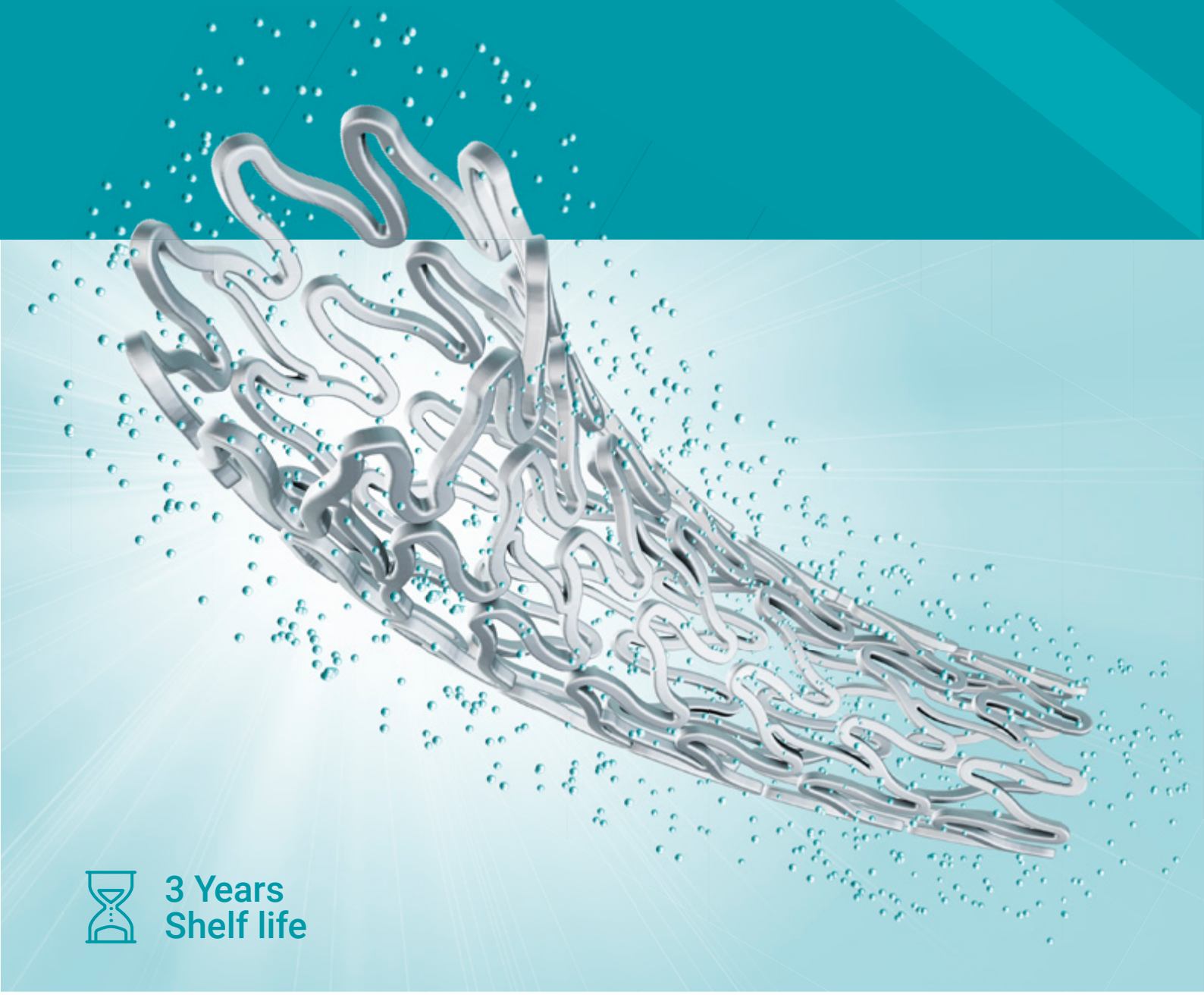
EUROLIMUS™

Sirolimus Eluting
Coronary Stent System



3 Years
Shelf life

Eurocor

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Coating

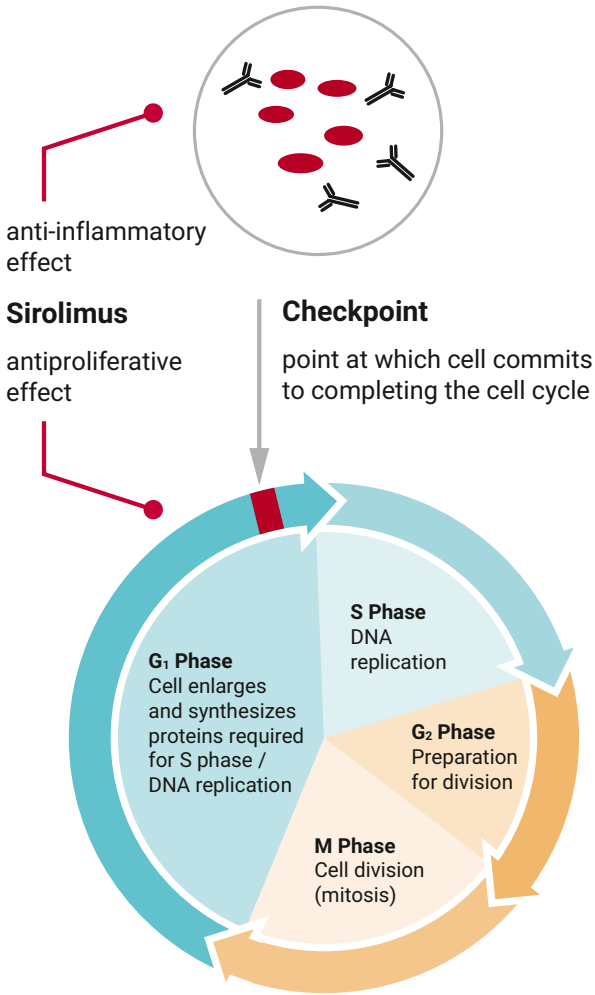
The Eurolimus is a drug eluting stent delivery system. The stent is coated with the active pharmaceutical ingredient sirolimus (1.4 µg/mm²) within a biodegradable PLGA matrix.

Sirolimus

- Sirolimus is a drug with an antiproliferative and anti-inflammatory effect which is used to coat coronary stents.
- Sirolimus is the generic name of the natural product rapamycin, produced by strains of the bacterium *Streptomyces hygroscopicus*.
- Sirolimus inactivates the TOR protein and thus blocks transition from the G1 phase to the S phase in the cell cycle and therewith triggers an antimigratory and antiproliferative effect on vascular smooth muscle cells.
- Sirolimus does not differ from other limus drugs in its cell target structures mTOR and FKBP-12.
- Sirolimus also inhibits the pro-inflammatory immune cell activation.

Biodegradable Polymer

The coating consists of a biocompatible and biodegradable PLGA 85/15 poly(lactide-co-glycolide) copolymer. The biodegradable polymer has outstanding characteristics allowing a durable but thin coating layer on the stent surface.



