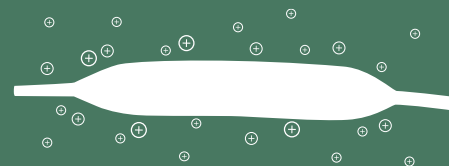


**FREEWAY™ 014 – latest
second-generation drug-releasing technology**
PTA balloon technology
specifically designed for
infrapopliteal interventions

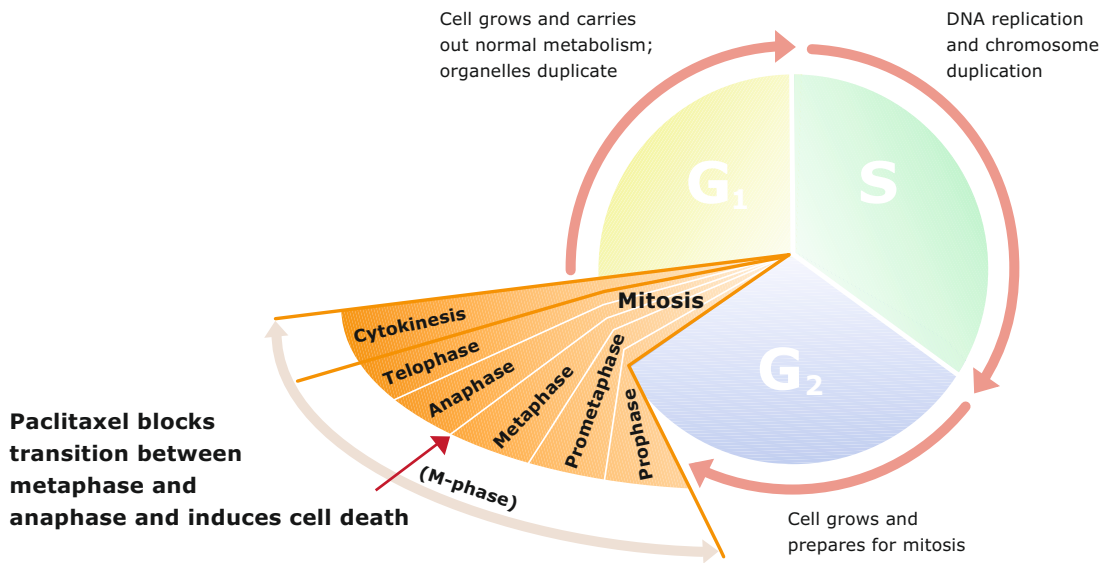
FREEWAY™ 014

Paclitaxel releasing
over the wire (OTW)
PTA balloon catheter



Paclitaxel

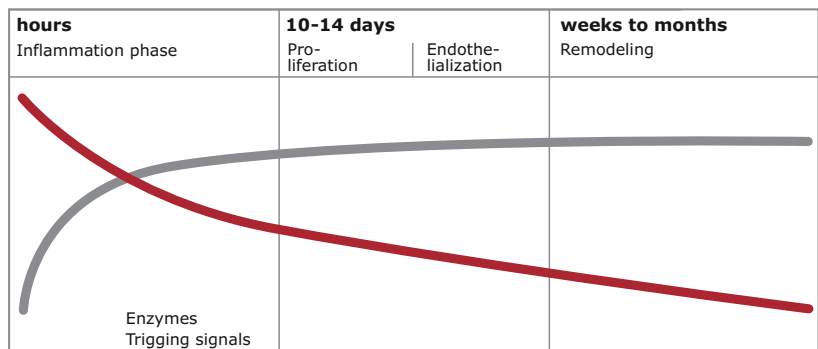
Paclitaxel prevents restenosis by blocking proper microtubular formation, thus it inhibits cell division and migration. It inhibits inflammatory processes. After balloon dilatation, injuries to the arterial wall stimulate inflammatory reaction, and the excretion of growth factors occurs as an important process along with the onset of cell division and the migration of smooth muscle cells. Paclitaxel inhibits platelet derived growth factor (PDGF) mediated vascular smooth muscle cell migration to the intima. Paclitaxel also inhibits extracellular matrix secretion and breakdown.



