

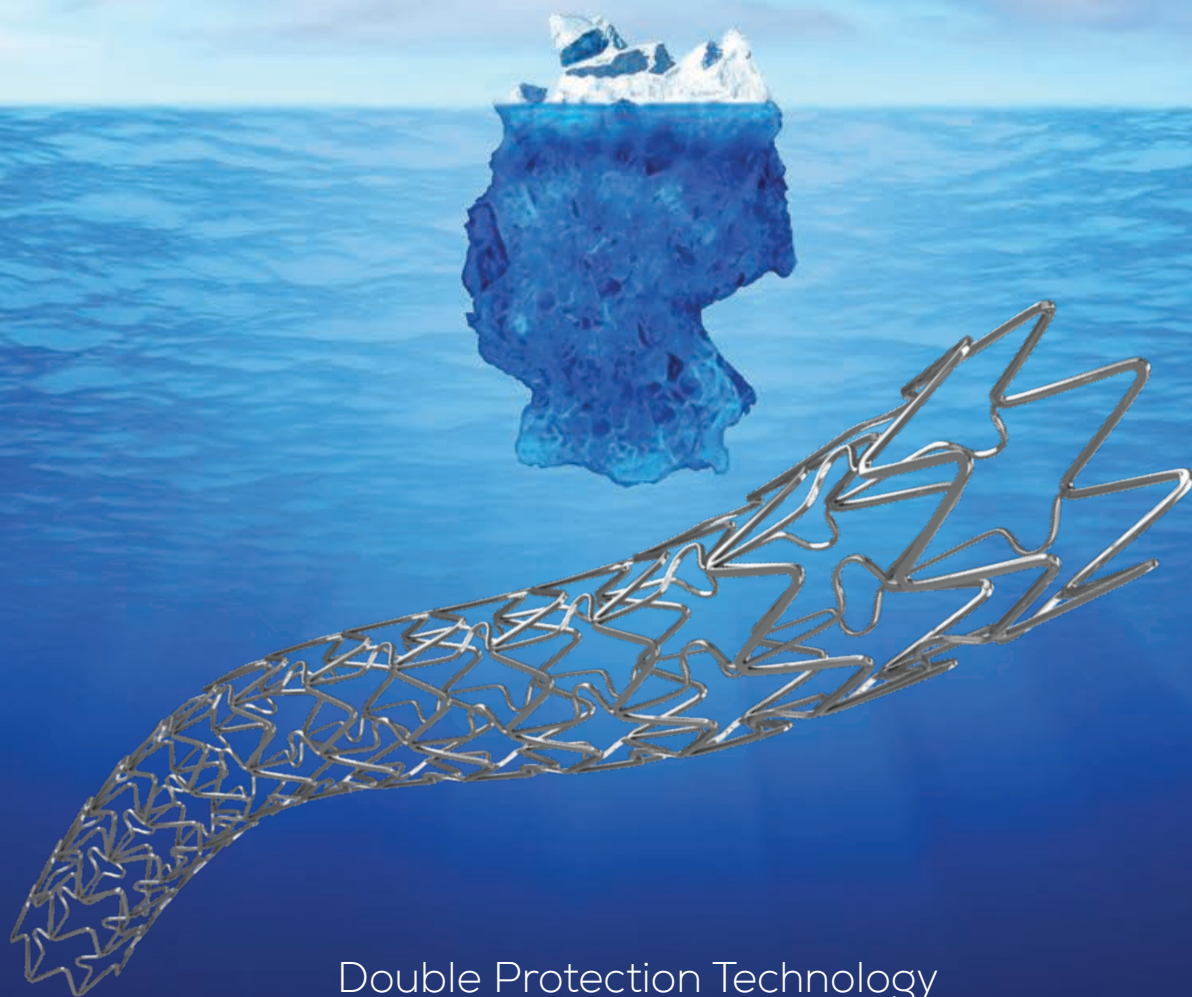
Interventional Cardiology

QualiMed®

A Q3 Medical Company

Sirolimus-Eluting Coronary Stent System

Biocompatible Alloy Stent with
Fast absorbing Bio-Polymer



Double Protection Technology

Regulatory Status
CE Mark Approved



Sirolimus-Eluting Coronary Stent System

Biocompatible Alloy Stent with Fast absorbing Bio-Polymer

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

BENEFITS

- > **Proven safety results - 0%** stent thrombosis at 5 years
- > **Open cell design** with excellent side branch access
- > **Low tip crossing profile** 0.018"
- > **Polymer:** Poly [D, L-Lactide-co-Glycolid] Polylactide 50% Polyglycolid 50%
- > **Drug:** Sirolimus
- > **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

