FREEWAY™ 035 Paclitaxel Eluting PTA Balloon Catheter

Technical Data Sheet

Description

The Eurocor Tech Freeway™ 035 Paclitaxel eluting PTA balloon catheter has an over-the-wire (OTW) design and a semi-compliant balloon mounted on the distal part of the catheter. It has a bi-luminal shaft design. The one lumen (guidewire lumen) permits the use of a guidewire with a maximum outer diameter of 0.89mm (0.035 inch). The other lumen (balloon inflation lumen) is used for balloon inflation and deflation with sterile saline solution or a mixture of saline and contrast media (1:1). The proximal part of the catheter includes one female luer-lock port connected to the inflation lumen, and one female luer-lock for the guidewire lumen.

Freeway 035 PTA is compatible with a 5F (1.67 mm) – 6F (2.00 mm) introducer sheath; the Freeway 035 AV Shunt is compatible with 6F (2.00 mm) and 7F (2.33 mm). The hydrophilic coating which covers the distal part of the catheter reduces friction, facilitating passage through the vessels. Two radiopaque markers indicating the beginning and the end of the balloon's cylindrical section are placed inside the balloon. They aid in positioning the balloon in the desired location, as well as, in conjunction with fluoroscopy, enable accurate positioning of the balloon within the vessel.
The Freeway 035 has a tapered and atraumatic tip for easy entry into peripheral arteries and to improve crossing of tight stenosis.

The device is available in different balloon sizes. Nominal balloon diameter and length are printed on the hub, on the pouch label and on the cardboard box label.

Fig. 1: Schematic drawing of the FREEWAY™ 035 Paclitaxel eluting PTA balloon catheter.

The coating of the balloon consists of a degradable, drug-eluting shellac-paclitaxel composite (mixture: 1.1), the mass proportion of paclitaxel is 3.0 µg per mm2 balloon surface. The coating layer of Freeway 035 is applied to release an effectual proportion of paclitaxel to the vessel wall of the artery at the dilated stenosis. The durable non-crystalline bioshell coating homogenously covers the balloon surface and protects the drug from mechanical abrasion and early wash off. The active ingredient paclitaxel inhibits the cell replication thus blocking the microtubules' decomposition during meta- and anaphase stages of mitosis. Paclitaxel selectively inhibits the proliferation of smooth muscle cells and does not influence non-proliferating cells. Therefore, paclitaxel effectively reduces the risk of restenosis in the vessel caused by smooth muscle cell proliferation. During the insertion of the balloon catheter and tracking to the coronary lesion, the three-folded balloon protects the loaded drug substance from early wash of effects. Paclitaxel is released at the lesion site. Bioavailability of paclitaxel is guaranteed by the drug-integral coating composition. Shellac is a biodegradable natural resin composed of shellolic and alleuritic acid. The film forming properties of shellac are used to coat products in the pharmaceutical and food industry; shellac has been toxicologically tested accordingly.

Medical Device Nomenclature

EMDN: C010402020199 PTA Dilatation Catheters – other
GMDN: 62551 Peripheral angioplasty balloon catheter, drug-coated
UMDNS: 17184 Catheters, Angioplasty, Balloon Dilatation

Intended Use and Contraindications

The FREEWAY™035 Paclitaxel eluting PTA Balloon Catheter is intended for restoring the diameter of the arterial lumen and avoiding restenosis for the treatment of lesions in peripheral arteries. The catheter is intended for widening stenosis in the iliac, popliteal, infra-popliteal and renal arteries and for treating obstructive lesions of native or artificial arterio-venous dialysis fistulas.

This balloon is also intended for stent post-dilatation in the peripheral vascular system.

Indications include de novo lesions, restenosis after realization of balloon and/or stent PTA, and pre-/post-dilatation in case of peripheral stent implantation.

The use of the FREEWAY™035 Paclitaxel eluting PTA Balloon Catheter is contraindicated in case of:

- Intolerance of paclitaxel and/or shellac
- Allergies to paclitaxel and/or shellac
- Severe allergy to contrast medium
- Pregnancy and lactation
- Haemorrhagic diathesis or disorders such as e.g. gastrointestinal ulceration or cerebral circulation disorders limiting the use of thrombocyte aggregation inhibitors and anticoagulation therapy
- Lesions that probably cannot be treated with PTA or other interventional techniques
- Contraindication for the co-medication required in each case
- Spasm without significant stenosis
- The use of the FREEWAY™035 PTA Balloon Dilatation Catheter and a drug-eluting stent at the identical target lesion should be avoided since an overdose or an interaction between the active substances cannot be ruled out.

