



POST MARKET SURVEILLANCE

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

Warranty / Guarantee

Stratus Medical Disposable RF Thermocouple Electrode is warranted for single use only, up to the use-by date shown on the sterile pack, 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.



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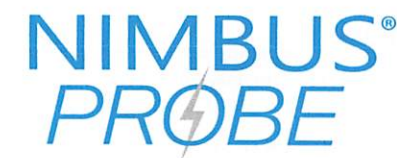
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DISPOSABLE RF THERMOCOUPLE ELECTRODE

REF

NDP-50-27-SS

NDP-100-27-SS

NDP-150-27-SS

Instructions for use

Caution

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

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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.

Inspect all packs before use and if packaging is damaged

It is important that the Operating Instructions, supplied with the Generator, be read and understood before use.

Warning

Stratus Medical RF Electrodes **MUST NOT BE BENT** when in use.

Bending will seriously affect the normal characteristics and technical factors of the Electrodes.

Connections

This Thermocouple Electrode is designed for use with an Adapter Cable and 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.

Handling

Stratus Medical recommends to handle the Electrode diligently and carefully as well as the unconditional observance of these instructions for use.

Warning

THIS STRATUS MEDICAL RF THERMOCOUPLE ELECTRODE IS FOR SINGLE USE ONLY

DO NOT RE-USE, DO NOT RE-STERILISE.

RE-STERILIZATION WILL SERIOUSLY AFFECT THE NORMAL CHARACTERISTICS AND TECHNICAL FACTORS.

THE CONNECTOR WILL NOT STAND MULTIPLE USE.

Products are free of Latex.

Symbols

These Symbols can be found on the product Label.



Catalogue number



Consult instructions for use



Caution consult instructions for use



Temperature limitation



Manufacturer

yyyy-mm-dd



Date of manufacture



Batch Code / Lot Number



Sterilized using Ethylene Oxide

yyyy-mm-dd



Use by



Do not reuse



Do not use if package is damaged



Unique device Identifier



Medical Device



For or by order of a Physician

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