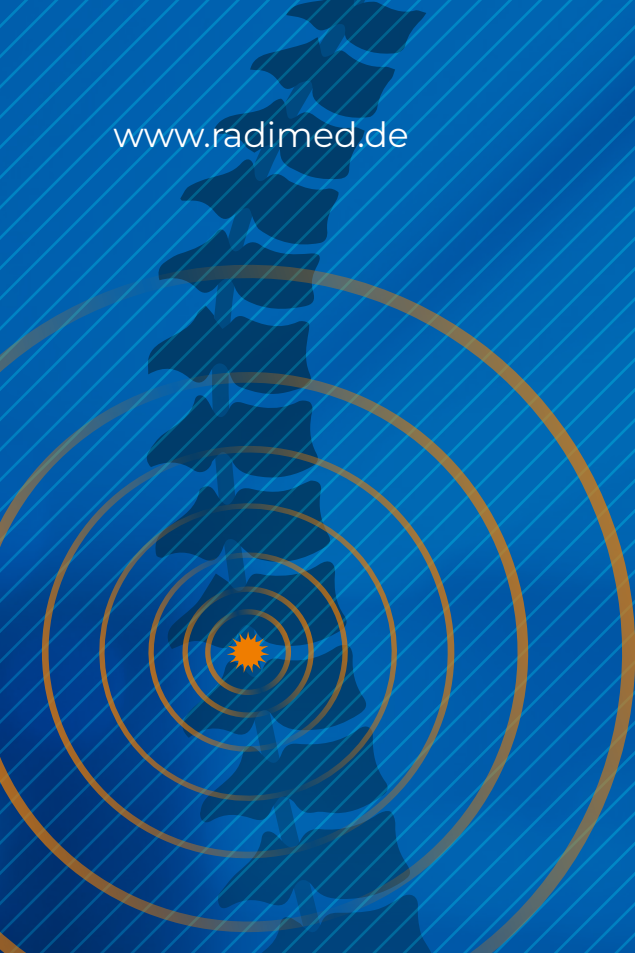


www.radimed.de

A graphic on the left side of the page shows a silhouette of a human spine and neck. Overlaid on this is a series of concentric orange circles that form a target, with a small orange sunburst icon at the center. The background of the left side is a blue field with a fine, diagonal grid pattern.

PRODUCT CATALOGUE

For minimally invasive pain therapy
on the spine and joints

Foreword

RADIMED GMBH – WHAT WE STAND FOR

Since 1999 we have been developing and marketing a highly specialized range of products for minimally invasive pain therapy on the spine and other selected joints in the heart of the Ruhr region. As shown in the graded model of pain therapy below the products are meant to potentially avoid complex operations.

Our many years of experience in the industry and trusting contact with our customers make us your competent partner when it comes to financially attractive medical technology in certified quality.

For you, the added value comes from high-quality products for your medical use, reliable delivery channels for maximum flexibility in patient care, and central contacts who take the time for your needs.

**YOU DEFINE THE GOAL;
WE PAVE THE WAY TO ACHIEVE IT.**

For further information, please feel free to get in touch with us in person or visit our website, www.radimed.de.

