BIOLUX P-III

Results for all-comers cohort at 12 months

Conclusions

- BIOLUX P-III 12-month outcomes confirm Passeo-18 Lux safety and effectiveness in infra-inguinal arteries:
  - 91.3% Freedom from Major Adverse Events (MAE)
  - 94.0% Freedom from Clinically-Driven Target Lesion Revascularization (CD-TLR)
  - 85.2% Primary Patency[1] (PP)
  - 98.4% Freedom from Major Amputations
- Benefit is consistently shown in a high risk population including a large proportion of CLI (38.3%) and BTK lesions (12.2%)

Study design

Prospective, international, multi-center, all-comers registry investigating safety and efficacy data on the Passeo-18 Lux DCB in a real world population with atherosclerotic disease of the infrainguinal arteries.

Endpoints

Primary endpoints

- **Clinical:** Freedom from Major Adverse Events (MAE) at 6 months
- **Performance:** Freedom from Clinically-Driven Target Lesion Revascularization (CD-TLR) at 12 months

Secondary endpoints

- Technical success
- Procedural success
- Device success
- Amputation-free survival at 6, 12 and 24 months
- Primary Patency (PP) rate at 12 and 24 months
- Freedom from CD-TLR at 6 and 24 months post index procedure
- Freedom from MAE at 12 and 24 months
- Clinical success defined as an improvement of Rutherford Classification (RC) at 6, 12 and 24-month follow-up of one class or more
- Changes in Ankle Brachial Index (ABI) measurements at 6, 12 and 24-month follow-up
- Patient-reported outcomes assessment: pain score, walking impairment questionnaire at 6, 12 and 24 months compared to the pre-procedure score

Principal investigator

Prof. G. Tepe, Klinikum Rosenheim, Germany

700 subjects with de novo or restenotic lesions in the infrainguinal arteries (441 patients in SFA) 47 sites world-wide

Passeo-18 Lux

6-month clinical follow-up

12-month clinical follow-up

24-month clinical follow-up

Dedicated Cohort:

Full-Cohort (FSC)
882 subjects

All-comers (ACG)
first 700 subjects enrolled

Subgroups:

- Superficial Femoral Artery (SFA)
- Critical Limb Ischemia (CLI)
- Below the Knee (BTK)
- Diabetes Mellitus (DM)
- TASC C&D
- In Stent Restenosis (ISR)
- Renal Insufficiency
- Heavily calcified lesions
- Popliteal lesions
- Occlusions

BIOLUX P-III

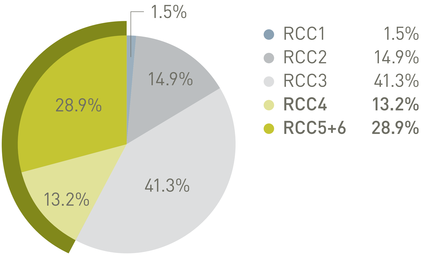
24-month results of the full cohort[1] (882 subjects)

Conclusions

- BIOLUX P-III is the 2nd largest real-world drug coated balloon (DCB) registry with no exclusion criteria
- 24-month outcomes continue to confirm Passeo®-18 Lux™ DCB's safety and effectiveness in infra-inguinal arteries:
  - 83.9% Freedom from Major Adverse Events[2] (MAE)
  - 88.8% Freedom from Clinically-Driven Target Lesion Revascularization[3] (Fcd-TLR)
  - 92.7% Freedom from Major Amputations
- Despite more than 76% of calcified lesions only 15.7% of lesions treated required a stent

Patient characteristics	n = 878 patients	
Age, yrs*	70 ± 10.2	
Male	562	64.0%
Hypertension	745	84.9%
Hyperlipidemia	589	67.1%
Smoking	593	67.5%
Current smokers	228/593	38.4%
History of PAOD	505	57.5%
Previous PVI / Surgeries	453	51.6%
Diabetes	**418**	**47.6%**
Coronary artery disease	369	42.0%
Cerebrovascular disease	168	19.1%
Renal Disease	314	35.8%

Rutherford Classification



42.1% CLI

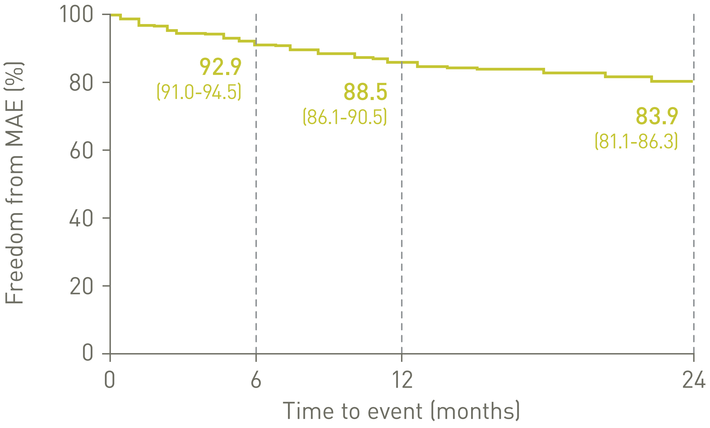
Lesion characteristics	n = 1,085 lesions	
Lesion length (mm)*	89.0 ± 77.0	
Reference vessel diameter (mm)*	4.7 ± 1.1	
Diameter stenosis (mm)*	86.9 ± 12.8	
De novo lesion	587	54.1%
Occlusion	270	24.9%
In-stent restenosis	160	10.7%
Re-stenosis	112	10.3%
Calcification		
None	259	23.9%
Mild	341	31.5%
Moderate	**316**	**29.2%**
Heavy	**167**	**15.4%**
TASC classification		
A	408	38.1%
B	315	29.4%
C	**199**	**18.6%**
D	**150**	**14.0%**

Lesion location	n = 1,085 lesions	
Iliac	7	0.6%
Common femoral artery	11	1.0%
Superficial femoral artery (SFA)	589	54.3%
Popliteal artery	**230**	**21.2%**
Anterior tibial artery	**63**	**5.8%**
Posterior tibial artery	**46**	**4.2%**
Tibioperoneal trunc	**40**	**3.7%**
Peroneal artery	36	3.3%
Other	20	1.8%

