LasCor
Laser Medical Devices

Open Irrigated Electrode - Laser Mapping and Ablation (ELMA) Catheter for Magnetic Navigation

RytmoLas®m

A cardiovascular laser catheter with magnetic pods placed in a highly flexible distal catheter segment.

INSTRUCTION FOR USE (IFU)

GENERAL DESCRIPTION

RytmoLas®m is a tripolar 8F ELMA catheter with a 15.0 cm 7F flexible distal segment with magnetic pods, designed for:

- **magnetic navigation** by using the Stereotaxis System,
- .**non-contact** percutaneous transluminal catheter directed **cardiovascular laser application.**
- .**high density (HD)-mapping** guided **localization** and
- .**selective ablation** of arrhythmogenic substrates
- .**selective** sympathetic modulation/denervation
- .**selective** HOCM and CHAGAS-VT ablation
- **infusion of liquids**.

For these applications, the following devices are needed:

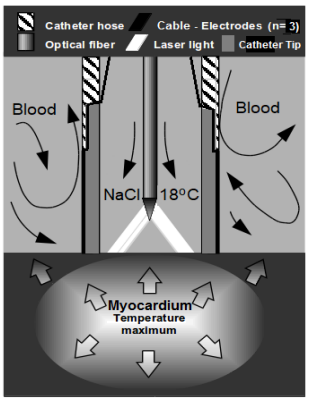
- .the magnetic navigation system Niobe Stereotaxis
- the laser ***CardioVascLas® LasCor®*** GmbH,
- .with its irrigation pump ***IriFlowLas® LasCor®*** GmbH
- .the noninvasive diagnostic **NAVIX system**
- a high frequency stimulation (**HFS**) device

The highly flexible distal segment of the catheter allows for a precise **orientation in the magnetic field**. Magnetic navigation towards the myocardial area of interest is performed under X-ray control and/or by the noninvasive **diagnostic NAVIX system**. Transcatheter application of 1064nm laser light is performed **without pressure** upon the myocardial wall. Heat is induced under **normothermic** conditions, deep intramurally, by selective absorption of photons in the arrhythmogenic myocardium whereas the **catheter itself is not heated up**.

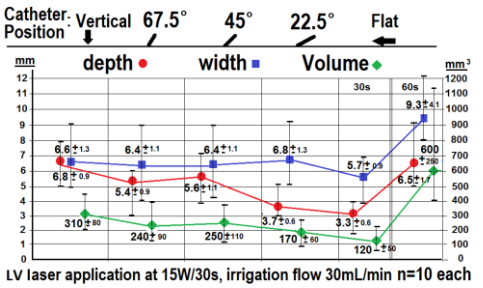
The three 5 mm long cable electrodes mounted at **≤2mm interelectrode distances** longitudinally on the catheter head allow for **HD mapping guided** localization of arrhythmogenic substrates, and for **online monitoring** of electrical potential amplitudes, without interfering with the electrophysiologic monitoring principles, **without hum** in the ECGs, **during laser application!** Laser-induced gradual weakening of potential amplitudes in the HD mapping electrograms indicates lesion growth and facilitates real-time verification of initial success. 1064nm laser light is **selectively** absorbed in myocardium, lesions are limited to the targeted arrhythmogenic substrate whereas transparent tissues such as the endo-and epicardium are not affected.

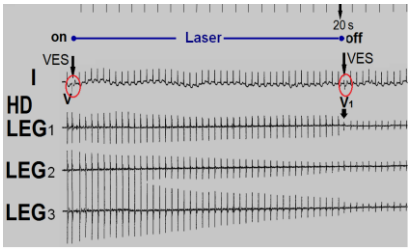
Laser lesions are **clear-cut**, produced **within seconds**, without tissue vaporization with crater or thrombus formation. The method is **not thrombogenic**. With the abolishment of electrical potential amplitudes in the HD mapping ECG electrogram **lesions are transmural** (Correlation Coeff. 0.9). Importantly, by **stopping radiation** with the permanent abolishment of potential amplitudes transmural lesions are **limited to the substrate**, **sparing adjacent tissues, such as lung and esophagus, from thermal damages.**

Catheter irrigation with heparinized saline, 5000IU/mL is mandatory. It washes away the blood **creating a free pathway** for the laser light and **avoids blood clotting** when the catheter is free floating in the blood stream. Penetration of blood into the catheter would burn the fiber tip and endanger the patient. In addition, saline irrigation at room temperature of 18°C performed continuously at a rate of 15 mL/min, and at a rate of 35 mL/min during radiation cools the irradiated endocardial surface. In general, during the laser treatment of up to 2 hours **volume overload of the patient is avoided**.