What is most important

Paclitaxel selectively inhibits the proliferation of smooth muscle cells. The endothelium cells show a better resistance to Paclitaxel than the smooth muscle cells due to the different affinity of the connective structure on the cell surface. Paclitaxel does not influence non-proliferating cells as a result of cytokine and growth factor stimulation. The FREEWAY Paclitaxel-releasing PTA balloon dilatation catheter enhances a smooth re-endothelialization process.

The stages of wound healing



Axel et al. Circulation 1997. Paclitaxel inhibits arterial smooth muscle cell proliferation and migration *in vitro* and *in vivo* using local drug delivery. Circulation 1997; 96:636-45

Paclitaxel distribution in tissue after acute dosing using **FREEWAY™ 014**
Paclitaxel distribution in tissue after chronic dosing using **DES**

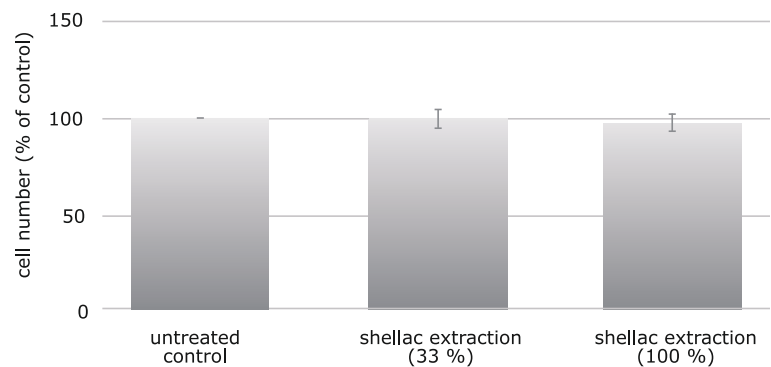
Shellac

The excellent film forming properties of shellac are used to coat gastric resistant tablets.

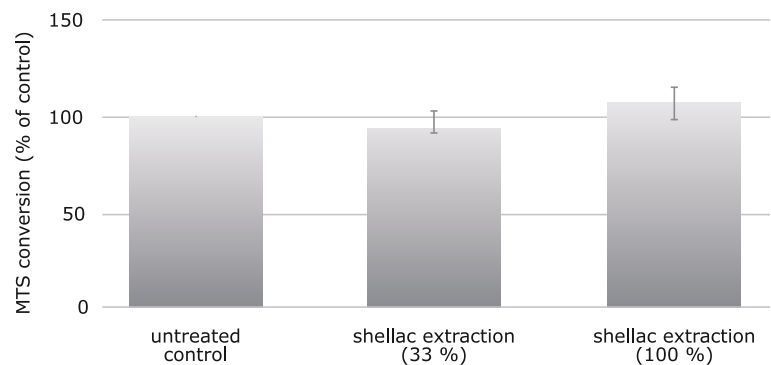
The FREEWAY™ 014 Bioshell coating matrix consists of a natural resin, which is EMEA and FDA approved (GRAS) as food additive under E 904.

Investigation of cytotoxicity

Shellac extraction product
(24 h extraction in cell culture medium)



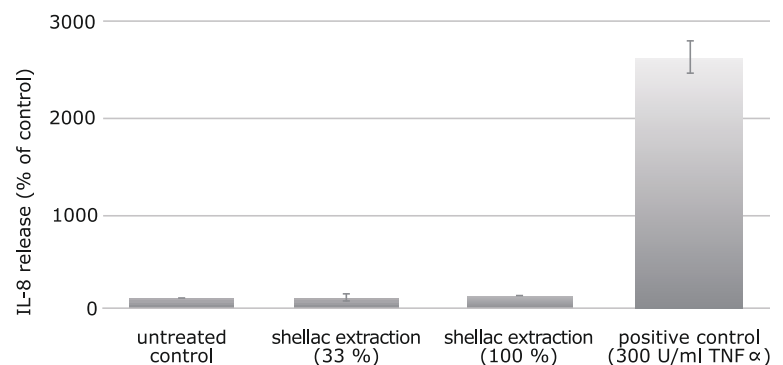
Quantification of cell quantity
Metabolic cell activity (MTS-assay)



