FREEWAY™ 035

Drug-Eluting PTA Balloon Technology

Specifically designed for peripheral interventions

Proven safety & efficacy [1, 3, 4, 5, 6]

Eurocor

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FREEWAY™ 035

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Balloon Coating

FREEWAY™ 035 utilizes an amorphous bioshell coating technology consisting of a 1:1 mixture of paclitaxel and shellac.

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.

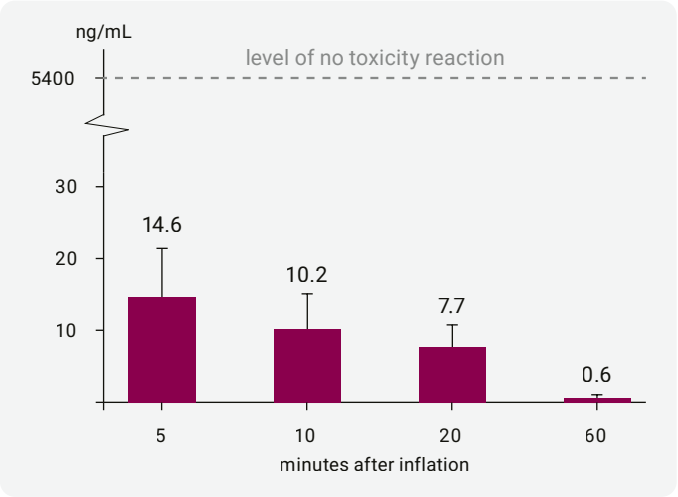
Shellac

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.

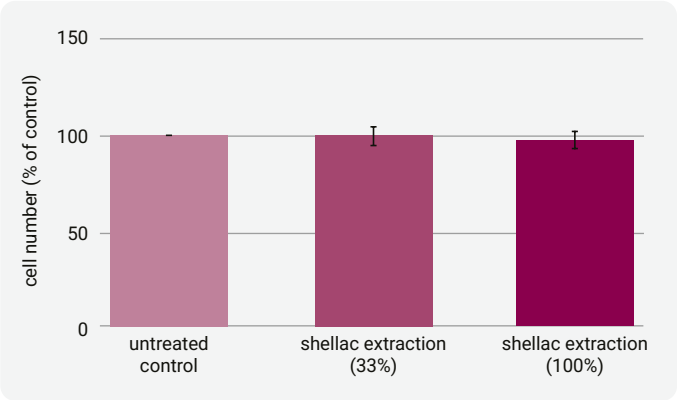
Amorphous Coating

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.

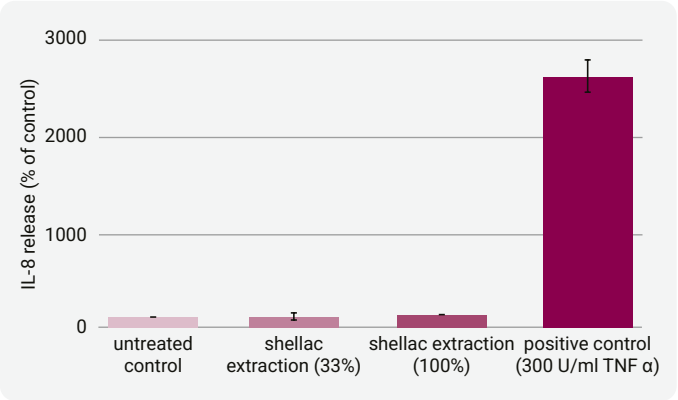
Paclitaxel blood plasma concentrations at 5, 10, 20 and 60 minutes after inflation (120 sec) with FREEWAY™ DEB. [1] Level of toxicity for paclitaxel plasma concentration calculated with a human body surface area of 1.9 m² and blood plasma content of 3.5 l. [2]



Investigation of cytotoxicity



Shellac extracts do not impair viability and metabolic activity of EC & SMC [3]



Shellac extracts show no signs of pro-inflammatory activation [3]

THE COATING MAKES THE DIFFERENCE™

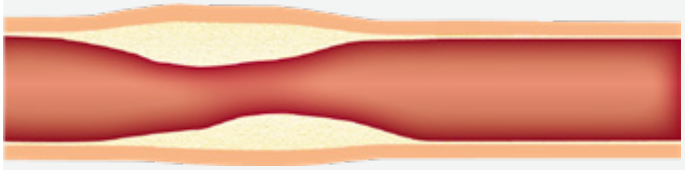
Amorphous coating minimizes wash-off effects.
Shellac does not show any cytotoxicity – Shellac is safe.

