### The Power of Clinical Research

### IN.PACT Pacific case report\*

Bilateral SFA disease with similar length and morphology. Treatment: right SFA IN.PACT Pacific drug eluting balloon, left SFA conventional PTA. At 6 months follow up the right femoral artery stayed open whereas the left side showed significant restenosis.



\* Courtesy Dr. M. Werk, Berlin

#### The IN.PACT clinical trial program (SFA)

Currently (Feb 2011), 6 different INPACT studies are enrolling or underway to investigate the effect of DEB in SFA/popliteal applications:

Study	No. of patients	District/ Indication	Туре	1° Endpoint		
DEB SFA IT Registry *	105	SFA / de-novo + restenotic (no ISR)	Single-arm multicenter IT	6m Patency		
PACIFIER *	90	SFA / de-novo + restenotic (no ISR)	RCT multicenter EU: DEB vs PTA	6m LLL		
IN.PACT SFA I	150	SFA / de-novo + restenotic (no ISR)	RCT multicenter EU: DEB vs PTA	12m MAE + Primary Patency		
ISAR STATH *	150	SFA / de-novo + restenotic (no ISR)	RCT multicenter DE: Stent vs DEB+Stent vs Atherectomy	6m %DS		
FAIR *	118	SFA / ISR	RCT multicenter EU: DEB vs PTA	6m DUS Rest. Rate		
ISAR PEBIS *	70	SFA / ISR	RCT multicenter DE: DEB vs PTA	6m %DS		
* investigator sponsored trial						

## **IN.PACT** Pacific

Technical Specifications

Order

Information

Catheter design Balloon material Balloon coating Usable shaft length Shaft diameter Introducer sheath compatibility Guidewire compatibility Nominal pressure

Ref N° 90 cm shaft length	Ref N° 130 cm shaft length
PCF 040 040 09P	PCF 040 040 13P
PCF 040 060 09P	PCF 040 060 13P
PCF 040 080 09P	PCF 040 080 13P
PCF 040 120 09P	PCF 040 120 13P
PCF 050 040 09P	PCF 050 040 13P
PCF 050 060 09P	PCF 050 060 13P
PCF 050 080 09P	PCF 050 080 13P
PCF 050 120 09P	PCF 050 120 13P
PCF 060 040 09P	PCF 060 040 13P
PCF 060 060 09P	PCF 060 060 13P
PCF 060 080 09P	PCF 060 080 13P
PCF 060 120 09P	PCF 060 120 13P
PCF 070 040 09P	PCF 070 040 13P
PCF 070 060 09P	PCF 070 060 13P
PCF 070 080 09P	PCF 070 080 13P
PCF 070 120 09P	PCF 070 120 13P

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Global Headquarters



• Balloon nominal diameter 2 Balloon nominal length **3** Shaft diameter **4** Usable shaft length





WELCOME TO PERIPHERAL

**POWER**.

**IN.PACT** Pacific

PACLITAXEL-ELUTING PTA BALLOON CATHETER 0.018"

# **Restenosis** Prevention A Short-Term Therapy for Long-Term Success in the SFA

TO INNOVATE

TO COLLAB

TO TREAT

Over the Wire (OTW), coaxial shaft Flexitec™ Xtreme FreePac<sup>™</sup> - Paclitaxel eluting formulation 90 and 130cm 3.9F 5F-6F 0.018" 7 bar

Balloon diameter (mm)	Balloon length (mm)	Recom. introducer sheath (F)	RBP (bar)
4.00	40	5	20
4.00	60	5	14
4.00	80	5	14
4.00	120	5	14
5.00	40	5	20
5.00	60	5	14
5.00	80	5	14
5.00	120	5	14
6.00	40	5	16
6.00	60	5	14
6.00	80	5	14
6.00	120	5	14
7.00	40	6	12
7.00	60	6	12
7.00	80	6	12
7.00	120	6	12

4

Innovating for life.

## **IN.PACT** Pacific PACLITAXEL-ELUTING PTA BALLOON CATHETER 0.018"

## The Power of Optimized Drug Delivery

#### How IN.PACT DEBs work

The proprietary FreePac<sup>™</sup> urea-paclitaxel coating on IN.PACT DEBs optimizes drug delivery:

- The IN.PACT DEB is delivered to the lesion using state of the art peripheral balloon catheters
- As the balloon unwraps, the FreePac coating is fully exposed and presented to the vessel wall
- Urea molecules in the coating separate and free the paclitaxel molecules, increasing their solubility and facilitating their absorption into the artery

IN.PACT's unique FreePac coating combines urea and paclitaxel molecules into a single compound that provides:

- Increased drug solubility and optimal diffusion into the vessel wall
- Rapid, short-term drug delivery within 30–60 seconds
- Continued antirestenotic protection as paclitaxel stays in the arterial wall for at least 28 days

## The Power of Lesion Specific Solutions

### Designed specifically for lower extremity treatments

- SFA de novo and restenotic lesions
- Popliteal de novo and restenotic lesions

#### Broad array of diameters and lengths

• Specifically designed for SFA and popliteal arteries

#### Proven Pacific Xtreme Balloon Platform

- FLEXITEC<sup>™</sup> Xtreme balloon material
- 6-folding balloon (5.0–7.0mm diameter)
- Superb trackability and deliverability



Balloon Diameters 4, 5, 6, 7mm

#### IN.PACT PACLITAXEL ELUTION TIMELINE

Paclitaxel is carried across the

vessel wall by the urea







## The Power of Results<sup>1,2</sup>

Next generation FreePac coating demonstrates excellent performance.

FreePac urea-based coating shows equivalent performance compared with Ac/Matrix coating.

Development of stenosis due to neointimal proliferation in porcine coronary arteries four weeks after stent implantation; overstretch about 1: 1.2, randomized comparison of 3 treatments:

Control n=14, Ac/Matrix n=12, FreePac n=12

#### Percent stenosis (angiography); negative values indicate persistent over-dilatation



*FreePac and Ac/Matrix vs. Control each p < 0.001; FreePac* vs. Ac/Matrix p = 0.25

By over-dilatation the lumen in all treated vessel segments was increased by 15-20% over the reference diameter resulting in a corresponding negative 'diameter-stenosis' Excessive neointimal proliferation reduces the lumen diameter in the control group (no paclitaxel) not only to the reference diameter but to a 27% stenosis, whereas the original enlarged diameter of the treated segments remain almost unchanged if treated with the paclitaxelcoated balloons with no difference between the Ac/Matrix and FreePac coating.

FreePac and Ac/Matrix vs. Control each p < 0.001; FreePac

difference between the Ac/Matrix and FreePac coating.

Significantly larger lumen diameter in paclitaxel-

treated arteries than in the control group and no

vs. Ac/Matrix p = 0.68





#### Neointimal area (histology)



FreePac and Ac/Matrix vs. Control each p < 0.001; FreePac vs. Ac/Matrix p = 0.82. Significantly less neointimal proliferation in paclitaxel

treated arteries and no difference between the Ac/ Matrix and FreePac coating.

#### literature:

Ac/Matrix coating

IN.PACT FreePac Matrix

Control

Paclitaxel-coated balloons - Survey of preclinical data. Schnorr B, Kelsch B, Cremers B, Clever YP, Speck U, Scheller B. Minerva Cardioangiol 2010;58:567-82

2 Dose Response to Paclitaxel-Coated Balloon Catheters in the Porcine Coronary Overstretch and Stent Implantation Model.

Kelsch B, Scheller B, Biedermann M, Clever YP, Schaffner S, Mahnkopf D, Speck U, Cremers B nvest Radiol 2011:46: 255-263

28 days