Radimed GmbH



Jan Henke
Director



Ralf Klein
Director

Graded model of pain therapy



®

RADIMED

3-4

5-6

7-8

9-10

11

12

13-14

15

16

17-18

Minimally invasive pain therapy

CONTENTS

Fine needles for pain therapy

Thermal denervation / RF stimulation therapy

Thermolesion cannulas for pain therapy

RF thermocouple electrodes
and connecting cables

CoATherm thermolesion generator

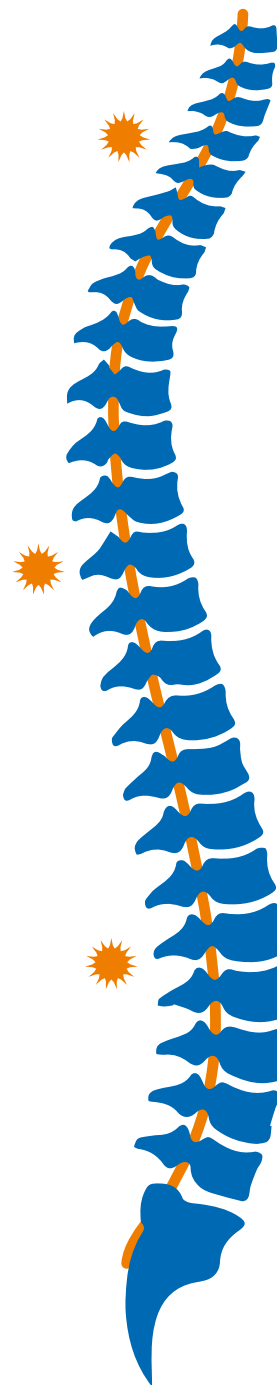
Accessories for Neuro N50

Percutaneous laser disc denervation /
decompression (PLDD)

SMART^m diode laser at 10W and 980nm

Sets and laser fibres for percutaneous
laser disc decompression (PLDD)

Quality management and regulatory affairs



Infiltrative

FINE NEEDLES FOR PAIN THERAPY

Special, long puncture cannulas to administer medications or guide a laser fibre as part of the pain therapy, for example on the spine



Radimed fine needles are available to the user in a variety of configurations. Different cutting shapes, lengths, surface coatings and the possible use of a guide cannula offer individually preferred variants for every user.

As well as the properties mentioned, the "IMS" type offers greater flexural rigidity as a result of the increased wall thickness, in addition to siliconisation.

POTENTIAL APPLICATIONS

- Facet infiltration
- Periradicular therapy
- Discography
- Sympathicolysis
- Holding and conveying laser fibres as part of intradiscal laser therapy (PLDD)

SHARP

Special bevels guarantee easy insertion, even into deep tissue regions.

The following cut types are available:

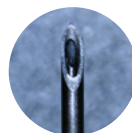
- Quincke cut: A short version of the facet cut
- Back cut: An angled cut with bevel at the back



*Facet
cut*



*Quincke
cut*



*Back
cut*

PUNCTURE-FREE

Unwanted puncture infections are minimised by the use of a stylet with an adapted cut angle. The stylet is optimally fitted into the respective fine needle.

SCALE

As an aid for positioning all fine needles are provided with a galvanically applied, abrasion-resistant depth scale.

SMOOTH

The fine needles of types "S" and "IMS" are provided with a special, smooth coating (dry siliconisation), which reduces the slide resistance of long fine needles.



COMBINABLE

Specifically for the thin 23G fine needles, we offer a 20G guide cannula with facet cut, to aid easy skin penetration and targeted guidance, even in the case of long variants.



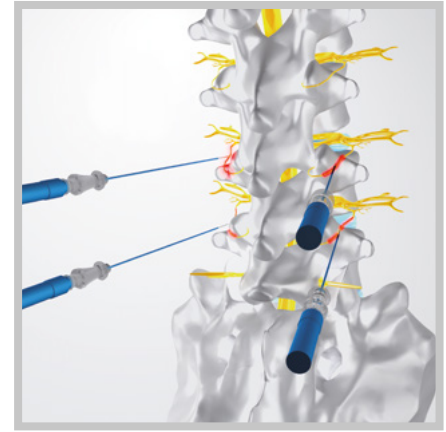
| Fine needles | Variants | | REF | Short name | Diameter | | | Length [mm] |
|---|-------------|---------------|---------------|-------------|----------|--------------|--------------|-------------|
| | | | | | External | | Internal | |
| | | | | | Gauge | Approx. [mm] | Approx. [mm] | |
| With no additional coating | Quincke cut | 10009 | 18/150C | Pink | 18 | 1.25 | 1.00 | 150 |
| | | 10010 | 18/200C | Pink | 18 | 1.25 | 1.00 | 200 |
| | | 10005 | 21/100C | Green | 21 | 0.80 | 0.50 | 100 |
| | | 10006 | 21/150C | Green | 21 | 0.80 | 0.50 | 150 |
| | | 10007 | 21/200C | Green | 21 | 0.80 | 0.50 | 200 |
| | | 10002 | 23/70C | Blue | 23 | 0.65 | 0.40 | 70 |
| | | 10003 | 23/100C | Blue | 23 | 0.65 | 0.40 | 100 |
| | | 10004 | 23/150C | Blue | 23 | 0.65 | 0.40 | 150 |
| | | 10014 | 23/200C | Blue | 23 | 0.65 | 0.40 | 200 |
| | | Siliconised | Back cut | 10001 S | 23/35CS | Blue | 23 | 0.65 |
| 10003 S | 23/100CS | | | Blue | 23 | 0.65 | 0.40 | 100 |
| | | 10011 S | 23/85CS | Blue | 23 | 0.65 | 0.40 | 85 |
| Guide cannula for 23 G (with facet cut) | | 10012 | FKC 20G | Transparent | 20 | 0.90 | 0.70 | 38 |
| Thick-walled and siliconised | Quincke cut | IMS/0.67-57C | IMS/0.67-57C | Purple | 23 | 0.67 | 0.30 | 57 |
| | | IMS/0.67-77C | IMS/0.67-77C | Purple | 23 | 0.67 | 0.30 | 77 |
| | | IMS/0.67-100C | IMS/0.67-100C | Purple | 23 | 0.67 | 0.30 | 100 |
| | | IMS/0.67-150C | IMS/0.67-150C | Purple | 23 | 0.67 | 0.30 | 150 |