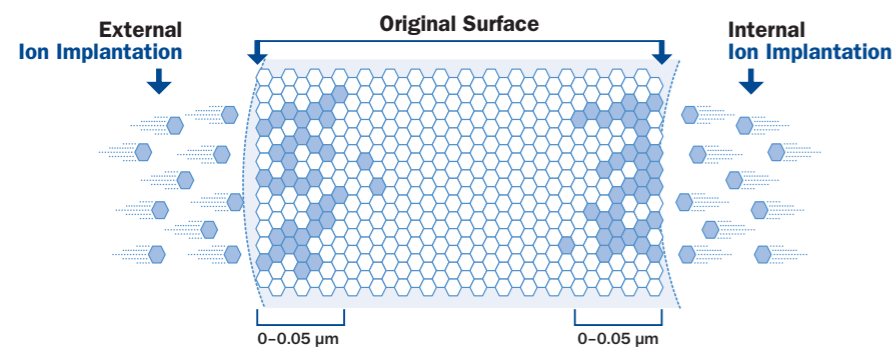


Figure 1: Under vacuum conditions carbon ions are shot with high load of energy on the stent surface, so that the ions are implanted within the metal lattice under the alloy's surface.

THE COATING

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

Sirolimus-Eluting Coronary Stent System does not need any other auxiliary polymer like parylene C

The controlled polymer degradation and release of Sirolimus 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 Sirolimus-Eluting Stents

(Long term release per square mm stent surface)

