

# **New Drug Coated Balloons in Femoro-Popliteal Disease in Korea**

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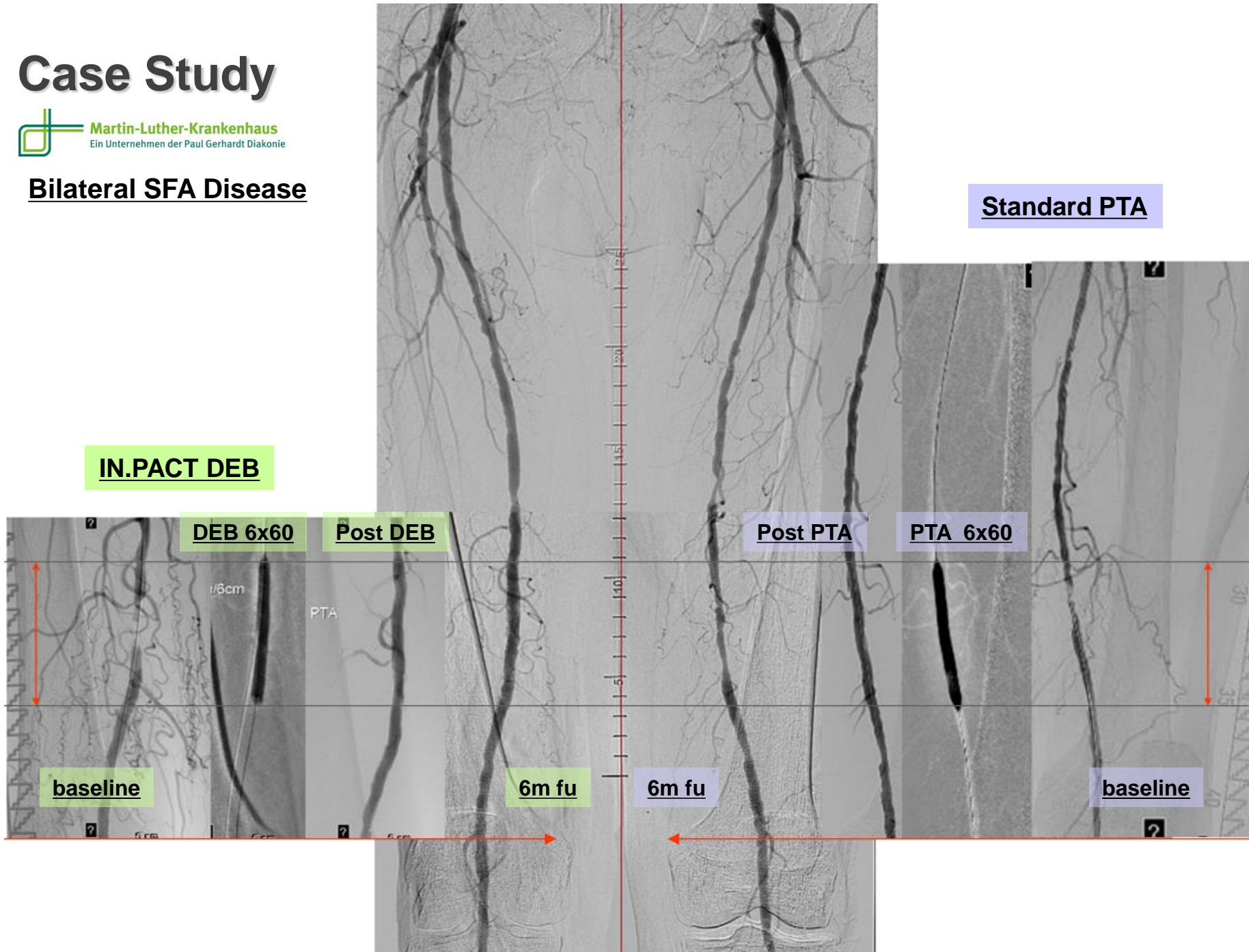
**Korea University Guro Hospital, Seoul, Korea**

# Contents

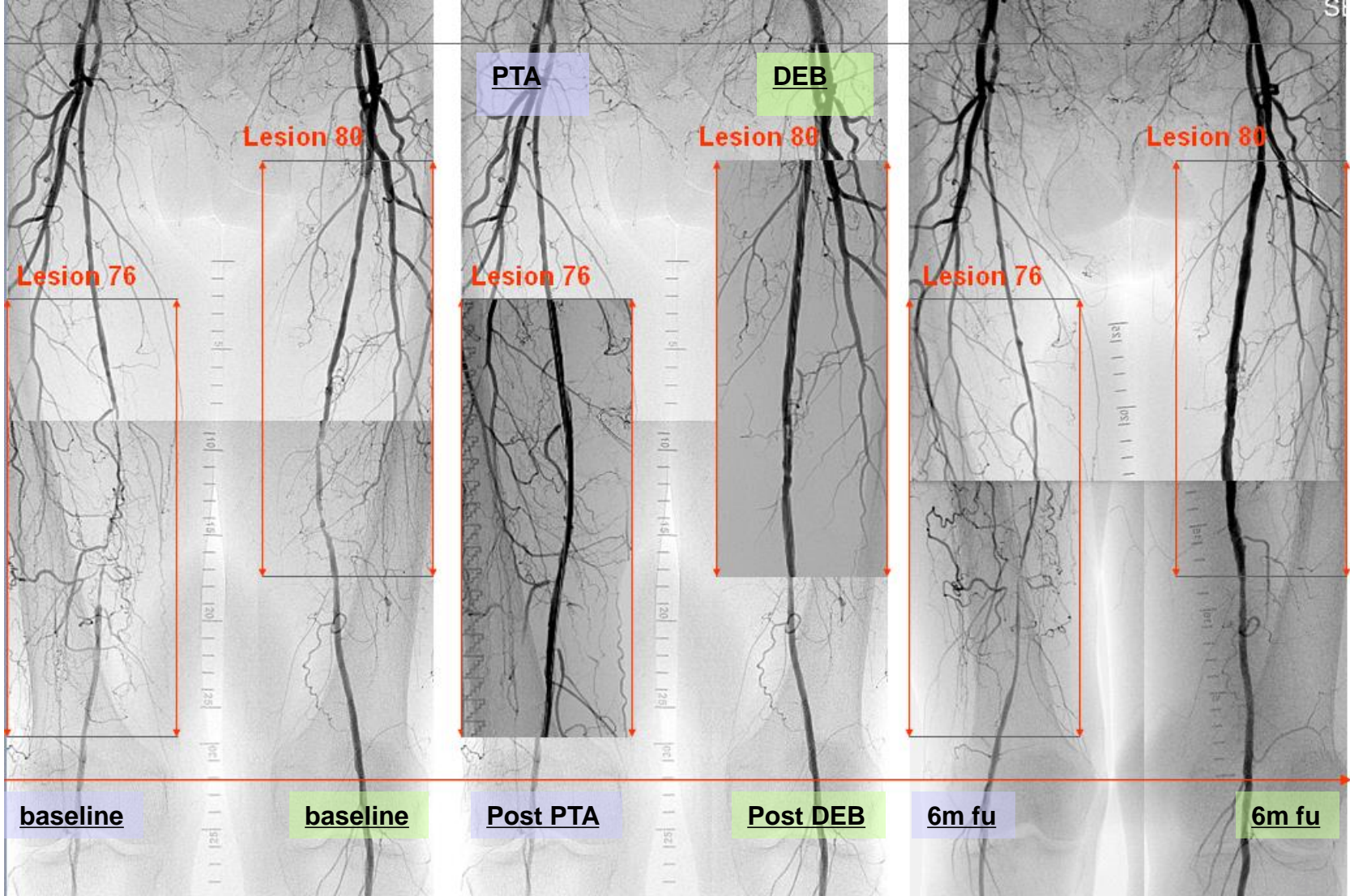
1. INPact DCB (Medtronic)
2. Lutonix DCB (Bard)
3. Passeo 18 Lux DCB (Biotronic)
4. Ranger DCB (Boston)-Pending

# Case Study

## Bilateral SFA Disease



# Case Study Bilateral SFA Disease



# Drug-coated balloons offer physicians an attractive value proposition for the treatment of lower limb disease

- Encouraging results have been seen in de novo, restenotic lesions, in-stent restenosis and in A-V access stenosis
- Some logical indications might include:
  - “no-stent” zones e.g. CFA lesions
  - segments prone to restenosis e.g. long AK lesions

## Benefits

- Anti-proliferative therapy while leaving nothing behind
- Broad anatomical applicability
- Easily repeatable
- Avoid stent fracture and ISR burden
- Preserve future options
- Matches patient’s quality of life expectations (improvement in walking capacity, Rutherford class)

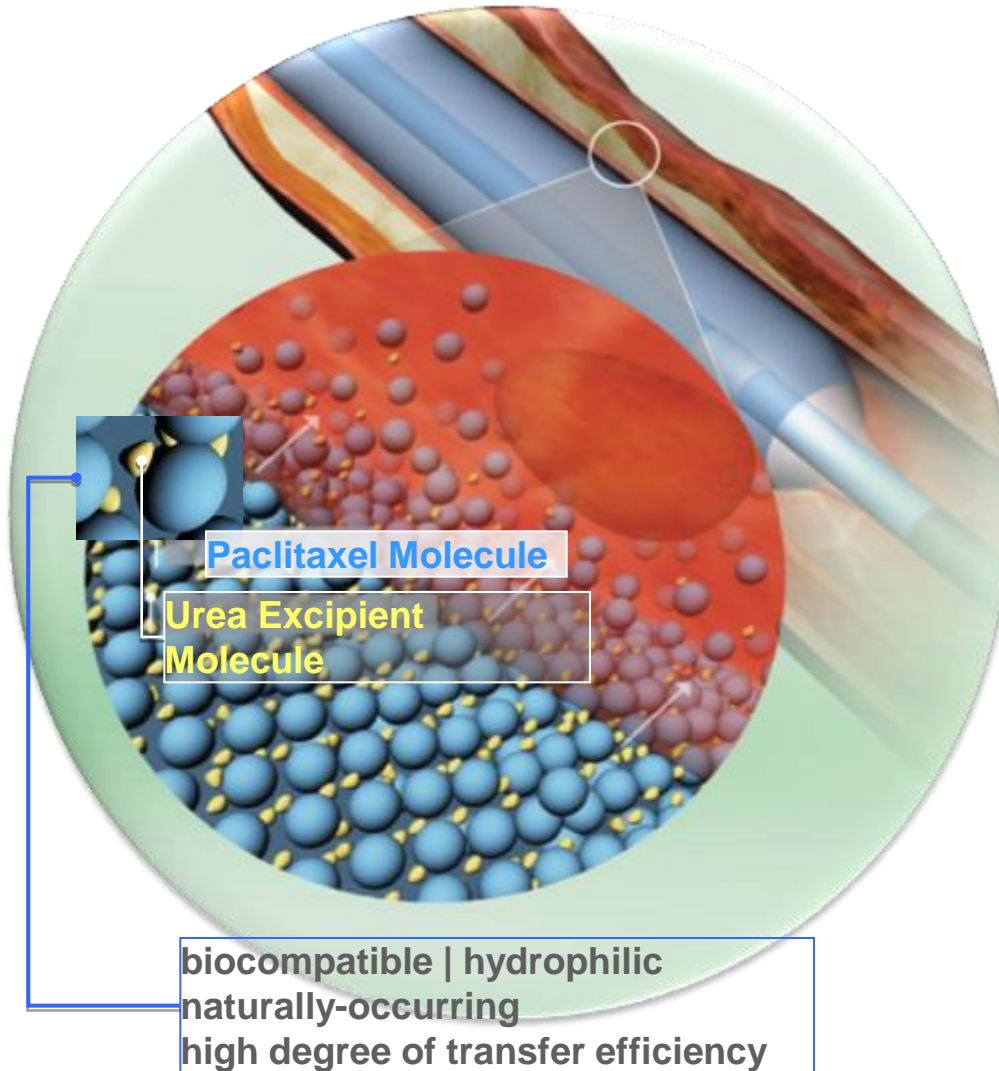
## Limitations

- Not proven in highly calcified lesions
- When provisional stent is required = higher procedural cost





