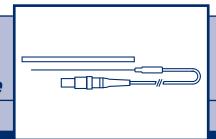
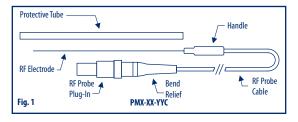


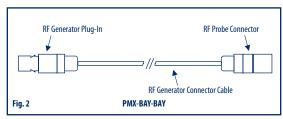
Radiofrequency Probe & Radiofrequency Generator Connector Cable

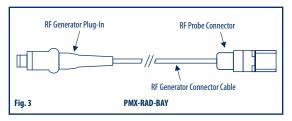
Pain Management

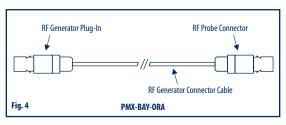


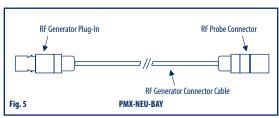
Instructions for Use

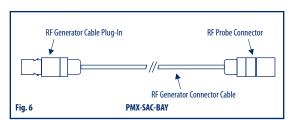














Non-Pyrogenic

Rx Only





(EN)

KIMBERLY-CLARK* Radiofrequency Probe & Radiofrequency Generator Connector Cable

Pain Management

Rx Only: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Device Description

The KIMBERLY-CLARK* Radiofrequency (RF) Probes (Fig. 1) are individual electrodes that are used with a disposable radiofrequency (RF) cannula (sold separately) of the corresponding gauge and length. The KIMBERLY-CLARK* Radiofrequency (RF) Generator Connector Cables [PMX-BAY-BAY (Fig. 2), PMX-RAD-BAY (Fig. 3), PMX-BAY-ORA (Fig. 4), PMX-NEU-BAY (Fig. 5) and PMX-SAC-BAY (Fig. 6)] respectively connect the KIMBERLY-CLARK* RF Probes to the Valleylab* RFG Series Generator, connect the KIMBERLY-CLARK* RF Probes to the Valleylab* RFG Series Generator, connect the KIMBERLY-CLARK* RF Generator (formerly Baylis Pain Management Generator) to the Smith & Nephew* Probe Model: 4-Pin Intradiscal Catheter, 4-Pin Intradiscal Catheter XL or 4-Pin Intradiscal Decompression Catheter, connect the KIMBERLY-CLARK* RF Probes to the STRYKER* RF Generator cable or STRYKER* RF Multi-Gen Cable .

Indications For Use

KIMBERLY-CLARK* Radiofrequency Probe and KIMBERLY-CLARK* Radiofrequency Generator Connector Cable will be used in conjunction with a radiofrequency generator to create lesions in nervous tissue.

Contraindications

For patients with cardiac pacemakers, a variety of changes can occur during and after the treatment. In sensing mode the pacemaker may interpret the RF signal as a heartbeat and may fail to pace the heart. Contact the pacemaker company to determine if the pacemaker should be converted to fixed-rate pacing during the RF procedure. Evaluate the patient's pacing system after the procedure.

Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the RF lesion generator.

If the patient has a spinal cord, deep brain, or other stimulator, contact the manufacturer to determine if the stimulator needs to be in the bipolar stimulation mode or in the OFF position.

This procedure should be reconsidered in patients with any prior neurological deficit

The use of general anesthesia is contraindicated. To allow for patient feedback and response during the procedure, treatment should be performed under local anesthesia.

Systemic infection or local infection in area of the procedure.

Blood coagulation disorders or anticoagulant use.

Warnings

- The Kimberry-Clark* RF Probes and RF Generator Connector Cables are shipped non-sterile and must be cleaned and sterilized prior to use as instructed in the Instructions for Use.
- The Kimberly-Clark* RF Probes and RF Generator Connector Cables are reusable devices. Failure to properly clean and sterilize the device can cause patient injury and/or the communication of infectious diseases from one patient to another.
- The Kimberly-Clark* RF Probes and RF Generator Connector Cables must be used with the correct connector cable. Attempts to use it with other RF Generator Connector Cables can result in electrocution of the patient or operator.
- Laboratory staff and patients can undergo significant x-ray exposure during RF procedures due to the continuous use of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- Discontinue use if inaccurate, erratic or sluggish temperature readings are observed. Use of damaged equipment may cause patient injury.
- Do not modify Kimberly-Clark* Equipment. Any modifications may compromise the safety and efficacy of the device.
- When an RF Generator is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment.
- The RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the RF Probe, particularly when operating the device.

- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Do not remove or withdraw the device while energy is being delivered.

Precautions

- Do not attempt to use the KIMBERLY-CLARK* RF Probes and RF Generator Connector Cables before thoroughly reading the Instructions for Use and the User's Manual for the RF Generator.
- The Kimberly-Clark* RF Probes and RF Generator Connector Cables should be used by physicians familiar with RF lesion techniques.
- Apparent low power output or failure of the equipment to function properly at normal settings may indicate: 1) faulty application of the dispersive electrode or 2) power failure to an electrical lead. Do not adjust treament parameters before checking for obvious defects or misapplication.
- In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application.
- It is the physician's responsibility to determine, assess and communicate to each individual patient all foreseeable risks of the RF lesion procedure.

