Kimberly-Clark*

SINERGY* Cooled Radiofrequency Kit

Pain Management

Instructions for Use

Kimberly-Clark

*Trusted Clinical Solutions**

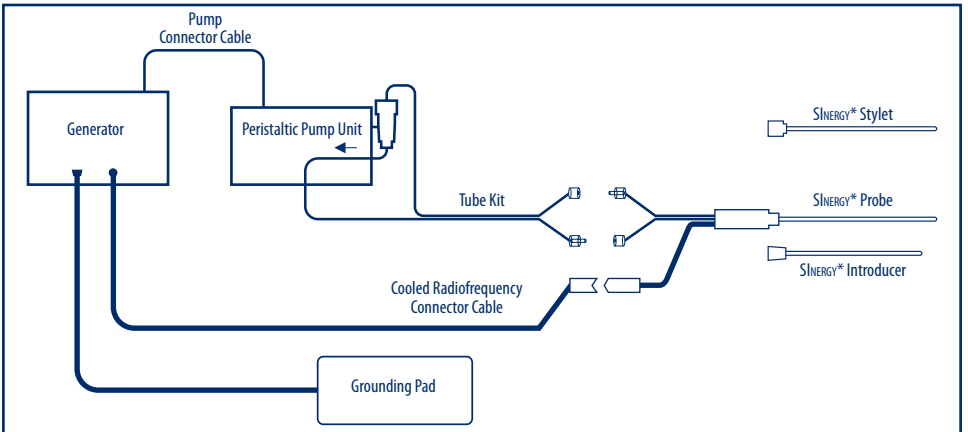

Fig. 1 **Monopolar System**

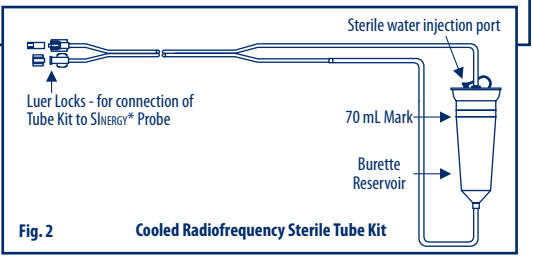

Fig. 2 **Cooled Radiofrequency Sterile Tube Kit**

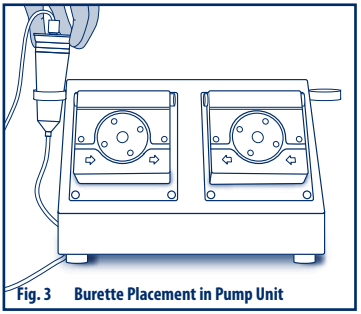

Fig. 3 **Burette Placement in Pump Unit**

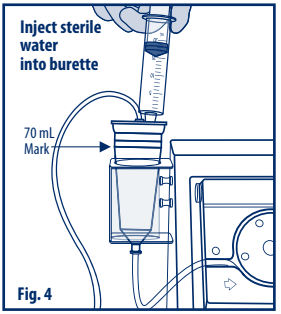

Fig. 4

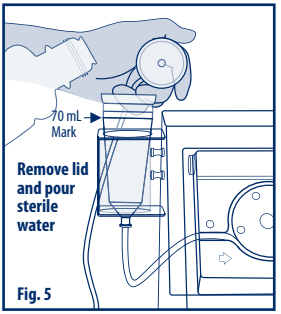

Fig. 5

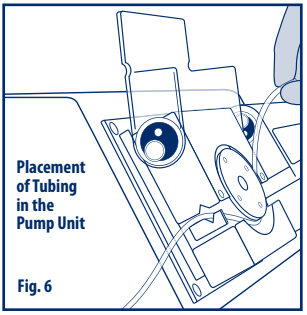

Fig. 6

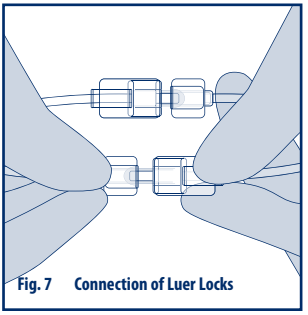

Fig. 7 **Connection of Luer Locks**

Single Use Only	STERILE EO	Do Not Use If Package Is Damaged	Rx Only	Attention: See Instructions for Use
Upper Limit of Temperature	Keep Away from Sunlight	Dispose of Properly	CE 0086	