Procedural details	n = 1,085 lesions	
Vessel preparation	793	73.1%
Pre-dilation	784	72.3%
Cutting/scoring balloon	56	5.2%
Rotational thrombectomy	28	2.6%
Atherectomy	29	2.7%
Technical success[4]	1068	98.4%
Bailout stenting	170	15.7%

*Data shown as mean ± SD

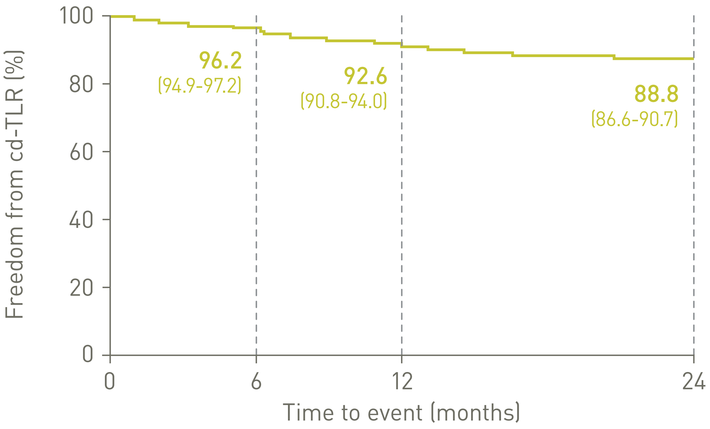
Freedom from MAE – Full-Cohort[2]
(adjudicated by an independent CEC)



24-m
83.9%
Freedom from MAE

Full-Cohort	6 months	12 months	24 months
Left at risk	763	663	283
Events	60	95	126

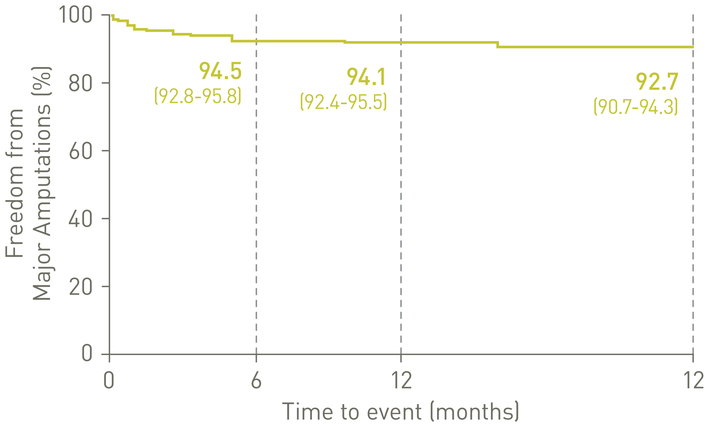
Freedom from cd-TLR – Full-Cohort[3]
(adjudicated by an independent CEC)



24-m
88.8%
Freedom from cd-TLR

Full-Cohort	6 months	12 months	24 months
Left at risk	962	838	348
Events	39	74	105

Freedom from Major Amputations – Full-Cohort



24-m
92.7%
Freedom from Major Amputations

Full-Cohort	6 months	12 months	24 months
Left at risk	798	722	320
Events	48	51	61

1. Tepe G. Real-world experience with a paclitaxel-coated balloon for the treatment of atherosclerotic infrainguinal arteries: 24-month results of the BIOLUX P-III full cohort. Presented at: LINC, Jan 22, 2019; Leipzig, Germany; 2. 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); 3. 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; 4. Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation).

BIOLUX P-III

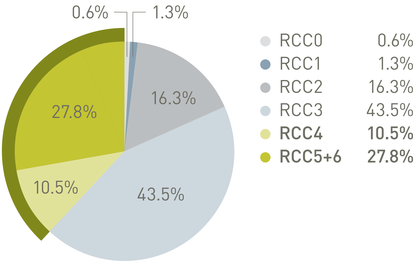
12-month results for the All-comers Cohort
(first 700 subjects enrolled)

Conclusions

- BIOLUX P-III 12-month outcomes confirm Passeo-18 Lux safety and effectiveness in infra-inguinal arteries:
  - 91.3% Freedom from Major Adverse Events (MAE)
  - 94.0% Freedom from Clinically-Driven Target Lesion Revascularization (CD-TLR)
  - 85.2% Primary Patency[1] (PP)
  - 98.4% Freedom from Major Amputations
- Benefit is consistently shown in a high risk population including a large proportion of CLI (38.3%) and BTK lesions (12.2%)

Patient characteristics	n = 700 patients	
Age, yrs*	70.0 ± 10.2	
Male	439	62.7%
Hypertension	595	85.0%
Hyperlipidemia	472	67.4%
Smoking	483	69.0%
Current smokers	191/483	39.5%
History of PAOD	411	58.7%
Previous PVI / Surgeries	373	53.3%
Diabetes	**330**	**47.1%**
Coronary Artery Disease	295	42.1%
Cerebrovascular Disease	145	20.7%
Renal Disease	255	36.4%
ABI target limb*	0.7 ± 0.2	

Rutherford Classification



CLI 38.3%

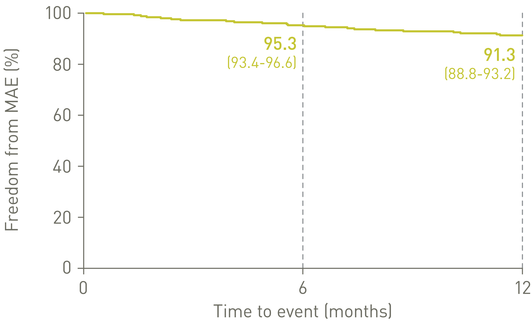
Lesion characteristics	n = 864 lesions	
Lesion length (mm)*	84.6 ± 73.3	
Reference vessel diameter (mm)*	4.8 ± 1.0	
Diameter stenosis (mm)*	86.4 ± 12.9	
De novo lesion	466	53.9%
Occlusion	205	23.7%
In-stent restenosis	97	11.2%
Re-stenosis	96	11.1%
Calcification		
None	216	25.1%
Mild	283	32.8%
Moderate	**260**	**30.2%**
Heavy	**103**	**11.9%**
TASC C/D		
A	361	42.2%
B	269	31.4%
C	**143**	**16.7%**
D	**83**	**9.7%**