Stent Design

Ultra Thin 65 µm Strutdesign

65 µm Struts
- Lower Crossing Profile
- Easier Crossability
- Less Vessel Injury

9 Crown Structure
- Excellent Vessel Coverage
- Reduced Local Force
- Homogeneous Drug Distribution

Interlinks
- Middle to Middle Design
- Slimmer, More Flexible Links
- Increased Deliverability and Increased Vessel Adaption

Crossing Profile
- Low profile (0.97 mm for expansion-Ø 3.0 mm)
- Capability to pass even long and tortuous lesions

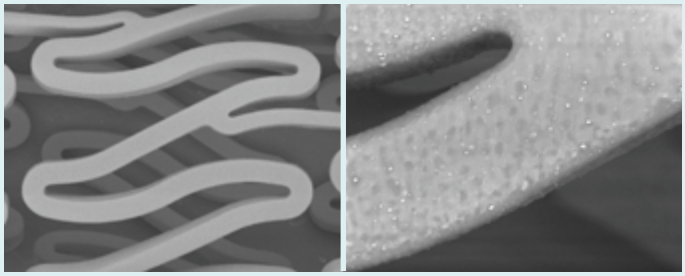
Asymmetrical Coating Thickness

Drug dose: 1.4 µg/mm²
Increase of the drug delivery efficiency due to the asymmetrical coating.

Matrix Thickness
↓ Abluminal Side: ~ 5 µm
Cross Section
↑ Luminal Side: ~ 3 µm

Coating Integrity

Coating remains intact up to a maximum post dilatation expansion of 4.5 mm.



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The Coating makes the difference

Homogeneous Drug Distribution

The alliance of a fully biodegradable polymer, together with sirolimus's 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 rates of late stent thrombosis.

