E-Magic Plus Drug Eluting Stent Delivery System

Technical Data Sheet

Description

The E-Magic Plus Drug Eluting Stent Delivery System, is combining the latest L605 CoCr stent technology with a fully biodegradable Poly DL-lactide-co-glycolide polymer. The system consists of a balloon expandable drug eluting stent premounted on a custom balloon delivery system. This catheter includes distally two coaxial lumens with a balloon located near the distal tip. One lumen is used for inflation of the balloon and the other permits the use of a guidewire (0.014" max) to facilitate advancements of the catheter to and through the stenosis. The material used for the balloon allows controlling the external diameter depending on the inflation pressure. The delivery system is compatible with 0.056 inch guiding catheter.

The E-Magic Plus Drug Eluting Stent Delivery System is a drug-device combination as it is coated with the anti-restenoic active pharmaceutical ingredient Sirolimus (1.3 µg/ mm^2) within a biocompatible PLLA & PLgA matrix. The new alliance of a fully biodegradable polymer, together with Sirolimus efficiency to prevent restenosis, assures homogeneous drug distribution and uniform release kinetics. Such combination is expected to demonstrate long term efficacy as well as extremely low rate of late stent thrombosis

Its ultra-low catheter profile, together with a tapered tip design, provides an optimal delivery, even to the most challenging lesions. It enables high pressure inflations, and can be used for post stent inflation. Two radiopaque markers placed in the cylindrical part of the balloon aid in accurate positioning of the stent within the vessel using fluoroscopy.

The cell structure is optimal for side branch access. The low profile and ultrathin struts of the stent ensure minimized trauma to the vessel wall and high flexibility and conformability.

UMDNS Code

The UMDNS codes for E-Magic Plus Drug Eluting Stent Delivery System are 17-461 (stent) and 17-521 (catheter).

Intended Use and Contraindications

The E-Magic Plus Drug Eluting Stent Delivery System is intended for use in patients with clinical symptoms of myocardial ischemia related to the pathological condition of one or more coronary arteries and who are regarded as being candidates for myocardial revascularization.

The E-Magic Plus Drug Eluting Stent Delivery System is contraindicated and patients must be excluded if any of the following criteria are met:

1. Known sensitivity to Sirolimus
2. Severe reaction to contrast agents that cannot be adequately pre-medicated prior to the E-Magic Plus index procedure
3. Patients in whom anti-platelet and / or anticoagulant therapy is contraindicated
4. In-stent restenosis
5. Myocardial Infarction less than 72 hours prior to E-Magic Plus index procedure
6. Direct stenting
7. Stenting of Saphenous Vein Grafts

Available Sizes and Ordering Information

Ordering Information		Balloon Diameter (mm)					
		2.25	2.50	2.75	3.00	3.50	4.00
Stent Length (mm)	8	EPCC 2.25-8	EPCC 2.50-8	EPCC 2.75-8	EPCC 3.00-8	EPCC 3.50-8	EPCC 4.00-8
	12	EPCC 2.25-12	EPCC 2.50-12	EPCC 2.75-12	EPCC 3.00-12	EPCC 3.50-12	EPCC 4.00-12
	16	EPCC 2.25-16	EPCC 2.50-16	EPCC 2.75-16	EPCC 3.00-16	EPCC 3.50-16	EPCC 4.00-16
	20	EPCC 2.25-20	EPCC 2.50-20	EPCC 2.75-20	EPCC 3.00-20	EPCC 3.50-20	EPCC 4.00-20
	24	EPCC 2.25-24	EPCC 2.50-24	EPCC 2.75-24	EPCC 3.00-24	EPCC 3.50-24	EPCC 4.00-24
	28	EPCC 2.25-28	EPCC 2.50-28	EPCC 2.75-28	EPCC 3.00-28	EPCC 3.50-28	EPCC 4.00-28
	32	EPCC 2.25-32	EPCC 2.50-32	EPCC 2.75-32	EPCC 3.00-32	EPCC 3.50-32	EPCC 4.00-32
	36		EPCC 2.50-36	EPCC 2.75-36	EPCC 3.00-36	EPCC 3.50-36	EPCC 4.00-36
	40		EPCC 2.50-40	EPCC 2.75-40	EPCC 3.00-40	EPCC 3.50-40	EPCC 4.00-40

