Instructions for preparation

Pre-cleaning immediately after use

Note: Please place the electrode in a separate container after use to avoid contamination with/by other products. For better cleaning, keep the electrode moist after use until cleaning.

Caution! The effectiveness of cleaning depends on the removal of coarse contaminants, which must be removed from the instruments immediately after use (within a maximum of 2 hours).
Decontamination can be impaired by dried or coagulated tissue. Therefore, particular attention should be paid to removing all contaminants by following the recommended procedures.

Caution: Take care to protect yourself during reprocessing and use appropriate protective equipment! **DO NOT** use ultrasonic cleaning devices, as these can damage the product and shorten its service life!

- Rinse under running water (temperature < 35 °C/ 95 °F) until no optical impurities are visible.
- Do not use alcohol-based solutions for cleaning to prevent a protein-fixing effect.
- **Caution**: If the connector has been accidentally immersed in liquid, allow the liquid to drain completely from the connector and let the product dry for at least 30 minutes.
- Remove all visible dirt manually using a clean, soft, lint-free cloth that you use only for this purpose.
- Never use metal brushes or steel wool.
- After removing coarse dirt, clean the product, including the cable and connector, with a disposable wipe.
- Rinse again for at least 1 minute under running water.

General information on reprocessing:

Only validated RDG and sterilization equipment whose cycles have been tested for performance may be used. The user must validate the cleaning/disinfection and sterilization processes themselves, taking into account the equipment used, the packaging methods, and the products to be sterilized.
In a worst-case scenario, the electrodes were subjected to 50 reprocessing cycles using an alkaline cleaner with a pH of 10.5 (Mediclean forte, Dr. Weigert), with an exposure time of 10 minutes, followed by sterilization (134°C, 5 minutes) in the Radimed Steribox (10094-44-0001). There were no negative effects on function. The product can therefore also meet any increased requirements for reprocessing, such as those specified in Appendix 7 of the KRINKO recommendation "Requirements for hygiene in the reprocessing of medical devices." The maximum number of reprocessing cycles is not limited numerically, but is only recognizable by damage/wear to the product (see section on inspection).

Mechanical, alkaline cleaning with thermal disinfection in the RDG

The concentrations, temperatures, and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as the specifications for rinsing, must be strictly adhered to.

Note: Proof of the basic suitability of the instruments for effective machine cleaning and disinfection was provided by an independent accredited testing laboratory using the RDG G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described below was taken into account.

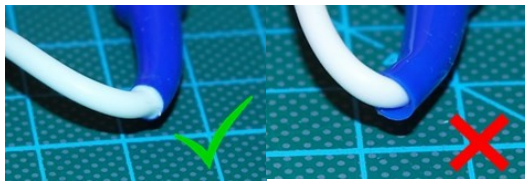
Caution: When selecting cleaning and disinfecting agents, please ensure that they do not contain the following ingredients:

- Acids (minimum permissible pH value 5.5)
- The use of rinse aids is not permitted

Cleaning/disinfection procedure in the washer-disinfector

- Before cleaning/disinfection, remove the protective cap from the electrode and place it in the RDG using a standard cleaning basket and a flexible cover (to protect the instruments from splashing). Make sure that the instruments do not touch each other.
- Cleaning agent Neodisher MediClean forte pH=10.5 (Dr. Weigert GmbH & Co. KG, Hamburg)
- Disinfection Thermal 93°C / 5 min
- Remove the instruments from the washer-disinfector after the program has ended. Check and pack the instruments as soon as possible after removal as follows:

Check:
After cleaning/disinfection, check all instruments for corrosion, damaged surfaces, chipping, contamination, and discoloration, and separate any damaged instruments. Instruments that are still contaminated must be cleaned and disinfected again.
All undercuts, marking tubes, and protective sleeves on the electrode are sealed and/or glued and must be checked for integrity after cleaning/disinfection.
1.) Firm attachment/bonding of the marking and serial number
2.) Adhesion/sealing of the anti-kink sleeves
In the event of a fault, the product must not be used any longer.



Sterilization

Notes prior to sterilization:
Ensure that the protective cap has been removed from the electrode. Before sterilization and before each use, the thermocouple electrode must be inspected for damage and corrosion. If damage or corrosion is present, the electrode must no longer be used!
Notes after sterilization:
After each sterilization and before use, connect the electrode to the generator and check that the temperature and impedance readings are within the normal range (room temperature). If the generator displays other values, the electrode must not be used and must be disposed of appropriately.

Packaging:

The Radimed N-50S/-100S/-150S nitinol electrodes can be packed directly in single-use sterilization packaging (double sterile packaging). Alternatively, the electrode can first be placed in a sterilization box and then sealed in single-use sterilization packaging (single sterile packaging).

The single-use sterilization packaging must meet the following requirements (material/process): DIN EN ISO ISO 11607 suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F) with sufficient steam permeability).
Sufficient protection of the instruments and sterilization packaging against mechanical damage must be ensured.

Sterilization procedure:

Caution:
Please ensure that the cable does not touch the metal housing of the autoclave or other metal instruments/containers, as this can reduce the service life of the product.