Adverse Events

Potential complications associated with the use of this device include but are not limited to: infection, nerve damage, increased pain, visceral injury, failure of technique, paralysis, and death.

Product Specifications

The $\mbox{Kimberty-CLark*}$ RF Probes should be used by physicians familiar with RF lesion techniques.

KIMBERLY-CLARK* RF Probe (Fig. 1)

The KIMBERLY-CLARK* RF Probes (PMP) are individual electrodes that are used with disposable RF cannula (sold separately) of the corresponding gauge and length.

- Available with straight and curved cannulae.
- Model number indicates cannula information.

Model Number Probe-XX-YYC, where:

- XX: indicates gauge of cannula associated with the probe
- YY: indicates length of cannula associated with the probe
- C: if present, indicates that cannula is curved.

Note: Please contact Kimberly-Clark for a list of all model numbers and sizes.

- RF Probes are shipped non-sterile and must be sterilized as per Instructions for Use prior to use.
- · Are supplied non-pyrogenic.
- Are supplied with the following additional parts:
 - protective tubing, to prevent bending or kinking of the RF Electrode during handling.
- Black 4-pin, male connector (Probe Plug-In) to connect the KIMBERLY-CLARK* RF Probe to the RF Generator Connector Cable.
- Color-coded bend relief which corresponds to the gauge of the cannula they should be used with:

White = 16G Pink = 18G Yellow = 20G Green = 21G Black = 22G

 Black probe cable for use with straight cannula and a white probe cable for use with curved cannula.

Storage Instructions

- KIMBERLY-CLARK* RF Probes should be stored in a cool, dry place.
- Store the RF Probes in the Sterilization and Storage Tray provided to reduce the risk of damage due to storage.

Special Handling Instructions

The KIMBERLY-CLARK* RF Probe is delicate due to its small diameter RF electrode. Do not bend, kink, or stress the RF electrode. Do not crush or splice the probe cable. Doing so could damage the temperature sensing mechanism in the device and lead to improper temperature measurement.

KIMBERLY-CLARK* RF Generator Connector Cables

- Five models (PMX-BAY-BAY, PMX-RAD-BAY, PMX-BAY-ORA, PMX-NEU-BAY, PMX-SAC-BAY)
- Shipped non-sterile and must be sterilized as per User's Manual prior to first use.

PMX-BAY-BAY (Fig. 2)

The KIMBERLY-CLARK* PMX-BAY-BAY connects the KIMBERLY-CLARK* RF Probe to the Generator (PMG).

- Two different connectors:
 - 1. 4-pin female RF Probe Connector (to connect to Probe)
 - 2. 14-pin male RF Generator Plug-In (to connect to Generator)

PMX-RAD-BAY (Fig. 3)

The Kimberly-Clark* PMX-RAD-BAY connects the Kimberly-Clark* RF Probe (PMP) to a Valleylab* RFG Series Generator.

- Two different connectors:
 - 1. 4-pin female RF Probe Connector (to connect to Probe)
 - 2. 14-pin male RF Generator Plug-In (to connect to Generator)

PMX-BAY-ORA (Fig. 4)

The KIMBERLY-CLARK* PMX-BAY-ORA connects the KIMBERLY-CLARK* RF Generator to the Smith & Nephew Probe Model: 4-Pin Intradiscal Catheter or 4-Pin Intradiscal Catheter XI

- Two different connectors:
 - 1. 4-pin female RF Probe Connector (to connect to Probe)
 - 2. 14-pin male RF Generator Plug-In (to connect to Generator)

Note: Cable should NOT be used with the Intradiscal decompression catheter if the aenerator in use is Generator Version 1.2 or lower.

Note: If using the PMG Version 2.0, ensure that the secondary thermocouple option is disabled. Refer to Generator-TD User Manual.

- Are used to connect an IDL probe (model 902002) to the KIMBERLY-CLARK* RF Generator.
- Should NOT be used with the IDL decompression catheter if the generator in use is PMG Version 1.2 or lower.
- Have two different connectors:
 - 1. 4-pin female RF Probe Connector (to connect to Probe)
 - 2. 14-pin male RF Generator Plug-In (to connect to Generator)

PMX-NEU-BAY (Fig. 5)

The Kimberly-Clark* PMX-NEU-BAY connects the Kimberly-Clark* RF Probes to the Neurotherm® Generator.

- · Two different connectors:
 - 1. 4-pin female RF Probe Connector (to connect to Probe)
 - 2. 4-pin male (metal) RF Generator Plug-In (to connect to Generator)

PMX-SAC-BAY (Fig. 6)

The Kimberly-Clark* PMX-SAC-BAY connects the Kimberly-Clark* RF Probes to the STRYKER® RF Generator or STRYKER® RF Multi-Gen.

- Two different connectors:
 - 1. 4-pin female RF Probe Connector (to connect to Probe)
 - 2. 12-pin male (metal) RF Generator Plug-In (to connect to Generator cable)

Storage Instructions

- KIMBERLY-CLARK* RF Generator Connector Cables should be stored in a cool, dry place.
- Store the RF Generator Connector Cables in the Sterilization and Storage Tray
 provided to reduce the risk of damage due to storage.

