BIOPACT RCT

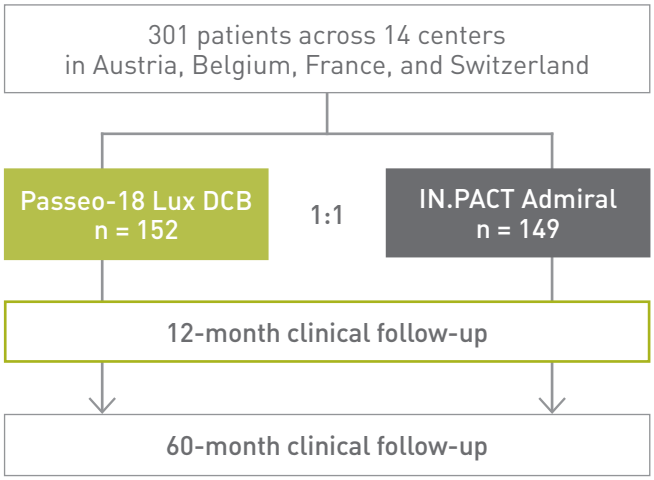
Head-to-head comparison of Passeo®-18 Lux® DCB to IN.PACT Admiral DCB at 12 Months[1]

Conclusions

- The BIOPACT RCT demonstrated the noninferiority of the low-profile[2] Passeo-18 Lux DCB compared to IN.PACT Admiral, with excellent safety and efficacy results at 12 months:
  - Freedom from CD-TLR[3]: Passeo-18 Lux, 97.2% vs IN.PACT Admiral, 97.0% (p = 0.0002)
  - Primary safety endpoint[4]: Passeo-18 Lux, 95.7% vs IN.PACT Admiral, 96.3% (p = 0.0008)
  - Primary patency[5]: Passeo-18 Lux, 88.2% vs IN.PACT Admiral, 89.1% (p = 1.00)

Study design

Physician-initiated, prospective, multicenter, single-blinded, 1:1 randomized controlled non-inferiority trial comparing the safety and efficacy of the Passeo-18 Lux drug-coated balloon versus the IN.PACT Admiral drug-coated balloon for treatment of stenotic, restenotic or occlusive lesions of the femoropopliteal arteries.



Endpoints

Primary Endpoints

- Efficacy: 12-month freedom from CD-TLR[2]
- Safety: composite of freedom from device- and procedure-related death through 30 days, freedom from major target limb amputation and clinically driven target vessel revascularization through 12 months

Secondary Endpoints

- 6- and 12-month freedom from MAE (all-cause death, clinically driven target vessel revascularization, major target limb amputation, or thrombosis at target lesion)
- 6- and 12-month primary patency
- 6- and 12-month freedom from all-cause mortality
- 6- and 12-month freedom from major target limb amputation

Patient characteristics	Passeo-18 Lux n = 152	IN.PACT Admiral n = 149
Age ± SD, years (range ± SD)	69 ± 8 (47-87)	67 ± 9 (44-90)
Diabetes mellitus	39 (25.7%)	44 (29.5%)
Hypertension	109 (71.7%)	118 (79.2%)
Hypercholesterolemia	110 (72.4%)	116 (77.9%)
Smoking	58 (38.2%)	74 (49.7%)
Previous arterial intervention	73 (48%)	55 (36.9%)
Previous coronary intervention	42 (27.6%)	37 (24.8%)
Rutherford Classification		
Class 2 Moderate	39 (25.8%)	35 (23.5%)
Class 3 Severe	101 (66.9%)	103 (69.1%)
Class 4 Ischemic Rest Pain	11 (7.3%)	11 (7.4%)

Lesion characteristics	Passeo-18 Lux	IN.PACT Admiral
Reference vessel diameter (mm)*	5.3 ± 0.7 (4-7)	5.4 ± 0.7 (4-7)
Lesion length (mm)*	74 ± 49.4 (4-180)	65.6 ± 39 (5-180)
% Stenosis (mm)*	84.1 ± 9.7 (50-99)	84.8 ± 9.4 (70-99)
Total occlusion	26 (17.1%)	31 (20.8%)
Calcification (moderate-severe)	**121 (79.6%)**	**106 (71.1%)**
Lesion location		
Proximal SFA	16 (10.5%)	15 (10.1%)
Mid SFA	71 (46.7%)	76 (51.0%)
Distal SFA	68 (44.7%)	54 (36.2%)
P1	16 (10.5%)	21 (14.1%)

Procedure details	Passeo-18 Lux	IN.PACT Admiral
Pre-dilatation	152 (100%)	149 (100%)
Bailout stenting	16 (10.5%)	17 (11.4%)
Postdilatation	23 (15.1%)	20 (13.4%)

* Data shown as mean ± SD (range)

