

MAGMA

Rapamycin-Eluting Coronary Stent System with Bio-Absorbable Polymer Coating

TECHNICAL SPECIFICATIONS

Description	Rapamycin-Eluting Coronary Stent System Stainless Steel
Balloon Characteristic	Semi-Compliant Rapid Exchange Catheter
Recommended Guidewire	0.014" (0.36 mm)
Recommended Guiding Catheter	5 F
Entry Tip Profile	min 0.45 mm (0.018")
Nominal Pressure	Ø 2.00 mm to Ø 4.00 mm: 9 bar
Rated Burst Pressure (RBP)	<ul style="list-style-type: none"> Ø 2.00 mm to Ø 3.50 mm: 18 bar Ø 4.00 mm: 16 bar
X-ray Balloon Marker	2 markers located on the inner distal shaft under balloon section
Carbon Impregnated Stent-strut-thickness	<ul style="list-style-type: none"> Small: 110 Micron Large: 115 Micron
Stent - Vessel - Ratio	Avg of 11.8% (mean vessel-diameter of 3.0 mm and mean stent length of 18 mm)
Depth of carbon ion implantation	50 nm

ORDER INFORMATION

Diameter (mm)	Stent Length (mm)				Balloon Length (mm)			
	10 12	14 15	18 20	24 25	28 30	34 35	38 40	
2.00	MR2010	MR2014	MR2018	MR2024	MR2028	MR2034	MR2038	
2.25	MR2210	MR2214	MR2218	MR2224	MR2228	MR2234	MR2238	
2.50	MR2510	MR2514	MR2518	MR2524	MR2528	MR2534	MR2538	
2.75	MR2710	MR2714	MR2718	MR2724	MR2728	MR2734	MR2738	
3.00	MR3010	MR3014	MR3018	MR3024	MR3028	MR3034	MR3038	
3.25	MR3210	MR3214	MR3218	MR3224	MR3228	MR3234	MR3238	
3.50	MR3510	MR3514	MR3518	MR3524	MR3528	MR3534	MR3538	
4.00	MR4010	MR4014	MR4018	MR4024	MR4028	MR4034	MR4038	
		14 16						

CE 0124



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INTERVENTIONAL
CARDIOLOGY



MAGMA

Rapamycin-Eluting Coronary Stent System with Bio-Absorbable Polymer Coating

Double-Protection Technology

Regulatory Status
CE Mark Approved

MAGMA

Rapamycin-Eluting Coronary Stent System with Bio-Absorbable Polymer Coating

The **MAGMA** Rapamycin-Eluting Coronary Stent System is the **first carbonized stent** (Inert Carbon Technology) with a completely **biodegradable** polymer coating which contains Rapamycin (Rapasorb™) as a **highly effective** drug for preventing thrombotic and re-stenotic events.

BENEFITS

- > **Zero stent thrombosis** during the entire implant period
- > **Polymer:** Poly (D, L-Lactide-co-Glycolid) Polylactide 50% Polyglycolid 50%
- > **Drug:** Rapamycin
- > **Coating Degradation:** 6 weeks in-vivo
- > **Drug load:** 2.0µg/mm²
- > **250 Patients** with over two years follow-up

INERT CARBON TECHNOLOGY

High speed bombardment of C⁺-ions under vacuum onto alloy's surface

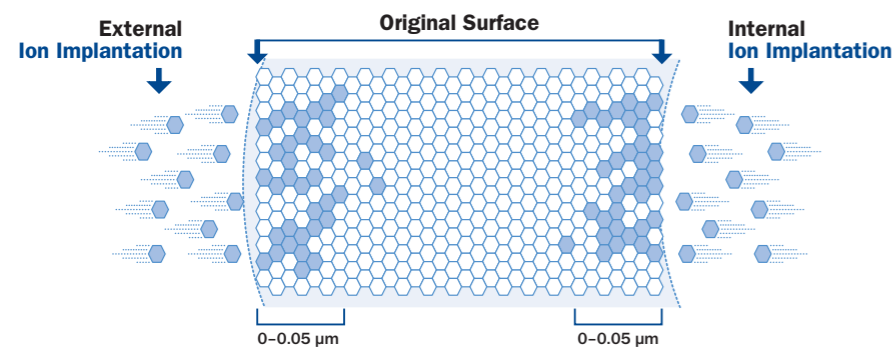


Figure 1: Under vacuum conditions carbon ions are shot with high load of energy on the stent surface, so that the ions are implanted within the metal lattice under the alloy's surface.

