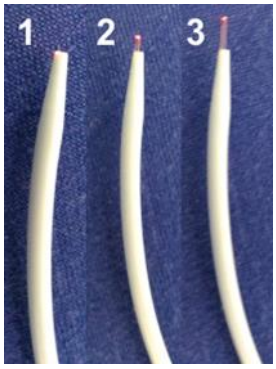


ISPunctureLas®

The distal end of the dilator with the optical fiber tip in:

***1** - idle position,*
***2** - stabilization, and in*
***3** - puncture position*

A flexible transseptal Laser puncture set Instructions for use

GENELAL DESCRIPTION

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

For side selective transseptal puncture are needed:

- *an 8.5 French long steerable sheath e.g., AGILIS*
- *a diode laser, preferably the 1064nm **CardioVascLas®** **LasCor®** GmbH*

Steerable guiding and introducer sets consist of a dilator, guidewire, and sheath, which are designed to provide flexible catheter positioning with its tip towards the area of interest at the right atrial septum.

The ***ISPunctureLas®*** is a 2.5-3m long optical fiber set that consists of a 400 or 600µm core diameter optical fiber stripped from its cladding and jacket at a length of 5 mm. The proximal end is provided with an SMA connector.

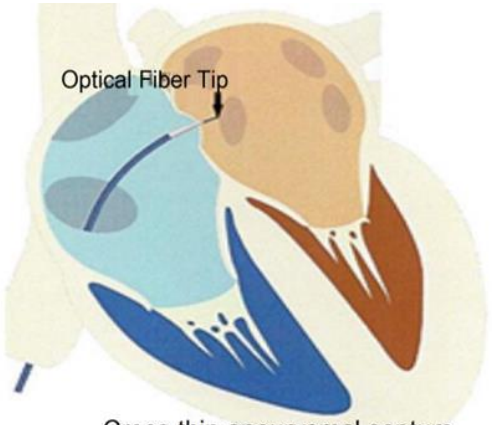
For the puncture procedure the optical fiber can be advanced with its tip beyond the dilators endhole by means of a two-step Click-valve connector. Introduced into the dilator the optical fiber must be positioned with its tip at the level of the dilator endhole. While in idle position the fiber tip does not shave off pieces of the sheath inner lumen when advanced in the sheath.

When in intimate contact with the interatrial septum the optical fiber is advanced with the click-valve and extends for approx. 2.0 mm from the dilator tip what allows for a stable positioning of the fiber tip upon the spot selected for puncture. In a second step the fiber is further advanced up to 5.0 mm from the dilators endhole simultaneously with the laser impact for the transseptal puncture.

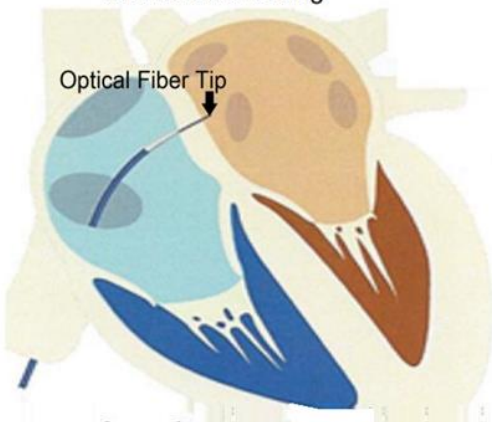
The ***ISPunctureLas®*** applies continuous wave laser light in a contact mode of radiation. Direct contact of the fiber tip with the interatrial septum instantly creates a virtual transseptal channel. The short time of local high temperatures does not result in thermal damage of adjacent atrial septal wall.

By applying a radiation at a power of 5-10W/≤3s (15-30J on 0.283 mm² = 18-106 J/mm²) the fiber tip can pop instantly without pressure even through fibrous or thick muscular septum or after postoperative Teflon patch after large ASD closure.