Lesion location	n = 864 lesions	
Common femoral	9	1.0%
SFA	492	56.9%
Popliteal artery	194	22.5%
Anterior Tibial Artery	**37**	**4.3%**
Posterior Tibial Artery	**20**	**2.3%**
Tibioperoneal trunc	**28**	**3.2%**
Peroneal artery	**19**	**2.2%**
Dorsalis Pedis	**1**	**0.1%**
Other	64	7.4%

Procedural details	n = 864 lesions	
Vessel preparation	626	72.5%
Pre-dilation	559	64.7%
Cutting/scoring balloon	36	4.2%
Rotational thrombectomy	28	3.2%
Atherectomy	16	1.9%
Technical success[2]	852	98.6%
Bailout Stenting	144	16.7%

* Data shown as mean ± SD

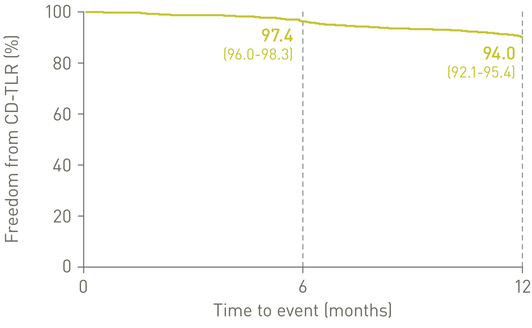
Freedom from MAE[3] – All-comers
(adjudicated by an independent CEC)



12-m
91.3%
Freedom from MAE

All-comers		6 months	12 months
Left at risk	700	629	526
Events	-	32	57

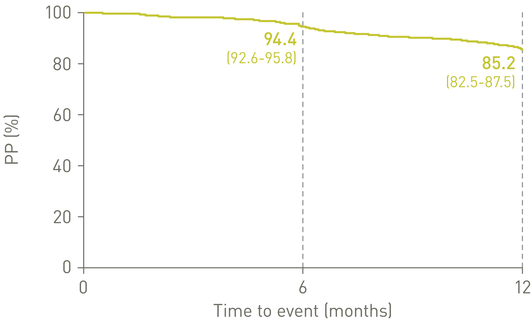
Freedom from CD-TLR – All-comers[4]
(adjudicated by an independent CEC)



12-m
94.0%
Freedom from CD-TLR

All-comers		6 months	12 months
Left at risk	864	788	660
Events	-	22	48

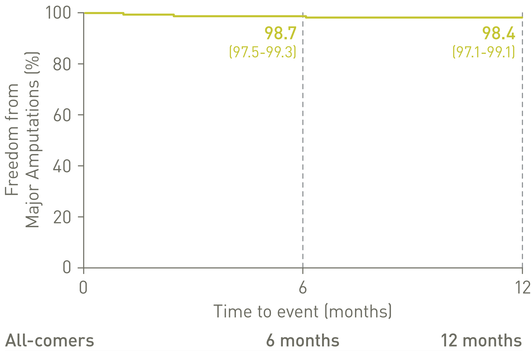
PP – All-comers[1,5]



12-m
85.2%
PP[1]

All-comers		6 months	12 months
Left at risk	864	764	600
Events	-	46	117

Freedom from Major Amputations – All-comers



12-m
98.4%
Freedom from Major Amputations

All-comers		6 months	12 months
Left at risk	705	655	570
Events	-	9	11

Lesion characteristics	
TASC C/D	26.4%
Calcification	74.9%
Moderate/heavy	42.1%

1. DUS not mandated - KM curve based on last contact date; 2. Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation); 3. 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; 4. Defined as freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual assessment of an angiogram with no clinically driven reintervention; 5. 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.

BIOLUX P-III

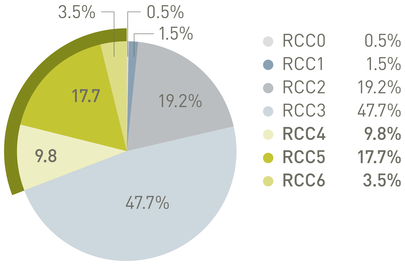
24-month results for Superficial Femoral Artery (SFA)

Conclusions

- Safety and Effectiveness of Passeo-18 Lux confirmed for the treatment of atherosclerotic lesions in the superficial femoral artery at 24 months:
  - 88.9 % Freedom from Major Adverse Events (MAE)
  - 91.7 % Freedom from Clinically-Driven Target Lesion Revascularization (FCD-TLR)
  - 78.0 % Primary Patency (PP)
  - 81.2 % of the population improved at least 1 Rutherford category
- 97.9% freedom of major target limb amputation with an increase of only 1 event between 6 months and 24 months after index procedure
- Passeo-18 Lux DCB benefit is consistently shown in subjects treated for lesions in the superficial femoral artery: the 24 months outcomes confirm the excellent 12 months results for both CD-TLR and PP proving that Passeo-18 Lux has sustained good clinical outcomes for long term

Patient characteristics	n = 441 patients	
Age, yrs*	69.3 ± 10.14	
Male	281	63.7%
Hypertension	369	83.7%
Hyperlipidemia	288	65.3%
Smoking	338	76.6%
Current smokers	137	40.5%
History of PAOD	264	59.9%
Previous PVI / Surgeries	246	55.8%
Diabetes	194	44%
Coronary Artery Disease	185	42%
Cerebrovascular Disease	92	20.9%
Renal Disease	152	34.5%
ABI target limb*	0.7 ± 0.21	

Rutherford Classification



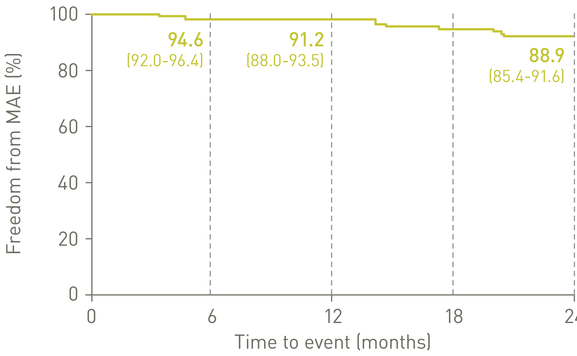
31% CLI

Lesion characteristics	n = 492 lesions	
Lesion length (mm)*	94.2 ± 76.9	
Reference vessel diameter (mm)*	5.11 ± 0.76	
Diameter stenosis (mm)*	85.8 ± 12.98	
Calcification		
None	115	23.4%
Mild	172	35.2%
Moderate	146	29.7%
Heavy	59	12.0%
TASC C/D		
A	200	40.7%
B	173	35.2%
C	78	15.9%
D	40	8.1%