# IN.PACT™ DEB with FreePac™ Coating Technology



## IN.PACT™

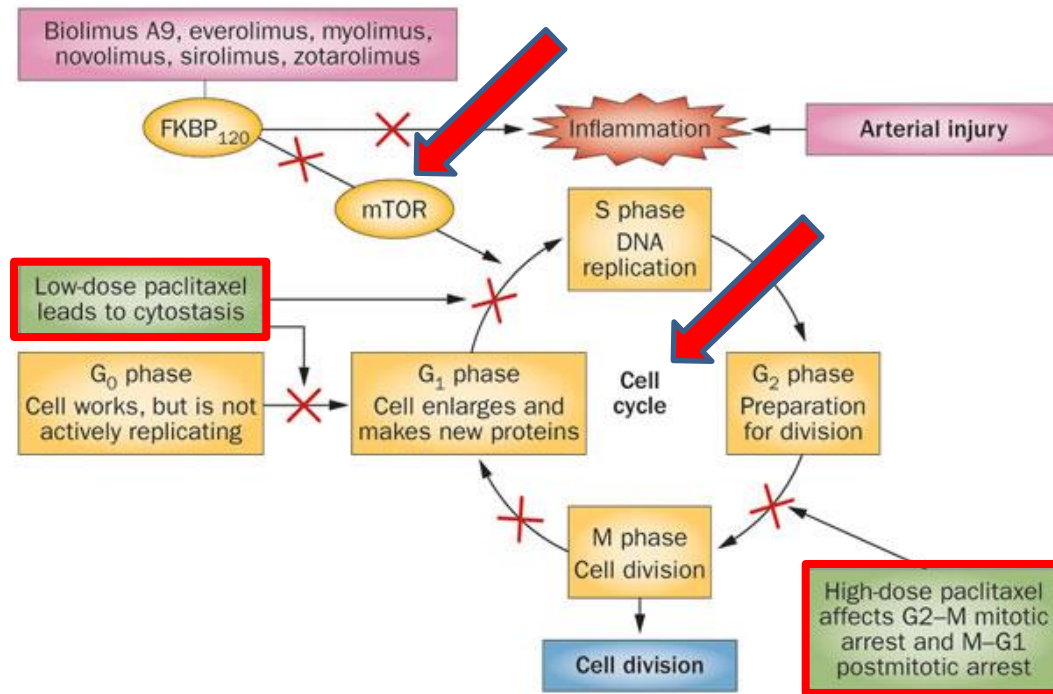
- Medtronic-Invatec DEB balloon line

## FreePac™

- Proprietary hydrophilic coating formulation
  - Urea separates Paclitaxel molecules
  - Increased drug solubility and optimal diffusion into vessel wall
  - Urea facilitates Paclitaxel absorption into the vessel wall

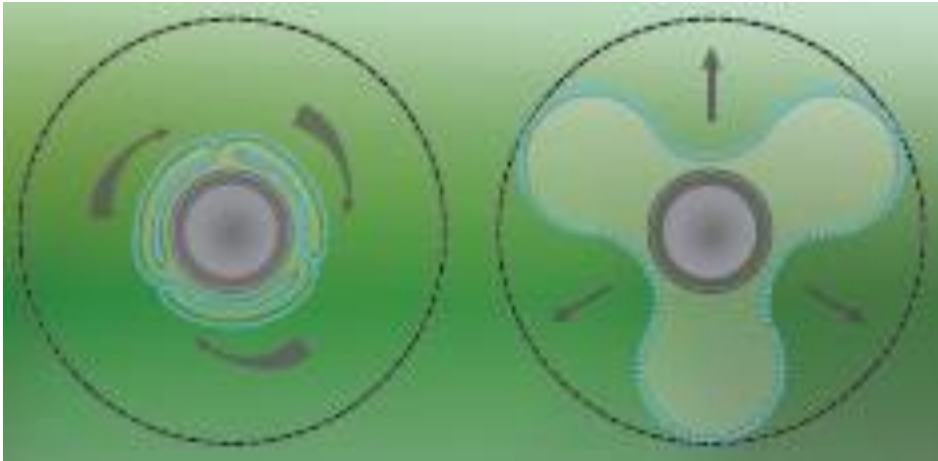
# Paclitaxel blocks the cell cycle directly

## Mode of action for Paclitaxel and Limus drugs

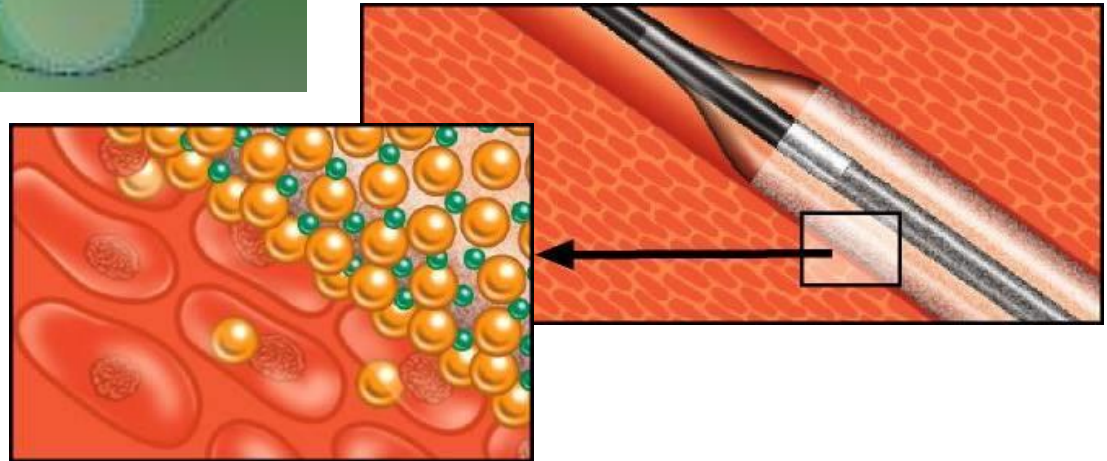
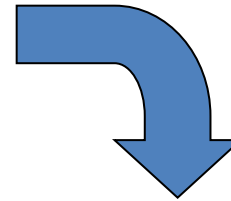


- Paclitaxel inhibits the cell cycle directly vs. limus drugs which act indirectly
- DCBs aim for a high-dose effect of paclitaxel, causing cell's mitotic arrest
- A low-dose effect is expected to sustain antiproliferation long term

# DEB Drug Transfer



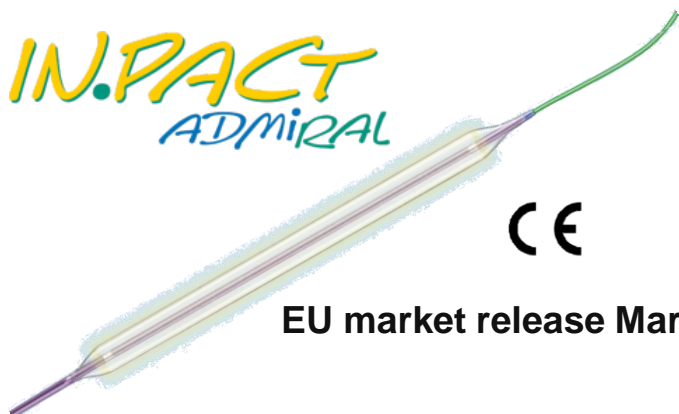
As the balloon unwraps, the drug-excipient coating is fully exposed to the vessel wall.



Paclitaxel's hydrophobicity along with the increased solubility conferred by the excipient allows for rapid drug transfer across the vessel wall.



# Device Description



EU market release March 2009

*Catheter design* Over the wire (OTW)

*Diameters* 4, 5, 6, 7 mm

*Lengths* 40, 60, 80, 120 mm

*Max recommended Guide wire* 0.035"

*Usable shaft length* 80 & 130 cm

*Balloon material* FLEXITEC™ Xtreme

*Coating* FreePac™

*Shaft diameter* 5F

*Introducer sheath compatibility* 5F - 6F

*Nominal pressure* 8 bar

*RBP* up to 18 bar

| REF No.<br>(shaft length 80 cm) | REF No.<br>(shaft length 130 cm) | Balloon<br>Diameter<br>(mm) | Balloon<br>Length<br>(mm) | Recom.<br>Introducer<br>sheath (F) | RBP |
|---------------------------------|----------------------------------|-----------------------------|---------------------------|------------------------------------|-----|
| SBI 040 040 08P                 | SBI 040 040 13P                  | 4                           | 40                        | 5                                  | 18  |
| SBI 040 060 08P                 | SBI 040 060 13P                  | 4                           | 60                        | 5                                  | 18  |
| SBI 040 080 08P                 | SBI 040 080 13P                  | 4                           | 80                        | 5                                  | 18  |
| SBI 040 120 08P                 | SBI 040 120 13P                  | 4                           | 120                       | 5                                  | 18  |
| SBI 050 040 08P                 | SBI 050 040 13P                  | 5                           | 40                        | 6                                  | 17  |
| SBI 050 060 08P                 | SBI 050 060 13P                  | 5                           | 60                        | 6                                  | 17  |
| SBI 050 080 08P                 | SBI 050 080 13P                  | 5                           | 80                        | 6                                  | 15  |
| SBI 050 120 08P                 | SBI 050 120 13P                  | 5                           | 120                       | 6                                  | 15  |
| SBI 060 040 08P                 | SBI 060 040 13P                  | 6                           | 40                        | 6                                  | 17  |
| SBI 060 060 08P                 | SBI 060 060 13P                  | 6                           | 60                        | 6                                  | 17  |
| SBI 060 080 08P                 | SBI 060 080 13P                  | 6                           | 80                        | 6                                  | 15  |
| SBI 060 120 08P                 | SBI 060 120 13P                  | 6                           | 120                       | 6                                  | 15  |
| SBI 070 040 08P                 | SBI 070 040 13P                  | 7                           | 40                        | 6                                  | 16  |
| SBI 070 060 08P                 | SBI 070 060 13P                  | 7                           | 60                        | 6                                  | 14  |
| SBI 070 080 08P                 | SBI 070 080 13P                  | 7                           | 80                        | 6                                  | 14  |



