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SAVER

Stellarex Vascular e-Registry

Stellarex in the Real World: Interim Results from the SAVER Registry

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On behalf of Prof. G Torsello, Dr. A Cremonesi, Dr. A Sauguet and the SAVER Investigators

Disclosure

Speaker name:

Frank Vermassen

I have the following potential conflicts of interest to report:

☑ Consulting

Prof. Vermassen has been compensated by Philips for his/her services in preparing and presenting this material for Philips' further use and distribution.

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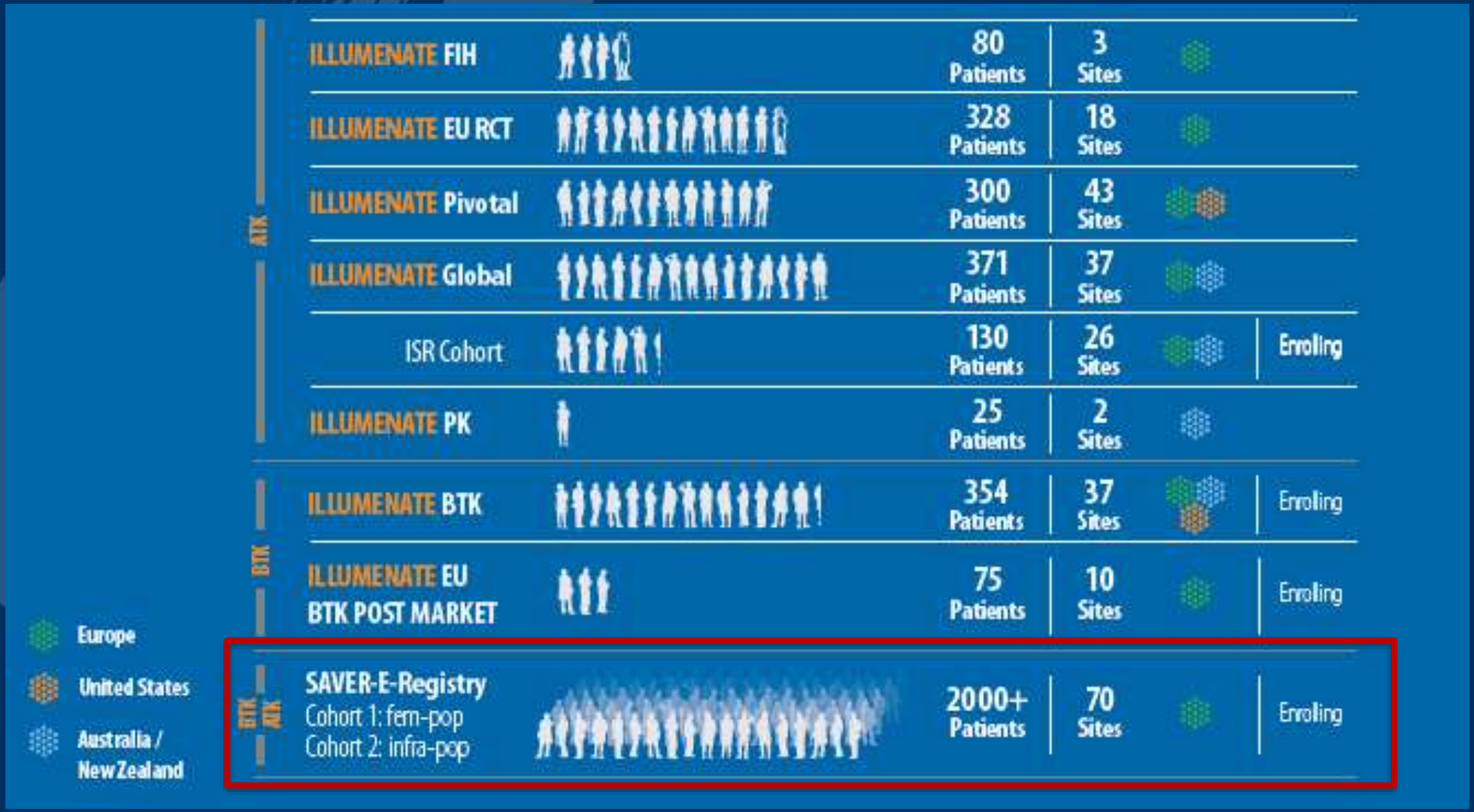
Stellarex DCB Clinical Program



