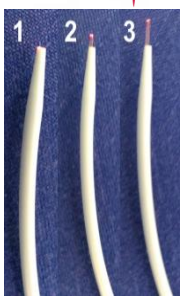
LasCor
Laser Medical Devices



ISPunctureLas®

Distal end of the dilator with the optical fiber tip in:

***1** idle position,*
***2** stabilizations, and in*
***3** puncture position*

A flexible transseptal Laser puncture set
Instructions for use (IFU)
GENELAL DESCRIPTION

The ***ISPunctureLas®*** is an optical fiber set designed for percutaneous, transluminal, **side selective** laser puncture of the interatrial septum.

For transseptal puncture with the ***ISPunctureLas®*** are needed:

- An 8.5 F long steerable introducer sheath: AGILIS NxT with an 8F 960 mm long dilator.
- A Laser with FSMA input connection ***CardioVascLas®*** ***980nm or 1064nm***

The St. Jude Medical (SJM™) AGILIS™NxT is a steerable introducer set that consists of a dilator, guidewire, and steerable sheath, which is designed to provide flexible catheter positioning with its tip towards the right atrial septum. For more details see also Agillis™NxT steerable introducer instruction for use (IFU) *ST. Jude Medical™*

The ***ISPunctureLas*** optical fiber set consists of a 600µm core diameter optical fiber. Its tip is plane polished, and the distal end is stripped at a length of 5 mm. Its proximal end has a FSMA connector provided with a time limiter chip.

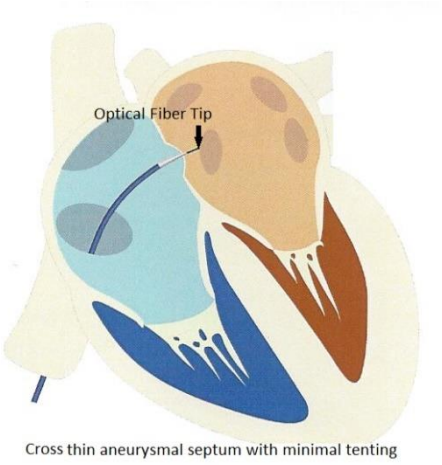
For the puncture of the septum the optical fiber can be advanced with its tip beyond the dilators endhole by means of a two-step Y-Click connector. The dilator must cover the optical fiber completely while in idle mode. Its tip does not shave off pieces of the sheath inner lumen when advanced for puncture because it is positioned at the dilators endhole without protruding from the hole.

While the feed the optical fiber will protrude approx. 2.0 mm. That helps for stable positioning of the fiber tip at the site of the septum selected for puncture. In a second step the fiber is further advanced for up to 5.0 mm from the dilators endhole and puncture of the septum is performed by applying simultaneously a laser impact of 3 seconds.

The ***ISPunctureLas®*** applies continuous wave laser light in a contact mode of radiation. Direct contact of the fiber tip with the tissue causes instant high temperature that vaporizes the tissue and creates a transseptal channel within seconds.

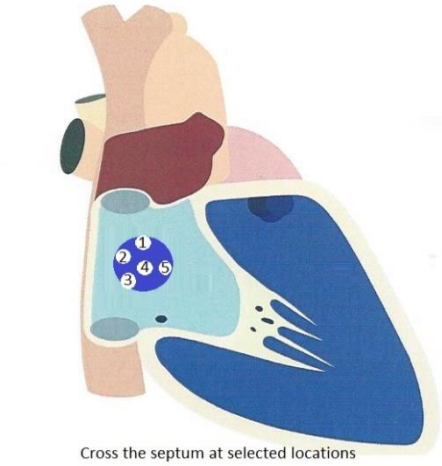
According to the 600µm core diameter of the optical fiber the channel is very narrow and ought to the thermal inertia of the tissue, the short time of high temperature does not result in thermal damages, coagulation, or carbonization, of adjacent tissue of the atrial wall.

