iVascular coating technology on Luminor:

The latest generation DEB

V. Riambau, MD. PhD

Prof. and Chief of Vascular Surgery Division,
Cardiovascular Institute, Hospital Clínic of Barcelona

University of Barcelona

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Disclosures:

Consultant: Bolton Medical/ Medtronic/ W.L. Gore/ Cordis/ Aptus / iVascular

Proctor: Cook/ Bolton Medical/ Medtronic/ W.L. Gore/Cordis

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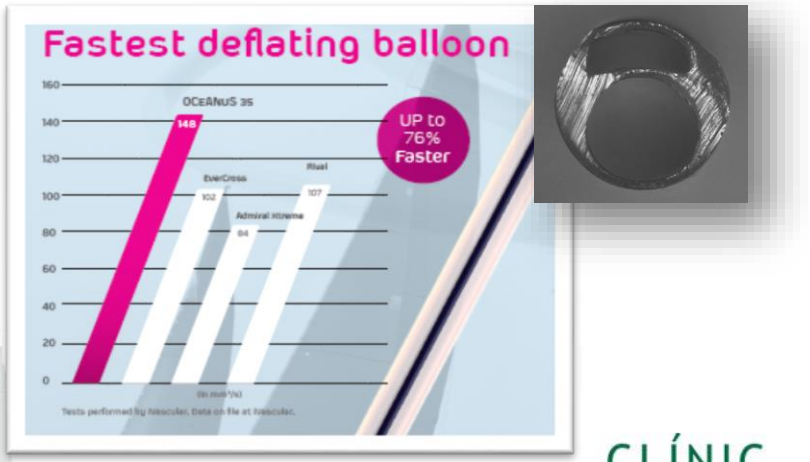
Oceanus 14 and 35 platforms

1. • Long tip with high crossing capability

2. • Good shape
   • Short Shoulders

3. • Quick deflation time



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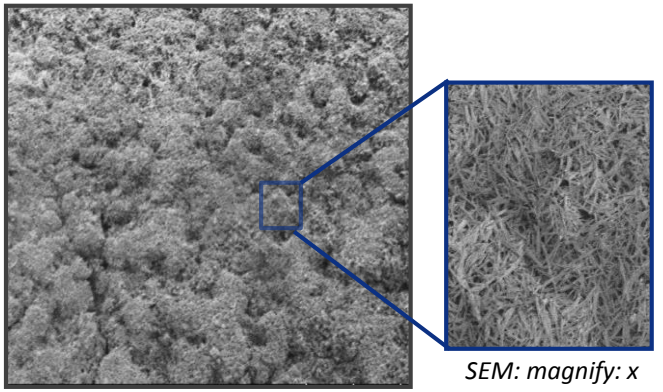
LUMINOR 14 and 35

1
- PTX microcrystalline structure
- Dosage: 3 µg/mm^2

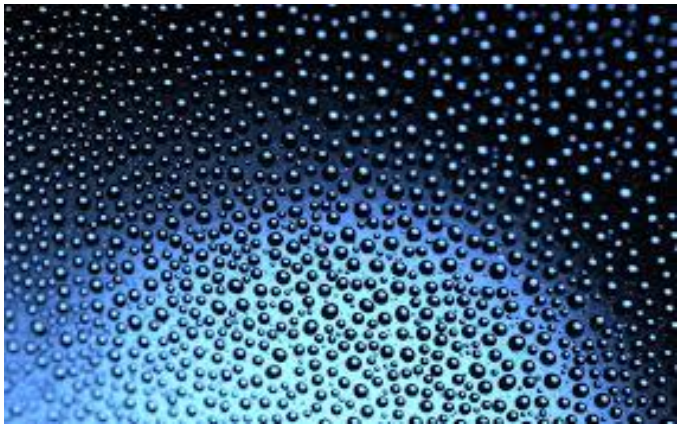
2
- Excipient: *Water Reduced Ester*
- Drug/excipient ratio: 80/20

3
- Transfertech® Coating technology



SEM: magnify: x250

SEM: magnify: x 1000



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TransferTech® Coating technology