SAVER: Stellarex Vascular e-Registry

ClinicalTrials.gov Identifier: NCT02769273

Registry of DCB use in lower limb real-world, real-practice

- **Multi-center European**
- **Imaging Core lab***
- **External Monitoring**
- **Clinical Event Committee adjudication**
- **Patient Follow up to 3 years**

* imaging cohorts for pre-defined subsets: CTO, ISR, long lesions, Ca++

- ☑ RC 2-3-4-5-6*
- ☑ Single limb or bilateral
- ☑ Fem-pop and/or BTK **
- ☑ Single or multiple lesions
- ☑ De-novo / restenotic / ISR
- ☑ Stenosis or CTOs
- ☑ TASC A-B-C-D
- ☑ Calcium of any grade / severity
- ☑ With or w/out pre-dil
- ☑ Lesion prep / post-treatment at operator's discretion

* **Interim analysis includes Cohort 1 only.*

To continue to assess the treatment by the Stellarex DCB in superficial femoral, popliteal, and/or infra-popliteal arteries in a broad, real-world, claudicant or critical limb ischemia patient population

SAVER Overview

Eligibility Details

- Symptomatic stenosis of the SFA/Pop intended to be treated with PTA using the Stellarex OTW DCB
- De novo or restenotic
- Rutherford 2 – 3
- Rutherford 4-6 (added later)

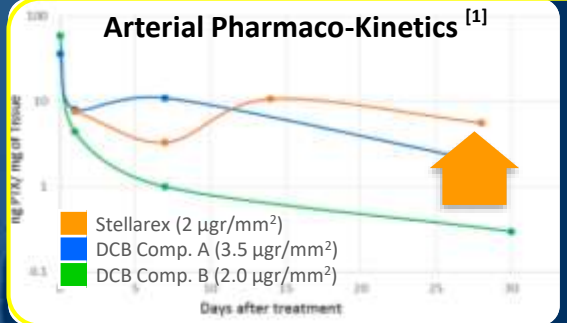
	Cohort 1 (Claudicants)	Cohort 2 (CLI)
Safety	Freedom from 30-day device and procedure related death and freedom from 12-month target limb major amputation and CD-TLR	Freedom from Composite MALE and perioperative death through 30 days
Efficacy	Freedom from 12-month CD-TLR	Freedom from CD-TLR at 6 months post-procedure

Study Device: Stellarex DCB

Spectranetics Proprietary open-folded coating technology

- **Low dose (2 µg/mm²) paclitaxel**
- **Hybrid-crystalline formulation**

Arterial Pharmaco-Kinetics [1]



- **Effective drug tissue transfer and residency (≥ 28 days)**

1. Superimposed PK curves from different datasets: R.Melder, EuroPCR 2012; Yazdani et.al. Catheterization and Cardivascular Interventions 83:132-140 (2014); data on file at Spectranetics

