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Eurolimus™
Product Overview

pre-market dossier for active customers

confidential

EUROLIMUS™
PRODUCT OVERVIEW

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MADE IN GERMANY

EUROLIMUS™
INDICATIONS

Eurolimus™, Sirolimus Eluting Coronary Stent System

- Treatment of **symptomatic ischemic coronary heart disease** (from *de novo lesions* & *restenosised lesions of the coronary arteries*)
- Treatment of **acute or suspected occlusions** (for patients with unsuccessful balloon dilatation)
- Prevents restenosis, assures **homogeneous drug distribution** and uniform release kinetics
- **Long term efficacy** & **extremely low rates of thrombosis** (acute, subacute, late & very late)

EUROLIMUS
Sirolimus Eluting Coronary Stent System

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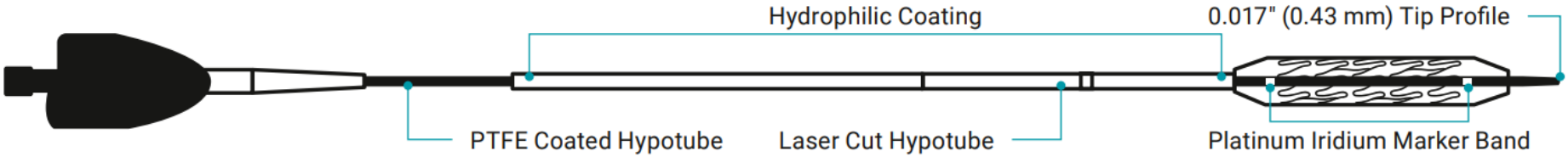
EUROLIMUS™
SPECIFICATIONS



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)
Foreshortening	< 2.5 %
Mechanical recoil	< 6 %
Metal coverage	< 13.6 %
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	Proprietary polyamide compound
	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)

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Sirolimus Eluting Coronary Stent System

DESIGN & COATING TECHNOLOGY

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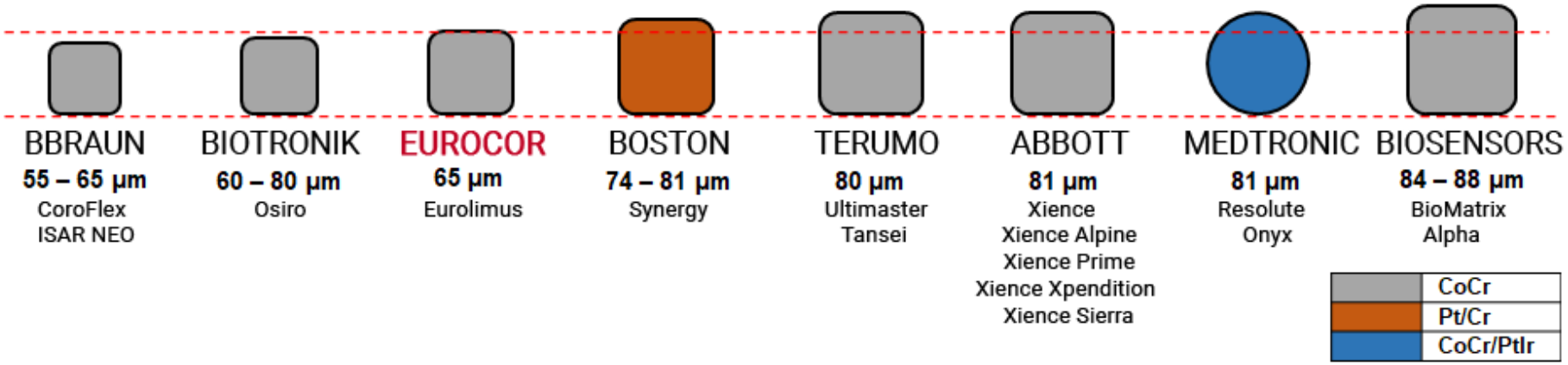
STENT DESIGN

STRUT & PROFILE

Low Strut thickness for smooth interventions



Crimped Profile

Expansion Diameter	Crimped Profile	Stent ID at RBP	Post Dilatation Limit
2.25	0.87 mm	2.49 mm	3.50 mm
2.50	0.91 mm	2.82 mm	3.50 mm
2.75	0.94 mm	3.03 mm	3.50 mm
3.00	0.98 mm	3.25 mm	4.00 mm
3.25	1.00 mm	3.53 mm	4.00 mm
3.50	1.01 mm	3.80 mm	4.50 mm
4.00	1.03 mm	4.31 mm	4.50 mm