The products are in individual, sterile packaging and available in units of 10 or 50.

Thermal denervation / stimulation

RF THERAPY

Effective pain relief with Radimed RF thermocouple electrodes, thermolesion cannulas and appropriate RF generators



The usual applications of HF treatment in pain therapy include the treatment of chronic musculoskeletal pain, e.g. in the spinal facet joints, sacroiliac joint and peripheral joints such as the knee, hip, elbow or foot.

INDICATION

Thermocoagulation and stimulation (PRF) is particularly suited to pain therapy for peripheral nerve structures in which pain is to be eliminated by means of denervation or nerve stimulation.

Among other things, this includes:

- Denervation of the facet joints (e.g. ramus medialis, dorsalis)
- Denervation in the knee (e.g. nervus genicularis, nervus saphenus)
- Denervation at the ankle/heel (e.g. nervus calcaneus)
- Denervation at the hip (e.g. nervus opturatorius, nervus femoralis)
- Denervation at the shoulder (e.g. nervus suprascapularis)

CONTRAINDICATIONS

The contraindications arise from the specifications of the HF devices.

The products are not intended for use on the central nervous system.

ADVANTAGES

- Minimally invasive
- Local anaesthesia, thus painless
- Can be performed on an outpatient basis
- No risk of scarring
- Short convalescence period with short incapacity for work
- Therapy can be repeated
- Good, standardised documentation

MEDICAL DEVICES – ALL FROM ONE SOURCE

RF therapy uses RF thermolesion generators, RF thermocouple electrodes and thermolesion cannulas as well as connecting cables and neutral electrodes. All products are supplied by Radimed to be compatible with one another.

TRAINING

On the basis of specification records, our staff will instruct you on how to use the products.



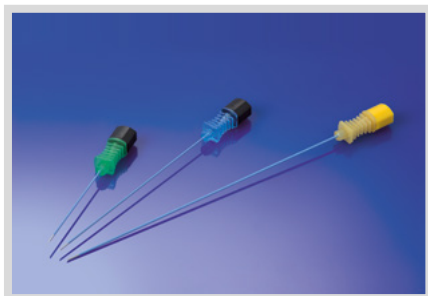
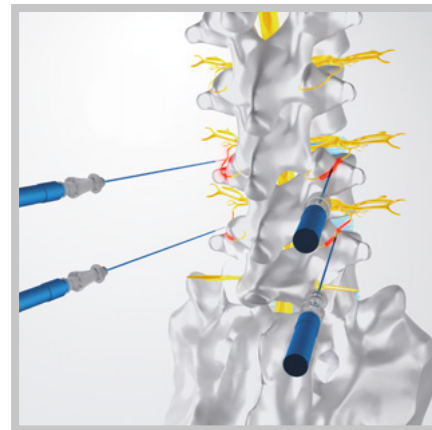
Please get in touch with us if you have any questions about the therapy or use of the RF thermocouple electrodes, thermolesion cannulas or RF generators.