Available Sizes

Balloon Size		Ordering Information	Shaft length
Diameter (mm)	Length (mm)		S: 80 cm L: 135 cm AV (Shunt): 40 cm
4	20	335-4020	S
4	40	335-4040	S
4	60	335-4060	S
4	80	335-4080	S
4	100	335-40100	S
4	120	335-40120	S
4	150	335-40150	S
4	190	335-40190	S
4	230	335-40230	S
5	20	335-5020	S
5	40	335-5040	S
5	60	335-5060	S
5	80	335-5080	S
5	100	335-50100	S
5	120	335-50120	S
5	150	335-50150	S
5	190	335-50190	S
5	230	335-50230	S
6	20	335-6020	S
6	40	335-6040	S
6	60	335-6060	S
6	80	335-6080	S
6	100	335-60100	S
6	120	335-60120	S
6	150	335-60150	S
6	190	335-60190	S
6	230	335-60230	S
7	20	335-7020	S
7	40	335-7040	S
7	60	335-7060	S
7	80	335-7080	S
7	100	335-70100	S
7	120	335-70120	S
7	150	335-70150	S
7	190	335-70190	S
7	230	335-70230	S
8	20	335-8020	S
8	40	335-8040	S
8	60	335-8060	S
8	80	335-8080	S
8	100	335-80100	S
4	20	335-4020	L
4	40	335-4040	L
4	60	335-4060	L

Balloon Size		Ordering Information	Shaft length
Diameter (mm)	Length (mm)		S: 80 cm L: 135 cm AV (Shunt): 40 cm
4	80	335-4080	L
4	100	335-40100	L
4	120	335-40120	L
4	150	335-40150	L
4	190	335-40190	L
4	230	335-40230	L
5	20	335-5020	L
5	40	335-5040	L
5	60	335-5060	L
5	80	335-5080	L
5	100	335-50100	L
5	120	335-50120	L
5	150	335-50150	L
5	190	335-50190	L
5	230	335-50230	L
6	20	335-6020	L
6	40	335-6040	L
6	60	335-6060	L
6	80	335-6080	L
6	100	335-60100	L
6	120	335-60120	L
6	150	335-60150	L
6	190	335-60190	L
6	230	335-60230	L
7	20	335-7020	L
7	40	335-7040	L
7	60	335-7060	L
7	80	335-7080	L
7	100	335-70100	L
7	120	335-70120	L
7	150	335-70150	L
7	190	335-70190	L
7	230	335-70230	L
8	20	335-8020	L
8	40	335-8040	L
8	60	335-8060	L
8	80	335-8080	L
8	100	335-80100	L
4	20	335-4020	AV
4	40	335-4040	AV
4	60	335-4060	AV
5	20	335-5020	AV
5	40	335-5040	AV
5	60	335-5060	AV

Balloon Size		Ordering Information	Shaft length
Diameter (mm)	Length (mm)		S: 80 cm L: 135 cm AV (Shunt): 40 cm
6	20	335-6020	AV
6	40	335-6040	AV
6	60	335-6060	AV
7	20	335-7020	AV
7	40	335-7040	AV
7	60	335-7060	AV
8	20	335-8020	AV
8	40	335-8040	AV
8	60	335-8060	AV

Compliance Charts

Compliance Chart FREEWAY™ 035

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Engineering for clinical success

Inflation atm/bar	Pressure kPa	Balloon Diameter (mm) 4.00	5.00	6.00	7.00	8.00
4	400	3.78	4.80	5.68	6.67	7.45
6	600	4.00*	5.00*	6.00*	7.00*	8.00*
8	800	4.15	5.15	6.16	7.19	8.31
10	1000	4.28	5.26	6.30	7.33****	8.53
11	1100	4.33	5.31	6.37	7.41	8.64
12	1200	4.40	5.37****	6.44****	7.48***	8.77***
13	1300	4.46	5.43	6.52	7.55	8.89
14	1400	4.53****	5.49***	6.59***	7.63**	9.00**
15	1500	4.60	5.58	6.67	7.70	9.12
16	1600	4.67** ***	5.64**	6.79**	7.78	9.25
17	1700	4.75	5.72	6.84		
18	1800	4.83	5.80			

