

FREEWAY™ 035 Paclitaxel releasing over the wire (OTW) PTA balloon catheter



FREEWAY™ 035 – latest second-generation drug-releasing technology PTA balloon technology specifically designed for peripheral interventions

FREEWAY™ 035 DEB: Technical data	
Design	Bilumen design - over the wire catheter
Balloon diameter	4.0 / 5.0 / 6.0 / 7.0 and 8.0 mm
Balloon length	20–150 mm
Usable catheter length (tip to strain relief)	80 cm and 135 cm
Guide wire diameter	0.035" (0.91 mm)
Coating	Hydrophilic coating
Balloon material	PA, Polyamid/Nylon
Balloon folding	4-folding for 4 mm and 5 mm 5-folding for 6 to 8 mm
Balloon characteristic	Semi-compliant
Recommended introducer sheath	5 F for 4.0 to 6.0 mm Diameter 6 F for 6.0 and length ≥ 100 mm 6 F for 7.0 and 8.0 mm Diameter
Nominal pressure	6 atm
Rated burst pressure	Balloon length 20 / 40 / 60 mm Diameter 4–6 mm: 16 atm Balloon length 20 / 40 / 60 mm Diameter 7–8 mm: 14 atm Balloon length 80 / 100 / 120 / 150 mm Diameter 4 mm: 16 atm Balloon length 80 / 100 / 120 / 150 mm Diameter 5–6 mm: 14 atm Balloon length 80 / 100 / 120 / 150 mm Diameter 7–8 mm: 12 atm
Packaging unit	1 unit

FREEWAY™ 035 Product order information

Balloon size Diameter x Length (mm)	Rated burst pressure (atm)	Recommended introducer sheath (F)	Order number	Usable catheter length (cm)	
				80	135
4.0 x 20	16	5	335-4020 S	•	•
4.0 x 40	16	5	335-4040 S	•	•
4.0 x 60	16	5	335-4060 S	•	•
4.0 x 80	16	5	335-4080 S	•	•
4.0 x 100	16	5	335-40100 S	•	•
4.0 x 120	16	5	335-40120 S	•	•
4.0 x 150	16	5	335-40150 S	•	•
5.0 x 20	16	5	335-5020 S	•	•
5.0 x 40	16	5	335-5040 S	•	•
5.0 x 60	16	5	335-5060 S	•	•
5.0 x 80	14	5	335-5080 S	•	•
5.0 x 100	14	5	335-50100 S	•	•
5.0 x 120	14	5	335-50120 S	•	•
5.0 x 150	14	5	335-50150 S	•	•
6.0 x 20	16	5	335-6020 S	•	•
6.0 x 40	16	5	335-6040 S	•	•
6.0 x 60	16	5	335-6060 S	•	•
6.0 x 80	14	5	335-6080 S	•	•
6.0 x 100	14	6	335-60100 S	•	•
6.0 x 120	14	6	335-60120 S	•	•
6.0 x 150	14	6	335-60150 S	•	•
7.0 x 20	14	6	335-7020 S	•	•
7.0 x 40	14	6	335-7040 S	•	•
7.0 x 60	14	6	335-7060 S	•	•
7.0 x 80	12	6	335-7080 S	•	•
7.0 x 100	12	6	335-70100 S	•	•
7.0 x 120	12	6	335-70120 S	•	•
7.0 x 150	12	6	335-70150 S	•	•
8.0 x 20	14	6	335-8020 S	•	•
8.0 x 40	14	6	335-8040 S	•	•
8.0 x 60	14	6	335-8060 S	•	•
8.0 x 80	12	6	335-8080 S	•	•
8.0 x 100	12	6	335-80100 S	•	•
4.0 x 20	16	5	335-4020 L	•	•
4.0 x 40	16	5	335-4040 L	•	•
4.0 x 60	16	5	335-4060 L	•	•
4.0 x 80	16	5	335-4080 L	•	•
4.0 x 100	16	5	335-40100 L	•	•
4.0 x 120	16	5	335-40120 L	•	•
4.0 x 150	16	5	335-40150 L	•	•
5.0 x 20	16	5	335-5020 L	•	•
5.0 x 40	16	5	335-5040 L	•	•
5.0 x 60	16	5	335-5060 L	•	•
5.0 x 80	14	5	335-5080 L	•	•
5.0 x 100	14	5	335-50100 L	•	•
5.0 x 120	14	5	335-50120 L	•	•
5.0 x 150	14	5	335-50150 L	•	•
6.0 x 20	16	5	335-6020 L	•	•
6.0 x 40	16	5	335-6040 L	•	•
6.0 x 60	16	5	335-6060 L	•	•
6.0 x 80	14	5	335-6080 L	•	•
6.0 x 100	14	6	335-60100 L	•	•
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7.0 x 80	12	6	335-7080 L	•	•
7.0 x 100	12	6	335-70100 L	•	•
7.0 x 120	12	6	335-70120 L	•	•
7.0 x 150	12	6	335-70150 L	•	•
8.0 x 20	14	6	335-8020 L	•	•
8.0 x 40	14	6	335-8040 L	•	•
8.0 x 60	14	6	335-8060 L	•	•
8.0 x 80	12	6	335-8080 L	•	•
8.0 x 100	12	6	335-80100 L	•	•