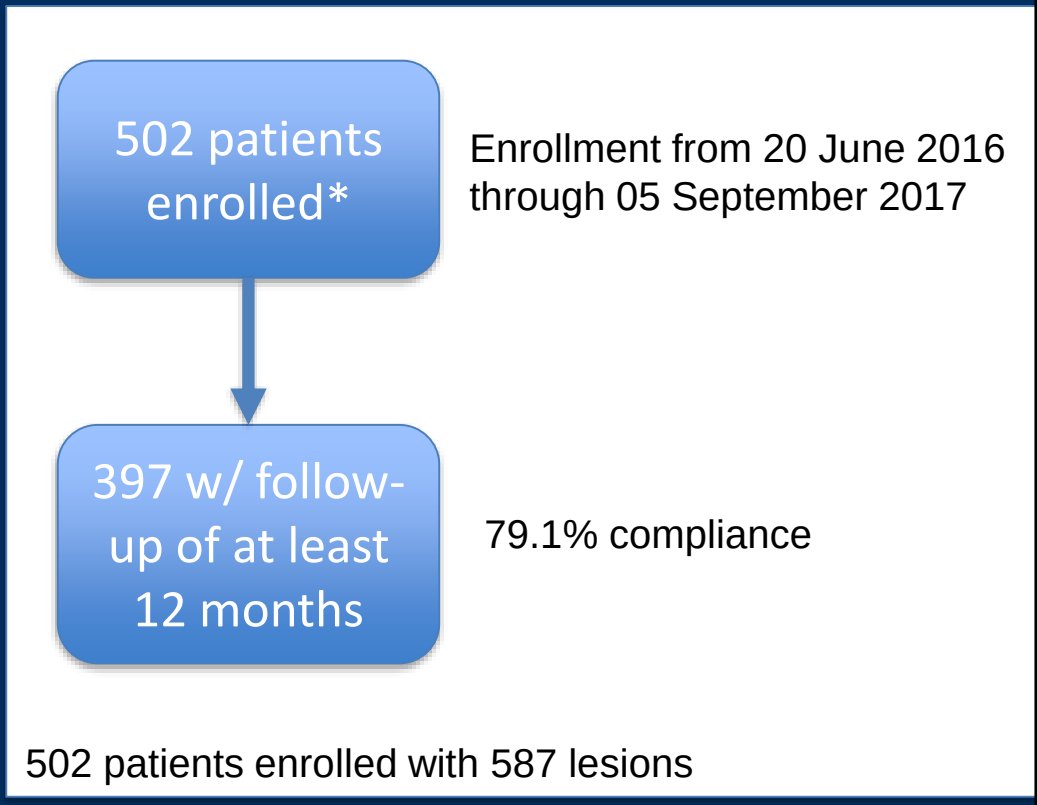
PTX particulate loss after transit [2]

- **Limited drug loss**

2. Number of particulates ≥10µm/mm of DCB length lost during transit. Data on file at Spectranetics

Interim Analysis of First 500 Subjects

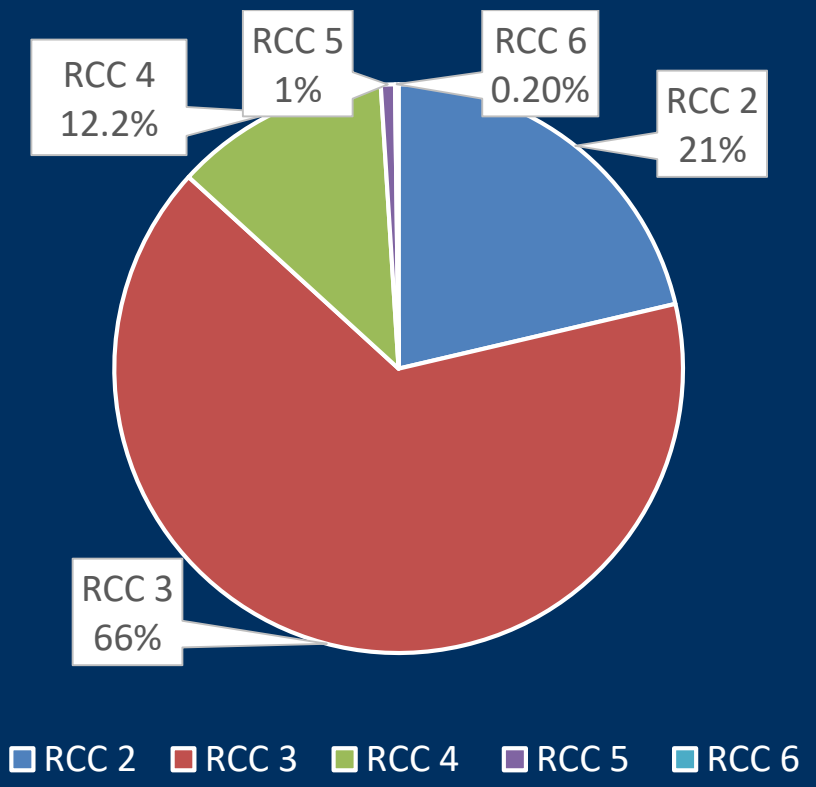
- 45 investigational sites in the EU
- All ATK patients enrolled up to this point of the study*



