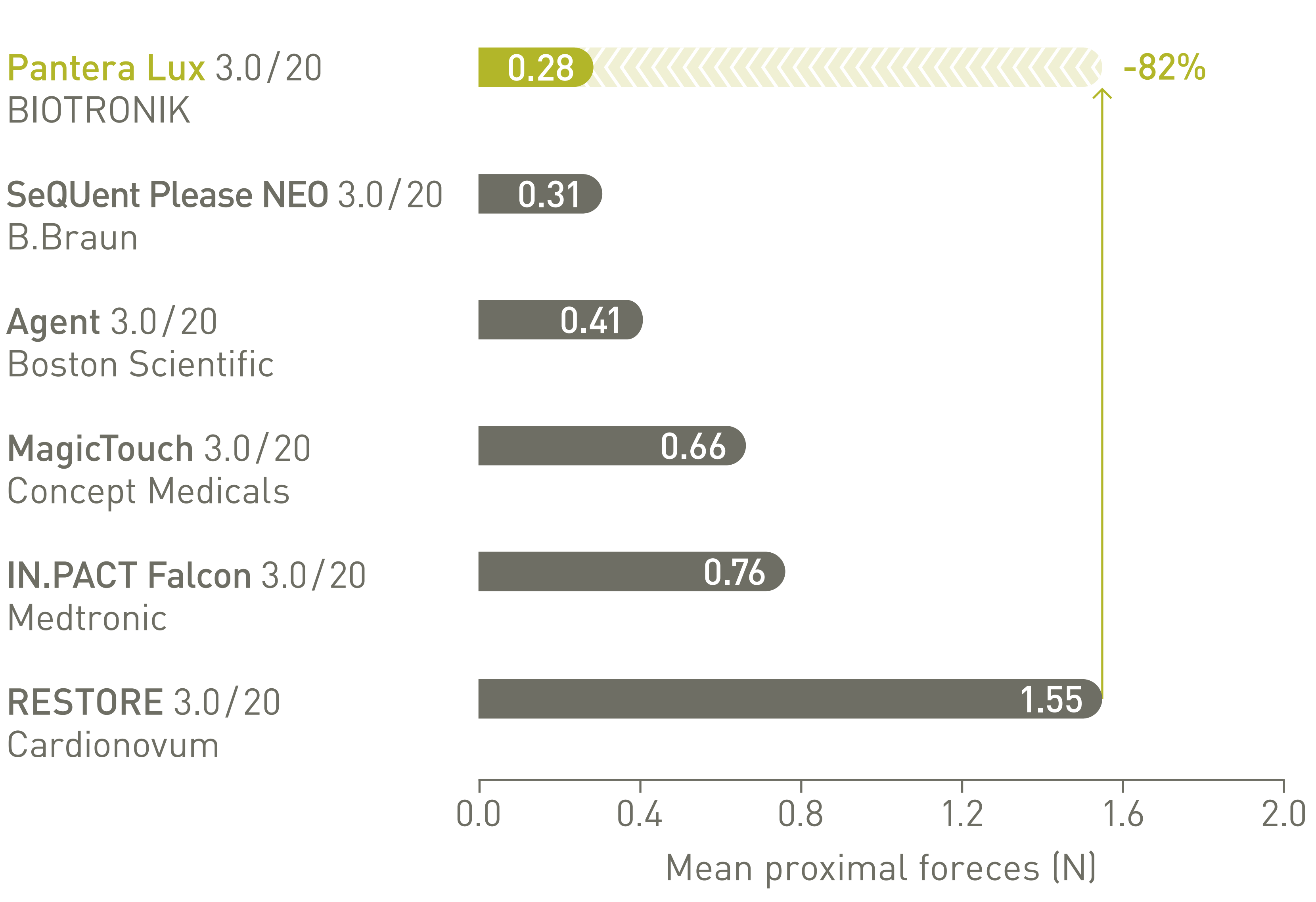
Better pushability¹⁵

136% more force transmitted from hub to distal tip.



Best in class crossability¹⁵

82% less force needed to cross lesions.



