Radimed Gesellschaft für Kommunikationsdienstleistungen und Medizintechnik mbH
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Thermolesion cannula - Instructions For Use

General notes for attention

The included instructions for use must be carefully observed when using the thermolesion cannula. Safety instructions for the use of the associated RF generator (thermolesion device) and the electrodes can be found in the corresponding instructions for use. The instructions for use of the RF thermolesion generator and the electrodes must have been read and understood in full.
Check that the sterile packaging is intact. Cannulas from damaged packaging must not be used.

Intended purpose

The thermolesion cannulas have electrical insulation of the cannula tube with a non-insulated area at the distal end and are intended for denervation/stimulation **of peripheral nerves** in the context of pain therapy.
They are suitable for use with Radimed RF thermoelectrodes and an RF thermolesion generator for pain therapy.

In addition, the cannulas are also suitable for introducing drugs commonly used in pain therapy into the body as part of pain management.

Warnings

Please note that thermolesion cannulas may only be used if their compatibility with the respective RF generator and the associated thermoelectrode has been checked.

The following table shows an example of the combination between Radimed thermolesion cannulas, Radimed electrodes and settings on the Neuro N-50 generator (please also refer to the operating instructions of the thermolesion generator for electrode settings!)

Radimed Cannula [REF]	Tip mm	Radimed Electrode (length)	Setting Neuro N50
10090	*4*	Radimed-50 x-x	TCU 405-4
10091-10	*10*	Radimed-100 x-x	TCU **410-10**
10091-10-G	*10*	Radimed-100 x-x	TCU **410-10**
10092	5	Radimed-150 x-x	TCU **415-5**

For generators other than the N50, proceed according to the instructions for use of the generator for correct cannula/electrode selection.

Preparations for the medical use of the system

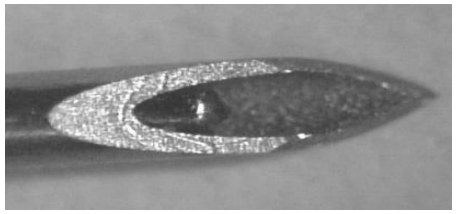
The cannulas are carefully packed. They are shipped in sterile condition in packaging in which they are protected from transport damage. The storage time with unopened storage packaging is indicated on the labelling.
Please check the integrity of the packaging and also use it for safe storage of the cannulas. The cannulas must be stored in the complete sterile packaging and the storage packaging until they are prepared for medical use. Please also observe the sterile goods regulation DIN 58953 Part 8.

Initial operation of the RF generator

Connect a thermoelectrode matching the cannula to the RF generator and start up the lesion generator as described in the corresponding operating manual.

Warnings

The length of the thermoelectrode used must match the length of the cannula! (Color match of cannula hub with electrode - see table on following page).
Electrodes that are too short can cause injury to the patient, as the temperature is then not measured at the point where the RF energy is conducted into the patient's body!
The following figure shows the correct position of a thermoelectrode inside the cannula.



The tip of the correctly placed electrode must be visible in the ground section of the cannula.
The thermoelectrode may only be inserted when the cannula is correctly positioned. The first insertion of the cannula may only be carried out with the stylet and not with the electrode in place or without the stylet (risk of punch infections).
Potential misplacement of the cannula in vivo should be verified by appropriate motoric stimulation as indicated by the RF lesion generator.

Note

If the impedance is too high, it is recommended to inject a small amount of 0.9% NaCl solution to increase the conductivity of the surrounding tissue.
For a positive result of the therapy, the correct position of the cannula tip must be verified by means of sensory stimulation according to the specifications of the RF lesion generator. Here, the pain known to the patient must be provoked at the lowest possible stimulation voltage.

Furthermore, ensure that the free tip of the cannula (TIP) is as parallel as possible to the structure to be denervated.

It should be noted that the ends of the nerve interrupted by the therapy may be recovered, so that a repetition of the therapy may be necessary.
This effect is more likely the shorter the denervated distance (caused, for example, by perpendicular rather than parallel cannula placement).

Other

Radimed GmbH accepts no responsibility for personal injury or damage to equipment resulting from improper handling or storage of the products. Radimed GmbH cannot be held liable for incidental or consequential damages, losses and costs directly or indirectly related to the use of this product. No warranty can be accepted for damage caused by incorrect storage or use.

