

BIOPACT RCT

Head-to-head comparison of Passeo™-18 Lux™ DCB to IN.PACT Admiral DCB at 36 Months¹

Conclusions

- The BIOPACT RCT demonstrated the non-inferiority of the low-profile Passeo™-18 Lux™ DCB compared to IN.PACT Admiral, with excellent safety and efficacy results at 12 months^{2,3}:
 - Freedom from CD-TLR[◇]: Passeo™-18 Lux™, 97.2 % vs IN.PACT Admiral, 97.0 % (p=0.0002)
 - Primary safety endpoint[△]: Passeo™-18 Lux™, 95.7 % vs IN.PACT Admiral, 96.3 % (p=0.0008)
- Non-inferiority of Passeo™-18 Lux™ DCB compared to IN.PACT Admiral is maintained at 36 months^{1,3}:
 - Freedom from CD-TLR[◇]: Passeo™-18 Lux™, 91.4 % vs IN.PACT Admiral, 92.7 % (p=0.009485)

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™ DCB versus the IN.PACT Admiral DCB (Medtronic) for treatment of stenotic, restenotic or occlusive lesions of the femoropopliteal arteries.

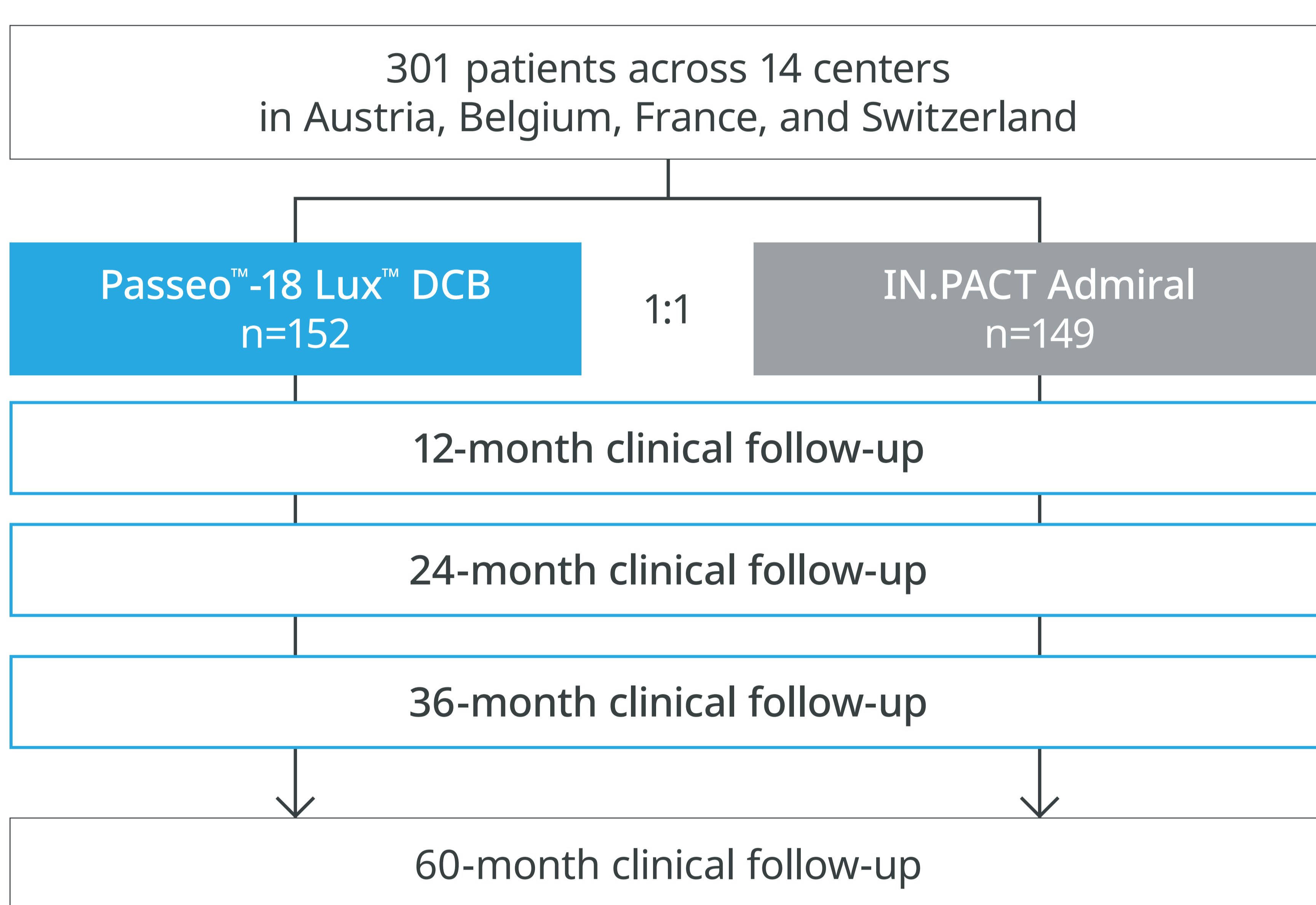
Endpoints

Primary endpoint

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