THE COATING

The biodegradable Polymer contains Poly-lactic-co-glycolic acid (PLGA) which will degrade 100% into carbon dioxide and water.

MAGMA does not need any other auxiliary polymer like parylene C

The controlled polymer degradation and release of Rapamycin is designed to terminate simultaneously and is completed within less than three months. This covers exactly the time where the drug is needed at most and is tailored uniquely to various immune response reactions occurring after stent implantation. This is understood as Rapasorb™ - Technology.

Release Kinetics of Rapamycin Eluting Stents

[Long term release per square mm stent surface]

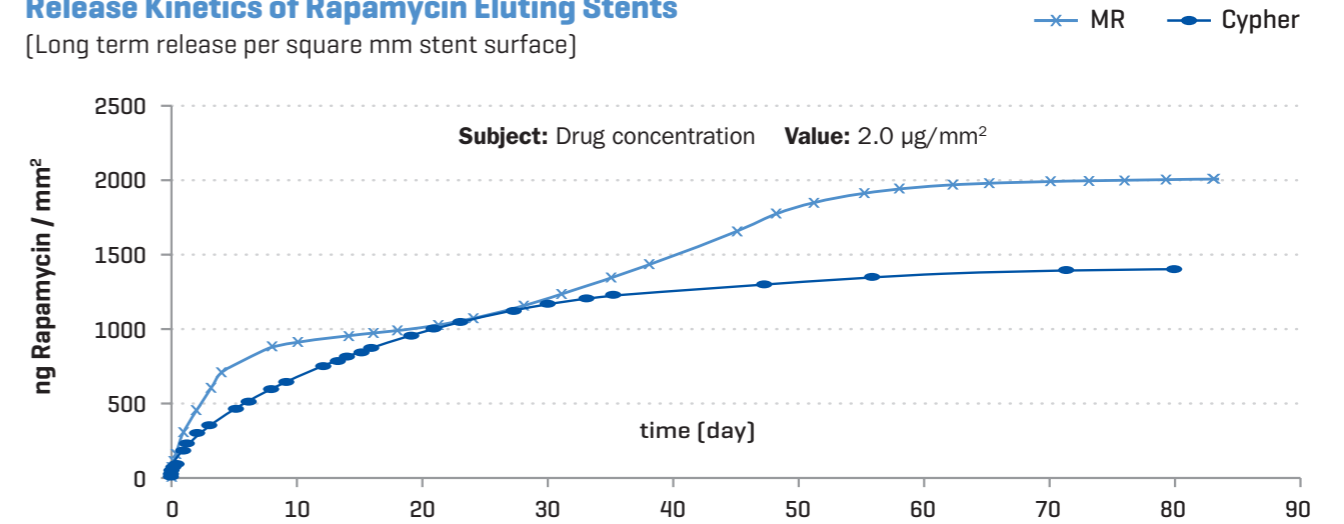
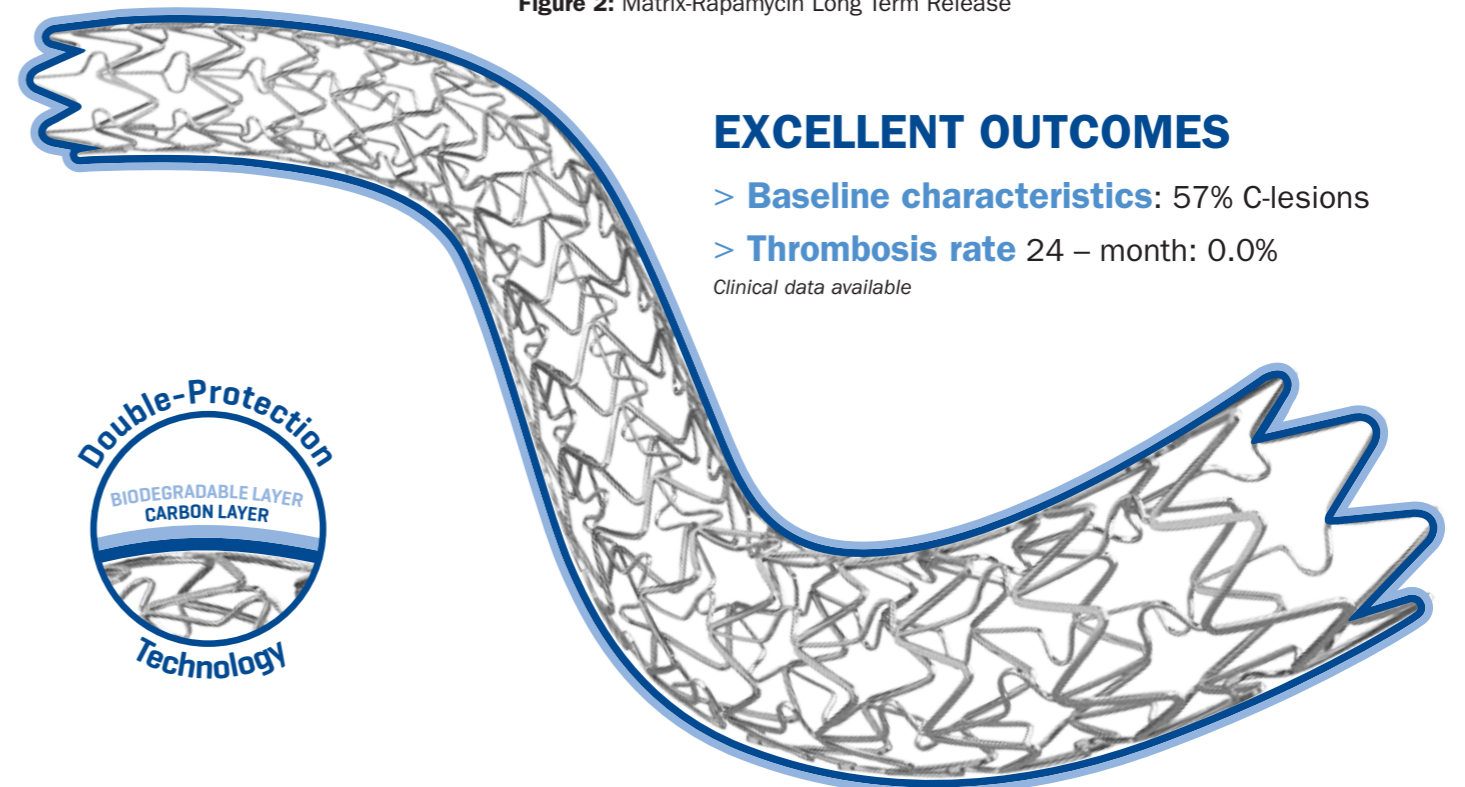