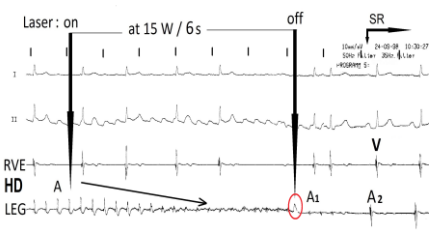


Scheme of the catheter end and of heat distribution in the myocardial wall



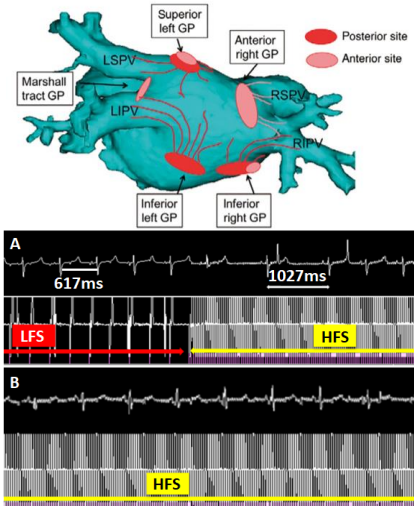


*Gradual dwindling of potential amplitudes in **HD** electrograms **without electrical hum during LV laser application**. **Note:** VES with laser on and off (Red ovals)*



***HD** mapping (LEG) in a patient with long lasting persistent AF showing **gradual dwindling** (oblique arrow) and abolishment (A_1) of potential amplitudes **during AF ablation** = **Online monitoring** of successful ablation (A_2). Spike laser **off** (red oval)*

Localization of ganglion Plexi outside the atria



A No atrial or ventricular capture during low frequency stimulation (LFS) at a point outside the localization of ganglion plexi whereas HFS - high frequency stimulation results in slowing of atrial rhythm from 617 ms to 1027 ms.
B After laser application aimed at the same point as in **A** no change in atrial cycle length is seen during HFS

Selective ganglion plexi (GP) modulation increases AF ablation success rate and reduces recurrences of AF and LA tachycardia.

APPLICATIONS

The ***RytmoLas®m*** applies the laser via an optical fibre with a highly divergent light beam in a **non-contact** mode of radiation The fibre tip is mounted at a given distance from the end-hole of the catheter and saline irrigation creates a 3-4mm clear channel for the light from the catheter tip to the target area.

Laserinduced absorptive heating is selective, depending on the composition of the target tissue and the laser wavelength used. When using the 1064nm laser light with its low absorption in water heat is initially created deep intramurally by **selective absorption of photons by myocytes**. Lesions are growing within seconds by photon scattering, and, eventually, by heat convection in the myocardial wall.

By means of the recommended power settings controllable intramural temperature maximum and transmural lesions limited to the myocardial walls are achieved without tissue vaporization with crater or thrombus formation.

Indications

The ***RytmoLas®m*** is an electrode catheter for **HD** mapping of intracardiac electrical potentials and for determination of conduction intervals. Indirect control of myocardial heating can be performed by continuous monitoring of laser-induced gradual attenuation of local potential amplitudes in the **HD** LEG recorded via the cable electrodes from the catheter tip.

Via its optical fiber the cardiac walls can be radiated with laser light. A divergent laser beam allows for radiation at lower power short duration **(LPSD)** without tissue vaporization with crater formation preserving the anatomical integrity of the heart and vessels and allows for selective sympathetic modulation of retrocardiac ganglion plexi.

Contraindications

The use of ***RytmoLas®m*** may be contraindicated if there is a known or suspected obstruction in the vessel access or a vessel spasm. Acute severe chronic diseases, especially a substantially reduced left ventricular function, obstruction of coronaries and angina pectoris, increase the procedure risk and may contraindicate its use.

SAFETY NOTES

Reuse

The ***RytmoLas®m*** is designed for single use only. Cleaning or reuse can result in serious complications. ***LasCor®*** will not be responsible for any direct or consequential damages or expenses which result from cleaning or reuse.

Sterilization

The catheters are shipped after sterilization with **EO**. Do not use products from opened or damaged packaging. Under appropriate storage conditions, we guarantee sterility in undamaged packaging until the expiry.
Sterile products should be stored at humidity of 45-70% and at temperatures of 18-25°C. They should not be exposed to direct sunlight and must be used before the expiry date on the packaging. (DIN 58953)

! The *RytmoLas®m* is for single use. Resterilization and reuse would jeopardize catheter function and would endanger the patient.

External Interference

The regulations for electromechanical devices apply to temporary leads and electrodes such as the catheters ***RytmoLas®m.*** If line-powered instruments are used close to the patient, adequate measures must be taken to avoid those extraneous electrical currents reach the external pacemaker, the lead, or the heart.

Such currents may trigger severe complications such as lethal arrhythmias. Use only such instruments that comply with protection class CF (cardiac floating) and follow the instructions given in their manuals.

Side effects and complications

Despite correct handling of the ***RytmoLas®m*** complications may occur such as:

- Vessel spasm and local bleeding
- Subcutaneous Hematoma.
- Rupture of a valve, Pneumothorax or hemothorax
- Thrombosis and embolism due to blood clotting or air bubbles
- Arrhythmias of the heart, e.g., ventricular fibrillation and AV block.

Catheter Check

During mapping and laser application the ***RytmoLas®m*** is subjected to a variety of mechanical and thermal strains. If catheter damage is suspected, both the mechanical and optical integrity of the catheter must be verified by visual inspection.

> **! This device should be exclusively applied by electrophysiologists who are trained and experienced in the field of cardiovascular laser application.**

Laser Safety

The ***RytmoLas®m*** must be used in compliance with current laser safety regulations. Operators and personnel must have sufficient knowledge about potential hazards and safety measures for medical laser application.

Safety Hazard

Laser coagulation of myocardium is performed by means of invisible continuous wave Nd:YAG laser light at 1064nm wavelength. Due to low absorption in water, it can easily penetrate the eyeball, and irreversible damage of the retina is the primary safety hazard.