** Interim analysis includes Cohort 1 only. Cohort 2 enrolled later in study.*
***5 patients enrolled on last date, exceeding 500 cutoff*

Baseline Patient Characteristics

Characteristic	Value
Age	69.9 ± 9.5 years
Male	68.9%
Diabetes	32.8%
Hypertension	80.7%
Hypercholesterolemia	70.2%
Renal Insufficiency	4.7%
Previous or current smoker	72.7%
Previous coronary revascularization	34.2%
Baseline ABI	0.68 ± 0.23
Previous Intervention of Study Limb	39.9%



Baseline Lesion Characteristics

N (Lesions)	587
De novo	72.8% (422/580)
Lesion Length (Mean ± SD)	111 ± 88 mm
Long Lesions >150 mm	23.2% (136/586)
Total occlusions	30.9% (176/570)
Calcification (Severe*)	22.7% (109/480)
Mild/Moderate	48.7% (234/502)
ISR	18.9% (111/587)
Baseline Diameter Stenosis	86.6% ± 13.7 (562)
Lesions per Subject	
1	85.3% (428/502)
2 or more	14.7% (74/502)
Lesion Location	
SFA only	76.3% (448/587)
Popliteal only	15.0% (88/587)
SFA & Popliteal	8.7% (51/587)

*Severe: >180° (both sides of the vessel at the same location) and greater than half the total lesion length

Procedural Characteristics

Characteristic	N Lesions = 587
Pre-dilatation	68.1% (400/587)
Number of Stellarex Balloons Used	
1	68.5%(402/587)
2	17.0% (100/587)
≥3	14.5% (85/587)
Post DCB Stent Placement	26.4% (153/579)
Post Procedure Final Stenosis	8.0% ± 11.0
Lesion Success[1]	98.9% (545/551)
Procedural Success[2]	98.2% (540/550)