Radiation at a power of 30W on a surface of 0.3 mm² will result in a power density of 100 W/mm², 3s=300J/ mm². On such a small surface transseptal puncture can be achieved without pressure on the septum including fibrous or thick muscular septal walls, or after postoperative patch-closure of atrial septal defects in ≤3 seconds. Successful transseptal puncture is not limited to the area of the foramen ovale.



Cross thin aneurysmal septum with minimal tenting


Cross fibrotic septum with minimal mechanical force



Cross the septum at selected locations
1 PFO closure **2** Mitral access **3** LAA closure
4 LV assist device **5** PV interventions

APPLICATIONS

Indications

The ***ISPunctureLas®*** is designed for left heart access by side selective interatrial septal puncture.

> **! Only fibers at lengths adapted to that of the dilator's length can be used for side selective interatrial puncture with the *ISPunctureLas®*.**

The interatrial septum is targeted after percutaneous puncture of a vein in the right or left groin (Seldinger technique) and advancement of the steerable AGILIS sheath via the inferior vena cava into the right atrium. Here the tip of the dilator is manipulated towards the area of interest upon the interatrial septum.

The guidewire is removed from the dilator and the dilator is flushed with saline and the syringe is kept in place. The optical fiber is wiped with saline, the syringe is removed, and the guidewire is introduced in the dilator's lumen.

The dilator must cover the optical fiber completely while in idle mode. The fiber tip should not protrude from the endhole. Dilator with fiber is introduced in the sheath.

The tip of the dilator is now manipulated towards the area of interest where the puncture is aimed at.

For stabilization of the dilator tip upon that area, the optical fiber is advanced for approximately 2.0 mm, first click, beyond the endhole of the dilator.

For puncture of the septum the fiber is advanced in a second step approximately for 5.0 mm and simultaneously the laser is activated for ≤3.0 s.

> **! Caution: if pericardial or aortic entry occurs, do not advance the dilator. If the optical fiber has penetrated the epicardium or the aorta, it must be withdrawn, and vital signs must be monitored closely.**

The optical fiber is subsequently removed, and the dilator tip is maintained in the created channel of the septum without to be pushed into the left atrial cavity.

Correct puncture can be confirmed by:

- a blood sample through the dilator that should be a red oxygenated arterial blood
- pressure monitoring shows a typical left atrial pressure waveform
- contrast injection show rapid dispersion of the dye into the left atrial cavity without epicardial / intramural deposit
- a guidewire advanced through the dilator can be deployed in left atrial and ventricular cavity.

Once a correct puncture is assured the dilator and the sheath are advanced into the left atrium, the dilator and guidewire are removed, the dilator flushed.
The interatrial septal area selected for the puncture procedure may vary depending on

the targeted left atrial anatomical structure e.g.:

- Patent foramen ovale closure
- Mitral valve access
- Left atrial appendage closure
- Left ventricular access for assist devices
- Pulmonary vein interventions

Ought to the side selective puncture of the interatrial septum these anatomical structures can be targeted directly, shortening catheterization procedure, and reducing risks. Side selective interatrial puncture for left heart access is a special claim of the ***ISPunctureLas®.***
The ***ISPunctureLas®*** is MRI-compatible.

In addition, delivering laser light in contact surgical procedures, the hand hold dilator with the protruding fiber tip is suitable for incisions, excisions, vaporization, ablation, and, for hemostasis or coagulation of tissue.

Contraindications

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

SAFETY NOTES

Reuse

The ***ISPunctureLas®*** 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.

> **! The *ISPunctureLas®* is for single use only. Sterilization and reuse would jeopardize its function and endanger the patient.**

Sterilization

The catheters are shipped after sterilization with Ethylene oxide (EO) or Electron ray (E-ray). Do not use products from opened or damaged packaging. Under appropriate storage conditions, we guarantee sterility in undamaged packaging until the expiry date (use before date).