[1] 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.

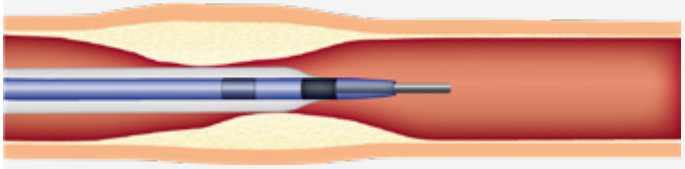
[2] Margolis J et al. "Systemic nanoparticle paclitaxel (nab-paclitaxel) for in-stent restenosis I (SNAPIST-I): a first-in-human safety and dose-finding study." Clinical cardiology 2007 30(4): 165-170.

[3] 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.

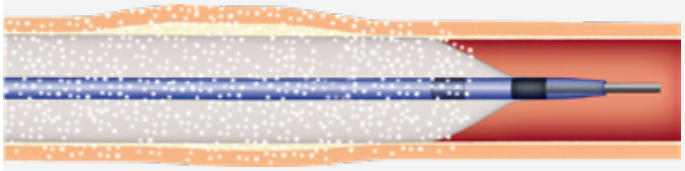
How it works



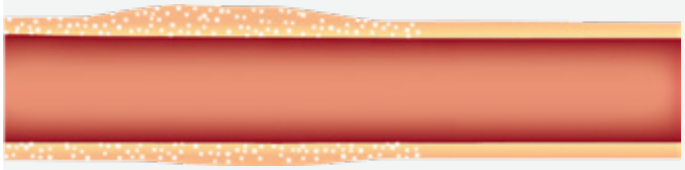
Various types of PAD indications are associated with the narrowing or occlusion of arterial blood vessels.



After predilatation, the FREEWAY™ 035 paclitaxel-eluting PTA balloon catheter is advanced to the lesion site.

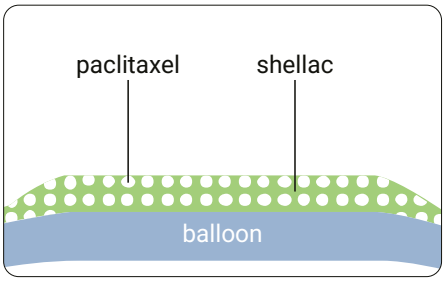


With the balloon well positioned, inflation for at least 120 seconds releases an optimal amount of the anti-proliferative drug.



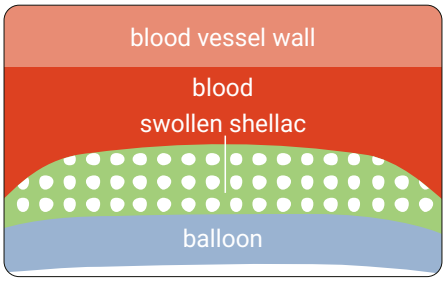
The balloon is withdrawn as the drug penetrates into the artery wall. Paclitaxel acts immediately and efficiently within a short period of time. The shellac coating remains on the balloon.

Coating Transfer



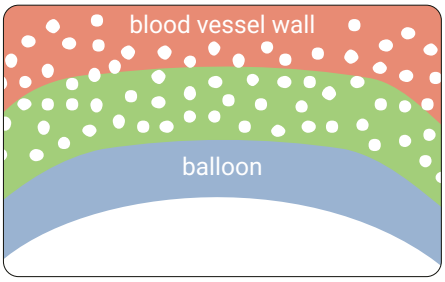
Coated balloon deflated

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

Balloon dilatation causes vascular injury which triggers smooth muscle cell proliferation in the intima, leading to restenosis. FREEWAY™ 035 delivers paclitaxel to the arterial wall and thereby inhibits neointimal hyperplasia and promotes re-endothelialization.