Procedural details	n = 492 lesions	
Vessel preparation	348/492	70.7%
Pre-dilation	337/348	96.8%
Cutting/scoring balloon	26/348	7.4%
Rotational thrombectomy	12/348	3.4%
Atherectomy	3/348	0.9%
Technical success[2]	484/492	98.4%
Bailout Stenting	98/492	19.9%

* Data shown as mean ± SD

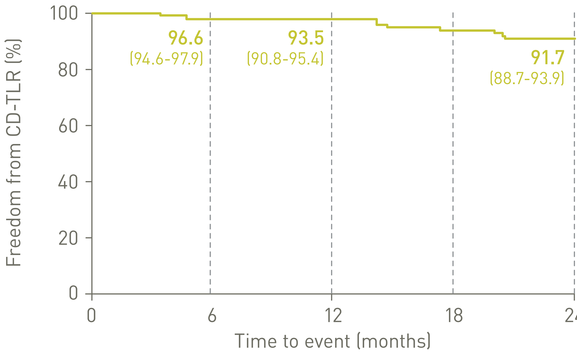
Freedom from MAE – SFA[1]



24-m
88.9%
Freedom from MAE

SFA		6 months	12 months	24 months
Left at risk	440	398	352	153
Events	-	23	37	45

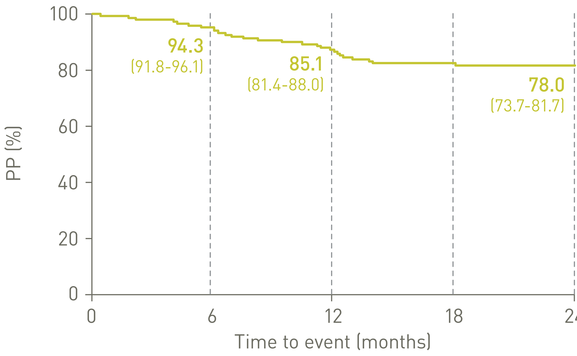
Freedom from CD-TLR – SFA[2]



24-m
91.7%
Freedom from CD-TLR

SFA		6 months	12 months	24 months
Left at risk	491	450	399	169
Events	-	14	27	33

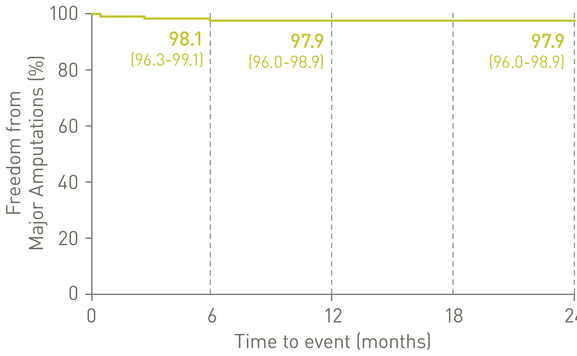
PP – SFA[3]



24-m
78.0%
PP[3]

SFA		6 months	12 months	24 months
Left at risk	491	437	361	144
Events	-	27	68	94

Freedom from Major Amputations – SFA



24-m
97.9%
Freedom from Major Amputations

SFA		6 months	12 months	24 months
Left at risk	443	414	380	262
Events	-	8	9	9

1. Major Adverse Event : Composite of freedom from 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; 3. Defined as freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual assessment of an angiogram with no clinically driven reintervention. DUS not mandated_ KM curve based on last contact date.

BIOLUX P-III

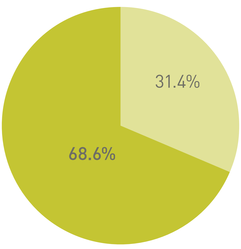
24-month results in Critical Limb Ischemia[1] patients

Conclusions

- At 24 months, Passeo®-18 Lux™ continues to demonstrate high clinical performance in challenging patient groups:
  - 81.1% Freedom from Major Adverse Events[2] (MAE)
  - 88.2% Freedom from Clinically-Driven Target Lesion Revascularization[3] (Fcd-TLR)
  - 85.4% Freedom from Major Amputations
- Evaluation suggests no dose dependency of the mortality rate in the full cohort and Critical Limb Ischemia (CLI) population observed

Patient characteristics	n = 328 patients	
Age, yrs*	71.1 ± 10.6	
Male	200	61.0%
Hypertension	284	86.6%
Hyperlipidemia	201	61.3%
Smoking	186	56.7%
Current smokers	74/186	39.8%
History of PAOD	173	52.7%
Previous PVI / surgeries	156	47.6%
Diabetes	**200**	**61.0%**
Coronary artery disease	144	43.9%
Cerebrovascular disease	71	21.6%
Renal disease	144	43.9%
ABI target limb*	0.64 ± 0.26	

Rutherford Classification



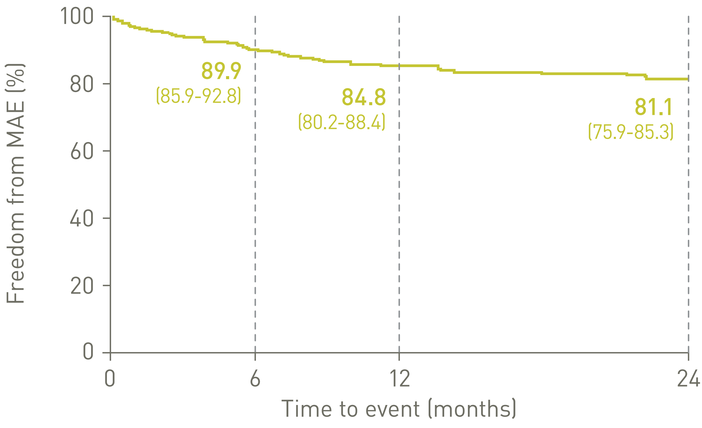
Lesion characteristics	n = 422 lesions	
Lesion length (mm)*	81.5 ± 65.7	
Reference vessel diameter (mm)*	4.3 ± 1.2	
Diameter stenosis (mm)*	87.5 ± 13.0	
De novo lesion	220	52.1%
Occlusion	114	27.9%
In-stent restenosis	42	10.0%
Restenosis	46	10.9%
Calcification		
None	88	20.9%
Mild	114	34.1%
Moderate	**130**	**30.8%**
Heavy	**60**	**14.2%**
TASC Classification		
A	144	34.4%
B	118	28.2%
C	**79**	**18.9%**
D	**78**	**18.6%**