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

Device Description

KIMBERLY-CLARK* Cooled Radiofrequency Sterile Tube Kit (sterile, single use, non-body contact): It is used for closed-loop circulation of sterile water through a KIMBERLY-CLARK* SINERGY* Cooled Radiofrequency (RF) Probe. It includes a burette and tubing.

KIMBERLY-CLARK* SINERGY* Cooled Radiofrequency Introducer (sterile, single use): It is to be used with the KIMBERLY-CLARK* SINERGY* Probes only. The SINERGY* Introducer provides a path for the SINERGY* Probe to the nervous tissue.

KIMBERLY-CLARK* SINERGY* Cooled Radiofrequency Probe (sterile, single use): It is inserted through a SINERGY* Introducer into or near nervous tissue. Sterile water circulates internally to cool the SINERGY* Probe while it delivers radiofrequency energy. A thermocouple in the SINERGY* Probe measures cooled electrode temperature throughout the procedure.

KIMBERLY-CLARK* SINERGY* EPSILON* Ruler (sterile, single use): It is a stainless steel, circular, ruler with a 10 mm radius. It is placed on the skin over the treatment site during the procedure.

KIMBERLY-CLARK* Radiofrequency QUICKCLAMP* Device (sterile, single use): It is placed on the skin over the treatment site during the procedure. It can be optionally used to support the SINERGY* Introducer and Probe.

Indications for Use

The KIMBERLY-CLARK* SINERGY* Cooled Radiofrequency (RF) Kit, in combination with the KIMBERLY-CLARK* Radiofrequency (RF) Generator (PMG-115-TD/PMG-230-TD) (formerly Baylis Pain Management Generator) is indicated for use to create RF 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 a 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 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, it should be performed under local anesthesia.

Systemic infection or local infection in area of the procedure.

Blood coagulation disorders or anticoagulant use.

Warnings

The SINERGY* Kit contains single-use devices. Do not reuse, reprocess, or resterilize this medical device. Reuse, reprocessing, or resterilization may 1) adversely affect the known biocompatibility of the device, 2) compromise the structural integrity of the device, 3) lead to the device not performing as intended, or 4) create a risk of contamination and cause the transmission of infectious diseases resulting in a patient injury, illness, or death.

The SINERGY* Probe must be used with the correct connector cable. Attempts to use it with other connector cables can result in electrocution of the patient or operator.

Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency 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 safety and efficacy of the device.

When the 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 Probes, 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 SINERGY* Kit before thoroughly reading the accompanying Instructions for Use and the User's Manual for the RF Generator and KIMBERLY-CLARK* Dispersive Electrode (PMA-GP-BAY).

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 increase power level before checking for obvious defects or misapplication.

To prevent the risk of ignition, make sure that flammable material is not present in the room during RF power application.

Only physicians familiar with RF lesion techniques should use the SINERGY* Kit components.

It is the physician's responsibility to determine, assess and communicate to each individual patient all forseeable risks of the RF lesion procedure.

The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised.

Proper sterile techniques must be used when assembling and filling the Tube Kit. Do not place the lid down on a non-sterile surface.

The Tube Kit should never be disconnected from the Probe when RF delivery is in progress. The lumen of the Tube Kit should not be obstructed in any way during the procedure, as this will stop cooling of the Probe.

Disconnect the Probe by pulling the connector, not the cable.

Handle the Probe safely when it is in use due to electric currents and the hot tip.

KIMBERLY-CLARK* Cooled Radiofrequency Sterile Tube Kit

The Tube Kit is for use with a single SINERGY* Probe.

Care must be taken to ensure all luer fittings are secure to prevent leaking. Do not disconnect luer fittings while the pump is running.

Arrange equipment to minimize tubing tripping hazards.