General enquiries: info@radimed.de // Orders: order@radimed.de

Thermal denervation / stimulation

THERMOLESION CANNULAS FOR PAIN THERAPY

Special, insulated cannulas for thermal denervation on the spine and other selected joints



Radimed thermolesion cannulas offer different lengths, diameters, shapes and uninsulated tips for the user for the user (straight and distally curved).

These are individually suited to the planned therapy in the selected target region.

POTENTIAL APPLICATIONS

Thermal denervation and non-destructive stimulation of:

- Facet joints (whole spine cervical/thoracic/lumbar) and sacroiliac joint
- Other peripheral structures (joints) at the shoulder, hip, knee and foot

MINIMALLY INVASIVE

Selected cutting shapes aid easy skin penetration.

Unwanted puncture infections are minimised with an adapted stylet.

SMOOTH

A special surface coating ensures smooth transition of the open tip point to the insulation layer.

SAFE TO COMBINE

The matching colours of the cannula hub and corresponding thermoelectrode help with the safe provision of materials that are compatible with one another.

In addition, the colour coding of the stylet cap describes the cannula diameter.

COMPATIBLE

Radimed thermolesion cannulas are compatible with many electrodes and devices for radio frequency therapy.

VARIABLE

Radimed thermolesion cannulas are available both in the straight variants and in a variant with a curved tip.

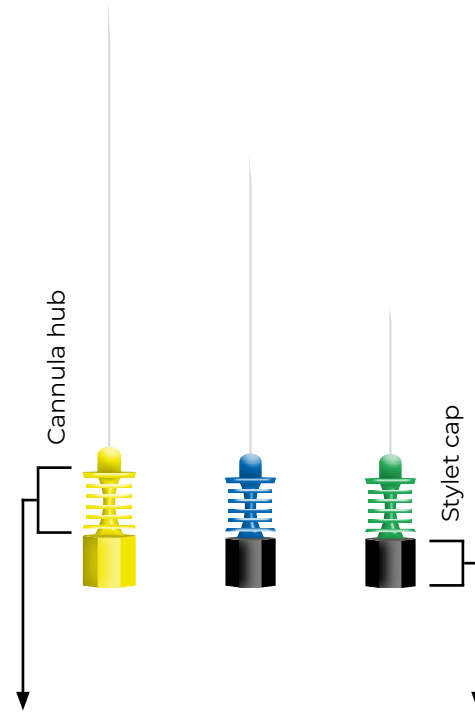
NON-INSULATED TIP VARIANTS



- Distally curved
- Straight



- Length: 5 mm
- Length: 10 mm



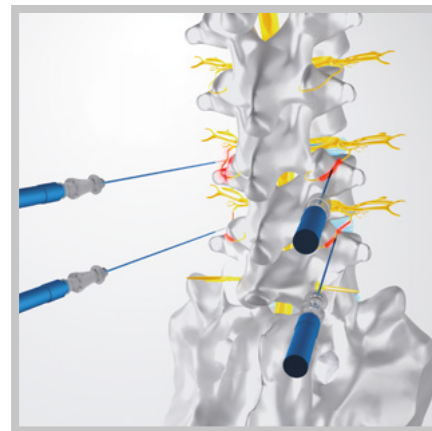
| | Variants | REF | Short name | Length (approx. mm) | TIP (mm) | Diameter | |
|-----------------------|------------------------------------|------------|----------------|---------------------|----------|----------|------------|
| | | | | | | Gauge | approx. mm |
| Thermolesion cannulas | Straight Siliconised | 10090 | TK/22-50-4 | 50 | 4 | 22 | 0.7 |
| | | 10091 | TK/22-100-5 | 100 | 5 | 22 | 0.7 |
| | | 10091-10 | TK/22-100-10 | 100 | 10 | 22 | 0.7 |
| | | 10092 | TK/20-150-5 | 150 | 5 | 20 | 0.9 |
| | Straight Not siliconised | 11095-10 | TK/18-100-10 | 100 | 10 | 18 | 1.25 |
| | Distally curved Not siliconised | 10091-10-G | TK/20-100-10-G | 100 | 10 | 20 | 0.9 |

The products are in individual, sterile packaging and available in units of 10 or 50.