Sterile products should be stored at humidity of 45-70%, at temperatures of 18-25°C should not be exposed to direct sunlight and must be used before the expiry date on the packaging ("Use before date"). (DIN 58953)

External Interference

There is no external interference with ***ISPunctureLas***®

Side Effects and Complications

Despite correct handling of the ***ISPunctureLas***® complications may occur in 0.5 to 2%:

- Cardiac perforation with cardiac tamponade
- Thrombus formation
- Thrombotic and air embolism
- Iatrogenic Septal Defect
- Injury to the Aorta or Atria

Catheter Check

During intravascular and intracardiac manipulations, especially during the laser puncture procedure, the ***ISPunctureLas***® is subjected to a variety of mechanical and thermal strains. If catheter damage is suspected, mechanical and optical integrity of the catheter must be verified by visual inspection.

Laser Safety

The ***ISPunctureLas***® 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. The transseptal laser puncture is performed by using continuous wave invisible Nd:YAG laser light with 980, 1064 or 1470nm wavelengths. This light may penetrate human eye and may damage the retina.

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 ***ISPunctureLas***® causes a laser area of 0.5 m radius, measured from the catheter tip (calculated according to laser safety regulation DGUV-V 11 for an irradiation at 10 W over 5 s). Safety hazards are significantly reduced, if laser emission is inhibited on the laser panel whenever the ***ISPunctureLas***® is handled outside the patient. Inside the patient, when the foot switch is enabled, no hazardous

! Treatment results and all the incidences caused using the *ISPunctureLas*® must be reported immediately to the manufacturer and to the local authorities.

radiation can be released into the operating room.

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 ***ISPunctureLas***® 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 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

An ***ISPunctureLas***® that is inserted into the patient cannot radiate hazardous laser light into the environment. Laser hazard increases 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 ***ISPunctureLas***® is already placed in the patient's body and to inhibit laser emission after laser application.

!! Never point a connected *ISPunctureLas*® towards a person or reflecting surfaces.
Enable laser radiation only when the *ISPunctureLas*® is positioned inside the body of the patient.
Disenabling of the laser footswitch is:
1. Advisable after each laser application, and
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 1064nm laser light.
Use eye protection that blocks 980nm, 1064 nm laser light.

Additional hazards can be provoked when the ***ISPunctureLas***® is handled inappropriately, especially when the optical cable is bent around sharp edges, or the protection tube is jammed under wheels or heavy weights. It must be strictly avoided to clean its distal end, to touch the striped distal end with its polished surface. Optimal function of the ***ISPunctureLas***® would be jeopardized.

HANDLING

Preparation of the Laser System

Calibration

Light transmission is measured by the manufacturer. Only qualitative control of the laser spot must be performed by operators.

! If the laser is provided with an LPS this must be inactivated before starting the transseptal laser puncture procedure!

PREPARATION OF THE PATIENT

Patients should be in a good clinical condition. Additional venous access line is needed for volume and electrolyte substitution, antithrombotic and optional drug treatment. Percutaneous puncture is performed under sterile conditions. The flexibility of the ***ISPunctureLas***® allows for venous accesses from the left and right femoral vein.

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

Connecting the Catheter

Main functions of the ***ISPunctureLas***® and its connections to external devices must be checked prior to a clinical application. This mainly includes:

- Integrity and sterility of the packaging
- Length of the dilator for optimal fiber tip positioning

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 optical cable, first remove the protective cap from the FSMA connector and engage it to the laser.

Be sure not to touch or soil the polished distal end of the optical fiber. Switch on the pilot laser and check the small, illuminated spot and 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 the catheter if light is leaking through the cable insulation or protecting tube.

Catheter Insertion

The following general description of transluminal percutaneous catheter-directed laser puncture procedure is a proposal based on general experience in the use of transseptal puncture by using the electrophysiological heart catheters. Investigators may change procedure details according to their personal experience.

! Only consultant cardiologists trained in transseptal puncture procedures, in the delivery of steerable sheaths, and in cardiovascular laser applications should use the *ISPunctureLas*®.

The ***ISPunctureLas***® is inserted percutaneously via a Guiding system, e.g., special long introducer sheaths and steerable guides such as the AGILIS (St. Jude). Introducers adapted to the ***ISPunctureLas***® are commercially available. Do not use inappropriate introducer sheaths or guiding catheters as they may jeopardize the functions of the ***ISPunctureLas***® and increase the complication rate!