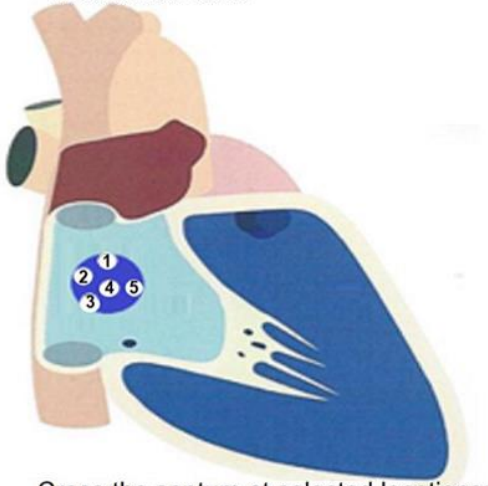
APPLICATIONS



Cross thin aneurysmal septum with minmal tenting



Cross fibrotic septum with minmal mechanical force



Cross the septum at selected locations:
1 PFO closure 2 Mitral access 3 LAA closure
4 LVaccess device 5 PV interventions

The ***ISPunctureLas®*** is designed for left heart access by means of side selective interatrial septal laser puncture. Prior to starting with the procedure review pre-procedural imaging. The fossa ovalis anatomy and available material, sheaths, and fiber set. Insert and advance fiber into the dilator to confirm position and relation of fiber tip to dilator endhole, the idle position, and the click-valve function.

The interatrial septum is targeted after puncture of a vein in the right or left groin (Seldinger technique), by advancement over a guidewire of a long steerable sheath e.g., AGILIS, via the inferior vena cava into the right atrium.

Fiber and dilator are removed and the optical fiber wiped with saline is fed into the saline flushed dilator and advanced with its tip up to the dilators endhole, in idle position.

The dilator must cover the optical fiber completely. The fiber tip should not extend from the dilators endhole.

!	Only optical fibers adapted to the dilator´s length can be used for interatrial septal laser puncture with the ***ISPunctureLas®***

The Dilator with the fiber is introduced in the sheath and its tapered tip is manipulated under X-ray control towards the area of interest where septal puncture is aimed at. If needed ultrasound, TEE and/or ICE can be helpful for targeting the septal area.

For stabilization of the dilator tip the optical fiber is advanced from idle position with the first step of the Click-valve for approximately 2.0 mm beyond the dilator´s endhole.

Watch whenever possible a slight tenting of the septum and adjust transseptal tent based on imaging. If an open foramen ovale is present or the sharp fiber tip penetrates during its manipulation the septum left atrial access is already achieved!

For laser puncture the fiber is advanced 5.0 mm, with a second click step, simultaneously the laser is activated. Radiation is stopped automatically after 3s but must be stopped immediately by releasing the foot pedal when septal penetration of the fiber is visible on the X-ray screen.

The interatrial septal area selected for left atrial access depends on the anatomical structure targeted for:

- LAA occlusion
- Mitral edge to edge repair, valve in valve therapy,
- Mitral valve implantation, valvuloplasty,
- Closure of PV leaks
- Valve ring, Valve in MAC
- Tandem heart
- LV and aortic valve disease
- TMVR, Catheter based annuloplasty
- Left ventricular access for assist-devices
- Pulmonary vein interventions, PVI
- True left atrial and ventricular pressure etc.

By using side selective septal puncture all these structures can be targeted directly shortening intervention procedure and reducing risks.

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 contra-indicate the use of the ***ISPunctureLas®***.

Difficulties may be encountered with:

- Anatomic variations heart chamber enlargements
- Congenital heart disease
- Aortic root aneurysm
- Spine deformities - Kyphoscoliosis
- Post heart surgery
- No blood aspired: needle intramural? Dissection? Give contrast; try another place.

SAFETY NOTES

Reuse

The ***ISPunctureLas®*** is designed, according to valid rules, for single use only. Cleaning or reuse can result in serious complications. ***LasCor®*** will not be responsible for any direct or consequential damage or expenses which result from cleaning or reuse.

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

Sterilization

The catheters are shipped after sterilization with ethylene oxide (EO). Do not use products from open or damaged packaging. Under appropriate storage conditions, we guarantee sterility in undamaged packaging until the expiry date. Products should be stored at humidity of 45-70% and at temperatures of 15-25°C. They should not be exposed to direct sunlight and must be used before the expiry date on the packaging (“Use before date”).

External Interference

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

Side Effects and Complications

Despite correct handling during routine puncture complications may occur in 0.5 to 4%. However, during the laser puncture no such complication was noted up to now:

- Death in 0.1-1%
- Cardiac perforation with pericardial effusion, tamponade in 0.5-4%.