* Nominal Pressure
** Rated Burst Pressure (RBP) for balloon length 20 – 60 mm
*** Rated Burst Pressure (RBP) for balloon length 80 – 150 mm
**** Rated Burst Pressure (RBP) for balloon length 190 – 230 mm

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Compliance Chart FREEWAY™ 035 AV Shunt

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Engineering for clinical success

Inflation atm/bar	Pressure kPa	Balloon Diameter (mm) 4.00	5.00	6.00	7.00	8.00
4	400	3.56	4.44	5.32	6.15	7.09
6	600	3.68	4.61	5.52	6.45	7.36
8	800	3.80	4.75	5.69	6.66	7.60
10	1000	3.91	4.89	5.86	6.85	7.80
11	1100	3.96	4.95	5.94	6.93	7.91
12	1200	4.00*	5.00*	6.00*	7.00*	8.00*
13	1300	4.04	5.05	6.08	7.09	8.13
14	1400	4.07	5.10	6.14	7.15	8.21
15	1500	4.10	5.14	6.20	7.21	8.30
16	1600	4.13	5.18	6.26	7.28	8.39
17	1700	4.15	5.22	6.33	7.35	8.50
18	1800	4.18***	5.26***	6.40***	7.42***	8.62** ***
19	1900	4.21	5.30	6.47	7.49	8.71
20	2000	4.24**	5.35**	6.54**	7.57**	8.81

* Nominal Pressure
** Rated Burst Pressure (RBP) for balloon length 20 – 40 mm
*** Rated Burst Pressure (RBP) for balloon length 60 mm and 20–60 mm for balloon Ø 8.00 mm

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Device Components and Raw Material

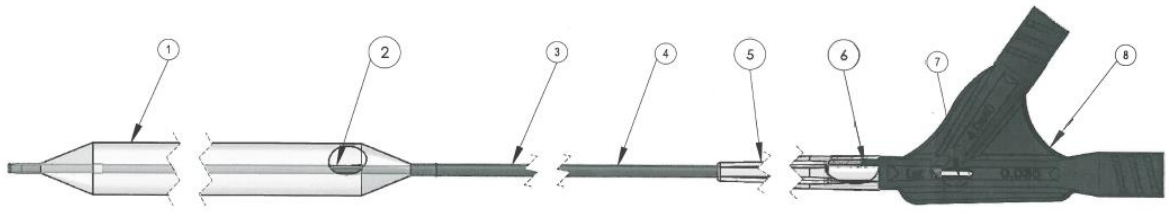


Fig. 2: Schematic drawing of the FREEWAY™ 035 Paclitaxel eluting PTA balloon catheter device components.

No.	Description	Material	Quantity
1	PTA Balloon	Grilamid L25	1
2	Stem Tubing	Pebax 7233	1
3	Hydrophilic coating	"Slip Skin"/MCTec BV	-
4	Bilumen Tubing	Pebax 7233	1
5	Molded Strain Relief	Pebax 4033	1
6	Gluing Tubing	Grilamid L25	1
7	Prox. Guidewire Tubing	Grilamid L25	1
8	Hub Bilumen	PC Makrolon 2458	1
-	Radiopaque Markers	Pt/Ir (90/10)	2

