EFFPAC–RCT: Final 6-months results with the Luminor DCB in femoropopliteal lesions

On behalf of the Investigators:

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Disclosure

Dierk Scheinert, MD

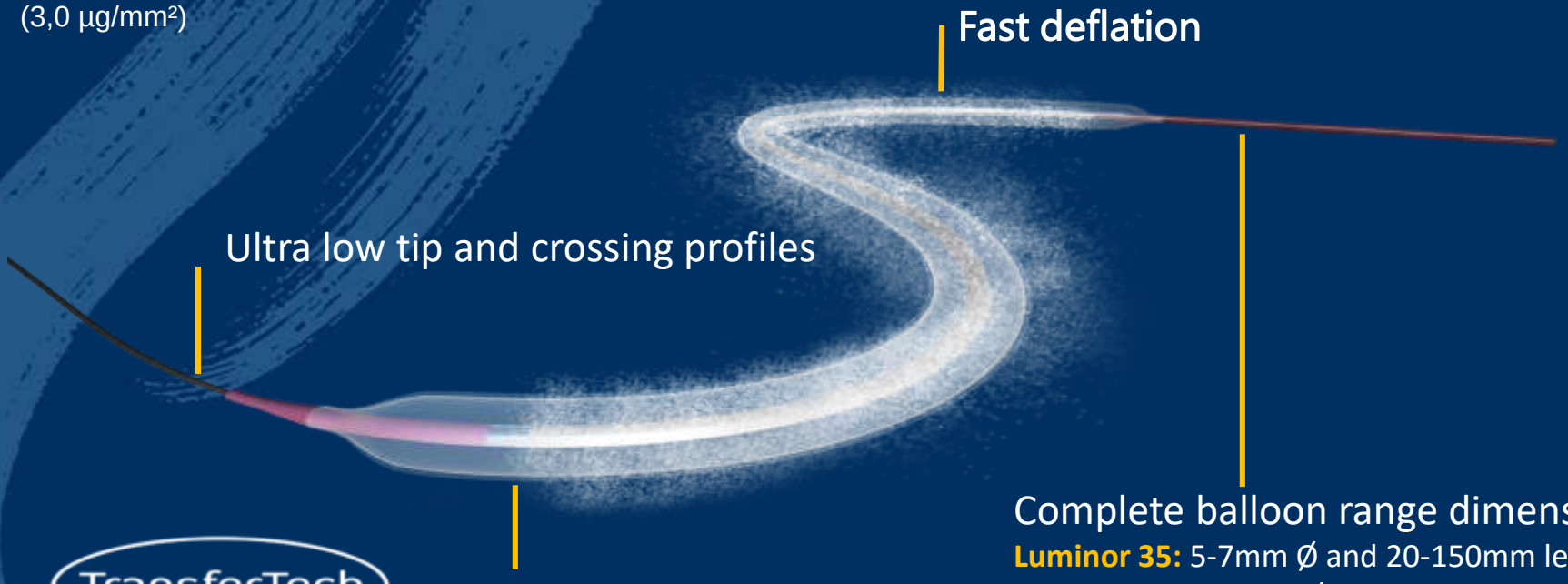
Advisory Board /Consultant:

Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies

iVascular luminor

Paclitaxel coated balloon

(3,0 µg/mm²)



Fast deflation

Ultra low tip and crossing profiles

TransferTech

Innovative and UNIQUE nanotechnology coating

Complete balloon range dimensions

Luminor 35: 5-7mm Ø and 20-150mm length

Luminor 18: 2-8 mm Ø and 20-200mm length

Luminor 14: 1.5-4mm Ø and 40-200mm length

EffPac-Trial

Design: Investigator-initiated, prospective, multi-centre, intention-to treat trial and 2 arms-randomized study

Objective: Safety and efficacy of the Luminor® Paclitaxel drug-eluting balloon in inhibiting restenosis and in ensuring long-term patency