> **! Never point a connected *RytmoLas®m or variant* towards a person or reflecting surfaces.**
>
> **! Enable laser radiation only when the *RytmoLas*®m is positioned inside the body. Disenabling of the laser footswitch is:**
>
> **1. advisable after each laser application, and is**
> **2. mandatory before removing the catheter from the patient.**
>
> **Check the laser beam profile only by means of the red pilot beam, never by releasing invisible and hazardous 1064 nm laser light.**
>
> **Use eye protection that blocks 1064 nm wavelength.**

Laser safety measures primarily include the prevention of inadvertent laser emission and eye protection for people staying inside the laser area, defined by the area, in which radiation exceeds the authorized value. The ***RytmoLas®m c***auses a laser area of 1.3 m radius, measured from the catheter tip, calculated according to laser safety regulation DGUV-V 11 (previously BGV B2) for an irradiation at 20 W/10 s.

Safety hazards are significantly reduced, if laser emission is inhibited on the laser panel whenever the ***RytmoLas®m* is handled outside the patient**. During catheterization however, a temporary laser area is caused inside the patient, when the foot switch is enabled, and no hazardous radiation can be released into the operating room. All severe incidences caused using the ***RytmoLas®*** or its variants must be reported immediately to the manufacturer and to the local authorities.

For safety report see Fax Template attached.

Thus, from a practical point of view, laser safety goggles are not necessary. However, laser goggles may be mandatory due to local safety regulations. To visualize the course of the non-visible laser beam, medical lasers are equipped with a harmless red pilot beam. This beam is suitable to control the radiation characteristics of the ***RytmoLas®m*** and to study the different beam properties in air and water.

Medical lasers and accessories such as optical fibers or catheters are controlled by a series of hardware switches to avoid inadvertent radiation or radiation under inappropriate conditions.

Before laser application can be started by pressing the laser foot switch, the catheter must have been flushed with saline, properly connected, and the foot switch must have been enabled on the laser front panel. Make sure to regularly check the functions of the laser safety chain.

RISK MANAGEMENT

A ***RytmoLas®m*** inserted into the patient cannot radiate hazardous laser light into the environment. Laser hazard increases only when the connected catheter is handled outside the patient, e.g., during visual inspection of the catheter. It is highly recommendable to enable the laser footswitch only when the ***RytmoLas®m*** is already placed on the target site in the patient's body and to inhibit laser emission after laser application.

Additional hazards can be provoked when the ***RytmoLas®m*** is handled inappropriately, especially when the optical cable is bent around sharp edges or is jammed under wheels or heavy weights.

The fiber tip of the ***RytmoLas®m*** mounted at a given distance from the end hole in the central lumen of the catheter tip is effectively protected against mechanical forces acting on the catheter during heart catheterization.

However, it must be strictly avoided to clean its distal end hole by means of sharp objects such as metal pins or cannula, as this might cause fiber breakage. In this case, application of the ***RytmoLas®m*** would not be safe anymore, and this could endanger patients.

HANDLING

Preparation of the Laser System

Calibration

The ***RytmoLas®m*** is optimized for radiation in an aqueous medium and cannot be calibrated in air. Light transmission is therefore measured by the manufacturer. Only qualitative control of the laser spot must be performed by operators (see chapter "Catheter Control").

Pump Triggering

Pump triggering via the laser footswitch should be checked before clinical use. Make sure that the footswitch changes the pump flow rate, and that laser light are only applied simultaneously with the start of the increased flow rate from 15mL/min continuous flow to 35mL/min, the lasing flow.

> **! *RytmoLas®m* must be irrigated during irradiation and be surrounded by an aqueous medium. Laser irradiation without irrigation can destroy the catheters and could endanger patients.**

PREPARATION OF THE PATIENT

The patients should be in a good clinical condition. Preferably, primary diagnosis is performed without anti-arrhythmic medication. A venous access line is needed for volume and electrolyte substitution, antithrombotic and optional for drug treatment.

Percutaneous puncture performed under sterile conditions allows access to the cardiovascular system via a vein or artery from the groin or an arm.

From there all the vessel segments and cardiac chambers can be reached. Left heart catheterization is practicable also via an open foramen ovale or after side selective interatrial septal laser puncture (see IFU: ***ISPunctureLas®***).

Connecting the Catheters

Main functions of the ***RytmoLas®m*** and its connections to external devices is to be checked prior to clinical application. This mainly includes:

- Integrity and sterility of the packaging,
- Catheter irrigation
- Laser spot

Thoroughly inspect the packaging and expiry date before opening. Draw the cover sheet off the double sterilization envelope and remove the catheter. For connection of the FSMA to the laser, first remove the protective cap.

> **! Inappropriate handling, bending around sharp edges, jammed under wheels or heavy weights can destroy the catheter.**

Be sure not to touch or soil the polished proximal end of the optical fiber. Insert the FSMA plug into the coupling port of the laser and fully tighten the screwcap until the safety interlock reacts by switching on the pilot laser. Check the course of the optical cable. It should not run next to wheels or across sharp edges.

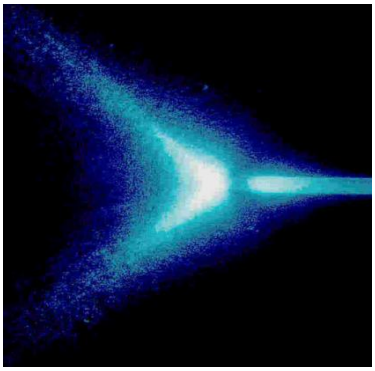
Avoid bending radii below 5 cm. Light should only be radiated from the catheter end hole. Do not use catheters if light is leaking through the cable or the catheter body.