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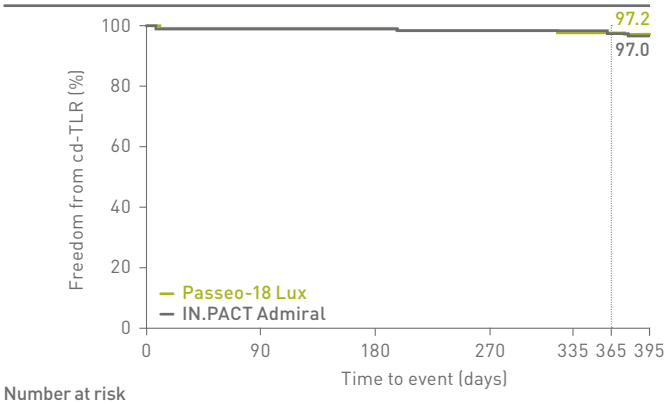
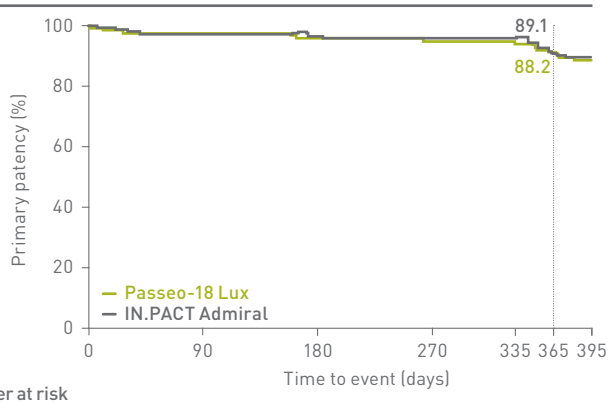
Freedom from CD-TLR[2]



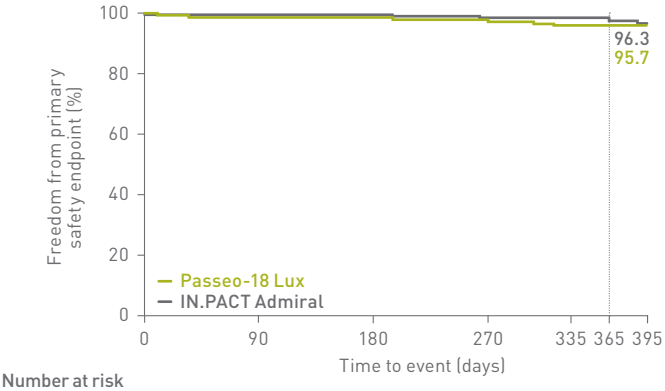
Number at risk							
IN.PACT Admiral	149	141	139	133	132	104	76
Passeo-18 Lux	152	149	145	141	137	114	78

Primary patency[5] (core lab adjudicated)



Number at risk							
IN.PACT Admiral	149	135	125	109	108	101	99
Passeo-18 Lux	152	137	131	113	112	109	105

Primary safety endpoint[4]



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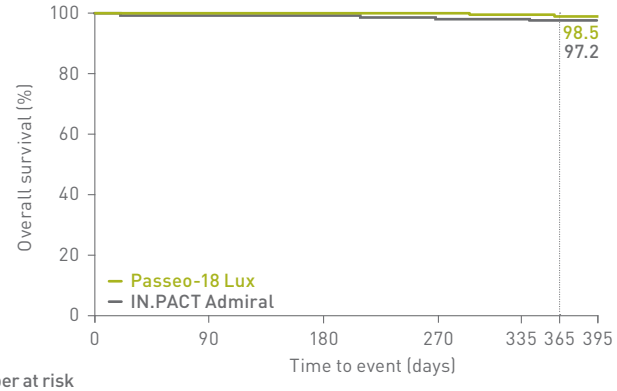
Survival



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Event	Passeo-18 Lux	IN.PACT Admiral
Death related to procedure/device	0	0
Target vessel revascularization	6	5
Major amputation	0	0

Passeo-18 Lux key outcomes

12-m **97.2%** Freedom from cd-TLR

12-m **95.7%** Freedom from primary safety endpoint

12-m **98.5%** Overall survival

12-m **88.2%** Primary patency

Principal investigator

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CD-TLR: Clinically Driven Target Lesion Revascularization, DCB: Drug-Coated Balloon, MAE: Major Adverse Events, P1: Popliteal Segment 1, SFA: Superficial Femoral Artery.

1. BIOPACT RCT: a third head to head DCB RCT. Deloose K. Presented at Paris Vascular Insights 2022; 2. BIOTRONIK data on file; 3. Freedom CD-TLR: Freedom from any reintervention at the target lesion due to symptoms, drop of ankle-brachial index (ABI) > 20% or ABI > 0.15 compared to postprocedural ABI; 4. Primary safety endpoint: composite of freedom from device- and procedure-related death through 30 days, freedom from major target limb amputation and clinically driven target vessel revascularization through 12 months; 5. Primary patency: composite of freedom from CD-TLR and binary restenosis (restenosis defined as duplex ultrasound [DUS] peak systolic velocity ratio ≤2.4 or ≤50% stenosis as assessed by an independent DUS core lab at 12-month follow-up).

The **Passeo-18® Lux® DCB** with its **Lux®** coating is part of the **Lux®** family of Paclitaxel-coated balloons from BIOTRONIK.

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