

The LINC logo features the letters 'LINC' in a white, sans-serif font, positioned over a stylized graphic of three curved, overlapping brushstrokes in shades of blue, red, and yellow.

LINC

The BIOFLEX PEACE logo is a white circular emblem with a thin grey border. Inside the circle, the text 'BIOFLEX' is written in a bold, blue, sans-serif font above the word 'PEACE' in a smaller, blue, sans-serif font. Above the text, there is a horizontal row of seven small blue dots of varying sizes.

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# BIOFLEX PEACE Registry 24-month Analysis<sup>1</sup>

Pulsar Efficacy: an All Comers Registry

**Claus Nolte-Ernsting**



**Michael Lichtenberg**



<sup>1</sup> Interim 24 months data analysis

# Disclosure

Speaker name: Claus Nolte-Ernsting, MD

I have the following potential conflicts of interest to report:

- Consulting: BIOTRONIK
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Study Design



## DESIGN:

**All-Comers registry.** Prospective, multicenter.  
Treatment of femoropopliteal atherosclerotic lesions using the **4F, Pulsar-18** stent

## PRINCIPAL INVESTIGATOR:

Dr. M. Lichtenberg (Arnsberg, DE)

## PRIMARY ENDPOINT:

6m Major Adverse Event (MAE) rate  
12m Primary Patency

## SECONDARY ENDPOINTS:

Primary Patency at 6 & 24m  
Freedom from TLR at 6, 12 & 24m  
Clinical success - improvement of  $\geq 1$  Rutherford Class  
- improvement in ABI

## Pre-defined sub-groups

Diabetic vs. non-diabetic  
Lesion length  $\leq 100$ mm vs.  $>100$ mm

**All-Comers Registry**  
**189 Subjects screened**

**BMS (per protocol) Pulsar-18**  
Exclusion of lesions other than femoropopliteal, as defined by protocol:  
**160 patients included in this analysis**

12m FUP

**N=139<sup>2</sup>**  
Primary Patency  
Freedom from TLR  
Clinical Success

24m FUP

**N= 79<sup>2</sup>**  
Primary Patency  
Freedom from TLR  
Clinical Success

<sup>2</sup> Not for all subjects all measures are available

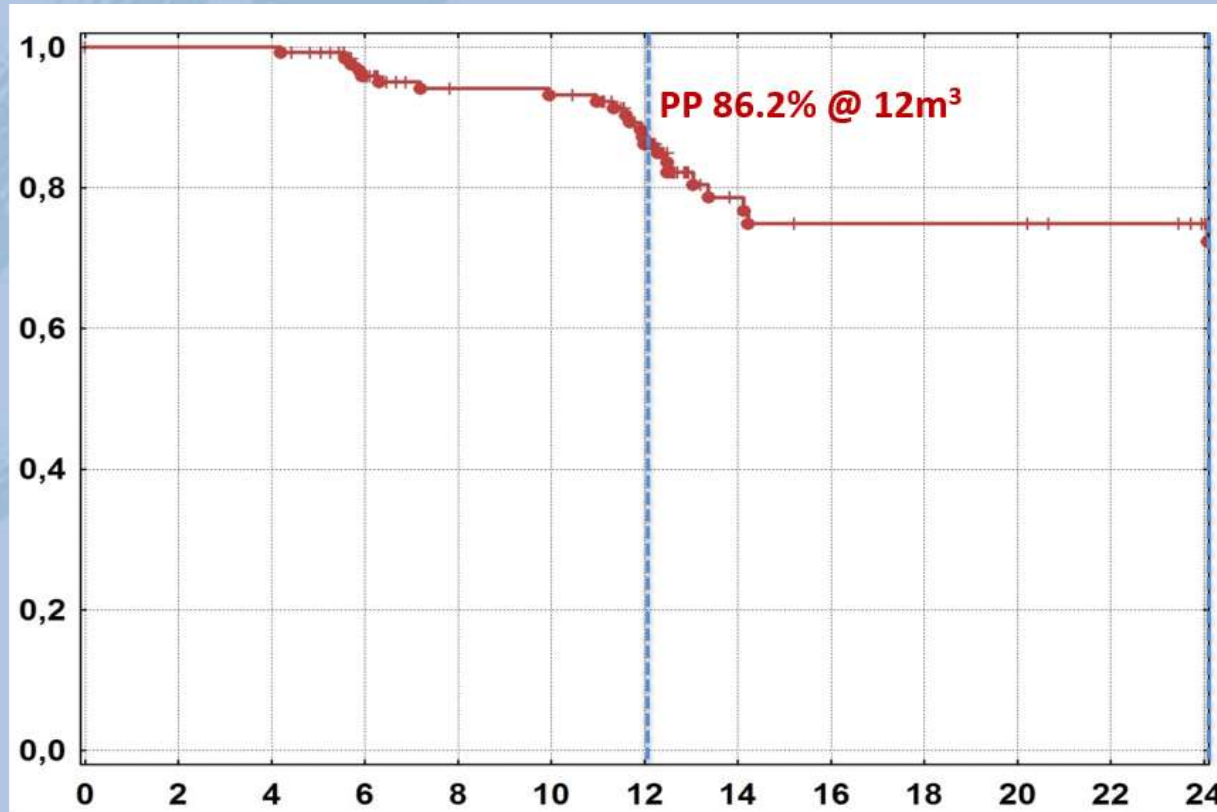
# Patient demographics & Lesion characteristics at baseline

