XLIMUS® SIROLIMUS ELUTING CORONARY STENT SYSTEM

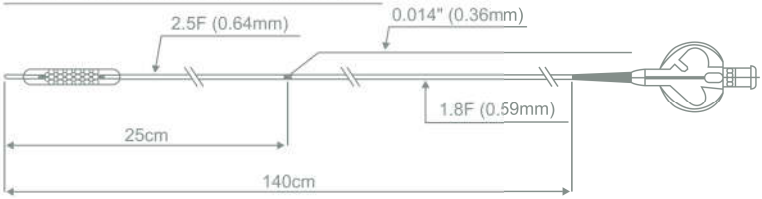
■ Device description

XLIMUS® is composed of a cobalt-chromium L605 stent coated with 1.25 µg/mm² of Sirolimus and mounted on to a balloon of the stent delivery catheter.

- MONORAIL™ balloon catheter;
- Two radiopaque markers which aid in the accurate placement of the stent;
- Stent diameters of 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50 and 5.00 mm and stent lengths of 8, 12, 16, 20, 24, 28, 32, 36 and 40 mm.

The XLIMUS® Sirolimus eluting coronary stent system consists of a RX (Rapid Exchange) Delivery System with 140 cm working length. The proximal catheter is a stainless steel hypotube shaft. The distal catheter is 25 cm long and made of a Polyamide material. A 0.014" PTCA guidewire is inserted into the guidewire entry hole, 25 cm from the catheter tip. The XLIMUS® stent is mounted onto the delivery balloon between two radiopaque markers, proximally and distally to the balloon. The stent is coated with 1.25 µg Sirolimus per mm² stent surface. The drug is incorporated into a biodegradable Poly (L-lactide) (PLLA) drug release matrix.

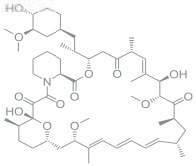
XLIMUS® Sirolimus eluting coronary stent system



■ Drug Component Description

The active ingredient in the XLIMUS® Sirolimus eluting Coronary Stent is Sirolimus (also known as rapamycin). Sirolimus is a macrocyclic lactone produced by *Streptomyces hygroscopicus*.
The computed description InChi of Sirolimus (also known as rapamycin) is InChI=1S/C51H79NO13/c1-30-16-12-11-13-17-31(2)42(61-8)28-38-21-19-36(7)51(60,65-38)48(57)49(58)52-23-15-14-18-39(52)50(59)64-43(33(4)26-37-20-22-40(53)44(27-37)62-9)29-41(54)32(3)25-35(6)46(56)47(63-10)45(55)34(5)24-30/h11-13,16-17,25,30,32-34,36-40,42-44,46-47,53,56,60H,14-15,18-24,26-29H2,1-10H3.
Its molecular formula is $C_{51}H_{79}NO_{13}$ and its molecular weight is 914.2.

The structural formula of sirolimus is shown below:



Sirolimus is a white to off-white powder and is insoluble in water, but freely soluble in benzyl alcohol, chloroform, acetone and acetonitrile.
Please refer to table Order Information and Sirolimus Content for the nominal dosages of Sirolimus on the XLIMUS® Sirolimus eluting Coronary Stent.

■ Order Information and Sirolimus Content

Product Reference	Nominal Expanded Stent Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Sirolimus Content (µg)
XL 2.25-8	2.25	8	33
XL 2.25-12	2.25	12	50
XL 2.25-16	2.25	16	66
XL 2.25-20	2.25	20	83
XL 2.25-24	2.25	24	99
XL 2.25-28	2.25	28	116
XL 2.25-32	2.25	32	132
XL 2.25-36	2.25	36	149
XL 2.25-40	2.25	40	166
XL 2.50-8	2.50	8	33
XL 2.50-12	2.50	12	50
XL 2.50-16	2.50	16	66
XL 2.50-20	2.50	20	83
XL 2.50-24	2.50	24	99
XL 2.50-28	2.50	28	116
XL 2.50-32	2.50	32	132
XL 2.50-36	2.50	36	149
XL 2.50-40	2.50	40	166
XL 2.75-8	2.75	8	49
XL 2.75-12	2.75	12	68
XL 2.75-16	2.75	16	91
XL 2.75-20	2.75	20	114
XL 2.75-24	2.75	24	137
XL 2.75-28	2.75	28	160