Lesion location	n = 442 lesions	
Iliac	1	0.2%
Common femoral artery	3	0.7%
Superficial femoral artery (SFA)	180	42.7%
Popliteal artery	109	25.8%
Other fem-pop	6	1.4%
Anterior tibial artery	**49**	**11.6%**
Posterior tibial artery	**28**	**6.6%**
Tibioperoneal trunc	**15**	**3.6%**
Peroneal artery	**22**	**5.2%**
Dosalis pedis artery	**1**	**0.2%**
Other infra-popliteal arteries	**4**	**0.9%**
Other (bypass)	4	0.9%

Procedural details	n = 442 lesions	
Vessel preparation	314	74.4%
Pre-dilation	307	72.7%
Cutting/scoring balloon	21	5.8%
Rotational thrombectomy	12	3.3%
Atherectomy	14	3.9%
Technical success[4]	418	99.1%
Bailout stenting	50	11.8%

* Data shown as mean ± SD

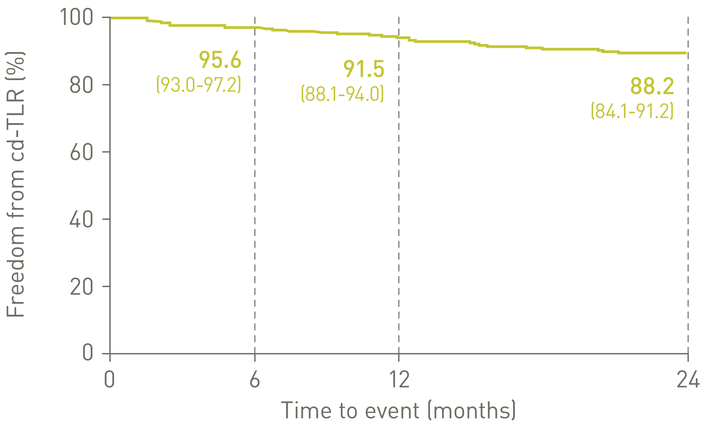
Freedom from MAE – CLI[2]
(adjudicated by an independent CEC)



24-m
81.1%
Freedom from MAE

CLI	6 months	12 months	24 months
Left at risk	257	222	85
Events	31	45	53

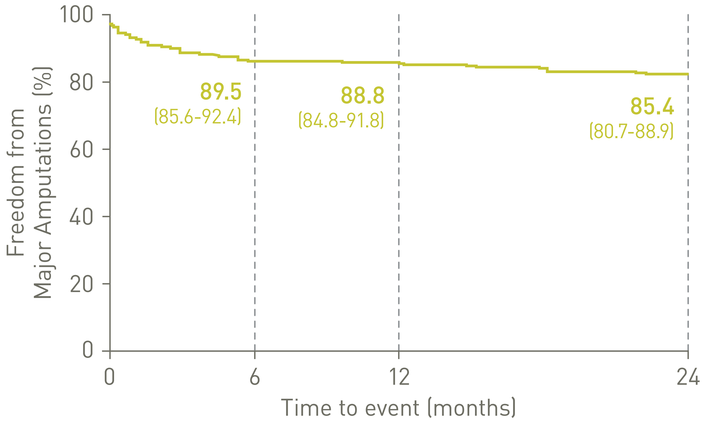
Freedom from cd-TLR – CLI[3]
(adjudicated by an independent CEC)



24-m
88.2%
Freedom from cd-TLR

CLI	6 months	12 months	24 months
Left at risk	342	294	109
Events	17	31	40

Freedom from Major Amputations – CLI



24-m
85.4%
Freedom from Major Amputations

CLI	6 months	12 months	24 months
Left at risk	269	242	91
Events	34	36	44

1. Brodmann M. 24-month outcomes of patients presenting with critical limb ischemia within the BIOLUX P-III registry – a real-world clinical trial treating atheriosclerotic arteries with a paclitaxel covered balloon. Presented at: LINC, Jan 22, 2019; Leipzig, Germany; 2. 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); 3. 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; 4. Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation).

BIOLUX P-III

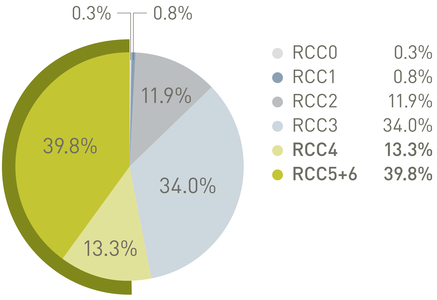
24-month results in Diabetic[1] patients

Conclusions

- Even in this complicated diabetic patient subset, the safety and effectiveness of Passeo®-18 Lux™ at 24 months after treatment for atherosclerotic lesions in infrainguinal arteries is confirmed:
  - 80.2% Freedom from Major Adverse Events[2] (MAE)
  - 87.5% Freedom from Clinically-Driven Target Lesion Revascularization[3] (Fcd-TLR)
  - 87.4% Freedom from Major Amputations

Patient characteristics	n = 460 patients	
Age, yrs*	69.7 ± 9.7	
Male	288	68.9%
Hypertension	371	88.8%
Hyperlipidemia	294	70.3%
Smoking	260	62.2%
Current smokers	86/260	33.1%
History of PAOD	252	60.3%
Previous PVI / Surgeries	215	51.4%
Coronary artery disease	214	51.2%
Cerebrovascular disease	85	20.3%
Renal disease	175	41.9%
ABI target limb*	0.7 ± 0.2	

