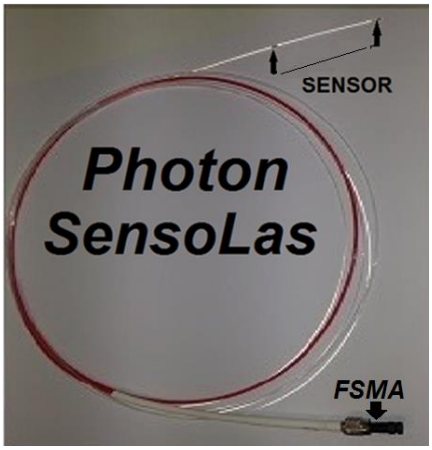
LasCor
Laser Medical Devices



An optical fiber set with isotropic probe and radiomarker

INSTRUCTION FOR USE (IFU)

GENERAL DESCRIPTION

The ***PhotonSensoLas***® is an optical fiber-based probe provided with a 10 cm long isotropic segment at its distal end (sensor) to be used for measuring light intensity in the esophagus during intracardiac laser application.

The ***PhotonSensoLas***® has especially been developed for sensing of continuous wave 1064 nm Nd:YAG laser light scattered in the mediastinum. The cylindrical sensor collects the light in a large solid angle with an identical efficiency. The probed light is transmitted along the optical fiber coupled via an FSMA 905 connector to a Photon counter the ***PhoDioLas*** that stops the laser automatically if a preset limit of photons is exceeded and overheating of the mediastinal structures, such as the lungs, nerves and esophagus is imminent. For this application, the following additional device is needed:

- A transparent esophageal bougie (commercially available)
- A photon counter with preset limits (***PhoDioLas*** – TBD!)

APPLICATIONS

Indications
The ***PhotonSensoLas***® is an esophageal sensor for indirect heat control of the gastroesophageal trajectory situated behind the left atrium. During laser application aimed at that region of the posterior left atrial wall adjacent to the esophagus, the scattered laser light may produce thermal damage to the esophagus.

Overheating of the esophageal wall may result in acute coagulation necrosis, muscle coagulation with the risk of perforation of the esophagus. In severe cases, life-threatening fistula between the esophagus and the left atrial cavity may occur.

The ***PhotonSensoLas***® may be used for photon measurement during laser radiation aimed at the posterior left atrial wall for ablation of cardiac arrhythmias such as atrial fibrillation. It may protect also other mediastinal tissues such as the lung and the nerves adjacent to the esophagus.

Contraindications
The use of the ***PhotonSensoLas***® may be contraindicated if there is a known or suspected damage, infection or obstruction in the mouth, naris, and throat or in the esophageal trajectory, and in the presence of varicose esophagus. Deformations after severe trauma may also increase procedural risks.

SAFETY NOTES

Reuse
The ***PhotonSensoLas***® is designed for single use. 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 ***PhotonSensoLas***® is ethylene oxide (EO) sterilized prior to shipment. Do not use products from opened or damaged packaging. Under appropriate storage conditions, we guarantee sterility in undamaged packaging until expiry date (use before date).

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.

Side Effects and Complications
Despite correct handling of the ***PhotonSensoLas***® complications may occur:

· Vomiting, nose bleeding, esophageal bleeding, hematoma
· Damage of throat, esophageal wall or bronchi
· Perforation of the esophagus
· Bradycardia, cardiac arrest, tachycardia

Catheter Check and Preparation for Insertion

!	**Warning!** **Inappropriate handling of the *PhotonSensoLas*® such as excessive bending or kinking may result in destruction of the catheter.** **This device should be exclusively applied by physicians / anesthetists who are trained and experienced in oesophageal and tracheal intubation, and in the field of cardiovascular laser application.** **DO NOT USE THE PHOTONSENSOLAS TO DELIVER LASER LIGHT**

During insertion and manipulation, the ***PhotonSensoLas***® is subjected to a variety of mechanical and thermal strains. The mechanical integrity of the catheter must be verified by visual inspection prior to its use and whenever a damage of the catheter is suspected.

Check the integrity of packaging and expiry date before opening. Open the sterilization pouch and draw out the sterile tray and remove the ***PhotonSensoLas®.***

Connect the SMA light output to the optoelectronic converting unit ***PhoDioLas***. Moisten the tube with Aqua bidest for smooth introduction of the probe in the lumen of the esophageal boogie already placed in the esophagus.

PREPARATION OF THE PATIENT

The patients, candidates for esophageal exploration should be in a good condition, in abortive state. An additional venous access line is recommendable for volume and electrolyte substitution, for antithrombotic, and, in case of emergency, i.v. drug treatment.

Esophageal positioning of the boogie
There is no vessel puncture or skin incision needed for the insertion of the ***PhotonSensoLas***®. After preparation of a permeable naris by cleaning and a local anesthetic, or by placing a bite ring between the teeth, the esophageal boogie is carefully inserted and advanced in the esophagus so that its distal end is positioned behind the left atrium. Insertion is supported by the patients concurrent swallowing.

