Disclosure

Speaker name:

Paul Myers

☐ 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
On-going Clinical Experience with Passeo-18 Lux Drug Coated Balloon

Associate Professor Paul Myers
Vascular Surgeon
Newcastle
Australia
Limitations of PTA & Stenting

- The well known limitations of POBA in treating (particularly) above knee stenotic disease led to the increased use of stents.

- Whlst stents gave good initial results, overall only small increments in late patency were seen over POBA.

- “Routine stenting was not associated with a significant reduction in the rate of re-stenosis or target vessel revascularization in comparison to POBA with provisional stenting”. Kasapis *Eur Heart J* 2009
Drug Coated Balloons (DCB) offer an attractive alternative for the treatment of lower limb disease

**Benefits**
- Anti-proliferative therapy while leaving nothing behind
- Broad anatomical applicability
- Avoid stent fracture and ISR burden
- Possibly ideal for ‘no-stent zones’
- Easily repeatable/Preserve future options
- Matches patient’s QOL expectations (improvement in walking capacity, Rutherford class)

**Limitations**
- Not yet proven in highly calcified lesions (eg. CFA)
- Requirement for anti-platelets agents post-procedure
- When provisional stent is required= higher procedural cost
Why Re-stenosis?

Re-stenosis comprises three distinct processes:

i. early elastic recoil,

ii. late vessel remodelling, and

iii. neo-intimal hyperplasia.
Mechanisms:
• vasoconstriction
• formation of mural thrombus
• leukocyte recruitment at the site of balloon injury
• vascular wall smooth muscle cell activation, proliferation, and migration

Causing the induction of:
• neo-intimal hyperplasia (48 hours – months)
• a re-modelling process

Where re-stenosis occurs:
• slow vasoconstriction (negative re-modelling) over weeks – months causing luminal narrowing independently of above factors
In-stent Re-stenosis

- **Main cause** is neo-intima formation characterised by the *proliferation* and *migration* of smooth muscle cells.

- Smooth muscle activity peaks at 28 days after stenting.

- With mechanical treatment only (i.e. angioplasty within the stent), repeat re-stenosis rates approach 50%.
Prevention of In-stent Restenosis

We need to be able to:

(i) limit intimal hyperplasia; (mostly by)

(i) inhibiting smooth muscle activation, proliferation and migration
Paclitaxel

- Paclitaxel is a highly lipophilic, crystalline powder
- High lipophilicity allows uptake in lipid-rich environments such as atherosclerotic plaque
- After short, single dose paclitaxel remains in cells for several days
- Thus sustained release is probably not as important as with sirolimus
Paclitaxel

- Burst dose at the time of injury i.e. pre-dilatation, may be the best timing for this drug

- Inhibits smooth muscle cell proliferation by binding to the cells and altering its cytoskeleton, interrupting the cell cycle and preventing replication

- Affects development of neo-intimal hyperplasia
## Not all DCBs are equal.
## Not all DCBs are proven.

<table>
<thead>
<tr>
<th>Device name</th>
<th>BIOTRONIK</th>
<th>Cook</th>
<th>Eurocor</th>
<th>Aachen Resonance</th>
<th>BARD</th>
<th>Medtronic</th>
<th>Boston Scientific</th>
<th>Cardio novum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passeo-18 LUX</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advance PTX</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freeway</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elutax</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lutonix</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IN.PACT (Admiral, Pacific)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ranger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legflow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Drug Concentration 3µg/mm²</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>2.2µg/mm²</td>
<td>2µg/mm²</td>
<td>3.5µg/mm²</td>
<td>2µg/mm²</td>
<td>✓</td>
</tr>
<tr>
<td>Excipient</td>
<td>✓</td>
<td>×</td>
<td>✓</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Insertion aid</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Positive randomized data against PTA</td>
<td>✓</td>
<td>×</td>
<td>✓</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4F compatible *</td>
<td>✓</td>
<td>✓</td>
<td>×</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>✓</td>
<td>×</td>
</tr>
</tbody>
</table>