Overexpansion capabilities

Asymmetric Coating

Matrix Thickness
Abluminal Side: ~ 5 µm

Cross Section

Matrix Thickness
Luminal Side: ~ 3 µm

Cross Section Diagram

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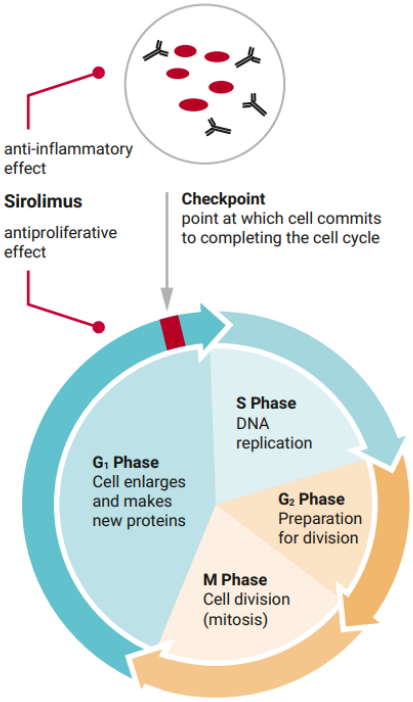
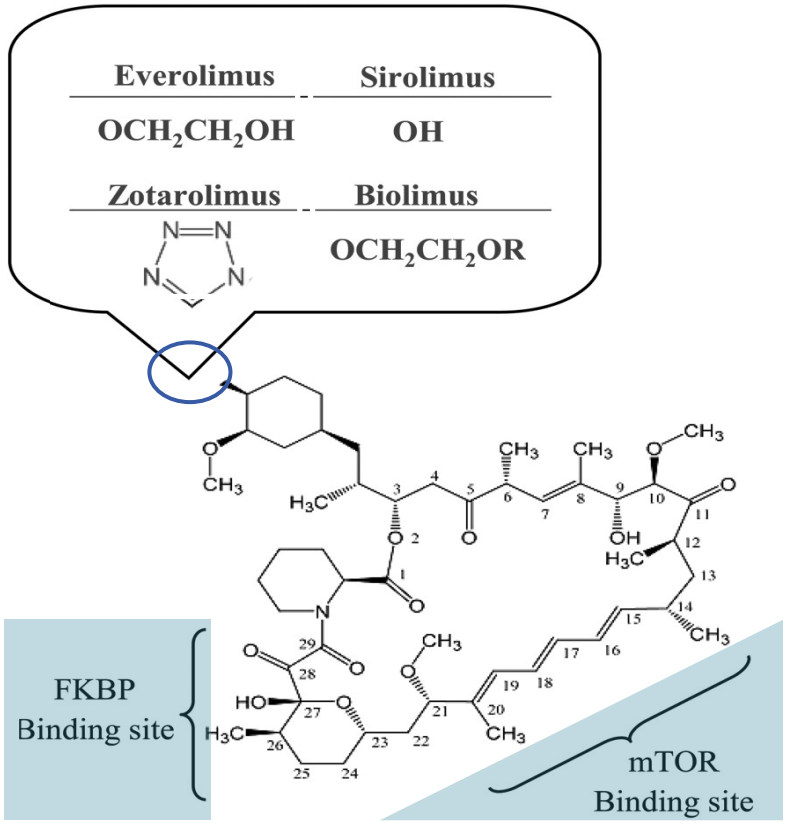
STENT DESIGN

