Paclitaxel-coated balloon treatment in patients with in-stent restenosis: Twenty-four month results of the real-world all-comers registry BIOLUX P-III

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Disclosure

Speaker name: Prof. Dr. Marianne Brodmann

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

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Passeo-18 Lux Paclitaxel-Coated Balloon

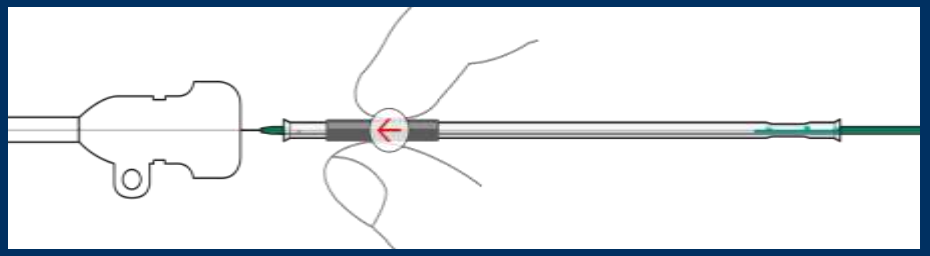
Passeo-18 balloon platform

Controlled compliance
Low profile
Highly deliverable

Paclitaxel	3 µg/mm²
Excipient	BTHC (Butyryl-tri-hexyl citrate), Hydrophobic
Sizes available	2.0 – 7.0 mm diameter 40-80-120 mm length

SafeGuard Insertion Aid:

- Protects the user and coating from contact and damage
- Reduces drug loss due to friction within the introducer sheath
- Pre-mounted on the balloon and does not require any preparation prior to use



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BIOLUX P-III Study Design

DESIGN	Prospective, global, multi-centre, real-world all-comers registry
STUDY GOALS	Further investigate Passeo-18 Lux DCB's efficacy and safety in infra-inguinal arteries in a real-world environment
PRIMARY ENDPOINTS	Freedom from MAE[1] at 6 months Freedom from CD-TLR[2] at 12 months
INCLUSION CRITERIA	Lesion(s) in the **infra-inguinal arteries** suitable for endovascular intervention, treated with or scheduled to be treated with the Passeo-18 Lux DCB
EXCLUSION CRITERIA	Failure to successfully cross the target lesion with a guidewire

BIOLUX P-III is the only real world registry in infra-inguinal arteries

No patient or lesion characteristic limitations

Use of additional devices allowed

47 sites, 16 countries (EU, Australia, Asia)

882 patients enrolled

(1) Major Adverse Event: Composite of device- and procedure-related mortality through 30 days, major target limb amputation and clinically driven target lesion revascularization (TLR). MAE are adjudicated by an independent Clinical Events Committee

(2) Clinically driven TLR is any re-intervention performed for ≥50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient

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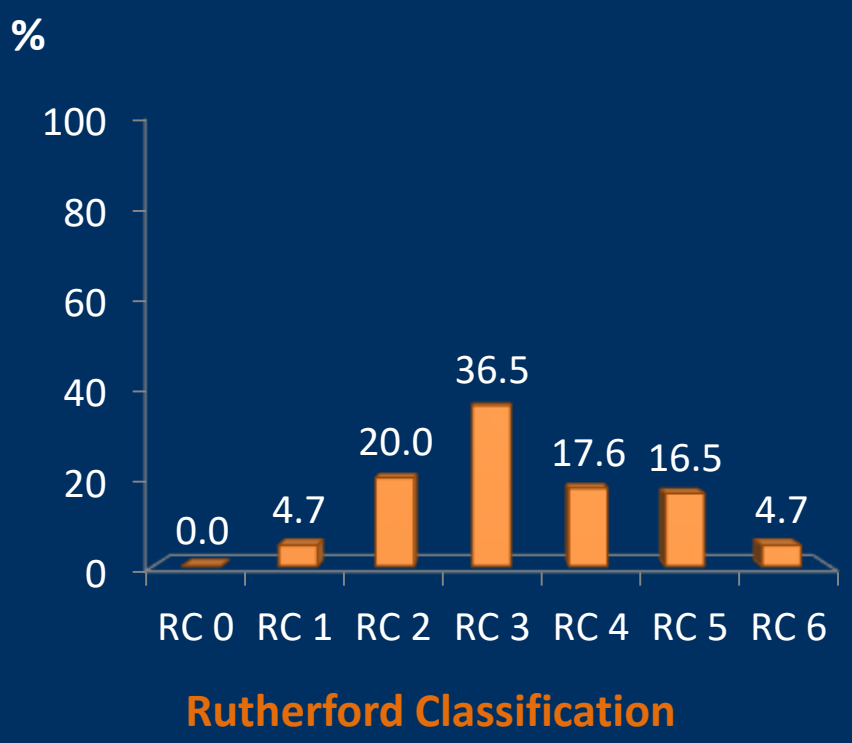
Baseline Details BIOLUX P-III

In-Stent Restenosis (ISR) Subgroup

# Subjects	N = 103
Age, yrs (mean ± SD)	70.37 ± 9.793
Male (n, %)	66 (64.1%)
Hypertension (n, %)	92 (89.3%)
Hyperlipidemia (n, %)	85 (82.5%)
Smoking history (n, %)	83 (80.6%)
Current Smokers	*26 (31.3%)*
History of PAOD (n, %)	94 (91.3%)
Previous PVI /Surgeries (n, %)	101 (98.1%)
Diabetes (n, %)	44 (42.7%)
Coronary Artery Disease (n, %)	44 (42.7%)
Cerebrovascular Disease (n, %)	17 (16.5%)
Renal Disease (n, %)	42 (40.8%)
ABI target limb (mean± SD)	0.66 ± 0.20
Cancer	16 (15.5%)



