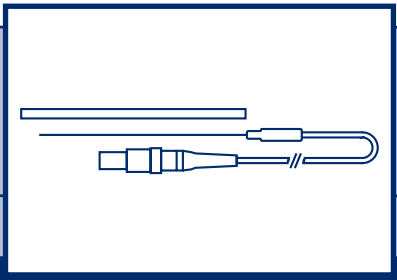
Kimberly-Clark*

Radiofrequency Probe & Radiofrequency Generator Connector Cable

Pain Management



Instructions for Use

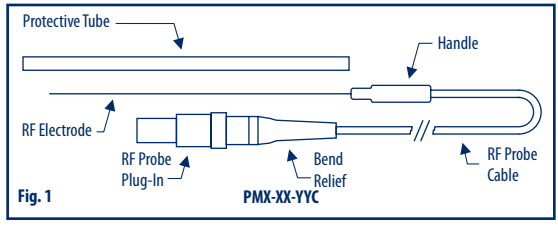


Fig. 1 **PMX-XX-YYC**

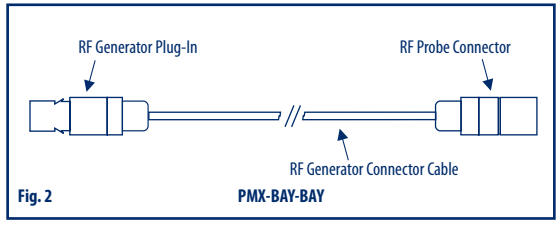


Fig. 2 **PMX-BAY-BAY**

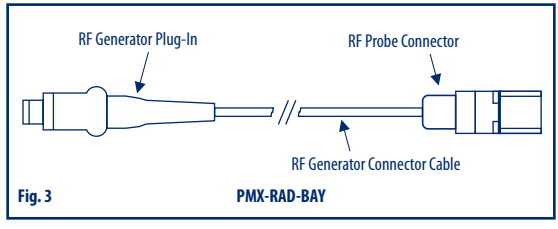


Fig. 3 **PMX-RAD-BAY**

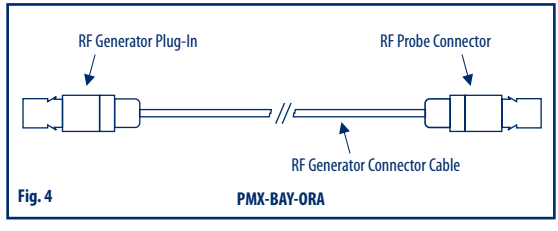


Fig. 4 **PMX-BAY-ORA**

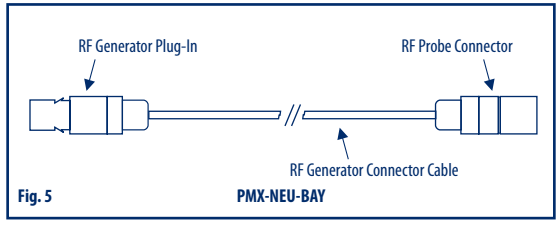


Fig. 5 **PMX-NEU-BAY**

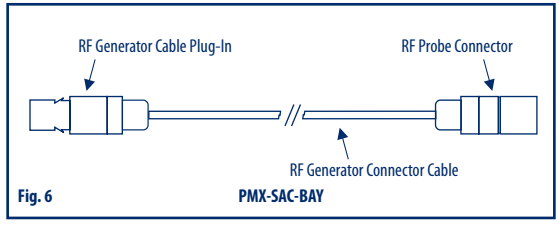


Fig. 6 **PMX-SAC-BAY**

NON STERILE	Non-Pyrogenic	Rx Only	Attention: See Instructions for Use	Dispose of Properly

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 RF Generator, connect the KIMBERLY-CLARK* RF Probes to the Valleylab® RFG Series Generator, connect the KIMBERLY-CLARK* RF Probes to the Neurotherm® 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 KIMBERLY-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 KIMBERLY-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 XL.

- 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 generator 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

1. Assemble all required equipment for the intended procedure and position the patient as necessary.
2. 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.
3. 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.
4. 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.
5. 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.
6. Attach the probe to the connector cable (via the Probe Plug-In and RF Probe Connector).
7. 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.
3. 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.
6. Remove Disposable Indifferent (dispersive) Patch (DIP) electrode from patient and discard.
7. Prepare the reusable probe and connector cable for cleaning and sterilization. Transfer the used Kimberly-Clark* RF Probe and Kimberly-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

1. 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.
6. 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 *(All 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 Kimberly-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 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 Kimberly-Clark* RF Nitinol 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.

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

1. Ensure that blood and other contaminants do not dry on the Kimberly-Clark* RF Nitinol 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.
6. 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 *(All 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

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

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 Nitinol 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 Nitinol 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 Nitinol 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 Nitinol 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 length of the cannula and ensure that the correctly sized probe is in use. Try another cannula of the same size.
RF Nitinol 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 Nitinol 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 Warranties

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

- 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 Nitinol 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 Nitinol Probe (PMP-N) 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 XL.

- 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 generator 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 Nitinol 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* Nitinol RF Probe 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* RF Nitinol 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 Nitinol Probes and RF Generator Connector Cables are shipped non-sterile. They must be sterilized prior to each use.
- **Visual Inspection:** Ensure RF Nitinol 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 Nitinol 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 Nitinol 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

1. Assemble all required equipment for the intended procedure and position the patient as necessary.
2. 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.
3. Connect the appropriate connector cable to the connector cable connection on the RF generator. Maintain access to the RF Nitinol Probe Connector on the connector cable in order to facilitate easy attachment of the probe.
4. 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.
5. 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.
6. Attach the probe to the connector cable (via the Probe Plug-In and RF Nitinol Probe Connector).
7. 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.
3. Disconnect the RF Nitinol 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.
6. Remove Disposable Indifferent (dispersive) Patch (DIP) electrode from patient and discard.
7. Prepare the reusable probe and connector cable for cleaning and sterilization. Transfer the used Kimberly-Clark* RF Nitinol Probe and Kimberly-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 Nitinol 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.