Thermal denervation / stimulation

RF THERMOCOUPLE ELECTRODES AND CONNECTING CABLES

RF electrodes, reusable or for single use, for denervation or stimulation of peripheral nerves as part of the pain therapy, for example on the spine



Radimed thermocouple electrodes are adapted specifically for use in combination with Radimed thermolesion cannulas.

The electrode tip records the temperature that occurs in the surrounding tissue and relays this to the RF generator.

The RF energy is emitted only until the preset temperature is reached on the instrument tip.

COMPATIBLE

The electrodes and connecting cables are compatible with many generators. Ask for the right model.

FLEXIBLE

The Nitinol material of the reusable electrodes offers a high level of flexibility and kink resistance.

INTERDISCIPLINARY

As well as their use in pain therapy on the spine, the electrodes can all be used in other areas, e.g. shoulder, hip or knee.

AVAILABLE

The sterile thermocouple electrodes for single use on a patient mean that a product ready for use at any time can be kept in stock for intervention, regardless of processing.

Particularly in the case of external reprocessing of the reusable electrodes, there can be bottlenecks in returns or damage owing to incorrect handling.

This is where the sterile, single-use electrodes are ideal, either as a backup solution or as a product for routine use.

CONNECTED

Radimed offers compatible cables for use with electrodes and different RF generators.



REUSABLE

The Nitinol electrodes are available in a reusable, autoclavable variant. As an option, we offer a corresponding sterilisation box.

SINGLE-USE

The single-use electrodes are intended for single use on one patient.

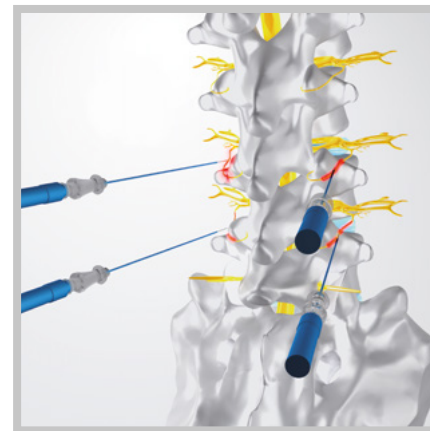
| Variants | | | REF | Short name | Length [mm] | Colour |
|------------|-----------------|-------------------------------|--------------|----------------|-------------|--------|
| Type | Material | Generator | | | | |
| Single-use | Stainless steel | Neuro N50 | 10094-22-1 | Radimed-50N-D | 50 | Green |
| | | | 10094-20-1 | Radimed-100N-D | 100 | Blue |
| | | | 10094-21-1 | Radimed-150N-D | 150 | Yellow |
| | | Other generators ¹ | 10094-22-1S | Radimed-50S-D | 50 | Green |
| | | | 10094-20-1S | Radimed-100S-D | 100 | Blue |
| | | | 10094-21-1S | Radimed-150S-D | 150 | Yellow |
| Reusable | Nitinol | Neuro N50 | 10094N-9-1L | Radimed-N50N | 50 | Green |
| | | | 10094N-10-1L | Radimed-N100N | 100 | Blue |
| | | | 10094N-11-1L | Radimed-N150N | 150 | Yellow |
| | | Other generators ¹ | 10094N-9-2 | Radimed-N50S | 50 | Green |
| | | | 10094N-10-2 | Radimed-N100S | 100 | Blue |
| | | | 10094N-11-2 | Radimed-N150S | 150 | Yellow |

¹ Please ask about the compatibility with your generator.

Thermal denervation / stimulation

CoATherm THERMOLESION GENERATOR

Generator for denervation or stimulation of peripheral nerves as part of the pain therapy on the spine



THERMOLESION

The CoATherm lesion generator is designed for temperature-controlled HF surgery as part of the pain therapy on the facet joints (thermo-denervation).

OPTIMISED

With its active temperature measuring in combination with Radimed electrodes, the RF generator offers a safe tool for denervation/coagulation with pinpoint accuracy.