Autoclave Case is:

- Shipped non-sterile.
- Should be used at all times to store the KIMBERLY-CLARK* Probe and KIMBERLY-CLARK* RF Generator Connector Cable.
- Steam sterilizable and should be used to hold the devices while they are being sterilized.
- NOT to be used with STERRAD®.

Inspection Prior to Use

Perform the following checks before the patient is presented for the procedure. These steps will allow you to verify that the equipment you will use is in proper working order. Do these tests in a sterile environment.

- Sterility Check: The Kimberly-Clark* RF Probes and RF Generator Connector Cables are shipped non-sterile. They must be sterilized prior to each use.
- Visual Inspection: Ensure RF Probes and RF Generator Connector Cables have no visible damage such as discoloration, cracks, label fading, cable splice, or kinks. Do NOT use damaged or defective equipment.
- Residual Moisture: Ensure the RF Probes and RF Generator Connector Cables are dry, Residual moisture can cause malfunctions.

Equipment Required

RF lesion procedures should be performed in a specialized clinical setting with fluoroscopic equipment. The RF equipment required for the procedure is as follows:

- Disposable RF Cannula
- RF Probe and corresponding RF Generator Connector Cable
- RF Generator
- Disposable Indifferent (dispersive) Patch (DIP) electrode meeting ANSI/AAMI standard HF-18 requirements for electrosurgical electrodes.

Instructions for Use

- Assemble all required equipment for the intended procedure and position the patient as necessary.
- Attach the Disposable Indifferent (dispersive) Patch (DIP) electrode. Read
 and follow the manufacturer's Instructions for Use of the (DIP) electrode
 to determine proper placement. Always use DIP electrodes that meet or
 exceed ANSI/AAMI HF-18 requirements.
- Connect the appropriate connector cable to the connector cable connection on the RF generator. Maintain access to the RF Probe Connector on the connector cable in order to facilitate easy attachment of the probe.
- With the stylet in the cannula, insert the cannula into the patient using fluoroscopic guidance to place the active tip at the desired lesion location
- Once the cannula is properly placed, carefully remove the stylet from the cannula and insert the (pre-sized) RF Electrode down the shaft of the cannula.
- Attach the probe to the connector cable (via the Probe Plug-In and RF Probe Connector).
- Stimulate and lesion as necessary. Refer to the RF Generator User's Manual for more information.

After the Procedure

- 1. Remove RF electrode of the probe from the cannula.
- 2. Remove cannula from the patient.
- Disconnect the RF Probe from the RF Generator Connector Cable by pulling on the plug body.

Caution: Prevent damage to your cable and probe. When pulling the connectors apart be sure to pull on the plug and not the cable.

- 4. Disconnect the RF Generator Connector Cable from the generator.
- 5. Discard the cannula.
- Remove Disposable Indifferent (dispersive) Patch (DIP) electrode from patient and discard.
- Prepare the reusable probe and connector cable for cleaning and sterilization. Transfer the used KIMBERILY-CLARK* RF Probe and KIMBERILY-CLARK* RF Generator Connector Cable to a carrying surface and cover them with a wet cloth to ensure that blood and other contaminants do not dry on the surface.

Cleaning and Sterilization Instructions

Danger

The Kimberly-Clark* RF Probe and Kimberly-Clark* RF Generator Connector Cable are shipped non-sterile and must be cleaned and sterilized as per these Instructions for Use prior to each use. Failure to properly clean and sterilize the device can cause patient injury and/or the communication of infectious diseases from one patient to another.

Important

The manufacturer recommends the user follow a quality control program for each sterilization cycle that meets or exceeds American Operating Room Nurses (AORN) Standards, Recommended Practices & Guidelines - 2000. This program includes, but is not limited to recording:

- Type of sterilizer and cycle used
- Lot control number
- · Load contents
- · Exposure time and temperature, if not provided by a recording chart
- Operator's name
- Results of sterilization process monitoring (i.e., chemical, mechanical, biological)

Cleaning and Decontamination

- Ensure that blood and other contaminants do not dry on the KIMBERLY-CLARK* RF Probe and the KIMBERLY-CLARK* RF Generator Connector Cable.
- 2. Remove the protective tube from the probe and follow the Instructions below for each piece separately.
- 3. Rinse all parts with deionized water until colorless run-off water occurs. Once the water runs clear soak the parts (except for the connectors) in deionized water at 22°C-48°C for 1 minute. Remove the probe and components from the water and scrub them with a soft bristle brush until they are visually clean. Note: Do not let the connectors soak. Wipe connectors as necessary until they are visually clean.
- 4. Soak the probe and components (except connectors) in an enzymatic cleaning solution for 20 minutes. Ensure that the temperature of the solution is below 55°C. Scrub again with a soft bristle brush, and rinse thoroughly using deionized water until all traces of detergent residue are removed.
- 5. Visually inspect the parts again for debris, if any is present repeat steps 3 and 4.
- Dry the surface of the device on the outside with a clean, dry towel. Put the protective tube back onto the probe and place all parts back in the Sterilization and Storage Tray.

