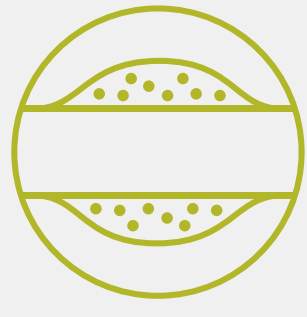




Clinically proven solution for in-stent restenosis and de novo lesions



Lux coating technology for rapid drug absorption



Advanced trackability

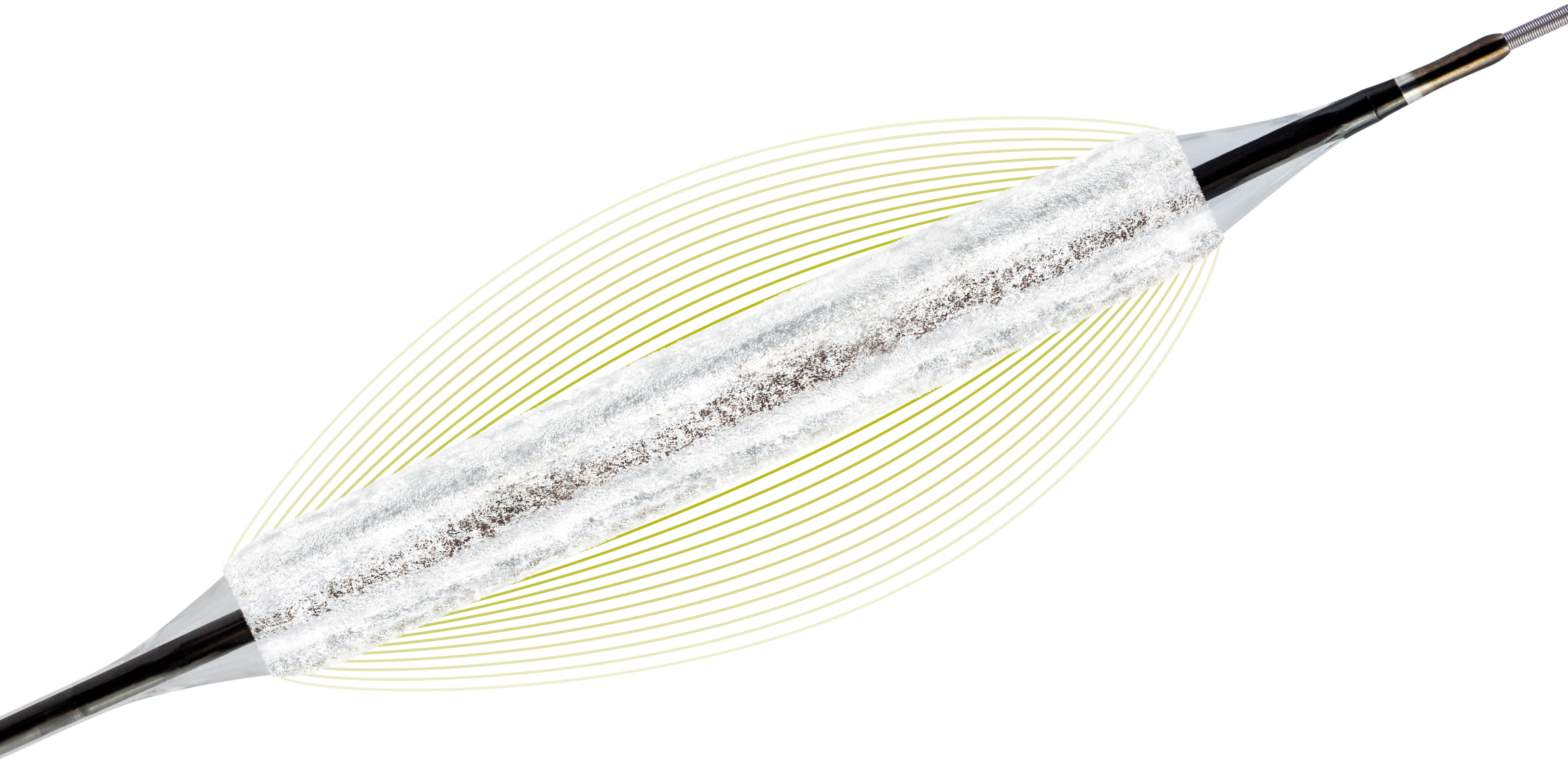


Technical data / ordering info

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

 **BIOTRONIK**  
excellence for life