STIMULATION

The generator offers the option of performing nerve stimulation before the intervention, to avoid ablation of the wrong nerve elements but also to optimise the cannula position.

EXTENDABLE

The RF generator is optionally available with a 4-channel multiplexer.

COMPATIBILITY

The CoATherm generator can be used with Radimed thermolesion cannulas, thermocouple electrodes and the corresponding connecting cable.

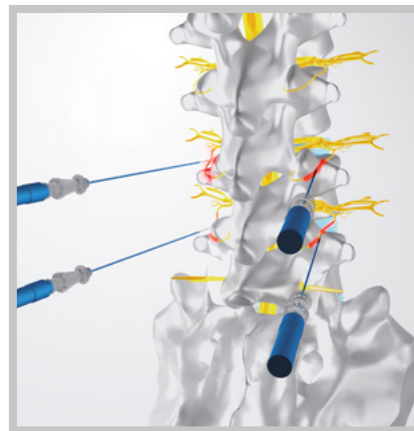
TRAINING

Radimed offers instruction in use of the device and related products on site where you are. If you have any questions, even after the instruction, please get in touch with us.

| Technical specifications data (excerpt) | | | |
|---|--------------|----------------|--|
| Coagulation temperature | 30°C – 110°C | Operating mode | Programmed and manual thermocoagulation with Radimed Thermocouple electrodes |
| HF frequency | 480 kHz | Manufacturer | Apru Korea CO Ltd. |
| HF power | 0.0 ... 50W | | |

Thermal denervation / stimulation

ACCESSORIES FOR NEURO N50



12



Accessories
still available
from us.

THERMOLESION

The Neuro N50 lesion generator is suitable for temperature-controlled HF surgery as part of the pain therapy.

PROVEN

For decades, this RF generator was the reference instrument in the area of RF thermolesion. It remains popular in the market, functional and proven. We therefore also continue to offer accessories for this generator.

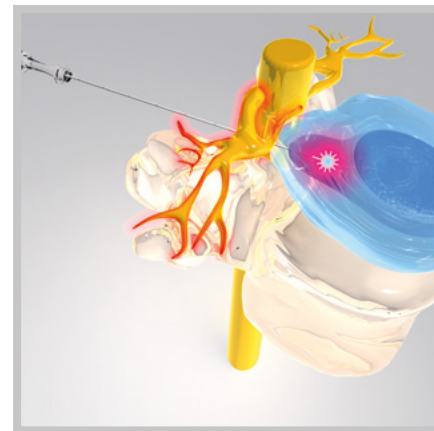
COMPATIBILITY

Radimed thermolesion cannulas, thermocouple electrodes and corresponding connecting cables are compatible with the Neuro N50.

Percutaneous laser disc denervation / decompression

PLDD

Successful treatment with Radimed laser fibres and the 980nm diode laser!



If the indication is confirmed correctly, PLDD is a modern, minimally invasive method to treat non-sequestered herniated discs in the cervical and lumbar spine after unsuccessful conservative therapy.

HOW IT WORKS

The pain therapy effect of intradiscal laser therapy is based on the following aspects: Denervation of pain receptors inside the annulus fibrosus, which occur as a result of neovascularisation in the case of degenerative and inflamed discs.

Other effects:

- Shrinkage of all disc parts as a result of heat exposure
- Solidification in the motion segment as a result of laser-stimulated, non-specific formation of scar tissue, owing to a change in collagen structure
- Effect on intradiscal, pre- and postganglionic inflammation mediators

EXAMPLES OF INDICATIONS

- Chronic discogenic vertebral pain syndrome with radicular or pseudoradicular symptoms
- Protrusion of a disc in the area of the cervical or lumbar spine
- Prolapse of a disc in the area of the cervical or lumbar spine with no tearing of the annulus fibrosus

CONTRAINDICATIONS

- Free sequestered disc inside the spinal canal
- Complete rupture of the annulus fibrosus
- Criteria for the occurrence of non-discogenic pain
- Progressive neurological deficits with axon-related motor losses

The products are not intended for use on the central nervous system.

TRAINING

On the basis of specification records, our staff will instruct you on how to use the products.