Sterilization (AII EXCEPT PMX-SAC-BAY)

The following sterilization methods have been validated for use with Kimberly-Clark* RF Probes and RF Generator Connector Cables:

- · Steam Sterilization
- · Gravity Displacement Steam Sterilization
- STERRAD® Sterilization

Sterilization (PMX-SAC-BAY)

The following sterilization methods have been validated for use with KIMBERLY-CLARK* PMX-SAC-BAY Generator Connector Cable:

- Steam Sterilization
- · Gravity Displacement Steam Sterilization

Steam Sterilization

Prevaccum: Wrapped: 132°C-135°C (270°F-275°F) for 3-4 min. Unwrapped: "flash" 132°C for 4 min.

Gravity Displacement Steam Sterilization

Wrapped: 132°C-135°C (270°F - 275°F) for 15 minutes Unwrapped: "Flash" 132°C- 135°C for 15 minutes

STERRAD® Sterilization

KIMBERLY-CLARK* RF Probes and RF Generator Connector Cables may be sterilized with the following STERRAD® systems:

- STERRAD® 100S
- STERRAD 50
- STERRAD 200
- STERRAD NX®
- STERRAD 100NX

All instructions given in the corresponding STERRAD® Sterilization System User's Guide must be followed.

Note: The KIMBERLY-CLARK* RF Probe and RF Generator Connector Cable should NOT be sterilized within the autoclave case. Any validated tray recommended for use with STERRAD® may be used.

Note: For effective sterilization, the protective tube MUST be removed during sterilization and placed next to the probe in the tray.

Warning

Kimberly-Clark has validated ONLY the previously mentioned cleaning and sterilization methods for the KIMBERLY-CLARK* RF Probe and KIMBERLY-CLARK* RF Generator Connector Cable. No other cleaning and sterilization methods have been tested. If any other type of cleaning or sterilization method is used on these products, it is up to the user to verify sterility. Failure to properly clean the device can lead to patient injury.

Troubleshooting

The following table is provided to assist the user in diagnosing potential problems.

PROBLEM	COMMENTS	TROUBLESHOOTING
No temperature measurement in treatment mode OR Inaccurate, erratic or sluggish temperature reading in treatment mode	In order to measure temperature the entire system must be connected and all devices must be in good working order.	Ensure that all connections are made: probe to connector cable connector cable to generator generator to power outlet Check for an error message on the generator. Visually inspect the probe or cable for damage. Ensure that devices are dry and at room temperature. If problem persists, discontinue use.
RF Probe does not fit into the RF Cannula	The fit of the probe in the cannula is very precise. In very rare situations the manufacturing of the probe and/or cannula may prohibit the correct fit.	Ensure that the stylet has been removed from the cannula. Ensure that the RF Electrode is completely smooth and clean. Check the gauge of the cannula and ensure that the correctly sized probe is in use. Try another cannula of the same size.
RF Probe Connector does not fit in RF Probe Plug-In	Each of the connectors is designed to connect in a specific way for safety reasons. If the connector "keys" are out of line the connectors won't fit together.	Check that the connector's keys are lined up in the proper orientation. Ensure that the connectors are clean and unobstructed.
RF Electrode Breaks or Kinks	Due to the small diameter shaft, the RF Electrode portion of the KIMBERLY-CLARK* RF Probe can withstand very little damage due to handling.	Discard Immediately.

Customer Service and Product Return Information

If you have any problems with or questions about this KIMBERLY-CLARK* Equipment, contact our technical support personnel:

Kimberly-Clark

1400 Holcomb Bridge Rd.

Roswell, GA 30076-2199

E-mail: InterventionalPain.KCHC@KCC.COM

U.S. Customers: 800-KCHELPS (800-742-1996)

International Customers: +1-770-587-7200

Notes

In order to return products under limited warranty you must have a return authorization number before shipping the products back to Kimberly-Clark.

Limited Warranty

Kimberly-Clark warrants that these products are free from defects in original workmanship and materials. If these products prove to be defective in original workmanship or original materials, Kimberly-Clark, in its absolute and sole discretion, will replace or repair any such product, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products that have been used for their normal and intended uses. Kimberly-Clark's limited warranty shall NOT apply to Kimberly-Clark's products which have been repaired, altered or modified in any way and shall NOT apply to Kimberly-Clark's products which have been improperly stored or improperly installed, operated or maintained contrary to Kimberly-Clark's Instructions. The warranty period for KIMBERUY-CLARK* RF Probe and RF Generator Connector Cables is 90 days from the date of purchase, unless otherwise stated.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind, which extend beyond the description of the warranties as previously mentioned. Kimberly-Clark disclaims and excludes all warranties, whether expressed or implied, of merchantability or fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Kimberly-Clark shall not be liable for damages for loss of profits or claims of buyer's customers for any such damages. Kimberly-Clark's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Kimberly-Clark to buyer which give rise to the claim for liability.

The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

and labor costs incidental to inspection, removal or restocking of product. This thave been used for their normal and inspection, removal or restocking of products that have been used for their normal and intended uses. Kimberhy-Clark's products which have been repaired, altered or modified in any way and shall NOT apply to Kimberhy-Clark's products which have been inproperly schored or thimproperly stored or maintained contrary to Kimberhy-Clark's products which have been improperly stored or improperly stored or maintained contrary to Kimberhy-Clark's Instructions. The warranty period for Kimbery-Clark's Instructions. The warranty period for Kimbery-Clark's Instructions. The bear of days of days from the date of purchase, Probe and RF Generator Connection Cables is 90 days from the date of purchase,

unless otherwise stated.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind, which extend beyond the description of the warranties as previously mentioned. Kimberly-Clark disclaims and excludes all warranties, whether expressed or implied, of merchantability or fitness for a particular use or purpose.

