Baylis MEDICAL

PAIN MANAGEMENT

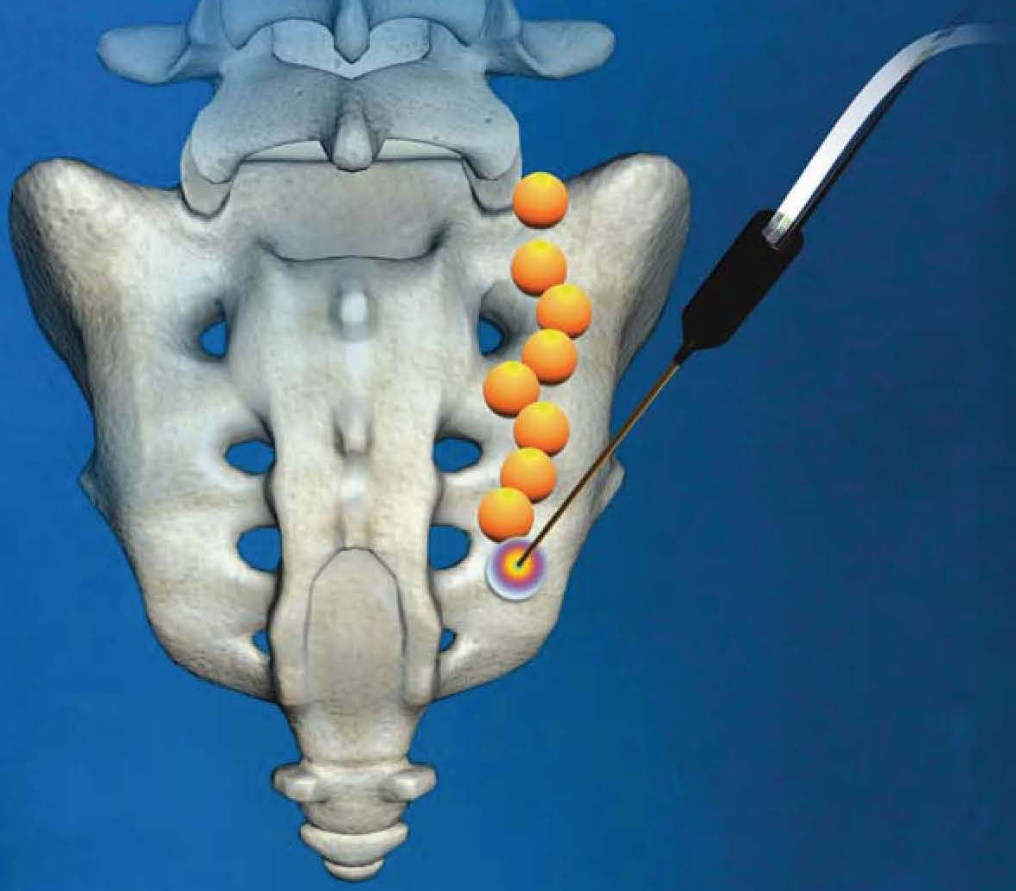
SInergy™ System

USER GUIDE

For effective denervation in the treatment of chronic sacroiliac joint pain

September 2008

PM1013 Rev 09/08



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2. Introduction

The Pain Management SInergy System, in combination with the Baylis Pain Management Generator (PMG-TD), is indicated for creating RF lesions in nervous tissue to treat patients with sacroiliac joint complex mediated pain. The procedure is known as sacroiliac joint radiofrequency neurotomy, and ablates the afferent nociceptive nerves Target structures include the lateral branches of the S1 though S3 dorsal roots and the dorsal ramus of the L5 dorsal root. These nerves are known to be responsible for sacroiliac joint complex mediated pain.

In this procedure, a Pain Management SInergy Introducer is placed at a point between the posterior sacral foramen and the sacroiliac joint. A Pain Management SInergy Probe is inserted through the introducer and into the tissue superficial to the posterior surface of the sacrum. Radiofrequency (RF) energy is delivered from and concentrated around the electrode. The electrode is internally-cooled with circulating water. RF energy heats the tissue while circulating water moderates the temperature in close proximity to the electrode. This combination creates large volume lesions without excessive heating at the electrode. Successive lesions are created by repositioning the introducer and electrode in a step-wise manner, until all lateral branches between the sacral foramina and the sacroiliac joint have been disrupted. For a list of equipment related to the Pain Management SInergy System, see Section 5.