No signs of pro-inflammatory activation

IL-8-release

Shellac extraction products (24 h)
Exposition of confluent HDMEC with
extraction products (24 h) tumour
necrosis factor α (TNF α) as a positive
control group



Peters K, Prinz C, Salamon A, Adam A, Stuhldreier G, Rychly J, Neumann H-G. Evaluation of shellac as coating of intravascular devices – Testing of *in vitro* compatibility by endothelial and smooth muscle cells. Jahrestagung der Deutschen Gesellschaft für Biomaterialien, 8.-10.10.2009, Tübingen

Neither direct contact to shellac-coated materials nor exposure to shellac extraction products impaired HDMEC and hSMC viability and function *in vitro*.

Shellac

Shellac is a natural resin composed of shellolic and alleuritic acid.

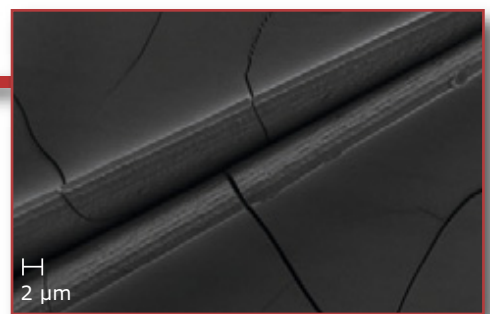
The coating consists of a 1:1 mixture of Paclitaxel with shellac applied to the balloon by a micro-pipetting procedure in a clean room under sterile conditions.



Exclusive bioshell coating



Compared to competitive products shellac gives the balloon a shiny appearance

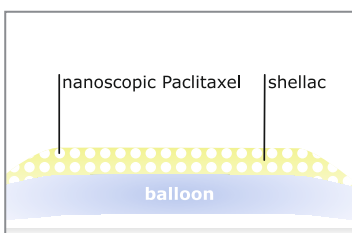


Shellac coating section. Scanned electron microscope image: 2/1000 mm scale*

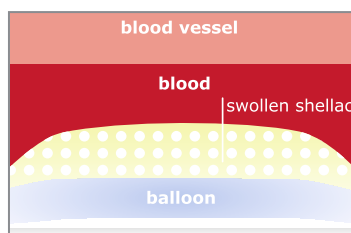
*Very smooth surface – less vulnerable to abrasion

The FREEWAY™ 014 Paclitaxel releasing balloon catheter

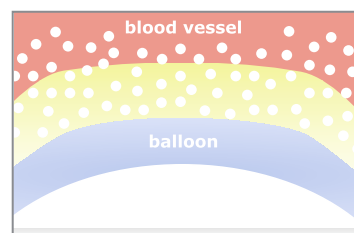
In contact with body liquid the hydrophilic shellac-network of the composite swells and opens the structure for the pressure-induced fast release of Paclitaxel on the inflated balloon.



coated balloon deflated

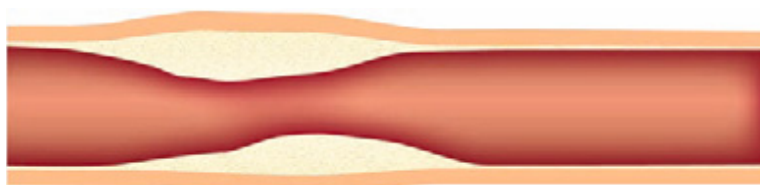


in contact with blood



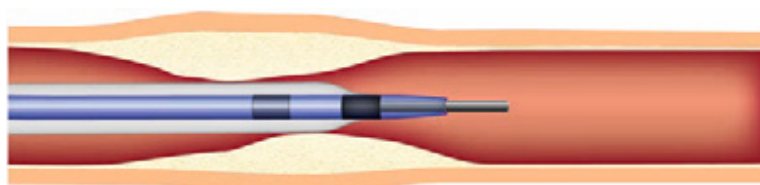
inflated balloon allows freed Paclitaxel to enter the vessel wall