Product Reference	Nominal Expanded Stent Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Sirolimus Content (µg)
XL 3.50-8	3.50	8	49
XL 3.50-12	3.50	12	68
XL 3.50-16	3.50	16	91
XL 3.50-20	3.50	20	114
XL 3.50-24	3.50	24	137
XL 3.50-28	3.50	28	160
XL 3.50-32	3.50	32	183
XL 3.50-36	3.50	36	206
XL 3.50-40	3.50	40	229
XL 4.00-8	4.00	8	57
XL 4.00-12	4.00	12	86
XL 4.00-16	4.00	16	115
XL 4.00-20	4.00	20	143
XL 4.00-24	4.00	24	172
XL 4.00-28	4.00	28	201
XL 4.00-32	4.00	32	230
XL 4.00-36	4.00	36	258
XL 4.00-40	4.00	40	287
XL 4.50-8	4.50	8	57
XL 4.50-12	4.50	12	86
XL 4.50-16	4.50	16	115
XL 4.50-20	4.50	20	143
XL 4.50-24	4.50	24	172
XL 4.50-28	4.50	28	201

XL 2.75-32	2.75	32	183	XL 4.50-32	4.50	32	230
XL 2.75-36	2.75	36	206	XL 4.50-36	4.50	36	258
XL 2.75-40	2.75	40	229	XL 4.50-40	4.50	40	287
XL 3.00-8	3.00	8	49	XL 5.00-8	5.00	8	57
XL 3.00-12	3.00	12	68	XL 5.00-12	5.00	12	86
XL 3.00-16	3.00	16	91	XL 5.00-16	5.00	16	115
XL 3.00-20	3.00	20	114	XL 5.00-20	5.00	20	143
XL 3.00-24	3.00	24	137	XL 5.00-24	5.00	24	172
XL 3.00-28	3.00	28	160	XL 5.00-28	5.00	28	201
XL 3.00-32	3.00	32	183	XL 5.00-32	5.00	32	230
XL 3.00-36	3.00	36	206	XL 5.00-36	5.00	36	258
XL 3.00-40	3.00	40	229	XL 5.00-40	5.00	40	287

■ Indications and usage

The XLIMUS® Sirolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete, de novo native coronary artery lesions with lesion length of up to 40mm in native coronary arteries with a reference diameter from 2.25 mm to 5.00 mm.

■ Contraindications

The XLIMUS® Sirolimus Eluting Coronary Stent System is contraindicated and patients must be excluded if any of the following criteria are met:

General Exclusion Criteria

1. Known sensitivity to Sirolimus or its derivatives, and PLLA polymer, known hypersensitivity to cobalt chromium L605.
2. Known sensitivity reaction to contrast agents that cannot be adequately premedicated prior to the XLIMUS® index procedure.
3. Patients in whom antiplatelet and / or anticoagulant therapy is contraindicated.
4. Patients with lesions that prevent complete inflation of an angioplasty balloon or proper stent placement.
5. The XLIMUS® Sirolimus Eluting Coronary Stent System is not indicated for use in non- coronary vessels.
6. The XLIMUS® Stent is not indicated for heavily calcified lesions.

■ Warnings and precautions

Warnings

- The implantation device carries an associated risk of subacute thrombosis, vascular complications, and/or bleeding events. There is a potential risk of vasculitis (local inflammatory reaction) Potential complication, which may be associated with the addition of Sirolimus to PLLA may not be limited to the above listed potential side effects.
- Please ensure that the inner package has not been opened or damaged as this may indicate the sterile barrier has been breached.

