

The LINC logo features a stylized, abstract shape in shades of red, orange, and yellow, resembling a flame or a dynamic motion, positioned above the letters 'LINC' in a white, sans-serif font.

LINC

Luminor[®] DCB in femoropopliteal lesions – EffPac trial results and soLo DCB study design

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Disclosure

Speaker's name: Marcus Thieme

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

Luminor

Paclitaxel coated balloon
(3,0 µg/mm²)

Ultra low tip and crossing
profiles

Fast deflation

Complete balloon range dimensions

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

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

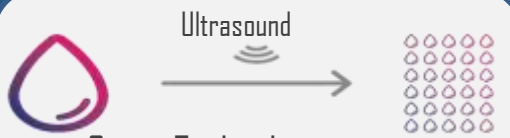
Luminor 14: 1.5-4mm Ø and 40-200mm length



Innovative and UNIQUE
nanotechnology coating


luminor

UNIQUE nanotechnology coating



Ultrasound

Spray Technology
Dosage of uniform diameter nanodrops by ultrasonic deposition



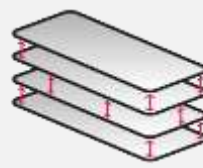

Uniform coating

Homogeneous drug dose



Multi-layer technology

- Coating durability during the procedure
- No cracking

Excipient **20%**

Paclitaxel **80%**

Excipient	Paclitaxel
• Organic ester	• Lipophilic
• Biocompatible	• Inhibition of stenosis
• Lipophilic	• Specific cellular receptors

Proprietary nanotechnology dosage system for an **uniform, flexible** and **ultrathin coating**

Dry-off

- Microcrystalline structure
- Optimal drug transfer to the vessel wall within 30-60s seconds

EffPac Trial

Investigator-initiated Multicenter Randomized Controlled Trial
to assess the

Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter
VS.
Uncoated Balloon Catheter

in the Superficial Femoral and Popliteal Arteries to Prevent Vessel
Restenosis or Reocclusion

11 Participating Sites

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

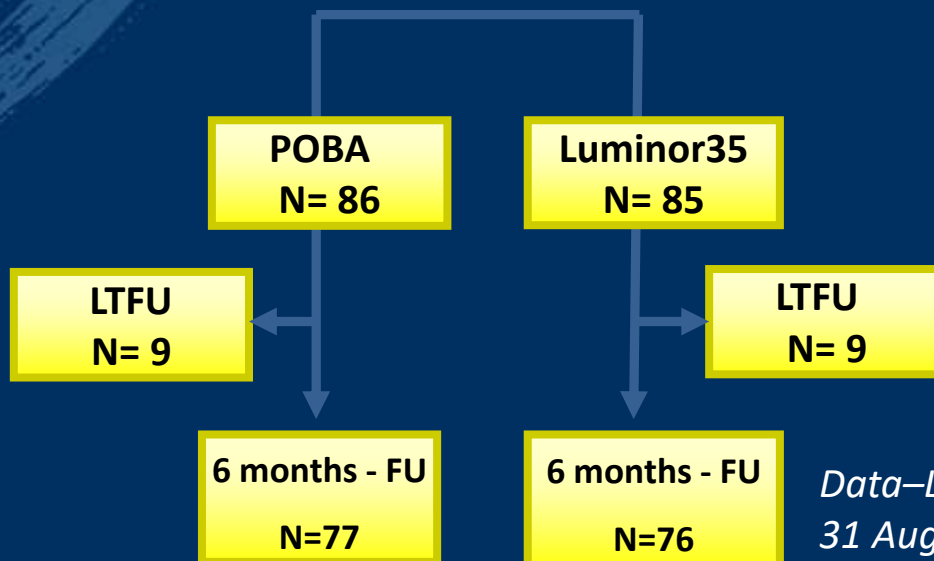
Trial Design and Endpoints

Endpoints		Baseline	6 months	12 months	24 months
Efficacy	Primary	Vessel diameter (mm)	<ul style="list-style-type: none"> Late Lumen Loss (LLL)* 	-	-
	Secondary		<ul style="list-style-type: none"> Freedom from Target Lesion Revascularization (TLR/TVR) Patency Change of ABI, Rutherford stage, QoL (WIIQ) , EQ-5D 		
Safety	Primary		<ul style="list-style-type: none"> Major and minor amputation rate at index limb Mortality, independent of cause 		

171/172 subjects
enrolled

Recruitment completed on 31 Dec. 2016

Randomization 1:1



Data-Lock-Point for 6 months-FUP on 31 Aug. 2017

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 and 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)

Significantly 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)*

*Kaplan-Meier estimates, clinically driven TLR

soLo-DCB Study

Design:

A prospective, global, multi-center, single-arm, real-world, observational study investigating the clinical use and safety of the Luminor® Paclitaxel-coated balloon

Objective:

To demonstrate safety and assess the clinical use and outcomes of the Luminor® Paclitaxel-coated balloon in a heterogeneous patient population in real-world clinical practice

Sponsor: Regiomed Vascular Center Sonneberg, Germany

Study Design and Endpoints

Enrollment

- Up to 500 patients at 15 sites in Europe
- Follow-up at 6 weeks (by phone); 6, 12 and 24 months (Duplex)

Inclusion

- Femoropopliteal lesions, treatable with Luminor[®] DCB per current IFU
- Male or non-pregnant female ≥ 18 years
- Rutherford class ≤ 4
- More than 70% stenosis or obstruction of femoropopliteal arteries
- At least 1 patent native outflow artery

Registry Design and Endpoints

Endpoints		6-months	12-months	24-months
Efficacy	Primary		<ul style="list-style-type: none"> Freedom from Target Lesion Revascularization (TLR/TVR) 	
	Secondary		<ul style="list-style-type: none"> Patency Change of ABI, Rutherford stage, QoL (WIIQ) , EQ-5D 	
Safety	Primary		<ul style="list-style-type: none"> Major and minor amputation rate at index limb Mortality 	

Conclusions

- The LUMINOR[®] Paclitaxel-coated balloon catheter demonstrates to be clinically highly effective and safe in inhibiting restenosis compared to POBA.
- The innovative coating technique matters and is shown not only in the patency and TLR data, but also in an improvement of the Rutherford stage.
- The results of the EffPac study allow direct comparison to other already completed RCTs applying Paclitaxel-coated balloons from different manufacturers in the same target vessel.
- soLo-DCB study will get the insights from a larger patient population.

EffPac-Trial results of 12-months follow-up will be presented on March 2018.

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