* At least 1 or more sizes

Sources: company web sites
- Freeway: FREERIDE Schulte KL Poster presentation LINC 2014
- Lutonix: LEVANT-I. JACC 2014; 7:10-9
- InPact Pacific: PACIFIER 12m data CCI. 2012:5:00-00.
Coating:
- PTX Drug 3µg/mm²
- Excipient: Butyryl-Tri Hexcyl Citrate (BTHC)

SafeGuard Insertion aid:
- Improves ease of handling
- Protects the user and balloon from contact and damage

Technology: Platform
- Ø: 3-7mm
- L: 40-120mm
Paclitaxel concentration strongly influences total drug load

- Paclitaxel concentration of 3μg/mm² may result in more drug available at the lesion site
- Safety profile was assessed in animal studies¹ and is confirmed in human clinical trials²
- Safety and efficacy of 3μg/mm² technologies is also supported by long term evidence in coronary and peripheral applications³

Source: 1. L105_VR_123081_A_Animal_PK_Final.doc  
2. BIOLUX P-I 12m Scheinert D. presented at TCT 2013; InPact Pacific: PACIFIER 12m data CCI. 2012;5:00-00  
Coating Technology: Excipient behaviour

- Coating characteristics are modified when surface is wetted
- **Hydrophilic excipients** are more soluble and **degrade faster**
- **Hydrophobic excipients** are less soluble and have **reduced drug loss** in physiological environments

### Device Excipient Type Solubility

<table>
<thead>
<tr>
<th>Device</th>
<th>Excipient</th>
<th>Type</th>
<th>Solubility*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passeo-18 Lux</td>
<td>Butyryl-tri-hexyl citrate (BTHC)</td>
<td>Hydrophobic * in water</td>
<td>Very low</td>
</tr>
<tr>
<td>IN.PACT</td>
<td>Urea</td>
<td>Hydrophilic</td>
<td>Fast dissolving</td>
</tr>
<tr>
<td>Lutonix</td>
<td>Polysorbate/sorbitol</td>
<td>Hydrophilic/hydrophobic</td>
<td>Fast dissolving</td>
</tr>
</tbody>
</table>

**Drug Coating Integrity**

(% drug load remaining on balloon after submerge and deployment)

- Passeo-18 Lux: 97.1%
- Lutonix 035: 74.2%
- IN.Pact Admiral: 88.4%

Simulated use of a 5mm x 40mm DCB in physiological solution at 37ºC

Source: Data on file at BIOTRONIK AG
Amount of paclitaxel reaching the lesion to have a therapeutic effect seems optimal in Passeo 18 Lux

**IN-VIVO RESULTS: 6m Follow Up**

- **PTA**
  - Therapeutic effect evidence: reduced NIH vs. PTA control

- **Passeo-18 Lux x 2**
  - ‘Double-dosing’ with second DCB had no additional therapeutic or toxic effect.

- **Passeo-18 Lux x 1**

References: L105_VR_123081_A_Animal_PK_Final.doc
DCB clinical study results show performance differences

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Vessels</th>
<th>Time-Point</th>
<th>BIOLUX P-I 6m BR</th>
<th>BIOLUX P-II 6m TLP</th>
<th>Myers Australia SFA-ISRA 27m PP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passeo-18 Lux (3µg/mm²)</td>
<td>88.5%</td>
<td>84.3%</td>
<td>97%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Vessels</th>
<th>Time-Point</th>
<th>LEVANT I 6m PP</th>
<th>LEVANT II 12m PP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix (3µg/mm²)</td>
<td>72%</td>
<td>65.2%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Vessels</th>
<th>Time-Point</th>
<th>PACIFIER SFA 6m BR</th>
<th>In.PACT I SFA 12m PP</th>
<th>In.PACT Deep BTK 12m PP</th>
<th>In.PACT SFA-IT SFA 12m PP</th>
</tr>
</thead>
<tbody>
<tr>
<td>In.Pact (3µg/mm²)</td>
<td>91.4%</td>
<td>82.2%</td>
<td>59%</td>
<td>83.7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: BIOLUX P-I and P-II, LEVANT I and II, PACIFIER, In.PACT I and Deep.*
BIOLUX P-III All-comers registry

Study Design

DESIGN:
Prospective, international, multi-centre, open label, all-comers registry to expand and understand the safety and efficacy data on the Passeo-18 Lux DRB in a real world population of subjects with obstructive disease of the infrainguinal arteries.