Limitation of Liability for Damages

In any clain or lawaint for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable for theory, the buyer specifically agins of buyer's customers for any such damages. damages for loss of profits or claims of buyer's customers for any such damages. Kimberly-clark's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Kimberly-Clark to buyer which give rise to the claim (The liability.

The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

Warning

verify sterility. Failure to properly clean the device can lead to patient or sterilization method is used on these products, it is up to the user to sterilization methods have been tested. If any other type of cleaning Кімвеяцу-Сіляк* RF Generator Connector Cable. No other cleaning and and sterilization methods for the Kimberly-Clark* RF Witinol Probe and Kimberly-Clark has validated ONLY the previously mentioned cleaning

Troubleshooting

The following table is provided to assist the user in diagnosing potential

RF Electrode Breaks or Kinks	ULGE to The Small diameter shaft, the Alameter shaft, the RF Electrode portion of the Klustery-Clark* **** **** **** *** *** *** *	Discard Immediately.
RF Vitinol Probe Connector does not fit in RF Probe Plug-In	Each of the connectors is designed to connect in a specific way for safety reason. "keys" are out of line the connectors won't for connectors won't for connectors won't for together.	c'heck that the connector's keys are lined up in the proper orientation. Ernsure that the connectors are clean and unobstructed.
Priviniol Probe does not fit into the RF Can- siun	The fit of the probe in the cannula is very precise. In very rare stitus and the probe and/or the probe and/or cannula may prohibit the correct fit.	Ensure that the stylet has been removed from the cannula. Ensure that the RF Electrode is completely smooth and dean. Check the length of the correctly and ensure that of the correctly sized probe is in use. Ity another cannula of the smoother cannula of the
No tem- perature measurement mode OR Inaccurate, erratic or aluggish temperature teading in treatment	In order to measure temperature the entire system must be connected and all devices must be in good working order.	Ensure that all connections are made: probe to connector cable connector cable to generator generator to power outlet Check for an error message on the generator. Wisually inspect the probe or cable for damage. Ensure intait devices are dry and at room temperature. If problem room temperature. If problem
PROBLEM	COMMENTS	TROUBLESHOOTING

Customer Service and Product Return Information

contact our technical support personnel: If you have any problems with or questions about this Кимвеких-Силкк* Equipment,

Roswell, GA 30076-2199 1400 Holcomb Bridge Rd. Kimberly-Clark

E-mail: InterventionalPain.KCHC@KCC.COM

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ot sub spemeb sittle can withstand very

U.S. Customers: 800-KCHELPS (800-742-1996)

International Customers: +1-770-587-7200

authorization number before shipping the products back to Kimberly-Clark.

discretion, will replace or repair any such product, less charges for transportation workmanship or original materials, Kimberly-Clark, in its absolute and sole workmanship and materials. If these products prove to be defective in original Kimberly-Clark warrants that these products are free from defects in original Limited Warranties

In order to return products under limited warranty you must have a return

Important

includes, but is not limited to recording: (AORN) Standards, Recommended Practices & Guidelines - 2000. This program each sterilization cycle that meets or exceeds American Operating Room Nurses The manufacturer recommends the user follow a quality control program for

- Type of sterilizer and cycle used
- Lot control number
- Load contents
- Exposure time and temperature, if not provided by a recording chart
- Operator's name

- (lasipoloid Results of sterilization process monitoring (i.e., chemical, mechanical,

Cleaning and Decontamination

- KIMBERLY-CLARK* RF Nitinal Probe and the KIMBERLY-CLARK* RF Generator Ensure that blood and other contaminants do not dry on the
- below for each piece separately. Remove the protective tube from the probe and follow the Instructions
- until they are visually clean. Note: Do not let the connectors soak. Wipe components from the water and scrub them with a soft bristle brush in deionized water at 22°C-48°C for 1 minute. Remove the probe and Once the water runs clear soak the parts (except for the connectors) Rinse all parts with deionized water until colorless run-off water occurs.
- are removed. thoroughly using deionized water until all traces of detergent residue solution is below 55°C. Scrub again with a soft bristle brush, and rinse cleaning solution for 20 minutes. Ensure that the temperature of the Soak the probe and components (except connectors) in an enzymatic connectors as necessary until they are visually clean.
- Visually inspect the parts again for debris, if any is present repeat steps
- Sterilization and Storage Tray. the protective tube back onto the probe and place all parts back in the Dry the surface of the device on the outside with a clean, dry towel. Put

Sterilization (All EXCEPT PMX-SAC-BAY)

noitexilizate meate Кімвеяцу-Сіляк* RF Probes and RF Generator Connector Cables: The following sterilization methods have been validated for use with

- Gravity Displacement Steam Sterilization
- STERRAD® Sterilization

The following sterilization methods have been validated for use with Sterilization (PMX-SAC-BAY)

noitexilirate meate Кімвеяцу-Сіляк* РМХ-SAC-BAY Generator Connector Cable:

- Gravity Displacement Steam Sterilization
- noiteailirate meate

Land And Jose 13. Sept. "Aself" :beggerwnU

Unwrapped: "Flash" 15°Cf -7°Z6F "AsaF" :baqqerwnU Wrapped: 132°C- 135°C (270°F - 275°F) for 15 minutes Gravity Displacement Steam Sterilization

Prevacuum: Wrapped: 132°C–135°C (270°F-275°F) for 3 – 4 minutes

STERRAD® Sterilization

sterilized with the following STERRAD $^{\!\circ}$ systems: KIMBERLY-CLARK* RF Witinol Probes and RF Generator Connector Cables may be

- STERRAD® 1005
- OS QARABATS
- STERRAD NX® STERRAD 200
- STERRAD 100NX
- Guide must be followed. rictions given in the corresponding STERRAD® Sterilization System User's STERRAD® Sterilization System User's

with STERRAD® may be used. NOT be sterilized within the autoclave case. Any validated tray recommended for use Note: The Kimberly-Clark* RF Nitinol Prode and RF Generator Connector Cable should

Note: For effective sterilization, the protective tube MUST be removed during

sterilization and placed next to the probe in the tray.

S

Connector Cables are shipped non-sterile. They must be sterilized prior to

the Smith & Nephew Probe Model: 4-Pin Intradiscal Catheter or 4-Pin Intradiscal

14-pin male – RF Generator Plug-In (to connect to Generator)

Note: Cable should NOT be used with the Intradiscal decompression catheter if the

is disabled. Refer to Generator-TD User Manual.

Are used to connect an IDL probe (model 902002) to the Kimberly-Clark* RF

to the Neurotherm® Generator.

OT 9dory 4 RIMBERLY-CLARK* PMX-SAC-BAY connects the KIMBERLY-CLARK* Ultinol RF Probe to

the STRYKER® RF Generator or STRYKER® RF Multi-Gen.

PMX-SAC-BAY (Fig. 6)

4-pin female - RF Probe Connector (to connect to Probe)

4-pin male (metal) – RF Generator Plug-In (to connect to Generator)

Sterility Check: The Kimberly-Clark* RF Nitinol Probes and RF Generator

These steps will allow you to verify that the equipment you will allow you to verify that the Perform the following checks before the patient is presented for the procedure.

Steam sterilizable and should be used to hold the devices while they are

bne 9dor9 lonitill 78 ** All Limbes to store the Kimberly-Clark* AF Witinol Probe and

Yer Generator Connector Cables in the Sterilization and Storage Tray

12-pin male (metal) - RF Generator Plug-In (to connect to Generator

Кімвевіч-Сіляк* ВҒ Generator Connector Cables should be stored in a cool,

working order. Do these tests in a sterile environment.

Кімвеяцу-Сіляк* ВF Generator Connector Cable.

provided to reduce the risk of damage due to storage.

Inspection Prior to Use NOT to be used with STERRAD®. being sterilized.

Shipped non-sterile.

Storage Instructions

Two different connectors:

Autoclave Case is:

1. 4-pin female – RF Probe Connector (to connect to Probe)

Two different connectors:

The Kimberly-Clark* PMX-NEU-BAY connects the Kimberly-Clark* RF Nitinol Prodes

PMX-NEU-BAY (Fig. 5)

2. 14-pin male – RF Generator Plug-In (to connect to Generator)

4-pin female – RF Probe Connector (to connect to Probe)

Have two different connectors:

use is PMG Version 1.2 or lower.

Should NOT be used with the IDL decompression catheter if the generator in

Note: If using the PMG Version 2.0, ensure that the secondary thermocouple option

generator in use is Generator Version 1.2 or lower.

4-pin female — RF Probe Connector (to connect to Probe)

Two different connectors:

The Kimberly-Clark* PMX-BAPY-ORA connects the Kimberly-Clark* RF Generator to

PMX-BAY-ORA (Fig. 4) 14-pin male – RF Generator Plug-In (to connect to Generator)

4-pin female — RF Probe Connector (to connect to Probe)

Two different connectors:

(PMP-N) to a Valleylab® RFG Series Generator. The Kimberly-Clark* PMX-RAD-BAY connects the Kimberly-Clark* RF Uitinol Prode

PMX-RAD-BAY (Fig. 3)

14-pin male — RF Generator Plug-In (to connect to Generator) 4-pin female – RF Probe Connector (to connect to Probe)

Two different connectors:

the Generator (PMG).

The Kimberly-Clark* PMX-BAY-BAY connects the Kimberly-Clark* RF Nitinol Prode to

PMX-BAY-BAY (Fig. 2)

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standard HF-18 requirements for electrosurgical electrodes. UMAA\IZNA pnitesode meeting (AIQ) datch (AIQ) electrode meeting blassodeid

the communication of infectious diseases from one patient to another.

properly clean and sterilize the device can cause patient injury and/or

sterilized as per these Instructions for Use prior to each use. Failure to

Connector Cable are shipped non-sterile and bard be cleaned and

Cleaning and Sterilization Instructions

nants do not dry on the surface.

patient and discard.

Discard the cannula.

After the Procedure

the cannula.

by pulling on the plug body.

Remove cannula from the patient.

.noitemrofni prom for mation.

Nitinol Probe Connector).