A physician using this equipment must be familiar with lumbar-sacral spine anatomy, image-guided spine procedures and sacroiliac joint injection techniques.

Important Message

This guide does not replace the information in the Instructions for Use provided with the components of the Pain Management SInergy System. The Instructions for Use includes important information such as warnings, precautions, contraindications, and trouble shooting. The Instructions for Use for each component must be read prior to use.

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3. *Physics of the Pain Management SInergy System*

Overview

This section briefly explains how the SInergy System heats nervous tissue.
In this section you will learn:

- The reason why high frequency alternating current is used to heat tissue.
- The reason why the SInergy Probes are internally-cooled.

Direct Current & Alternate Current

Electric current refers to the amount of charge that passes through a surface per measure of time. At an atomic level, current is the flow of electrons. A current that moves in the same direction around a circuit is referred to as Direct Current (DC). A current whose direction alternates continuously back and forth is referred to as Alternating Current (AC) (see **Figure 1**). The number of times that the current alternates back and forth in a second is known as frequency. Frequency is measured in Hertz. For example 60 Hertz means that the current alternates back and forth 60 times per second.

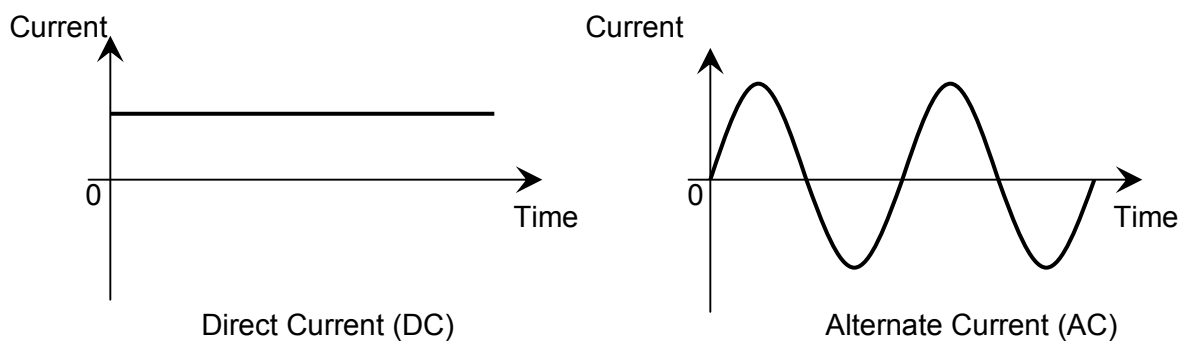

Figure 1: Direct Current (DC) and Alternate Current (AC) signal amplitudes.

Resistive Heating with DC

Electrical conductance is the property of a material that determines the ability of current to flow through it and is based on the availability of loose electrons in the material. Resistance is the opposite of conductance. Copper wire, for instance has high conductance and is a good conductor while rubber has low conductance and is a very poor conductor. Since rubber is a poor conductor, this means that it is a good resistor. In a resistor, as current passes through the material, energy is used. The harder it is to pass current through a material, due to lower conductance, the more energy is used. The energy that is used does not disappear but is converted to a different form of energy, often in the form of heat. The conversion of electrical energy to thermal energy by passing current through a material with resistance is called resistive heating. A good example of resistive heating is an electric toaster. The metal filament in the toaster is

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made of nickel and chromium, which has an ideal resistance to convert electricity to heat.

Biological tissue is not a very good conductor when using direct current. Resistive heat can be generated but the flow of current cannot be controlled easily and it can damage the cells. Using direct current to heat tissue may produce unpredictable tissue temperatures and irregular shaped lesions. Excessive temperatures would lead to burning of tissue, gas formation, and uncontrolled destruction of tissue[10].

Ionic Heating with AC

Another way electrical energy is converted to heat in tissue is by ionic heating. To overcome the drawback of direct current, use of alternating current for medical applications was pioneered by Cushing and Bovie in the 1920s, originally for hemostasis[8]. Later in the 1950s, Aranow and Cosman deployed alternating current for creating neural lesions[1]. Alternating current conducts through tissue with less resistance and more control than direct current. The greater the alternating current frequency, the greater the conductance[4]. Alternating current causes the charged molecules, or ions, in the tissue to follow the directional variation of the alternating current resulting in molecular vibration. The molecular vibration produces heat due to frictional forces.[7,9] This effect is called ionic heating.