Note: Proof of the basic suitability of the instruments for effective steam sterilization was provided by an independent accredited testing laboratory. The following procedures were taken into account:

Sterilizers with fractionated vacuum process:

Sterilization box:	Radimed REF 10094-44-0001 (286x150x20mm) With silicone mat
Sterilization barrier:	Steriking, REF RB54-3P, 250mm x 100m
Temperature:	134° C
Minimum time:	5 minutes

Drying process and storage:

After 5 minutes of steam sterilization at 134°C. Minimum drying time: 30 minutes. After drying, please allow the electrode to cool to room temperature before reuse.
After sterilization, the instruments must be stored in the sterilization packaging in a dry and dust-free place.
Maintenance:
Instrument oils must not be used.

Connection:

This thermocouple electrode has been developed for use with RF thermolesion generators from NeuroTherm (types JK2 3,4 & 25, NT 1000, NT1100 & NT2000) and TOP (TLG-10) and can be connected directly to these generators without an intermediate cable. With an appropriate connection cable, the electrode can also be used with other RF thermolesion generators. After connection and before use, make sure that the temperature and impedance readings on the lesion generator are within the normal range (compare with room temperature).

Thermoläsion cannula:

Radimed Cable	Generator
RADIMED Cable AK-F50 / A304	Apro Korea AK-F50 or A304
RADIMED Cable S/N	Smith & Nephew Electrothermal 20S
RADIMED Cable B	Baylis (Halyard) PMG-115
RADIMED Cable R	Radionics RFG-3C /3cCplus
RADIMED Cable C	Cosman RFG1A, RFG1B, and G4
RADIMED Cable S	Stryker Multigen
RADIMED Cable OW	OWL diros URF-3AP

This thermocouple electrode has been developed for use with a Radimed thermolesion cannula for peripheral nerve denervation. There is no adjustment option for the lengths, as production tolerances in manufacturing make this unnecessary. Be sure to select the correct cannula length!

Electrode	Radimed thermal cannula	
Radimed-50S	5cm	TK/xx-50-yy
Radimed 100S	10 cm	TK/xx-100-yy
Radimed-150S	15 cm	TK/xx-150-yy

Correct positioning of the tip:

The tip of the thermocouple electrode must be visible in the grinding eye of the cannula (within the non-insulated area). This must be checked before each use. (See also the instructions for Radi-med thermolesion cannulas).

Warning:

Remove the electrode before **each** positioning, repositioning, or removal of a cannula. Otherwise, the electrode may be damaged. Radimed electrodes must **not be bent** during use or preparation. Bending will impair the normal

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Market observation:

We would like to ask you to provide us with feedback on the clinical use and performance of the product. This will help us to develop new product ideas and support our ongoing improvement measures. Simply scan the QR code opposite with your mobile phone. Thank you!

Handling:

It should be noted that due to varying biological tissue properties, no product can deliver the same effective and reproducible results under all possible conditions.
tissue properties, no product can deliver the same effective and reproducible results under all possible conditions.
Radimed has no influence whatsoever on the handling, diagnosis, application, and use of the product on the patient by the physician. Radimed therefore cannot guarantee complication-free and successful therapy.

Radimed accepts no responsibility for injuries resulting from the use of the product and any associated costs. Radimed will replace products if the defect in the product is attributable to Radimed.

Radimed recommends that the electrodes be handled with care and caution and that the instructions for use of all components be read and understood carefully to ensure the longest possible service life of the product. Careful handling is a basic requirement for a long service life of the electrode. The service life of the product is subject to influences beyond Radimed's control. Improper handling can seriously impair or destroy the normal characteristics and technical factors of the electrode.
Pulling on the cable or wiping the cable with the plug or application part attached can cause the cable to break internally and cause irreparable damage. When wiping, it is essential to avoid tension between the cable and the plug.

If you have any questions about use, reprocessing, or training, please contact us directly.

The product is latex-free.

Operating instructions for RF thermocouple electrode FLEX

Thermocouple electrode for peripheral RF denervation for the

Radimed-N50S
Radimed-N100S
Radimed-N150S

Connection to RF generators with temperature-controlled power control, in combination with RADIMED connection cables

Warning notices

The product must be cleaned, disinfected, and sterilized before use!

Use only by doctors.

Before use, the RF generator, neutral electrode and the Radimed thermolesion cannulas must be read and understood. must be read and understood before use.

Attach the patient leads and connectors so that

Avoid contact with the patient or other cables. Active electrodes that are temporarily not in use should be stored in a place that is isolated from the patient.

Not approved for use in MRI

Not suitable for use on the central nervous system—brain, meninges, spinal cord—(Def.gem.VO(EU)2017/745)

All serious incidents related to this product must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is located

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Intended use

Reusable medical devices for temperature-controlled denervation or stimulation of peripheral nerves by delivering
high-frequency energy through an RF cannula into the target region

Indication

Indicated for conditions that require temperature-controlled denervation or stimulation of peripheral nerves for pain management

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Contraindications

RF denervation is not a good idea for people with pacemakers, implantable defibrillators, neurostimulators, or other active implants. If this is you, check with the doctor who's doing the implant.
physician responsible for the implantation.

Patient group

Due to its use in the field of pain therapy caused by degenerative structural changes, the patient group consists of older
adults.