Radimed Gesellschaft für Kommunikationsdienstleistungen und Medizintechnik mbH
Lothringer Straße 36b
D - 44805 Bochum - Germany
Tel.: +49 - 234 – 89 00 29 – 0 / Fax: +49 - 234 – 89 00 29 – 9 / email: info@radimed.de

CE 0044

Laserfiber for Percutaneous Laser Disc Decompression (PLDD) – Instructions for Use

Area of use and limitations

Radimed Laser Fibers are medical fiber optic probes for coagulation and vaporization during percutaneous laser discus decompression (PLDD).

Contraindications for the application are sequestered disk prolapse and prolapse with disruption of the annulus fibrosus (grade of dislocation IV and V), severe loss of height as well as instabilities of the segment to be treated. Low water content (black disc) can result in reduced denervation potentials. MODIC changes of type II and III are also contraindications.
Excluded are treatments near clamps or implants because of the danger of heating and destruction. Current treatment guidelines must be respected. Use on central nervous and circulatory system is prohibited.

To ensure correct and safe use, this product may only be used by physicians who are familiar with the use of medical laser systems and the therapeutic use of fiber optic probes.

Possible risks in relation to usage

Please refer to the instructions for use of the medical laser and respective medical literature for a thorough inspection of possible side effects. A non-exhaustive list of possible side effects includes burn, swelling, bleeding, pain, infections, paresthesia by damage of close nerve cells, perforation during use in the vicinity of sensitive areas (blood vessels, intestine…). Selection of incorrect or elevated laser energy may cause unintended tissue reactions in the focused tissue. Laser treatment should only last for the period necessary for the effect of ablation, coagulation or vaporisation.

Laser radiation can ignite dressing and covering material as well as the patient's body gases. Appropriate safety distance and safety measures have to be kept.
When using laser systems with great depth of penetration in an aqueous environment (e.g. Nd:YAG laser), care should be taken that neighbouring blood filled vessels are not coagulated. The absorption spectrum of haemoglobin is markedly different from that of water and depends on oxygen content!

Compatibility testing

Laser fibers may only be used when their compatibility with the corresponding laser system has been checked. Radimed fibers are compatible with laser systems with wavelengths from 400 nm to 2200 nm and a numerical aperture of 0.20.

Maximum output power must not exceed 100W. It must be checked whether the connection port of the laser system can connect to the plug of the fiber.

Recommendations for use

Before beginning the laser treatment, all instructions for use for the used instruments must have been read and fully understood. When in doubt, please refer to the respective technical service or supplier and refrain from treatment until full clarification.

Make sure that the fiber can be inserted easily into the working canal and always protrudes from the instrument during the entire treatment.

During the treatment, it should be checked that the distal fiber end is not damaged or contaminated. Residues lower the laserpower which is usable for treatment and leads to overheating of the fiber, lowering its life expectancy.

Possible residue can be removed after several seconds of cooling or low radiation by careful rubbing against tissue. Burned tissue should be removed carefully with a sterile, wet cloth from the fiber tip.

Laser pyrolysis products (gases, vapours, particles, infectious aerosols, ...) generated during treatment should be collected with an extraction system above the treatment zone. Gas embolisms may occur when using rinsing gas.

Typical treatment parameters and laser settings are to be taken from the respective literature depending on the application. It must be started with low power and, during treatment, the laser settings are to be adjusted according to the observed tissue effects.

Warnings

The use of medical devices can lead to biological risks. Medical devices must be used and be disposed of in accordance with legal regulations and acknowledged practice.
It must be made sure the fiber can easily be led into the working canal and reaches out of the instrument during the entire treatment.
The general regulations and information regarding safe handling of laser radiation must be applied (including eye protection). Relevant safety information must be taken from labelling of the laser system and their instructions for use.
Elevated care is necessary when working with medical laser fibers. These laser fibers can be damaged through load, impact or bending. These damages influence functionality and/or correct operation/treatment.