The body is a complex system that uses electric current for a wide range of functions from regulating a heart beat to sending the sense of touch from a finger to the brain. If alternating current is applied to the body using frequencies similar to those used by the body, it can interfere with physiological functions causing unwanted effects. This is avoided by using a frequency beyond those used by the body. Alternating current with a very high frequency, in the order of 500 kHz, does not affect physiological functions.

RF Generators in the Market Today

Today, modern AC generators use a frequency between 400 and 600 kilohertz which is in the radiofrequency (RF) range and are generally referred to as RF generators. RF generators are now equipped with automatic temperature control and impedance monitoring. Temperature control allows for effective lesion formation whereas impedance monitoring detects changes in tissue resistance to electric current. Impedance monitoring also aids in electrode placement because impedance varies between different tissues[7,10]

Monopolar Electrode Systems

Monopolar System Physics

In medical applications RF current is delivered to tissue by an electrode usually on the end of a probe or insulated cannula. Ionic heating of tissue is a function of the current density, or current per unit area. RF current flows out of the electrode radially, and as a result, current density progressively decreases away from the electrode[2]. This is illustrated in **Figure 2**, where a circle represents an electrode, and arrows represent the current flowing radially from the electrode. The current, shown by the arrows is denser in areas closer to the electrode. Consequently, ionic heating is greatest at the proximity of the electrode and decreases with increasing distance. RF devices often contain temperature sensors. Note that the electrode itself does not heat up. Instead the tissue heats from ionic heating and the heat conducts back to the electrode[10], where the sensor indicates the tissue temperature local to the electrode. This decreasing gradient of

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current density limits the size of the heat lesion that can be produced. With a constant power a heat lesion will only grow to a limited size because the amount of heat created will come to equilibrium with the heat removed by the surrounding tissue and blood flow.

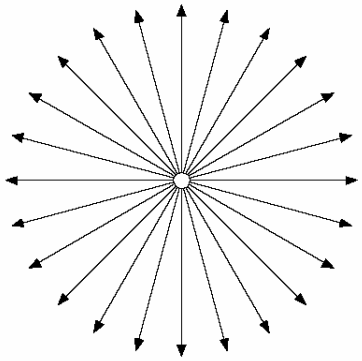

Figure 2*: Current density, represented by arrows, around an electrode, represented by the circle. Note how the tail ends of the arrows are more concentrated at the electrode and less dense as the arrows radiate away from the electrode.*

A way to increase the volume of tissue heated using RF is to increase the power. However, increasing power also has its limitations. As power increases, so does the temperature of the tissue in close proximity to the electrode. Exceeding 95°C may cause cavitations, tissue charring, and uncontrolled lesion formation. It has been demonstrated that tissue impedance (the measurement of tissue resistance to alternating current) decreases as the temperature increases, up to 60 to 70°C; further increase in temperature however, leads to a rapid increase in tissue impedance[3]. As tissue impedance increases at high temperatures the further flow of current becomes more difficult and harder to control.

Internally-Cooled RF Systems

Another means of increasing the volume of the lesion is by using internally-cooled RF electrodes. This technique was first proposed by Wittkampf in 1988[12]. The hollow lumens of internally-water cooled probes permit continuous cooling of the electrode with a fluid. Internally-cooled RF electrodes act as heat sinks that remove heat from tissue adjacent to the electrode. Consequently, time, duration, or power deposition can be increased during the procedure without causing high impedance and tissue charring around the electrodes[11]. As a result, internally-cooled electrodes can produce much larger lesions compared to non-cooled electrodes[6]. Furthermore, the tissue in proximity to the electrode does not need to be as hot in order to reach target temperatures at greater distances away from the electrode (**Figure 3**).

The water used for circulation in cooled RF lesions need only be room temperature. When used for cooled RF, water temperatures of 5°C have been shown to not significantly affect lesion size in *ex vivo* hepatic ablations compared to water temperatures of 25°C[5]. However, increasing flow rate of the coolant has been demonstrated to significantly affect lesion size[13].

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In summary, by cooling the tissue adjacent to the electrode with cool water, a larger volume lesion can be created. This is accomplished by increasing the time of the procedure, or the energy output of the RF generator.