MEDICAL DEVICES – ALL FROM ONE SOURCE

All the required components for PLDD are offered. Access to the disc is via a 21G or 18G fine needle with a length of 15cm (20cm available on request). A fibre optic fixing device is offered, which prevents accidental slipping of the laser fibre inside the fine needle.

PHYSICAL EFFECTS

Main laser systems mentioned in the literature in connection with PLDD:

Nd:YAG solid-state laser with 1024nm wavelength – deep penetration depth with strong thermal effects

Ho:YAG solid-state laser with 2100nm wavelength – very shallow penetration depth with only local thermal effects

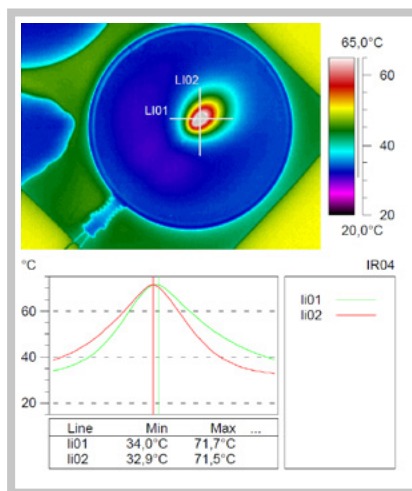
Diode laser (semiconductor laser) with 980nm wavelength as the optimal solution between penetration depth and thermal effects

MANY YEARS OF EXPERIENCE

Continuous development of the process since 1986 is demonstrated by many reports on experience and studies in the literature, with the result that modern, highly efficient diode laser systems (980nm) are being used more and more often in PLDD.

ADVANTAGES

- Minimally invasive percutaneous access from 0.8mm
- Local anaesthesia or light anal-gosedation, thus painless
- Can be performed on an outpatient basis
- No risk of scarring
- Short convalescence period with short incapacity for work
- Therapy can be repeated



Temperature distribution in the case of irradiation at 980nm

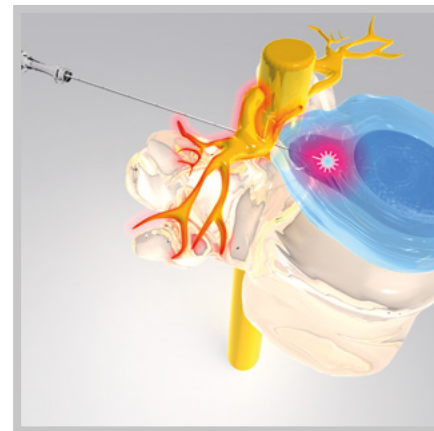
Please get in touch with us if you have any questions about the therapy or use of fine needles, laser fibres, fibre fixing adapters or the laser.

General enquiries: info@radimed.de // Orders: order@radimed.de

Percutaneous laser disc denervation / decompression

SMART^m (10W AND 980nm) DIODE LASER

The diode laser for use as part of percutaneous laser disc decompression (PLDD) on the spine



OPTIMISED

The advantages of the Nd:YAG laser, which has been described many times in the literature, are optimised with an even shallower penetration depth in the case of the diode laser.

ECONOMICAL AND PORTABLE

Thanks to the low investment requirements and low operating costs, the laser system SMART^m is a valuable addition to the existing, technical equipment. With its light weight of 2kg, it offers the user a mobile system.

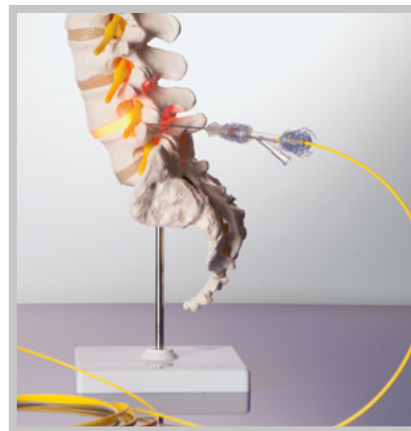
MICROLASER

The system allows use of the thinnest laser fibres with an external diameter of 0.4mm and a core diameter from 200µm.