FREEWAY™ 014, infrapopliteal PTA balloon 0.014" OTW

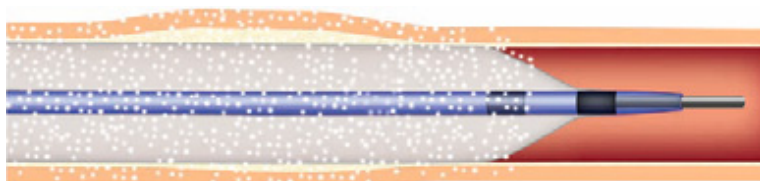


How it works

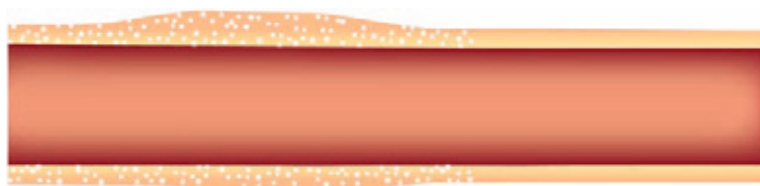
PTA causes vessel wall injury. Hyperplasia of the inner vessel wall resulting in lumen narrowing is the natural reaction to this injury. Immediately after the 'controlled injury' set by the angioplasty procedure the key pathways start to contribute to the formation of neointimal hyperplasia. Due to injury from cracking plaque material, neointimal hyperplasia can slowly narrow the lesion, causing massive neointimal proliferation in treated lesion area.



After predilatation, the FREEWAY™ 014 Paclitaxel releasing PTA balloon is advanced to the lesion site.



With the balloon well positioned, inflation for at least 30 seconds releases the anti-proliferative drug.



The balloon is withdrawn as the drug penetrates into the artery wall. Paclitaxel will act immediately, over a short term, to inhibit cell re-growth. The shellac coating remains on the balloon.

The science of FREEWAY™ 014 – shellac conclusion

1:1 mixture Paclitaxel with shellac: proven and safe short-term drug release

Paclitaxel is applied in a final concentration of 3 $\mu\text{g}/\text{mm}^2$ to the surface of the balloon.

Tissue concentrations of Paclitaxel reached by this coating is inflation time dependent, after 30 seconds or more of inflation a concentration of 200 $\mu\text{M}/\text{L}$ is reached.

FREEWAY™ 014

Paclitaxel releasing over the wire

FREEWAY™ 014 – OTW balloons for successful infrapopliteal interventions

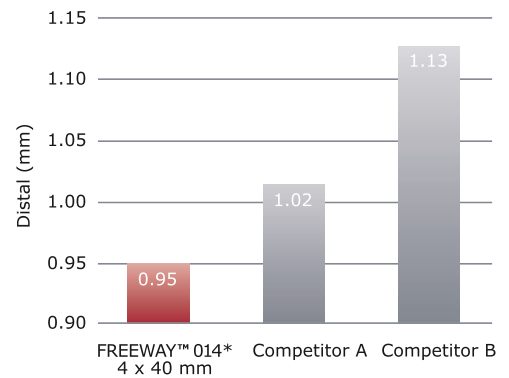
A treatment concept with excellently developed products

- low balloon crossing profile
- low tip entry profile
- short deflation time
- hydrophilic shaft coating

Reach your destination with an enhanced OTW 0.014" balloon designed to cross smoothly and deflate quickly.