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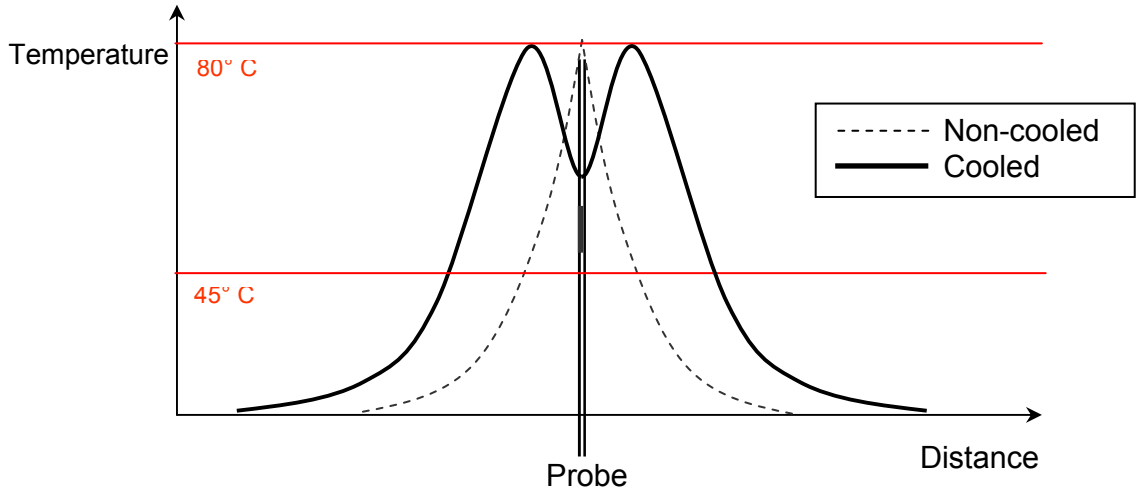

***Figure 3**: Temperature distribution of non-cooled and cooled RF electrodes.*

The circulation of coolant through an electrode also affects the shape of the lesion.
A monopolar cooled RF electrode, for example, can be designed to create a lesion that is either spherical or elliptical in shape. A portion of this lesion can project distally from the probe, heating tissue that might otherwise be difficult to access.
These distinct lesion characteristics allow perpendicular electrode placement towards the target. In the case of the spherical lesion created by the SInergy System, varying degrees of obliquity will have no effect on the orientation of the lesion (**Figure 4**).

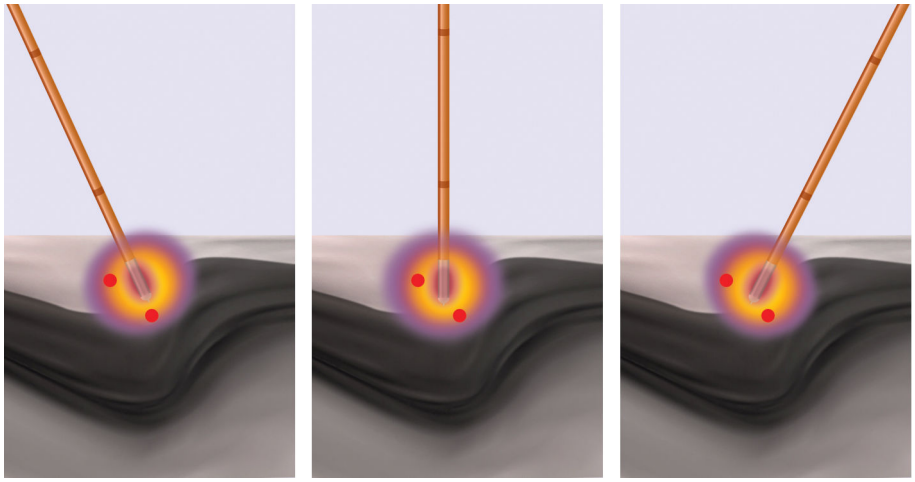

***Figure 4**: Spherical lesions allow perpendicular or oblique placement towards the target structure.*

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4. Benefits of the Pain Management SInergy System

Internally-Cooled for Greater Power Applications
The SInergy System electrodes are internally-cooled which allows for greater power to be delivered. Increasing power enables the creation of large-volume, spherical lesions. When these lesions are positioned appropriately, the inherent variability of nerve target location can be overcome in a practical and efficient manner.

