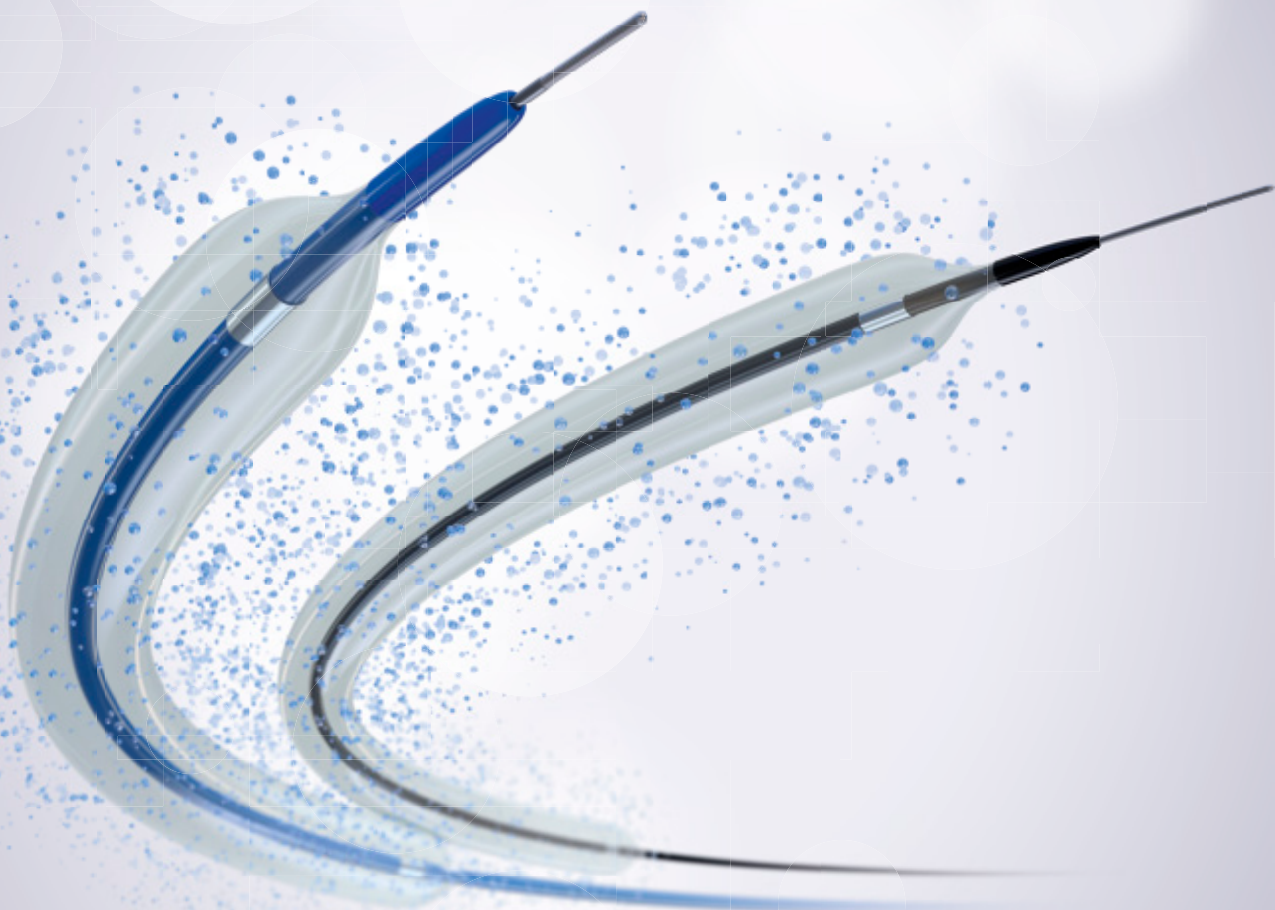


FREEWAY™

SHUNT BALLOON CATHETER

HIGH PRESSURE DEB FOR THE TREATMENT
OF SHUNT STENOSIS



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

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

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

The feasibility study presented at LINC 2015, showed a low re-intervention rate of 11% at follow up.