Plug the electrical cables in the ECG unit according to chapter "Connections". Insert sterile original tubing into the peristaltic pump.

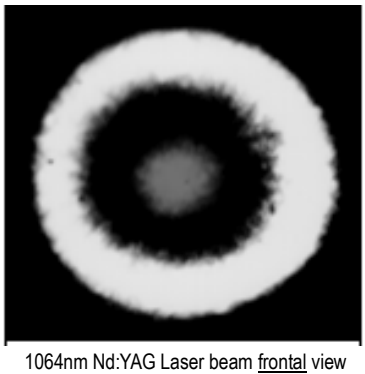
Connect the inflow to heparinized saline and the outgoing line to the laser catheter. Set the pump flow to 35mL/min and flush the line and catheter to remove air bubbles. By releasing the footswitch, a continuous flow of 15mL/min saline must leave the distal catheter end. Control the tightness of all connections. The tubing must not be distended by excessive pressure.

Test: set the continuous background flow rate to 15 ml/min, and lasing flow rate to 35 mL/min. Start the background flow and step on the laser footswitch while laser emission is still inhibited. The pump must now automatically switch to the lasing rate. When releasing the footswitch, the pump must return to the continuous background flow of 15mL/min.

Eventually, inspect the laser spot of the laser catheters. This test must be performed after irrigation, as the dry catheter radiates a completely different laser beam. Dip the catheter tip into a white cup filled with sterile water or saline. Avoid reflective metal surfaces. The laser spot must be visible as a clear-cut continuous ring ("Donut"). An additional spot may be visible in its center that must not be brighter than the ring. Do not use catheters with anomalous laser spots.



1064nm Nd:YAG Laser beam lateral view



1064nm Nd:YAG Laser beam frontal view

Catheter Insertion
The following description is a proposal based on general experience in the use of electrophysiological heart catheters. Investigators may change procedure details according to their personal experience.

The ***RytmoLas®m*** is inserted percutaneously via commercially available introducers. Its distal segment is provided with magnetic pods for magnetic navigation in the cardiovascular system (IFU: ***Stereotaxis*** St. Louis, USA). Its distal electrodes are used for **HD** mapping and alternatively **HF** stimulation for localization of sympathetic innervation. In addition, pairs of cables located more proximally are used for the noninvasive diagnostic NAVIX system.

Do not use inappropriate introducer sheaths or guiding catheters as they may jeopardize the functions of the ***RytmoLas®m*** and may increase the complication rate!

Procedure

After aseptic skin preparation and sterile covering of the insertion area, the vein or the artery in the groin or arm is punctured (Seldinger technique), or access to the vessel is achieved by cut down. Then, the vessel is hold by a tourniquet and is opened by a tiny cut for the sheath or catheter insertion.

Connect the laser catheter to the manyfold, to the laser and the peristaltic pump and flush the laser catheter fully to remove air bubbles.

Introduce the catheter into the inserted sheath or through the vessel prepared for direct access after losing the torniquet.

Advance the catheter under continuous flushing with saline and under X-ray and NAVIX control to the targeted heart chamber or vessel segment.

Catheter manipulation
The ***RytmoLas®m*** can be advanced, withdrawn and twisted by using the magnetic navigation system according to the instructions (see IFU) of the Stereotaxis-Niobe system.

Laser Application
The laser is used in the continuous wave irradiation mode at a distal laser power of 10W or 15W depending on the thickness of the target tissue: atrial, ventricular or vessel wall. To avoid inadvertent release of laser light, triggering by the laser, footswitch must be dis-enabled during catheter insertion and manipulation.

After HD mapping-guided positioning of the catheter tip in intimate contact upon the cardiac area or the vessel segment of interest, laser radiation is enabled by means of the laser button on the laser front panel and laser radiation can be released by pressing the laser footswitch.

Simultaneously with the start of laser radiation the peristaltic pump flow increases to the preset flow rate of 35mL/min and laser alarm sounds. Radiation is terminated automatically after the preset pulse duration or by releasing the footswitch.

Longer application times are achieved by consecutive pulses. In this effort, the default pulse durations should be applied, and the radiation statistics displayed on the laser panel should be documented.

For safety reasons, the laser footswitch should be disenabled immediately after each laser application, no matter if the catheter remains in the patient for further treatments.

!	**Disenable laser radiation before removing the catheter from the patient.**

Laser radiation may produce a painful sensation of heat or pressure in the chest, or pain in the kidney or vessel region, respectively. In rare cases analgesics may be required.

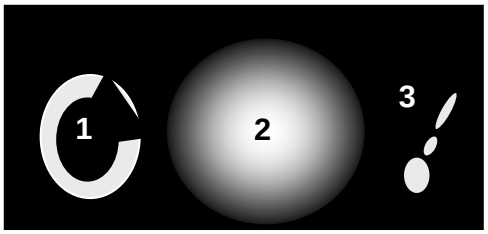
Amplitude reduction in the HD electrocardiograms recorded via the cable electrodes of the ***RytmoLas®m*** during laser radiation is a marker for effective laser application and stable catheter position.