# Pantera Lux



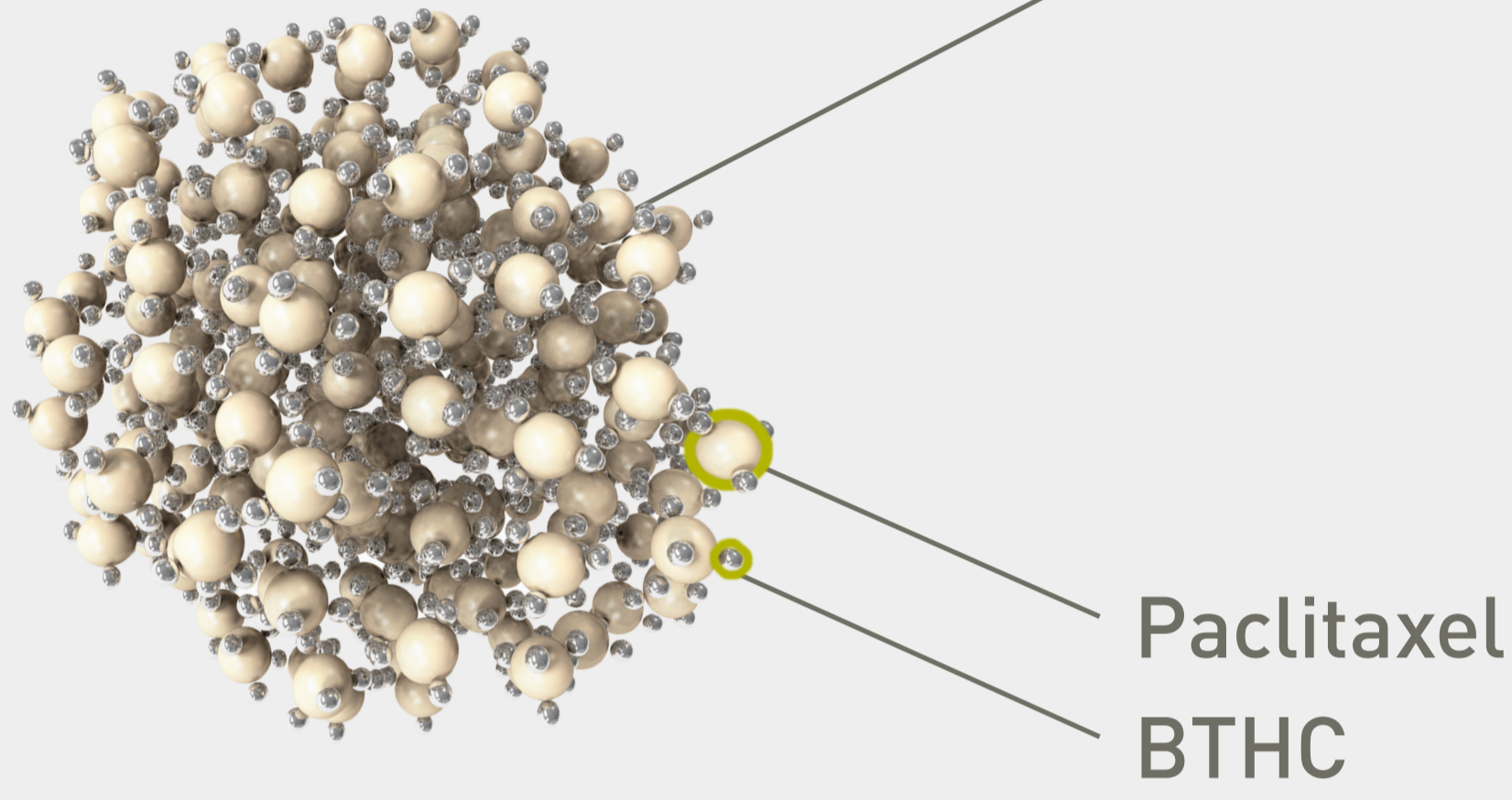


# Clinically proven solution for in-stent restenosis and de novo lesions

Clinical outcomes from multiple studies<sup>1-8</sup> 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.



**1,800+**  
patients  
treated in clinical  
studies<sup>1-8</sup> with  
Pantera Lux