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



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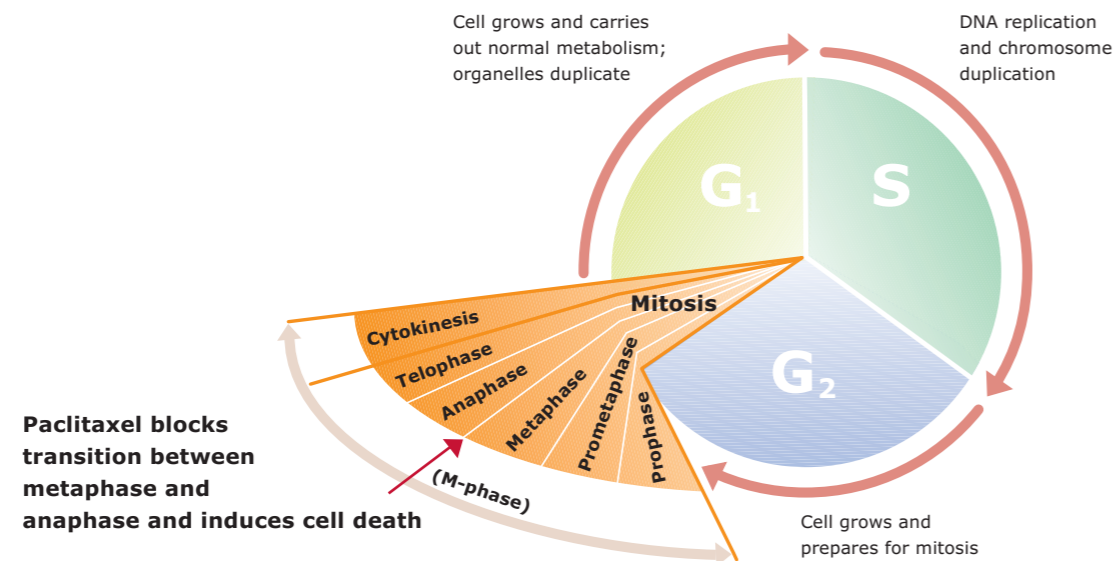
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B383/2806/10



Paclitaxel

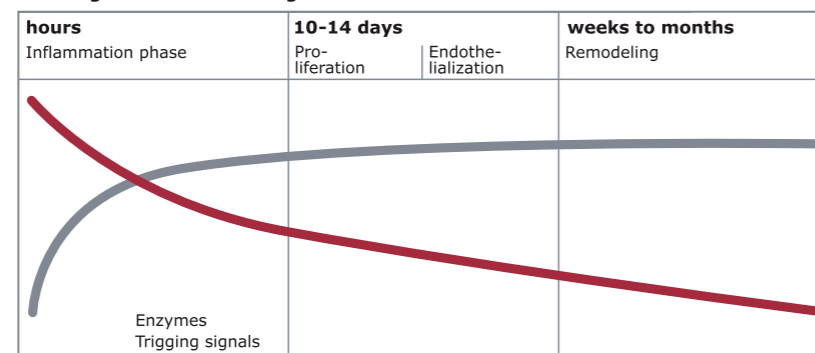
Paclitaxel prevents restenosis by blocking proper microtubul formation, thus it inhibits cell division and migration. It inhibits inflammatory processes. After balloon dilatation, injuries to the arterial wall stimulate inflammatory reaction, and the excretion of growth factors occurs as an important 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 are more resistant 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



Paclitaxel distribution in tissue after acute dosing using **FREEWAY™ 035**
Paclitaxel distribution in tissue after chronic dosing using DES