EFFECTIVE BIOSHELL COATING [1, 4, 5, 6]

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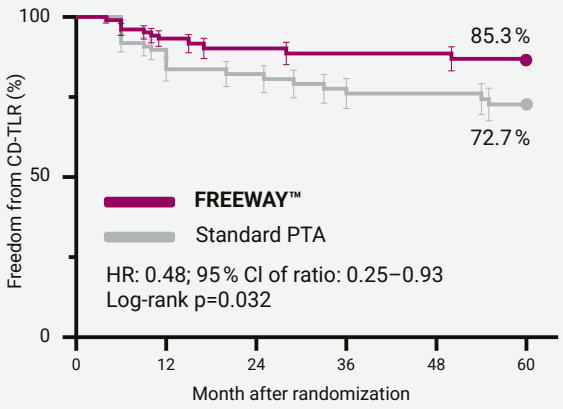
Freeway Long-term Study [4]

1:1 Randomization
148 Patients in 13 centers in Austria and Germany

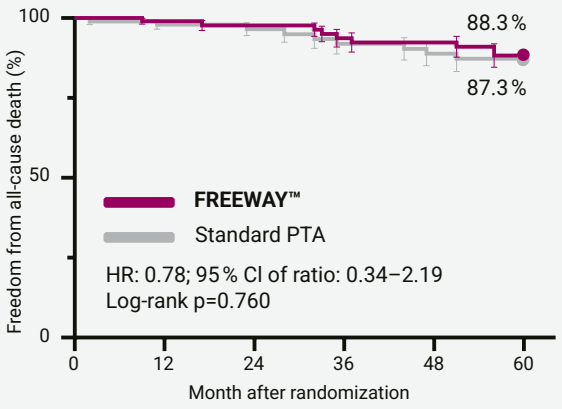
→ Nitinolstent + **FREEWAY™** DEB post dilatation (n=105) → 12 months follow-up (n=98) [5] → 5-year follow-up (n=75) [4]

→ Nitinolstent + PTA postdilatation (n=99) → 12 months follow-up (n=79) [5] → 5-year follow-up (n=73) [4]

5 Year Freedom from CD-TLR



5 Year Freedom from all-cause death



Significantly reduced need for clinically-driven target lesion revascularization at 5 years (FREEWAY™ 85.3 % vs PTA 72.7 %, p=0.032)

No elevated mortality

No trend for any accumulation of causes of death in both groups

No difference in administered paclitaxel dose in alive vs. died patients

No difference in minor or major amputations in both groups

[4] Hausegger K et al. "Long-term Follow-up and Mortality Rate of Patients of the Randomized Freeway Stent Study." Cardiovasc Intervent Radiol 2024 47(2), 186-193

[5] Tacke J et al. "The Randomized Freeway Stent Study: Drug-Eluting Balloons Outperform Standard Balloon Angioplasty for Postdilatation of Nitinol Stents in the SFA and PI Segment." Cardiovasc Intervent Radiol 2019 42(11): 1513-1521.

Freeway Stent Study [5]

FREEWAY™ Δ 16.4 %
better Primary Patency

at 12 months compared to post-stent dilatation with standard balloon

Study type and focus

- randomized multicenter trial in Austria and Germany
- 204 patients with *de novo* or restenotic lesions that needed stent implantation

Main findings at 12 months follow-up

1. **significantly higher primary patency**
2. **clearly lower target lesion revascularization rate**
3. **significantly better improvement in Rutherford clinical classifications and**
4. **proven safety due to low major adverse events rate**

for patients treated with stent + FREEWAY™ 035 DEB compared to stent + standard balloon PTA.

Primary Patency at 12 months

stent postdilatation with **FREEWAY™** DEB

stent postdilatation with standard PTA

PACUBA Trial [6]

FREEWAY™ Δ 27.3 %
better Primary Patency

at 12 months compared to PTA with standard balloon

Study type and focus

- randomized study in Austria
- 74 patients with in-stent restenosis

Main findings at 12 months follow-up

1. **significantly higher primary patency**
2. **clearly lower target lesion revascularization rate**
3. **clearly better improvement in Rutherford clinical classifications and**
4. **proven safety due to low major adverse events rate**

for patients treated with FREEWAY™ 035 DEB compared to standard balloon PTA.