## Lux coating technology for rapid drug absorption

### Drug Paclitaxel

- 3.0 µg Paclitaxel /mm<sup>2</sup> balloon surface
- Anti-proliferative

### Excipient Butyryl-tri-hexyl citrate (BTHC)

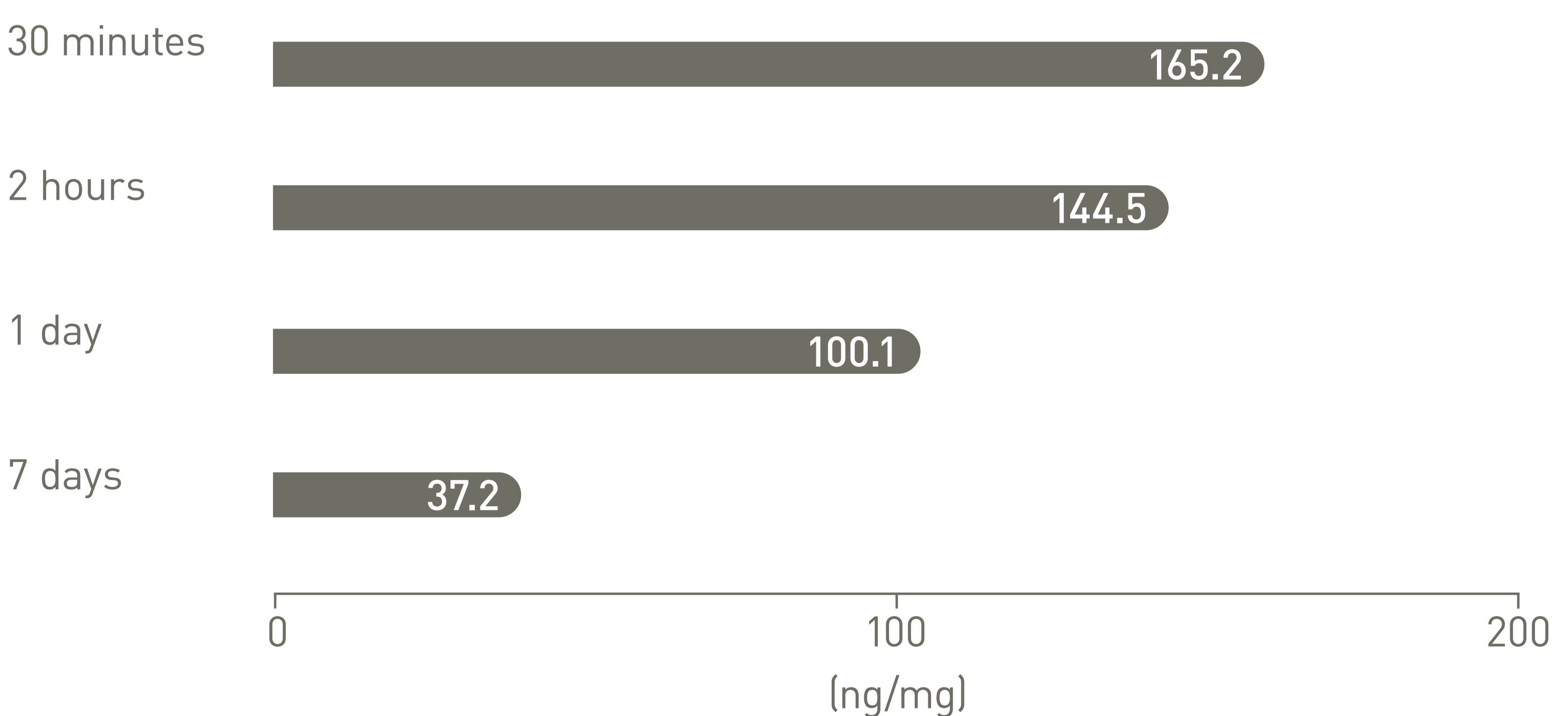
- Degrades to citric acid and alcohol, rapidly metabolized
- Keeps Paclitaxel in microcrystalline structure