Polymer Degradation / Drug Release

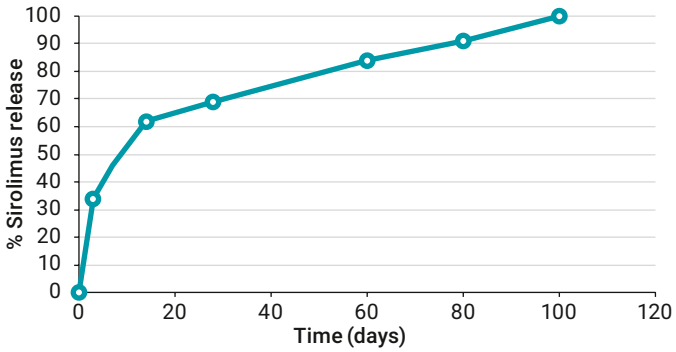
The Eurolimus coating allows a simultaneous polymer resorption and drug release within 3–4 months, to match the procedure-triggered biological response.

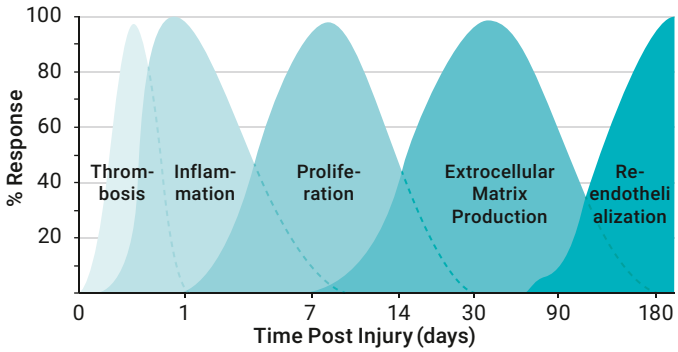
Degradable Polymer Formulation PLGA 85 / 15
PLGA 85/15 poly(lactide-co-glycolide) Copolymer

The copolymer and the homopolymers are generally considered as **non-toxic** and **biocompatible**.

The degradation products lactic acid and glycolic acid are metabolites of the natural cellular metabolism are fully assimilated.

Both substances are decomposed to carbon dioxide and water over 3–4 months.





Clinical Insights

2 European Centers
Italy & Greece

367 Patients
25.6 months
± 5.7 months follow-up

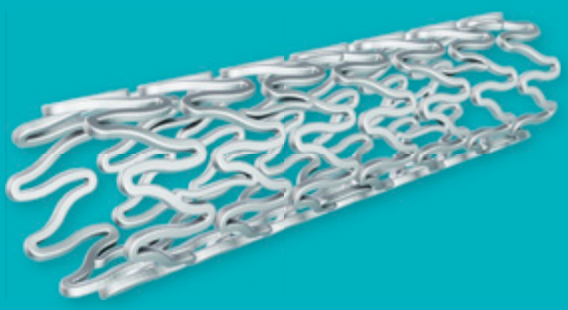
Location of Target Lesions
LAD 42.32 %
RCA 35.68 %
LCX 21.37 %
LM 0.62 %

End Points
Stent Thrombosis 0.27 %
MACE 5.72 %*
TLF 3.00 %

* all TLR, TVR & NON-TVR events resolved by PCI

3 Years Shelf life

Dry sterilization
No start of polymer degradation
100 % repeatability of drug release
Shelf life of 3 Years



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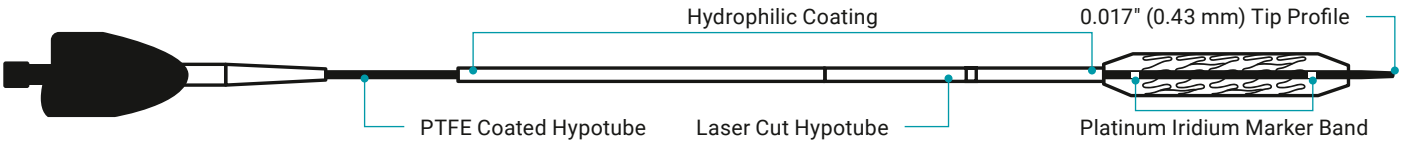

Stent Specifications

Type of design	Open-cell, 3 interlinks
Design detail	9 crowns
Material	Cobalt Chromium L605
Expansion range	2.25 mm – 4.00 mm
Strut thickness	0.0026" (65 µm)
Strut width (main segment)	0.0028" (72 µm)
Strut width (interlink)	0.0023" (58 µm)
Shortening	< 2 %
Mechanical recoil	< 5 %
Metal coverage	< 18 %
Matrix thickness	3 – 5 µm
Drug / Polymer	Sirolimus / PLGA
Drug load	1.4 µg / mm²