Secondary endpoints (selected)

- Freedom from MAE* - up to 60 months
- 6-, 12-, 24-, 36-, 48- and 60-month primary patency^φ
- 6-, 12-, 24-, 36-, 48- and 60-month freedom from all-cause mortality
- 6-, 12-, 24-, 36-, 48- and 60-month freedom from major target limb amputation
- 6-, 24-, 36-, 48- and 60-month freedom from CD-TLR[◇]



[◇] Kaplan-Meier estimate for freedom CD-TLR, defined as 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.
[△] Primary safety endpoint defined as 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.
^φ Primary patency defined as 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 6- and 12-month follow-up).
 * all-cause death, CD-TVR, major target limb amputation, or thrombosis at target lesion.

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)*	74.0±49.4 (4-180)	65.6±39 (5-180)
% Stenosis*	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 %)

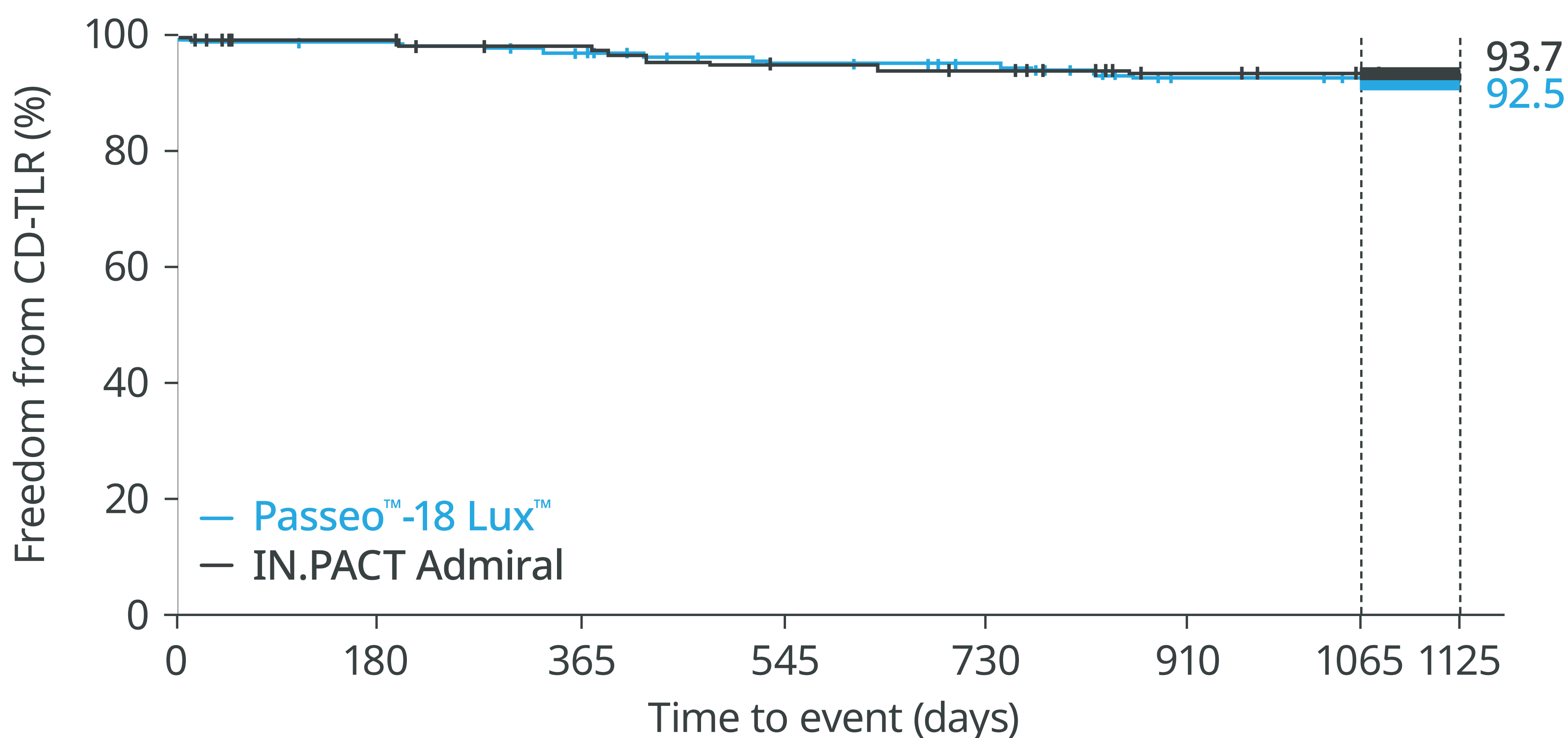
* Data shown as mean±SD (range)





