

Market surveillance

We would like to ask you to give us feedback on the clinical use and performance of the product. On the one hand, to take account of the constantly increasing requirements of medical device legislation, but also to enable us to develop new product ideas and to support us in our continuous improvement measures.

Using the QR code below will take you to a questionnaire regarding the use of the product.

The questions relate exclusively to the RF electrode to be combined. If you have any comments on the adapter cables, you can add them at the end of the short survey.

Thank you for your co-operation.

You can select the language at the beginning of the questionnaire.



For further questions or if user training is desired, please contact Radimed GmbH.





Type A

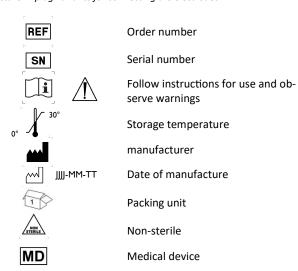
For connection or reusable thermoelement electrodes



Type B

For connection of sterile thermoelement electrodes for single use

Picture 1: plug variants for connecting the electrodes





Intermediate Cable

For use with RADIMED RF-Thermoelement-Electrodes

and Thermolesion generators according to the compatibility table

Instruction for Use

Attention

Application only by trained and skilled personnel.

Warnings

Before use, the operating instructions accompanying the generator, the thermocouple electrodes and the thermolesion cannulae must be read and understood.





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Intended purpose

For connecting Radimed RF thermocouple electrodes to thermolesion generators (according to compatibility table).

<u>Indications / contraindications / patient target group(s)</u>

As an accessory, the product has no medical indication or patient target group of its own (see instructions for use of the thermocouple electrode, if applicable).

Intended users:

appropriately trained professionals

Warnings

DO NOT STERILIZE.

DO NOT USE IF UNUSUAL READINGS ARE DISPLAYED ON THE GE-NERATOR.

DO NOT USE IF SIGNS OF DAMAGE OR CORROSION ARE PRESENT. No validation regarding sterilization has been performed for this intermediate cable, as it is used as a non-sterile product outside the sterile area.

Connecting / checking the cable

Connect the smaller plug (type A, or type B, according to Figure 1) of the cable to the Radimed thermocouple electrode. Connect the large device plug to the thermolesion generator.

After connection and before each use, make sure that the temperature and impedance readings on the generator are in the normal range.

Caution

Disconnect the generator by holding the plug and do not pull on the cable.

Handling

Radimed recommends careful and cautious handling of the cable as well as unconditional compliance with these instructions for use in order to achieve the longest possible service life. The life of the cable is significantly influenced by careful handling. Radimed does not limit the number of uses a cable can achieve. The service life of the cable depends on many factors that are beyond Radimed's control.

Storage

The cable should be stored in a cool, dry place; extreme temperatures should be avoided.

PRECAUTIONS

The product is not validated for ETO or steam sterilization because it is not used in a sterile environment.

If the cable needs to undergo cleaning, the cable can be handled according to the following instructions:

This does not represent reprocessing instructions according to KRINKO/ BfArM for the cable, as it does not need to be reprocessed.

Manual cleaning (if necessary)

Note: Avoid allowing dirt to dry after use to facilitate cleaning. Caution: The user should wear appropriate protective clothing when cleaning.

- Rinse the product under running tap water (30-40°C) to remove 1) visible soiling.
- Prepare an enzymatic cleaner such as Prolystica 2X according to the manufacturer's instructions. Immerse the cable in blood dissolving enzymatic solution. Be careful not to immerse the connector as this may damage it. Allow the cable to soak for at least 30 minutes.

CAUTION:

1)If the plug has been accidentally immersed in liquid, allow the liquid to drain completely from the plug by inverting it and allow the product to dry upside down for at least 30 min before use.

- 3) Thoroughly remove coarse contaminants by wiping with a soft, lint-free cloth using water or blood-dissolving enzymatic solution until the product is visually clean. After removing the coarse contaminants, clean the product with a disposable wipe using blood-dissolving enzymatic solution.
- Rinse the product with lukewarm, filtered water (RO water / deionized water) until no residue of the cleaning liquids is visible. Dry the cable with a lint-free cloth. Filtered compressed air can be used if necessary (<40psi).
- 5) Finally, visually inspect the product and, if necessary, repeat the points described above until the product is visually completely clean.

Use of ultrasonic cleaners

PLEASE DO NOT USE ULTRASONIC CLEANERS. THESE CAN CAUSE DAMAGE TO THE PRODUCT AND REDUCE THE SERVICE LIFE OF THE PRODUCT.

| Compatibility table | | | |
|-------------------------|----------------|---|---|
| REF | Shortname | RF Generator | Туре А |
| 10094-12- 10pin-kurz | Cable ST-10 | Neuro N50 (new Version) | |
| 10094-12- 12pin-kurz | Cable ST-12 | Neuro N50 (old Version) | |
| 10094-14-1 | Cable S/N | Smith&Nephew Electrothermal 20S | |
| 10094-14-2 | Cable C | Cosman RFG1A & 1BG4 | For Reus |
| 10094-14-4 | Cable AK-F50 | Apro Korea AK-F50 | conn |
| 10094-14-5 | Cable RA | Radionics RFG 3C | For connection of Reusable electrodes |
| 10094-14-6 | Cable M | Stryker MultiGen LG | n of odes |
| 10094-14-7 | Cable AK-A304 | Apro Korea AK-A304 | |
| 10094-14-8 | Cable B4 | Baylis PMG-115—4 PIN | |
| 10094-14-9 | Cable B | Baylis PMG-115—14 PIN | |
| 10094-14-10 | Cable OW | OWL (Diros) URF-3AP | |
| REF | Shortname | RF Generator | Туре В |
| 10094-25-1 | Cable ST-10D | Neuro N50 (new Version) | |
| 10094-26-1 | Cable ST-12D | Neuro N50 (old Version) | |
| 10094-27-1 | Cable S/N D | Smith&Nephew Electrothermal 20S | 6 |
| 10094-27-2 | Cable B-D | Baylis PMG-115 (14-Pin) | teril |
| 10094-27-20 | Cable B-D4 | Baylis PMG-115 (4-Pin) | For co |
| 10094-27-6 | Cable C-D | Cosman RFG1A & 1BG4 | For connection of Sterile, single-use electrod |
| 10094-27-5 | Cable R-D | Radionics RFG 3C | |
| 10094-27-8 | Cable OW-D | OWL (Diros) URF-3AP | ı of ectro |
| 10094-27-3 | Cable N-D | Neurotherm JK2,3,4&25; NT1000, NT1100; NT2000; NT2000ix | des |
| 10094-27-7 | Cable M-D | Stryker MultiGen I | |
| 10094-27-4 | Cable AK-F50D | Apro Korea AK-F50 | |
| 10094-27-9 | Cable AK-A304D | Apro Korea AK-A304 | |
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