If electrical potential amplitudes in the **HD** mapping ECG remain unchanged throughout the first 5 seconds of radiation, laser application should be terminated, and the catheter be repositioned.

Catheter Control
Whenever suspecting a reduced catheter performance or a malfunction, the laser catheter should be inspected.

This includes its general appearance and the shape of the laser beam profile. Post-application laser beam inspection is analogous to the initial catheter check after unpacking.

Do not use catheters with deteriorated beam profile.



Deteriorated beam profiles:
1. **Interrupted ring (tip deformation casts a shadow): *Reduced effect*, potential overheating of the catheter**
2. **Diffuse radiation (following contamination of the fibre tip): *Reduced effect.***
3. **Collimated and** partly **asymmetrical radiation (due to fibre breakage) DANGER! High risk of perforation; increased laser safety hazard.**

Radiation from a damaged optical fiber can cause severe complications such as endomyocardial burning with tissue vaporization and crater formation, perforation, rupture of chordae and valves, and may produce steam pop and thrombi with the risk of myocardial infarction and stroke.

Connections

ECG Recordings
The ***RytmoLas®m*** is provided with three pin electrodes according to E-DIN 42802-2. Due to the symmetrical electrode arrangement, the plugs are not labeled. Electrodes are **framing the radiation field**. The standard wiring yields a bipolar tip deflection. As there is no direct interference between laser light and the recorded electrical current, the **HD** mapping electrogram can be continuously monitored even **during** laser application without special input filtering.

In addition, electrode pairs positioned more proximally at different distances from each other are usable for the noninvasive diagnostic NAVIX system.

In case of cardioversion / defibrillation, the plugs must be removed from units that are not protected against DC shock application. There is no electrical connection between the laser and the patient or the operation field. Defibrillators cannot harm the laser.

Laser
The laser catheters are connected to a diode laser via a flexible optical fiber provided with an SFMA connector at its proximal end. As light transmission and radiation characteristics of the catheter depend on the laser model, for cardiovascular laser Applications use only the Laser:

CardioVascLas® 1064 nm ***LasCor®*** GmbH

Catheter Irrigation
The catheter is flushed continuously with heparinized saline by means of a peristaltic pump via an irrigation tube with female Luer connector. Irrigation must be performed by a laser-triggered peristaltic pump. This is mandatory for a safe and correct application of all the open-irrigated laser catheters.

Irrigation is to be performed at a rate of at least 15 mL/min, rate that is automatically increased to 35 mL/min during laser application. Manual pump adaptation is not recommendable. Do not use other pumps than the laser peristaltic pump:

IriFlowLas® LasCor® GmbH

EXCLUSION OF LIABILITY

The laser catheter is used in the thoroughly aggressive environment of the human body. Moreover, the needed flexibility and the very small diameter of the catheter invariably result in limited reliability.

Catheter can fail for any number of reasons, among which there are medical complications, rejection reactions of the body, fibrosis, dislocation, erosion or migrating through body tissue or resulting from a break or tear in insulation.

Despite the greatest possible care taken in development, choice of components, assembly, and final control prior to delivery, the ***RytmoLas®m*** can become damaged by negligent handling or other influences, during or after introduction.

As a result, we do not assure or guarantee in any way that a disturbance or discontinuation of function will not occur, nor that the human body will not reject the introduced catheter, nor that there will be no medical complications, including myocardial perforation, because of introducing the catheter.

Since the accessories can become damaged by negligent handling or other influences before, during or after introduction, we do not assure or guarantee in any way that a disturbance or discontinuation of function will not occur.

The ***RytmoLas®m*** is sold in "as is" condition. No responsibility will be assumed for any deficiencies that are not immediately declared upon delivery of the goods. The purchaser assumes the total risk related to the quality and function of the catheter and accessories when they are put into use.

LasCor® assumes no responsibility whatsoever for any loss, damage, or injury, be it directly or indirectly related to the catheter or accessories or determined to be subsequent damage resulting from the use thereof.

In cases of defects found prior to its use the no contaminated catheter can be replaced by the manufacturer, provided the catheter is sent back with documents describing the defect found.

Consequently, ***LasCor®*** does not and will not assume any expenses incurred by the purchaser or a third party, ensuing from the use, malfunction or total failure of any catheter or accessories.

This exclusion encompasses physician's fees, costs of hospitalization, costs incurred by using medicinal products, any secondary expenses, and all subsequent damages.

Let it be known that no institution, organization, or individual has ever been empowered or in any other manner obtained the right to issue any notification deviating from the above or to make any guaranty in the name of ***LasCor®***.

NOTE

After its use the catheter is biologically contaminated and must be disposed according to the local regulations. The catheter does not contain toxic components that would need special measures.