Puncture Procedure:

- After aseptic skin preparation of the insertion area and sterile covering of the groin, the femoral vein is punctured by using Seldinger technique.
- Remove the syringe leaving the needle in place
- Straighten a J-shaped guide wire by its tip deflector and put it on the joining flange of the cannula.
- Advance the guide wire through the cannula into the vein and, under fluoroscopic guidance, place the wire in the superior vena cava or the right atrium
- Remove the needle, press the vein slightly to minimize bleeding, to prevent air embolism and fix the guide wire.
- The proximal part of the guide wire must remain outside patient over a length of 110 cm.
- If necessary, make a small incision to widen the puncture site for insertion of the tapered vessel dilator, insertion of the dilator and the guiding sheath
- Flush the dilator of the guide (e.g., AGILISs) and push the dilator with the overriding sheath over the wire and advance it under fluoroscopic guidance into the atrium.
- Remove the guide wire and the dilator and flush the sheath with heparinized saline through its side arm.
- Flush the lumen of the dilator with heparinized saline and insert the optical fiber into the dilator and fix its proxymal end in the Y-Click connector so that the optical fiber tip is still completely protected within the dilator.
- Test the advancement of the optical fiber tip about 2 mm beyond the dilators endhole with the first step of the Y-connector and withdraw the fiber.
- Connect the FSMA connector of the puncture set to the laser and insert the dilators tip into the hemostatic valve, push it into the sheath and advance the dilator with the optical fiber through the sheath, and, under X-ray guidance, beyond the endhole of the sheath.
- manipulate the tip of the dilator towards the area of interest and fix it by advancement of the fiber tip by the first step of the Y-Click connector.
- once brought in desired position, advance the fiber tip by means of the second step of the Y-Click and, simultaneously activate the laser for ≤3 s via the foot switch and push the fiber tip through the septum.
- Immediately release the Y-Click switch and remove the optical fiber. The tip of the dilator is now trapped in the septal wall.

Puncture Control

To make sure that the interatrial septal laser puncture procedure has been performed successfully, please make several of the following controls:

- Aspiration with a syringe should show arterial blood,
- flushing of the dilator with heparinized saline is performed easily without resistance.
- dye injection under X-ray imaging is dissipated into the left atrium and no deposit of contrast medium is seen,
- advancement of a guidewire through the dilator is seen deployed into the left atrial cavity and can be advanced through the mitral valve up to the left ventricle.

If this is the case transseptal puncture was successful, the dilator tip can be pushed over the guidewire into the left atrial cavity together with the overriding sheath, until the distal end of the sheath is also advanced into the left atrium.

Now the dilator can be removed, and the sheath is prepared for left heart procedures with various instruments and purposes.

Laser

The ***ISPunctureLas®*** is connected to a diode laser via a flexible optical fiber provided with a LasCor connector at its proximal end. As light transmission and radiation characteristics of the catheter depend on the laser model, only the Laser ***CardioVascLas®*** with inactivated LPS should relate to the ***ISPunctureLas®.***

Catheter manipulation

The ***ISPunctureLas*** can be manipulated by advancing, withdrawing, and twisting the steerable guide.

For targeting selective sites of the interatrial septum, the tip of the dilator is manipulated towards that area and the optical fiber is advanced with the first step of the Y-Click for 2.0 mm beyond its endhole.

Thereby, the dilator tip is kept in a stable position prior to the puncture without the danger of displacement of the tip. Flexibility of the ***ISPunctureLas*** allows maintenance of a stable position upon the targeted area in the beating heart.

Laser application

Laser light is applied in a continuous mode of radiation at 5-10W / 3-5s. Laser energy application depends on the anatomical structure the left atrial access is aimed at: Foramen Ovale, fibrous or muscular atrial wall or Teflon patch.

For puncture of a fibrous tissue or a thicker muscular wall a higher energy is to be applied. The chosen level of energy density depends also on the experience of the operator.

To avoid inadvertent radiation, the laser must remain disenabled during the catheter manipulations.

