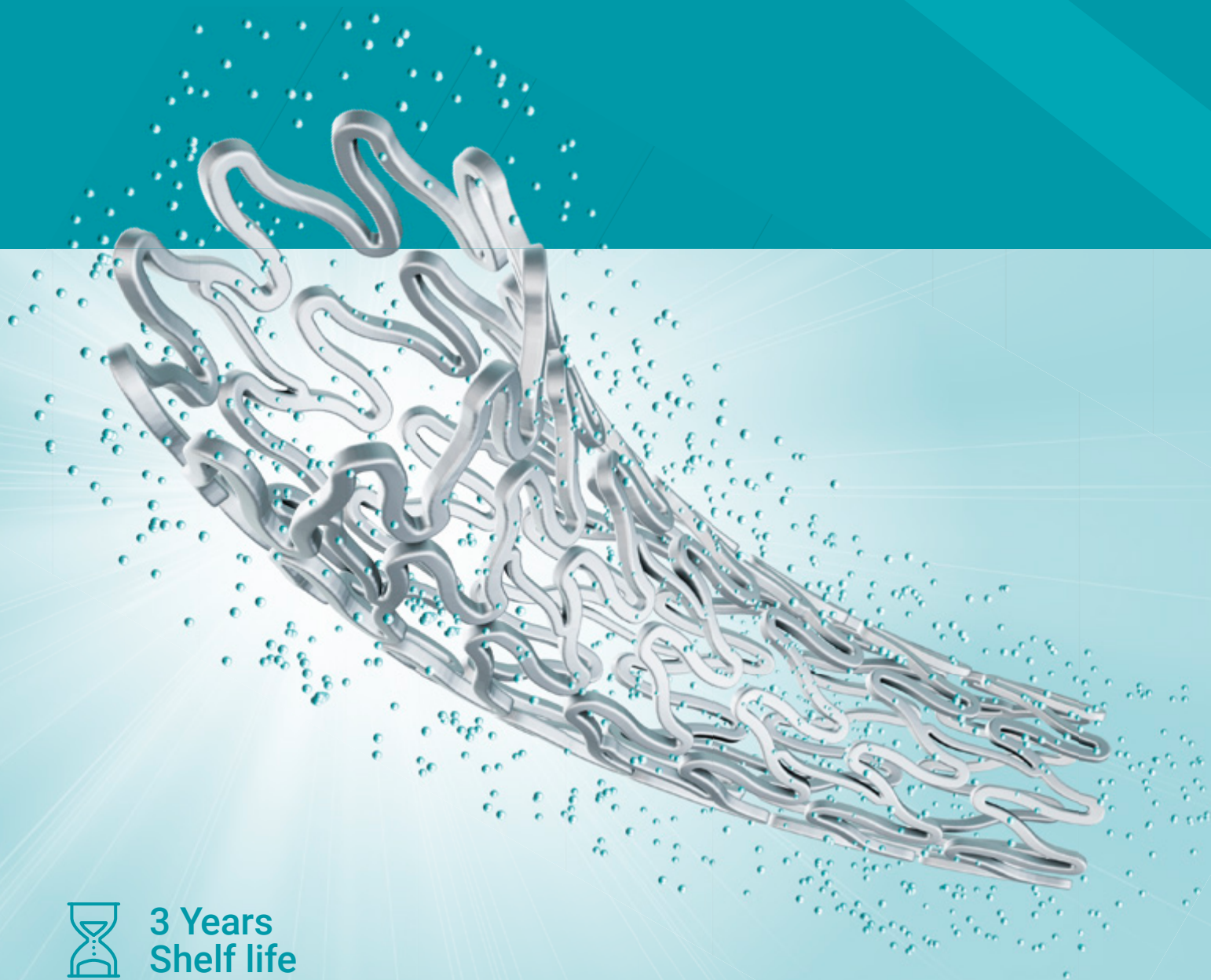


# EUROLIMUS™

Sirolimus Eluting  
Coronary Stent System



3 Years  
Shelf life

# EUROLIMUS™

Sirolimus Eluting Coronary Stent System

## Coating

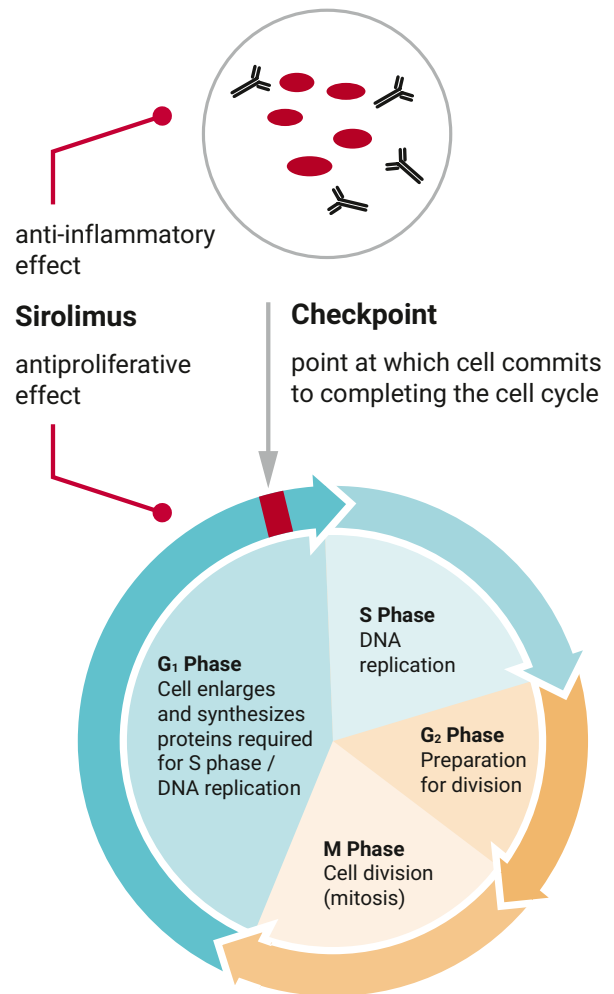
The Eurolimus is a drug eluting stent delivery system. The stent is coated with the active pharmaceutical ingredient sirolimus ( $1.4 \mu\text{g}/\text{mm}^2$ ) within a biodegradable PLGA matrix.

### 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 $\mu\text{m}$ Strutdesign

#### 65 $\mu\text{m}$ Struts

- Lower Crossing Profile
- Easier Crossability
- Less Vessel Injury



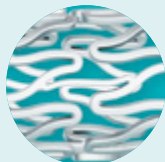
#### 9 Crown Structure

- 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- $\varnothing$  3.0 mm)