TECHNICAL DATA: *RytmoLas®m*

Body size: 8F, Useable length: 130.0 cm, Total: 300.0 cm
Silicon tube 7F, 15 cm
4 magnetic pads: 2.2x1.5x5.5mm
Cable electrodes: 3 + 2 + 2, conductor resistance: <4Ω
Optical fiber core: 400µm, numerical aperture 0.22
Distal beam divergence 70°
Seven electrical plugs: 2 mm-pins
Laser connector: FSMA with time limiter
Irrigation tube: 15 cm with Luer-Lock female
3-way Connector with 4 openings

CATALOG No.: M 002-130-XXX
UDI-DI: 4260691560023
PACKAGING: carton box with 1 sterile set
Delivery box: 10 sterile sets with IFUs

SYMBOLS

This medical product is labelled according to **DIN EN ISO 15223-1:2022-02** by using the following graphical symbols:

MD	**Medical Device**
	Manufacturer
LOT	**Lot number**
	Date of manufacturing
STERILE EO	**Sterile, sterilization method**
	For single use only
	Regard operating manual
	To be used until
CE 0481	

Annexes:

1. Patient Information
2. Patient's Statement and Written Informed Consent

!	**The patient information sheet must be handed out to and must be signed by the patient together with the informed written consent.**

3. Fax Template: Post Market Clinical Follow-up compelling after the use of the catheter.

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Patient Information
Selective Laser Catheter Ablation of Cardiac Arrhythmias

What It's All About?

Introduction

Catheter ablation of cardiac arrhythmia is not an operation; it is a non-surgical, percutaneous, minimally invasive technique that selectively destroys the abnormal electrical pathway or other abnormal myocardium causing your arrhythmia. The treatment involves only percutaneous puncture or a tiny incision in the skin and is done under local anesthesia without putting you to sleep. You will be awake during the procedure and be able to talk with the staff. The procedure is used for treating rapid heart rhythms that have not responded adequately to medication. The information obtained during high density endocardial mapping, the exploration of the heart with the laser catheter ***RytmoLas®m*** enables doctors to localize the site of the origin of your arrhythmia or vessel segment involved in your high blood pressure and to destroy it selectively.

Current catheter ablation techniques utilize radiofrequency (RF) energy or by freezing (Cryoablation). Laser catheter ablation is a new promising method for the treatment of cardiac arrhythmias developed with the intention to reduce the risks and to increase the success for arrhythmia ablation and for the treatment of hypertension.

For the laser procedure, doctors insert the ***RytmoLas®m*** percutaneously after puncture or cut down for access to a vessel, a vein or artery, in the groin or arm. The catheter is advanced through an introducer set, under X-ray and/or NAVIX control into the heart chambers or vessel segments of interest. For some left heart catheterization procedures side selective transseptal puncture can be performed by using the laser catheter set ***ISPunctureLas®***.
Doctors position the catheter so that it lies in intimate contact to the abnormal diseased arrhythmogenic focus in your heart, or vessel segment and then pass laser light through the catheter. The irradiated area of the heart that produces the arrhythmia or vessel segment selectively heats up and diseased structures are coagulated/ablated.

During laser application doctors have immediate control of lesion formation by monitoring electrograms recorded via the ***RytmoLas®m*** and can stop the radiation when local electrical activation is abolished, thereby saving the adjacent lung, nerves, and esophagus from thermal damages. If the treatment is successful, you will be cured from your attacks of rapid and/or irregular heart rhythm. Laser application is painless and in case if you have a pacemaker or an ICD implanted it does not jeopardize the function of the device. The ***RytmoLas®m*** is not NMR compatible.

Clinical studies are not yet available but will soon be carried out / are in process.

Alternate Therapies to the Laser Catheter Ablation

1. Antiarrhythmic Medication (which was not successful in the treatment of your arrhythmia).
2. Permanent Cardiac Pacing (Pm) or Implantation of and Cardioverter Defibrillator (ICD)
3. Antiarrhythmic Cardiac Surgery (for selected patients).
4. Radiofrequency Catheter Ablation (the routine catheter ablation procedure up to now).
5. Cryoballoon pulmonary vein isolation (PVI)
6. Ultrasound catheter ablation is a new method still under investigation for AF ablation (unknown long-term results)
7. Pulsed field Ablation (A new experimental method especially for AF ablation)
8. Laser balloon ablation designed selectively for Pulmonary vein ablation.

Preparing for the Ablation Procedure

Unless you are already hospitalized, you will probably be admitted to the hospital or, in some cases, you may undergo the treatment in a cardiac electrophysiology unit as an outpatient. Several routine laboratory tests will be performed including an ECG and blood tests.

Blood tests may be done one or two days ahead of catheter ablation. The doctor performing the ablation procedure will review your medical history and examine you. You may be seen by the doctor at the office several days before the procedure. The doctor will explain the ablation technique, its purpose, potential benefits, and possible risks. This is a good time to ask questions and, most importantly, to share any feelings or concerns you may have about the ablation intervention.

You will be asked to sign a consent form, a document that allows drugs to be injected directly into the vein if necessary. To help you relax, you will be given a sedative if necessary. Generally, you will be asked **not** to eat or drink anything after midnight, to allow for an empty stomach. If you are scheduled for an afternoon study, you may be given a light breakfast. You may have a small amount of water with medication.

You may be asked to stop taking certain medications for two or three days before the ablation procedure. Be sure to check with your doctor several days before the intervention. Bring a list of all the medications you are currently taking. It is very important for the doctor to know the exact names and dosages of any medication that you take. Be sure to mention to the doctor if you have had allergic reactions to any medication.

For your comfort, empty your bladder as completely as possible before the procedure starts. Once preparations are completed, you will be taken to the electrophysiology laboratory where the procedure will be performed. You will be transferred to an X-ray table. For your security the table has a large camera above it and television screens close by. The equipment in the lab also includes heart monitors and various instruments and devices. The lab team generally includes the electrophysiologist, a cardiologist with special training, an assistant, nurses, and technicians.