# LUTONIX<sup>®</sup> 035

Drug Coated Balloon PTA Catheter

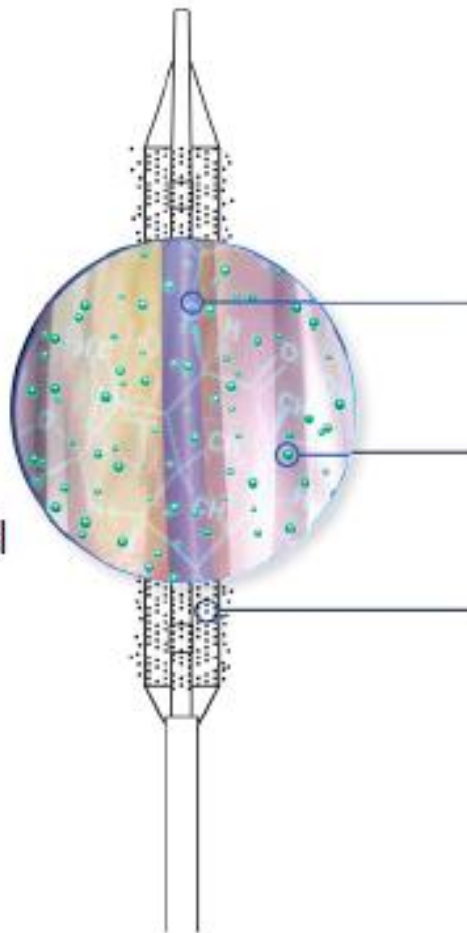
A STEP AHEAD IN SFA TREATMENT

# LUTONIX<sup>®</sup> 035 Formulation



LUTONIX<sup>®</sup> 035 has an optimized formulation designed to maximize efficacy without compromising safety

LUTONIX<sup>®</sup> 035's effective 2  $\mu\text{g}/\text{mm}^2$  dose of paclitaxel reduces exposure of the drug, but provides a therapeutic effect to achieve patency of the target vessel



## Drug + Carrier = Coating

### Drug

LUTONIX<sup>®</sup> 035 drug dose of Paclitaxel is 2 $\mu\text{g}/\text{mm}^2$

### Carrier

Polysorbate and Sorbitol

### Coating

Facilitates therapeutic drug retention and release of drug at the treatment site

# LUTONIX<sup>®</sup> 035 Design: Coating Integrity

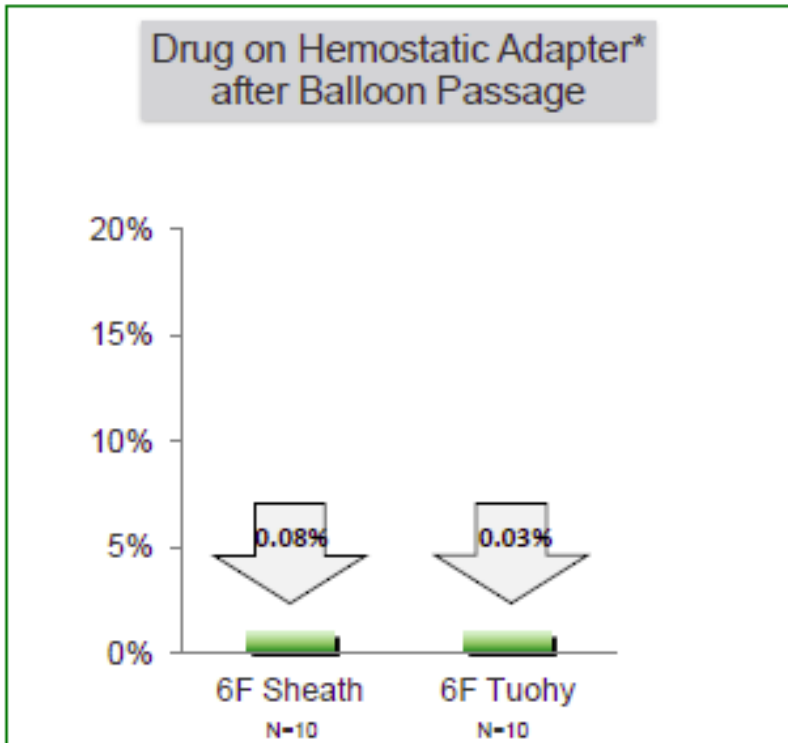
## Sheath/Tuohy Passage Test



Limit drug flaking during balloon preparation and handling \*

Potentially minimizing unnecessary drug exposure to staff and patients\*

LUTONIX<sup>®</sup> 035 has a durable coating, with  $\leq 0.08\%$  drug dose lost within the introducer sheath during insertion.\*



**Durability** of coating preserved through sheath value or tuohy insertion

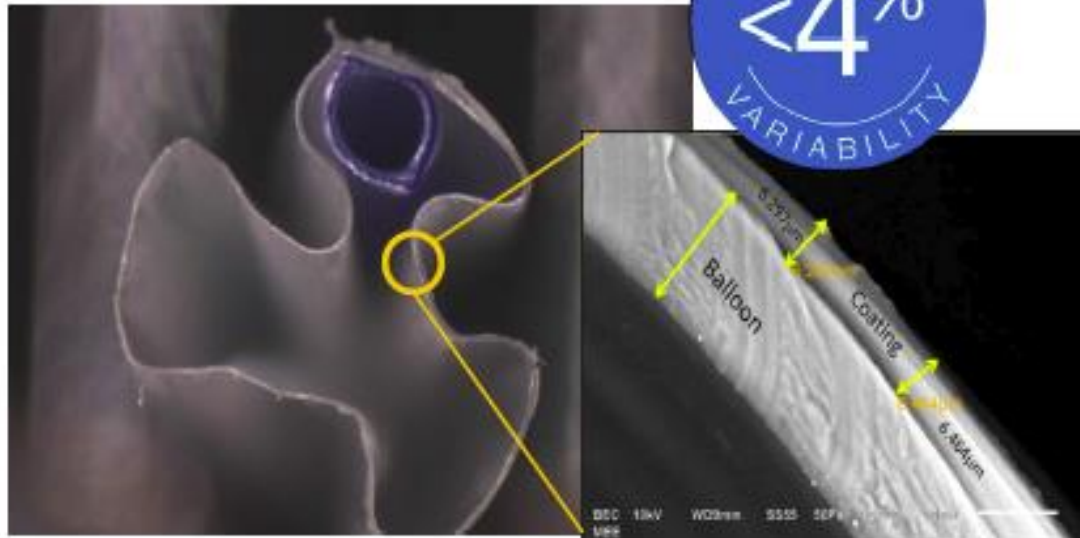
\*Bench test data on file. Bench results may not be indicative of clinical performance. Different test methods may yield different results.



# Coating Uniformity

## Coating Variability Analysis

DRUG DOSE  
**<4%**  
VARIABILITY



### Coating Uniformity Analysis\*

|                                  |        |
|----------------------------------|--------|
| Segment-to-Segment Variability   | ± 4.0% |
| Longitudinal Segment Variability | ± 2.7% |

**LUTONIX® 035 is uniformly coated while inflated allowing for 360° paclitaxel coverage to the target vessel.\***

\*Bench test and pre-clinical animal study data on file. Bench results and pre-clinical data may not be indicative of clinical performance. Different test methods may yield different results.