At 3 years¹

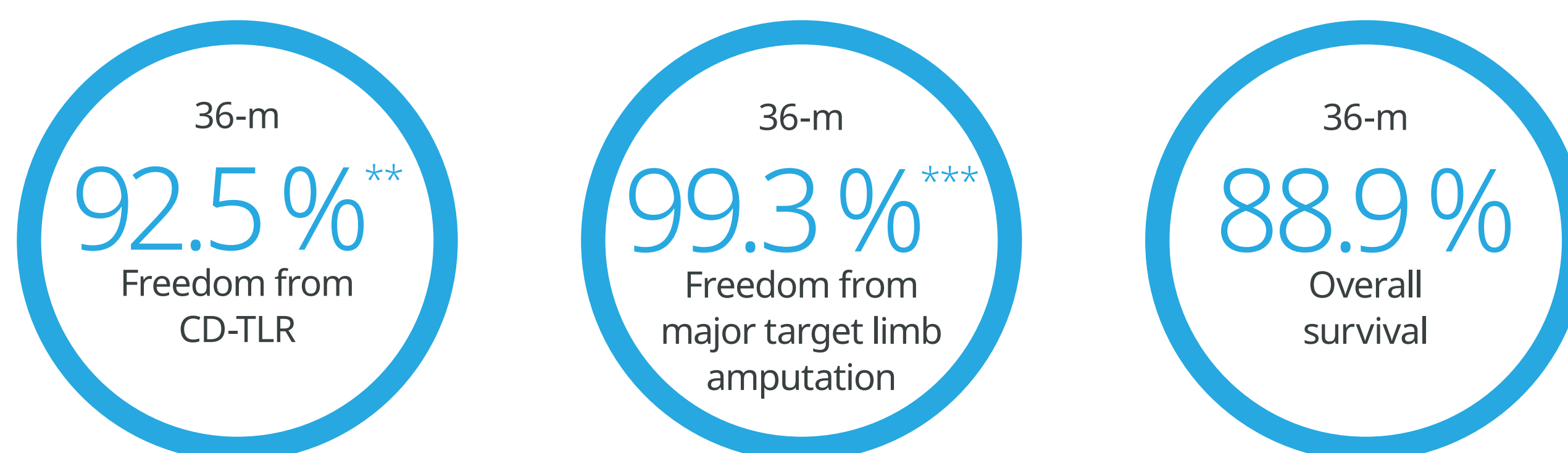
Freedom from clinically-driven TLR



Number at risk

IN.PACT Admiral	149	143	138	131	128	120	115	6
Passeo™ -18 Lux™	152	150	144	137	131	121	117	6

Passeo™ -18 Lux™ key outcomes



^{**} Kaplan-Meier estimate

^{***} Crude rates shown; data do not account for patients who died, withdrew consent, or were not evaluated at the 3-year follow-up.

Principal investigator: Dr. Koen Deloose, Dendermonde, Belgium

References:

- 1 Deloose K. The head-to-head Passeo-18 Lux vs IN.PACT Admiral BIOPACT RCT: latest release of the 36 month outcomes. Presented at: LINC 2025; January 28-30, 2025; Leipzig, Germany.
- 2 Deloose KR, Lansink W, Brodmann M, et al. Head-to-Head Comparison of 2 Paclitaxel-Coated Balloons for Femoropopliteal Lesions. JACC: Cardiovascular Interventions 2023;16:2900-14.
- 3 Data on file.

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

The Passeo-18™ Lux™ DCB with its Lux™ coating is part of the Lux™ family of Paclitaxel-coated balloons.

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