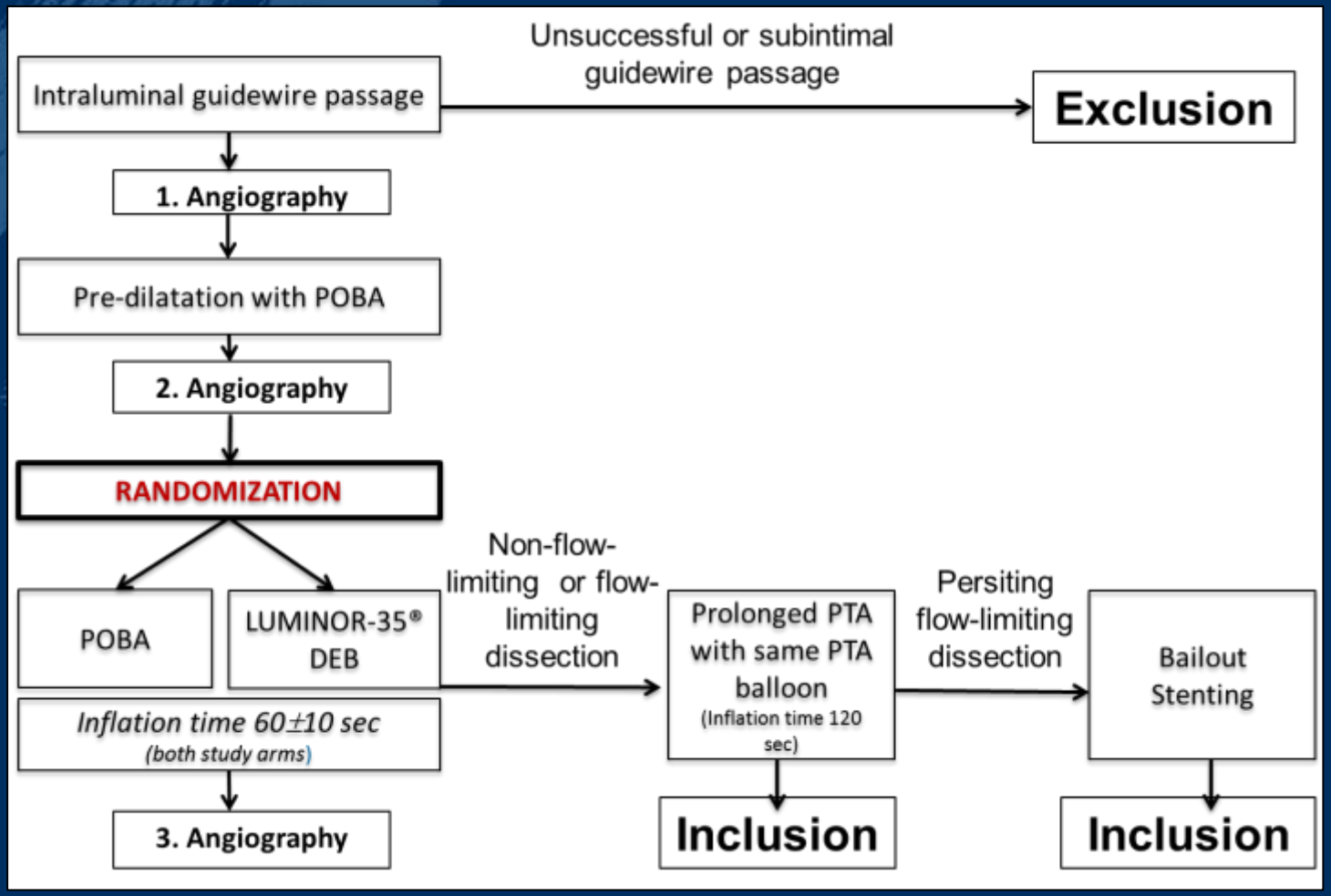
Sponsor: University of Jena, Germany

Representative of the sponsor:
Prof. Dr. Ulf Teichgräber, Jena University Hospital

Participating Sites

01 Jena	PD Dr. R. Aschenbach, *University Hospital Jena*
02 Leipzig	Prof. Dr. Dierk Scheinert, *University Hospital Leipzig*
03 Bad Krozingen	Prof. Dr. Thomas Zeller, *Heart Center*
04 Hamburg	Dr. S. Sixt, *Angiologikum*
05 München	PD Dr. M. Treitl, *University Hospital*
06 Berlin	Prof. Dr. K. Brechtel, *„Ihre Radiologen“*
07 Sonneberg	Dr. M. Thieme, *Medinos Clinic*
08 Karlsbad	Prof. Dr. E. Blessing, *SRH-Clinic*
09 Heidelberg	Dr. B. Vogel, University Heidelberg
10 Arnsberg	Dr. M. Lichtenberg, *Clinic Arnsberg*
11 Krusel	Dr. P. von Flotow, *Westpfalz Clinic*