KIMBERLY-CLARK*
Radiofrequency Nitinol 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) Nitinol Probes **(Fig. 1)** are individual electrodes that are used with a disposable radiofrequency (RF) cannula (sold separately) of varying gauge and corresponding length. The KIMBERLY-CLARK* Radiofrequency (RF) Generator Connector Cables [PMX-BAY-BAY **(Fig. 2)**, PMX-RAD-BAY **(Fig. 3)**, PMX-BAY-ORA **(Fig. 4)** and PMX-NEU-BAY **(Fig. 5)** and PMX-SAC-BAY **(Fig. 6)**] respectively connect the KIMBERLY-CLARK* RF Nitinol Probes to the RF Generator, connect the KIMBERLY-CLARK* RF Nitinol Probes to the Valleylab® RFG Series Generator, connect the KIMBERLY-CLARK* RF Nitinol Probes to the Neurotherm® 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 Nitinol Probes to the STRYKER® RF Generator cable or STRYKER® RF Multi-Gen cable.

Indications For Use

KIMBERLY-CLARK* Radiofrequency Nitinol 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 KIMBERLY-CLARK* RF Nitinol 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 Nitinol 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 Nitinol 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 Nitinol 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 Nitinol 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 treatment 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, bleeding, nerve damage, visceral injury, increased pain, failure of technique, paralysis and death.

Product Specifications

The KIMBERLY-CLARK* RF Nitinol Probes should be used by physicians familiar with RF lesion techniques.

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

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

- 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

  C: if present, indicates that cannula is curved.

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

- RF Nitinol 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 Nitinol Probe to the RF Generator Connector Cable.
- Black probe cable for use with straight cannula and a white probe cable for use with curved cannula.

Storage Instructions

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

Special Handling Instructions

The KIMBERLY-CLARK* RF Nitinol 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)

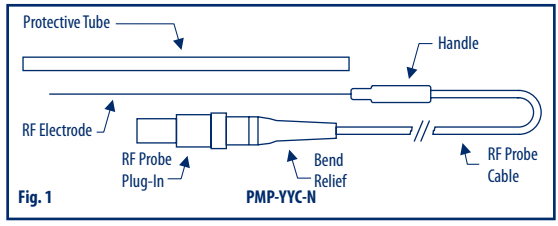


Fig. 1 **PMP-YYC-N**

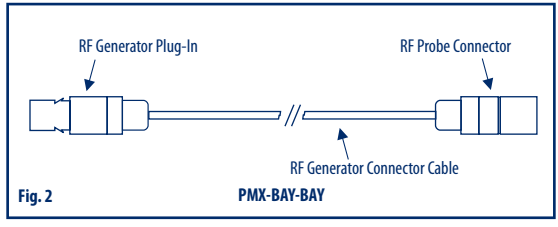


Fig. 2 **PMX-BAY-BAY**

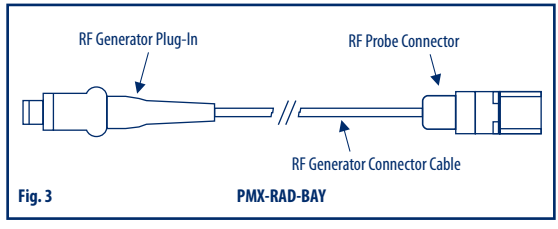


Fig. 3 **PMX-RAD-BAY**

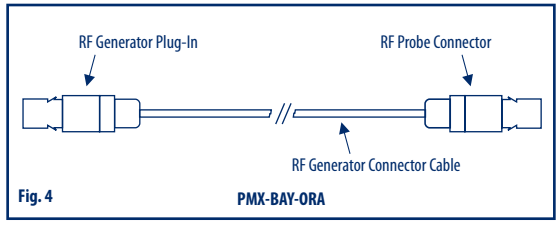


Fig. 4 **PMX-BAY-ORA**

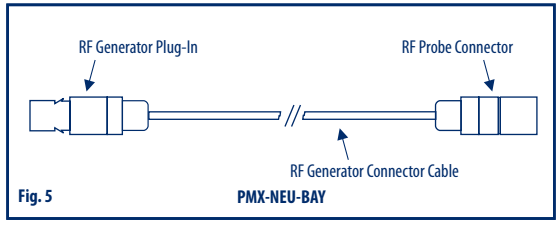


Fig. 5 **PMX-NEU-BAY**

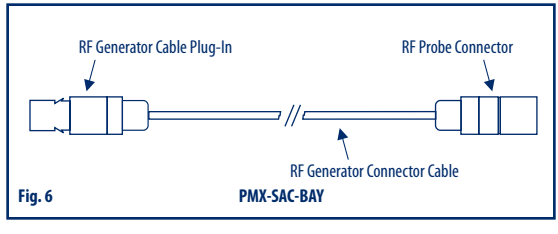


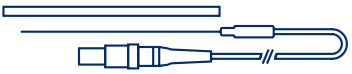
Fig. 6 **PMX-SAC-BAY**

NON STERILE	Non-Pyrogenic	Rx Only	Attention: See Instructions for Use	Dispose of Properly

Kimberly-Clark*

Radiofrequency Nitinol Probe & Radiofrequency Generator Connector Cable

Pain Management



Instructions for Use

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076 USA
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