ANTIPLATELET REGIMEN:

- Administration of appropriate anticoagulant, antiplatelet and coronary vasodilatory therapy is critical for a successful long-term result! An antiplatelet regimen of Clopidogrel or Ticlopidine, is required according to the indications for duration expressed in 2016 AHA/SCAI Guideline focused update on duration of DAPT in patients with Coronary Artery Disease. Acetylsalicylic acid is to be administered indefinitely to reduce the risk of thrombus and restenosis.
- Persons allergic to cobalt-chromium or Sirolimus may suffer from an allergic reaction to the implant.
- Implantation of the stent should be performed only by cardiologists who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilation of the arterial segment containing the stent. The long-term outcome following repeat dilation of coronary stents is unknown at present.
- Low concentrations of Sirolimus, as eluted from the stent surface, might induce local genotoxic effects. Since no long-term genotoxicity testing has been completed at this time, the patient's benefit from using the XLIMUS® Stent System should be weighed against these potential risks for the patient. Due to extreme low dose concentration of Sirolimus (287µg, stent length 40mm, diameter 4.0mm) if compared with a daily systemic dose of 2mg (2000µg,) of Rapamune (Sirolimus) for a lifetime in patients who require immunosuppressive treatment any risk potential of carcinogenicity, reproductive toxicity and genotoxic effects is considered as non significant.

When multiple stents are required (multi vessel disease) stent material should be of identical chemical and physiochemical composition to avoid dissimilar metal corrosion. The extent of the patients exposure to drug and polymer is directly related to the number of stents implanted. Use of more than two XLIMUS® Stents has not received adequate clinical evaluation. However, the length of one XLIMUS® stent of 40mm does not contain more drug amount than for example more stents of shorter lengths, which may add up to one total stent length of 40mm.

Precautions

DRUG INTERACTIONS:

Drug interaction studies have not been conducted with the XLIMUS® Stent. Sirolimus is extensively metabolized by Cytochrome P450 3A4 in the gut wall and liver and undergoes efflux from enterocytes of the small instine by P-glycoprotein (P-gp). Therefore absorption and subsequent elimination of systemically absorbed drug may be influenced by other drugs that affect these proteins. Drugs that may increase Sirolimus blood concentration include Calcium channel blockers (nicardipine), antifungal agents (clotrimazole fluconazole, itraconazole) Macrolide antibiotics (clarithromycin, troleandomycin), Gastrointestinal prokinetic agents (cisapride, metoclopramide), other drugs (bromocriptine, cimetidine, danazol, HIV-protease inhibitors). Drugs that may decrease Sirolimus levels include Anitconvulsants (carbamazepine), phenobarbital, phenytoin) and Antibiotics/rifabutin, rifapentine). These lists not all inclusive and care should be exercised when drugs or other substances that are metabolized by Cytochrome P450 3A4 (CYP3A4) are administered concomitantly with implantation of the XLIMUS® Stent. The mechanism or mechanisms by which the XLIMUS® Stent affects neointimal production has not been completely established. It is however known, that Sirolimus inhibits T-lymphocyte activation and smooth muscle cell and endothelial cell proliferation in response to cytokine and growth factor stimulation. In cells it binds to the immunophilin, cytosolic protein FK-binding protein 12 (FKBP12). The Sirolimus-FKBP-12 binds to and inhibits the activation of the mammalian Target of Rapamycin (mTOR), leading to inhibition of cell cycle from G1 to S phase.

