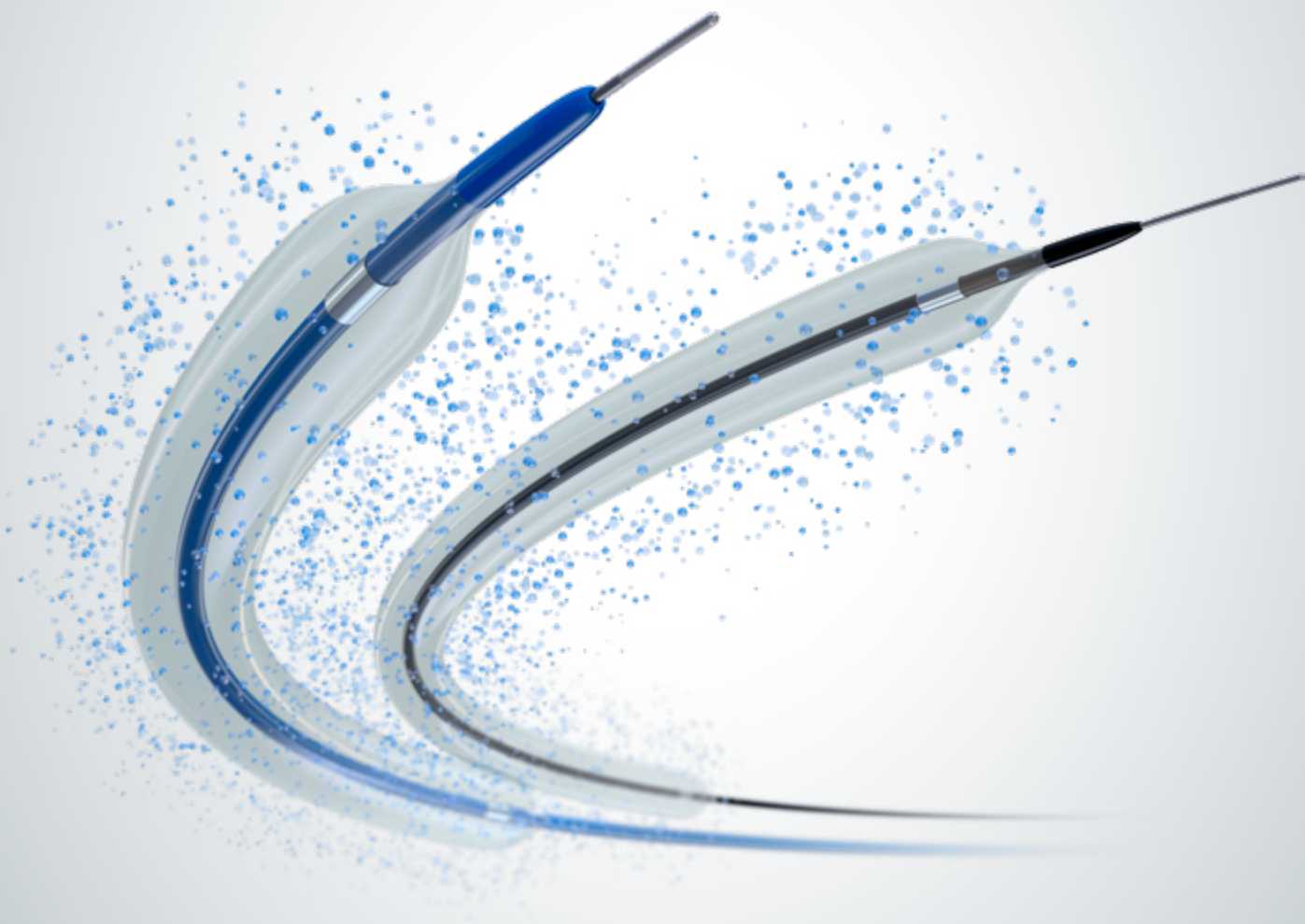


FREEWAY™ 014

DRUG-ELUTING PTA BALLOON TECHNOLOGY

SPECIFICALLY DESIGNED FOR INFRAPOPLITEAL INTERVENTIONS



PROVEN SAFETY & EFFICACY ^{1, 2}

FREEWAY™ 014 – DRUG-ELUTING PTA BALLOON TECHNOLOGY

THE COATING MAKES THE DIFFERENCE

FREEWAY™ 014 – COATING CHARACTERISTICS

- **3 μ g/mm² paclitaxel**
- **Coating composition of shellac and paclitaxel (1:1 ratio)**
- **Proven safety of coating**^{1, 2}