Remove RF electrode of the probe from the cannula.

Danger

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The Kimberly-Clark* RF Uitinol Probe and Kimberly-Clark* RF Generator

cover them with a wet cloth to ensure that blood and other contami-

sterilization. Transfer the used Kımberıv-Clark* ${\rm FF}$ Uitinol Probe and 7. Prepare the reusable probe and connector cable for cleaning and

KIMBERLY-CLARK* RF Generator Connector Cable to a carrying surface and

Remove Disposable Indifferent (dispersive) Patch (DIP) electrode from

Disconnect the RF Generator Connector Cable from the generator.

the connectors apart be sure to pull on the plug and not the cable.

Disconnect the RF Nitinal Probe from the RF Generator Connector Cable

Caution: Prevent damage to your cable and probe. When pulling

Stimulate and lesion as necessary. Refer to the RF Generator User's

Aftach the probe to the connector cable (via the Probe Plug-In and RF

the cannula and insert the (pre-sized) AF Electrode down the shaft of

using fluoroscopic guidance to place the active tip at the desired lesion

Connector on the connector cable in order to facilitate easy attachment

to determine proper placement. Always use DIP electrodes that meet or

and follow the manufacturer's Instructions for Use of the (DIP) electrode Attach the Disposable Indifferent (dispersive) Patch (DIP) electrode. Read

1. Assemble all required equipment for the intended procedure and posi-

nection on the RF generator. Maintain access to the RF Nitinol Probe Connect the appropriate connector cable to the connector cable con-

4. With the stylet in the cannula, insert the cannula into the patient

exceed ANSI/AMI HF-18 requirements.

tion the patient as necessary.

Once the cannula is properly placed, carefully remove the stylet from

RF Generator AF Witinol Probe and corresponding RF Generator Connector Cable

Disposable RF Cannula

Instructions for Use

fluoroscopic equipment. The RF equipment required for the procedure is as RF lesion procedures should be performed in a specialized clinical setting with

Equipment Required

tor Cables are dry. Residual moisture can cause malfunctions.

Residual Moisture: Ensure the RF Nitinol Probes and RF Generator Conneccable splice, or kinks. Do NOT use damaged or defective equipment. Cables have no visible damage such as discoloration, cracks, label fading, Visual Inspection: Ensure RF Mitinol Probes and RF Generator Connector

(EV)

Radiofrequency Nitinol Probe & Radiofrequency Generator Connector Cable KIMBERLY-CLARK*

physician. A Only: Federal (A.2.U) law restricts this device to sale by or on the order of a

Device Description

the Neurotherm® Generator, connect the Kimвɛnzч-С∟люк* RF Generator (formerly Valleylab® RFG Series Generator, connect the Kimberur-Clark* RF Nitinol Probes to Probes to the RF Generator, connect the Kimberly-Clark* RF Nitinal Probes to the and PMX-SAC-BAY (Fig. 6)] respectively connect the Kimberly-Clark* RF Nitinol PMX-RAD-BAY (Fig. 3), PMX-BAY-ORA (Fig. 4) and PMX-NEU-BAY (Fig. 5) Radiofrequency (RF) Generator Connector Cables [PMX-BAY-BAY (Fig. 2), separately) of varying gauge and corresponding length. The Kiмвєвич-Силяк* electrodes that are used with a disposable radiofrequency (RF) cannula (sold The Kimberity-Clark* Radiofrequency (RF) Nitinol Probes (Fig. 1) are individual

Generator cable or STRYKER® RF Multi-Gen cable. Sion Catheter, connect the Kimberly-Clark* RF Nitinol Probes to the STRYKER® RF Intradiscal Catheter, 4-Pin Intradiscal Catheter XL or 4-Pin Intradiscal Decompres-

Reallis Pain Management Generator) to the Smith & Wephew® Probe Model: 4-Pin

Indications For Use

generator to create lesions in nervous tissue. Generator Connector Cable will be used in conjunction with a radiofrequency Кимвеягу-Силяк* Radiofrequency Nitinol Probe and Кимвеягу-Силяк* Radiofrequency

Contraindications

monitoring and electrical apparatus to be used on the patient in addition to the Check the compatibility and safety of combinations of other physiological the RF procedure. Evaluate the patient's pacing system after the procedure. to determine if the pacemaker should be converted to fixed-rate pacing during as a heartbeat and may fail to pace the heart. Contact the pacemaker company after the treatment. In sensing mode the pacemaker may interpret the RF signal For patients with cardiac pacemakers, a variety of changes can occur during and

manufacturer to determine if the stimulator needs to be in the bipolar stimula-If the patient has a spinal cord, deep brain, or other stimulator, contact the RF lesion generator.

This procedure should be reconsidered in patients with any prior neurological tion mode or in the OFF position.

and response during the procedure, treatment should be performed under local The use of general anesthesia is contraindicated. To allow for patient feedback

Systemic infection or local infection in area of the procedure. anesthesia.

Blood coagulation disorders or anticoagulant use.