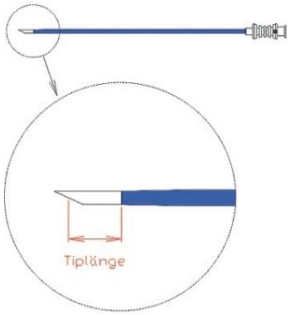
Thermal lesion cannulas may only be used by appropriately trained physicians!

Mode of action

Thermolesion cannulas are used to transfer the energy generated by an RF generator into the human body. For this purpose, they are completely insulated except for an "active" tip at the distal end of the cannula. The energy is transmitted into the body at this non-insulated site, causing heating of the tissue and thereby coagulation of the target region. Heating occurs via direct tissue heating by RF energy and not by heating of the tissue by the cannula itself. Target regions are peripheral nerve structures that are to be denervated to interrupt pain conduction as part of pain therapy.
The RF generator can then regulate the power through the tissue temperature at the cannula tip, which is transmitted by the electrode, so that a previously set target temperature at the tissue is not exceeded.
The lesion size results primarily from the cannula geometry (thickness and free TIP).

Construction of the cannulas

The electrically insulated cannulas have been developed for applications with various RF generators and are available in different versions (diameter, length, free TIP - without insulation).
The tip length of Radimed cannulas is measured from the center of the ground joint to the insulation transition.



Reuse

The cannulas are supplied sterile and are intended for single patient use only.
Proper function is guaranteed only for single use.
Tissue adhesion after coagulation can lead to temperature measurement errors and thus to incorrect functioning of the overall system.

Reprocessing the cannulas can damage the insulation layer and thus lead to serious injuries to the patient in the course of use!

Thermal processes in particular destroy the plastic cannula hub, which is necessary for proper and safe positioning of the thermoelectrode!

Disposal

Disposal after use via discard container for medical cannulas.

Warning

The thermolesion cannula are NOT intended for use on the central nervous system (def. according to 93/42/EEC, or VO(EU)2017/745: "brain, meninges and spinal cord").

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Symbols used (according to DIN EN 15223-1)

- Do not re-use
- Use-by date
- LOT — Batch number
- REF — Part number / Order number
- STERILE EO — Sterilized with ethylene oxide
- Single sterile barrier system
- Non pyrogenic
- Manufacturer
- Date of manufacture
- Consult instructons for use
- Indication of the storage conditions: store in indicated temperature range
- Store away from direct sunlight
- Store dry
- Do not use if packaging is damaged
- MD — Medical device

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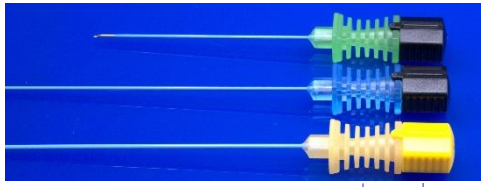
Please contact Radimed GmbH if you have any questions or if user training is required.

Note on color coding

The color coding listed below describes the relationship between the color of the cannula hub and stylet cap and the dimensions of the cannula.

The color of the cannula hub codes the length of the cannula: **green = 50 mm, blue =100 mm, yellow =150 mm** - analogously, the electrodes are marked accordingly.
The color of the stylet cap always codes the diameter, **black=22G, yellow=20G, pink=18G, white = 16G** (according to DIN EN ISO 6009).



Thermolesion cannulas	Variants	REF	Short name	Length	TIP	Diameter	
				Approx.[mm]	[mm]	Gauge	Approx.[mm]
	straight, siliconized	**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, non siliconized	**11095-10**	**TK/18-100-10**	**100**	**10**	**18**	**1,25**
		11093-10	**TK/16-100-10**	**100**	**10**	16	1,6
	distally curved, non siliconized	**10091-10-G**	**TK/20-100-10-G**	**100**	**10**	**20**	**0,9**

Feedback on the Application

Dear Customer,
Please help us to fulfill **our legal obligations to monitor the market** and fill out a short questionnaire about our thermolesion cannulas (approx. 3min.) as a user. Please note that the questionnaire is only available in German.
The information is, of course, provided anonymously.

Simply scan the adjacent link (QR code). You can easily answer the questions via your cell phone.

Thank you very much.