PRINCIPAL INVESTIGATOR:
Prof. G. Tepe, Rosenheim (DE)

PRIMARY ENDPOINT:
Freedom from clinically-driven TLR within 12 months post-index procedure.

SECONDARY ENDPOINTS: (selected)
• Freedom from clinically-driven TLR within 24 months post-index procedure
• Primary patency at 12 and 24 months
• MAE at 6, 12 and 24 months
• Quality of Life (QOL) assessment questionnaires: Pain scale, SF-12, WIQ at 6, 12 and 24 months.

600 patients at ca. 55 clinical sites EU/APAC
First patient inclusion: Q4/2014

6 months: MAE, change in ABI, RC

12 months: freedom from TLR, primary patency, MAE, change in ABI

24 months: freedom from TLR, primary patency, MAE, change in ABI
### Study Design

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Safety</th>
<th>Performance</th>
<th>Core lab.</th>
<th>All-Comers</th>
<th>SFA</th>
<th>Popliteal</th>
<th>BTK</th>
<th>AV Access</th>
<th>Calc.</th>
<th>Long lesions</th>
<th>ISR</th>
<th>Vessel Prep.</th>
<th>TASC C&amp;D</th>
<th>PROs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BIO LUX P-I</strong></td>
<td>FIM RCT: SFA Passeo-18 Lux vs. PTA 60 subjects</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scheinert DE</td>
<td>JEVT – to be published Feb 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BIO LUX P-II</strong></td>
<td>FIM RCT: Infrapopliteal Passeo-18 Lux vs. PTA 72</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zeller DE</td>
<td>subjects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BIO LUX P-III</strong></td>
<td>All-Comers Registry Passeo-18 Lux 700 subjects</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tepe DE</td>
<td>JEVT – planned submission Jan 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BIO LUX P-III</strong></td>
<td>Registries Passeo-18 Lux 100-1000 per Satellite</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satellites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BIO LUX 4EVER</strong></td>
<td>Single-arm, SFA Passeo-18 Lux + Pulsar-18 120</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bosiers BE</td>
<td>subjects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BIO LUX-AV</strong></td>
<td>RCT, AV Fistula Passeo-18 Lux vs. PTA 120 subjects</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terasse CA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DEBAS-I</strong></td>
<td>Single-centre Pulsar-18 + Passeo-18 Lux 100</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mwipatayi AU</td>
<td>subjects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANZ LUX Experience</strong></td>
<td>Retrospective Registries Passeo-18 Lux in ISR 61</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myers AU</td>
<td>&amp; 29 subjects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Robertson AU</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Economic impact of Drug Coated Balloons

Per year:

DCB c. €90K less costly than PTA therapy due to lower repeat intervention costs, despite the greater DCB purchase costs.

- DCB dominated all other options by lower lifetime costs and greater effectiveness.
- DCB represents a cost-effective alternative to PTA with bail-out BMS.

Sources:

Original article

Cost-effectiveness analysis of enhancements to angioplasty for infrainguinal arterial disease

B. C. Kearns, J. A. Michaels, M. D. Stevenson and S. M. Thomas

Section of Health Economics and Decision Science, School of Health and Related Research, University of Sheffield, Sheffield, UK

Correspondence to: Mr B. C. Kearns, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA, UK (e-mail: b.kearns@sheffield.ac.uk)
Lake Macquarie Experience
Newcastle
Australia

- Registry investigating the performance of the Passeo-18 Lux drug coated balloon for the treatment of *in-stent* restenosis (ISR).

- Registry investigating the performance of the Passeo-18 Lux drug coated balloon for the treatment of *common femoral artery primary stenosis*.

- All patients were treated within Australian TGA Special Access Scheme (SAS).

- All necessary SAS approvals obtained prior to treatment.
• **61 patients with ISR** treated by one operator June 2011 – December 2014.

• **13 patients** with second in-stent restenosis

• **Additional 11 patients** treated for CFA stenosis.