# Durability Matters: Drug Loss During Dry Inflate Shake Test

**LUTONIX® 035**  
Drug Coated Balloon PTA Catheter



0.05% Drug Loss

**In.Pact™**  
Drug Eluting Balloon



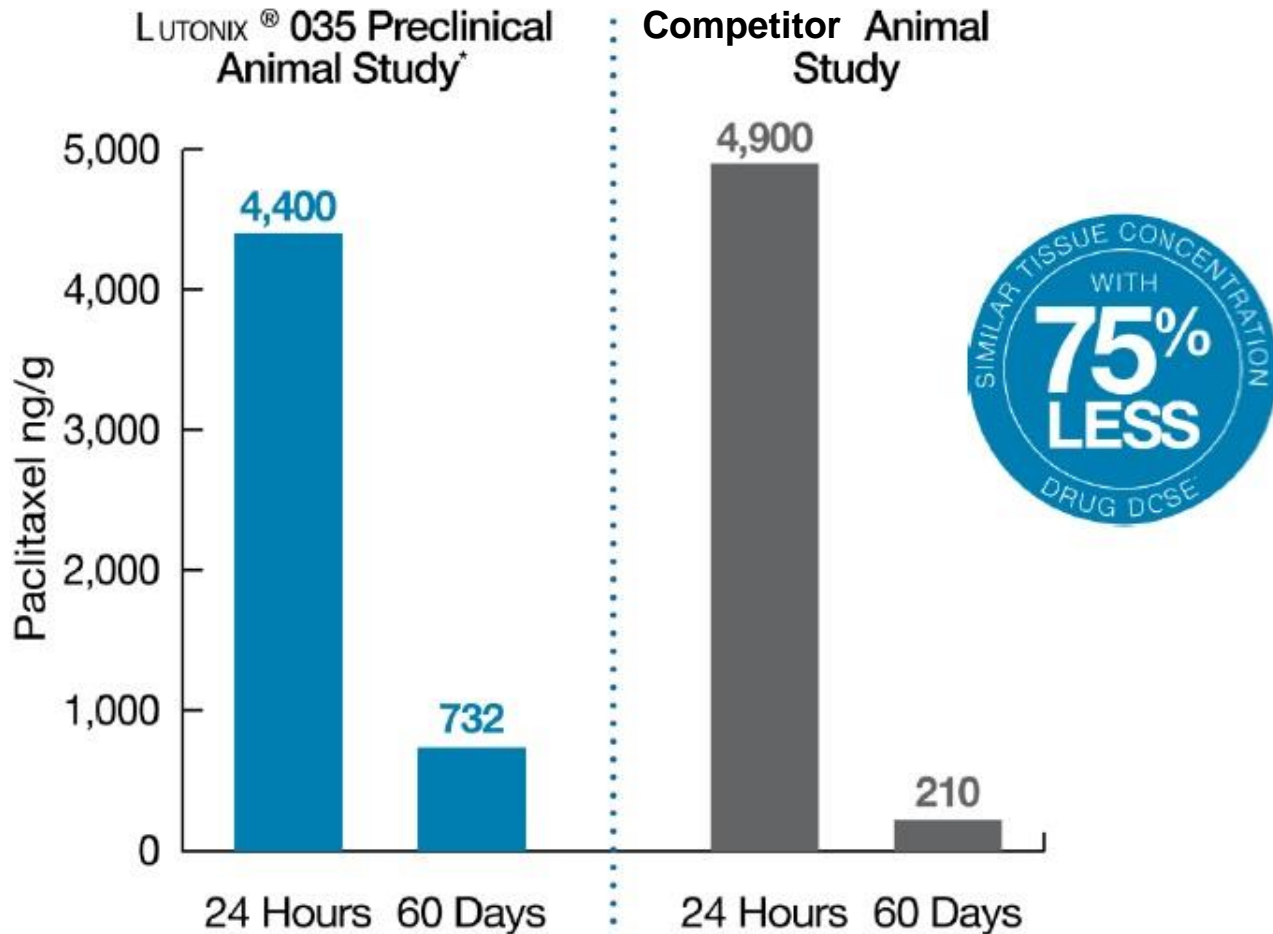
10.61% Drug Loss

LUTONIX® 035 balance of 2.0  $\mu\text{g}/\text{mm}^2$  of paclitaxel and carriers polysorbate and sorbitol, minimizes unwanted drug loss

\*Dry Inflate/Shake Bench Test data on file, Bard Peripheral Vascular, Tempe, AZ. Dry Inflate/Shake test measured the average drug content lost after balloon was inflated, and after lightly knocking each device against the sides of the centrifuge tube, left and right, five times. n=5 for both devices tested. Bench test results may not be indicative of clinical performance. Different test methods may yield different results.

# DCB Tissue Concentration

## Rapid Uptake with Sustained Therapeutic Dose of Paclitaxel Arterial Tissue Concentration



# Product Offering

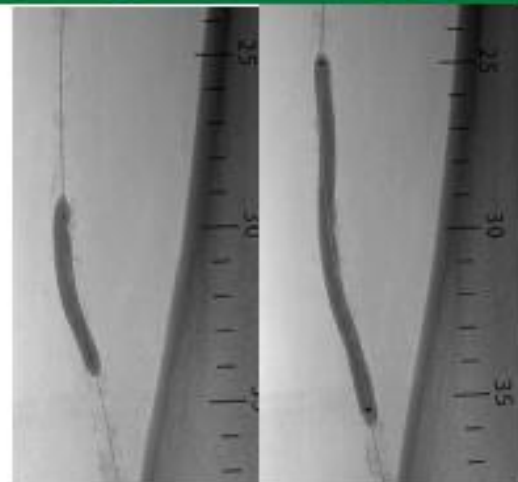
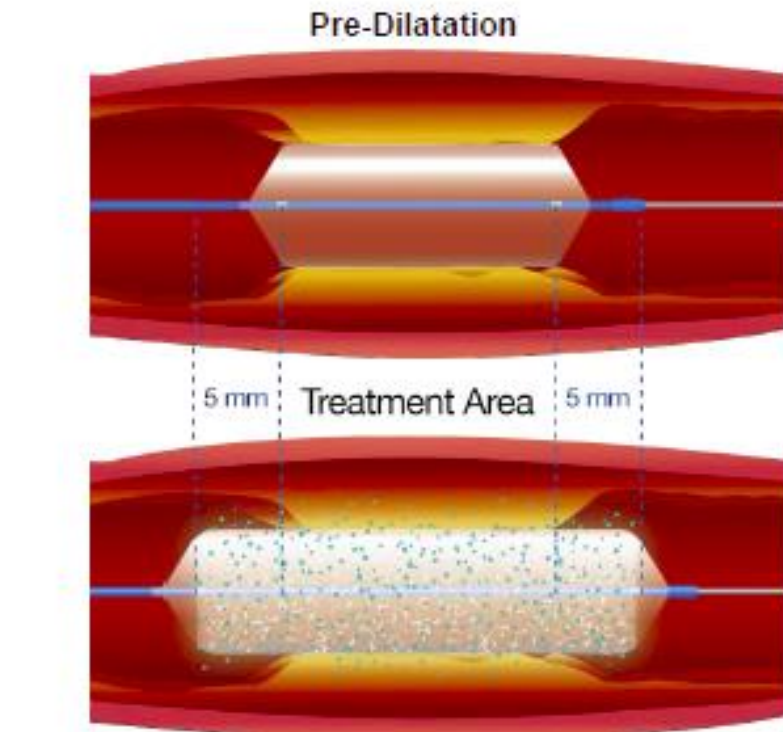


- 035 Guidewire Compatible, Nylon, Semi-compliant Balloon
- Over the wire, Co-axial shaft
- 2 Radiopaque platinum: 1mm markers delineate balloon length
- Balloon protector sleeve and stylet in place

| Dia. (mm) | Balloon Lengths (mm) |    |    |     |     |     | Nominal (atm) | RBP (atm) | Sheath Profile |
|-----------|----------------------|----|----|-----|-----|-----|---------------|-----------|----------------|
| 4         | 40                   | 60 | 80 | 100 | 120 | 150 | 6             | 12        | 5 Fr           |
| 5         | 40                   | 60 | 80 | 100 | 120 | 150 | 6             | 12        | 5 Fr           |
| 6         | 40                   | 60 | 80 | 100 | 120 | 150 | 7             | 12        | 6 Fr           |

# Pre-Dilatation

- Adequately pre-dilate to at least 1 mm of the reference vessel diameter
- After pre-dilation, LUTONIX® 035 should extend approximately 5 mm proximally and distally beyond the pre-dilatation injury segment
- Use of a radiopaque ruler or vascular tape is recommended to ensure appropriate placement of the LUTONIX® 035



Pre-dilatation

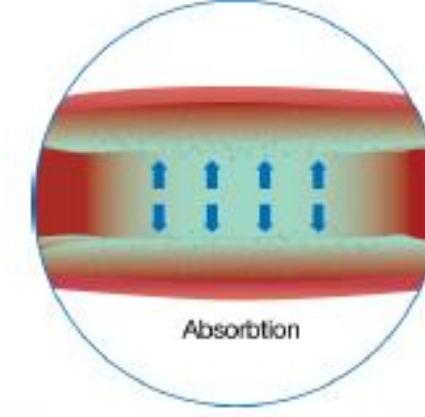
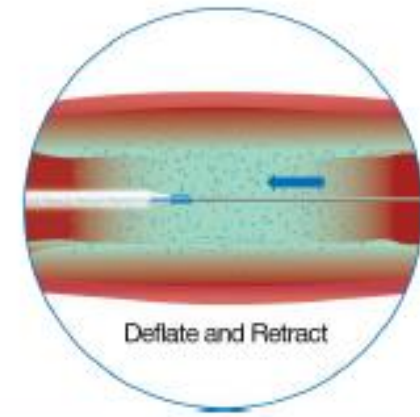
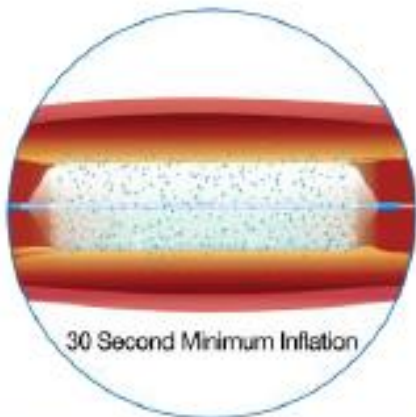
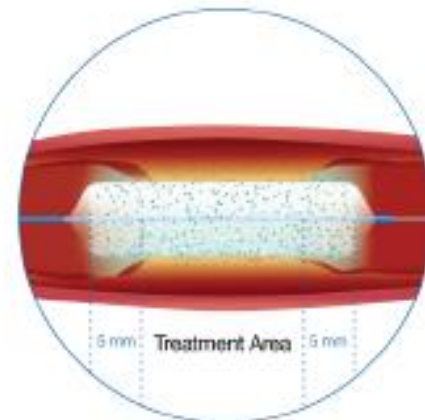
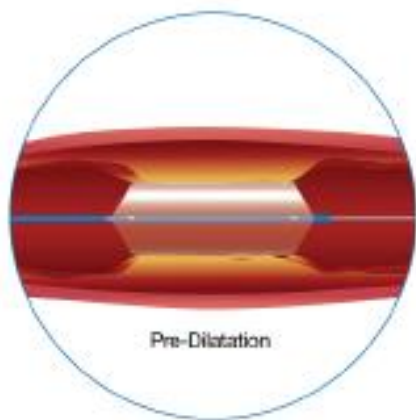
Treatment with  
LUTONIX® 035



# Procedure Summary

## Key Procedure Goals

1. Complete dilation of the diseased segment to reference vessel diameter
2. Complete coverage of treatment area with drug (DCB)






# Passeo-18 Lux

Vascular Intervention // Peripheral


## Passeo-18 Lux


Drug-Coated Balloon/0.018"/OTW  
Indicated for lower limb arteries

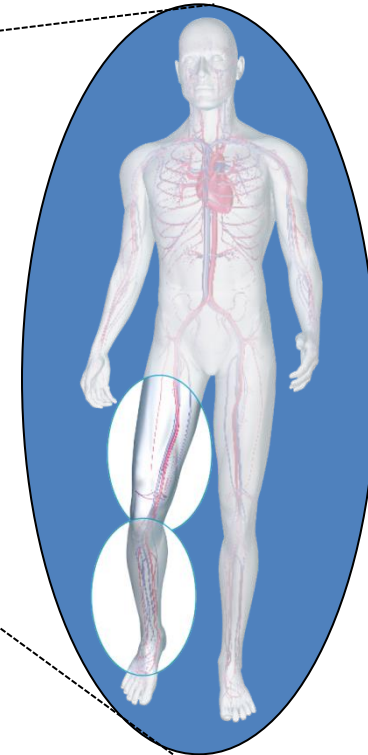


- Clinically proven to reduce restenosis and the need for reinterventions<sup>1</sup>
- Lux coating technology optimizes drug transfer for maximized efficacy
- Low profile, highly deliverable Passeo-18 balloon platform
- Innovative SafeGuard insertion aid for unrivaled safety and ease of handling

<sup>1</sup> BOLDUX P-I and BOLDUX P-II Randomized Clinical Trials

 **4F** Solutions

 **BIOTRONIK**  
excellence for life



## Indications

The Passeo-18 Lux catheter is indicated to dilate de novo or restenotic lesions in the infrainguinal arteries.

