FREEWAY™

SHUNT BALLOON CATHETER

HIGH PRESSURE DEB FOR THE TREATMENT
OF SHUNT STENOSIS

FREEWAY™ – Shunt DEB protects AV fistulas
and shunt grafts from early restenosis

Eurocor

FREEWAY™ – SHUNT BALLOON CATHETER

THE COATING MAKES THE DIFFERENCE

FREEWAY™ 035 AV SHUNT – BALLOON CHARACTERISTICS

- **High pressure balloon (rated burst pressure up to 20 atm)**
- **3µg/mm² paclitaxel**
- **Coating composition of shellac and paclitaxel (1:1 ratio)**
- **Proven safety of coating** [1, 2]

Amorphous coating

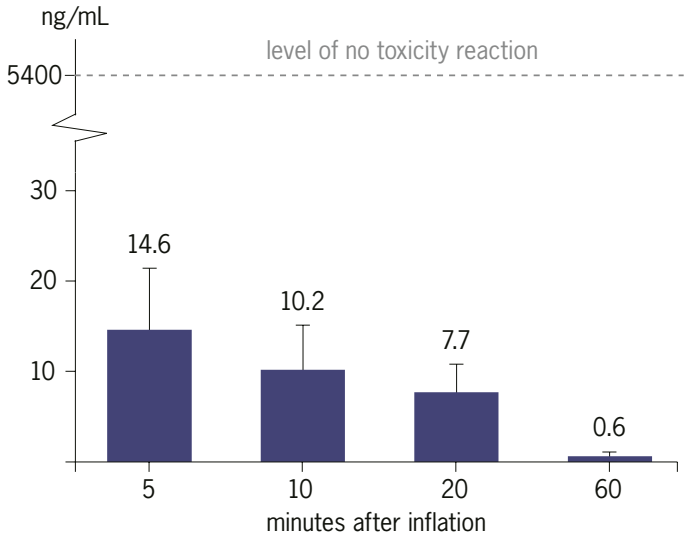
The durable non-crystalline bioshell coating homogenously covers the balloon surface and protects the drug from mechanical abrasion and early wash off, resulting in a low paclitaxel blood plasma concentration.

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.

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.

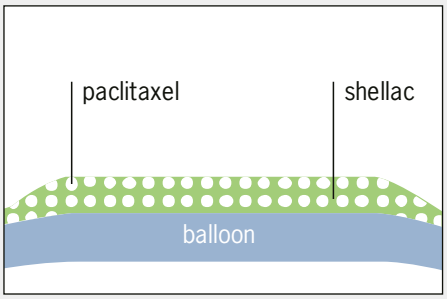


Paclitaxel blood plasma concentrations at 5, 10, 20 and 60 minutes after inflation (120 sec) with FREEWAY DEB.[2] Level of toxicity for paclitaxel plasma concentration calculated with a human body surface area of 1.9 m² and blood plasma content of 3.5l.[3]

[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.

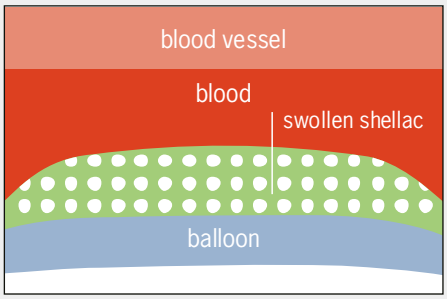
[2] Pavo N et al. "Coating of intravascular balloon with paclitaxel prevents constrictive remodeling of the dilated porcine femoral artery due to inhibition of intimal and media fibrosis." J Mater Sci Mater Med 2016 27(8): 131.

[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.



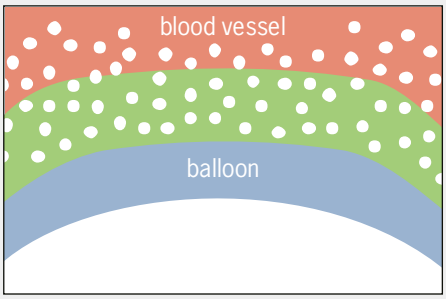
coated balloon deflated

The FREEWAY™ 035 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 µg/mm².



in contact with blood

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.



inflated balloon allows freed paclitaxel to enter the vessel wall

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™ 035 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.

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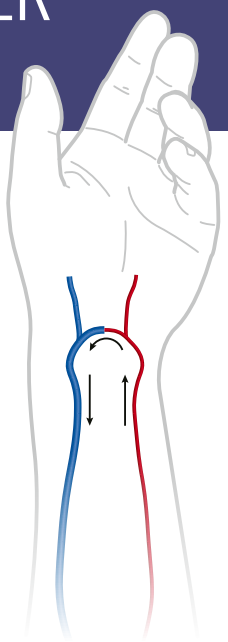
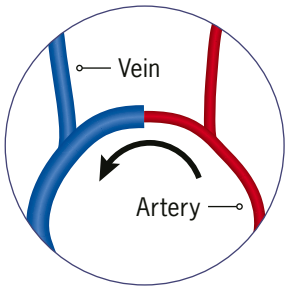
HIGH PRESSURE DEB FOR THE TREATMENT OF SHUNT STENOSIS