SIROLIMUS VS LIMUS ANALOGS

Sirolimus mTOR inactivation



Limus Analogs Comparison



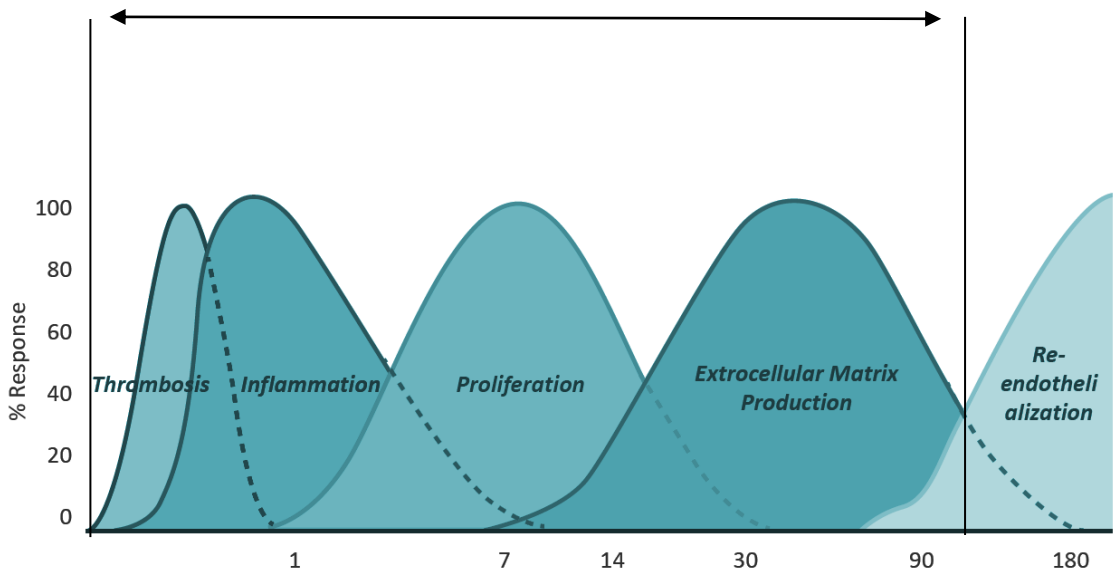
Molecular structure of Limus drugs is not altered in the two essential binding sites that interact with target structures mTOR and FKBP-12

Drug's mode of action is essentially the same

COATING MATRIX

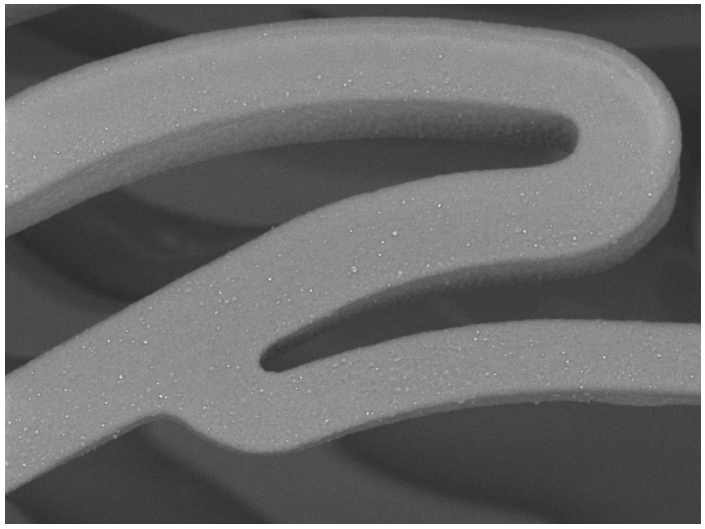
THE COATING MAKES THE DIFFERENCE™

Eurolimus® drug release



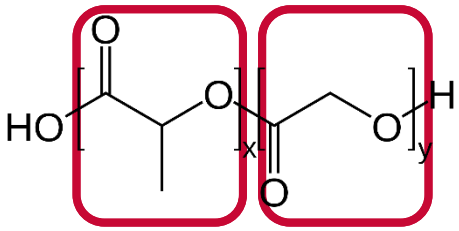
Drug release covers entire restenotic cascade (100 days)

Coating Structure



SEM of coating 600 x

Polymer Matrix



Lactic acid glycolic acid

- Initial burst phase followed by second phase of progressive release through thicker drug depleted layer.
- PLGA 85/15 degradable polymer formulation regarded as **non toxic** and **biocompatible**
- Both substances are **fully decomposed to water and carbon dioxide** between 10-13 weeks

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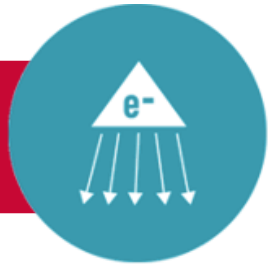
COATING MATRIX
STERILIZATION

Superior Sterilization for optimal performance & shelf life

Electron Beam sterilization utilizes direct current or linear accelerator to emit high energy electrons.