- Don´t advance when you don´t see tenting. Don´t push too hard (Pericardiocentesis in room!)
- Puncture of or injury to the aorta
- Vasovagal reaction
- Thrombus on wire or transseptal system
- Embolism, stroke 1% (use heparin!)
- Thrombotic and air embolism
- Iatrogenic Septal Defect
- Injury to the Atria
- Arrhythmias (AF, AV-block, BBB, etc.)
- Transient ST segment elevation

!	Treatment results and all the incidents caused using the ***ISPunctureLas®*** must be reported immediately to the manufacturer and to the local authorities. For the safety report (SSCP) see Fax Template attached.

During laser puncture with the ***ISPunctureLas®*** ***c***omplications have not occurred up to now.

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 fiber and introducer set 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 laser light with 980; 1064 or 1470nm wavelengths. This light may penetrate the 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 2.6m radius, measured from the catheter tip (calculated according to laser safety regulation VBG 93 for an irradiation at 10 W over a preset application time limited to 3s maximum. Safety hazards are significantly reduced if laser emission is inhibited on the laser touchpad whenever the ***ISPunctureLas®*** is handled outside the patient. Inside the patient, when the foot switch is enabled, no hazardous radiation can be released into the operating room. From a practical point of view, laser safety goggles are not necessary during the TP procedure. 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 650nm, <3mW 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 (limited to 3 seconds!).

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 catheter.

! !	➢ Never point a connected ***ISPunctureLas®*** towards a person or reflect structures. ➢ Check the laser light beam profile only by using the red pilot beam, never by releasing invisible hazardous 1064nm laser light. ➢ Use eye protection that blocks 1064nm laser light ➢ Enable laser radiation only when the ***ISPunctureLas®*** is positioned inside the body of the patient. ➢ Disenabling the laser foot switch is mandatory before removing the optical fiber set from the patient.

Enable the laser footswitch only when the ***ISPunctureLas®*** is already placed in the patient's body and inhibit laser emission immediately after laser application prior to remove the optical fiber set from the patient.

Additional safety hazards

can be caused also 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 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 light at the tip of the optical fiber must be performed by operators.

Preparation of the patient

Patients should be in 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 and local anesthesia. The flexibility of the ***ISPunctureLas®*** allows painless venous access from the femoral veins.

Connecting the Catheter

Check prior to laser connection and clinical application of the ***ISPunctureLas®***:

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

Thoroughly inspect the packaging and expiry date before opening. Draw the off the cover sheet of the double sterilization envelope and pass the catheter under sterile conditions with the inner envelope to the operator. For connection of the FSMA to the laser, hand it over to the non-sterile technical assistance who will first remove the protective cap from the connector, position the chip sleeve over the FSMA screwcap, engage it to the laser, and fully tighten the screwcap until the safety interlock reacts by switching on the pilot laser.

Be sure not to touch or soil the polished distal end of the optical fiber. Switch on the pilot laser and check the 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 leaks through the cable insulation (cladding/jacket) or the protective 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 heart catheters. Investigators may change procedure details according to their personal experience.

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

The ***ISPunctureLas®*** is inserted percutaneously via commercially available steerable sheaths e.g., AGILIS. Do not use inappropriate sheaths or guiding catheters as they may jeopardize the functions of the ***ISPunctureLas®.***

Puncture Procedure

- After aseptic skin preparation and sterile covering of the groin the vein is punctured (Seldinger technique).
- Remove the syringe leaving the needle in place.
- Straighten a J-shaped guidewire with its tip deflector and put it on the joining flange of the cannula.
- Advance the guidewire through the cannula into the vein and place its distal floppy end under fluoroscopic guidance in the high right atrium.
- Remove the needle, press the vein slightly to minimize bleeding and fix the wire.
- If necessary, make a small incision to widen the puncture site for insertion of the tapered dilator tip.
- Flush the dilator and push the dilator with the overriding sheath over the guidewire and advance it under fluoroscopic guidance into the right atrium.
- Try to access the left atrium via an open foramen ovale.
- If this is not practicable remove guidewire and dilator and flush the sheath with saline through its side arm.
- Flush the lumen of the dilator with saline and insert the optical fiber into the straight dilator and fix the dilator with its Luer end in the Click-valve.
- The optical fiber tip should be in idle position completely protected within the dilator.
- Test the extension of the optical fiber tip 2 mm with the first klick and 5 mm with the second klick.
  See figure: haemostatic Y-Click-Push-Valve (page 6)
- Connect the FSMA to the laser, insert the dilator tip into the sheath and advance it under fluoroscopic guidance through sheath into the right atrium.
- Manipulate the tip of the dilator under fluoroscopic guidance, if needed under TEE, ICE control, towards the area of interest and stabilize the dilator tip position upon the septum by advancing the fiber with the first Click step.
- Once brought in stable desired position and septal puncture is not yet achieved by the optical fiber tip, advance the fiber 5 mm with the second click-step and simultaneously activate the laser via the foot switch.
- Don´t push the puncture set too hard, watch septal tenting, and push the tapered dilator tip in the septum channel created by the optical fiber.
- Release the foot switch and the Click switch immediately when the dilator tip penetrates the Septum.
- If the tip of the dilator is still trapped in the puncture channel replace the fiber with the guide wire and advance it into the left atrial cavity.
- Make sure the guide wire is in the left atrium, remove dilator and guidewire and flush the sheath with saline.