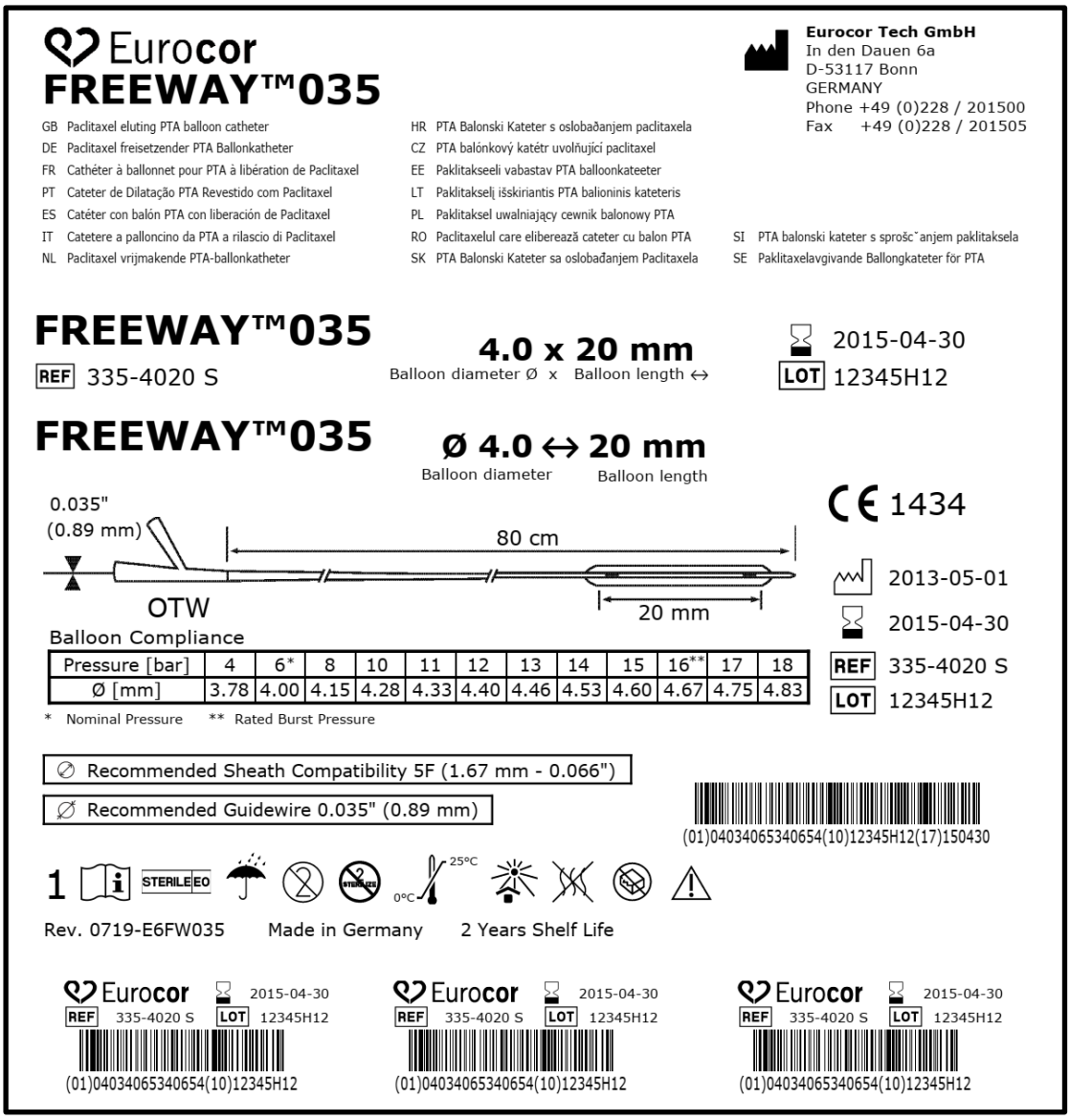
Accessories

Accessories	Description	Body contact?
Guidewire	Tiny wire that is used to navigate through the vessel until the destination, it allows to guide other catheters, for example balloon catheters, to easily reach the treatment site.	Yes
Inflation Device	Used to create, maintain and monitor the pressure of a balloon catheter during an angioplasty procedure. A mixture of saline and contrast media inside the Inflation Device is used to inflate and deflate the balloon catheter.	No
Contrast medium	Iodine based contrast media are substances used to enhance the visibility of internal structures. The addition of contrast media to the Balloon inflation liquid allows a better visibility of the balloon catheter during angiography procedures under fluoroscopy.	No
Saline solution	Saline (saline solution) is used in a mixture with contrast media for inflation of the balloon catheter.	No
Introducer Sheath	Device that allows to introduce catheters, for example balloon catheters, into the vessel to perform endoluminal procedures such as angioplasty.	Yes
Syringe	For preparation of the catheter prior to procedure a syringe with a Luer lock system is used for preparation of the catheter prior to the procedure.	No
Guiding catheter (Coronary arteries)	Catheter with especially bended tip that allows to guide and enter the guidewire in the coronary arteries.	Yes