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Lesion Characteristics BIOLUX P-III ISR

Lesion Characteristics	N = 116
Lesion Length, mm (mean ± SD)	90.2 ± 76
Reference Vessel Diameter, mm (mean ± SD)	5.0 ± 0.8
Diameter Stenosis (%)	81.9 ± 13.4
Calcification (n, %)	
None	50 (43.1%)
Mild	34 (29.3%)
Moderate	15 (12.9%)
Heavy	17 (14.7%)
TASC Classification (n, %)	
A	43 (37.4%)
B	48 (41.7%)
C	17 (14.8%)
D	7 (6.1%)

Lesion Location	N (%)
Iliac	3 (2.6)
SFA	85 (73.9)
Popliteal artery	15 (12.9)
Other fem-pop	6 (5.2)
Posterior tibial	1 (0.9)
Tibioperoneal trunk	2 (1.7)
Peroneal artery	1 (0.9)
Other (bypass)	3 (2.6)

Procedure Details BIOLUX P-III ISR

Vessel Preparation (per lesion)	58.6% (68/116)
Pre-dilation (per total used devices)	89.2% (66/74)
Cutting/scoring balloon (per total used devices)	9.5% (7/74)
Atherectomy (per total used devices)	1.4% (1/74)

Technical Success[1]	98.3% (114/116)
Bailout stenting	7.8% (9/116)

(1) Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation)

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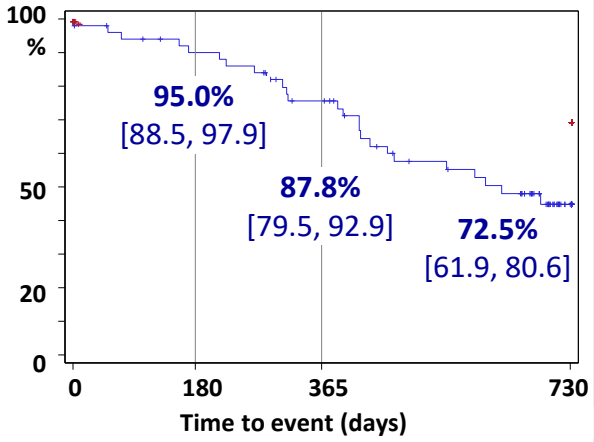
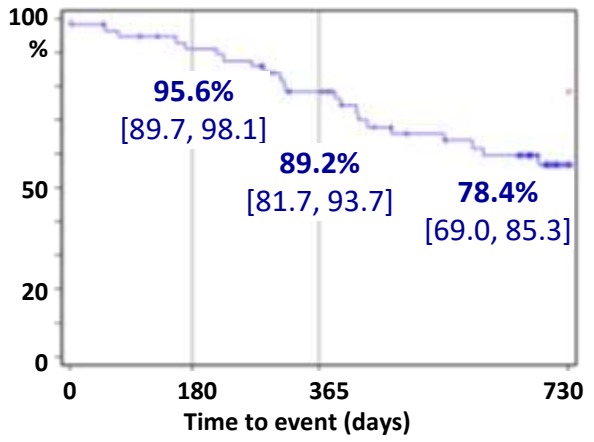
24-Month Outcomes BIOLUX P-III ISR

Freedom from major adverse events[1]



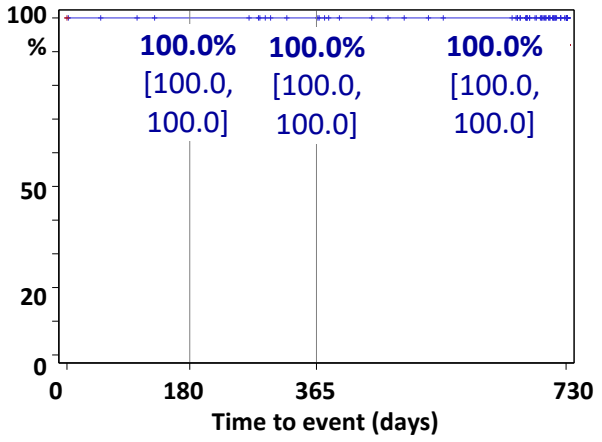
Patients (baseline: 103)	180 days	365 days	730 days
Left at risk	94	82	28
# Events	5	12	25

Freedom from clinically driven target lesion revascularization[2]



Lesions (baseline: 116)	180 days	365 days	730 days
Left at risk	107	91	36
# Events	5	12	22

Freedom from major target limb amputations



Limbs (baseline: 95)	180 days	365 days	730 days
Left at risk	91	85	38
# Events	4	10	57

(1) Major Adverse Event : Composite of device and procedure related mortality through 30 days, major target limb amputation and clinically driven target lesion revascularization (TLR). MAE are adjudicated by an independent Clinical Events Committee (CEC)

(2) Any re-intervention performed for ≥ 50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient adjudicated by an independent CEC

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BIOLUX P-III ISR Conclusion

- **BIOLUX P-III, the second largest completed drug-coated balloon (DCB) registry in infrainguinal arteries** globally (882 enrolled/877 treated patients), continues to demonstrate high clinical performance of the Passeo-18 Lux DCB after 24 months
- In the ISR population (**103 patients)**, at 24 months after treatment with Passeo-18 Lux**:**
  - ✓ **78.4% Freedom from clinically-driven TLR**
  - ✓ **72.5% Freedom from major adverse events**
  - ✓ **100% Freedom from major target limb amputations**
- Safety and effectiveness of Passeo-18 Lux for atherosclerotic infrainguinal lesions at 24 months is confirmed **even in this complicated ISR subset**

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Thank you for your attention!

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