Under X-ray control and guided by the X-ray marker on the ***PhotonSensoLas***® the sensor is positioned with its full isotropic length behind the left atrium. In order to stabilize the position of the sensor the outer end of the catheter is now fixed close to the operating field.

EXCLUSION OF LIABILITY

The ***PhotonSensoLas®*** is used in a moderate aggressive environment of the human body. The required flexibility invariably results in limited reliability.

Probes can fail for any numbers of reasons, among which there are medical complications, rejection reactions of the body, dislocation, erosion, or migration through body tissue or resulting from a break or tear of its components.

Despite the greatest possible care taken in development, choice of components, assembly and final control prior to delivery, probes can become damaged by negligent handling or other influences, during or subsequently to 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, as a result of introducing the boogie or probe.

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.

We are not responsible for any inconvenience defects or complications attributable to the instruments or tools introduced and used via the ***PhotonSensoLas®***.

The ***PhotonSensoLas®*** is sold in "as is" condition and 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 system 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 not yet 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 physicians' fees, costs of hospitalization, costs incurred by using medical 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 above or to make any guaranty in the name of ***LasCor®***.

TECHNICAL DATA: *PhotonSensoLas®*

An Isotropic Probe Model IP159, Sensor with radiomarker

Mechanical dimensions:	OD distal tip 1.59 mm (1/16")
	Overall length 3 m
Optical characteristics:	isotropy +/- 10%
	(Standard deviation from 40° to 320°, in air)
Wavelength range:	480 -1100 nm

Optical fiber:	fiber material Silica, low OH core
Diameter:	400 µm
Numerical aperture	0.37
min. bending radius	47 mm
Fiber connector	FSMA 905

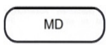
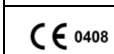
Esophageal boogie/dilator CH 12:

Length	85 cm
Tube	CH 12
With central lumen; lumen and funnel graduation:	
	45, 55, 65, 75 cm

Catalog No.: **S 006-300-XXX**
UDI-DI: **4260691560061**

PACKAGING: carton box with 1 sterile set,
Delivery box: with 10 sterile set

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

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

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 (PMCF) is compelling after the use of the probe.**

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Patient Information
Transoesophageal Probe for Laser light Detection

What it's all about

Dear Patient,

Atrio-esophageal fistula is among the most dangerous complications of radiofrequency or Cryoballoon ablation of atrial fibrillation. Atrio-esophageal fistula is associated with high mortality even if the correct diagnosis is made relatively early because. However, the diagnosis of the complication often is delayed because of the significant time delay of its occurrence after the ablation procedure (which mostly is 1–4 weeks) and unspecific initial symptoms. The mechanism most likely leading to atrio-esophageal fistula is the induction of thermal esophageal injury during the ablation procedure. The incidence of esophageal injury after radiofrequency ablation of atrial fibrillation has been described between 5% and almost 50%.

Despite esophageal temperature measurements with various techniques thermal injury of the esophagus during atrial fibrillation ablation by using radiofrequency current or Cryoballoon cannot be ruled out. Therefore, esophageal movements with a deviator or avoidance of energy application aimed at the posterior left atrial wall adjacent to the esophageal trajectory were recommended. However, these procedures produce patient discomfort or reduces substantially success rate of atrial fibrillation ablation.

As esophageal injury may occur also after laser ablation your doctor has decided to use the esophageal probe ***PhotonSensoLas®*** that stops laser application automatically when thermal damage of the esophagus is imminent, prior to its occurrence! However, this safety chain is applicable exclusively when laser catheter ablation is performed by using the continuous wave 1064nm laser light.

There is no vessel puncture or skin incision needed for the insertion of the ***PhotonSensoLas®***. After preparation of a permeable naris by cleaning and a local anesthetic, or by placing a bite ring between the teeth, the esophageal boogie is carefully inserted and advanced in the esophagus so that its distal end is positioned behind the left atrium. Thus, insertion of the boogie in the esophagus and of the ***PhotonSensoLas®*** into the boogie usually is painless, and anesthesia is not needed.

If you need more information please ask your doctor.

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 transoesophageal light sensor and the possible complications and risks, I have received a complete file of *Patient Information* (one page) and I have no further questions.

Herewith I agree with the proposed placement of an oesophageal probe with a light sensor during laser catheter ablation, with the emergency interventions, necessary for the treatment of possible complications, and with the follow-up controls or studies.
I do not give my consent for the use of an esophageal probe during laser catheter ablation because (comment): …… …… …… …… …… …… ……

Delete what not applicable.

Patient: _____ _____ _____
Name (print) Date Signature

Investigator: _____ _____ _____
Name (print) Date Signature

Post Market Clinical Follow-up (PMCF) for Transoesophageal Laser Light Measurement

Please Fax to +49 (0)89 759 5770 ***PhotonSensoLas® catalogue number*** **S-006-300-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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