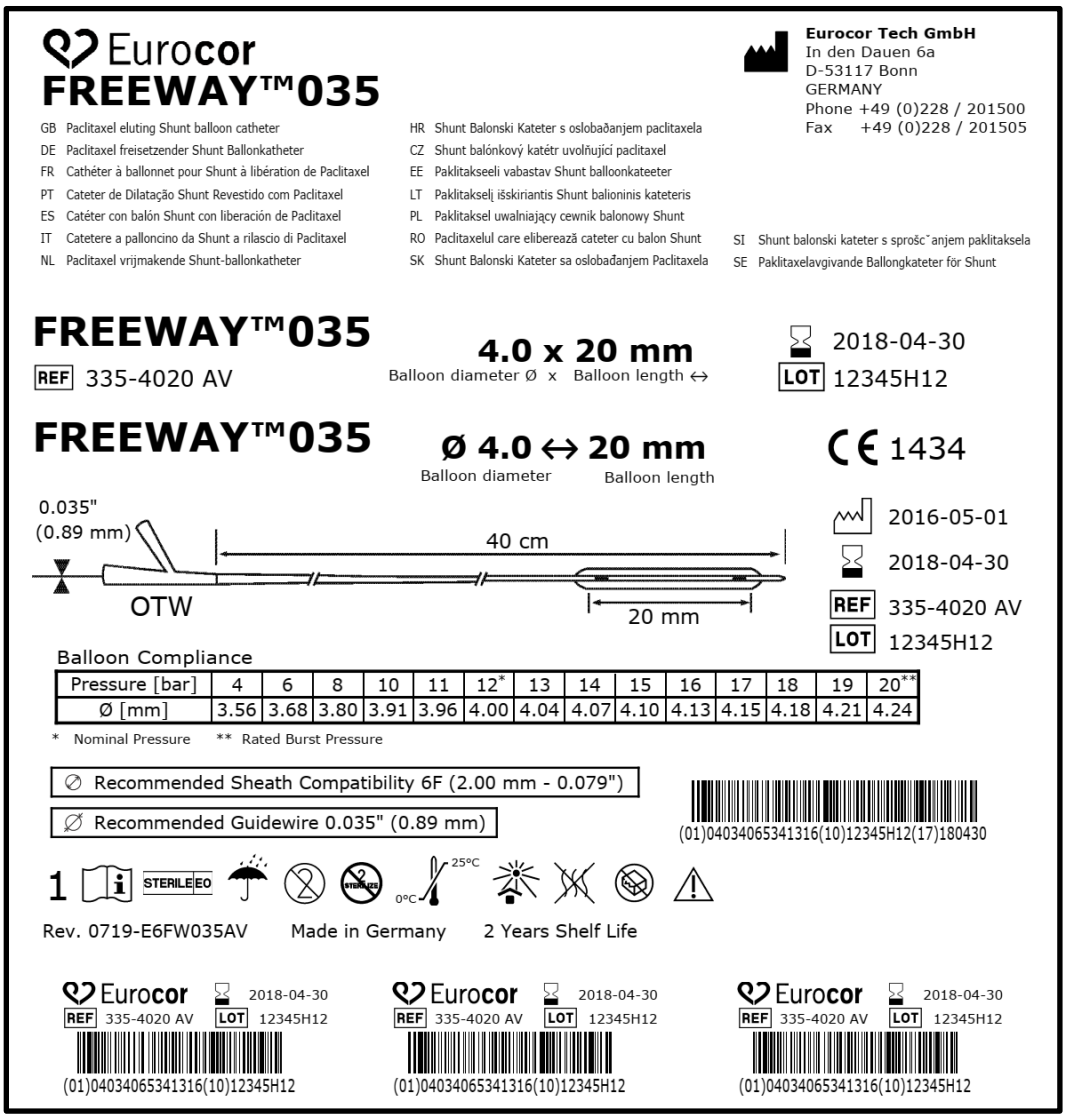
Labelling

Identical product labels are placed on the inner pouch and on the carboard box with the following information:

- Company Product Designation
- Company Product Code
- Quantity
- Company LOT Number
- Manufacturing Date
- Expiry Date
- Storage conditions
- Balloon Compliance
- Requirements for Introducer Sheath
- Requirements for Guidewire
- Shelf life