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

Shellac

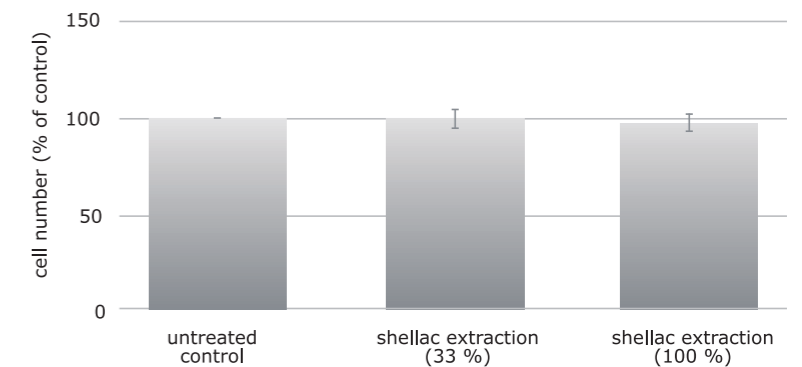
The coating makes the difference

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

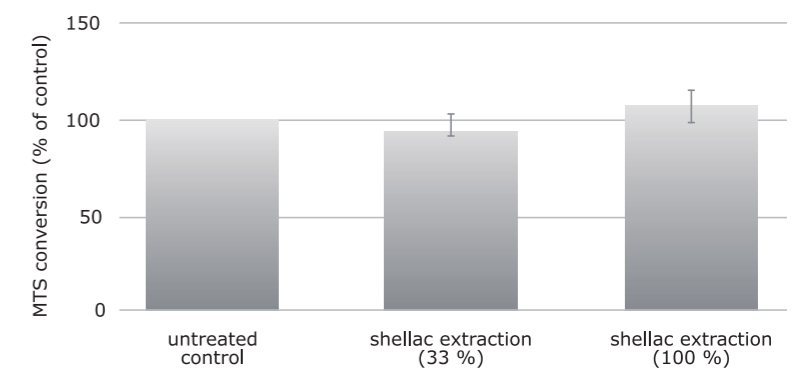
The FREEWAY™ 035 Bioshell coating matrix consists of a natural resin, which is EMEA and FDA approved (GRAS) as food additive under E 904.

Investigation of cytotoxicity

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



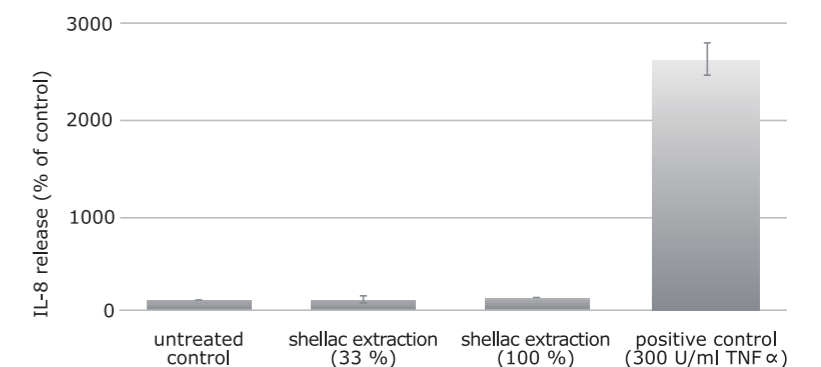
Quantification of cell quantity
Metabolic cell activity (MTS-assay)



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

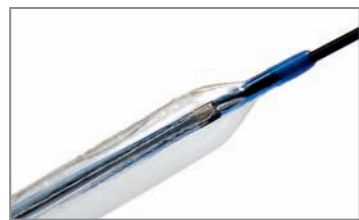


Neither direct contact to shellac-coated materials nor exposure to shellac extraction products impaired HDMEC and hSMC viability and function *in vitro*.

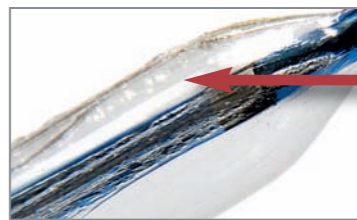
Peters K, Prinz C, Salamon A, Adam A, Stuhldreier G, Rychly J, Neumann H-G. Evaluation of shellac as coating of intravascular devices – Testing of *in vitro* compatibility by endothelial and smooth muscle cells. Jahrestagung der Deutschen Gesellschaft für Biomaterialien, 8.-10.10.2009, Tübingen

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

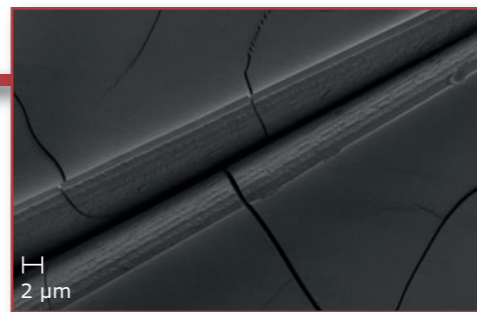
The coating consists of a 1:1 mixture of Paclitaxel with shellac applied to the balloon by a micro-pipetting procedure in a clean room under sterile conditions.