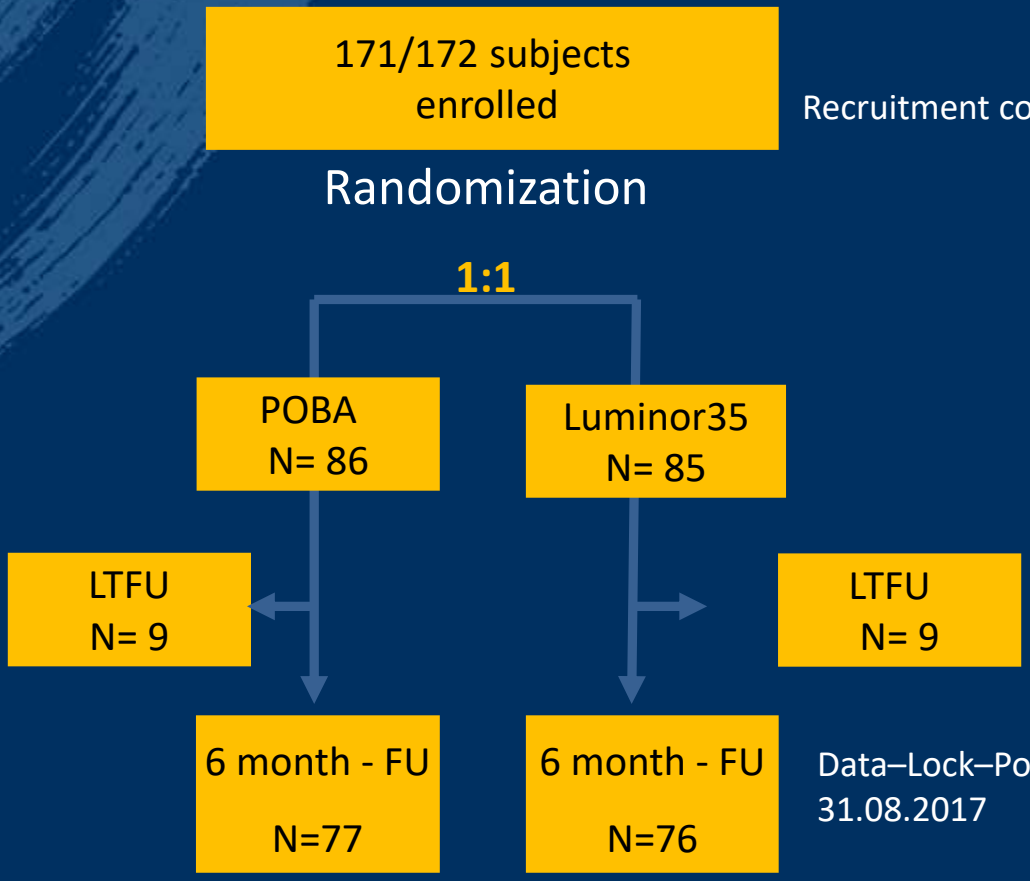
Flowchart


Intraluminal guidewire passage
Unsuccessful or subintimal guidewire passage
Exclusion
1. Angiography
Pre-dilatation with POBA
2. Angiography
RANDOMIZATION
POBA
LUMINOR-35® DEB
Inflation time 60±10 sec
(both study arms)
3. Angiography
Non-flow-limiting or flow-limiting dissection
Prolonged PTA with same PTA balloon
(Inflation time 120 sec)
Inclusion
Persiting flow-limiting dissection
Bailout Stenting
Inclusion

Trial Design and Endpoints

Endpoints		Baseline	6 month	12 month	24 month
Efficacy	Primary	Vessel diameter (mm)	• Late Lumen Loss (LLL)*	-	-
	Secondary		• Freedom from Target Lesion Revascularization (TLR/TVR) • Patency • Change of ABI, Rutherford stage, QoL (WIQ) , EQ-5D		
Safety	Primary		• Major and minor amputation rate at index limb • Mortality, independently of cause		

Distribution



Recruitment completed on 31.12.2016

Data–Lock–Point for 6 month-FUP on 31.08.2017

Baseline Patient Characteristics

	LUMINOR®	POBA
Age - yr	68.0 ± 7.5 (85)	68.1 ± 8.8 (86)
Male - % (no.)	60.0% (51/85)	69.8% (60/86)
Diabetes mellitus - % (no.)	36.5% (31/85)	40.7% (35/86)
Hypertension - % (no.)	87.1% (74/85)	84.9% (73/86)
Hyperlipidemia - % (no.)	70.6% (60/85)	68.6% (59/86)

Baseline Patient Characteristics

		LUMINOR®	POBA
Rutherford Clinical Category			
Mild claudication	1	0% (0/85)	0% (0/85)
Moderate claudication	2	15.3% (13/85)	21.2% (18/85)
Severe claudication	3	81.2% (69/85)	77.6% (66/85)
Ischemic rest pain	4	2.4% (2/85)	1.2% (1/85)
Minor tissue loss	5	1.2% (1/85)	0% (0/85)
Major tissue loss	6	0% (0/85)	0% (0/85)
ABI (treated leg)		0.73 ± 0.23 (69)	0.74 ± 0.23 (69)