Puncture Control

Correct puncture can be confirmed when:

- The guidewire is deployed into the left atrial cavity and can be advanced through the mitral valve into the left ventricle.
- Aspiration with a syringe through the dilator shows red oxygenated arterial blood.
- Flushing of the dilator with heparinized saline is performed easily without resistance.
- Pressure monitoring shows a typical left atrial pressure waveform.
- Dye injections under X-ray imaging show rapid dispersion of the dye into the left atrial cavity without deposit.

If this is the case transseptal puncture was successful, the dilator tip can be pushed deeper into the left atrial cavity together with the overriding sheath until the distal end of the sheath is also positioned into the left atrium. Now the dilator can be removed, and the sheath is flushed with saline and prepared for left heart procedures with various instruments.

! !	**Caution**: if pericardial or aortic perforation occurs, do not advance the dilator and the sheath into LA. If the optical fiber tip has penetrated the epicardium or the aorta the fiber must be withdrawn, and another side targeted. However, if the dilator has penetrated the aorta or the epicardial space it should be kept in place, urgent surgical support requested, and vital signs must be monitored closely.

The ***ISPunctureLas®*** is connected to a diode laser with a FSMA connector with a chip-sleeve at its proximal end.

Catheter manipulation

The ***ISPunctureLas®*** can be manipulated with steerable sheaths as described above. 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 upon the atrial septum in the beating heart.

Laser Application

Laser light is applied in a continuous mode of radiation at 10W and is stopped automatically after 3s (preset time), or immediately after septal puncture is observed on the Xray screen. Laser energy applications depend on the anatomical structure of the interatrial septa: aneurysmatic, thin, fibrous, muscular atrial wall or Teflon patch, etc. For puncture of a fibrous tissue or a thicker muscular wall laser impact can be repeated in the same or another side of the septum.

Only after correct orientation of the ***ISPunctureLas®*** is certain the touchpad is activated, and laser radiation can be applied by pressing the foot switch. Simultaneously with the start of laser the optical fiber is advanced manually by the Click-valve extending up to 5.0 mm beyond the endhole of the dilator tip.

Laser application is accompanied by an acoustic signal. Radiation ends automatically after the preset time of 3.0 s or earlier by releasing the foot switch.

For safety reasons the laser should be disenabled immediately after the laser impact. Even when remaining inside the patients´ 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 after introduction.

As a result, we do not assure or guarantee in any way that a disturbance or discontinuation of function will 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.

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

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.

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®***.

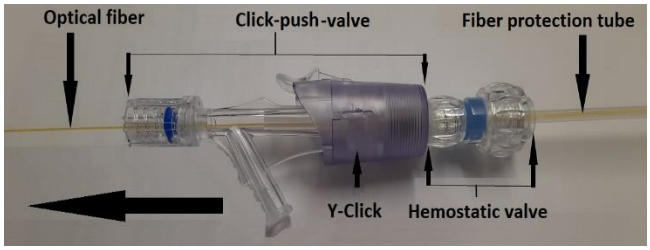
NOTE
After its use the catheter is biologically contaminated and must be disposed according to the local regulations.

The catheter does not contain toxic components that would need special measures.

In cases of catheter defects detected **prior to use**, **non-contaminated catheter** can be replaced by the manufacturer, provided the catheter is sent back with documents describing the detected defect, according to our fax template.