- Sterilization is performed **completely dry**
- **0% degradation of the polymer**
- **100 % repeatability of drug release & working mechanism**
- **Guarantees synchronized drug & polymer release**

3 Year
Shelf Life

EUROLIMUS™
CLINICAL PROGRAM

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STUDY OVERVIEW

CENTER OVERVIEW

Two completed Studies on real world patients undergoing percutaneous coronary intervention in Europe

Milan, Italy

171 Patients
Follow-up 25.6 ± 5.7 months

Retrospective Single Center

Thessaloniki, Greece

196 Patients
Follow-up 27.8 ± 5.2 months

Retrospective Single Center

End Points

Target Lesion Failure
MACE
Stent Thrombosis

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ENDPOINTS
CLINICAL INDICATORS

Study Endpoints

MACE

Composite

- Repeat Revascularization (any, including all target & non-target vessels)
- All-cause-mortality
- Any MI (Myocardial Infarction)

Stent Thrombosis

As defined by the Academic Research Consortium

TLF

Composite

- Cardiac Death
- Clinically Driven TLR (Target Lesion Revascularization)
- Target vessel MI (Q-wave or non Q-wave Myocardial Infarction), CABG (Coronary Artery Bypass Graft)

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COHORT DEMOGRAPHICS

PATIENT STATUS & MEDICAL HISTORY

Milan, Italy

Demographics	Total	%
N	171	
Age (mean)	70.0 ± 11.9	
Male	138	80.7
BMI	27.2 ± 5.1	
Diabetic	37	25.0
History of MI	35	20.7
History of stroke TIA	6	3.6
Smoker (current)	35	21.7
Hypertension	127	80.9
Hyperlipoproteinemia	71	42.0
Peripheral Vascular Disease	6	3.6

Thessaloniki, Greece

Demographics	Total	%
N	196	
Age (mean)	66.7 ± 10.7	
Male	159	79.8
BMI	27.6 ± 3.3	
Diabetic	54	27.6
History of MI	37	18.8
History of stroke TIA	12	6.1
Smoker (current)	119	60.7
Hypertension	85	43.4
Hyperlipoproteinemia	107	54.6
Peripheral Vascular Disease	9	4.6

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COHORT DEMOGRAPHICS

PATIENT STATUS & MEDICAL HISTORY

Milan, Italy

Cardiac Status	Total	%
Chronic stable angina	59	34.5
Silent Ischemia	26	15.2
Unstable angina	26	30.2
MI (Stemi)	38	63.3
MI (Nstemi)	22	36.7

Cardiac History	Total	%
Prior PCI	45	26.3
Prior CABG	29	16.9
Prior MI (> 72h)	25	14.6

Coronary Vessel Disease	Total	%
1 vessel	134	78.4
2	30	17.5
3	7	4.1

Thessaloniki, Greece

Cardiac Status	Total	%
Stable angina	84	42.9
Unstable angina	27	13.8
MI (Stemi)	42	21.4
MI (Nstemi)	43	21.9

Cardiac History	Total	%
Prior PCI	18	9.2
Prior CABG	8	4.1
Prior MI (> 72h)	16	8.2

Coronary Vessel Disease	Total	%
1 vessel	161	82.2
2	32	16.3
3	3	1.5

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LESION LOCATIONS

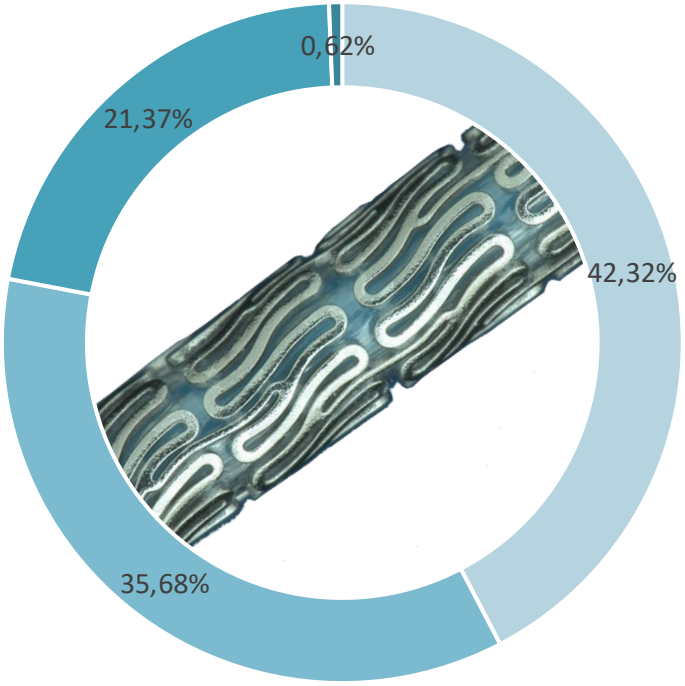
TARGET LESIONS

Location of target lesions

Milan, Italy

- LAD: 88, 38.4%
- RCA: 92, 40.2%
- LCX: 46, 20.1%
- LM: 3, 1.3%

Total of **229 lesions**



Total distribution of treated target lesion distribution

Thessaloniki, Greece

- LAD: 116, 54.8%
- RCA: 80, 31.6%
- LCX: 57, 22.5%
- LM: 0, 0.0%

Total of **253 lesions**

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COHORT DEMOGRAPHICS

PROCEDURE CHARACTERISTICS

Milan, Italy

Left ventricular ejection	Total	%
Fraction	56.6 ± 9.8	34.5
Fraction ≤ 35 %	11	6.4