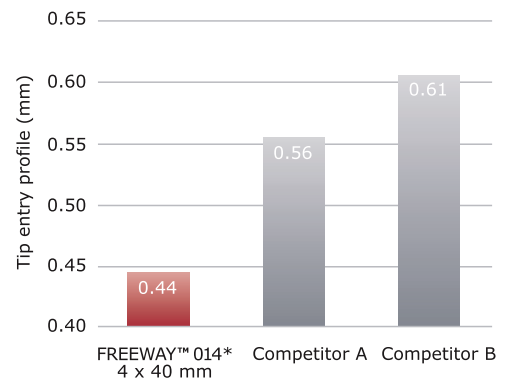
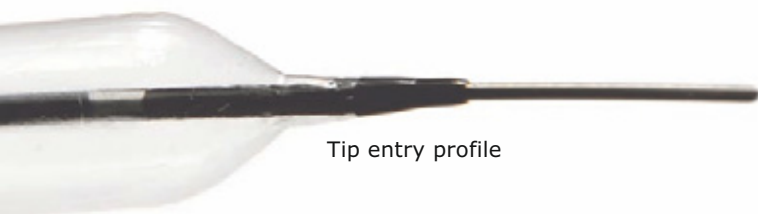
Balloon crossing profile*

- Low-primary crossing profile
- excellent trackability and flexibility



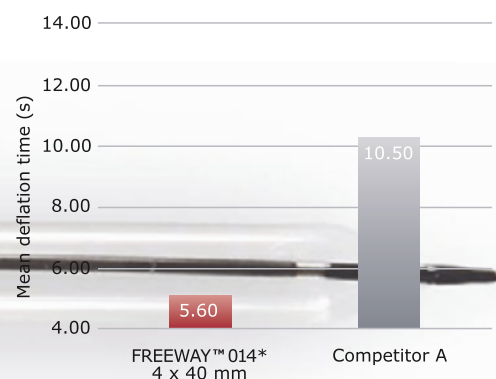
Low tip entry profile*

- Low-profile tapered tip for easier lesion crossing
- excellent crossability and navigation of infrapopliteal vessels including case of challenging anatomy

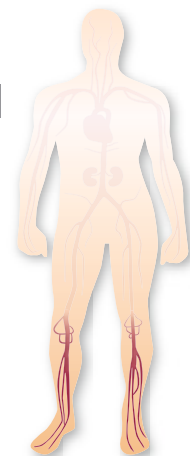


Greatly reduced deflation*

- Superior deflation time compared to competition
- for fast and safe treatments



*Eurocor data on file (4 x 40 mm, 0.014" balloon)



FREEWAY™ 014, infrapopliteal PTA balloon 0.014" OTW

Latest, second-generation drug-eluting technology with an immediate short-term drug release effect

An innovative therapeutic treatment concept with excellent trackability for challenging infrapopliteal lesions

Ultra-low profile balloons especially designed for infrapopliteal interventions

- 2–4 mm balloon diameter
- 40–150 mm balloon length
- 120 cm and 150 cm shaft lengths

FREEWAY™ 014, infrapopliteal PTA balloon 0.014" OTW

An innovative concept with many benefits:

- **Delivers** drug locally over a short period of time
- **Avoids** chronic inflammation
- **Simplifies** the procedure – is as easy to use as a standard PTA balloon catheter
- **Crosses** lesions smoothly due to the low profile
- **Respects** original vessel anatomy
- **Treats** lesions where stents are not a viable solution
- **Allows** short-term antiplatelet therapy
- **Reduces** the incidence of restenosis
- **Enables** re-intervention

The Eurocor way of science: for outstanding patient results



**FREEWAY™ 014 – latest, second-generation drug-releasing technology,
0.014" OTW infrapopliteal PTA balloon technology specifically designed
for infrapopliteal interventions**

Technical data

FREEWAY™ 014: DEB	
Design	Coaxial design - OTW
Shaft diameter	dis. 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)
Coating	Hydrophilic coating on distal shaft
Balloon material	PA, Polyamid/Nylon
Balloon folding	Bi-fold for 2.0 mm Tri-fold for 2.5 to 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/bar Diameter 3.0-4.0 mm: 14 atm/bar
Packaging unit	1 unit

FREEWAY™ 014 Product order information

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

Photos: mauritius images/Alamy (cover); mauritius images/Busse Yankushev (page 3)