Instructions for preparation

Pre-cleaning directly after application

Note: Please collect the electrode in a separate container after use to avoid contamination with other products.

For better cleaning, keep the electrode moist after use until cleaning.

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

Caution: Pay attention to personal protection 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 the probe under running water (temperature < 35 °C/ 95 °F) until no more optical impurities are visible.
- Do not use solutions containing alcohol for cleaning to prevent a protein-fixing effect.
- **Caution**: If the connector has been accidentally immersed in liquid, allow the liquid to run out of the connector completely and allow the product to dry for at least 30 minutes.
- Remove all visible dirt manually using a clean, soft and lint-free cloth that you only use for this purpose.
- Never use metal brushes or steel wool.
- After removing the 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 preparation:

Only validated washer-disinfectors and sterilisation units whose cycles have been tested for their performance may be used.
The user must validate the cleaning/disinfection and sterilisation processes himself, taking into account the devices he uses, the packaging methods and the products to be sterilised.

As part of a worst-case scenario, the electrodes were subjected to 50 reprocessing cycles using an alkaline cleaner at pH=10.5 (Mediclean forte, Dr. Weigert), exposure time 10 minutes and subsequent sterilisation (134°C, 5 minutes). There were no negative influences on the function. This means that the product can also fulfil any increased reprocessing requirements that may be necessary, e.g. in accordance with Annex 7 of the KRIN KO recommendation "Hygiene requirements for the reprocessing of medical devices".

Automated, alkaline cleaning with thermal disinfection in the washer-disinfector

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 automated cleaning and disinfection was provided by an independent accredited test laboratory using the washer-disinfector 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 agents and disinfectants, please ensure that they do not contain the following ingredients:

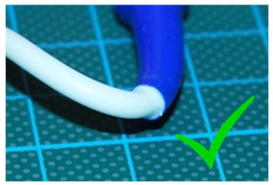
- Acids (minimum permissible pH value 5.5)
- The use of rinse aids is not permitted

Cleaning/disinfection process in the washer-disinfector

- Before cleaning/disinfecting, remove the protective cap from the electrode and place it in the washer-disinfector using a standard cleaning basket and a flexible cover (to protect the instruments from being whirled up). 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 / 5min
- Remove the instruments from the washer-disinfector at the end of the programme. Check and pack the instruments as soon as possible after removal as follows:

Control:

After cleaning/disinfection, check all instruments for corrosion, damaged surfaces, chipping, soiling and discolouration and discard damaged instruments. Instruments that are still dirty must be cleaned and disinfected again.
All undercuts, labelling tubes and protective sleeves on the electrode are cast and/or glued and must be checked for intactness after cleaning/disinfection.
1.) Fixed position/adhesion of the labelling and serial number
2.) Bonding the anti-kink sleeves



Sterilisation

Instructions before sterilisation:
Make sure that the protective cap is removed from the electrode. Before sterilisation 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!
Instructions after sterilisation:
After each sterilisation and before use, connect the electrode to the generator and check that the temperature and impedance display are within the normal range (35- 38°C body temperature). If the generator indicates 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 packaged directly in single-use sterilisation packaging (double packaging).

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

Sterilisation procedure:

Attention:
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 sterilisation was provided by an independent accredited test laboratory. The following procedures were taken into account:

Sterilisers with fractionated vacuum processes:
Temperature: 134° C
Minimum time: 5 minutes

Sterilisers with gravitational displacement process:
Temperature: 134° C
Minimum time: 15 minutes

Drying process and storage:
After 5 min or 15 min steam sterilisation at 134°C. Minimum drying time: 30 min. After drying, please allow the electrode to cool down to room temperature before reuse.
After sterilisation, the instruments must be stored dry and dust-free in the sterilisation packaging.

Connection:

This thermocouple electrode has been developed for use with the RF thermolesion generators from NeuroTherm (type JK2 3.4 & 25, NT 1000, NT1100 & NT2000) and TOP (TLG-10) and can be connected directly to this generator 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 displays on the lesion generator are within the normal range (comparison with room temperature).

Thermolesion cannula:

Radimed cable	Generator
RADIMED Cable AK-F50	Korea CoATherm AK-F50RADIMED
Cable S/N	Smith & Nephew Electrothermal 20S
RADIMED Cable B	Baylis (Halyard) PMG-115
RADIMED Cable	RRadionics RFG-3C /3cCplus
RADIMED Cable	CCosman RFG1A, RFG1B and G4
RADIMED Cable	SStryker Multigen
RADIMED Cable	OWOWL diros URF-3AP

This thermocouple electrode has been developed for use with a Radimed thermolesion cannula for facet denervation. It is not possible to adjust the lengths, as the production tolerances during manufacture make this unnecessary. Make sure you select the correct cannula length!

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

Correct positioning of the tip:

The tip of the thermocouple electrode must be visible in the contact tip of the cannula (within the non-insulated area). This must be checked before each application. (See also the instructions for the Radimed 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 reprocessing. Bending will seriously impair the normal properties and technical factors of the electrode.

RADIMED GmbH
Lothringer Straße 36b DE-
44805 Bochum

Phone: +49 234 89 00 29 0
Fax: +49 234 89 00 29 9
E-mail: info@radimed.de

Market observation:

We would like to ask you to give us feedback on the clinical use and performance of the product. On the one hand, to enable us to develop new product ideas and, on the other, to support us in our continuous improvement measures.

Handling:

It should be taken into account that due to different biological 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 doctor.

Radimed cannot guarantee a complication-free and successful therapy.

Radimed accepts no responsibility for injuries resulting from use and any associated costs. Radimed will replace products if the defect in the product was caused by Radimed.

No employee of Radimed shall be deemed authorised to change the aforementioned conditions, to extend liability, or to accept or agree to additional product-related obligations.

Radimed recommends handling the electrodes carefully and cautiously and to read and understand the instructions for use of all components carefully in order to ensure the longest possible service life of the product. Careful handling is a basic prerequisite for a long service life of the electrode. The service life of the product is subject to influences beyond the control of Radimed. Poor handling can seriously impair or destroy the standard features and technical factors of the electrode.

The product is latex-free.

CE 0044

Operating instructions for RF thermocouple electrode FLEX

For use with RADIMED connection cables

REF

Radimed-N50S

Radimed-N100S

Radimed-N150S

Attention

Use only by trained and experienced personnel.

Warnings

Product must be cleaned, disinfected and sterilised before use!

Please follow the cleaning/disinfection and sterilisation instructions.

Before use, the operating instructions enclosed with the generator, the neutral electrode and the Radimed thermolesion cannulas must be read and understood.

instructions have been read and understood.

The patient cables and plug connections should be positioned so that contact with the patient or other cables is prevented.
is avoided. Temporarily unused active electrodes should be stored in a place that is isolated from the patient.

Used in combination with Radimed thermolesion cannulas for therapy of the facet joints and pulsed RF stimulation.

NOT suitable for use on the central nervous system (Def. acc. to 93/42/EEC)

REF	Catalogue number
SN	Follow the instructions for use
	Observe instructions for use
	Observe the warning notice
	Storage temperature
	Manufacturer
YYY-MM-DD	Date of manufacture
	Quantity
NON STERILE	Not sterile