Delivery System Specifications

Usable length		138 cm
Length guidewire lumen		27 cm
Recommended guide catheter		5F (min. I.D. 0.056")
Material	**Balloon**	Polyamide
	Distal shaft	Polyamide, multilayer tube
		Hydrophilic coating
	Proximal shaft	Stainless steel, PTFE coated
Shaft size	**Proximal**	1.9 F
	Distal	2.8 – 3.0 F, depending on balloon-Ø
Folding		3-fold balloon
Marker bands		Embedded Platinum / Iridium
Tip entry profile		0.017" (0.43 mm)
Max. guidewire		0.014" (0.36 mm)

Compliance Chart

Pressure (MPa / bar/atm)	Balloon Ø (mm)						
	2.25	2.50	2.75	3.00	3.25	3.50	4.00
	Compliance (mm)						
0.6 / 6	2.21	2.24	2.68	2.92	3.18	3.40	3.92
0.7 / 7	2.23	2.46	2.71	2.96	3.22	3.45	3.96
0.8 / 8	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**4.00**
0.9 / 9	2.27	2.53	2.78	3.03	3.28	3.55	4.04
1.0 / 10	2.29	2.56	2.81	3.06	3.32	3.59	4.09
1.1 / 11	2.32	2.59	2.84	3.09	3.35	3.62	4.12
1.2 / 12	2.34	2.62	2.86	3.12	3.38	3.65	4.15
1.3 / 13	2.36	2.65	2.89	3.14	3.41	3.69	4.19
1.4 / 14	2.38	2.68	2.91	3.17	3.44	3.72	4.23
1.5 / 15	2.40	2.71	2.94	3.20	3.47	3.76	4.27
1.6 / 16	2.42	2.74	2.97	3.22	3.50	**3.80**	**4.31**
1.7 / 17	2.45	2.78	3.00	**3.25**	**3.53**	3.84	4.36
1.8 / 18	2.47	**2.82**	**3.03**	3.28	3.56	–	–
1.9 / 19	**2.49**	2.86	3.07	–	–	–	–
2.0 / 20	2.51	–	–	–	–	–	–

Nominal Pressure 0.8 MPa / 8 bar | Rated Burst Pressure | – Do not exceed

Product Ordering Information

Stent Length (mm)	Balloon Diameter (mm)						
	2.25	2.50	2.75	3.00	3.25	3.50	4.00
8	EULI 2.25-08	EULI 2.50-08	EULI 2.75-08	EULI 3.00-08	EULI 3.25-08	EULI 3.50-08	EULI 4.00-08
10	EULI 2.25-10	EULI 2.50-10	EULI 2.75-10	EULI 3.00-10	EULI 3.25-10	EULI 3.50-10	EULI 4.00-10
13	EULI 2.25-13	EULI 2.50-13	EULI 2.75-13	EULI 3.00-13	EULI 3.25-13	EULI 3.50-13	EULI 4.00-13
16	EULI 2.25-16	EULI 2.50-16	EULI 2.75-16	EULI 3.00-16	EULI 3.25-16	EULI 3.50-16	EULI 4.00-16
18	EULI 2.25-18	EULI 2.50-18	EULI 2.75-18	EULI 3.00-18	EULI 3.25-18	EULI 3.50-18	EULI 4.00-18
23	EULI 2.25-23	EULI 2.50-23	EULI 2.75-23	EULI 3.00-23	EULI 3.25-23	EULI 3.50-23	EULI 4.00-23
28	EULI 2.25-28	EULI 2.50-28	EULI 2.75-28	EULI 3.00-28	EULI 3.25-28	EULI 3.50-28	EULI 4.00-28
33	EULI 2.25-33	EULI 2.50-33	EULI 2.75-33	EULI 3.00-33	EULI 3.25-33	EULI 3.50-33	EULI 4.00-33
38	EULI 2.25-38	EULI 2.50-38	EULI 2.75-38	EULI 3.00-38	EULI 3.25-38	EULI 3.50-38	EULI 4.00-38
43	EULI 2.25-43	EULI 2.50-43	EULI 2.75-43	EULI 3.00-43	EULI 3.25-43	EULI 3.50-43	EULI 4.00-43
48	EULI 2.25-48	EULI 2.50-48	EULI 2.75-48	EULI 3.00-48	EULI 3.25-48	EULI 3.50-48	EULI 4.00-48

Available on special request

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