

NIMBUS[®] PROBE

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POST MARKET SURVEILLANCE

Stratus Medical encourage feedback and intelligence from the clinical performance of their products to enable them to create new innovative ideas and assist with continual product improvement.

Warranty /Guarantee

This Stratus Medical RF Thermocouple Electrode is warranted for three months from the date of supply if it has been diligently and carefully handled.

It shall be observed that, due to the biological differences of the persons to be treated, no product is always absolutely effective under all environmental conditions and circumstances.

Stratus Medical has no influence on the application of the product on the diagnosis of the patient and on the handling of the product, outside of the Company. Stratus Medical can neither guarantee a beneficial or a complication-free application of the product.

Stratus Medical therefore assumes no liability for damages or costs. Stratus Medical will replace products showing a deficiency which is to be represented by Stratus Medical.

Symbols

These symbols can be found on the product label.



Catalogue number



Serial number



Consult instructions for use



Caution consult instructions for use



Temperature limitation



Manufacture

yyyy-mm



Date of manufacture



For or by order of a Physician



Quantity



Non Sterile

CE
2797

Designed and manufactured by:-

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NITINOL
RF THERMOCOUPLE ELECTRODE

REF

NRP-50-27-N
NRP-100-27-N
NRP-150-27-N

Instructions for use

WARNING
"NON-STERILE"

Caution
Federal (USA) law restricts this device to sale by or on the order of a physician.

www.stratusmedical.com

Indications for use

Stratus Medical RF Thermocouple Electrodes are intended for use in the lesioning of peripheral nerve tissue.

Warnings

DO NOT USE IN THE CENTRAL NERVOUS SYSTEM.

Must be manually cleaned and sterilized before first and every use.

It is important that the instructions for use, supplied with the Generator, be read and understood before each use.

Connections

This Thermocouple Electrode is designed for use with a RF Lesion Generator.

After connecting and before each use ensure that there is a temperature reading between 35°C and 38°C (body temperature) on the Lesion Generator temperature indicator.

Disposable Cannula

This Thermocouple Electrode has been designed to be used with a RF disposable cannula.

Ensure that the correct length of disposable cannula is used.

Thermocouple Electrode tip position

The tip of the Thermocouple Electrode, when in the cannula, should be visible to the eye within the non-insulated tip of the cannula. This should always be checked with each cannula prior to use.

Warning

ALWAYS remove the electrode before positioning, repositioning or removing a cannula. Failure to comply may cause damage to the electrode.

Handling

Stratus Medical recommends to handle the Electrode diligently and carefully as well as the unconditional observance of these instructions for use in order to achieve greatest possible serviceable life.

The serviceable life is influenced to a considerable degree by the careful handling. Poor handling may seriously affect the normal characteristics and technical factors of the electrode.

Stratus Medical do not place any limit on the number of times the Electrode can be used or autoclaved.

The lifetime of the Electrode is subject to many factors which are outside the control of Stratus Medical.

Manual Cleaning Procedure (Before sterilization)

Note : Keep the Electrode moist after use to facilitate cleaning.

Caution : The effectiveness of the subsequent cleaning process depends in the removal of gross soil. decontamination may be impaired by dried or coagulated tissue. Therefore, particular attention should be paid to removing all debris by following the recommended procedure.

Caution : Operatives should wear appropriate levels of protective clothing.

- 1) Remove the protection tube then rinse the Thermocouple Electrode with running tap water at 30-40°C (86-104°F) to remove visible soil until visibly clean.
- 2) Prepare an enzymatic cleaner such as Prolystica 2 x concentrate enzymatic per manufacturers recommendations.

Immerse the Thermocouple Electrode in the blood-dissolving enzymatic solution, taking care not to immerse the connector end as damage to the product may occur.

Caution : Allow them to soak for a minimum of 30 minutes. If the connector is inadvertently immersed allow the solution to drain out of the connector by inverting it for a minimum of 30 minutes prior to sterilization.

- 3) Thoroughly clean, rinse and remove gross matter, i.e blood, mucous, tissue from the product until visually clean, using a disposable, clean soft non-linting cloth moistened with prepared blood dissolving enzymatic cleaning solution and a sterile brush with rigid nylon bristles and / or a sterile syringe. Thoroughly pay particular attention to areas, like crevices, lumens and other hard to reach places where soil may be shielded. Use a sterile pipe-cleaner to thoroughly brush all crevices and lumen.
- 4) Using a disposable clean soft non-linting cloth, moistened with prepared blood dissolving enzymatic cleaning solution, wipe the cable and connector thoroughly until the device is visually clean paying particular attention to areas, like crevices, lumens and other hard to reach places where soil may be shielded.
- 5) Using ambient temperature filtered RO / DI water, rinse the product until there are no visible signs of the cleaning solution remaining. Dry the Devices with a clean soft non-linting cloth. Filtered pressurised air may be used to aid drying (<40 psi).
- 6) Visually inspect the product for any remaining soil and repeat the above steps if necessary.

Use of ultrasonic cleaners

DO NOT USE ULTRASONIC CLEANERS AS DAMAGE TO THE PRODUCT MAY OCCUR AND REDUCE THE USEFUL LIFE OF THE PRODUCT.

Sterilization

Caution (Before sterilization)

Before sterilization, remove and dispose of any protection tube and inspect the Thermocouple Electrode, Cable and Connector for any signs of damage or corrosion.

Do not use if any damage or corrosion is observed.

Caution (After sterilization)

After sterilisation and before each use, plug the Thermocouple Electrode into the Lesion Generator and ensure the readings of temperature are between 35°C and 38°C (body temperature) and valid impedance range based on generator model. Do not use if any of the readings are not within the specified ranges. If the generator does not display a correct body temperature or impedance reading, discontinue use of the RF electrode and dispose of appropriately.

Steam Sterilization (Moist heat) Procedure

Caution : Ensure that the cable does not contact the metal housing of the Autoclave, or other metal instruments during the cycle, as this may reduce the effective life of the product.

Note : The following steam sterilization Autoclave cycles have been validated for the sterilization of NiTiNi Re-usable RF Thermocouple Electrodes.

Wrapped (Porous load)

Kingauro 600 (1-ply polypropylene) wrap to be used or a similar FDA cleared wrap/pouch.

Pre-vacuum Air removal sterilizer.

Temperature : 132°C (270°F)

Exposure time : 4 minutes

Gravity displacement sterilizer.

Temperature : 132°C (270°F)

Exposure time : 15 minutes

Drying Procedure

Following 132°C (270°F) steam sterilization cycle for 4 minutes or 15 minutes. Minimum drying time 30 minutes.

After drying allow the Electrode to cool down to room temperature before renewed use.

General Notes :

It is advised that sterilization equipment should have validation certification and performance qualification test undertaken of their process cycles for effective processing. Healthcare facilities should validate the process they use employing the actual equipment, wrapping methods and operators that routinely process these products.

Products are free of Latex.

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