- Capability to pass even long and tortuous lesions

### Asymmetrical Coating Thickness

#### Drug dose: $1.4 \mu\text{g}/\text{mm}^2$

Increase of the drug delivery efficiency due to the asymmetrical coating.

#### Matrix Thickness

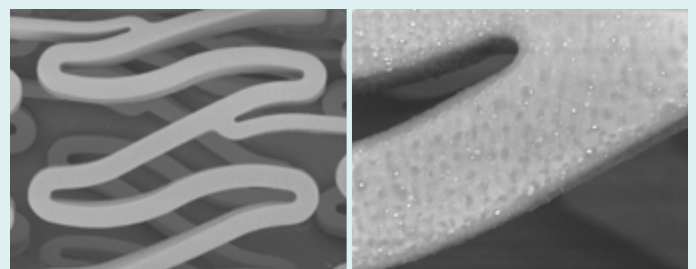
↓ Abluminal Side:  $\sim 5 \mu\text{m}$

Cross Section

↑ Luminal Side:  $\sim 3 \mu\text{m}$

### Coating Integrity

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



# EUROLIMUS™

Sirolimus Eluting Coronary Stent System

## 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

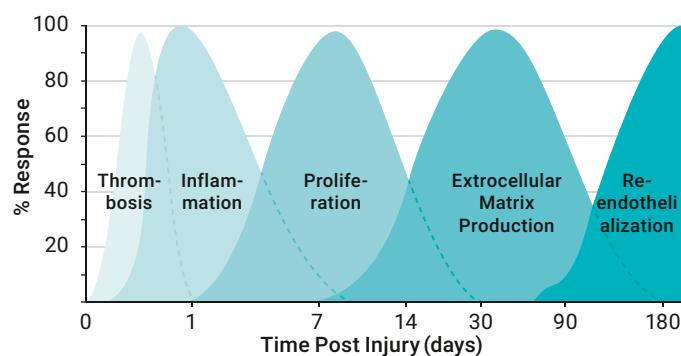
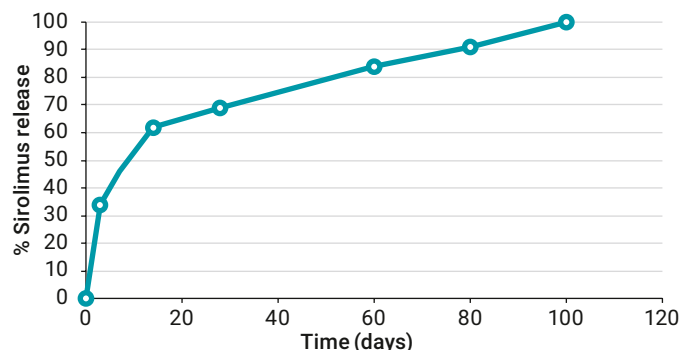
The Eurolimus coating allows a simultaneous polymer resorption and drug release within 3–4 months, to match the procedure-triggered biological response.