Warnings

- prior to use as instructed in the Instructions for Use. Cables are shipped non-sterile and must be cleaned and sterilized The Kimberly-Clark* RF Nitinol Probes and RF Generator Connector
- the device can cause patient injury and/or the communication of Cables are reusable devices. Failure to properly clean and sterilize The Kimberly-Clark* RF Nitinol Probes and RF Generator Connector
- Cables must be used with the correct connector cable. Attempts The Kimberly-Clark* RF Nitinol Probes and RF Generator Connector infectious diseases from one patient to another.
- Laboratory staff and patients can undergo significant x-ray expoelectrocution of the patient or operator. to use it with other RF Generator Connector Cables can result in
- adequate measures must be taken to minimize this exposure. well as increased risk for somatic and genetic effects. Therefore, imaging. This exposure can result in acute radiation injury as sure during RF procedures due to the continuous use of fluoroscopic
- readings are observed. Use of damaged equipment may cause Discontinue use if inaccurate, erratic or sluggish temperature
- compromise the safety and efficacy of the device. Do not modify Кімвевгу-Сілек* Equipment. Any modifications may
- electrical fields may interfere with other electrical medical equip-When an RF Generator is activated, the conducted and radiated

Pain Management

- dling of the RF Probe, particularly when operating the device. power. Patient or operator injury can result from improper han-The RF Generator is capable of delivering significant electrical
- in contact with grounded metal surfaces. During power delivery, the patient should not be allowed to come
- Do not remove or withdraw the device while energy is being

Precautions

- User's Manual for the RF Generator. Connector Cables before thoroughly reading the Instructions for Use and the Do not attempt to use the Kimberly-Clapk* AF Nitinal Probes and AF Generator
- should be used by physicians familiar with RF lesion techniques. The Kimberly-Clark* RF Nitinol Probes and RF Generator Connector Cables
- parameters before checking for obvious defects or misapplication. electrode or 2) power failure to an electrical lead. Do not adjust treatment at normal settings may indicate: 1) faulty application of the dispersive Apparent low power output or failure of the equipment to function properly
- not present in the room during RF power application. la order to prevent the risk of ignition make sure that flammable material is
- each individual patient all foreseeable risks of the RF lesion procedure. It is the physician's responsibility to determine, assess and communicate to

not limited to: infection, bleeding, nerve damage, visceral injury, increased pain, Potential complications associated with the use of this device include but are

Adverse Events

failure of technique, paralysis and death.

RF lesion techniques. The Kimberly-Clark* RF Nitinol Probes should be used by physicians familiar with Product Specifications

KIMBERLY-CLARK* Nitinol RF Probe (Fig. 1)

corresponding length. are used with disposable RF cannula (sold separately) of varying gauge and The Kimberity-Clark* RF Nitinal Probes (PMP) are individual electrodes that

- Available with straight and curved cannulae (16-22 gauge).
- Model number indicates cannula information.
- Model Number PMP-YYC-N, where:
- YY: indicates length of cannula associated with the probe
- Note: Please contact Kimberly-Clark for a list of all model numbers and sizes. if present, indicates that cannula is curved.
- RF Nitinol Probes are shipped non-sterile and must be sterilized as per
- Stred lenoitibae gniwollof off thiw boilgque or A Are supplied non-pyrogenic.

Instructions for Use prior to use.

- protective tubing, to prevent bending or kinking of the RF Electrode
- Black 4-pin, male connector (Probe Plug-In) to connect the .pnilbned pnirub
- use with curved cannula. Black probe cable for use with straight cannula and a white probe cable for KIMBERLY-CLARK* RF Nitinol Probe to the RF Generator Connector Cable.
- Кімвєвич-Сіляк* ВF Mitinol Probes should be stored in a cool, dry place. Storage Instructions

Special Handling Instructions reduce the risk of damage due to storage.

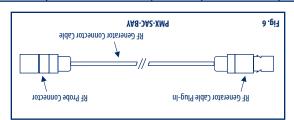
device and lead to improper temperature measurement. probe cable. Doing so could damage the temperature sensing mechanism in the electrode. Do not bend, kink, or stress the RF electrode. Do not crush or splice the The Kimberly-Clark* RF Nitinol Probe is delicate due to its small diameter RF

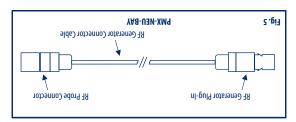
Store the RF Nitinol Probes in the Sterilization and Storage Tray provided to

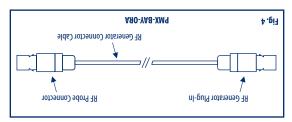
Кімвергу-Сідрк* RF Generator Connector Cables

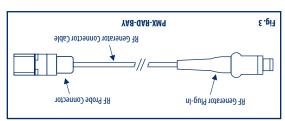
(YA8-JA2-XM9) Five models (PMX-BAY-BAY, PMX-RAD-BAY, PMX-BAY-ORA, PMX-NEU-BAY,

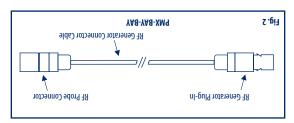
Dispose of Properly

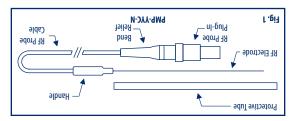




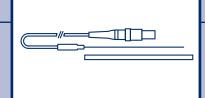








*Ximberly-Clark



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Radiofrequency Nitinol Probe & Radiofrequency Generator Connector Cable

Instructions for Use

Pain Management

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