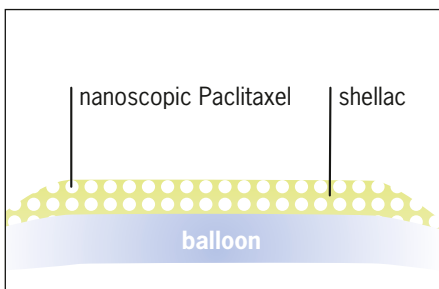
- For the treatment of AV fistulas
- Reduces re-intervention
- Preserves future treatment option



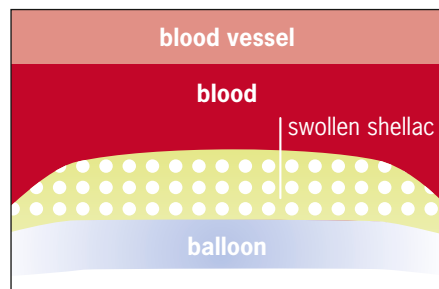
FREEWAY™ – SHUNT DEB BIOSHELL COATING MATRIX

The FREEWAY™ – Shunt DEB bioshell coating matrix consists of paclitaxel and shellac, a natural resin composed of shellolic and aleuritic acid. Shellac is EMA and FDA approved (GRAS) as food additive under E 904. The excellent film forming properties of shellac are used to coat gastric resistant tablets.

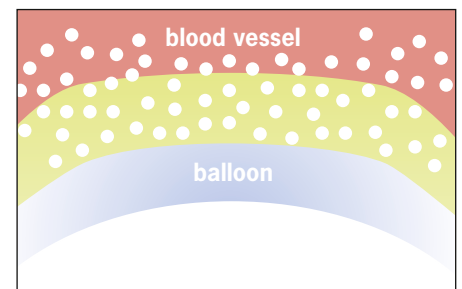
The coating consists of a 1:1 mixture of paclitaxel with shellac applied to the balloon. In contact with body liquid the hydrophilic shellac-network of the composite swells and opens the structure for the pressure-induced fast release of paclitaxel on the inflated balloon.