| Technical specifications of the 10-Watt system | | | |
|--|-------------------------------------|----------------|-----------------------|
| Power | 10W at the end of the fibre | Operating mode | Pulsed or CW |
| Fibre connection | SMA 905, core diameter 200 – 1000µm | Display | Colour display |
| Fibre types | NA = 0.22 | Data input | Touch screen |
| Wavelength | 980nm | Weight | 2kg |
| Pilot laser | 650nm | Manufacturer | Lasotronix Sp. Z.O.O. |

SETS AND LASER FIBRES FOR PLDD

Your equipment for safe and flexible use:
Laser fibre, fibre optic fixing device
(PLDD adapter) and fine needle, available
singly or as a set



MICROINVASIVE

The practical set for PLDD is compatible with many current laser systems.

ADAPTABLE

For safe use, the laser fibres are cut specifically to the length of the compatible fine needles.

FIXED

In addition, with the aid of the fibre optic fixing device, the location of the laser fibre inside the fine needle can be fixed so that unwanted slipping and therefore lasering inside the fine needle are prevented. The protective hose also protects against kinks here.

The system moreover allows rotation of the fibre and the escape of potential gases.

| Laser equipment | REF | Short name | Diameter | | Length [mm] | Combinable fine needles |
|-----------------|--------------|----------------------|--|-----------------------|-------------------------------|-------------------------|
| | | | Core (Quartz glass) | Sheath (Polyimide) | Total (mm) Cut length (mm) | |
| | Laser fibres | 10016-22 | WF 360-20 DIODE 0,22 | 360 | 420 | 3000 – 200 |
| | On request: | | | | | |
| | 10017-22 | WF 360-25 DIODE 0.22 | 360 | 420 | 3000 – 250 | 18/200 – 21/200 |
| PLDD adapter | 10020 | PLDD adapter | For fibre fixing on the Radimed fine needles | | | |
| Sets | 10104-22 | PLDD set 18G | Sets for diode lasers comprising 360µm laser fibre, PLDD adapter and 18G/150mm fine needle | | | |
| | 10105-22 | PLDD set 21G | Sets for diode lasers comprising 360µm laser fibre, PLDD adapter and 21G/150mm fine needle | | | |

Quality and regulations

QUALITY MANAGEMENT AND REGULATORY AFFAIRS

The competence of Radimed GmbH is distinguished by over 25 years of experience in the area of conformity assessment of medical devices.



As a manufacturer of medical devices, Radimed GmbH uses a comprehensive quality management system for compliance with the regulatory requirements. To guarantee the product quality, the QM system is based on harmonised standard DIN EN ISO 13485.

The importance of quality management has increased further with the commencement of the European Regulation on Medical Devices (MDR).

Radimed GmbH conducts conformity assessment processes for medical devices in accordance with directive 93/42/EEC, and in future in accordance with regulation (EU) 2017/745, which are certified and monitored by a notified body. The products bear the CE mark.

QM SYSTEM

For continuous improvement and monitoring of our product quality, our QM system includes processes e.g. such as:

- Documentation
- Complaint handling
- CAPA
- Audit
- Training
- Change control

QUALITY

Safe, high-quality products are achieved through monitored production and validated/verified processes.

COMPLAINTS

If you are unhappy with the products or the service, or if problems occur, please contact us directly, so that we can improve.

TRACEABLE

All Radimed products have batch or serial numbers and can be fully traced.

IDENTIFIABLE

The UDI marking including bar code helps to identify the products quickly and easily.

MONITORED SAFELY

Even after the products are placed on the market, their constant monitoring continues with market surveillance.

As a user of our products, you can take part in our surveys and help us to obtain important information for their evaluation.

Scan the QR codes below for quick, easy access to the relevant surveys. Each questionnaire takes only approx. 2 minutes to complete.



Go to the user survey ->
FINE NEEDLES



Go to the user survey ->
THERMOLESION CANNULAS



Go to the user survey ->
LASER FIBRES FOR PLDD



Go to the user survey ->
RF ELECTRODES

www.radimed.de



Radimed GmbH

Lothringer Straße 36 b · 44805 Bochum · Germany

Phone: +49 (0)234 890029-0 · Fax: +49 (0)234 890029-9

E-Mail: info@radimed.de