



POST MARKET SURVEILLANCE

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

Warranty / Guarantee

This Stratus Medical product is warranted for 90 days 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. Employees of Stratus Medical shall not be authorised to amend the aforementioned conditions, to extend liability, or to accept or consent to additional product-related obligations.

Symbols

These Symbols can be found on the product label

	Catalogue number
	Serial number
	Consult instructions for use
	Temperature limitation
	Manufacturer
	Distributor
yyyy-mm-dd	Date of manufacture
	Packaging Unit
	Non Sterile
	Unique device Identifier
	Medical Device
	Authorised Representative in the EU
	For or by order of a Physician



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Adapter Cable

For use with

**Stratus Medical Reusable Radiofrequency (RF)
Reusable Electrodes and RF lesion generator
according to Compatibility Chart**

REF

**RPC-ST ALL
RPC-R
RPC-C
RPC-B14
RPC-SN
RPC-AK

RPC-B4

RPC-OWA**

Instructions for use

WARNINGS

NON STERILE

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

See cleaning instructions if required.

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.

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Only use with :

Stratus Medical RF Re-usable Electrode

This Stratus Medical Adapter Cable is a **NON-STERILE reusable cable**

Indications for use

To connect RF Electrode to a Radiofrequency (RF) Generator Stratus Medical RF Electrodes are intended for use in the lesioning of peripheral nerve tissue.

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.

Connections:

This adapter cable is for connecting a Stratus Medical RF Re-usable Electrode to a RF Lesion Generator.

Adapter Cable: Connect the silver metal 4 pin socket of the Stratus Medical Adapter Cable to the Stratus Medical RF Electrode, align the red dots on the connector bodies and push the connectors together until they "click".

Connect plug into the RF Lesion Generator.

(SEE COMPATIBILITY CHART A)

RPC-B4 Adapter Cable: Connect the silver metal 4 pin socket of the Stratus Medical Adapter Cable to the Stratus Medical RF Electrode, align the red dots on the connector bodies and push the connectors together until they "click". Connect the plug of the Stratus Medical Adapter Cable into one of the inputs of the Baylis Multi-RF, 4 Probe Adapter Cable.

Then plug the 14 way Multi-RF Cable connector into the Baylis RF Lesion Generator (V Series).

(SEE COMPATIBILITY CHART B)

RPC-OWA *Adaptor Cable:* Connect the silver metal 4 pin socket of the Stratus Medical Adapter Cable to the Stratus Medical RF Electrode, align the red dots on the connector bodies and push the connectors together until they "click". Connect the plug of the Stratus Medical Adaptor Cable into the four probe cable adapter (MLA-4) which connects into the probe receptacle on the front panel of the Diros URF-3AP RF Lesion Generator.

(SEE COMPATIBILITY CHART C)

After connection and before each use ensure that the readings of temperature and impedance on the Generator are within the normal range. (Refer to the generator operating instructions).

Caution

Disconnect from the Generator holding the Connector. Do not pull on the Cable to disconnect as damage will occur.

Handling

Stratus Medical recommends to handle the 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 do not place any limit on the number of times the Cable can be used. The lifetime of the Cable is subject to many factors which are outside the control of Stratus Medical.

Storage

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

Disposal

In order to facilitate the safety disposal of the product, national regulations of potentially contaminated medical devices must be observed when disposing of this product.

Compatibility Chart A

STRATUS CABLE REF	RF ELECTRODE	RF GENERATOR	PLUG
RPC-ST-ALL	NRP-50,100,150-27-SS NRP-50,100,150-27-SS-CE NRP-50,100,150-27-N NRP-50,100,150-27-N-CE	Stryker MultiGen1	12 pin
RPC-R		Radionics RFG-3c plus RFG-3D, RFG 3CF	2 pin
RPC-C		Cosman RFG1A & 1B G4	4 pin
RPC-B14		Baylis PMG-115/230 V2 & V3 Halyard V4	14 pin
RPC-SN		Smith & Nephew Electrothermal 20S	8 pin
RPC-AK		Apro Korea Coatherm AK-F50	6 Pin

Compatibility Chart B

STRATUS CABLE REF	RF ELECTRODE	RF GENERATOR	PLUG
RPC-B4	NRP-50,100,150-27-SS NRP-50,100,150-27-SS-CE NRP-50,100,150-27-N NRP-50,100,150-27-N-CE	Baylis PMG – 115/230 V2 & V3 Halyard V4	4 pin

Compatibility Chart C

STRATUS CABLE REF	RF ELECTRODE	RF GENERATOR	PLUG
RPC-OWA	NRP-50,100,150-27-SS NRP-50,100,150-27-SS-CE NRP-50,100,150-27-N NRP-50,100,150-27-N-CE	OWL (Diros) URF-3AP	4 pin

PRECAUTIONS:

This product is not validated for ETO or steam sterilisation because it is not used within the sterile field. See cleaning instruction below if required. After cleaning and before each use, plug the Cable into the RF Generator and a Stratus Medical RF Electrode to ensure that the Cable is working correctly and the impedance and temperature readings are within the normal range.

Manual Cleaning Procedure (If required)

Caution : Operatives should wear appropriate levels of protective clothing.

1. Rinse the Cable with running tap water at 30-40°C (86-104°F) 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, 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.

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.

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.

Use of ultrasonic cleaners

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

Before and after use and cleaning:

Inspect the Cable for any signs of damage or corrosion.
Do not use if any damage or corrosion is observed.

Products are free of Latex.

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