INTERVENTIONAL CARDIOLOGY

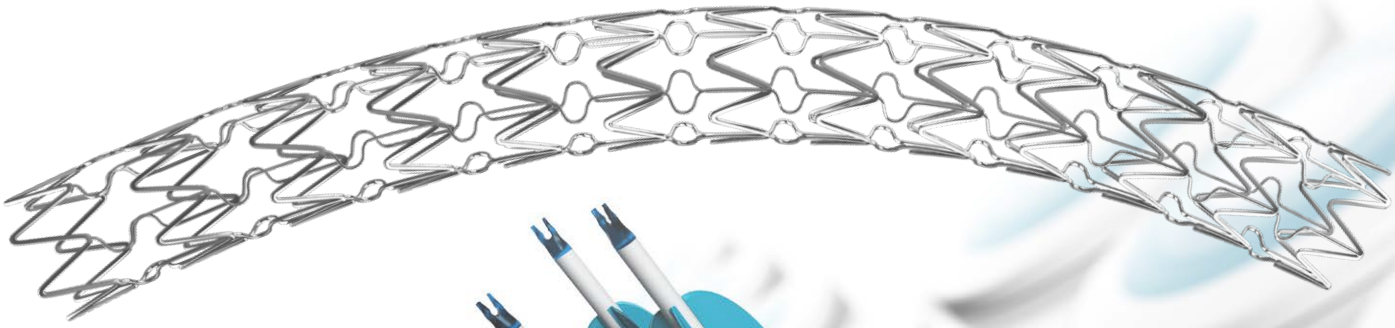
»amg« International

A Q3 Medical Company

ITRIX II

Sirolimus-Eluting Coronary Stent Implantation System

Biocompatible Alloy Stent with Fast absorbing Bio-Polymer



Double Protection Technology

CE MARK APPROVED

ITRIX// Sirolimus-Eluting Coronary Stent Implantation System

Biocompatible Alloy Stent with Fast absorbing Bio-Polymer

The **ITRIX//** Sirolimus-Eluting Coronary Stent Implantation 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

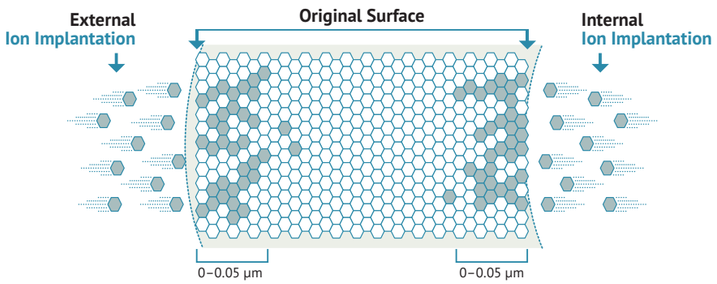


Figure 1: Under vacuum conditions carbon ions are shot with high load of energy on the stent surface, so that the ions are implanted within the metal lattice under the alloy's surface.

THE COATING

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

ITRIX// 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 Coronary Stent Implantation System

(Long term release per square mm stent surface)