[5] Tacke J et al. "The Randomized Freeway Stent Study: Drug-Eluting Balloons Outperform Standard Balloon Angioplasty for Postdilatation of Nitinol Stents in the SFA and PI Segment." Cardiovasc Intervent Radiol 2019 42(11): 1513-1521.

[6] Kinstner CM et al. "Paclitaxel-eluting balloon versus standard balloon angioplasty in in-stent restenosis of the superficial femoral and proximal popliteal artery: 1-year results of the PACUBA trial." JACC 2016 9(13): 1386-1392.

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Preclinical Program

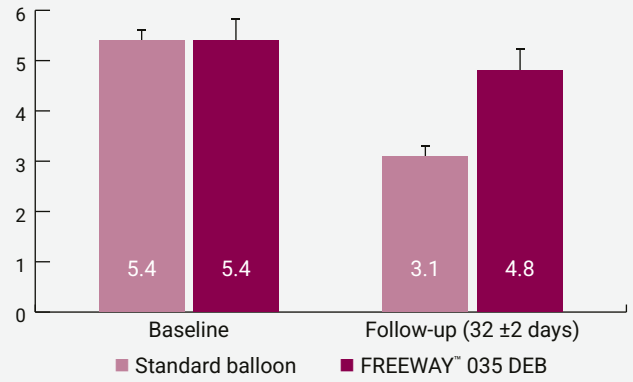
FREEWAY™ 035 DEB

Domestic swine femoral arteries (n = 54) underwent percutaneous overstretch balloon dilation, controlled by optical coherence tomography (OCT). Paclitaxel tissue uptake was measured at 1h, 1 and 3 days.

- No delay in endothelialization, no disadvantages in injury and inflammation score compared to standard balloon dilatation (femoral arteries 32 ± 2 days).
- FREEWAY™ 035 DEB demonstrated safety and efficacy in a preclinical model of overstretch injury in peripheral arteries.
- Reaching the effective concentration of paclitaxel in the arterial wall with FREEWAY™ 035 DEB inflation.

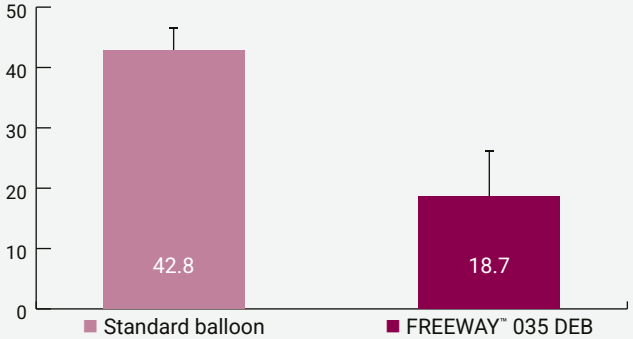
Minimum Lumen Diameter (mm)

Minimum lumen diameter of femoral arteries at baseline and 32 days follow-up. FREEWAY™ 035 DEB inhibited fibrin accumulation in the intima and media, **leading to significantly less constrictive remodeling and reduced neointimal hyperplasia** of the injured vessel compared to uncoated balloons. [1]



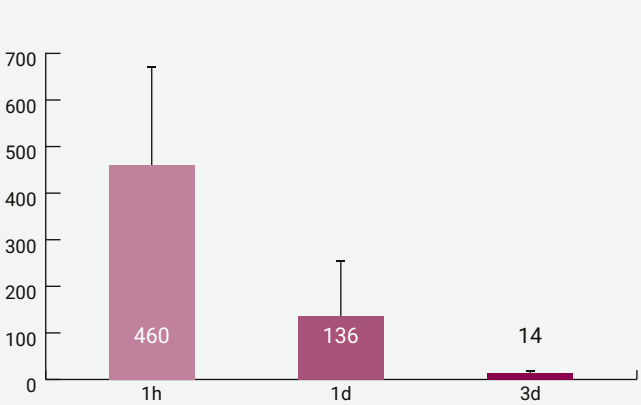
Area Stenosis (mm²) at FU

Vessels treated with FREEWAY™ 035 DEB show **significantly lower area of stenosis** in at 32 days follow-up compared to uncoated balloon treatment. [1]