# Passeo-18 Lux – Device Specifications

## Balloon Catheter

|                            |   |
|----------------------------|---|
| Catheter type              | OTW   |
| Recommended guide wire     | 0.018"  |
| Tip                        | Short, tapered  |
| Balloon markers            | 2 swaged markers (zero profile)                               |
| Shaft                      | 3.8F, hydrophobic coated                                      |
| Usable length              | 90 and 130 (150*) cm  |
| Introducer size            | 4F (ø 2.0, 2.5, 3.0, 4.0 mm); 5F (ø 5.0, 6.0, 7.0 mm)         |
| Nominal Pressure (NP)      | 6 atm   |
| Rated Burst Pressure (RBP) | 15 atm (ø 2.0, 2.5, 3.0, 4.0, 5.0 mm); 12 atm (ø 6.0, 7.0 mm) |

## Coating

|                 |   |
|-----------------|---|
| Drug            | Paclitaxel  |
| Drug dose       | 3.0 µg/mm <sup>2</sup>  |
| Delivery matrix | Paclitaxel and butyryl-tri-hexyl citrate (BTHC)                                       |
| Coated area     | Cylindrical section of the balloon, exceeding the proximal and distal balloon markers |

\*Passeo-18 Lux diameter 2 mm

# Passeo-18 Lux – Ordering Information

## Compliance and Compatibility charts

| Balloon<br>Diameter x Length [mm] |            |              |            |            |            |            |            |
|-----------------------------------|------------|--------------|------------|------------|------------|------------|------------|
|                                   | 2 x 40-120 | 2.5 x 40-120 | 3 x 40-120 | 4 x 40-120 | 5 x 40-120 | 6 x 40-120 | 7 x 40-120 |
| NP (atm)                          | 6          | 6            | 6          | 6          | 6          | 6          | 6          |
| ∅ [mm]                            | 2.0        | 2.5          | 3.0        | 4.0        | 5.0        | 6.0        | 7.0        |
| RBP (atm)                         | 15         | 15           | 15         | 15         | 15         | 12         | 12         |
| ∅ [mm]                            | 2.1        | 2.6          | 3.3        | 4.3        | 5.2        | 6.3        | 7.2        |

| Catheter<br>Length [cm] | Balloon<br>Diameter [mm] | Balloon<br>Length [cm] |        |        |
|-------------------------|--------------------------|------------------------|--------|--------|
|                         |                          | 40                     | 80     | 120    |
| 90                      | 2.0                      | 379860                 | 379861 | 379862 |
|                         | 2.5                      | 379866                 | 379867 | 379868 |
|                         | 3.0                      | 370843                 | 370848 | 370853 |
|                         | 4.0                      | 370844                 | 370849 | 370854 |
|                         | 5.0                      | 370845                 | 370850 | 370855 |
| 90                      | 6.0                      | 370846                 | 370851 | 370856 |
|                         | 7.0                      | 370847                 | 370852 | 370857 |
|                         | 2.0                      | 379863                 | 379864 | 379865 |
| 130                     | 2.5                      | 379869                 | 379870 | 379871 |
|                         | 3.0                      | 370858                 | 370863 | 370868 |
|                         | 4.0                      | 370859                 | 370864 | 370869 |
|                         | 5.0                      | 370860                 | 370865 | 370870 |
| 130                     | 6.0                      | 370861                 | 370866 | 370871 |
|                         | 7.0                      | 370862                 | 370867 | 370872 |

4F

5F

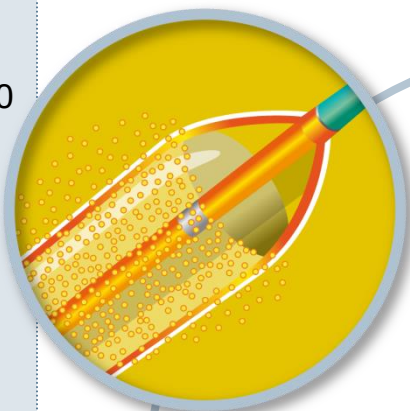
4F

5F

# Passeo-18 Lux combines proven technologies for treating lower limb arteries

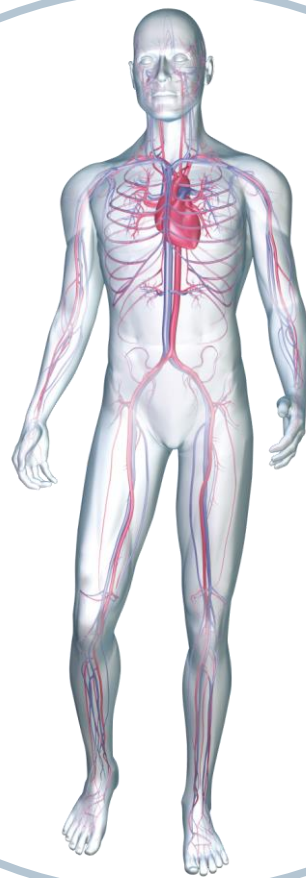
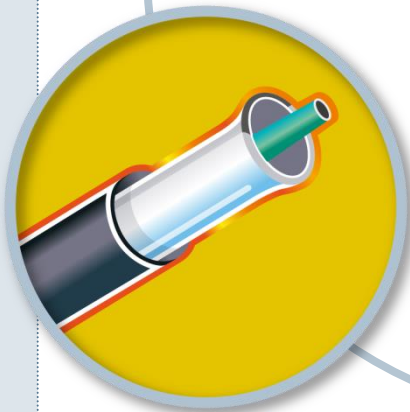
## Coating Technology

- Drug: paclitaxel (3.0  $\mu\text{g}/\text{mm}^2$ )
- Excipient: butyryl-tri-hexyl citrate (BTHC)
- Process: Micro-pipetting



## SafeGuard Insertion Aid

- Improves ease of handling
- Protects the user and balloon from contact and damage

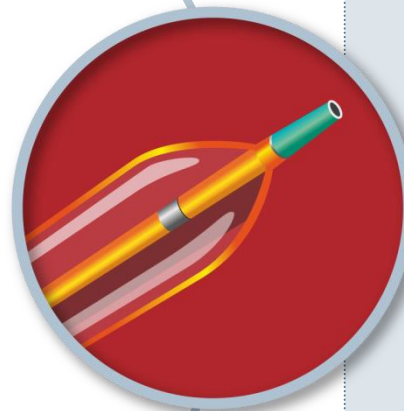


## Balloon Platform

Passeo-18  
Balloon  
Catheter

Ø (mm): 2.0,  
2.5, 3.0, 4.0,  
5.0, 6.0, 7.0

L (mm): 40,  
80, 120



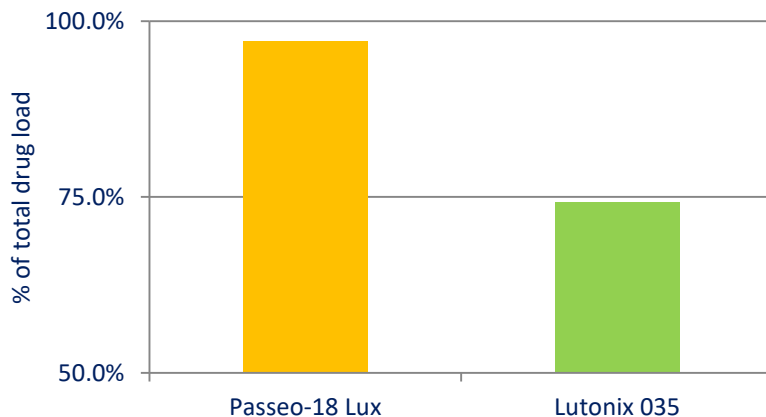
# BTHC improves coating integrity and durability

| Device        | Excipient                        | Type                        | Solubility*     |
|---------------|----------------------------------|-----------------------------|-----------------|
| Passeo-18 Lux | Butyryl-tri-hexyl citrate (BTHC) | Hydrophobic                 | Very low        |
| Lutonix       | Polysorbate/sorbitol             | Hydrophilic/<br>hydrophobic | Fast dissolving |
| In.Pact       | Urea                             | Hydrophilic                 | Fast dissolving |

- Coating characteristics are modified when surface is wettened
- **Hydrophilic excipients** are more soluble and **dissolve faster**
- **Hydrophobic excipients can improve coating integrity** ensuring more drug is available at the lesion site

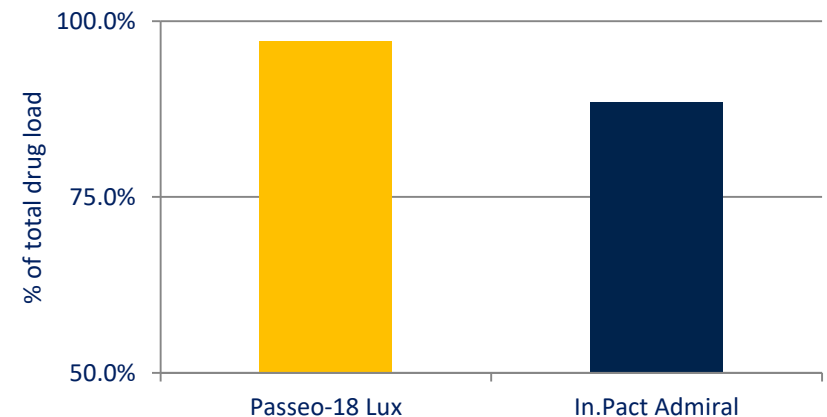
## Coating Integrity\*

After submerging and deployment of a 5x40mm balloon in physiological solution at 37° C