Coated balloon deflated



In contact with blood



Inflated balloon allows freed paclitaxel to enter the vessel wall

FREWAY™ – SHUNT BALLOON CATHETER

HIGH PRESSURE DEB FOR THE TREATMENT OF SHUNT STENOSIS

FIRST EXPERIENCE WITH DEB IN AV-FISTULAS

Prospective Registry-Design

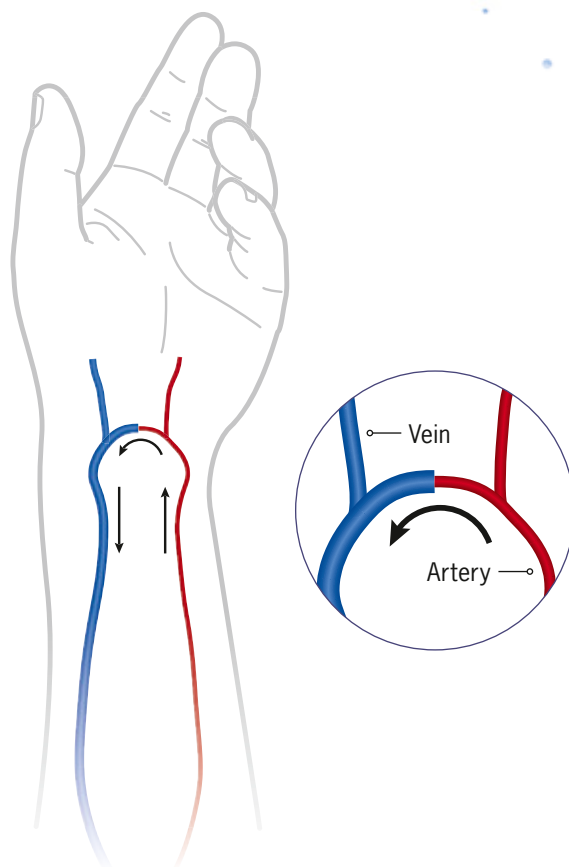
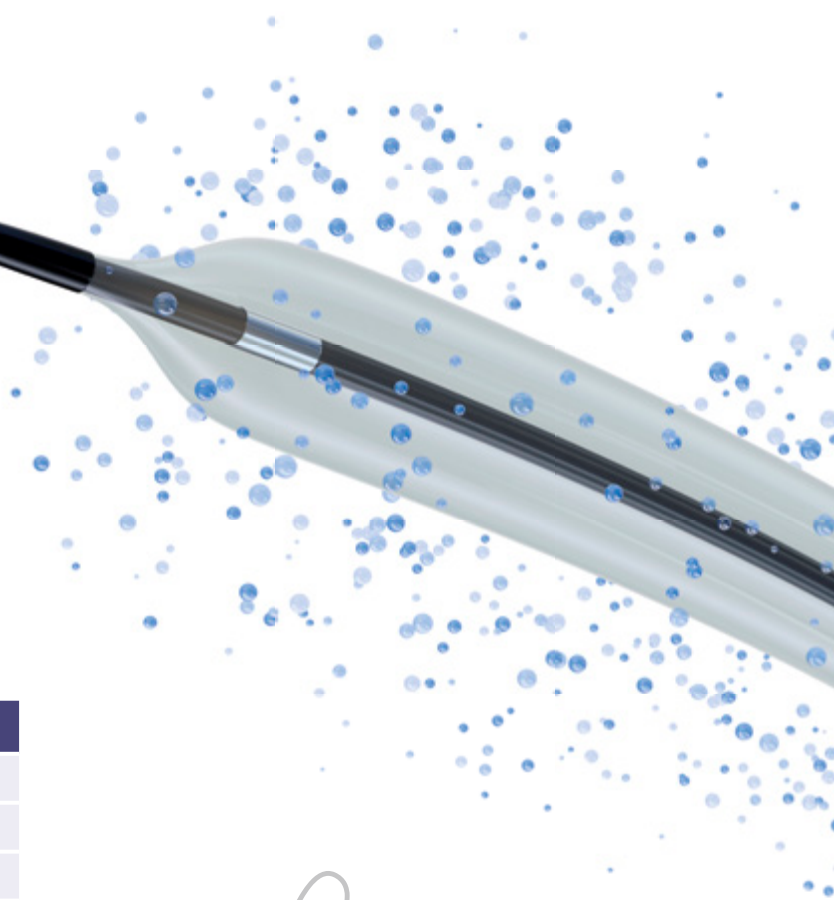
- 33 lesions
- DEB dilatation with mandatory predilatation
- Planned follow-up by ultrasound: 3 months
- St. Joseph Hospital Berlin

BASELINE LESIONS (N=33)

ACCESS TYPE	
AV-Fistula (Cimino)	30.3%
AV-Fistula Basilic	6.1%
AV-Fistula Cephalic	18.2%
AV-Graft	45.5%
Target Lesion Location	
Arterial	6.1%
Venous	90.9%
Anastomosis	3.0%
Lesion Characteristics	
Reference Vessel Diameter [mm]	5.80 ± 0.76
Lesion Length [mm]	16.17 ± 11.67
Stenosis Percentage	84.09%

REVASCULARIZATIONS DURING FOLLOW UP

FOLLOW UP	
Re-Intervention	11.0%



FREEWAY™ – SHUNT BALLOON CATHETER

HIGH PRESSURE DEB FOR THE TREATMENT OF SHUNT STENOSIS

TECHNICAL INFORMATION

FREEWAY™ – SHUNT BALLOON CATHETER	
Design	Bilumen design – over the wire catheter
Balloon diameter	4.0 / 5.0 / 6.0 / 7.0 mm
Balloon length	20 and 40 mm
Usable catheter length (tip to strain relief)	40 cm
Guide wire diameter	0.035" (0.89 mm)
Coating	Hydrophilic coating
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	5 F for 4.0 to 6.0 mm Diameter
	6 F for 7.0 mm Diameter
Nominal pressure	12 atm
Rated burst pressure	20 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	5	40	335-4020 AV
4.0 × 40	20	5	40	335-4040 AV
5.0 × 20	20	5	40	335-5020 AV
5.0 × 40	20	5	40	335-5040 AV
6.0 × 20	20	5	40	335-6020 AV
6.0 × 40	20	5	40	335-6040 AV
7.0 × 20	20	6	40	335-7020 AV
7.0 × 40	20	6	40	335-7040 AV

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