### Lux coating technology

- For rapid drug absorption into the vessel wall<sup>9</sup>
- Improving bioavailability at the target site<sup>9</sup>

## Prolonged tissue retention at the target site<sup>9, 10</sup>

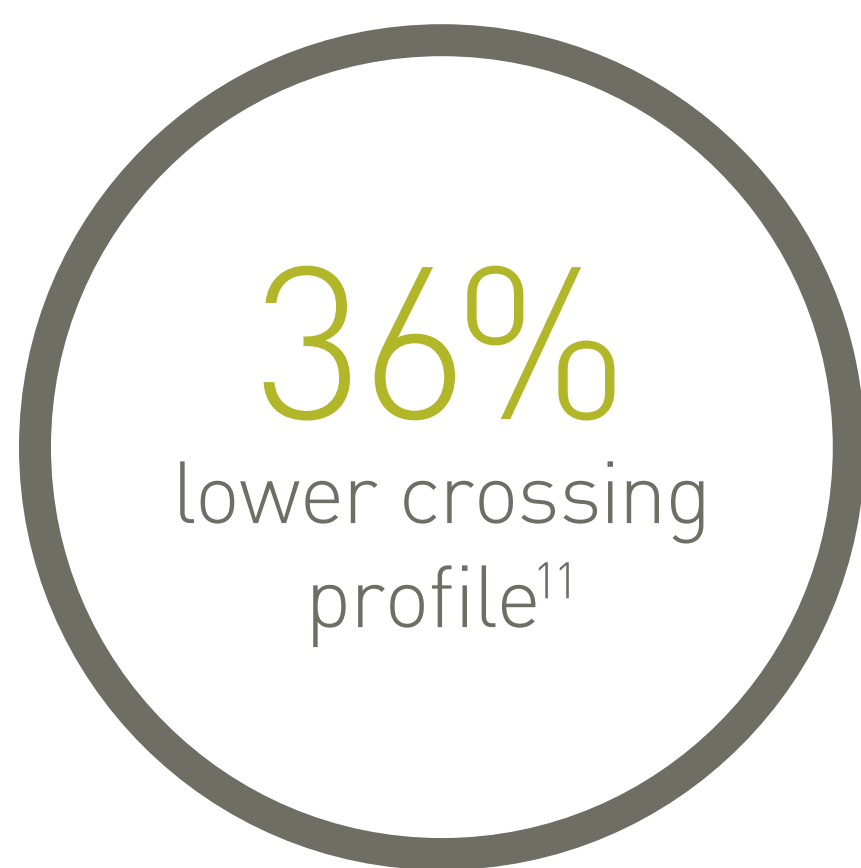
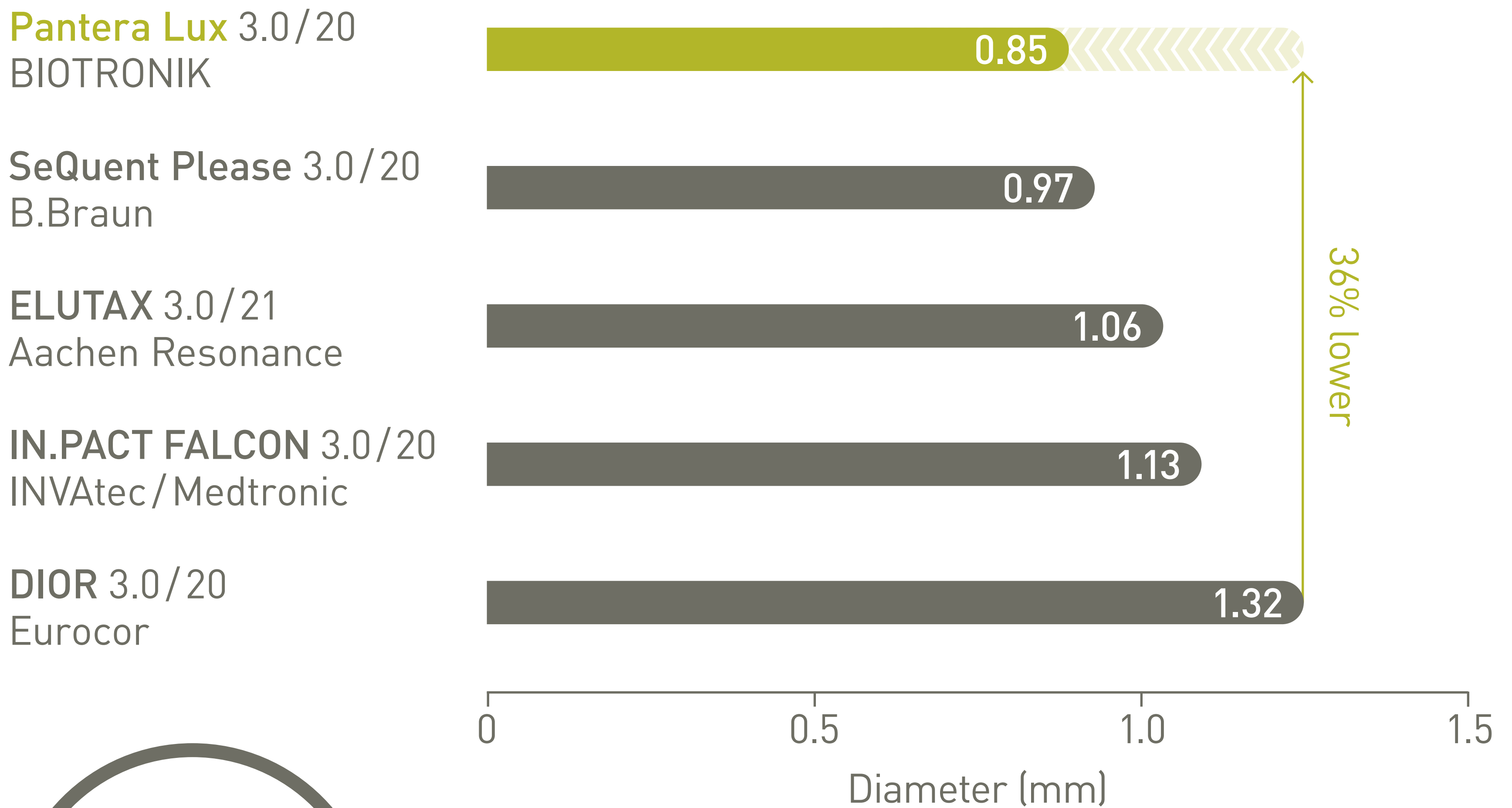
Pig coronary artery Paclitaxel tissue concentrations