## Coating Integrity\*

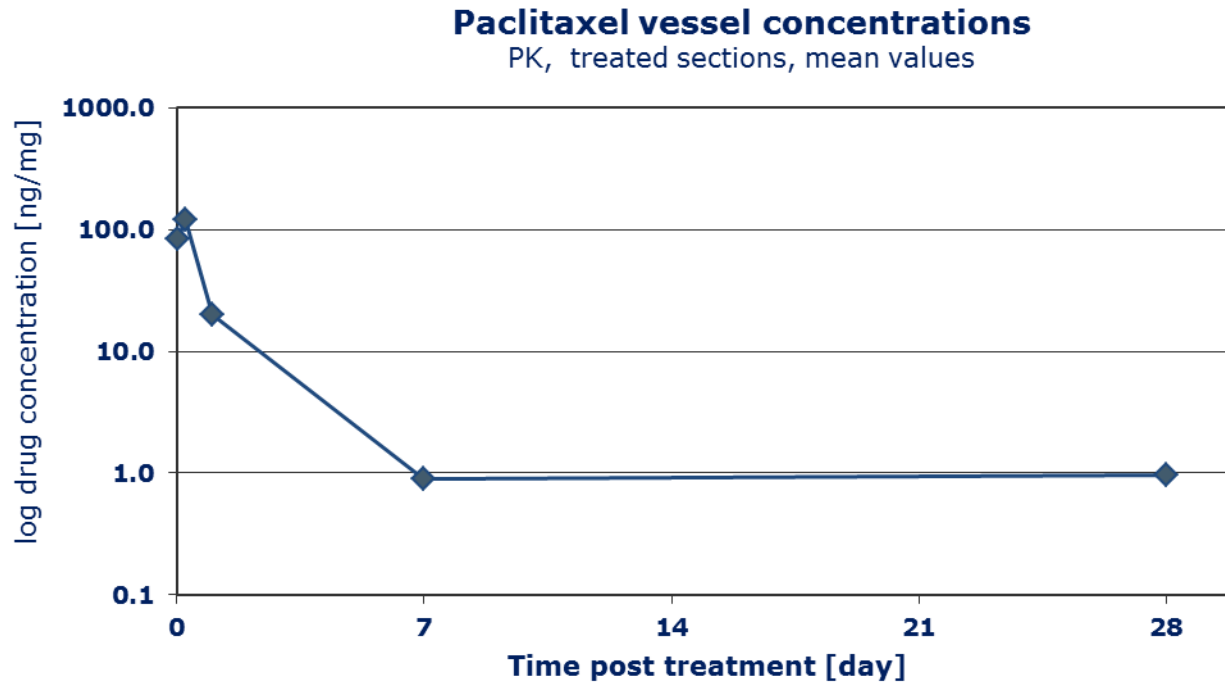
After submerging and deployment of a 5x40mm balloon in physiological solution at 37° C



\*In water  
Data on file at BIOTRONIK (IIB Test)



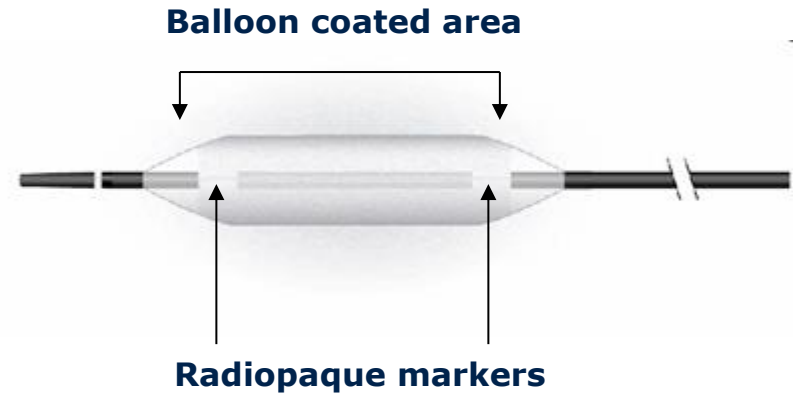
# Passeo-18 Lux delivers sufficient drug to give long lasting therapeutic effect



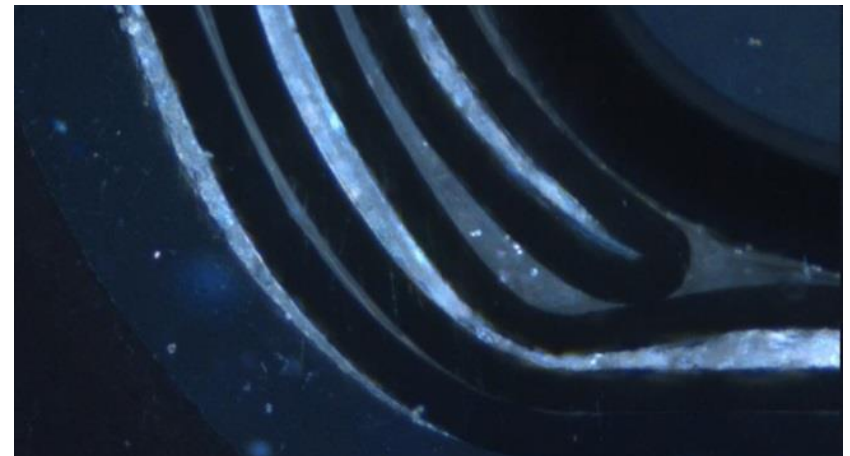
- A high tissue concentration is achieved after balloon inflation
- Drug concentration rapidly declines within 7 days
- Therapeutic effect is sustained at 28 days
- Prolonged presence of drug in vessel tissue is important for clinical efficacy

# Lux coating technology coating process

- The Lux coating extends from the cylindrical portion of the balloon and onto the shoulders of the balloon
- Coating extends outside the margins of the markers
- This ensures proper delivery of the drug to the entire region that is contacted by the balloon during inflation, minimizing the risk of 'geographic miss'

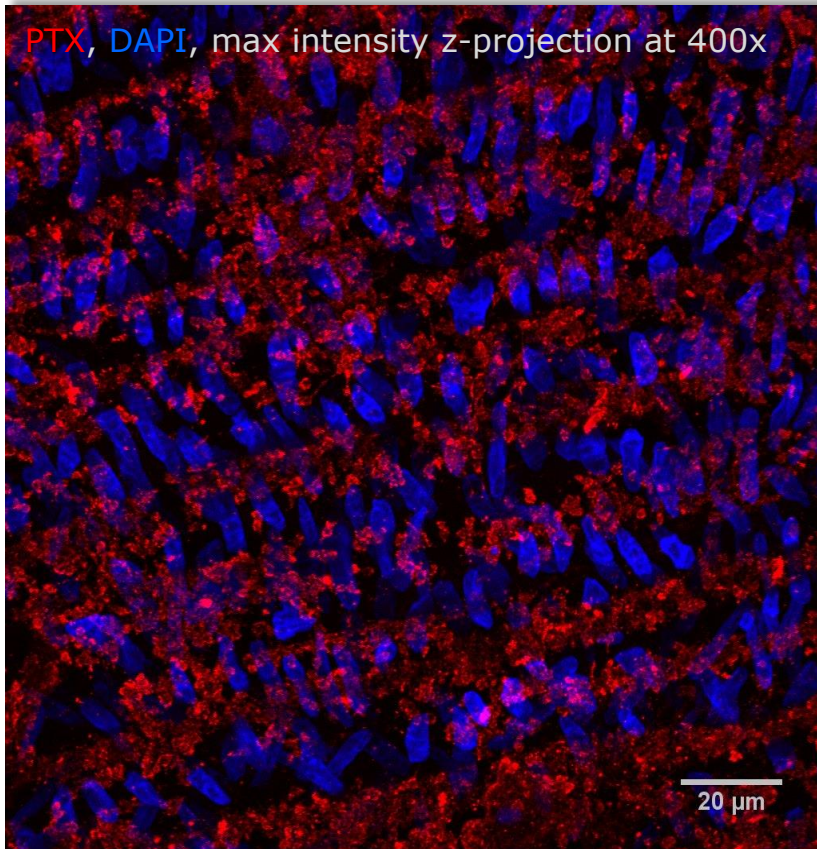


- Passeo-18 is 'Lux' coated while the balloon is folded to reduce overall balloon profile
- Microscopy provides evidence of Lux coating on the outer surface of the balloon and within the balloon folds
- With this coating process, drug is sheltered within the balloon folds



# Lux coating technology achieves uniform drug distribution to the vessel wall

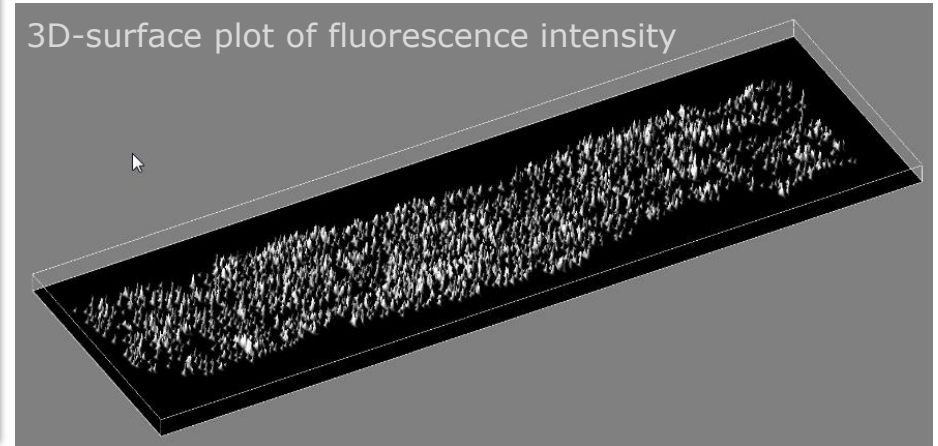
Drug distribution in target arterial tissue in rabbit iliac model



Whole sample scan of fluorescently labeled paclitaxel in a rabbit iliac artery



3D-surface plot of fluorescence intensity



# **Ranger™ Drug Coated Balloon**

# Product Overview

Ranger DCB is designed to provide consistent and predictable drug delivery



## PROVEN

Clinically proven in both randomized & and real-world trials, the Ranger SFA-Trial has achieved among the highest freedom from TLR rate of 94.4% at 6 months



## TRANSPAX™ Coating Technology

Proprietary TransPax coating is designed for optimal drug transfer minimizing risk for particulate loss downstream