1. Final residual %DS ≤ 50% after using the DCB
2. %DS ≤ 50% after using the DCB without complications

Primary Safety Endpoint

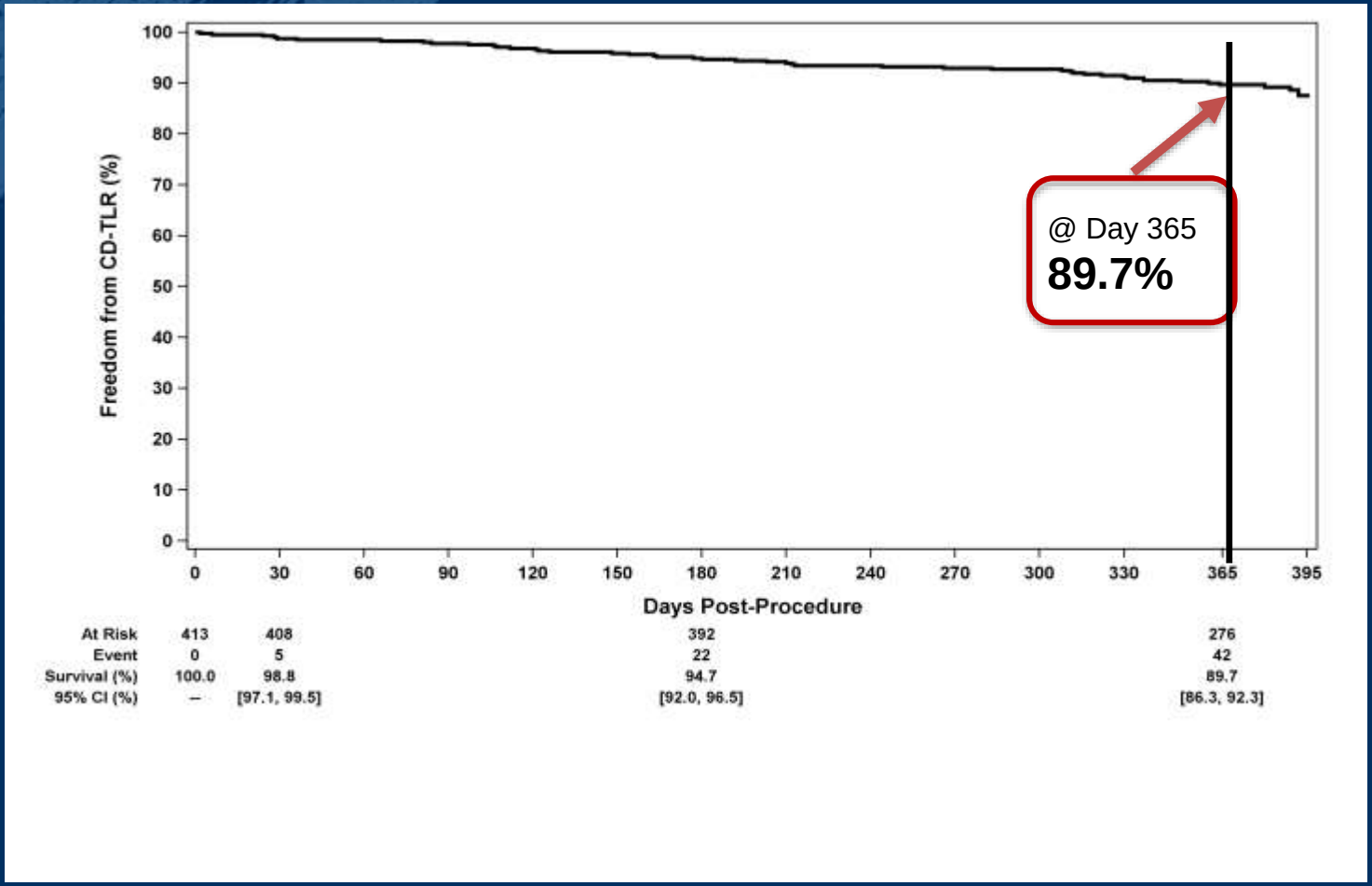
Freedom from device/procedure-related death through 30 days post-procedure and freedom from target limb major amputation and CD-TLR through 12 months post-procedure:

88.9% (367/413)

Procedural Complications	Frequency
Procedural Complications	1.0% (6/586)
Death	0.0% (0/586)
Stroke	0.0% (0/586)
MI	0.0% (0/586)
Emergent Surgical Revascularization	0.2% (1/586)
Significant Distal Embolization	0.9% (5/586)
Target Vessel Thrombosis	0.2% (1/586)

Primary Efficacy Endpoint:

Freedom from clinically-driven CD-TLR at 1 year
(CEC Adjudicated)