Baseline Angiographic Data

	LUMINOR®	POBA	p value
Lesion Length (cm)	5.9 ± 4.3 (84)	5.6 ± 3.9 (86)	0.731
Total Occlusion	20.2% (17/84)	25.6% (22/86)	0.468
Calcification			0.094
none/mild	54.2% (45/83)	44.2% (38/86)	
moderate	42.2% (35/83)	44.2% (38/86)	
severe	3.6% (3/83)	11.6% (10/86)	
Diameter Stenosis (%)	88.0 ± 9.8 (85)	90.1 ± 8.8 (86)	0.191
Reference Vessel Diameter (mm)	5.4 ± 0.6 (85)	5.4 ± 0.7 (86)	0.732
# of Patent Run-off Vessel			0.311
0	0% (0/85)	1.2% (1/86)	
1	22.4% (19/85)	22.1% (19/86)	
2	41.2% (35/85)	31.4% (27/86)	
3	36.5% (31/85)	45.3% (39/86)	

Procedural Characteristics

	LUMINOR®	POBA	p value
Vessel preparation: Pre-dilatation performed	100% (84/84)	98.8% (85/86)	1.000
Dissection	37.6% (32/85)	40.7% (35/86)	0.755
Stent rate	15.3% (13/85)	18.8% (16/85)	0.684

Efficacy: Late Lumen Loss - LLL

*** LLL =** difference between the diameters (in mm) at 6 months follow-up minus post-procedure

	LUMINOR®	POBA	Difference, 95% CI (LUMINOR® vs. POBA)	p value
LLL 6M (mm)*	0.14 [CI: -0.38; 0.67]	1.06 [CI: 0.54; 1.59]	-0.92 [CI: -1.36; -0.49]	<0.001

* Estimated LLL (Mean, 95% CI) from linear mixed model adjusted for center

Efficacy: Improvement of Rutherford after 6M

Improvement of Rutherford Stages	LUMINOR®	POBA
Deterioration of 1 stage	1.4% (1/74)	0% (0/82)
No improvement	13.5% (10/74)	25.0% (18/82)
Improvement of 1 stage	12.2% (9/74)	20.8% (15/82)
Improvement of 2 stages	28.4% (21/74)	26.4% (19/82)
Improvement of 3 stages	44.6% (33/74)	27.8% (20/82)

Significant higher improvement of LUMINOR® compared to POBA (p=0.021)

Efficacy:
Target Lesion Revascularization (TLR)

	LUMINOR®	POBA	Relative Risk, 95% CI (LUMINOR® vs. POBA)	Number needed to treat (NNT)	p value
TLR 6M (%)	1.3 (1/76)	17.1 (13/76)	0.082 [CI: 0.012; 0.560]*	7	<0.001

*Relative Risk Reduction (RRR) = 91.8%, Cochran-Mantel-Haenszel estimate, adjusted for center

Efficacy:
Target Lesion Revascularization (TLR)

Study	DCB 6 mo TLR (%)	Control 6 mo TLR (%)
EFFPAC 2017 Luminor (iVascular)	**1.3 (1/76)**	**17.1 (13/76)**
THUNDER Tepe et al. 2008 Paccocath coating	4.2 (2/48)	37.0 (20/54)
AcoArt I Trial Jia et al. 2016 Orchid (Acotec)	6.1 (6/99)	38.8 (38/98)
FEMPAC Werk et al. 2008 Paccocath DCB	6.7 (3/45)	33.3 (14/42)
CONSEQUENT 2017 SeQuent Please (B. Braun)	8.9 (7/78)	30.7 (23/75)
RANGER Bausback et al. 2017 Ranger DCB	5.6 (4/71)	12.0 (4/34)
BIOLUX P-I Trial Scheinert et al. 2015 Passeo-18 Lux (Biotronik)	3.8 (1/26)*	4.2 (1/24)*

Efficacy: Patency

	LUMINOR®	POBA	Relative Risk*, 95% CI (LUMINOR® vs. POBA)	Number needed to treat (NNT)	p value
Patency (%)	94.7 (72/76)	75.0 (57/76)	1.26 [CI: 1.100; 1.443]	6	<0.001

* Interpretation: Relative chance for patency is increased by 26% in the LUMINOR® group

Primary patency: Freedom from restenosis (determined by duplex ultrasound PSVR <2.5) and freedom from TLR at 6 months

Safety: Adverse Events

	LUMINOR®	POBA	p value
Minor Amputation (%)	0 (0/85)	1.2 (1/86)	1.000
Major Amputation (%)	0 (0/85)	0 (0/86)	1.000
Death (not related, %)	0 (0/85)	2.3 (2/86)	0.497

Conclusions

- The LUMINOR® Paclitaxel-coated balloon catheter demonstrates to be clinical highly effective and safe in inhibiting restenosis compared to POBA
- The innovative coating technique matters and is shown not only in the patency, LLL and TLR data, but also in an improvement of the Rutherford stage
- The results of the study allow direct comparison to other already-completed RCTs applying Paclitaxel-coated DEB from different manufacturers in the same target vessel

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