Do NOT perform cooled RF lesion procedures if water is not circulating through the Tube Kit, water is leaking or air bubbles are seen in the tubing. Immediately stop the procedure and correct circulation before restarting the procedure.

Do NOT pinch the tubing of the Tube Kit.

KIMBERLY-CLARK* SINERGY* Cooled Radiofrequency Introducer

Be careful while handling the SINERGY* Introducer. The sharp tip can cause injury to the operator if handled carelessly.

Handle the Introducer safely when it is in use due to electric currents.

Do not move the Introducer without the stylet fully inserted.

Choose the properly sized Introducer.

KIMBERLY-CLARK* SINERGY* Cooled Radiofrequency Probe

While inserting the Probe through the SINERGY* Introducer watch the fluoroscope for any buckling. Do not attempt to further insert the Probe if any buckling is observed or significant resistance is felt.

Do not move the SINERGY* Introducer when the Probe is in it. If repositioning is needed, retract the Probe from the Introducer and then reposition the Introducer with the stylet inserted.

The "Cooled RF Temp" displayed on the RF Generator refers to the cooled electrode temperature and not the hottest tissue temperature.

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 Tube Kit is comprised of a burette and flexible tubing fitted with luer locks for connection to the SInergy* Probe.

The SInergy* Introducer includes an insulated stainless steel cannula and a stylet.

The SInergy* Probe is comprised of an electrically insulated shaft with an active tip that functions as an electrode for RF energy delivery, a handle, tubes with luer locks and a cable with a 7-pin connector.

The SInergy* Epsilon* Ruler is comprised of a circular stainless steel ruler with radius 10 mm and spoke length 10 mm.

The SInergy* Probe, SInergy* Introducer, Tube Kit, SInergy* Epsilon* Ruler and QuickClamp* Device are ethylene oxide sterilized and supplied sterile. The devices should be stored in a cool, dry environment.

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

Inspection Prior to Use

The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised.

Equipment Required

Procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit. The equipment required to perform RF procedures include:

- SInergy* Cooled Radiofrequency Probe
- SInergy* Cooled Radiofrequency Introducer(s)
- Cooled Radiofrequency Peristaltic Pump Unit and Cable
- Cooled Radiofrequency Sterile Tube Kit
- SInergy* Epsilon* Ruler (optional)
- Radiofrequency QuickClamp* Device (optional)
- Cooled Radiofrequency Connector Cable
- Dispersive Electrode
- Radiofrequency Generator (PMG-115-TD/PMG-230-TD)

Instructions for Use
Monopolar System (Fig. 1)

Assemble all the equipment required for the procedure. Set up the Radiofrequency Generator (PMG-115-TD/PMG-230-TD) and the Pump Unit, as directed in their Instructions for Use. Connect the Connector Cable to the RF Generator as described in its Instructions for Use.

Open the package in the sterile field using appropriate sterile techniques. Inspect the devices visually to make sure there is no damage to them. Do NOT perform the procedure with any damaged equipment.

Kimberly-Clark* Cooled Radiofrequency Sterile Tube Kit (Fig. 2)

1. Place the burette into the burette holder on the side of the Pump Unit. The side of the burette with 2 or 3 ports indicates the top of the burette. **(Fig. 3)**
2. Fill the burette with room temperature sterile water. Use sterile handling techniques. Fill the burette to the 70 mL mark. Burette can be filled by injecting sterile water through a port in the lid, or by temporarily removing the lid and pouring sterile water in.
   Warning! BE SURE TO FILL THE BURETTE TO THE 70 mL MARK. Not filling the burette to the 70 mL mark will result in an inadequate supply of water for circulation.
   Use ONLY sterile room temperature water.
   Ensure the lid is snapped back onto the body of the burette after filling.
   Inject sterile water into burette OR remove lid and pour sterile water. **(Fig. 4-5)**
3. Place the thick-walled tubing coming out of the bottom of the burette into the pumphead of the Pump Unit. Place the tubing in the channels of the L-shaped bracket to ensure that the tubing is not obstructed while closing the pumphead. Close the lid on the pumphead to clamp down on the tubing. **(Fig. 6)**
4. Remove the caps on the male and female luer locks. Connect the appropriate luer lock to the corresponding luer lock on the Probe. Do not over tighten the connection.
   Caution! Connect one Tube Kit to one SInergy* Probe. **(Fig. 7)**
5. At the end of the procedure, discard the Tube Kit appropriately.