Patient Lesion characteristics		N = 186
Mean Lesion length (cm) (n=185)		11.6 ± 10.3
Age (mean (sd))		69.7 (10.46)
Mean ref. vessel diameter		4.97 mm
Hypertension		141 (88.1%)
Mean implanted stent diameter		5.77 mm
Dyslipidemia		127 (79.4%)
Smoker (current or previous)		51 (27.4%)
Diabetes		65 (35.1%)
Refractory angina		34 (18.3%)
CL		
Ru		
TASC A lesion		40 (21.5%)
TASC B lesion		65 (35.1%)
TASC C lesion		34 (18.3%)
TASC D lesion		40 (21.5%)
Calcification		4 (2.7%)
0 None		62 (41.3%)
1 Mild		35 (18.8%)
2 Moderate		60 (40.0%)
3 Severe		73 (39.2%)
4		12 (8.0%)
5		43 (23.1%)
6		9 (6.0%)
		35 (18.8%)
		2 (1.3%)
Ar	<b>Moderate &amp; Severe</b>	<b>78 (41.9%)</b>
Walking capacity (mean in meter) (n=41)		130.2

Stent oversizing mean **0.8mm**



# Primary Patency up to 24 m<sup>1</sup>



PP 74.2% @ 24m<sup>3</sup>

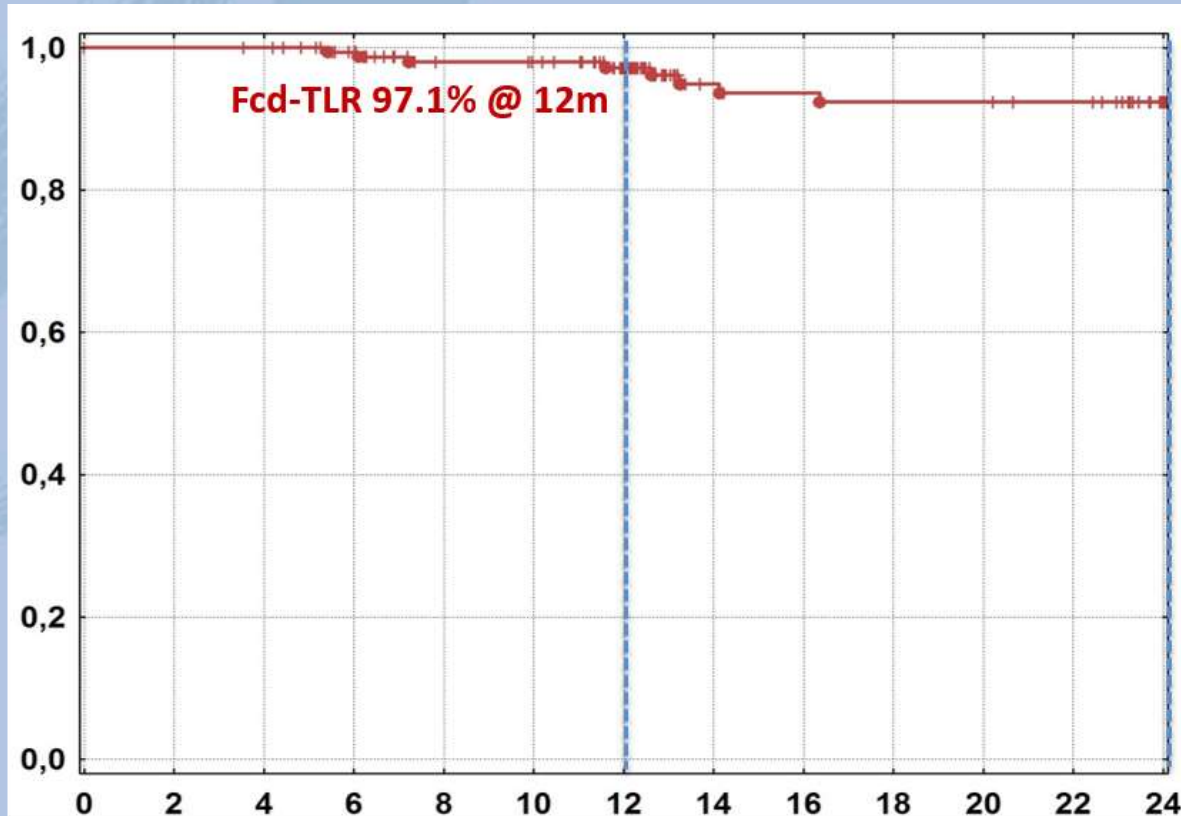
Time point (m)	0	6	12	24
Patient at Risk (n)	127	115	80	31
Survival (%)	-	95.9	86.2	74.9

<sup>1</sup> Interim 24 months data analysis

<sup>3</sup> Imaging cohort, where duplex data was available



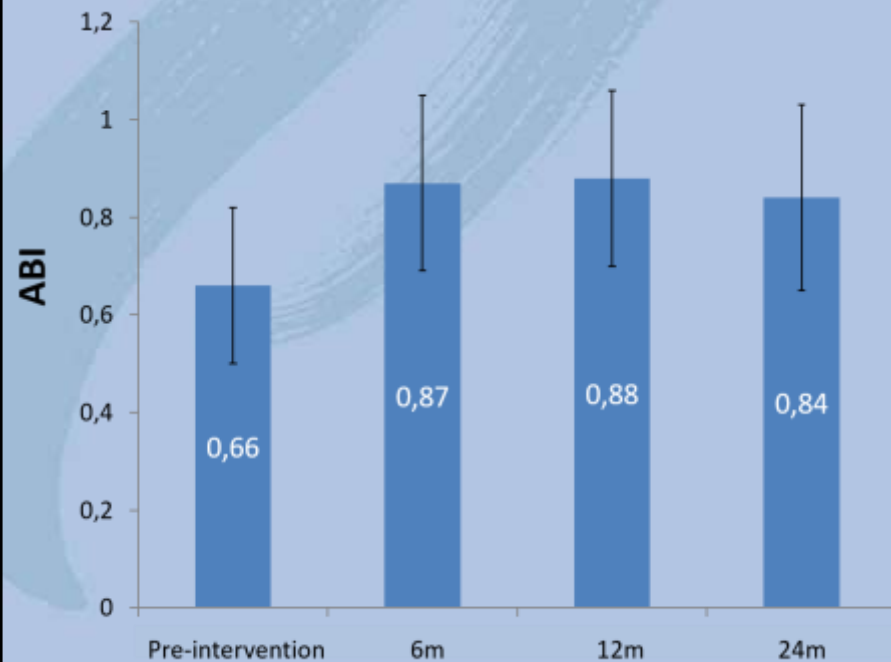
# Freedom from cd-TLR up to 24 m<sup>1</sup>