Dosage of uniform diameter nanodrops by direct ultrasonic deposition

Folded – Outside the wings

- **Ultrathin multilayer coating:**
  - Increases **adhesion** to balloon
    - **Lower loss** related to manipulation
  - Improves **durability**:
    - **Lower loss** during navigation
  - Improves mechanical properties
  - **Fast absorption:** 30-60s

luminor/essential:
Coating: uniform w/o accumulation

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luminor 14

References

References Working Cathter Length 100 cm

Ballon diameter (mm)	Ballon length (mm) 40	60	80	120	150	200 XL
1.5	BP DPC14 100 150 040	BP DPC14 100 150 060	BP DPC14 100 150 080			
2.0	BP DPC14 100 200 040	BP DPC14 100 200 060	BP DPC14 100 200 080	BP DPC14 100 200 120	BP DPC14 100 200 150	BP DPC14 100 200 200
2.5	BP DPC14 100 250 040	BP DPC14 100 250 060	BP DPC14 100 250 080	BP DPC14 100 250 120	BP DPC14 100 250 150	BP DPC14 100 250 200
3.0	BP DPC14 100 300 040	BP DPC14 100 300 060	BP DPC14 100 300 080	BP DPC14 100 300 120	BP DPC14 100 300 150	BP DPC14 100 300 200
3.5	BP DPC14 100 350 040	BP DPC14 100 350 060	BP DPC14 100 350 080	BP DPC14 100 350 120	BP DPC14 100 350 150	BP DPC14 100 350 200
4.0	BP DPC14 100 400 040	BP DPC14 100 400 060	BP DPC14 100 400 080	BP DPC14 100 400 120		

References Working Cathter Length 150 cm

Ballon diameter (mm)	Ballon length (mm) 40	60	80	120	150	200
1.5	BP DPC14 150 150 040	BP DPC14 150 150 060	BP DPC14 150 150 080			
2.0	BP DPC14 150 200 040	BP DPC14 150 200 060	BP DPC14 150 200 080	BP DPC14 150 200 120	BP DPC14 150 200 150	BP DPC14 150 200 200
2.5	BP DPC14 150 250 040	BP DPC14 150 250 060	BP DPC14 150 250 080	BP DPC14 150 250 120	BP DPC14 150 250 150	BP DPC14 150 250 200
3.0	BP DPC14 150 300 040	BP DPC14 150 300 060	BP DPC14 150 300 080	BP DPC14 150 300 120	BP DPC14 150 300 150	BP DPC14 150 300 200
3.5	BP DPC14 150 350 040	BP DPC14 150 350 060	BP DPC14 150 350 080	BP DPC14 150 350 120	BP DPC14 150 350 150	BP DPC14 150 350 200
4.0	BP DPC14 150 400 040	BP DPC14 150 400 060	BP DPC14 150 400 080	BP DPC14 150 400 120		

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luminor 35

References

References Working Cathter Length 80 cm

Ballon diameter (mm)	Ballon length (mm) 20	40	60	80	120	150
5.0	BP DPC35 080 500 020	BP DPC35 080 500 040	BP DPC35 080 500 060	BP DPC35 080 500 080	BP DPC35 080 500 120	BP DPC35 080 500 150
6.0	BP DPC35 080 600 020	BP DPC35 080 600 040	BP DPC35 080 600 060	BP DPC35 080 600 080	BP DPC35 080 600 120	BP DPC35 080 600 150
7.0	BP DPC35 080 700 020	BP DPC35 080 700 040	BP DPC35 080 700 060	BP DPC35 080 700 080	BP DPC35 080 700 120	

References Working Cathter Length 140 cm

Ballon diameter (mm)	Ballon length (mm) 20	40	60	80	120	150
5.0	BP DPC35 140 500 020	BP DPC35 140 500 040	BP DPC35 140 500 060	BP DPC35 140 500 080	BP DPC35 140 500 120	BP DPC35 140 500 150
6.0	BP DPC35 140 600 020	BP DPC35 140 600 040	BP DPC35 140 600 060	BP DPC35 140 600 080	BP DPC35 140 600 120	BP DPC35 140 600 150
7.0	BP DPC35 140 700 020	BP DPC35 140 700 040	BP DPC35 140 700 060	BP DPC35 140 700 080	BP DPC35 140 700 120	