Key One-Year Clinical Secondary Endpoints

Safety Endpoints

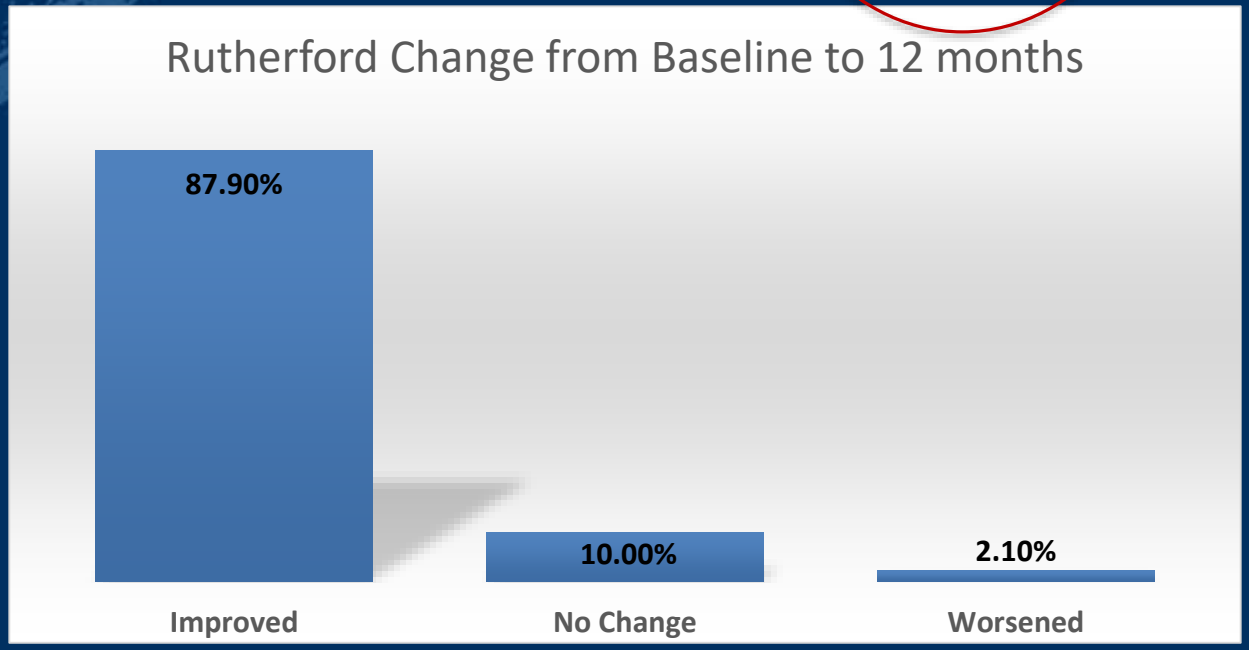
Endpoint	Rate
All-Cause Death	2.5% (10/408)
Cardiovascular Death	1.5% (6/404)
Amputation	1.0% (4/403)
Major Amputation	0.5% (2/403)

Efficacy Endpoints

Endpoint	Rate
Target Lesion Revascularization (TLR)	11.4% (47/413)
Clinically-Driven TLR	11.1% (46/413)
Target Vessel Revascularization (TVR) (exclusive of TLR)	0.5% (2/402)
Clinically-Driven TVR	0.5% (2/402)

Additional Secondary Outcomes

Outcome	Baseline	12 Months*	Change
ABI (Mean ± SD)	0.7 ± 0.2	0.9 ± 0.2	0.2 ± 0.3
WIQ (Mean ± SD)	45.6 ± 14.8	58.2 ± 18.1	12.7± 15.1
6 Minute Walk Test (Mean ± SD)	46.5 ± 31.8	120.0 ± 127.3	73.5 ± 95.5
EQ-5D (Mean ± SD)	39.9 ± 32.3	41.6 ± 34.7	1.7 ± 14.1



**Values at 12 months comprise those with paired observations available (baseline and 12 months)*

SAVER Registry Conclusions

Interim analysis of the SAVER Registry confirms:

- Excellent 12-month Stellarex safety profile, with CV-related death and major amputation rates around 1% and **no procedure/device-related death**
- Procedural complications were low with distal embolization and thrombosis rates at <1% respectively
- Stellarex demonstrated a 12-month

  All-Cause Mortality rate of 2.5%

  CD-TLR rate of 11%
- 88% of patients had improved Rutherford category, with correlated improvements in Quality of Life scales at 12 months
- Reinforced safety profile and effectiveness for Stellarex in a real-world patient population.

Special Thanks to all the SAVER Sites & Investigators

UZ Gent
UZ Antwerpen
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Langensteinbach GmbH
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Klinikum Konstanz
Krankenhäuser Landkreis
Freudenstadt GmbH
The John Radcliffe Hospital
Royal Bournemouth and
Christchurch Hospital
Stoke Mandeville Hospital
Saint George's University
Hospitals NHS Foundation
Hôpital Ambroise Paré
Clinique Pasteur
Clinique Rhône Durance
Clinique Médipole De Savoie
Clinique Générale Annecy
Clinique Saint Augustin
Polyclinique de la Baie
Clinique Tivoli
Clinique Sarrus teinturiers Rive
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