Compliance Chart

Pressure (atm)		Compliance (mm) 4	6	8*	10	12	14**	16**	18	20
Balloon	**2.25**	2.20	2.22	2.25	2.30	2.34	2.37	2.40	2.42	2.46
Balloon	**2.50**	2.35	2.40	2.50	2.58	2.64	2.70	2.76	2.82	2.85
Balloon	**2.75**	2.60	2.65	2.75	2.83	2.89	2.95	3.01	3.08	3.12
Balloon	**3.00**	2.80	2.85	3.00	3.08	3.14	3.20	3.26	3.35	3.40
Balloon	**3.50**	3.35	3.40	3.50	3.58	3.66	3.74	3.80	3.86	3.92
Balloon	**4.00**	3.79	3.85	4.00	4.08	4.16	4.24	4.30	4.36	4.42

*** Nominal pressure: 8 atm**

****RBP is 16 atm except for balloon ∅ 3.50 mm with length > 35 mm it is a 14 atm**

Device Components and Raw Material

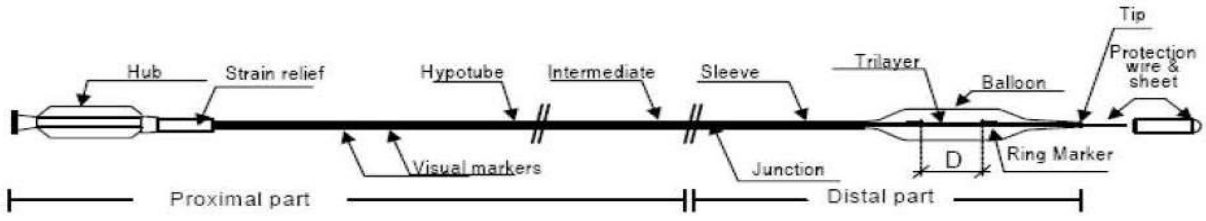

Fig. 2: Schematic presentation of E-Magic Plus product components. The distance between ring markers (in mm); D: balloon working length, tolerance ± 0.5 mm.

Fig. 3: Photo of stent.

Technical Data

Device	Component	Raw Material
Catheter	Hub	Polycarbonate
	Marker band	Platinum/Iridium
	Soft Tip	Polyether black amide
	Intermediate Tubing(Rapid Exchange)	Polyamide
	Balloon	Polyamide trifold
	Stain Relief	Megol
	Dispenser	Polyethylene
	Guide Wire	Stainless Steel
	Distal Tubing	Pebax
	Proximal Tubing	Stainless Steel
Bare Metal Stent	CoCr alloy Tube	L 605 Medical Grade
	Tube Diameter	1.6 mm
	Strut Thickness	60 µm
	Strut Width	65 µm
	Stent gap between struts (3.0 mm deployed stent)	2.81 mm
	Stent crossing profile 3.0 mm stent	0.039”
	Number of stent crowns	8
Drug (Immunosuppressive Agent)	Immunosuppressive Agent	Sirolimus
	Chemical Formula	$C_{51}H_{79}NO_{13}$
	Molecular Weight	914.2 g/mol
	Drug Dose	1.3 µg/mm^2 in CoCr Stent
	Coating Type	Spray-Coating
Packaging	Thermoformed support	Aluminum Pouch
	Peel able pouch	Tyvek
	Moisture Absorbent	Silica Gel Pillow pack 3gm
	Box	Cardboard

Crossability

Stent Diameter (mm)	2.25	2.50	2.75	3.00	3.50	4.00
Crossing Profile (mm/inches)	0.88 mm / 0.035”	0.90mm / 0.035”	0.95mm / 0.037”	1.00mm / 0.039”	1.04mm / 0.041”	1.12mm / 0.044”

Sterilization

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

Storage

The E-Magic Plus has to be stored at a temperature between 0°C and 30°C protected from light and humidity in its original packaging.

Shelf life

The shelf life of the E-Magic Plus Drug Eluting Stent Delivery System is 1.5 years after the manufacturing date.

Certification Requirements

The E-Magic Plus Drug Eluting Stent Delivery System is classified as a Class III medical device under the consolidated Medical Device Directive 93/42/EEC Annex IX, Rules 8 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.