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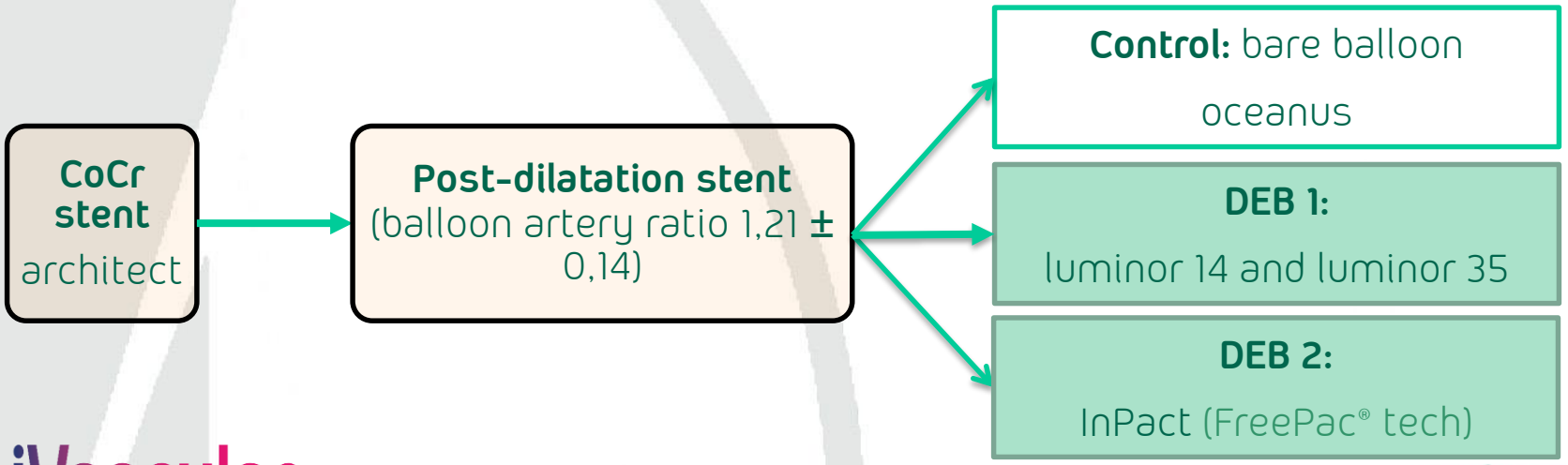
Preclinical data

Luminor vs InPact vs POBA

- Healthy arteries, swine model
- Domestic pigs: 25 ± 3 kg; n = 17
- 28-day follow-up: angiography and histology
  - **Restenosis:** % diameter and area of stenosis, late-loss and neointimal area
  - **Vascular healing parameters:** injury score, inflammation, fibrin and endothelization



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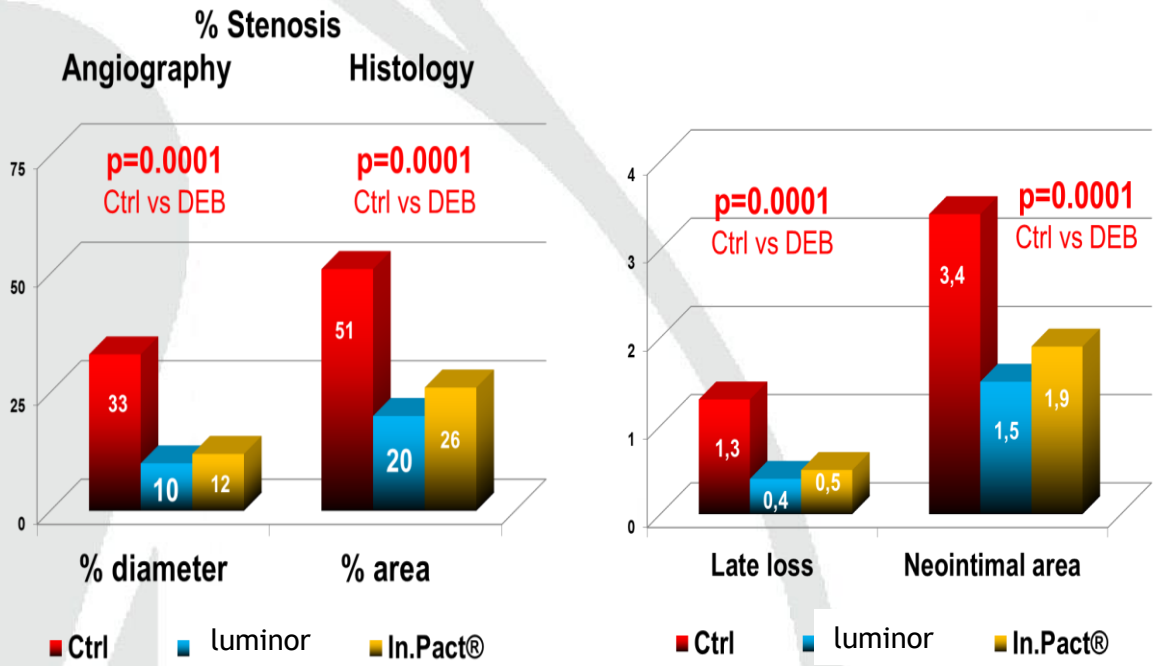
Preclinical data

