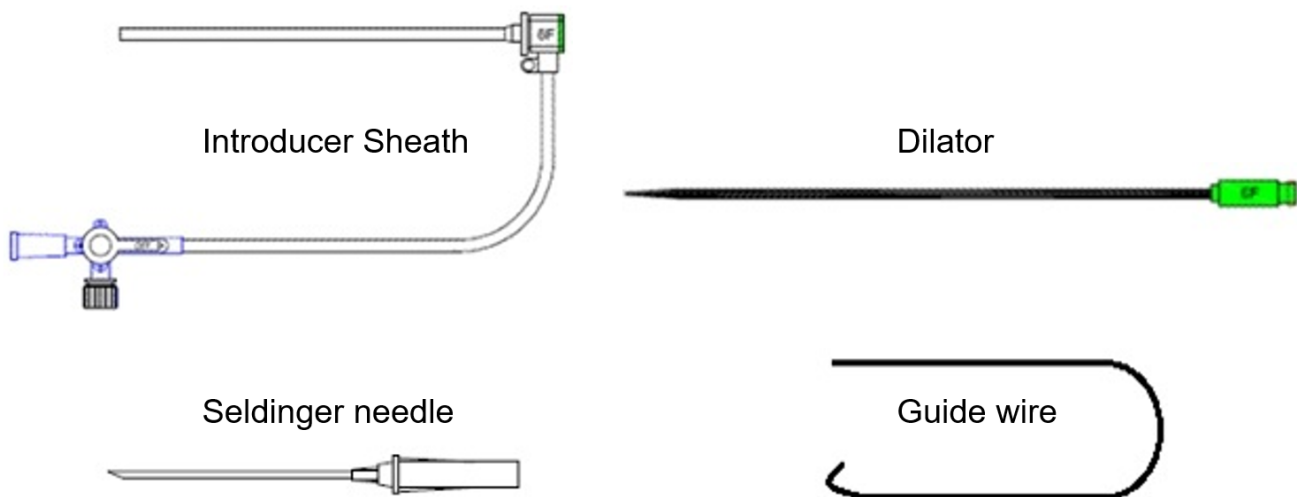


Instructions for use LGO-Introducer Set

1. LGO-Introducer Set

The LGO-Introducer Set is an introducer set for peripheral veins and has got a size of 6F and a length of 110 mm. The set consists of the following components:

- Introducer Sheath 6F x 110 mm
- Dilator 6F x 170 mm
- Seldinger needle 18G x 70 mm
- Guide wire 0.038"



The following devices are commonly used together with the LGO-Introducer Set:

- in phlebology: LGO-Saturn Side Fiber Probe®
- Medical laser together with suitable laser safety goggles.

This device is to be used only by physicians who are experienced in creating entrances to the vein system. It must not be inserted into the central nervous system or into the central circulatory system. Follow clinical guidelines for handling sterile goods.

2. Application guidelines and safety rules

2.1. Indications

The LGO-Introducer Set allows smooth introduction of the devices for example the LGO-Saturn Side Fiber Probe® into the vein, creating a safe gap between the medical fiber and the vein wall. The set has been developed to reduce complications resulting from intravascular medical interventions.

2.2. Warnings and symbol explanation

The use of medical devices may be associated with biological risks. Medical devices shall be used and disposed of in accordance with legal requirements and accepted practice.

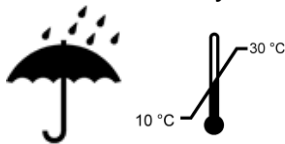
Prior to use it must be ensured that all instruments provided for the medical treatment are compatible with each other. If a laser manufacturer offers the LGO-Introducer Set as a genuine accessories product, the compatibility test with the laser fiber of the manufacturer has already been performed and does not need to be performed again.

Always hold the Introducer Sheath in place when maneuvering other devices through it.

Do not leave the Introducer Sheath in place for long time in the vessel without the guidewire as support.

Do not use the LGO-Introducer Set with any high pressure injector.

When using the LGO-Introducer Set during a laser treatment make sure that never during the treatment there is laser radiation emitted inside the introducer sheath. To ensure this the laser probe shall always extend from the introducer sheath sufficiently and the introducer sheath needs to be removed early enough during pull-back.



The product must be kept in a dry place and at the given temperature range.



Prior to use check the packaging for damage. Do not use if the packaging is damaged.



The product has been sterilized with ethylene oxide (EO).



Do not reuse. This product is intended for use with a single patient during a single treatment. Sterility and performance cannot be guaranteed after reprocessing.



Mind the instructions. It is necessary for the user to consult the instruction for use prior to use.



Expiration date: Indicates the date after which the medical device must no longer be used.



Manufacturer: Symbol indicates the manufacturer of the medical device according to the guidelines 90/385/EEC, 93/42/EEC and 98/79/EC.



Batch code: Indicates the batch number of the manufacturer so that the batch can be identified.

3. Use of the LGO-Introducer Set

3.1. Preparation

Examine the extremities of the patient thoroughly. Determine the location of the saphenofemoral junction (or junctions) and the entire course of the vein.

Make the site aseptic and anesthetize as clinically required.

Take out all components of the LGO-Introducer Set from its packaging under sterile conditions.

Use saline for flushing. After having flushed the side port extension tube with its stopcock, turn off the stopcock to prevent blood from flowing out when inserting into the blood vessel.

Insert dilator into sheath through the hemostasis valve and fix it (90° rotation).

Caution: The dilator must be locked to the introducer to avoid damage when inserting into the blood vessel. If the thread does not lock, stop using it and replace it by a new device.

3.2. Procedure

Puncture the Seldinger needle into vessel as 45 degree.

While holding the Seldinger needle insert the guidewire through the Seldinger needle as far as necessary.

Caution: Do not advance the guide wire when resistance comes across. Determine the cause of resistance before proceeding.

Hold the guide wire tightly and then remove the Seldinger needle over it. Hold the pressure on the site until the introducer/dilator is placed. Use sterile cloth to clean blood on the guidewire outside, then put the sterile cloth on the puncture site to prevent bleeding.

Insert the guidewire from the end of the dilator, hold tightly when the dilator is approaching the skin, and rotate gently while pushing into the vessel. It may be necessary to make a small cut of the skin.

Hold the sheath tightly and carefully remove the dilator (90° rotation) and guide wire together to leave only the sheath in the blood vessel.

Use a syringe connected to the stopcock to draw out any potential air from the side-port extension line. After that, flush the side port using saline. Turn off the stopcock to maintain fluid in side-port extension tube.

Insert laser optic fiber for example the LGO-Saturn Side Fiber Probe® into sheath as clinically required.

Remove the sheath according to the progress of the surgery.

Press the puncture site with sterile material to prevent a bleeding of the puncture site or wider hematoma.

4. Liability and warranty

Light Guide Optics International Ltd does not accept any liability for personal injuries as well as for damage of the laser device due to an inappropriate handling and storage of the LGO-Introducer Set.

Light Guide Optics International Ltd cannot be held responsible for indirect damages or consequential damages, losses and expenses with respect to a direct or indirect application of these products.

Light Guide Optics International Ltd does not accept any responsibility neither in terms of the application of the LGO-Introducer Set nor in terms of possible side effects of the medical laser treatment with this device.



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