Amount of Lesions	Total	%
Average per patient	1.34	
1 lesion	124	72.5
2 lesions	36	21.1
3 lesions	11	6.4

Lesion Characteristics	Total	%
RVD	3.38 ± 0.51	
Small vessels RVD (< 2.75 mm)	25	11.1
Diameter Stenosis	83.01 ± 13.31	
Total Occlusions	27	11.79

Thessaloniki, Greece

Cardiac Status	Total	%
Fraction	59.7 ± 7.6	

Amount of Lesions	Total	%
Average per patient	1.29	
1 lesion	152	77.6
2 lesions	35	17.9
3 lesions	6	1.5
4 lesions	3	1.5

Lesion Characteristics	Total	%
RVD	3.09 ± 0.34	
Small vessels RVD (< 2.75 mm)	16	6.2
Diameter Stenosis	86.6 ± 10.7	
Total Occlusions	28	11.1

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ENDPOINT RESULTS

MILAN, ITALY

Follow up results (25.6 ± 5.7 months)

TLF

	Total	%
Target Lesion Failure	2	0.9
Cardiac Death	0	0
MI – Attributed to target vessel	0	0
Q-wave	0	0
Non Q-wave	0	0
Clinical Driven TLR	2	0.9
Solved by PCI	2	0.9

MACE

	Total	%
MACE	8	3.9
Cardiac Death	0	0
Non Cardiac Death	3	1.7
MI (all)	0	0
TLR	2	0.9
By PCI	2	0.9
TVR	2	0.9
By PCI	2	0.9
Non TVR	1	0.4
By PCI	1	0.4

Thrombosis

	Total	%
Thrombosis (all)	0	0
Acute Stent thrombosis [1]	0	0
Subacute stent thrombosis [2]	0	0
Late stent thrombosis [3]	0	0
Very late stent thrombosis [4]	0	0

Events

	Total	%
Ischemic Events	0	0
Hemorrhagic/Vascular Events	1	0.6
Hematological Dyscrasia	0	0
Other Complications [5]	6	3.5

[1] ≤ 24 hours [2] > 24 hours ≤ 30 days [3] > 30 days [4] > 1 year
[5] Dialysis (FU 12 months), Pulmonary Oedema, acute heart failure (1 month post-PCI), Intramural hematoma of aortic root from coronary dissection (at discharge), acute kidney failure (FU 12 months), Mitral-clip procedure (FU 12 months)

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COHORT DEMOGRAPHICS

THESSALONIKI, GREECE

Follow up results (25.6 ± 5.7 months)

TLF

	Total	%
Target Lesion Failure	9	4.6
Cardiac Death	2	1.0
MI – Attributed to target vessel	2	1.0
Q-wave	1	0.5
Non Q-wave	1	0.5
Clinical Driven TLR	5	2.6
Solved by PCI	5	2.6

MACE

	Total	%
MACE	13	8.4
Cardiac Death	2	3.0
Non Cardiac Death	4	2.0
MI (all)	3	2.6
MI – target vessel	1	0.9
MI – non-target vessel	2	1.7
TLR	5	2.0
By PCI	5	2.0
TVR	1	0.4
By PCI	1	0.4
Non TVR	1	0.7
By PCI	1	0.7

Thrombosis

	Total	%
Thrombosis (all)	1	0.5
Acute Stent thrombosis [1]	0	0
Subacute stent thrombosis [2]	1	0.5
Late stent thrombosis [3]	0	0
Very late stent thrombosis [4]	0	0

Events

	Total	%
Ischemic Events	0	0
Hemorrhagic/Vascular Events	1	0.5
Hematological Dyscrasia	0	0
Other Complications	0	0

[1] ≤ 24 hours [2] > 24 hours ≤ 30 days [3] > 30 days [4] > 1 year

THANK YOU FOR YOUR ATTENTION!

Eurocor

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