Efficacy

- >50% less restenosis than control
- 23% less restenosis than DEB 2 In.Pact



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Clinical Program at a glance

Study	Product	Study type	Patient/ Injury type	Centers	Countries	Patients	Primary endpoint	Secondary endpoint	Status
LUMINOR REGISTRY	DEB luminor 14 luminor 35	Multicentric prospective registry	SFA Popliteal artery Tibial artery	10	Spain	250	Primary patency - 12m MAE - 12m	Clinical success - 12m Hemodynamical success - 12m Quality of Life	on going
EFFPAC	DEB vs POBA luminor 35 oceanus 35	Randomized multicentric prospective study	SFA	11	Germany	172	LLL - 6m	TLR - 6m/12m MACE - 6m/12m	on going
LUMINOR RETROSPECTIVE REGISTRY	DEB luminor 35	Monocentric retrospective registry	SFA	1	Germany	18	TLR - 6m MAE - 6m	Device and procedure success	finished
EVOLUTION	SE STENT iVolution	Multicentric prospective clinical study	Femoropopliteal artery	4	Belgium	120	Primary patency (12m)	Primary patency rate (1 & 6 month follow-up) Technical success TLR- 1m/6m/12m Clinical success- 1m/6m/12m Serious adverse events	on going
SWEDEPAD	DEB DES	Randomized multicentric prospective study	Peripheral arterial disease Critical limb ischemia Intermittent claudication	30	Sweden	3800	Amputation rate (in patients with critical limb ischemia) Health-related quality of life (in patients with intermittent claudication)	Aputation free survival TLR (12m) Patency (12m) Improvement clinical symptoms (1-12m) QoL	on going
POST MARKETING SURVEILLANCE	All iVascular products	Prospective registry	SFA and BTK			All comers	Primary patency - 12m MAE - 12m	Clinical success - 12m	on going

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Luminor Spanish Registry

Overview

Observational, prospective, multicentre study with single-arm treatment for stenotic or occlusive lesions or in-stent stenosis of the femoro-popliteal (FP) and below the knee (BTK) vessels

PRIMARY ENDPOINT	**Primary patency**, defined as freedom from >50% restenosis as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) <3 in the target vessel with no re-intervention, and freedom of serious adverse events defined as death, amputation and TLR during a minimum of 12-month follow-up period

PATIENTS	250/10 centers	FOLLOW UP	12 months

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Luminor Spanish Registry

Intermediate Results
Demographics

Table 1. Baseline Demographics	
Patients	**143**
Lesions	165
Male	75,6%
Age / years	70,66
Diabetes	70,4%
Smoking and ex-smoking	58,5%
Arterial Hypertension	80,0%
Hyperlipidemia	58,5%
Chronic Renal Failure	19,3%

Table 2. Rutherford Class	
Rutherford Class	
2	8,4%
3	19,6%
4	14,7%
5	57,3%

Rutherford 4-5: 72%

Table 3. Lesion Characteristics	
Lesion length (mm)	68,2
Chronic Total Occlusions	**49,1%**
Stenosis	50,9%
Target Vessels	
• Femoropopliteal	**66,9%**
• Below the Knee	23,8%
• Combined segments	9,3%