Amorphous coating

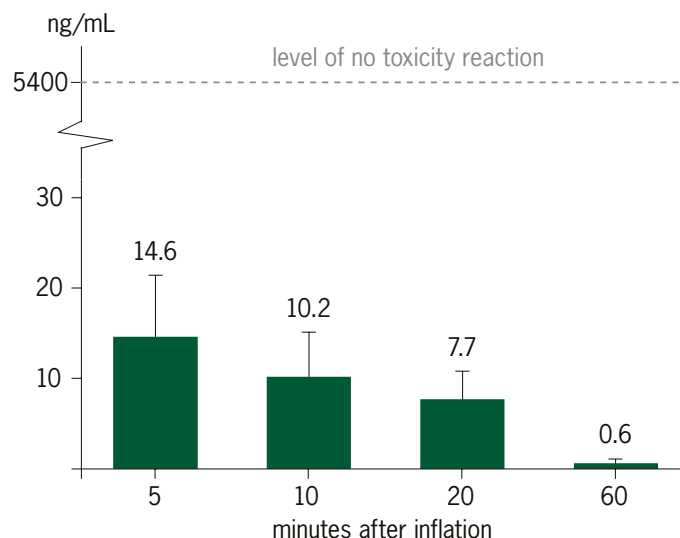
The durable non-crystalline bioshell coating homogenously covers the balloon surface and protects the drug from mechanical abrasion and early wash off, resulting in a low paclitaxel blood plasma concentration.

Shellac

Shellac is a natural resin composed of shellolic and alleuritic acid. The excellent film forming properties of shellac are used to coat pharmaceutical products and in the food industry.

Paclitaxel

Paclitaxel is an active ingredient that inhibits the cell replication thus blocking the microtubules decomposition during the metaphase and anaphase stages of mitosis. By selectively inhibiting the proliferation of smooth muscle cells, paclitaxel does not influence non-proliferating cells.

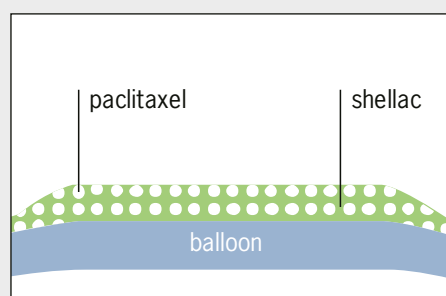


Paclitaxel blood plasma concentrations at 5, 10, 20 and 60 minutes after inflation (120 sec) with FREEWAY DEB.² Level of toxicity for paclitaxel plasma concentration calculated with a human body surface area of 1.9 m² and blood plasma content of 3.5l.³

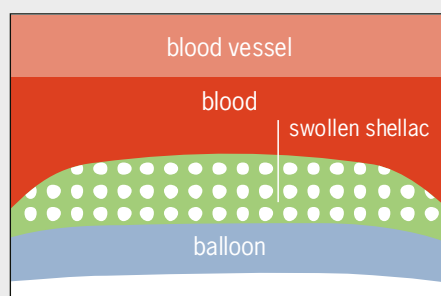
¹ Peters K et al. "In Vitro Evaluation of Cytocompatibility of Shellac as Coating for Intravascular Devices." Trends Biomater Artif Organ 2012 26(2): 110-11.

² Pavo N et al. "Coating of intravascular balloon with paclitaxel prevents constrictive remodeling of the dilated porcine femoral artery due to inhibition of intimal and media fibrosis." J Mater Sci Mater Med 2016 27(8): 131.