STENT HANDLING PRECAUTIONS:

- **For single use only!**

- The XLIMUS® Sirolimus Eluting Coronary Stent System is designed for use as a single unit. Do not resterilize or reuse the product that has reached or exceeded its Expiry Date on the product label.
- The stent should not be removed from its delivery balloon. The stent is not designed to be crimped onto another balloon.
- In the event the XLIMUS® Stent is not deployed, follow product withdrawal procedures and avoid handling of the stent with bare hands.
- Special care must be taken not to handle or in the way disrupt the stent position on the delivery device.This is most important during catheter removal from packaging, placement over the guidewire, and advancement through the hemostasis valve adapter and guiding catheter hub.
- Excessive manipulation, e.g., rolling the mounted stent, may cause coating damage or dislodgment of the stent from the delivery balloon.
- Use only the appropriate balloon inflation media (see Section Operator's Instructions). Do not use air or any gas medium to inflate the balloon.
- Stent contact with any fluid prior to placement is not recommended as there is a possibility of drug release. However, if it is absolutely necessary to flush the balloon with sterile/isotonic saline, contact time should be limited (1 minute maximum).

Stent Placement – Precautions

Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described Operator's Instructions. Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilation, placement of additional stents, or other). The target lesion must be sufficiently predilated prior to stent implantation. Do not expand the stent if it is not properly positioned in the vessel (see **Section Stent System Removal – Precautions**). Placement of the stent has the potential to compromise side branch patency. Balloon pressures should be monitored during inflation. **Do not exceed rated burst pressure as indicated on product label** (see Table 1). Use of pressures higher than specified on product label may result in a ruptured balloon and potential intimal damage and dissection. The vessel should be pre-dilated with appropriate diameter balloon having a 1:1 ratio with the vessel diameter. Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma or pseudoaneurysm.

Stent System Removal – Precautions

If removal of a Stent System is required prior to deployment, ensure the guiding catheter is coaxially positioned relative to the Stent System and cautiously withdraw the Stent System into the guiding catheter. Should unusual resistance be encountered when withdrawing the Stent System into the guiding catheter, the Stent System and the guiding catheter should be removed as a single unit. This must be done under direct visualization with fluoroscopy. Do not at tempt to pull the Stent System back into the guiding catheter as dislodgment of the stent from the balloon may occur.

When removing the entire Stent System as a single unit:

Do not pull the Stent System into the guiding catheter. Maintain guidewire placement across the lesion and carefully pull back the Stent System until the proximal balloon marker of the Stent System is aligned with the distal tip of the guiding catheter.

- The guiding catheter and the Stent System should be carefully removed from the coronary artery as a single unit.
- The Stent System should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten allowing safe withdrawal of the Stent System into the guiding catheter and the subsequent removal of the Stent System and the guiding catheter from the arterial sheath.
- Failure to follow these steps, and/or applying excessive force to the Stent System can potentially result in loss of, or damage to, the stent or stent system components such as the balloon.

Post Implant – Precautions

- Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry or coating.
- Do not perform Magnetic Resonance Imaging (MRI) scan on patient's post-stent implantation until the stent has been completely endothelialized (90 days) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.
- Prescribe an antiplatelet therapy (i.e., clopidogrel or ticlopidine) for a period of 6 months to reduce the risk of stent thrombosis.

Drug Interactions

Possible interactions of Sirolimus with concomitantly administered medications have not been formally investigated. Drug interactions of systemic levels of Sirolimus with possible concomitant medications are outlined in the labeling for finished pharmaceuticals containing Sirolimus. Given that the amount of Sirolimus loaded onto each XLIMUS® Stent system is released locally, at considerably lowest levels, drug interactions are unlikely to be detectable. This is reinforced since systemic levels of Sirolimus have not been detected post stent placement in clinical trials.

Pregnancy

This product has not been tested in pregnant women or men intending to father children; therefore recipients of this device should be advised to avoid becoming pregnant. While there is no contraindication, the risks and reproductive effects remain unknown.