• **Duplex scan @ 1 day, 3 months, 6 months and thereafter.**

• **At least 6 month follow-up available on 59 ISR and 7 CFA patients.**
## Baseline Demographic Data

### Patient data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age</td>
<td>72 years (38-86)</td>
</tr>
<tr>
<td>Smoker</td>
<td>N=51</td>
</tr>
<tr>
<td>Hypertension</td>
<td>n=58</td>
</tr>
<tr>
<td>Diabetes</td>
<td>n=24</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>n=32</td>
</tr>
<tr>
<td>Hypercholesteraemia</td>
<td>n=50</td>
</tr>
</tbody>
</table>
### VESSEL DEMOGRAPHICS
(In-stent Restenosis)

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Iliac</td>
<td>14</td>
<td>23</td>
</tr>
<tr>
<td>SFA/Popliteal</td>
<td>36</td>
<td>59</td>
</tr>
<tr>
<td>Tibio-peroneal Trunk</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Femoro-popliteal Graft Stent</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-stent Restenosis</td>
<td>61</td>
<td>N/A</td>
</tr>
<tr>
<td>Average treated lesion Length (cm) SFA</td>
<td>6.2</td>
<td>N/A</td>
</tr>
<tr>
<td>Pre-dilatation prior to DCB</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>
Follow-up Data
(In-stent Restenosis Cases)

Duration:
• Average 27 months (range 2-43 months)
• 59 > 6 months

Results:

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency¹</td>
<td>54/61</td>
<td>89</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>54/61</td>
<td>89</td>
</tr>
</tbody>
</table>

Primary Patency (freedom from >50% restenosis on duplex ultrasound or PSVR <2.5 in the target vessel)
# Primary Patency by Vessel Type
(In-stent Restenosis)

<table>
<thead>
<tr>
<th>Number</th>
<th>Primary Patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (n=61)</td>
<td>89</td>
</tr>
<tr>
<td>SFA/POP (n=36)</td>
<td>97</td>
</tr>
<tr>
<td>Stent graft (n=1)</td>
<td>0</td>
</tr>
<tr>
<td>Tibioperoneal (n=7)</td>
<td>100</td>
</tr>
<tr>
<td>Renal (n=3)</td>
<td>100</td>
</tr>
<tr>
<td>Iliac (n=14)</td>
<td>65</td>
</tr>
</tbody>
</table>
Recurrences

• **Common iliac** – 4 @ 9, 11, 13 and 30 months. All treated with PTFE-covered stents.

• **EIA** – 1 @ 38 months. Re-dilated

• **SFA** – 1 @ 23 months. Re-dilated.

• **Vein graft origin** - 1 @ 10 months. Re-dilated.
Common Femoral DCB’s

11 CFA primary stenoses in severe vasculopathies dilated using Passeo 18 Lux.

• Average follow up 15 months (range 2-25).
  • No significant re-stenosis as yet
Deaths

Total 4:

- 15 months – SFA
- 16 months – SFA
- 18 months – CFA
- 36 months – SFA.

Stent related - nil

Recurrence - nil
SFA/popliteal in-stent restenosis
SFA/popliteal in-stent restenosis
post-Passeo 18 Lux angioplasty
Tibio-peroneal in-stent restenosis
Tibio-peroneal in-stent restenosis post-Passeo 18 Lux angioplasty
CONCLUSIONS

Passeo 18 Lux

- Interventionally safe i.e. the engineering “works”
- No evidence of systemic effects or adverse outcomes
- CIA bare metal stent results not as durable
- Early excellent results for in-stent re-stenosis are being very well maintained at 6 months – over 3 ½ year follow-up
- Results particularly good in SFA and tibio-peroneal trunk re-stenosis
CONCLUSIONS

In-stent Re-stenosis

Increasingly strong, on-going evidence that Passeo 18 Lux paclitaxel-coated balloons are a significant advance in preventing further in-stent restenosis.
CONCLUSIONS

Common Femoral

Passeo 18 Lux may be useful for de novo applications in “non-stent” areas such as the common femoral artery
On-going Clinical Experience with Passeo-18 Lux Drug Coated Balloon

Associate Professor Paul Myers
Vascular Surgeon
Newcastle
Australia