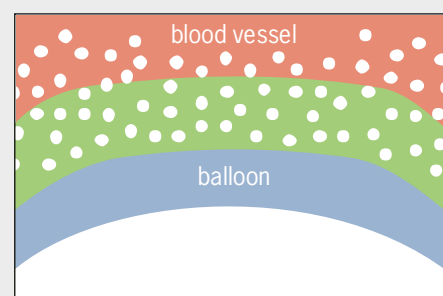
³ Margolis J et al. "Systemic nanoparticle paclitaxel (nab-paclitaxel) for in-stent restenosis I (SNAPIST-I): a first-in-human safety and dose-finding study." Clinical cardiology 2007 30(4): 165-170.



coated balloon deflated



in contact with blood



inflated balloon allows freed paclitaxel to enter the vessel wall

The FREEWAY™ 014 amorphous bioshell coating matrix consists of a 1:1 mixture of paclitaxel with shellac applied to the balloon surface by a micro-pipetting procedure in a clean room under sterile conditions. Paclitaxel is applied in a final concentration of 3 μ g/mm².

In contact with body liquid the hydrophilic shellac matrix of the composite swells and opens the structure for the pressure-induced fast release of paclitaxel from the inflated balloon.

After balloon dilatation, injuries to the arterial wall stimulate inflammatory reaction, the excretion of growth factors and the onset of vascular smooth muscle cell division and migration to the intima. The FREEWAY™ 014 Paclitaxel-eluting PTA balloon catheter delivers a proper concentration of paclitaxel to the arterial wall, thus prevents restenosis and enhances a smooth re-endothelialization process after balloon dilatation.

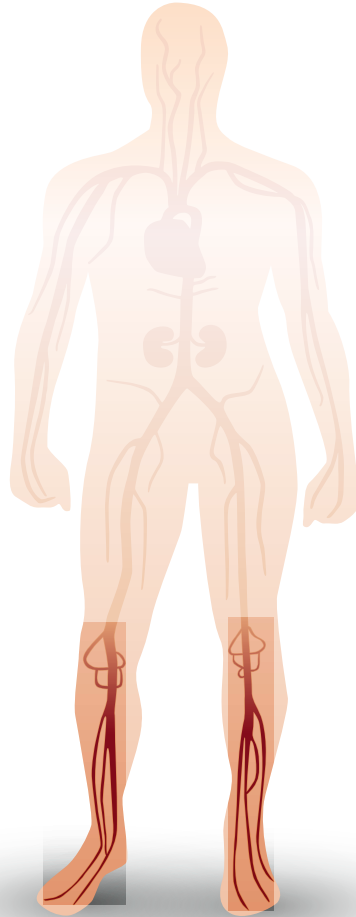
FREEWAY™ 014 – DRUG-ELUTING PTA BALLOON TECHNOLOGY

SPECIFICALLY DESIGNED FOR INFRAPOPLITEAL INTERVENTIONS

FREEWAY™ 014 – ADVANCED PRODUCT FEATURES

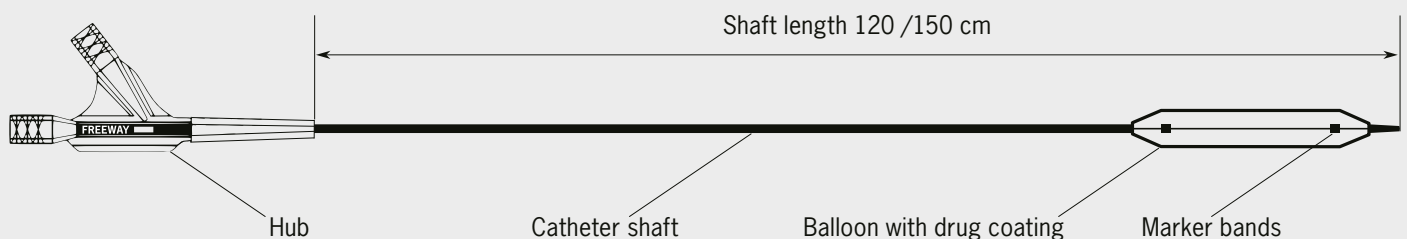
Concept benefits:

- **Delivers** drug locally over a short period of time
- **Safety** due to non-crystalline coating
- **Crosses** lesions smoothly due to the low profile
- **Treats** lesions where stents are not a viable solution
- **Enables** re-intervention



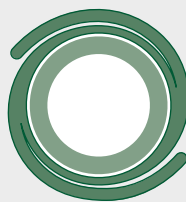
Balloon characteristics:

