

NIMBUS[®] PROBE

Warranty /Guarantee

This Stratus (Nimbus) RF Adapter Cable is warranted for three months from the date of purchase, under the condition of diligence and careful handling.

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 cannot 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 represented by initial defect at the time of purchase.

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



Date of manufacture

yyyy-mm



Packaging unit



Non Sterile



Unique device Identifier



Medical Device



For or by order of a Physician

NIMBUS[®] PROBE



Designed and manufactured by:-

Minta Medical Limited

Caddick Road,
Knowsley Business Park,
Knowsley, Prescot,
Merseyside, UK,
L34 9HP

Tel : +44 (0) 151 548 6818

Fax : +44 (0) 151 548 5578

www.mintamedical.co.uk

Distributed by:

Stratus Medical, LLC

32303 FM 2978

Magnolia, TX 77354

USA

www.stratusmedical.com



Radimed GmbH

Lothringer Str. 36b,

DE-44805 Bochum,

Germany

+49 234 89 00 29-1

www.stratusmedical.com

©Minta Medical Limited (Stratus) RPC-B4 Iss. 11 Pub. 19.07.2021

NIMBUS[®] PROBE

RF ADAPTER CABLE

REF

RPC-B4

Instructions for use

Warnings

"NON-STERILE"

This cable is not validated for ETO or steam sterilization because it operates well outside of the sterile field.

See cleaning instructions.

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

Caution

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

www.stratusmedical.com

General Description

This Stratus (Nimbus) Adapter Cable is a NON-STERILE, reusable cable to connect the Stratus (Nimbus) RF Thermocouple Electrode to one of the inputs of the Baylis Multi-RF Adapter Cable and then into the Baylis® RF Lesion Generator (V3 Series).

Indications for use

Stratus (Nimbus) RF Adapter Cables are intended for connecting Stratus (Nimbus) RF Thermocouple Electrodes to various RF Lesion Generators.

Contraindications

None

Warnings

DO NOT STERILISE.

DO NOT USE IF THERE ARE ANY ABNORMAL READINGS.
DO NOT USE IF THERE ARE ANY SIGNS OF DAMAGE OR CORROSION.

The Operating Instructions, supplied with the Generator, must be read and understood before use.

SUGGESTED INSTRUCTIONS FOR USE :

Stratus (Nimbus) RF Adapter Cable : Connect the silver metal female end of this Adapter to Stratus (Nimbus) RF Thermocouple Electrode, align the red dots on the connector bodies and push the connectors together until they "click". Connect the 4 pin plug at the other end into one of the inputs of the Baylis Multi-RF, 4 Probe Adapter Cable and then plug the 19 way Multi-RF Cable connector into the Baylis RF Lesion Generator (V3 Series).

After connection and before each use ensure that the readings of temperature and impedance on the Generator are within the normal range.

Caution

Disconnect from the Generator holding the Connector.
Do not pull on the Cable to disconnect.

Handling

Stratus Medical recommends to handle the Adapter Cable 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 Adapter Cable can be used. The lifetime of the Adapter Cable is subject to many factors which are outside the control of Stratus Medical.

Storage

The Adapter Cable should be stored in a cool dry place : avoid exposure to extreme temperatures.

PRECAUTIONS :

This product is not validated for ETO or steam sterilization because it is not used within the sterile field. See cleaning instruction below. After cleaning and before use, plug the Adapter into the RF Generator and an Stratus (Nimbus) RF Thermocouple Electrode to ensure that the Adapter is working correctly and the impedance and temperature readings are within the normal range.

Manual Cleaning Procedure (Before and after every use)

Note : Do not allow visible soil to dry or harden after use to facilitate cleaning.

Caution : Operatives should wear appropriate levels of protective clothing.

- 1) Rinse the Adapter Cable with running tap water at 30-40°C (86-104°F) to remove soil until visibly clean.
- 2) Prepare an enzymatic cleaner such as Prolystica 2 x concentrate enzymatic per manufacturers recommendations.

Immerse the Adapter Cable in the blood-dissolving enzymatic solution, taking care not to immerse the connectors as damage to the product may occur. Allow them to soak for a minimum of 30 minutes.

Caution :

If the connectors are inadvertently immersed allow the solution to drain out of the connector by inverting it for a minimum of 30 minutes prior to use.

- 3) Thoroughly clean, rinse and remove gross matter, i.e blood, mucous, tissue from the Adapter Cable 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 connectors 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.

Products are free of Latex.