Figure 2: Matrix-Rapamycin Long Term Release



EXCELLENT OUTCOMES

- > **Baseline characteristics:** 57% C-lesions
 - > **Thrombosis rate** 24 – month: 0.0%
- Clinical data available*

COMPLIANCE TABLE

Pressure (bar)	Balloon Diameter (mm)							
	2	2.25	2.5	2.75	3	3.25	3.5	4
4	1.80	2.10	2.30	2.55	2.75	3.00	3.15	3.70
5	1.84	2.13	2.34	2.59	2.80	3.05	3.22	3.76
6	1.88	2.16	2.38	2.63	2.85	3.10	3.29	3.82
7	1.92	2.19	2.42	2.67	2.90	3.15	3.36	3.88
8	1.96	2.22	2.46	2.71	2.95	3.20	3.43	3.94
9	2.00	2.25	2.50	2.75	3.00	3.25	3.50	4.00
10	2.04	2.28	2.54	2.79	3.05	3.30	3.57	4.06
11	2.08	2.31	2.58	2.83	3.10	3.35	3.64	4.12
12	2.12	2.34	2.62	2.87	3.15	3.40	3.71	4.18
13	2.16	2.37	2.66	2.91	3.20	3.45	3.78	4.24
14	2.20	2.40	2.70	2.95	3.25	3.50	3.85	4.30
15	2.24	2.43	2.74	2.99	3.30	3.55	3.92	4.36
16	2.28	2.46	2.78	3.03	3.35	3.60	3.99	4.42
17	2.32	2.49	2.82	3.07	3.40	3.65	4.06	-
18	2.36	2.52	2.86	3.11	3.45	3.70	4.13	-
NP	9	9	9	9	9	9	9	9
RBP	18	18	18	18	18	18	18	16
Mean CP	0.96	0.96	0.98	0.98	1.01	1.05	1.21	1.20