Rutherford Classification



53.1% CLI

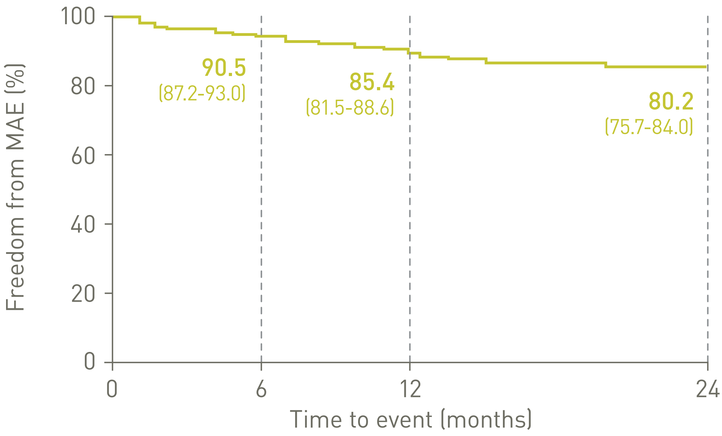
Lesion characteristics	n = 516 lesions	
Lesion length (mm)*	85.63 ± 73.25	
Reference vessel diameter (mm)*	4.5 ± 1.17	
Diameter stenosis (mm)*	86.93 ± 12.76	
De novo lesion	294	57.0%
Occlusion	116	22.5%
In-stent restenosis	50	9.7%
Re-stenosis	56	10.9%
Calcification		
None	106	20.6%
Mild	160	31.1%
Moderate	156	30.4%
Heavy	92	17.9%
TASC Classification		
A	183	36.0%
B	144	28.3%
C	102	20.1%
D	79	15.6%

Lesion location	n = 516 lesions	
Iliac	3	0.6%
Common femoral artery	4	0.8%
Superficial femoral artery (SFA)	256	49.6%
Popliteal artery	108	20.9%
Anterior tibial artery	41	7.9%
Posterior tibial artery	30	5.8%
Tibioperoneal trunc	26	5.0%
Peroneal artery	21	4.1%
Others	8	1.6%

Procedural details	n = 516 lesions	
Vessel preparation	375	72.7%
Pre-dilation	380	73.6%
Cutting/scoring balloon	23	4.46%
Rotational thrombectomy	12	2.33%
Atherectomy	13	2.52%
Technical success[2]	509	98.6%
Bailout stenting	73	14.1%

* Data shown as mean ± SD

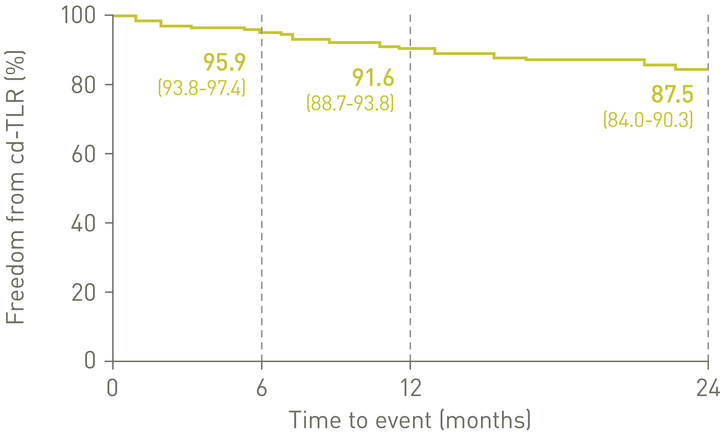
Freedom from MAE – Diabetics[1]
(adjudicated by an independent CEC)



24-m
80.2%
Freedom from MAE

Diabetics	6 months	12 months	24 months
Left at risk	349	298	116
Events	38	57	73

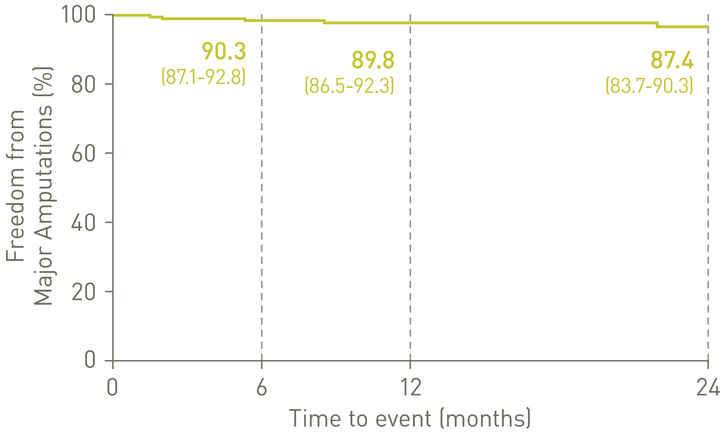
Freedom from cd-TLR – Diabetics[2]
(adjudicated by an independent CEC)



24-m
87.5%
Freedom from cd-TLR

Diabetics	6 months	12 months	24 months
Left at risk	444	379	145
Events	20	39	54

Freedom from Major Amputations – Diabetics



24-m
87.4%
Freedom from Major Amputations

Diabetics	6 months	12 months	24 months
Left at risk	364	324	125
Events	41	43	51

1. Dahm J. Diabetic patients in a real-world clinical trial treated for peripheral arterial disease with a paclitaxel covered balloon. 24-month results of the BIOLUX P-III All Comers registry. Presented at: LINC, Jan 22, 2019; Leipzig, Germany; 2. 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); 3. 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; 4. Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation).