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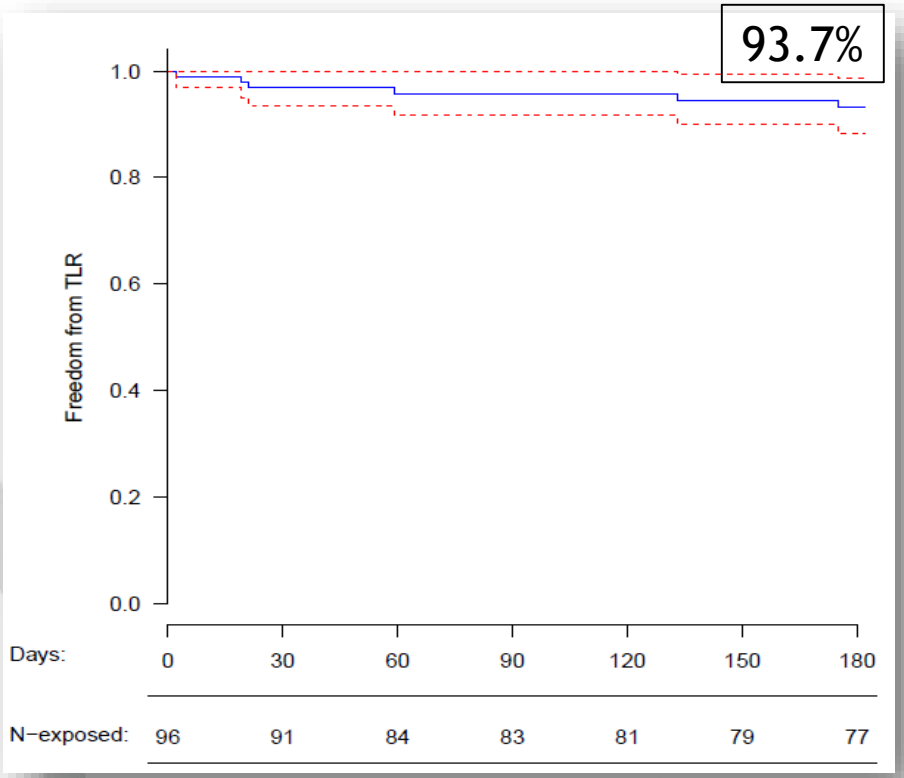
Luminor Spanish Registry

Intermediate Results
6-months follow-up

Table 4. Main interim results	
30-day-mortality	1,4%
6-month Follow-up (96 pax)	
All-cause mortality	9,4%
Major amputations	8,3%
TLR	6,3%

Freedom of TLR up to 6 month-follow-up



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EffPac trial

Overview

Phase III Multicenter Randomized Controlled Trial to Assess the Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter versus Uncoated Balloon Catheter in the Superficial Femoral and Popliteal Arteries to Prevent Vessel Restenosis or Reocclusion

OBJECTIVE	Safety and efficacy of the luminor paclitaxel drug-eluting balloon in inhibiting restenosis and in ensuring long-term patency

PATIENTS	172/10 centers	FOLLOW UP	6 and 12 months

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EffPac trial

Participating sites

001 Jena	→ **Prof. U. Teichgräber**, Universitätsklinikum Jena
002 Leipzig	→ **Prof. D. Scheinert**, Universitätsklinikum Leipzig
003 Bad Krozingen	→ **Prof. T. Zeller**, Herzzentrum Bad Krozingen
004 Hamburg	→ **Dr. med. S. Sixt**, Angiologikum GmbH
005 München	→ **PD Dr. med. M. Treitl**, Universitätsklinikum München
006 Berlin	→ **Prof. Dr. med. S. Duda**, Ihre-Radiologen
007 Sonneberg	→ **Dr. med. M. Thieme**, Medinos Kliniken Sonneberg
008 Karlsbad	→ **Prof. Dr. E. Blessing**, SRH Karlsbad-Langensteinbach
009 Heidelberg	→ **Dr. B. Vogel**, Universitätsklinikum Heidelberg
010 Arnsberg	→ **Dr. M. Lichtenberg**, Karolinen-Hospital Arnsberg

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EffPac trial

Endpoint

PRIMARY ENDPOINT	**Late lumen loss (LLL)** defined as difference between the diameters (in mm) at 6 months follow-up minus post-procedure
SECONDARY ENDPOINT	- Occurrence of restenosis defined as incidence of restenosis ≥50% - Freedom from Target lesion / vessel revascularization (TLR and TVR) - Rutherford stage @ 6M and 12M - Ankle-brachial index (ABI) @ 6M and 12M - Walking distance to baseline @ 6M and 12M - "Quality of Life" according to the WiQ and EQ5D @ 6M and 12M