Contaminated catheters can be returned using the return form under sterile conditions.

Figure: Haemostatic Y-Click-Push-Valve



The haemostatic Y-Click-Push-Valve of the optical fiber set ***ISPunctureLas®*** for the advancement of the fiber tip in two steps, 2 and 5 mm, beyond the endhole of the sheath dilator tip

TECHNICAL DATA	**Version 2024-12-16**
ISPunctureLas® - an Optical Fiber Set	
Fiber core diameter	400µm or 600µm
Working length	100 cm
Total Length	250 cm
Numerical aperture	0.22
Beam divergence fiber in water	70°
Laser-connector	FSMA

Order data	
Catalogue No.:	**T 005-100-XXX**
Packaging:	**carton box with one sterile set**
Delivery box:	**with 10 single carton boxes**
UDI-DI:	**4260691560054**

CE 0481	**0481 ecm Aachen expired 2024** **0123 TÜV SÜD in process**

Annexes:
1. **Patient Information**
2. **Patient's Statement + Written Informed Consent**
3. **Fax Template: Post Market Clinical Follow-up (PMCF)**

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

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Patient Information

Side-selective Interatrial Septal Laser Puncture Procedure by using the optical fiber set *ISPunctureLas®*

What it's all about?

Dear Patient,

For your diagnosis or treatment a transseptal puncture of the interatrial septum is needed. Routinely, the septum is punctured with a long steel stilet, the Brockenbrough needle. Severe side effects range between 1%-4%. Alternatively, radiofrequency (RF) needles are available that allow to cross the septum at precise locations around the foramen ovale, even puncture of moderate fibrotic septum, while reducing mechanical force and the risk of embolism.

However, the RF power source with a disposable grounding pad for the return of RF energy, and various transseptal guiding sheaths are needed for controlled catheter movements in the left heart. In addition, puncture of dense fibrous or thicker muscular septa remote from the foramen ovale may be difficult to cross the septum by RF needles.

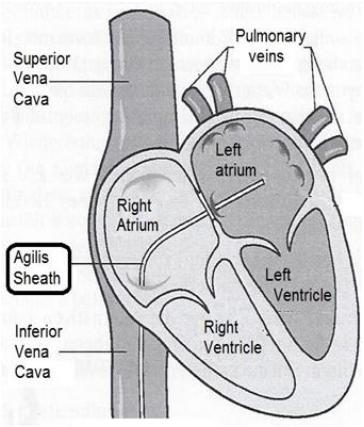
In contrast to that, side selective interatrial laser puncture by using the optical fiber set ***ISPunctureLas®***, based on a clinical study in 57 procedures in Patients of whom 13 were aged ≥75 is feasible in any septal area regardles of its anatomic structure thin and aneurysmatic, fibrous and thick or even teflon patch. 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 with minimal risk if any.

In addition, the tip of the optical fiber does not shave off small pieces of the sheath because the optical fiber tip in idle position is at the level of the dilators endhole prior to being introduced in the sheath with the curved distal end hold stretched. With the first step of the hemostatic Y-push-click-valve the optical fiber is extended 2.0 mm from the endhole of the dilator brought in a stable position upon the interatrial septum. With a second step the fiber is further advanced 5mm with simultaneous laser application, so the septum is punctured almost instantly, in 1-3 seconds.

With the thin flexible optical fiber a tiny channel is created in the septum. Control of successfull puncture is performed prior to the advancement of the dilator tip with the overriding steerable AGILIS sheath into the left atrium. An important safety aspect. The ***ISPunctureLas®*** is adapted to the approved steerable guiding and introducers used for the laser puncture procedure, e.g. AGILIS sheath. These are positioned in your left heart and after removal of the dilator and fiber can be used for various left heart diagnosis or treatment instruments and procedures including cardiovascular laser catheter applications.

Indications for Septal Puncture:

- 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 to the left heart

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 in the intra-atrial septum, within the right or left atrial cavity

Relative are

- Marked cardiac or thoracic deformity e.g. Kyphoscoliosis
- abnormal cardiac anatomy including Dextro-cardia, severe enlargement of the heart chambers
- Aortic root aneurysm
- Post heart surgery
- Anticoagulation must also be considered because it may also represent a certain risk.