The Radimed Laser Fiber must not be bend too tightly:

core diameter	permitted bending radius
≤ 400 µm	≥ 21 mm
≤ 600 µm	≥ 31 mm

After connection to the laser device the pilot beam must be visible as a frontally radiating dot. If this is not the case, the product must not be used.

After treatment the fiber has to be checked for damages. In the unlikely event of a breaking fiber tip which stays inside the patient's body (or if this is suspected), appropriate clinical measures have to be adopted.

Fibers should only be used under sterile operation room conditions. The sterile packaging has to be controlled for integrity. Fibers from damaged packages may not be used. Fibers with damages on the distal fiber tip or on the launching plug may not be used.

The guarantee for the laser fibers applies exclusively to their single use on one patient.

Preparations for the medical use of the fiber

The laserfibers are carefully packed. They are supplied in a sterile state in packaging which protects them from transport damage. The storage time with unopened packaging is given on the label. Please check that the packaging is in perfect condition and also use this packaging for the safe storage of the laserfibers. The fibers must be stored in the complete sterile packaging and the storage packaging till their preparation for medical use. Please also observe the Sterile Goods Ordinance DIN 58953 Part 8.
The laserfibers can be damaged or even destroyed from carelessness during storage or when unpacking. The end surfaces of the glass fibers on the launching plug and on the distal fiber tip are particularly sensitive to mechanical effects.

To be avoided (among others):

- Throwing, hitting or stressing with sharp-edged or heavy objects
- Extreme bending
- Storage temperatures above those on the labels
- In general, temperatures above 50°C
- Storage at relative humidity above 70%
- Exceeding the use-by date

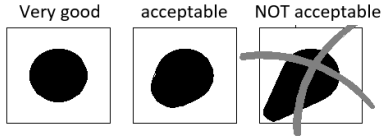
Visible inspection before use

Check sterile packaging for damage before opening. The following issues have to be noted:

- Check the fibers by visual inspection
- Do not subject the distal fiber end or the launching plug (SMA) to inappropriate stress and check for integrity
- Check the cleanness of the launching plug
- Avoid every contact between the fiber and non-sterile objects
- Do not let the fiber fall onto a hard surface

Connect the laser fiber to your laser system, as described in the instructions for your laser system.

Hold the distal end of the fiber vertically on a light surface and switch on the pilot laser beam, depending on the instrument type. The pilot beam must give a circular and homogenous image. If this is not the case, the laser fiber may not be used.



Rev. 5 / Effective 06/2022

Radimed Gesellschaft für Kommunikationsdienstleistungen und Medizintechnik mbH
Lothringer Straße 36b
D - 44805 Bochum - Germany
Tel.: +49 - 234 – 89 00 29 – 0 / Fax: +49 - 234 – 89 00 29 – 9 / email: info@radimed.de

CE 0044

Laserfiber for Percutaneous Laser Disc Decompression (PLDD) – Instructions for Use

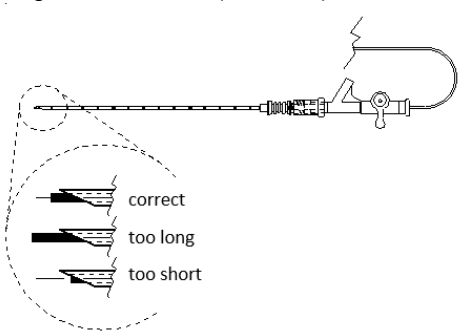
Connecting to the laser system with PLDD components

The protective tubing is removed on the distal end of the Radimed fiber. This design is meant for the use in combination with fine needles or other accessories.

Guide the fiber carefully through the free lumen of the accessory. Please then check the fibers tip quality again, using the light spot of the pilot beam laser and the correct protrusion of the fiber. The fiber should easily be led into the fine needle and accessory and protrude by approx. 1 mm out of the tip of the fine needle, as sketched below, and has to be fixed in position by a fixing device.