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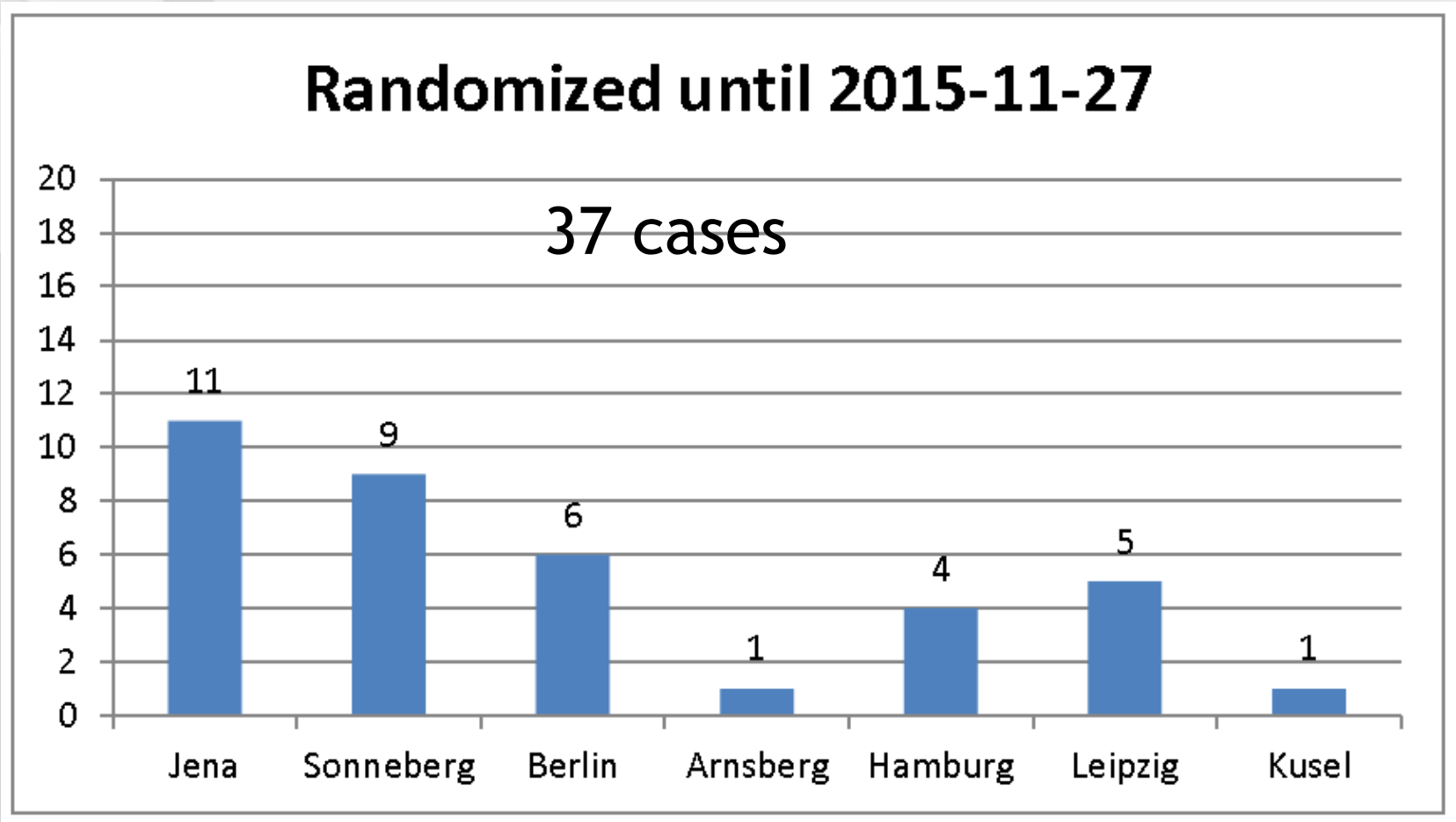
EffPac trial



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Summary

- LUMINOR is a tested drug coated balloon with unique coating technology (TransferTech®)
- Preclinical and Clinical studies, are demonstrating that LUMINOR is safe and efficient for patients suffering from lower limb ischemia even with challenge morphological arterial lesions
- More clinical data are desirable in order to get more knowledge about the real benefit of this new technology
- iVascular is committed to facilitate further clinical research within the oncoming years

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