Exclusive bioshell coating



Compared to competitive products shellac gives the balloon a shiny appearance

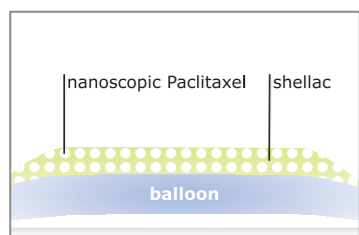


Shellac coating section (scanned electron microscope image)*

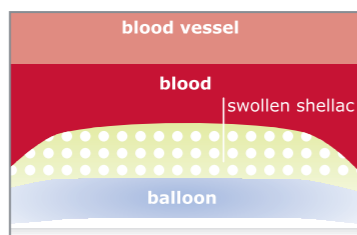
*Very smooth surface – less vulnerable to abrasion

The FREEWAY™ 035 Paclitaxel releasing balloon catheter

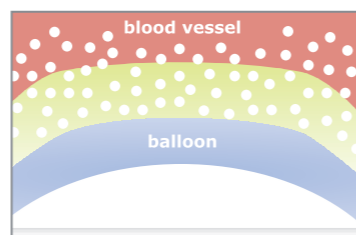
In contact with body liquid the hydrophilic shellac-network of the composite swells and opens the structure for the pressure-induced fast release of Paclitaxel on the inflated balloon.



coated balloon deflated

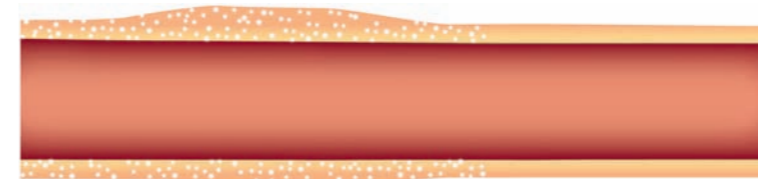
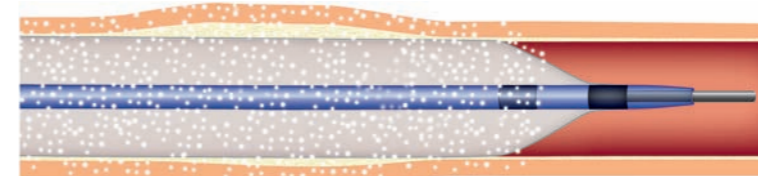
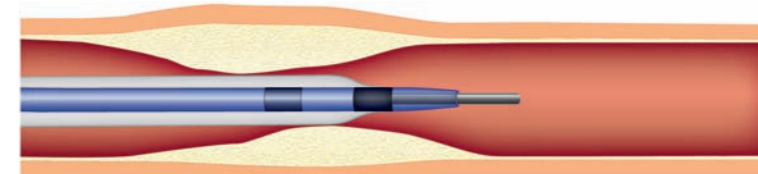
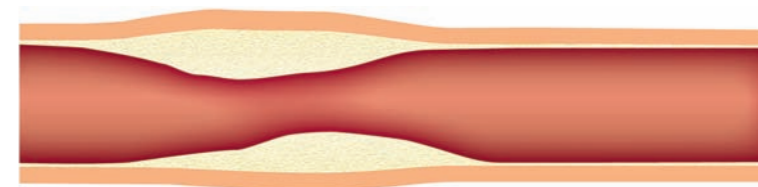


in contact with blood



inflated balloon allows freed Paclitaxel to enter the vessel wall

FREEWAY™ 035, peripheral PTA balloon 0.035" 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™ 035 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™ 035 – shellac conclusion

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

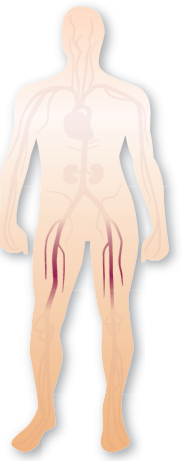
Paclitaxel is applied in a final concentration of 3 µg/mm² to the surface of the balloon.

Tissue concentrations of Paclitaxel reached by this coating is inflation time dependent: after 30 seconds or more of inflation a concentration of 200 µM/L is reached.