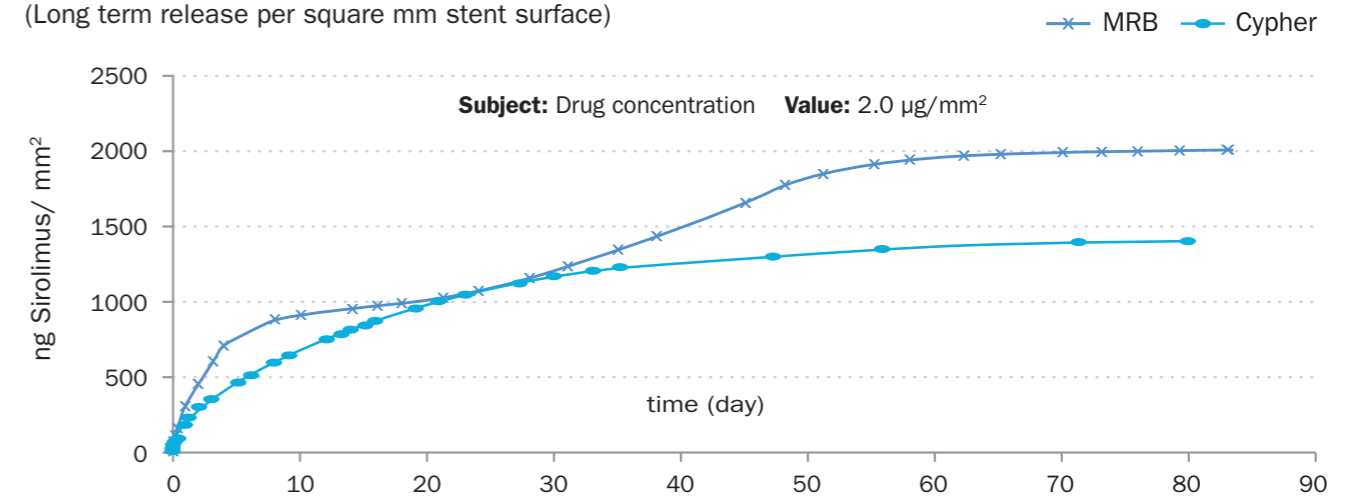
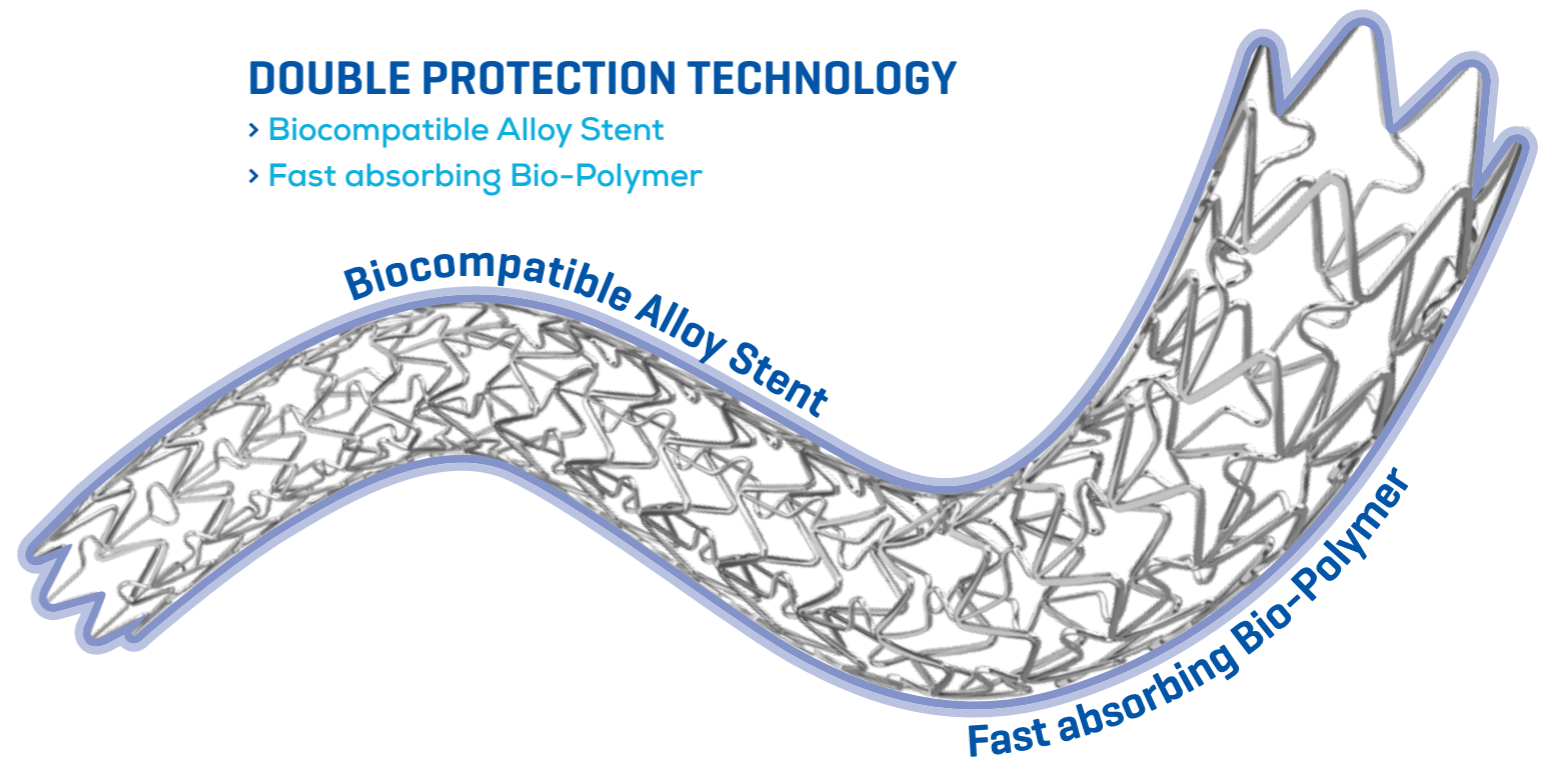


Figure 2: Matrix-Sirolimus Long Term Release

DOUBLE PROTECTION TECHNOLOGY

- > Biocompatible Alloy Stent
- > Fast absorbing Bio-Polymer



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	-
Nominal pressure	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

Sirolimus-Eluting Coronary Stent System

Biocompatible Alloy Stent with Fast absorbing Bio-Polymer

TECHNICAL SPECIFICATIONS

Description	Sirolimus-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	MRB2010	MRB2014	MRB2018	MRB2024	MRB2028	MRB2034	MRB2038
2.25	MRB2210	MRB2214	MRB2218	MRB2224	MRB2228	MRB2234	MRB2238
2.50	MRB2510	MRB2514	MRB2518	MRB2524	MRB2528	MRB2534	MRB2538
2.75	MRB2710	MRB2714	MRB2718	MRB2724	MRB2728	MRB2734	MRB2738
3.00	MRB3010	MRB3014	MRB3018	MRB3024	MRB3028	MRB3034	MRB3038
3.25	MRB3210	MRB3214	MRB3218	MRB3224	MRB3228	MRB3234	MRB3238
3.50	MRB3510	MRB3514	MRB3518	MRB3524	MRB3528	MRB3534	MRB3538
4.00	MRB4010	MRB4014	MRB4018	MRB4024	MRB4028	MRB4034	MRB4038
		14 16					

CE 1434

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