During the Ablation Procedure

After being positioned on the table, you will be hooked to a variety of monitors and manifolds, and you will be covered with sterile sheets. The staff will be wearing sterile gowns and gloves. The area where the catheter will be inserted (groin, arm, or neck) is cleansed thoroughly. A local anesthetic is injected into the skin with a tiny needle to numb the area. This may cause a stinging sensation.

A small incision is made in the skin, and a needle is used to puncture the blood vessel into which the catheter will be inserted. The catheters are directed to the targeted diseased myocardial area or vessel segment by magnetic navigation and will transmit laser light via a flexible optical fiber mounted coaxially in the catheter that is flushed with saline through its central lumen.

For one to several laser application over 15 seconds the site of the arrhythmia origin or culprit vessel area responsible for you high blood pressure will be heated up selectively and coagulated/ablated without tissue vaporization with crater formation. Without the risk of perforation of the heart or vessel wall. Within days, the irradiated area will be transformed into a scar. In general, this process can cure you persistently from your heart rhythm disturbance or your arterial or pulmonary hypertension.

You will be awake during the procedure; although medication will be given to help you relax. The staff will be monitoring your process constantly. Let the staff know at any time if you experience pain or discomfort. The laser procedure is not painful, although you may feel some discomfort during the insertion of the catheters or during laser application. There may also be some discomfort from lying still for a long time. You will not feel the catheters moving through the blood vessels and in your heart.

During the procedure, doctors may stimulate your heart with electrical impulses. You will not feel these impulses, but they may induce the arrhythmia that has caused your complaints in the past. It is important that you tell the doctor or nurse immediately if you feel any palpitations, lightheadedness, and shortness of breath or chest pain. An arrhythmia induced during the procedure will often stop by itself.

If an arrhythmia persists, especially if it is very rapid, it may cause you to faint for a moment. If this occurs, the doctor can deliver an electric shock to your heart, so called cardioversion or defibrillation, to restore a normal heart rhythm. Outside of the electrophysiologic lab, such arrhythmias could be dangerous and life-threatening. In the lab, however, well-trained personnel have the equipment and medication to handle these arrhythmias.

If the doctors can induce an arrhythmia in the electrophysiology lab, they may be able to localize the site of arrhythmia origin in your heart and to ablate this region. If that treatment is successful, you will be cured from your arrhythmia, or a formerly ineffective medication will now keep you off symptoms.

Sometimes, laser ablation procedures can be quite lengthy. Depending on the arrhythmia and the findings, procedures may last two to four hours. The insertion of catheters is accompanied by certain risks. Some patients may develop bleeding at the insertion site. Blood collects under the skin resulting in local swelling and “bruise”. Both swelling and bruise will disappear in time as the blood is slowly absorbed by the body.

Less frequently, ablation procedures may be associated with more serious complications. These include damage to blood vessels, formation of blood clots and infection. Fatalities such as myocardial infarction, perforation and tamponade, pulmonary embolism, and stroke and even death are extremely rare but were reported after radiofrequency ablation procedures. Up to now, the laser ablation procedure, during and after over 1000 experimental laser applications and over 600 applications in humans, in a multicenter clinical study trial, has never been associated with complications.

However, procedure related laser complications cannot be completely ruled out because this device is still investigational. Although in patients who undergo arrhythmia ablation procedures with the laser method did not yet experience complications, you should be aware of the risk. To learn about your particular risk, you should discuss the matter with the doctor.

After the Ablation Procedure

After the ablation procedure the catheters are removed, the doctor or nurse will apply slight pressure over the groin for about 10 to 20 minutes. The doctor may close the incision with a few stitches. This is done to prevent bleeding.

Subsequently, a dressing will be applied over the wound or puncture. You will then be transported to your room or to the recovery area. You will probably be allowed to drink and eat following the procedure but check with the nurse. You will lie flat in bed for two to four hours to allow a small seal to form over the puncture of the vessel. During this time, you may move your legs and foot or wiggle your toes. You may move your arms freely unless an arm was used for the insertion. Eventually an ultrasound doppler control will be performed to check the permeability of the catheterized vessel.

If you can go home after the procedure, please remember the following to ensure a quick recovery:

- Limit your activities during the first 24 hours at home. You can move about, but do not strain or lift heavy objects.
- If you notice new blood on the dressing, place your fingers over the site and press for about 20 minutes. If bleeding continues, call your doctor, or the nearest emergency room while continuing to apply pressure.
- You may shower the day after the procedure but wait another day or two before taking a bath. If the dressing over the groin was not removed in the hospital, you may remove it the day after the procedure.
- A black-and-blue mark (bruise) or a small lump under the skin at the insertion site is common. These generally disappear within three to four weeks.
- Call your doctor if the insertion site becomes painful or warm to touch.
- Ask your doctor when you can return to normal activities, usually one or two days after procedure, and if there are any specific restrictions.
- Ask your doctor about your medication, which ones to continue and which ones to stop.

Follow-up Ablation Procedure

If successful, the laser irradiation treatment has coagulated the arrhythmogenic site in your heart, thereby modifying electrical activation and/or electrical conduction within the heart. By doing so, abnormal sites in the heart cannot initiate or sustain rapid heart rhythms, and your arrhythmia will be cured.