■ **Potential adverse events**

Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to:

- Abrupt stent closure
- Access site hematoma
- Acute myocardial infarction
- Acute/subacute stent occlusion
- Allergic reactions to anticoagulant
- Angina
- Cardiac Arrhythmia
- Cardiogenic shock
- Death
- Dissection
- Emboli
- Heart Failure
- Hypersensitivity reaction
- Hypotension/Hypertension
- Ischemia myocardial
- Partial stent deployment
- Perforation or Rupture
- Pseudo Aneurysm, femoral
- Renal Failure
- Respiratory Failure
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent migration
- Stent thrombosis
- Stroke, cerebrovascular accident
- Total occlusion of coronary artery
- Vessel trauma requiring surgical intervention

■ Important patient information

Physicians should consider the following in counselling patients about this product:

- The risks associated with stent placement,
- The risks associated with a Sirolimus eluting stent,
- The risks of early discontinuation of the antiplatelet therapy,
- The risks of late stent thrombosis with DES use in higher risk patient subgroups,
- The risk/benefit issues for this particular patient,
- Alteration to current life-style immediately following the procedure and over the long term.

■ How supplied

Sterile: This device is sterilized with ethylene oxide gas. It is intended for single use only.
Non-pyrogenic. Do not use if package is opened or damaged.
Contents:
One (1) XLIMUS® Sirolimus Eluting Coronary Stent System
One (1) Instructions for Use Manual
One (1) XLIMUS® Compliance Chart

■ Operator's instructions

Inspection Prior to Use

Carefully inspect the sterile package before opening. Do not use after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package), contact your local CARDIONOVUM Representative for return information. Do not use if any defects are noted.
NOTE: If at any time during use of the Premounted Stent System the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

Materials Required (not included in Stent System package)

Quantity	Material
1	Appropriate guiding catheter (see Table 1 – Stent Delivery System Specifications)
1	20 ml (cc) syringe Normal Heparinized Saline
1	0.014 in. /0.36 mm guidewire
1	Rotating hemostatic valve Diluted contrast medium 1:1 with normal heparinized saline
1	Inflation Device
1	Torque Device
1	Pre-deployment dilation catheter
1	Three-way stopcock
1	Flushing needle with luer fitting

Preparation Packaging Removal

Step	Action
1.	Carefully remove the delivery system from its XLIMUS® tubing for preparation of the delivery system. Do not bend or kink hypotube during removal.
2.	Remove the product mandrel and stent XLIMUS® by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent XLIMUS and gently remove distally.

NOTE: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

Guidewire Lumen Flush

Step	Action
1.	Flush Stent System guidewire lumen with normal heparinized saline using flushing needle.
2.	Verify that the stent is positioned between the proximal and distal balloon markers. Check for bends, kinks and other damage. Do not use if any defects are noted.

Balloon Preparation

Step	Action
1.	Take care that the stent and the carrier balloon do not come into contact with liquids, since otherwise the medication coating may be released pre maturely. However, if it is absolutely necessary to flush the balloon with saline, contact time should be limited (1 minute maximum).
2.	Prepare inflation device/syringe with diluted contrast medium.
3.	Attach inflation device/syringe to stopcock; attach to inflation port. Do not bend the hypotube when connecting to inflation device/syringe.
4.	With tip down, orient Stent System vertically.
5.	Open stopcock to Stent System; pull negative for 30 seconds; release to neutral for contrast fill.
6.	Close stopcock to Stent System; purge inflation device/syringe of all air.
7.	Repeat steps 4 through 6 until all air is expelled. If bubbles persist, do not use device.
8.	If a syringe was used, attach a prepared inflation device to stopcock.
9.	Open stopcock to Stent System.
10.	Leave on neutral.

Delivery Procedure

Step	Action
1.	Prepare the vascular access site according to standard PTCI practice.
2.	Predilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel.
3.	Maintain neutral pressure on inflation device attached to Stent System.
4.	Backload Stent System onto proximal portion of guidewire while maintaining guidewire position across target lesion.
5.	Fully open rotating hemostatic valve to allow for easy passage of the stent and prevent damage to the stent.
6.	Ensure guiding catheter stability before advancing the Stent System into the coronary artery. Carefully advance the Stent System into the hub of the guiding catheter, keeping the hypotube straight.