Posá et al.: CCI 2010

FREEWAY™ 035

Paclitaxel releasing over the wire (OTW) PTA balloon catheter



FREEWAY™ 035 – OTW balloons for successful peripheral interventions

A treatment concept with extraordinary developed products

- Wide spectrum of balloon catheters for treating long, diffuse lesions
 - Up to 150 mm balloon length
 - High rated burst pressure up to 16 atm for treating calcified lesions
- Nominal pressure of 6 atm
- Elaborated catheter technology with good crossability, trackability and pushability for treatment of diffuse lesions
 - Dual-lumen shaft design with hydrophilic lubricious coating on distal shaft
- Precise, controlled dilatation
 - Controlled compliance for accurate balloon vessel sizing
 - Flat shoulders
- Short deflation time

Reach your destination with an enhanced FREEWAY™ OTW 0.035" balloon designed to cross smoothly and deflate quickly.

FREEWAY™ 035, peripheral PTA balloon 0.035" OTW

Eurocor's latest, second-generation drug-eluting technology with an immediate short-term drug release effect

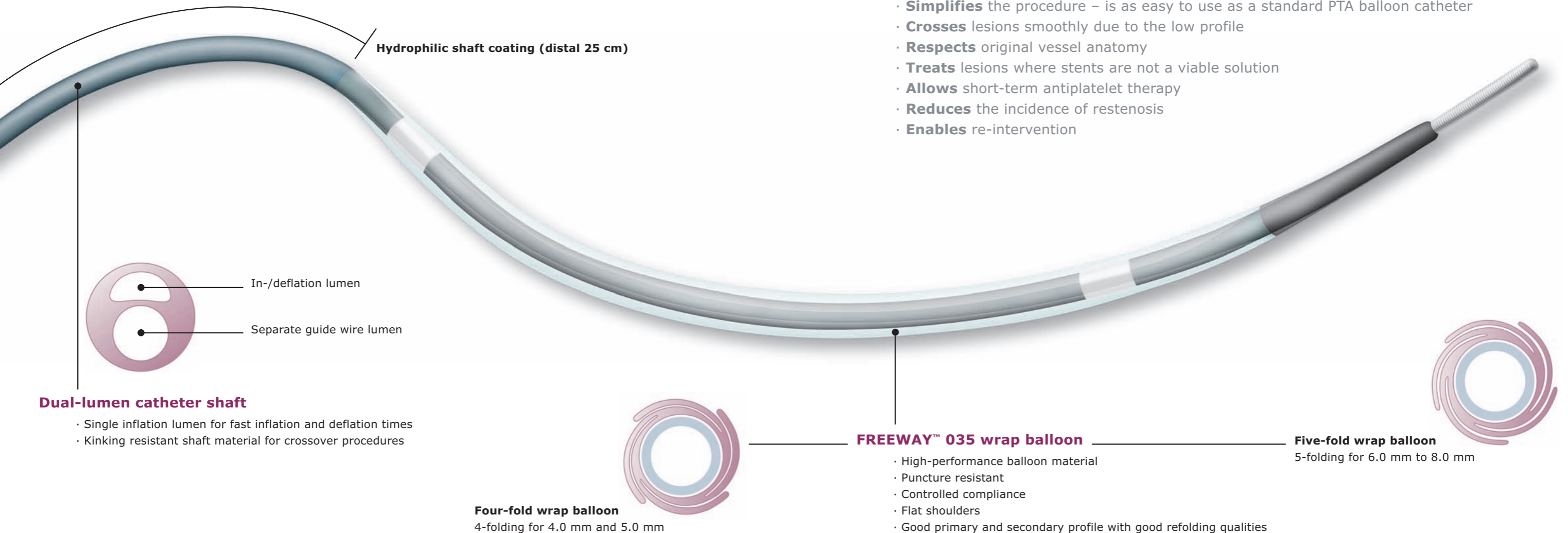
An innovative therapeutic treatment concept specifically designed for peripheral interventions

- 4–8 mm balloon diameter
- 20–150 mm balloon length for 4-7 mm and 20-100 mm balloon length for 8 mm diameter
- 80 cm and 135 cm shaft lengths

FREEWAY™ 035, peripheral PTA balloon 0.035" 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



Hydrophilic shaft coating (distal 25 cm)

In-/deflation lumen

Separate guide wire lumen

Dual-lumen catheter shaft

- Single inflation lumen for fast inflation and deflation times
- Kinking resistant shaft material for crossover procedures

Four-fold wrap balloon

4-folding for 4.0 mm and 5.0 mm

FREEWAY™ 035 wrap balloon

- High-performance balloon material
- Puncture resistant
- Controlled compliance
- Flat shoulders
- Good primary and secondary profile with good refolding qualities

Five-fold wrap balloon

5-folding for 6.0 mm to 8.0 mm