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

The copolymer PLGA 85/15 and the respective monomer components lactide and glycolide 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

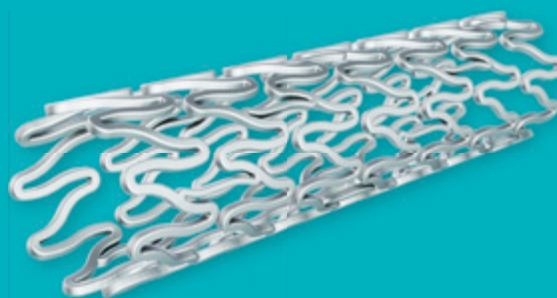


**Dry sterilization**

**No start of polymer degradation**

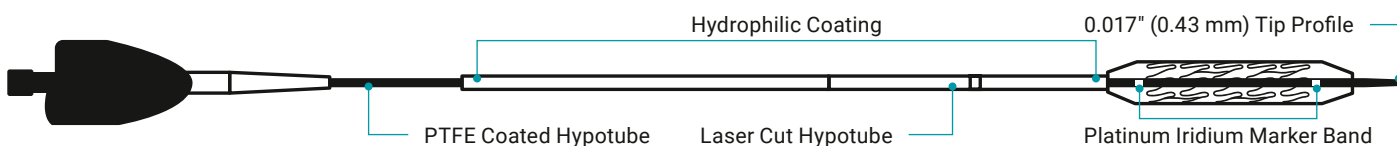
**100 % repeatability of drug release**

**Shelf life of 3 Years**



# EUROLIMUS™

Sirolimus Eluting Coronary Stent System



## 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 / mm <sup>2</sup> |

## 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<br>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<br>(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<br>(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

Manufactured By:



Exclusive UK Distributor



Eurocor Tech GmbH is a wholly owned subsidiary of Opto Eurocor Healthcare Limited and is part of the Opto Circuits Group.

Rev. Nr.  
1221 B14 EULI EN





# EUROLIMUS™

Sirolimus Eluting Coronary Stent System

Manufactured By:



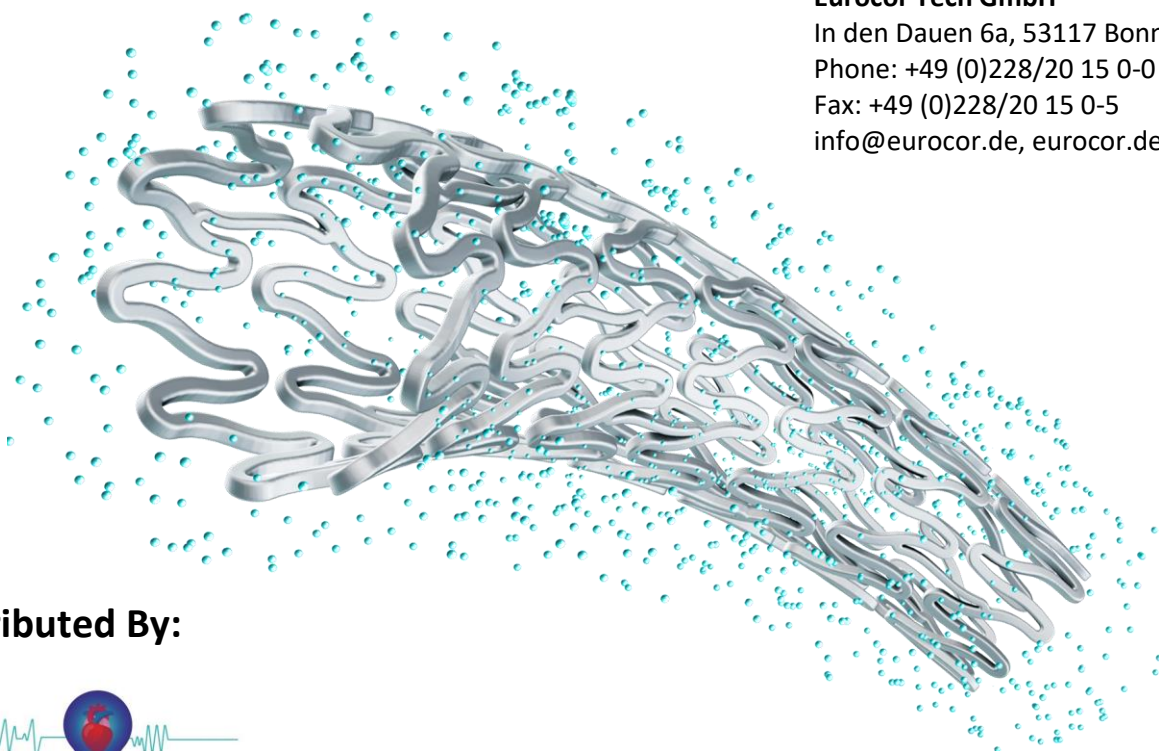
**Eurocor Tech GmbH**

In den Dauen 6a, 53117 Bonn, Germany

Phone: +49 (0)228/20 15 0-0

Fax: +49 (0)228/20 15 0-5

info@eurocor.de, eurocor.de



Distributed By:



**Innovation  
Medical Devices**

Dedicated To Discovery, Committed To Care

**For More Information & Ordering Enquiries please contact**

**The Exclusive UK Distributor Innovation Medical Devices Ltd**

 **(+44) 07428 120 152**

 **Imedidevices@outlook.com**  
**Info@imedicdevices.com**

 **www.imedicdevices.com**

 **Innovation Medical Devices**  
**Bedford Heights, Bedford, MK41 7PH, UK**  
**Company No: 11642659 VAT No: 314340543**