BIOLUX P-III

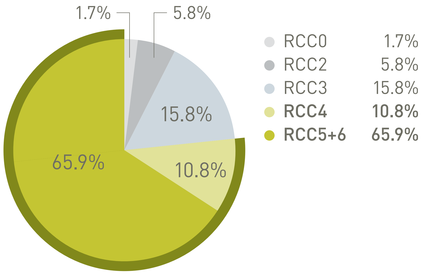
12-month results in BTK patients

Conclusions

- BIOLUX P-III 12-month outcomes confirm Passeo-18 Lux DCB safety and effectiveness in infra-popliteal arteries, despite a high risk population (65.9% RCC5+6 and 49.1% TASC C&D):
  - 16.9% Major Adverse Events (MAE)
  - 92.4% Freedom from Clinically-Driven Target Lesion Revascularization (CD-TLR)
  - 78.8% Primary Patency (PP) for the imaging cohort*
  - 92.2% Freedom from Major Amputations
  - 87.5% of the BTK subjects improved at least 1 Rutherford Clinical Classification
- BIOLUX P-III BTK results are a strong signal that DCB provide a safe and effective treatment for BTK lesions[1]

Patient characteristics	n = 150 patients	
Age, yrs**	72.2 ± 10.1	
Male	111	74.0%
Hypertension	126	84.0%
Hyperlipidemia	91	60.7%
Smoking	72	48.3%
Current smokers	20/72	27.8%
History of PAOD	77	51.3%
Previous PVI / Surgeries	62	41.3%
Diabetes	**94**	**62.7%**
Coronary Artery Disease	60	40.0%
Cerebrovascular Disease	28	18.7%
Renal Disease	55	36.7%

Rutherford Classification



76.7% CLI

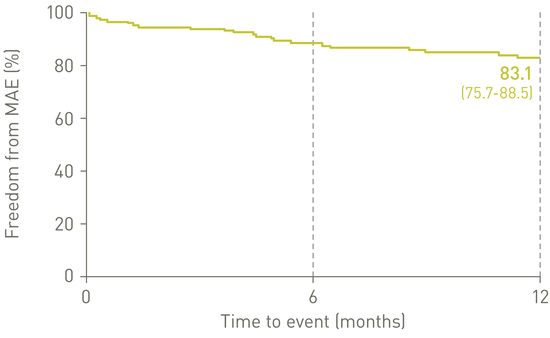
Lesion characteristics	n = 184 lesions	
Lesion length (mm)**	79.0 ± 72.0	
Reference vessel diameter (mm)**	3.0 ± 0.6	
Diameter stenosis (mm)**	86.3 ± 12.7	
De novo lesion	125	67.9%
Occlusion	34	18.5%
In-stent restenosis	4	2.2%
Re-stenosis	21	11.4%
Calcification		
None	57	31.1%
Mild	60	33.9%
Moderate	**49**	**26.8%**
Heavy	**17**	**9.3%**
TASC C/D		
A	59	33.7%
B	30	17.1%
C	**37**	**21.1%**
D	**49**	**28.0%**

Lesion location	n = 184 lesions	
Anterior Tibial Artery	63	34.2%
Posterior Tibial Artery	46	25.0%
Tibioperoneal trunc	39	21.2%
Peroneal artery	36	19.6%

Procedural details	n = 184 lesions	
Vessel preparation	134	72.8%
Pre-dilation	123	66.8%
Cutting/scoring balloon	2	1.1%
Rotational thrombectomy	1	0.5%
Atherectomy	6	3.3%
Technical success[2]	179	97.3%
Bailout Stenting	2	1.1%

* Duplex ultrasound or angiogram
** Data shown as mean ± SD

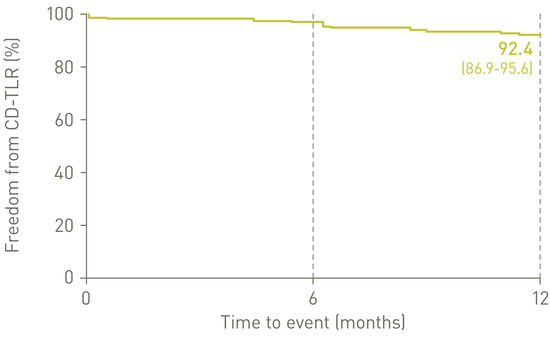
Freedom from MAE – BTK[3]
(adjudicated by an independent CEC)



12-m
83.1%
Freedom from MAE

BTK		6 months	12 months
Left at risk	150	116	86
Events	-	16	23

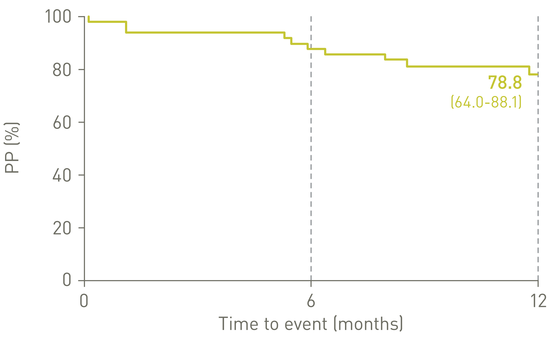
Freedom from CD-TLR – BTK[4]
(adjudicated by an independent CEC)



12-m
92.4%
Freedom from CD-TLR

BTK		6 months	12 months
Left at risk	184	150	116
Events	-	5	12

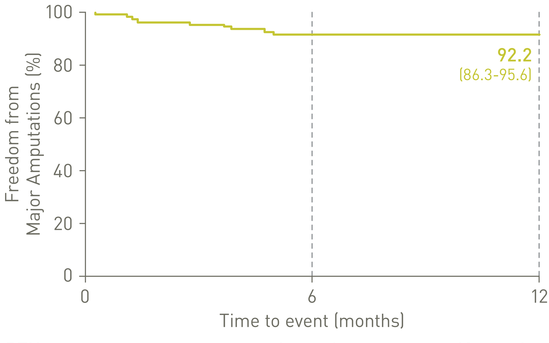
Primary Patency for the imaging cohort* - BTK[5]



12-m
78.8%
PP[5]

BTK		6 months	12 months
Left at risk	49	43	26
Events	-	6	10

Freedom from Major Amputations – BTK



12-m
92.2%
Freedom from Major Amputations

BTK		6 months	12 months
Left at risk	150	122	94
Events	-	10	11

1. Tepe G., BIOLUX P-III: Passeo-18 Lux Real-World All-Comers Registry: 12-month results for BTK. Presented at: Charing Cross, April, 2018, London, United Kingdom; 2 Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation); 3. 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; 4. 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; 5. Defined as freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual assessment of an angiogram with no clinically driven reintervention.