FREEWAY™ 035 AV SHUNT – CLINICAL PROGRAM

The FREEWAY™ 035 DEB is a clinically proven therapeutical option for AV shunt patients



- **4 AV registries show solid results**
- **Reduces re-intervention**
- **Preserves future treatment option**

German AV Registry [4]

- 22 hemodialysis patients
- Follow-up results (N=18)
- **Very low re-intervention rate** of only 11%

Access type

Cimino:	30.3%
Basilic:	6.1%
Cephalic:	18.2%
AV-Graft:	45.5%

Italian AV Registry [5]

- 27 hemodialysis patients
- Follow-up results (N=27)
- **Significantly longer time to re-intervention** after FREEWAY™ 035 DEB treatment compared to standard balloon angioplasty
- Time to re-intervention: FREEWAY™ 7.6 months vs. 4.8 months standard balloon; p<0.001

Access type

Distal:	29.6%
Mid-arm:	11.1%
Proximal:	59.2%

Turkish AV Registry [6]

- 52 hemodialysis patients
- Follow-up results (N=52)
- **Significantly higher primary patency rate** at 12 months follow-up and **significantly longer** mean **fistula survival** time for patients treated with FREEWAY™ 035 DEB
- Primary patency: FREEWAY™ 65.4% vs. 34.6% standard balloon; p<0.05
- Fistula survival: FREEWAY™ 9.81 months vs. 7.58 months standard balloon; p<0.05

Access type

Radiocephalic:	78.8%
Brachiocephalic:	21.2%

Turkish AV Registry II [7]

- 96 hemodialysis patients (32 FREEWAY™ – 64 PTA)
- **Significantly higher primary patency rate** at 6 months: 96.9% DEB vs 20.3% PTA p<0.001
- Longer median fistula survival after treatment compared to standard balloon PTA 220 days vs. 152.5 days
- Lesser recurrence of fistula dysfunction 21.9% vs 31.3% compared to PTA

Access type

Brachiocephalic:	18.8%
Radiocephalic:	56.3%
Brachiobasilic:	25.0%

[4] Duda S et al. "First experience with DCB in AV-fistulas." Presentation at LINC 2015

[5] Troisi N et al. "Freeway paclitaxel-releasing balloons to treat recurrent stenosis of arteriovenous fistula in hemodialysis patients." Minerva cardioangiologica 2018 66(3): 233-237.

[6] Çildağ MB et al. "The primary patency of drug-eluting balloon versus conventional balloon angioplasty in hemodialysis patients with arteriovenous fistula stenoses." JPN J Radiol 2016 34(10): 700-704.

[7] Yildiz I "The Efficacy of Paclitaxel Drug-Eluting Balloon Angioplasty Versus Standard Balloon Angioplasty in Stenosis of Native Hemodialysis Arteriovenous Fistulas: An Analysis of Clinical Success, Primary Patency and Risk Factors for Recurrent Dysfunction." Cardiovascular and interventional radiology 2019 42(5): 685-692.

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HIGH PRESSURE DEB FOR THE TREATMENT OF SHUNT STENOSIS

TECHNICAL DATA

FREEWAY™ – SHUNT BALLOON CATHETER	
Balloon name	FREEWAY™ 035
Design	Bilumen design – over the wire catheter
Balloon diameter	4.0 / 5.0 / 6.0 / 7.0 / 8.0 mm
Balloon length	20, 40 and 60 mm
Usable catheter length (tip to strain relief)	40 cm
Guide wire diameter	0.035" (0.89 mm)
Shaft coating	Hydrophillic
Balloon coating	Paclitaxel (3µg/mm²) within a shellac matrix (1:1 ratio)
Balloon material	PA, Polyamid/Nylon
Balloon folding	4-folding for 4 mm and 5 mm 5-folding for 6 mm and 7 mm
Balloon characteristics	Semi-compliant
Recommended introducer sheath	6 F for 4.0 to 6.0 mm Diameter 7F for 7.0 to 8.0 mm Diameter
Recommended balloon inflation time	120 sec
Nominal pressure	12 atm
Rated burst pressure	Balloon length 20/40 mm, Diameter 4–7 mm: 20 atm Balloon length 60 mm, Diameter 4–7 mm: 18 atm Balloon length 20/40/60 mm, Diameter 8 mm: 18 atm
Packaging unit	1 unit

PRODUCT ORDERING INFORMATION

Balloon size diameter × length (mm)	Rated burst pressure (atm)	Recommended introducer sheath (F)	Usable catheter length (cm)	Order number
4.0 × 20	20	6	40	335-4020 AV
4.0 × 40	20	6	40	335-4040 AV
4.0 × 60	18	6	40	335-4060 AV
5.0 × 20	20	6	40	335-5020 AV
5.0 × 40	20	6	40	335-5040 AV
5.0 × 60	18	6	40	335-5060 AV
6.0 × 20	20	6	40	335-6020 AV
6.0 × 40	20	6	40	335-6040 AV
6.0 × 60	18	6	40	335-6060 AV
7.0 × 20	20	7	40	335-7020 AV
7.0 × 40	20	7	40	335-7040 AV
7.0 × 60	18	7	40	335-7060 AV
8.0 × 20	18	7	40	335-8020 AV
8.0 × 40	18	7	40	335-8040 AV
8.0 × 60	18	7	40	335-8060 AV

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