Tissue paclitaxel concentration (ng/mg) Inflation time 120s

Inflation of **120s** with FREEWAY™ DEB leads to long presence and high concentration of paclitaxel in the arterial wall [1] – crucial for inhibition of neointimal proliferation and restenosis.



[1] 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.

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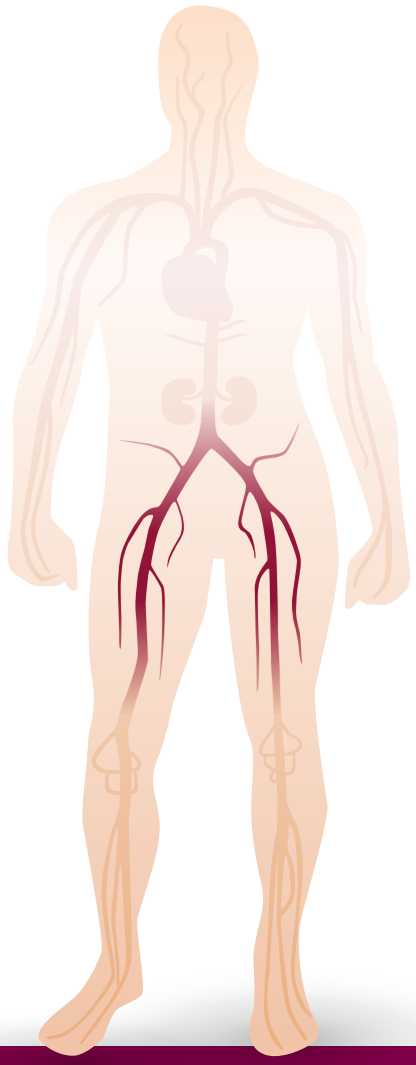
Advanced Product Features

- Wide spectrum of balloon catheters for treating long, diffuse lesions
- Elaborated catheter technology with hydrophilic lubricious coating on distal shaft and good crossability, trackability and pushability for treatment of diffuse lesions
- Precise, controlled dilatation
  - Controlled compliance for accurate balloon vessel sizing
  - Flat balloon shoulders

Dual-lumen catheter shaft

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



Advanced Product 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

FREEWAY™ 035 – DRUG-ELUTING PTA BALLOON TECHNOLOGY	
Design	Bilumen design – catheter
Balloon diameter	4.0 / 5.0 / 6.0 / 7.0 and 8.0 mm
Balloon length	20 – 230 mm
Usable catheter length (tip to strain relief)	80 cm and 135 cm
Guide wire diameter	0.035" (0.91 mm)
Shaft coating	Hydrophilic
Balloon coating	Paclitaxel (3 µg/mm²) within a shellac matrix (1:1 ratio)
Balloon material	PA, Polyamid/Nylon
Balloon characteristic	Semi-compliant
Recommended introducer sheath	5 F for 4.0 mm Diameter / 6 F for 5.0 and 6.0 mm Diameter / 7 F for 7.0 and 8.0 mm Diameter
Recommended balloon inflation time	120 sec
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 190 / 230 mm, Diameter 4 mm: 14 atm
	Balloon length 80 / 100 / 120 / 150 mm, Diameter 5 – 6 mm: 14 atm
	Balloon length 190 / 230 mm, Diameter 5 – 6 mm: 12 atm
	Balloon length 80 / 100 / 120 / 150 mm, Diameter 7 – 8 mm: 12 atm
	Balloon length 190 / 230 mm, Diameter 7 mm: 10 atm
Packaging unit	1 unit

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Product ordering information