Preparing for the Ablation

Unless you are already hospitalized, you will probably be admitted to the hospital or, in some cases, you may undergo the treatment in outpatient hypertension unit.

Several routine laboratory tests will be performed prior to the intervention including an ECG, blood tests, and possibly ambulatory long-term blood pressure measurements. These 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 that allows injection of drugs 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 6 hours or drink two hours anything prior to the intervention but 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. Please 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 or contrast medium.

For your comfort, empty your bladder as completely as possible before the procedure starts. Once preparations are completed, you will be taken to the catheter laboratory where the procedure will be performed. You will be transferred to an X-ray or NMR table. 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 angiologist with special training, radiologist, an anaesthetist, an assistant, nurses, and technicians.

Puncture 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.

1. The groin where the guiding sheath and subsequently the laser catheter will be inserted is cleansed and disinfected thoroughly.
2. A local anaesthetic is injected into the skin with a tiny needle to numb the area. This may cause a stinging sensation. If necessary, sedative medication can be given.
3. A small incision is made in the skin, and a needle system is used to puncture the vein.
4. A flexible guide wire is introduced through the needle, and the needle is removed whereas the wire is advanced through the vein and its distal end is positioned in the right atrial cavity.
5. A steerable guiding set will be advanced over the guidewire into the right atrium and manipulated with its tip towards the septal area of interest.
6. A Push-Click-Valve of the ***ISPunctureLas®*** allows for a stepwise extension of the optical fiber tip from the endhole of the dilator tip and for septal laser puncture.
7. The optical fiber will be replaced by the guidewire to insure correct access to the left heart. If this is the case the dilator with sheath is advanced into the left heart.
8. Subsequently, guidewire and dilator are replaced by a laser ablation catheter or by other instruments e.g. for mitral valve replacements, left atrial appendage closure devices, etc.

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 transseptal laser puncture procedure by using the ***ISPunctureLas®*** is not painful, and it is safe, no complications occurred up to now.

However, the insertion of catheters in the heart following the puncture procedure can be 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 renal lesions of coagulation necrosis cannot occur provided laser applications are not performed in small artery ramifications close to the kidney hilum. However, laser procedure-related complications cannot be completely ruled out and of the risks. To learn about your particular risk, you should discuss the matter with the doctor.

Side effects and complications

- Cardiac perforation and tamponade of the right or the left atrial wall and of the aortic wall varies between 1%- 4%. - pericardial effusion must be controlled by echocardio-graphy but often may solve spontaneously but in rare cases surgical intervention and drainage is needed.
- Aortic puncture with severe bleeding may require surgical emergency treatment.
- Thrombus in the left atrium and on the transseptal sheath is reported in 8%-11%.
- Stroke is rare but cerebral lesions are detected on magnetic resonance imaging in 7% to 13% after other atrial puncture techniques.
- Maintaining an activated clotting time >300 seconds during PVI has been suggested to prevent left atrial thrombus formation. If detected on TEE or 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 the treatment of large air emboli with dramatic symptoms.
- Iatrogenic atrial septal defect is rare but can occur after withdrawal especially of the transseptal sheath. Electiv closure of the defect should be considered in selected cases.
- Arrhythmias such as atrial fibrillation, slow heart rate – AV-block.
- Less common are 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 that may necessitate treatment with antibiotics or even local surgical intervention.
- Persistent swelling can occur in extremely rare cases caused by lymph stasis in the extremity through which the catheter was inserted.

Complications are extremely seldom and did not yet occure up to now. 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.

The puncture procedure may be performed easier and with lower risk when transesophageal or intracardiac echocardiography is used for control of catheter manipulation and pricise orientation of the optical fiber tip towards the selected septal area where laser puncture is aime at.
If you need more information please ask your doctor.

After the Puncture Procedure

After successful transeptal laser puncture without complication a catheter is introduced, and laser treatment can be performed. Also, other devices designed for minimally interventional left heart catheter treatments can be used. For more details of your specific treatment 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 laser ablation procedure and the possible complications and risks, I have received a complete file of **Patient Information,** and I have no further questions.

Herewith I agree with the proposed Renal ☐ Pulmonary ☐ Laser catheter denervation, 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

Further comments:

LasCor Laser Medical Devices
Cardiovascular Laser Application

Fax Template

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

Please fax to +49 (0)89 759 5770	***ISPunctureLas®* T 005-100-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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