## PLATFORM

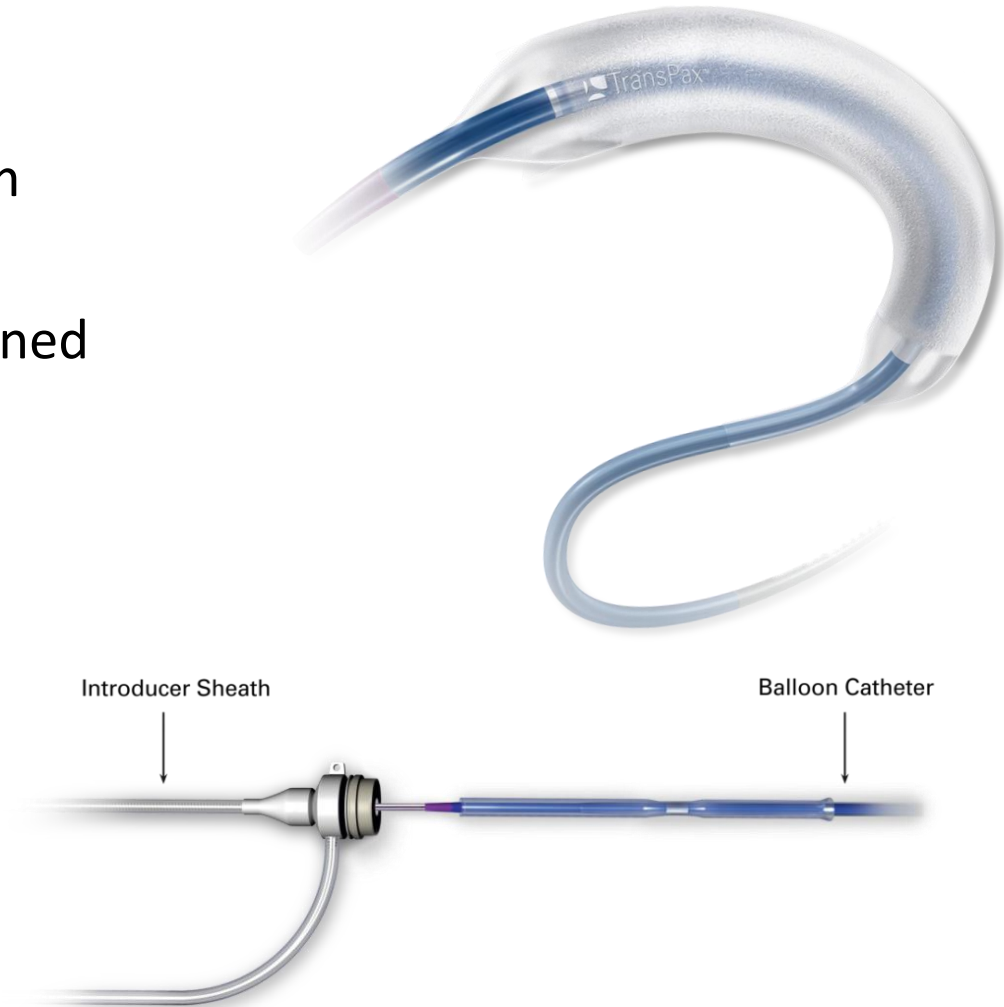
Loading tool and proven Sterling balloon contribute to coating integrity, deliverability and ease of use



# Next Generation Drug Coated Balloon

Boston Scientific Ranger™ DCB

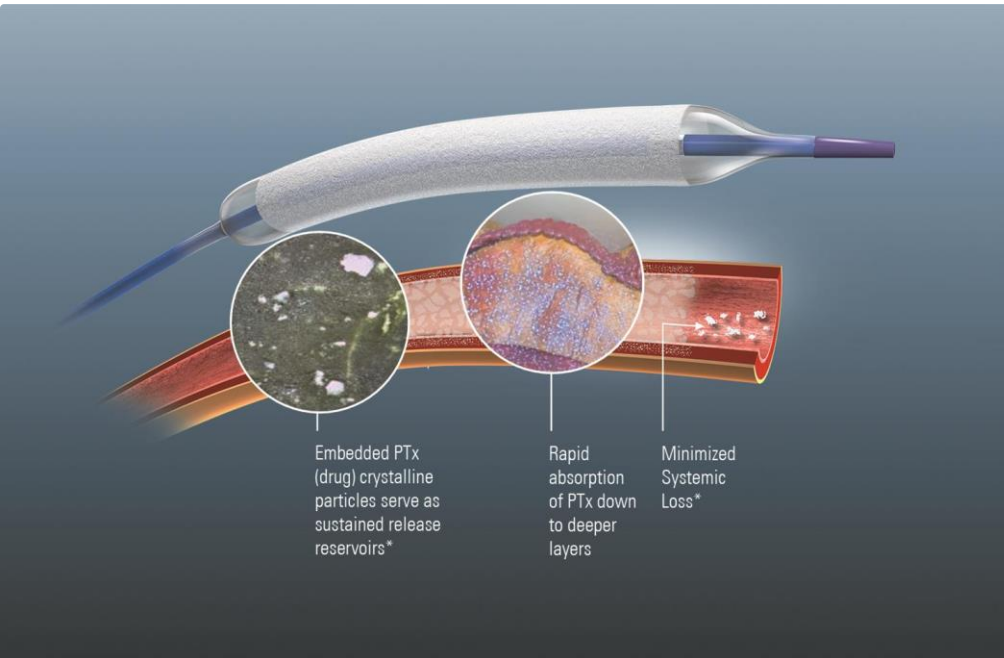
- Device CE-marked July 2014
  - Sterling 0.018" balloon platform
  - TransPax™ coating technology
  - Ranger™ DCB loading tool designed to protect the drug coating
- 
- Size matrix:
    - SFA: 4-8 mm; 30-100 mm
    - BTK: 2-4 mm; up to 150 mm



# Ranger™ DCB Coating Technology

## TransPax™ Technology

Paclitaxel, Excipient: Citrate ester (acetyl tributyl citrate – ATBC)

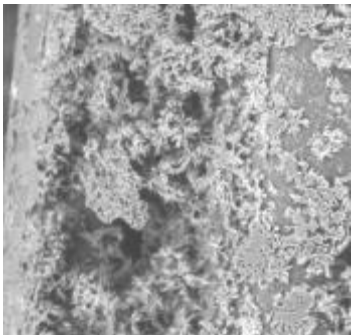


Designed to:

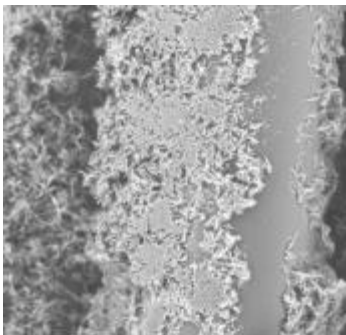
- Balance hydrophilic and hydrophobic properties
- Allow adhesion to the balloon during tracking and deployment
- Allow transfer to the vessel wall during balloon inflation
- Minimize particulate loss

# Coating Integrity: Adherence During Hydration

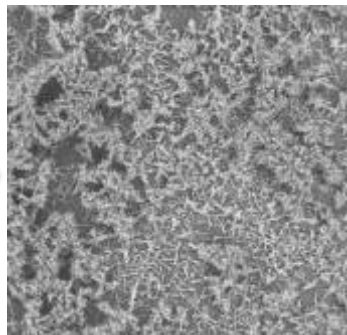
**TransPax™  
Coating**



**T = 0 min**



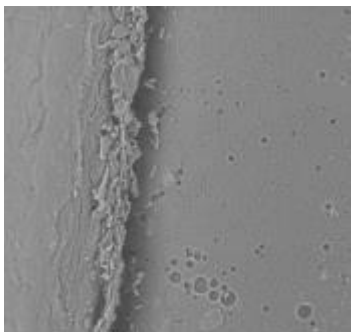
**3 min**



**10 min**

**TransPax coating  
remained adhered  
to the balloon  
during hydration**

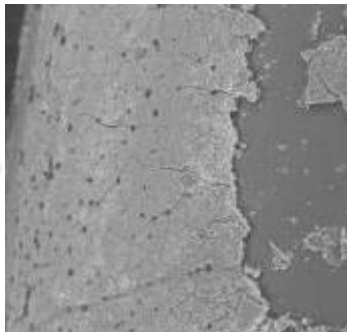
**IN.PACT™  
Coating**



**T = 0 min**



**3 min**

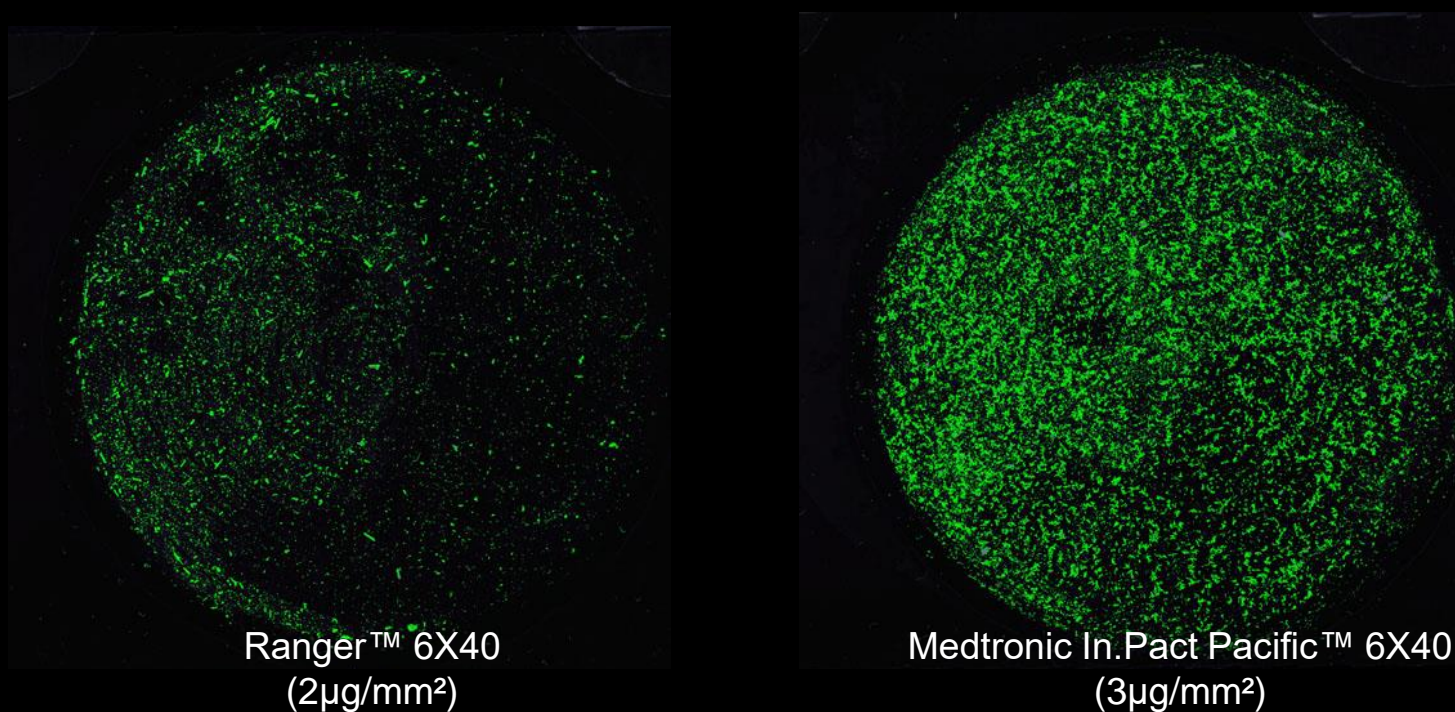


**10 min**

**IN.PACT coating  
started to crack  
and flake off after  
a few minutes of  
hydration**

DCBs were submerged in phosphate buffered saline at 37°C and the coating was imaged at 300X.  
Data on file – Boston Scientific. Bench test results are not necessarily indicative of clinical performance.