Balloon size diameter × length (mm)	Rated burst pressure (atm)	Recommended introducer sheath (F)	Order number
Usable catheter length 80 cm			
4.0 × 20	16	5	335-4020 S
4.0 × 40	16	5	335-4040 S
4.0 × 60	16	5	335-4060 S
4.0 × 80	16	5	335-4080 S
4.0 × 100	16	5	335-40100 S
4.0 × 120	16	5	335-40120 S
4.0 × 150	16	5	335-40150 S
4.0 × 190	14	5	335-40190 S
4.0 × 230	14	5	335-40230 S
5.0 × 20	16	6	335-5020 S
5.0 × 40	16	6	335-5040 S
5.0 × 60	16	6	335-5060 S
5.0 × 80	14	6	335-5080 S
5.0 × 100	14	6	335-50100 S
5.0 × 120	14	6	335-50120 S
5.0 × 150	14	6	335-50150 S
5.0 × 190	12	6	335-50190 S
5.0 × 230	12	6	335-50230 S
6.0 × 20	16	6	335-6020 S
6.0 × 40	16	6	335-6040 S
6.0 × 60	16	6	335-6060 S
6.0 × 80	14	6	335-6080 S
6.0 × 100	14	6	335-60100 S
6.0 × 120	14	6	335-60120 S
6.0 × 150	14	6	335-60150 S
6.0 × 190	12	6	335-60190 S
6.0 × 230	12	6	335-60230 S
7.0 × 20	14	7	335-7020 S
7.0 × 40	14	7	335-7040 S
7.0 × 60	14	7	335-7060 S
7.0 × 80	12	7	335-7080 S
7.0 × 100	12	7	335-70100 S
7.0 × 120	12	7	335-70120 S
7.0 × 150	12	7	335-70150 S
7.0 × 190	10	7	335-70190 S
7.0 × 230	10	7	335-70230 S
8.0 × 20	14	7	335-8020 S
8.0 × 40	14	7	335-8040 S
8.0 × 60	14	7	335-8060 S
8.0 × 80	12	7	335-8080 S
8.0 × 100	12	7	335-80100 S

Balloon size diameter × length (mm)	Rated burst pressure (atm)	Recommended introducer sheath (F)	Order number
Usable catheter length 135 cm			
4.0 × 20	16	5	335-4020 L
4.0 × 40	16	5	335-4040 L
4.0 × 60	16	5	335-4060 L
4.0 × 80	16	5	335-4080 L
4.0 × 100	16	5	335-40100 L
4.0 × 120	16	5	335-40120 L
4.0 × 150	16	5	335-40150 L
4.0 × 190	14	5	335-40190 L
4.0 × 230	14	5	335-40230 L
5.0 × 20	16	6	335-5020 L
5.0 × 40	16	6	335-5040 L
5.0 × 60	16	6	335-5060 L
5.0 × 80	14	6	335-5080 L
5.0 × 100	14	6	335-50100 L
5.0 × 120	14	6	335-50120 L
5.0 × 150	14	6	335-50150 L
5.0 × 190	12	6	335-50190 L
5.0 × 230	12	6	335-50230 L
6.0 × 20	16	6	335-6020 L
6.0 × 40	16	6	335-6040 L
6.0 × 60	16	6	335-6060 L
6.0 × 80	14	6	335-6080 L
6.0 × 100	14	6	335-60100 L
6.0 × 120	14	6	335-60120 L
6.0 × 150	14	6	335-60150 L
6.0 × 190	12	6	335-60190 L
6.0 × 230	12	6	335-60230 L
7.0 × 20	14	7	335-7020 L
7.0 × 40	14	7	335-7040 L
7.0 × 60	14	7	335-7060 L
7.0 × 80	12	7	335-7080 L
7.0 × 100	12	7	335-70100 L
7.0 × 120	12	7	335-70120 L
7.0 × 150	12	7	335-70150 L
7.0 × 190	10	7	335-70190 L
7.0 × 230	10	7	335-70230 L
8.0 × 20	14	7	335-8020 L
8.0 × 40	14	7	335-8040 L
8.0 × 60	14	7	335-8060 L
8.0 × 80	12	7	335-8080 L
8.0 × 100	12	7	335-80100 L

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

Rev. Nr.: 0825 B FW035 EN