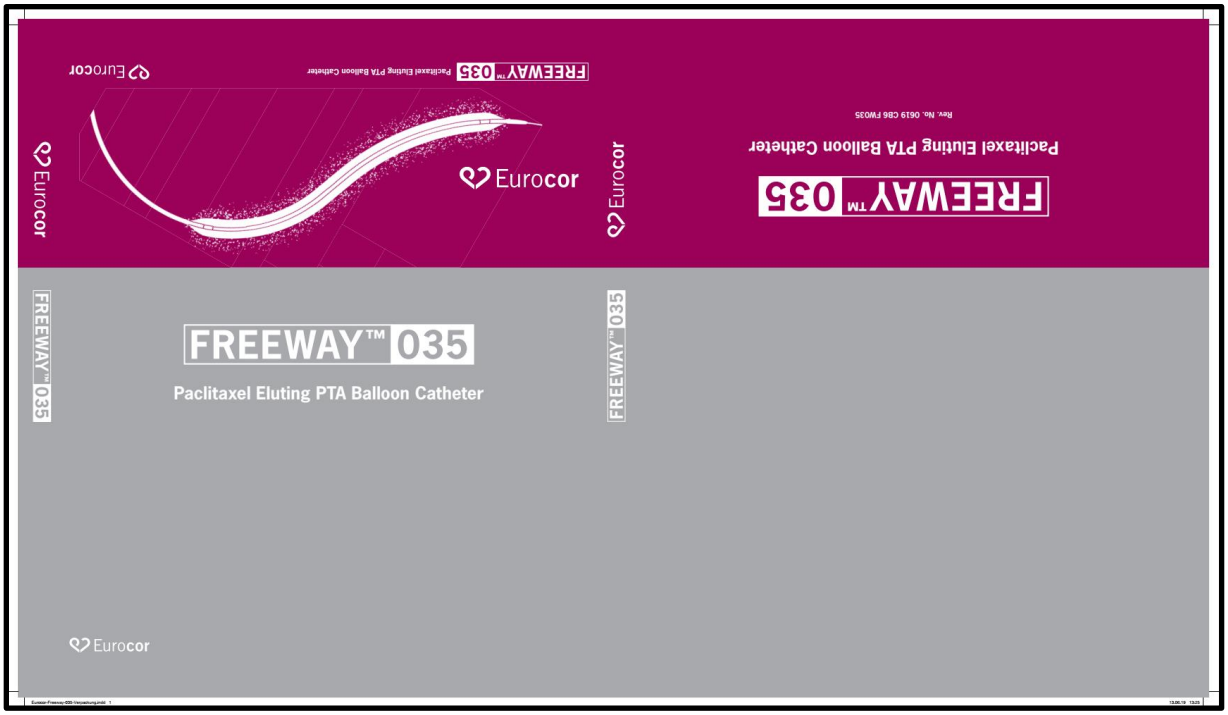
FREEWAY™ 035 Label



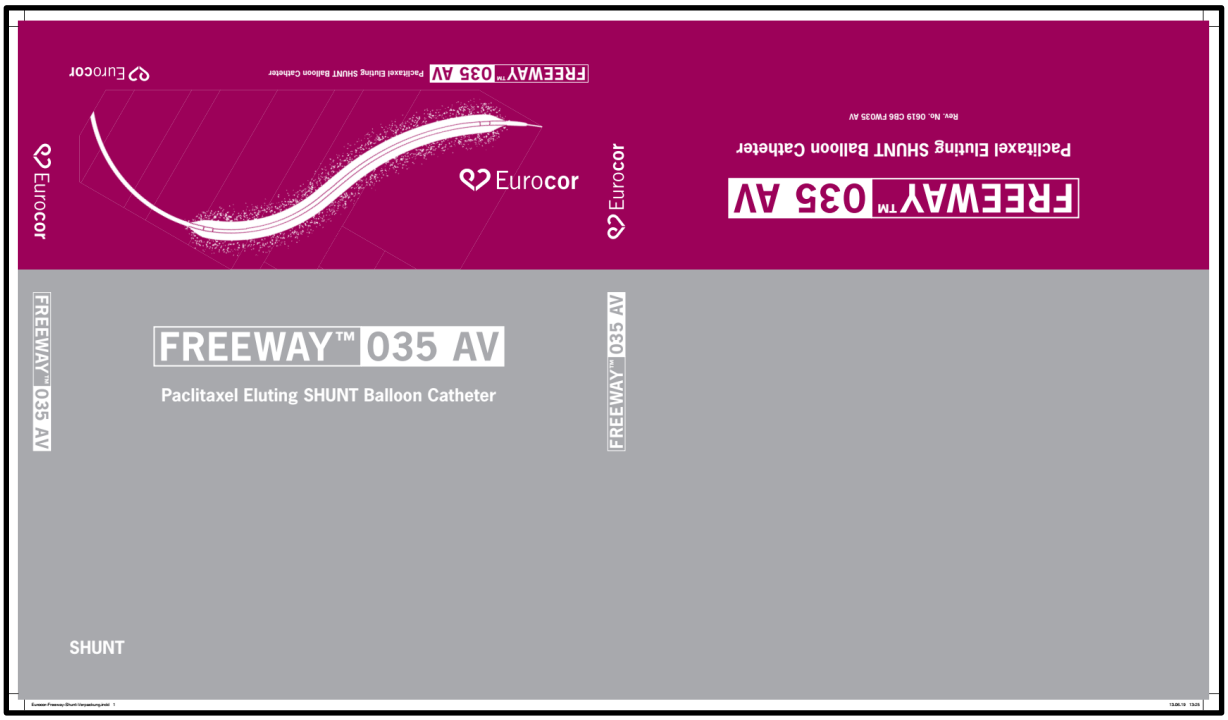
FREEWAY™ 035 AV Label

Packaging

The FREEWAY™ 035 Paclitaxel eluting PTA balloon catheter is packed inside a dispenser which is placed inside a protective peel pouch (Tyvek) conform to EN 868 standard before being packaged into an outer folded cardboard box.



FREEWAY™ 035 Packaging



FREEWAY™ 035 AV Packaging

Product Specifications

Design

Bi-lumen design – over the wire

Characteristic

Semi-Compliant

Balloon Folding

4-folding for Ø 4.0 mm and Ø 5.0 mm
5-folding for Ø 6.0 mm and Ø 8.0 mm

Folding direction

Clockwise (view from tip)

Radiopaque Markers

One radiopaque marker at distal and one at proximal end of the balloon; markers are swaged.

Recommended Introducer Sheath

5 F for Ø 4.0 mm, Ø 5.0 mm and Ø 6.0 mm with length ≤80 mm
6 F for Ø 6.0 mm with length ≥ 100 mm and Ø ≥ 7.0 mm

Product Dimensions

Usable Catheter Length (tip to strain relief)

PTA: 800 ± 20 mm or 1350 ± 20 mm
Shunt: 400 ± 20 mm

Usable Balloon Length

PTA: 20, 40, 60, 80, 100, 120, 150, 190, 230 mm
Shunt: 20, 40, 60 mm
Tolerance at nominal pressure: ± 5%

Balloon Diameter