Kimberly-Clark* SInergy* Cooled Radiofrequency Introducer

1. With the stylet in the Introducer, carefully insert the Introducer into the patient using fluoroscopic guidance to place it at the desired lesion location.
2. Once the Introducer is in the proper position, carefully remove the stylet from the Introducer.
3. Repeat steps 1-2 with a second Introducer if necessary.

Kimberly-Clark* SInergy* Cooled Radiofrequency Probe

1. Insert the Probes into the tissue through the Introducer. Never force the Probe in if significant resistance is felt.
2. Attach the dispersive electrode to the RF Generator and place the dispersive electrode pad on the patient as directed in the Instructions for Use and User's Manual accompanying the package.
3. Connect the Probe to the Tube Kit.
4. Connect the 14-pin connector of the Connector Cable into the RF Generator. Connect the Probe to the 7-pin Connector on the Connector Cable.
5. Select the Treatment Mode in the RF Generator. Set advanced settings and the parameters for RF delivery in the RF Generator as described in the User's Manual.
6. Perform the procedure as described in the RF Generator User's Manual. The procedure comprises pre-cooling, treatment and optional post-cooling stages.
   Note: *Other than reproduction of their usual referred pain or irritation due to Probe introduction, monitor the patient for unexpected symptoms that may indicate, for example, spinal cord or nerve root irritation. If these indications are suspected, discontinue energy delivery.*
7. After treatment remove the Probes and the Introducer and discard as biohazards. Remove the Dispersive Electrode from the patient and discard appropriately. Disconnect the Connector Cable from the RF Generator. Follow standard hospital techniques to handle reusable items.

Troubleshooting

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

PROBLEM	TROUBLESHOOTING
No temperature measurement OR Inaccurate, erratic or sluggish temperature reading	Ensure all connections are made: • Probe(s) to Connector Cable • Connector Cable to the RF Generator • RF Generator to power outlet Check for an error message on the RF Generator Visually inspect the Probe or cable for damage. Ensure that devices are dry and at room temperature. If problem persists, discontinue use.
Water does not flow through the Probe and Tube Kit	• Stop the procedure immediately. • Check the luer lock connections to ensure the Tube Kit is connected to the Probe. • Check the pump to ensure the lid is not open. • Check RF Generator for any error messages.
Probe Connector does not fit in Probe Plug-in	Check that the connector's keys are lined up in the proper orientation. Ensure that the connectors are clean and unobstructed.
Damage to Insulation on Probe or Introducer	Do not use. Discard immediately.

PROBLEM	TROUBLESHOOTING
Water is not circulating through tubing during SINERGY* pre-cooling, ON and post-cooling states.	• Ensure the Tube Kit is correctly connected to the Probe. • Ensure the Tube Kit has been correctly placed in the pumphead. • Ensure the burette reservoir has been filled. • Visually inspect the Tube Kit tubing and joints for leaks and occlusions. • Ensure that the float ball in the burette is floating and not occluding the outflow of water from the burette. • Ensure the pump tubing (thick-walled tubing that is coming directly out of the bottom port of the burette) is placed in the pumphead.
Water is not dripping into the burette.	Check to see if water is running down the wall of the burette.
Float is stuck on bottom port of the burette.	Close the pumphead lid. Gently shake the burette to try and loosen the ball from the bottom of the burette.
The lid of the burette cannot be removed.	Inject sterile water through the port of the lid, rather than removing the lid.
Tube Kit breaks, is leaking or is occluded.	Immediately discard the Tube Kit.

Customer Service and Product Return Information

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

Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

Email: 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 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 Probes 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 above. Kimberly-Clark disclaims and excludes all warranties, whether expressed or implied, of merchantability or fitness for a particular use of 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.