NOTE: If the physician encounters resistance to the Stent System prior to exiting the guiding catheter, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the Stent System as a single unit (see **Section Stent System Removal – Precautions**).

7. Advance the Stent System over the guidewire to target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque balloon markers as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Section Stent System Removal – Precautions). The inside edges of the marker bands indicate both the stent edges and balloon shoulders inflated Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.
8. Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

Deployment Procedure

Step Action

1. Inflate the Stent System expanding the stent at the nominal pressure (see Table 1). Higher pressures may be necessary to expand the stent to optimize stent apposition against the arterial wall. Balloon pressure must not exceed rated burst pressure (see Table 1).
2. Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3. Deflate balloon by pulling negative on inflation device until balloon is fully deflated.
4. Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall. All efforts should be taken to assure that the stent is not underdilated.
5. If stent sizing/apposition requires optimization, readvance the Stent System balloon, or another balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.
6. Inflate the balloon to the desired pressure while observing under fluoroscopy. Deflate the balloon (see Balloon Compliance Chart supplied with device).
7. Reconfirm stent position and angiographic result. Repeat inflations until the desired result is achieved.

Removal Procedure

Step Action

1. Ensure balloon is fully deflated.
2. Fully open rotating hemostatic valve.

While maintaining guidewire position and negative pressure on inflation device, withdraw Stent System (see **Section Stent System Removal – Precautions**).

In Vitro Information

Refer to Balloon Compliance Chart supplied with device for stent inner diameter at nominal pressure to rated burst pressure (see Table 1). Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your CARDIONOVUM representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

■ **Stent Implant Card - takes in force on 26 May 2021**

The implanting healthcare facility or healthcare provider that treats the patient should fill out the attached implant card and provide it to the patient. The empty implant card is supplied by CARDIONOVUM together with the implanted device in a package and should be filled by the doctor in according to the instructions on the card after the treatment.

Explanation of the symbols used on the implant card:

	**Patient Name**
	**Implant Date**
	**Healthcare institution**
	**Manufacturer**
	**Patient Information website**
	**Medical Device Name**

LOT	**LOT number/ Batch code, LOT-Nummer / Chargencode**
UDI	**Unique device identifier (UDI)**

All other required information on the XLIMUS Sirolimus Eluting Coronary Stent System, coronary artery disease, and the stent implantation procedure can be found by patient on the CARDIONOVUM's website: https://cardionovum.de/xlimus/

■ **Important note to the physician**

As the XLIMUS® Sirolimus Eluting Coronary Stent System is a medical device and not a pharmaceutical drug the cardiologist must inform the patient about the risk associated with the procedure, the risk associated with the XLIMUS® Sirolimus Eluting Coronary Stent System, pre- and post procedure treatment and care.

■ **Warranty**

CARDIONOVUM warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond CARDIONOVUM control directly affect the instrument and the results obtained from its use. CARDIONOVUM's obligation under this warranty is limited to the repair or replacement of this instrument and CARDIONOVUM shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. CARDIONOVUM neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.
CARDIONOVUM assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instrument.
XLIMUS® is a trademark of CARDIONOVUM.

■ **Advice:**

The stent delivery system is used for stent deployment only. After stent deployment, reuse of the balloon catheter is not allowed. The Products are for single use only and should not be cleaned, disinfected and resterilized. This form of conditioning would lead to unsterile Products and could cause infections to the patient and also risk of balloon rupture.

Explanation of symbols used on the package labels.


Do not re-use


Consult instructions for use


Date of manufacture

Reference number


Manufacturer

Batch code

Sterilized using ethylene oxide


Use by Date


Outer Diameter


Keep Dry

French size

Temperature limit

Nominal pressure

Rated Burst Pressure


Do not use if package is damaged


Keep away from sunlight

Do not resterilize


Non pyrogenic

Medical Device

CE 1434

CARDIONOVUM GMBH

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