In rare cases, medication may be needed for the treatment of arrhythmias after the ablation procedure. Follow-up examinations can be performed in the outpatient clinic. If results indicate that medication is still required, needs adjustment or is not effective, you may be brought back to the electrophysiology lab for a follow-up study or to repeat the arrhythmia ablation attempt.

For your long-term follow-up, you will be seen by your doctor in his office or at the outpatient department of the hospital for a regular control including physical examination and ECG registration at one week, and one, three, six months and one year after the laser ablation procedure.

In addition, you should come to your doctor whenever you feel again a rapid heart rate, or you have other signs or symptoms which in your opinion may be related to the ablation procedure. For such instances it is recommendable to visit the nearest office of a cardiologist or outpatient department of a hospital that can register an emergency electrocardiogram for documentation of your heart rhythm.

Eventually, a last control will be performed by a visit at the office of your doctor or by telephonic information about your health state concerning your heart rhythm and by a recent ECG strip which must be sent to your doctor that has performed the ablation procedure.

Artificial Pacemaker (Pm)

In case of His-bundle ablation, intentional or inadvertent, you will receive an artificial pacemaker. This is a device that is implanted inside the body, ready to pace (stimulate) the heart. It is used in the treatment of markedly slow heart rhythms. A pacemaker has two parts: a pulse generator that contains the battery and electrical circuitry and pacing wires that carry electrical impulses from the pulse generator to the heart muscle.

A Pm senses the person's heartbeat and responds accordingly. If it senses that the heart beats too slowly or pauses too long, the Pm sends electrical impulses that stimulate the heart to contract.

Direct-Current Electrical Cardioversion (DC-shock)

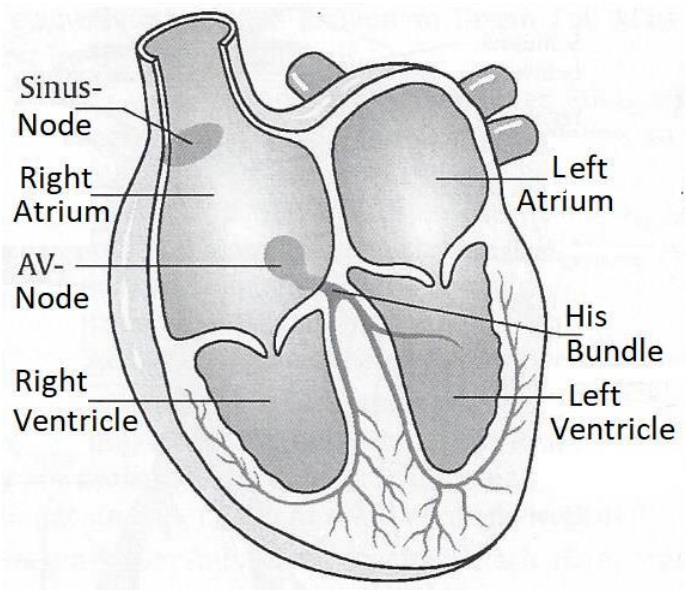
Electrical cardioversion is a procedure that delivers an electrical shock to the heart to restore a normal sinus rhythm. It is used in the treatment of certain rapid heart rhythms. During the DC-shock procedure, paddles are placed on the chest and an electric shock is delivered to the heart through the chest wall.

The shock causes all the heart cells to fire at once. This momentarily stops all electrical activity in the heart and allows the sinus node to take command again and pace the heart, so that your normal heart rhythm is restored. Cardioversion is effective but does not prevent arrhythmias from recurring.

Implantable Cardioverter-Defibrillator (ICD)

An implantable cardioverter-defibrillator is a device that is implanted inside the person's body, ready to deliver an electric shock to the heart when needed. ICDs are most often used in people who have experienced life-threatening tachycardia such as ventricular tachycardia or ventricular fibrillation. The device continuously monitors the heart rhythm. If it senses a life-threatening tachycardia, it delivers one or more electrical shocks to the heart and restores a normal rhythm.

Don't hesitate and ask your doctor if you need more information or if some of the above is still unclear to you or if you would like to know more about the procedure, possible complications, and risks. Your doctor will give you further information.



Scheme of the human heart chambers, showing its impulse formation: the Sinus Node and the AV-node, and the conduction system: the His-bundle and its ramifications

Patient's Statement and Written Informed Consent

Signature File in accord with 21 CFR 50 with the Patients Statement

I had detailed discussion(s) with my doctor (print)_____
Concerning my questions, problems, concerns and doubts of the laser ablation procedure and the possible complications and risks, I have received a compete file of **Patient Information** (five pages) and I have no further questions.

Herewith I agree with the proposed laser ablation procedure, with the emergency interventions, necessary for the treatment of possible complications, including cardiac Pacemaker implantation if needed, and with the follow-up studies.

I do not give my consent for laser catheter ablation because (comment):
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……

↑
Delete what not applicable.

Patient:_____ _____ _____
Name (print) Date Signature

Investigator:_____ _____ _____
Name (print) Date Signature

Post Market Clinical Follow-up (PMCF) for Laser Ablation of Cardiac Arrhythmias

Please fax to +49 (0)89 759 5770 ***RytmoLas®m*** **M 002-130-XXX**

Patient ID: Hospital / Health Service Unit:

Diagnosis: Physician (print): _____

If no events: please mark with **X** here **O** Signature_____

Or describe…….……

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