82%
easier crossability
vs. RESTORE¹⁵





Pantera[®] Lux[®] DCB

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

The Pantera[®] Lux[®] DCB with its Lux[®] coating is part of the Lux[®] family of Paclitaxel-coated balloons from BIOTRONIK.

*Indication as per IFU (may differ in countries not accepting CE mark); 1. Tölg R et al. Coronary artery treatment with paclitaxel-coated balloon using a BTHC excipient: clinical results of the international real-world DELUX registry EuroIntervention. 2014; 10(5): 591-599; 2. Hehrlein C et al. Twelve-month results of a Paclitaxel Releasing Balloon in Patients Presenting with In-stent Restenosis First-in-Man (PEPPER) trial. Cardiovascular Revascularization Medicine. 2012; 13(5): 260-264; 3. Kufner S, Joner M, Schneider S et al. Neointimal Modification With Scoring Balloon and Efficacy of Drug-Coated Balloon Therapy in Patients With Restenosis in Drug-Eluting Coronary Stents. JACC Cardiovasc Interv. 2017; 10(13): 1332-1340; 4. Jensen C et al. Angiographic and clinical performance of a paclitaxel-coated balloon compared to a second-generation sirolimus-eluting stent in patients with in-stent restenosis: the BIOLUX randomised controlled trial. EuroIntervention. 2018; 14: 1096-1103; 5. Nguyen V.P.T et al. Comparison of clinical outcomes of two different types of paclitaxel-coated balloons for treatment of patients with coronary in-stent restenosis. Heart and Vessels. 2019; 1-9. doi: 10.1007/s00380-019-01388; 6. Assadi-Schmidt A et al. SeQuent Please vs. Pantera Lux drug coated balloon angioplasty in real life: Results from the Düsseldorf DCB registry, Int J Cardiol. 2016. doi: 10.1016/j.ijcard.2016.12.022; 7. Vos NS et al. Safety and feasibility of a Paclitaxel-eluting balloon angioplasty in Primary Percutaneous coronary intervention in Amsterdam (PAPPA): one year clinical outcome of a pilot study. EuroIntervention. 2014; 10(5): 584-590; 8. Vos N S et al. Paclitaxel-Coated Balloon Angioplasty Versus Drug-Eluting Stent in Acute Myocardial Infarction (The REVELATION Randomized Trial). JACC: Cardiovascular Interventions. 2019; 1-9. doi:10.1016/j.jcin.2019.04.016; 9. Worthley S, Hendriks R, Worthley M et al. Paclitaxel-eluting balloon and everolimus-eluting stent for provisional stenting of coronary bifurcations: 12-months results of the multicenter BIOLUX-I study. Cardiovasc Revasc. Med. 2015; 16(7): 413-417; 10. Jim MH et al. Six month angiographic result of supplementary paclitaxel-eluting balloon deployment to treat side branch ostium narrowing (SARPEDON). Int J Cardiol. 2015; 187:594-597; 11. Roncalli J et al. Paclitaxel Drug-Coated Balloon After Bare-Metal Stent Implantation, an Alternative Treatment to Drug-Eluting Stent in High Bleeding Risk Patients (The Panelux Trial). J INVASIVE CARDIOL. 2019;31(4):94-100; 12. García-Touchard A, Goicolea J, Sabaté M et al. A randomised trial of paclitaxel-eluting balloon after bare metal stent implantation vs. bare metal stent in ST-elevation myocardial infarction (the PEBSI study). EuroIntervention. 2017; 12(13): 1587-1594; 13. Venetsanos D, Omerovic E, Sarno G et al. Long term outcome after treatment of de novo coronary artery lesions using three different drug coated balloons. International Journal of Cardiology. 2020; 1-7. doi: 10.1016/j.ijcard.2020.09.054; 14. Radke PW et al. Vascular effects of paclitaxel following drug-eluting balloon angioplasty in a porcine coronary model: the importance of excipients. EuroIntervention. 2011 Oct; 7(6): 730-7; 15. BIOTRONIK data on file.

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