PTA: 4.0, 5.0, 6.0, 7.0, 8.0 mm
Shunt: 4.0, 5.0, 6.0, 7.0, 8.0 mm
Tolerance at nominal pressure: ± 5%

Balloon Shoulder Angel

shall be 22.5° (single angel)

Length of Catheter Tip

5.0 mm ± 0.5 mm - atraumatically rounded

Dimensions Stem Tubing

1.30 mm ± 0.03 mm x 1.00 mm ± 0.03 mm

Outer Diameter Shaft Tubing

1.70 mm +0.06 mm / -0.03 mm (5.1 F)

Max. Guidewire Diameter

Recommended guidewire: 0.035”

Sterilization

The catheter will be delivered sterile. The method of sterilization is ETO. Re-sterilization of the device is prohibited.

Storage

The FREEWAY™ 035 catheter must be stored at a temperature between 0°C and 25°C protected from light and humidity in its original packaging.

Shelf life

The shelf life of the FREEWAY™ 035 Paclitaxel eluting PTA balloon catheter is two (2) years after the manufacturing date.

Certification Requirements

The FREEWAY™ 035 is classified as a Class III medical device under the consolidated Medical Device Directive 93/42/EEC Annex IX, Rules 6 and 13.

Eurocor Tech GmbH is certified according to the EN ISO 13485:2016 by PCBC S.A. (Notified Body 1434).

The Quality Assurance System complies with the MDD 93/42/EEC, Annex II.