# Coating Integrity








- DCBs were delivered in a peripheral track model with fluid recirculation
- Particulates lost downstream were collected with a 5 µm polycarbonate filter and are shown as green dots

Fluid recirculation ~320 ml/min  
Fluid temp 37°C

# Peripheral Drug-Coated Balloon Sector

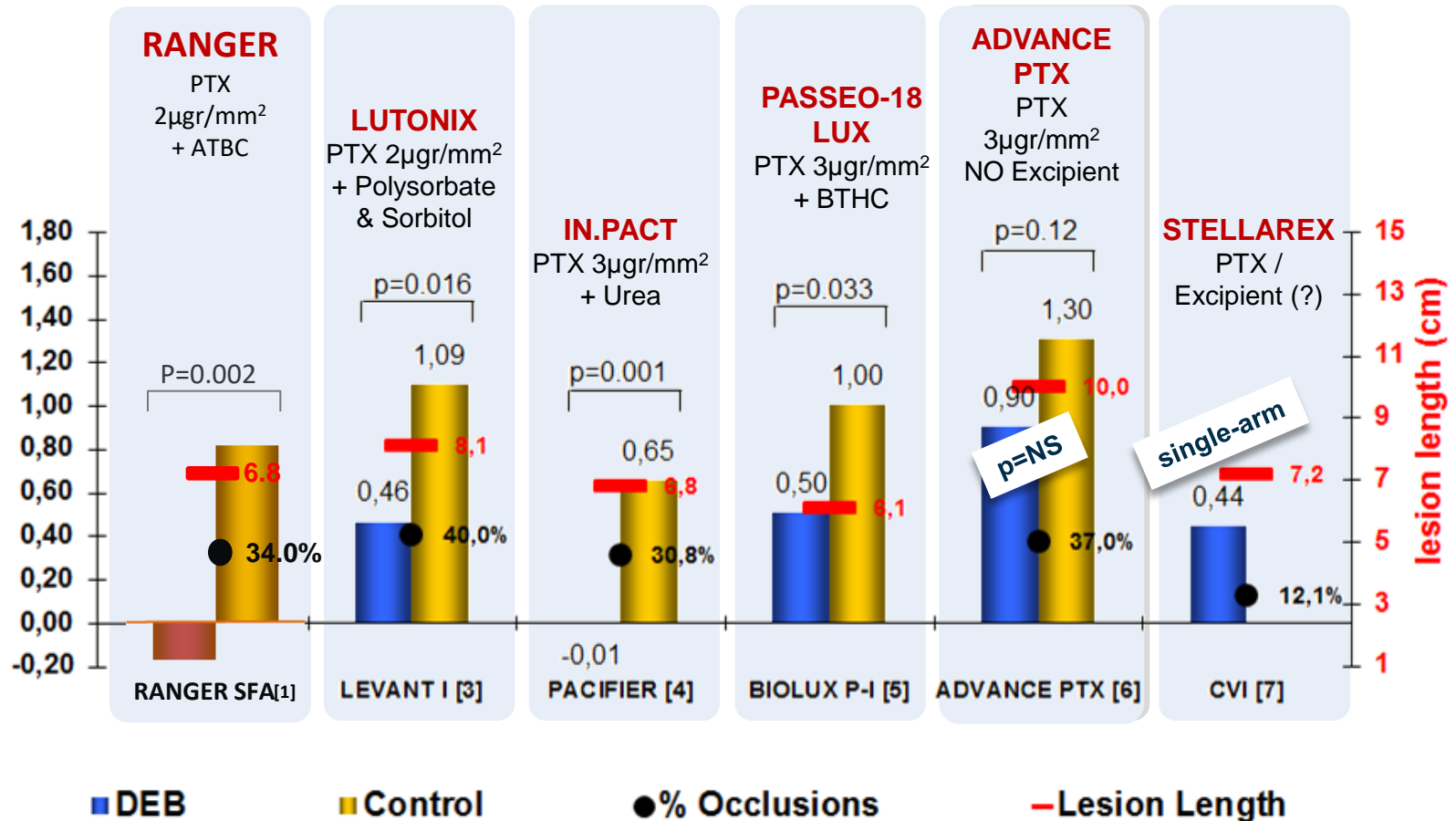
## Device Overview Matrix

| Company                     |    |  <b>BIOTRONIK</b><br>excellence for life |  <b>BARD</b> |  <b>Boston Scientific</b> |  <b>Medtronic</b> |  <b>Spectranetics</b><br><small>Always Reaching Further</small> |           |
|-----------------------------|----|---|---|--|--|--|-----------|
| Device name                 |    | Passeo-18 Lux   | Lutonix 035<br>Lutonix 014  | Ranger   | In.Pact<br>(Admiral, Pacific,<br><del>Amphirion</del> )  | Stellarex  |           |
| Catheter type               |    | OTW   | OTW   | OTW/RX   | OTW  | OTW  |           |
| Drug Coating                |    | Paclitaxel  | Paclitaxel  | Paclitaxel   | Paclitaxel   | Paclitaxel   |           |
| Drug Conc.                  |    | 3µg/mm <sup>2</sup>   | 2µg/mm <sup>2</sup>   | 2µg/mm <sup>2</sup>  | 3.5µg/mm <sup>2</sup>  | 2µg/mm <sup>2</sup>  |           |
| Coating excipient           |    | Lux:<br>BTHC  | Polysorbate and<br>Sorbitol   | TransPax:<br>Acetyl Tributyl<br>Citrate (ATBC)   | FreePac:<br>Urea   | EnduraCoat:<br>Polyethylene glycol<br>(PEG)  |           |
| Catheter Platform<br>(0.0") | 35 | L   |   | 40-150 mm  |  | 40-120 mm  | 40-120 mm |
|                             |    | ∅   |   | 4-12mm   |  | 4-7mm  | 4-6 mm    |
|                             | 18 | L   | 40-120 mm   |  | 30-150 mm  | 40-120 mm  |           |
|                             |    | ∅   | 2-7mm   |  | <b>2-8 mm</b>  | 4-7mm  |           |
|                             | 14 | L   |   | 40-120 mm  |  | 40-120 mm  |           |
|                             |    | ∅   |   | <b>2-4 mm</b>  |  | <b>Recalled</b><br>2-4 mm  |           |





# DCB Feasibility Trial data in perspective

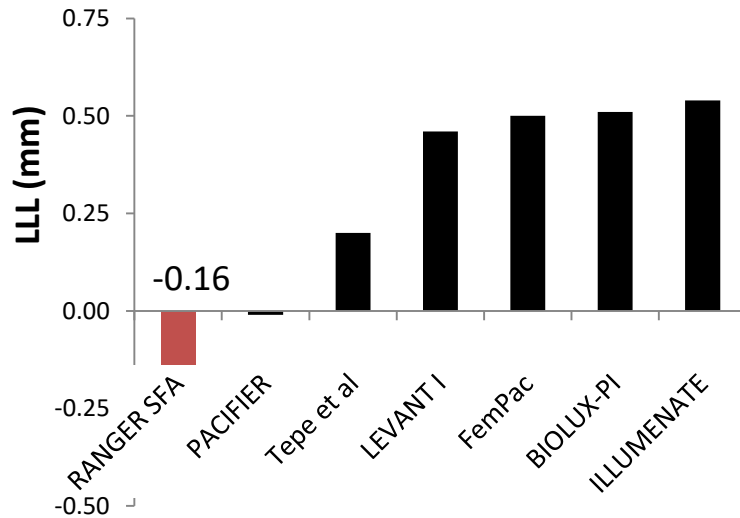


[1] Ranger SFA RCT presented at CIRSE 2016 by Prof Scheinert, Principal Investigator.; [3] D.Scheinert - TCT 2012 oral presentation; [4] M.Werk et al. - Circulation CI 2012; [5] D.Scheinert - EuroPCR 2012 oral presentation; [6] D.Scheinert - LINC 2013 oral presentation; [7] S.Duda - EuroPCR 2013 oral presentation

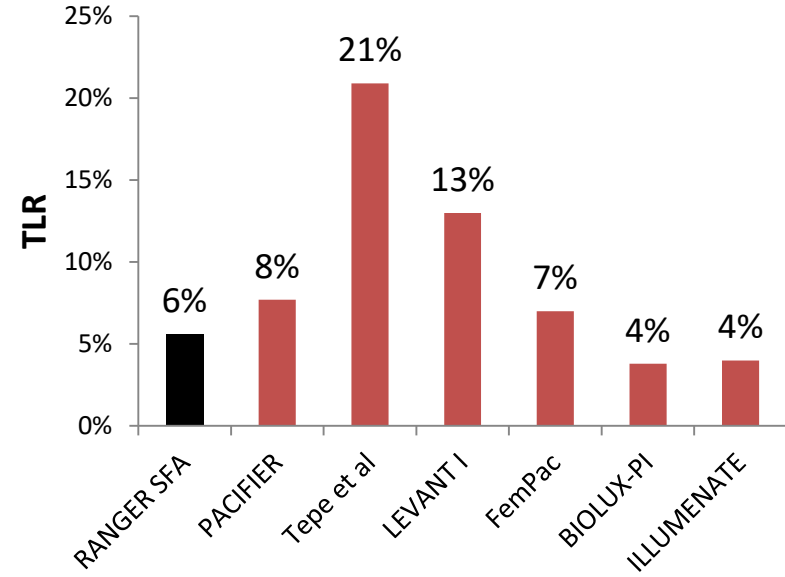
Data from different clinical trials not intended for comparison. For educational use only.

# SFA DCB Studies- 6 month Results in perspective

## Late Lumen Loss



## 6-month TLR



| Trial              | RANGER SFA | PACIFIER        | Tepe et al         | LEVANT I | BIOLUX-PI     | ILLUMENATE |
|--------------------|------------|-----------------|--------------------|----------|---------------|------------|
| Therapy            | Ranger     | IN.PACT Pacific | DCB- not specified | Lutonix  | Passeo-18 Lux | Stellarex  |
| Mean lesion length | 6.8        | 7.0             | 5.7                | 8.1      | 6.1           | 7.2        |

PACIFIER- Werk M, et al. *Circ Cardiovasc Interv.* 2012;5(6):831-840.; Tepe G, et al. *Jendovasc Ther.* 2015;7:27-33. ; LEVANT I- Scheinert D, et al. *JACC Cardiovasc Interv.* 2014;7(1):10-9 ; BIOLUX PI- Scheinert D, et al. *J Endovasc Ther.* 2015;22(1):14-21. ; ILLUMENATE- Schroeder H, et al. *Catheter Cardiovasc Interv.* 2015;86(2):278-86.  
 Data from different clinical trials not intended for comparison. For educational use only.



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- Calcified and tortuous lesion intervention
- Device update and technical tips and tricks in CTO intervention

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- Aorta and Branched Vessel
- Aorto-iliac Intervention
- Femoro-popliteal CTO
- BTK CTO

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