- Over the wire (OTW) PTA balloon catheter for successful infrapopliteal interventions
- Low balloon crossing profile
- Low tip entry profile
- Short deflation time
- Wide spectrum of balloon catheters for treating long, diffuse lesions
 - Up to 150mm balloon length
- Elaborated catheter technology with good crossability, trackability and pushability for treatment of diffuse lesions
- Precise, controlled dilatation
 - Controlled compliance for accurate balloon vessel sizing
 - Flat shoulders



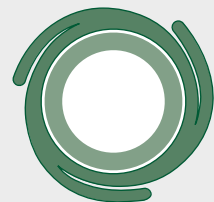
Coaxial catheter shaft design

Kinking resistant shaft material for crossover procedures



Two-fold wrap balloon

2-folding for 2.0 mm



Three-fold wrap balloon

3-folding for 2.5 mm to 4.0 mm

FREEWAY™ 014 – DRUG-ELUTING PTA BALLOON TECHNOLOGY

SPECIFICALLY DESIGNED FOR INFRAPOPLITEAL INTERVENTIONS

TECHNICAL DATA

FREEWAY™ 014 – DRUG-ELUTING PTA BALLOON TECHNOLOGY	
Design	Coaxial design – OTW
Shaft diameter	distal 3.1 F / medial 3.8 F / proximal 3.8 F
Balloon diameter	2.0 / 2.5 / 3.0 / 3.5 and 4.0 mm
Balloon length	40–150 mm
Usable catheter length (tip to strain relief)	120 cm and 150 cm
Guide wire diameter	0.014" (0.36 mm)
Shaft coating	Hydrophilic
Balloon coating	Paclitaxel (3µg/mm²) within a shellac matrix (1:1 ratio)
Balloon material	PA, Polyamid/Nylon
Balloon folding	2-folding for 2.0 mm
	3-folding for 2.5–4.0 mm
Balloon characteristic	Semi-compliant
Recommended introducer sheath	4 F
Nominal pressure	6 atm
Rated burst pressure	Diameter 2.0–2.5 mm: 16 atm
	Diameter 3.0–4.0 mm: 14 atm
Packaging unit	1 unit

PRODUCT ORDERING INFORMATION

Balloon size diameter × length (mm)	Rated burst pressure (atm)	Recommended introducer sheath (F)	Order number	Balloon size diameter × length (mm)	Rated burst pressure (atm)	Recommended introducer sheath (F)	Order number
Usable catheter length 120 cm (L)				Usable catheter length 150 cm (XL)			
2.0 × 40	16	4	114-2040 L	2.0 × 40	16	4	114-2040 XL
2.0 × 80	16	4	114-2080 L	2.0 × 80	16	4	114-2080 XL
2.0 × 120	16	4	114-20120 L	2.0 × 120	16	4	114-20120 XL
2.0 × 150	16	4	114-20150 L	2.0 × 150	16	4	114-20150 XL
2.5 × 40	16	4	114-2540 L	2.5 × 40	16	4	114-2540 XL
2.5 × 80	16	4	114-2580 L	2.5 × 80	16	4	114-2580 XL
2.5 × 120	16	4	114-25120 L	2.5 × 120	16	4	114-25120 XL
2.5 × 150	16	4	114-25150 L	2.5 × 150	16	4	114-25150 XL
3.0 × 40	14	4	114-3040 L	3.0 × 40	14	4	114-3040 XL
3.0 × 80	14	4	114-3080 L	3.0 × 80	14	4	114-3080 XL
3.0 × 120	14	4	114-30120 L	3.0 × 120	14	4	114-30120 XL
3.0 × 150	14	4	114-30150 L	3.0 × 150	14	4	114-30150 XL
3.5 × 40	14	4	114-3540 L	3.5 × 40	14	4	114-3540 XL
3.5 × 80	14	4	114-3580 L	3.5 × 80	14	4	114-3580 XL
3.5 × 120	14	4	114-35120 L	3.5 × 120	14	4	114-35120 XL
3.5 × 150	14	4	114-35150 L	3.5 × 150	14	4	114-35150 XL
4.0 × 40	14	4	114-4040 L	4.0 × 40	14	4	114-4040 XL
4.0 × 80	14	4	114-4080 L	4.0 × 80	14	4	114-4080 XL



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Eurocor Tech GmbH is a wholly owned subsidiary of Opto Eurocor Healthcare Ltd and is part of the Opto Circuits Group.

The device fulfils the requirements for CE marking – Notified Body 1434.

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