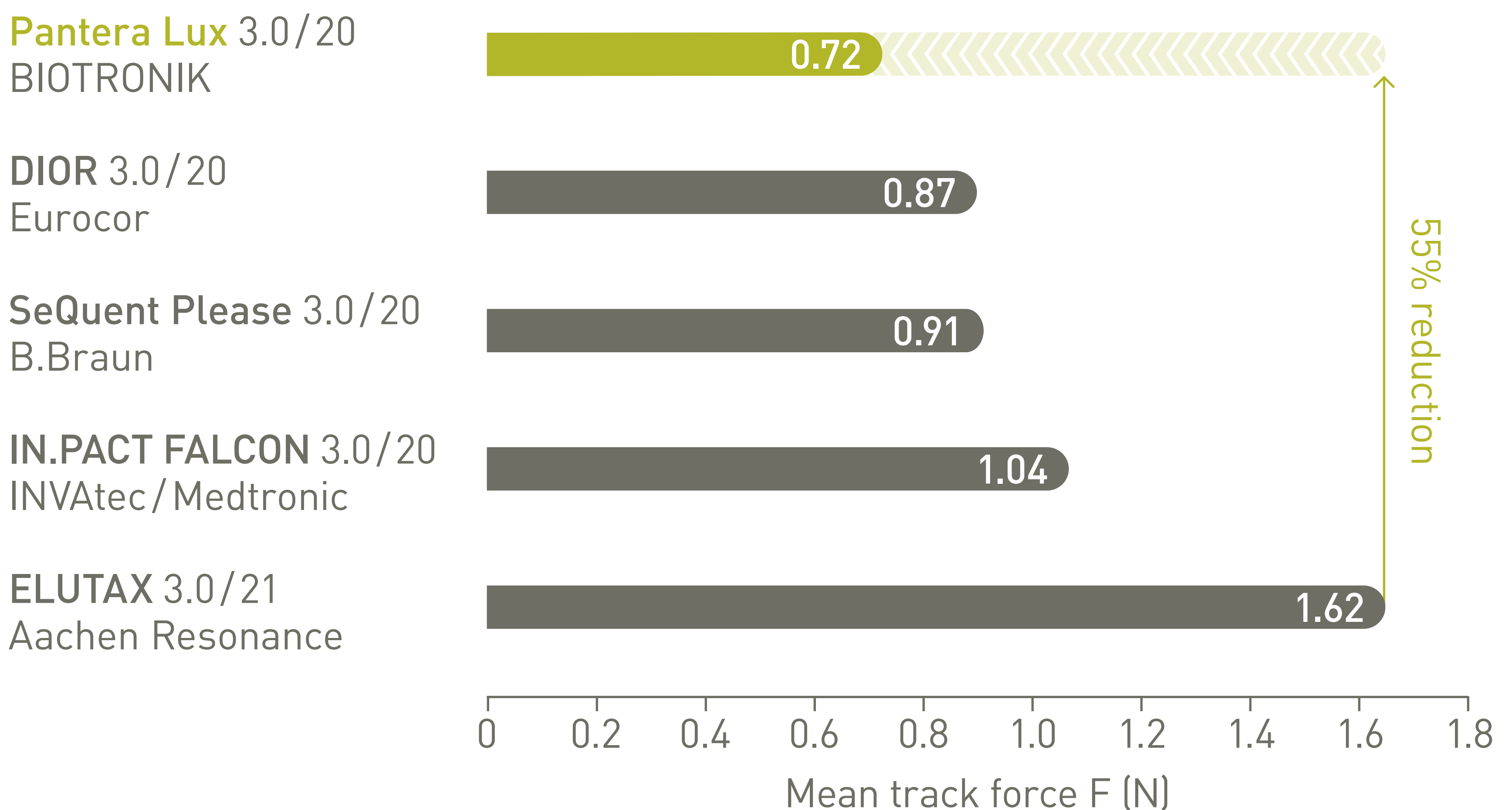
# Advanced trackability

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

## Low crossing profile<sup>11</sup>



## Low track force<sup>11</sup>







# Pantera Lux

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)                                    |  |
| <b>Coating</b>             |   |  |
| Drug                       | Paclitaxel  |  |
| Drug dose                  | 3.0 µg/mm <sup>2</sup>  |  |
| 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<br>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).