Once a correct orientation of the ***ISPunctureLas®*** is assured the safety button of the laser is released and radiation can be applied by pressing the foot switch.

Simultaneously with the start of the laser the optical fiber is advanced manually by the Valve-Click up to 5.0 mm beyond the endhole of the dilator tip.

Laser application is accompanied by an acoustic signal. Radiation is ended automatically after the preset time of two to three seconds.

For safety reasons the laser should be disenabled immediately after the impact. Even when remaining inside the patient's body for a possible repeat of the puncture.

EXCLUSION OF LIABILITY

The ***ISPunctureLas®*** 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.

Catheters 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 ***ISPunctureLas®*** can become damaged by negligent handling or other influences, during or subsequent to introduction.

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

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 ***ISPunctureLas®*** 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 non-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 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

ISPunctureLas® - an Optical Fiber Set

Core diameter fiber	600µm
Working length	96 cm
Total length	150mm
Numerical Aperture	0.22
Light beam divergence	13°
Laser connector	FSMA connector.

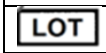
Catalog No.: T 005-096-XXX

UDI-DI: 4260691560054

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

SYMBOLS

This medical product is labelled 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 compelling after the use of the catheter.

Version: 2023-03-09

LasCor® GmbH Laser - Medical Devices
No 4 Schlesierstraße, Taufkirchen, D – 82024 Germany
Tel.: +49 89 759 5596 Fax: +49 89 759 5770
E-Mail: info@lascor.de www.lascor.de (with IFUe)

Patient Information
Side-selective Interatrial Transseptal Laser Puncture Procedure

What it's all about?

Dear Patient,

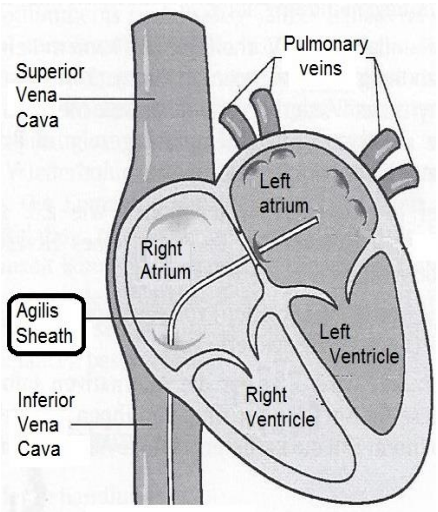
For your diagnosis or treatment a transseptal puncture of the interatrial septum is needed. Routinely, the interatrial septum is punctured with a long needle, the Brockenbrough needle. Severe side effects range between 1%-4%. Alternative, radiofrequency (RF) needles are available. RF needles allow for cross the septum at precise locations around the foramen ovale, even puncture of fibrotic septum while reducing mechanical force and the risk of embolism. However, a RF power source with a disposable grounding pad for the return of RF energy, and various transseptal guiding sheaths are needed for controlled movements in the left heart. In addition, puncture of very dense fibrous or thicker muscular septa remote from the foramen ovale may be difficult to cross by RF needles.

In contrast to that, side selective interatrial laser puncture is feasible in any septal area regardles of its thickness or dense fibrous structure. This allows for a more precise selective targeting of left heart regions such as pulmonary veins, atrial appendage, lateral left atrial wall, mitral valve, and left ventricular cavity. The tip of the optical fiber does not shave off small pieces of the sheath as it is positioned at the dilators endhole. Moved 2.0 mm beyond the endhole a stable position upon the interatrial septum is achieved. With a 5.0 mm fiber advancement and simultaneous laser application at 30W the septum is punctured in only 3-5 seconds.

With the thin, 0.6 mm flexible optical fiber a tiny channel through the septal wall is achieved in 3-5 seconds of laser application. Control of successfull puncture is made by blood sample, left atrial pressure measurement, and guidewire exploration of the atrial cavity prior to the advancement of the tapered dilator tip and the overriding steerable AGILIS sheath into the left atrium. The optical fiber set ***ISPunctureLas®*** is adapted to the steerable guiding and introducer AGILIS sheath which after removal of the laser puncture set is used for the various left heart diagnosis or treatment instruments and procedures.