The laser fiber may not be retracted through the cannula when the system is in place inside a patient in order to avoid unwanted shear of the fiber at the cut of the cannula.

To avoid slipping of the fiber inside the cannula, the fiber must be fixed properly. For this, the Radimed fixing device can be used (REF: 10020).



Procedure of therapy

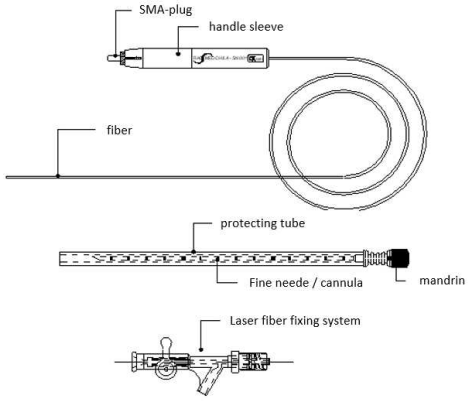
The selection of therapy and the suitable laser parameters comply with the state of art and are not part of this instruction for use. The selection of the suitable laser parameters (laser power, energy, total energy) depends on the selection of the laser system. They are not comparable among each other, because the physical effects on the tissue are very different. Please follow the instructions for use of the laser system.

Before the first application of the laser fiber the physician should familiarize himself with tissue effects resulting from using the laser fiber with low energy and short pulses.

After the fiber was fixed as explained in the previous step so that it protrudes by approx. 1mm over the distal end of the cannula/instrument, the fiber and fixing device are separated from the cannula/fine needle and sterilely put aside. The fine needle can then be put into the target region with its respective mandrin under radiologic guidance.

When the position is reached, the mandrin is removed from the fine needle and the fiber with its fixing device is reintroduced into the fine needle. By determining the length prior to inserting the fine needle, it is ensured that the fiber protrudes correctly by 1mm out of the fine needle.

Components for PLDD (optional accessories)



When using fine needles, correct inner diameters have to be chosen.

Core diameter	Possible fine needle
≤ 400 µm	21G / 18G
≤ 600 µm	18G

The outer protective sheath of the fibers is made up to a cannula length according to the marking of the laser fibers.

Disclaimer

Radimed GmbH shall not be liable for any personal injury and damages of the laser system caused by incorrect utilization or improper storage.

Radimed GmbH shall not be liable for immediate damage or consequential damages or losses and expenses which relates to indirect or direct handling of these products.

Radimed GmbH does neither take over responsibility related to the use of Radimed fibers nor related to possible side effects of the laser treatment with this fiber.

Reuse and reprocessing

Laserfibers are intended for single patient use and may not be reprocessed.

A complete reprocessing (cleaning, disinfection, sterilization) of the fiber can cause a maceration of the polyimide coating resulting in micro fissuring and associated difficulties (bioburden, mechanical stability).

Furthermore, reprocessing can result in damaging of the proximal fibers ending and therefore it can also cause consequential damage on the laser system.

For more information or if training for users is desired, please contact:

Radimed GmbH
Lothringer Str. 36 b – D-44805 Bochum
Tel: + 49 (0) 234-890029-0
E-Mail: info@radimed.de

Symbols

	Do not re-use: The medical device is intended for single patient use. If re-used, sterility and function are not existent anymore.
	Use until: Displays the expiry date of the medical device.
LOT	**Batch:** Displays the batch of the manufacturer to trace back the product.
REF	**Reference**
STERILE EO	**Sterilized by ethylene oxide**
	Manufacturer: Displays the manufacturer according to EC Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Date of manufacture
	Consider the instructions for use: The user has to read and understand the instructions for use.
	Storage conditions: The medical device has to be stored in a dry place and within the given temperature range.
	Check the packaging for damage before use; do not use if packaging is damaged.

Rev. 5 / Effective 06/2022