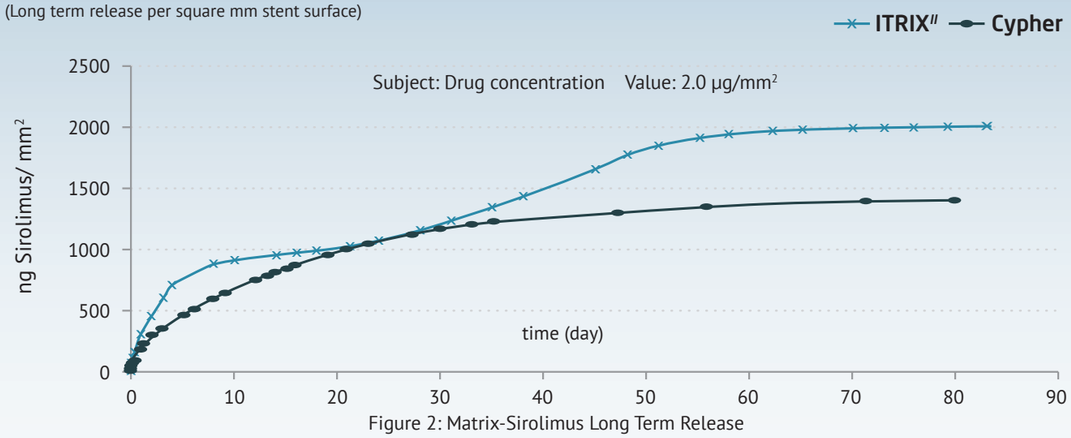
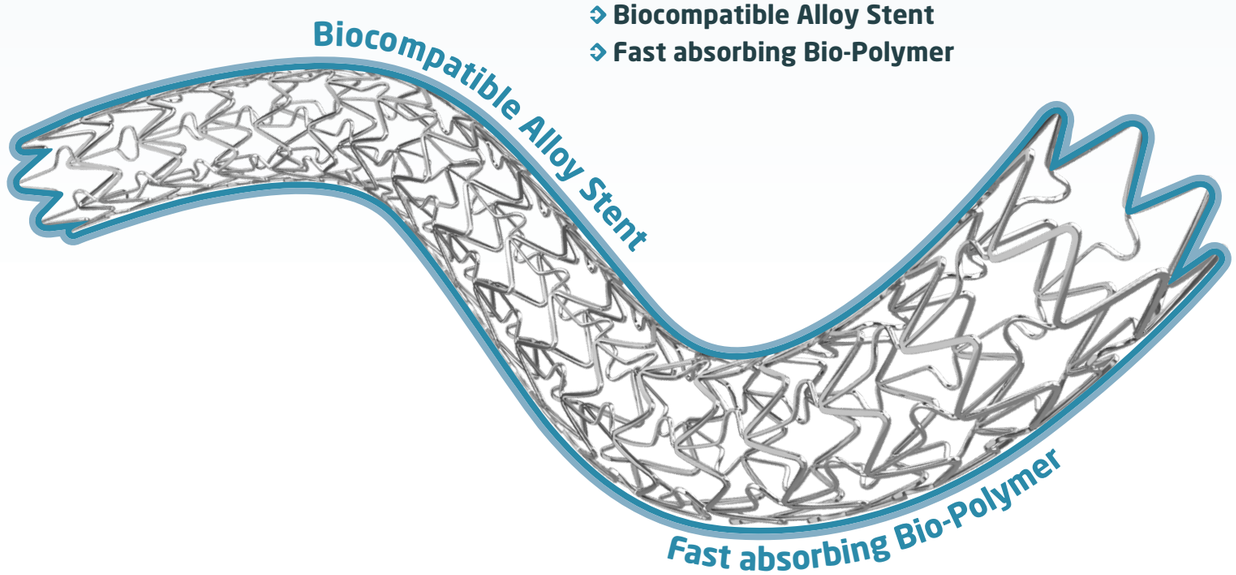


Figure 2: Matrix-Sirolimus Long Term Release

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

ITRIX// Sirolimus-Eluting Coronary Stent Implantation System

Biocompatible Alloy Stent with Fast absorbing Bio-Polymer

TECHNICAL SPECIFICATIONS

Description	Sirolimus-Eluting Coronary Stent Implantation System | Stainless Steel | Bioactive Carbonized Stent Platform
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)	• 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	• 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	20 ICS 10 MRB	20 ICS 14 MRB	20 ICS 18 MRB	20 ICS 24 MRB	20 ICS 28 MRB	20 ICS 34 MRB	20 ICS 38 MRB
2.25	22 ICS 10 MRB	22 ICS 14 MRB	22 ICS 18 MRB	22 ICS 24 MRB	22 ICS 28 MRB	22 ICS 34 MRB	22 ICS 38 MRB
2.50	25 ICS 10 MRB	25 ICS 14 MRB	25 ICS 18 MRB	25 ICS 24 MRB	25 ICS 28 MRB	25 ICS 34 MRB	25 ICS 38 MRB
2.75	27 ICS 10 MRB	27 ICS 14 MRB	27 ICS 18 MRB	27 ICS 24 MRB	27 ICS 28 MRB	27 ICS 34 MRB	27 ICS 38 MRB
3.00	30 ICS 10 MRB	30 ICS 14 MRB	30 ICS 18 MRB	30 ICS 24 MRB	30 ICS 28 MRB	30 ICS 34 MRB	30 ICS 38 MRB
3.25	32 ICL 10 MRB	32 ICL 14 MRB	32 ICL 18 MRB	32 ICL 24 MRB	32 ICL 28 MRB	32 ICL 34 MRB	32 ICL 38 MRB
3.50	35 ICL 10 MRB	35 ICL 14 MRB	35 ICL 18 MRB	35 ICL 24 MRB	35 ICL 28 MRB	35 ICL 34 MRB	35 ICL 38 MRB
4.00	40 ICL 10 MRB	40 ICL 14 MRB	40 ICL 18 MRB	40 ICL 24 MRB	40 ICL 28 MRB	40 ICL 34 MRB	40 ICL 38 MRB
		14 | 16					

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