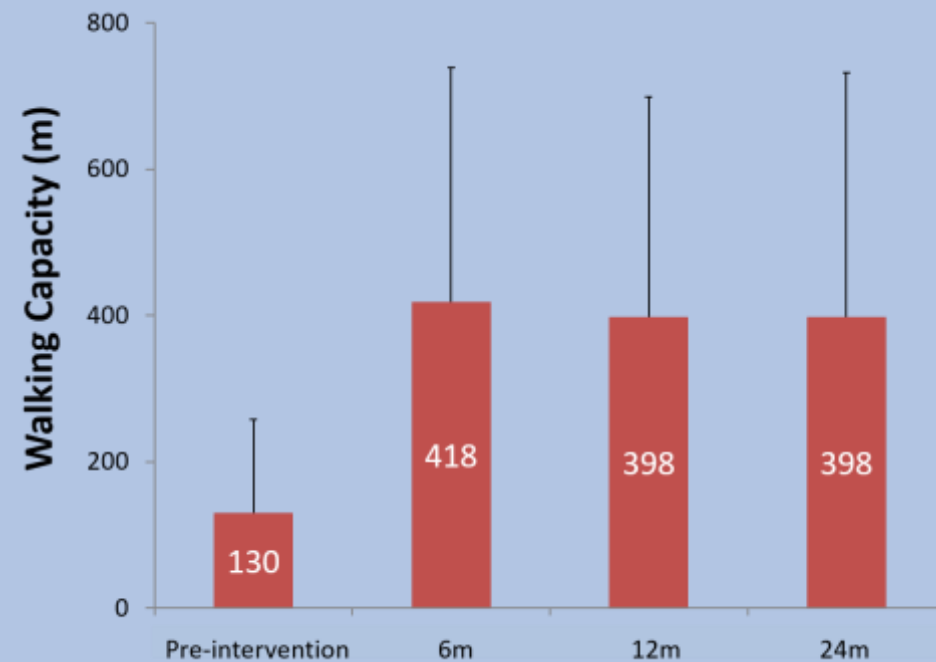
Time point (m)	0	6	12	24
Patient at Risk (n)	160	148	114	51
Survival (%)	-	99.3	97.1	92.3

<sup>1</sup> Interim 24 months data analysis

## Change in ABI up to 24 months<sup>1</sup>



## Pain Free Walking Capacity up to 24 months<sup>1</sup>



<sup>1</sup> Interim 24 months data analysis



# Conclusions



- **The 12m Primary Patency of 86.2% and Freedom from cd-TLR of 97.1%** are in line with published data for the Pulsar 18 stent
- **The interim 24m Primary Patency of 74.2%<sup>6</sup> and Freedom from cd-TLR of 92.3%** are indicative of a **long term positive trend**
- **Clinical success of 81.0%** (Improvement in Rutherford Class  $\geq 1$ )
- **Mean stent oversizing of 0.8 mm** suggests that in the real-world, interventionalists are applying “minimal oversizing” to reduce the **COF to least possible**



# **BIOFLEX PEACE 24 months full cohort data will be presented**

**Today at 15.00  
Room 3 – Technical Forum**

**15.00 – 16.30**

**BIOTRONIK Symposium:**

**Minimal is optimal in SFA therapy, reducing metal burden**

**BIOFLEX PEACE: Pulsar-18 all-comers registry 12-month &  
24-month results for the full cohort**

**Presented by Michael Lichtenberg, MD**



**Klinikum Arnsberg**

Akademisches Lehrkrankenhaus  
Westfälische Wilhelms-Universität Münster



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