Indications

- Percutaneous balloon Mitral Valvuloplasty
- Transcatheter Mitral Valve replacement
- Transcatheter Mitral Valve Repair
- Mitrial Paravascular Leak Repair
- Mitral Valve in Valve Implantation
- Left Atrial Appendage Occlusion
- Transcatheter Mitral Valve Repair (Mitral Clip)
- Pulmonary Vein Isolation Atrial Fibrillation Ablation
- Percutaneous Left Ventricular assist device



Alternative access

The left heart can be catheterized also retrogradely via the aortic route. This approach allows for catheterization of the left ventricle retrogradely, but this approach is unusual for access to the left atrium which is diffcult to reach via the mitral valve. For the aortic route puncture of the femoral or brachial artery is needed which beares a higher risk of bleeding.

Contraindications

Absolute: are thrombi on the intra-atrial septum or within the right or left atrial cavity, and relative are marked cardiac or thoracic deformity, abnormal cardiac anatomy including Dextro-cardia. Anticoagulation must also be considered because it may also represent a certain risk.

Side effects and complications

Cardiac perforation and tamponade of the right or the left atrial wall and of the aortic wall varies between 1% to 4%. Tamponade and pericardial effusion must be controlled by echocardiography but often may solve spontaneously. In rare cases surgical intervention and drainage is needed. Aortic puncture with severe bleeding may require surgical emergency treatment.

Thromboembolism with thrombus formation in the left atrium and on the transseptal sheath is reported in 8%-11%. Although clinical stroke is rare, cerebral lesions are detected on magnetic resonance imaging in 7% to 13%. Antitrombotic treatment, maintaining an activated clotting time >300 seconds during PVI has been suggested to prevent LA thrombus formation. If detected on **T**rans**E**sophageal **E**cho (TEE) or by **I**ntra**C**ardiac **E**cho (ICE), intracardiac thrombus can be effectively removed with vigorous aspiration.

Air embolism is often a clinically silent event. However, coronary ischemia, stroke, hypotension and cardiac arrest have been reported. Although most cases of air embolism are self-limiting, prompt interventions including volume loading, oxygenation, manual thrombectomy, vasopressors, and hyperbaric oxygen can be effective in treating patients with large air emboli and those with dramatic symptoms.

Iatrogenic atrial septal defect is rare but can occur after withdrawal of the transseptal sheath. A persistent defect may occur when large-bore sheath are used. Elective closure of the defect should be considered in selected patients.

Less common complications of the transseptal puncture procedure include vena cava perforation, coronary artery dissection, acute pericarditis, local bleeding with hematoma or pseudo-aneurysm at the punctured vessel in the groin, infection of the insertion sites or impaired healing of wounds is rare but may necessitate treatment with antibiotics or even local surgical intervention, persistent swelling can occur in extremely rare cases caused by stasis of lymph in the extremity through which the catheter was inserted.

.

The procedure is performed under X-ray guidance. However, radiation exposure is low so that repeated procedures are possible without serious radiation damages. Radiation exposure may be an issue for women with suspected pregnacy or radiation sensitive patients. By using the ***ISPuctureLas***® incidences or complications were not reported so far.

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 interatrial septal laser puncture procedure and the possible complications and risks, I have received a complete file of Patient Information (two pages) and I have no further questions.

Herewith I agree with the proposed laser puncture procedure, 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 laser catheter ablation because (comment): …… …… …… …… ……

Delete what not applicable.

Patient: _____ _____ _____

Name (print) Date Signature

Investigator: _____ _____ _____

Name (print) Date Signature

LasCor Laser Medical Device
Cardiovascular Laser Applications

Post Market Clinical Follow-up (PMCF) for Side Selective Transseptal Laser Puncture Procedure

Please Fax to +49 (0)89 7595 770 ***ISPunctureLas® catalog number:*** **T 005-096-XXX**

Patient ID: Hospital / Health service Unit:

Diagnosis: Physician (print):_____

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

Or describe events..... .....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....