NIMBUS® PROBE

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.

REF	Catalogue number
SN	Serial number
	Consult instructions for use
	Caution consult instructions for use
	Temperature limitation
	Manufacture
yyyy-mm	Date of manufacture
	Quantity
NON STERILE	Non Sterile
UDI	Unique device Identifier
MD	Medical Device
Rx only	For or by order of a Physician

NIMBUS® PROBE

CE
2797

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NIMBUS® PROBE

NITINOL RF THERMOCOUPLE ELECTRODE

For direct connection to Neurotherm and Top RF Lesion Generators and for use with Radionics, Baylis (Halyard), Cosman, Stryker, Owl Diros, Smith & Nephew and Apro Korea RF Lesion Generators with a Stratus Medical Intermediate (Adapter) Cable.

REF

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

Instructions for use

Indications for use
Minta® RF Thermocouple Electrodes are intended for use in the lesioning of peripheral nerve tissue only.

Contraindication
NOT FOR USE IN THE CENTRAL NERVOUS SYSTEM

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Warnings
Must be cleaned and sterilised before each 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 Neurotherm RF Lesion Generator and connects directly to the socket on the Lesion Generator without an intermediate cable. It is also designed for use with other RF Lesion Generators with an intermediate cable.

After connecting and before each use ensure that there is a correct body temperature reading between 35°C and 38°C 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 within the non-insulated tip of the cannula.
This should always be checked with each cannula prior to use.
If the tip cannot be seen directly by eye then carefully introduce the cannula's stylet into the bevelled end of the cannula until it contacts the electrode and note the distance when the stylet is withdrawn.

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. 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. Poor handling may seriously affect the normal characteristics and technical factors of the Electrode.

Manual Cleaning Procedure (Before sterilisation)
Note : Keep the Electrode moist after use to facilitate cleaning.
Caution : The effectiveness of the subsequent cleaning process depends on 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.
Allow them to soak for a minimum of 30 minutes.

Caution :
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 sterilisation.

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.

Sterilisation
Caution (Before sterilisation)
Before sterilisation, 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.
Do not sterilise the protection tube.

Caution (After sterilisation)
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 Sterilisation (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 : Minta Medical has validated the following steam sterilisation Autoclave cycles for the sterilisation of Minta® Nitinol Re-usable RF Thermocouple Electrodes.

Wrapped (Porous load)
Kimguard 600 (1 ply polypropylene) wrap to be used or a similar CE cleared wrap / pouch.

Pre-vacuum Air removal steriliser.
Temperature : 134°C (274°F)
Exposure time : 4 minutes

Gravity displacement steriliser.
Temperature : 134°C (274°F)
Exposure time : 15 minutes

Drying Procedure
Following 134°C (274°F) steam sterilisation 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 sterilisation 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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