* Duplex ultrasound or angiogram

BIOLUX P-III

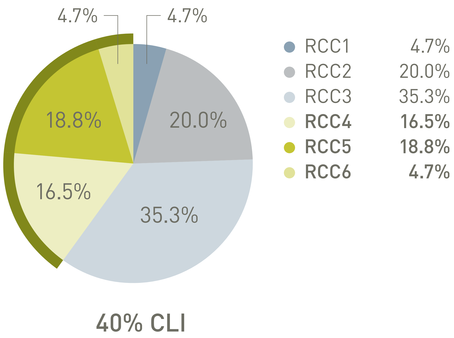
12-month results for In-Stent Restenosis (ISR)

Conclusions

- Safety and effectiveness of Passeo-18 Lux confirmed for the treatment of in-stent restenosis in infra-inguinal arteries at 12 months:
  - 88.8% without Major Adverse Events (MAE)
  - 90.1% Freedom from Clinically-Driven Target Lesion Revascularization (CD-TLR)
  - 77.3% Primary Patency (PP)
  - No major target limb amputations
  - 81% of the population improved at least 1 Rutherford category
- Passeo-18 Lux DCB benefit is consistently shown in the high risk factor population presenting with in-stent restenosis

Patient characteristics	n = 103 patients	
Age, yrs*	70.4 ± 9.79	
Male	66	64.1%
Hypertension	92	89.3%
Hyperlipidemia	85	82.5%
Smoking	83	80.6%
Current smokers	26	25.2%
History of PAOD	94	91.3%
Diabetes	44	42.7%
Coronary Artery Disease	44	42.7%
Cerebrovascular Disease	17	16.5%
Renal Disease	42	40.8%
ABI target limb*	0.7 ± 0.2	

Rutherford Classification



40% CLI

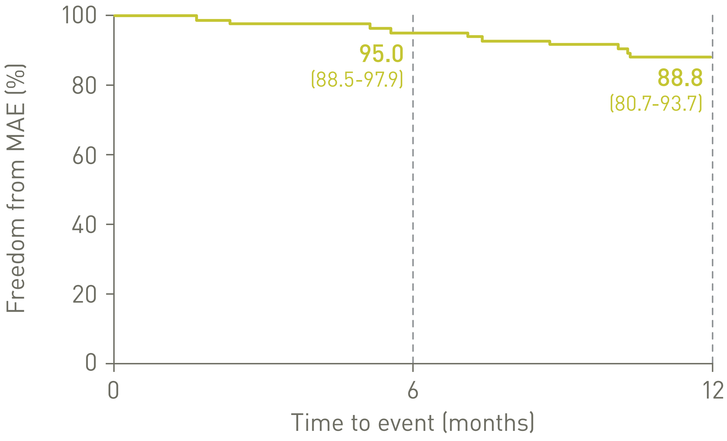
Lesion characteristics	n = 116 lesions	
Lesion length (mm)*	90.2 ± 75.99	
Reference vessel diameter (mm)*	5.0 ± 0.84	
Diameter stenosis (%)	81.2 ± 15.27	
Calcification		
None	50	43.1%
Mild	34	29.3%
Moderate	15	12.9%
Heavy	17	14.7%
TASC C/D		
A	43	37.1%
B	48	41.4%
C	17	14.7%
D	7	6.0%

Lesion location	n = 116 lesions	
SFA	85	73.3%
Popliteal artery	15	12.9%
PTA	1	0.9%
Tibioperoneal trunc	2	1.7%
Peroneal artery	1	0.9%
Others	12	10.3%

Procedural details	n = 116 lesions	
Vessel preparation	68/116	58.6%
Pre-dilation	66/68	97.1%
Cutting/scoring balloon	7/68	10.3%
Atherectomy	1/68	1.5%
Technical success[1]	114/117	98.3%

* Data shown as mean ± SD

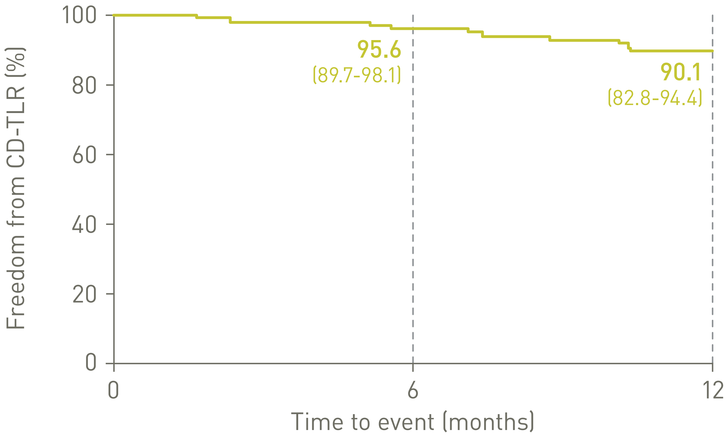
MAE – ISR[1]



12-m
88.8%
Freedom from MAE

ISR		6 months	12 months
Left at risk	102	94	83
Events	1	5	11

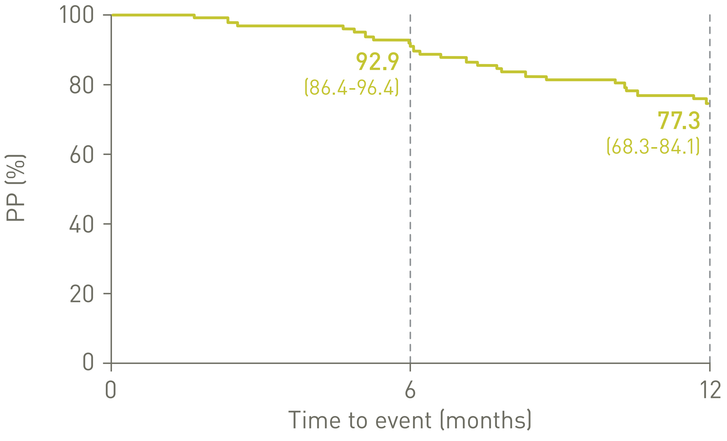
Freedom from CD-TLR[2] - ISR



12-m
90.1%
Freedom from CD-TLR

ISR		6 months	12 months
Left at risk	115	107	92
Events	1	5	11

PP – ISR[3]



12-m
77.3%
PP[3]

ISR		6 months	12 months
Left at risk	115	104	79
Events	1	8	25

1. Major Adverse Event : Composite of freedom from 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; 3. Defined as freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual assessment of an angiogram with no clinically driven reintervention. DUS not mandated_ KM curve based on last contact date.

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