Temperature Control
Temperature sensors at the electrode tips allow the RF generator to control the power delivery and the rate of internal electrode cooling. In this manner, lesion shape and size will remain consistent. This is particularly important in an area of the anatomy that contains multiple tissue types near the target structure. Note that the temperatures at the electrode tips are reflective of the surface of the cooled electrodes, and not the maximum lesion temperature.

Spherical Lesions
The spherical shape of the lesion allows perpendicular, oblique or parallel approaches towards the target structure. The distally projecting portion of the lesion will form around ridges, and within crevices on irregularly shaped surfaces.

Safe & Easy Placement
Placement of the SInergy probes is straight-forward and results in minimal disturbance to the overlying soft tissue. Introducers and electrodes are directed at the target using a "down the beam" perpendicular approach. To reposition towards adjacent targets, the introducer is retracted slightly and pivoted about the skin, rather than creating additional skin punctures.

Summary of System Benefits

The SInergy System creates reproducible, large volume lesions by utilizing:

- Temperature controlled radiofrequency energy application
- Internally-cooled electrodes
- Application specific electrode design
- Impedance monitoring
- User-friendly design and interface

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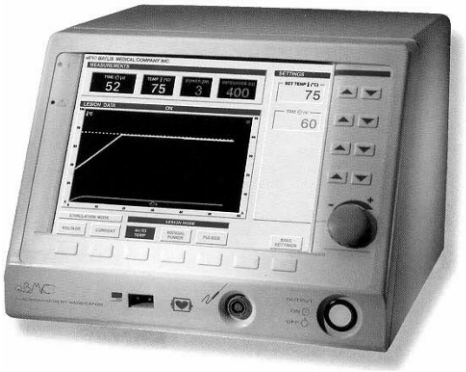
5. *Technical Description of the Equipment*

Overview

In this section you are going to learn about all of the components of the SInergy System. You will learn the function of each device and the relationship of the device within the system.

Baylis Pain Management Generator (Model PMG-TD V2.2 or higher)

Important features:



- A software-based, computerized radiofrequency generator.
- Several safety features are incorporated into the control algorithm. For example, the generator can detect broken or improperly set-up equipment and give appropriate error messages.
- It is designed to power and control the pump unit, and provide automatically controlled parameters designed for the procedure.

Pain Management Pump Unit (Model TDA-PPU-1)

Important features:

- The pump unit circulates sterile water through the SInergy Probe. This is achieved via closed-loop fluid circuit. The closed-loop fluid circuit includes a Pain Management Tube Kit and a SInergy Probe.
- The Pain Management Pump comes with a connector cable which connects it to the generator (PMG-TD) for power and speed control.

Pain Management Cooled RF Connector Cable (Model: CRX-BAY-CRP)

Important features:

- Used to connect SInergy Probe to the generator.
- Provides access to the Cooled RF mode in the generator.
- Transmits RF energy from the generator to the probe.
- Transmits signals from the temperature sensor in the probe to the generator.

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Pain Management SInergy Probe (Model SIP-17-150-4 and SIP-17-75-4)

Important features:

- One probe is required for a procedure.
- The probe delivers RF energy, creating a spherical lesion centered about the active tip.
- Sterile water is circulated internally within the electrode during the procedure, which cools the electrode. The sterile water is contained and does not contact patient tissue.
- Each probe has a temperature sensor at the distal end of the electrode. The temperature sensor measures temperature and provides control of RF energy delivery throughout the procedure.
- Each probe includes a 4' cable and tubing extension to reach out of the sterile field.

Pain Management SInergy Introducer (Model SII-17-150 and SII-17-75)

Important features:

- An introducer is comprised of a fully-insulated cannula and a sharp trocar-tipped stylet.
- The 17-gauge introducer allows for accurate placement of the probe.

Pain Management Tube Kit (Model TDA-TBK-1)

Important features:

- One tube kit is required for a procedure.
- It is used for circulation of sterile water through the SInergy Probe for the purpose of cooling the electrode.
- The Pain Management Pump Unit pumps water through the tube kit. The Tube Kit comprises medical grade tubing and a burette that holds sterile water.

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Pain Management *Epsilon*™ Ruler
(Model SIA-E10)
Important Features:

- Open, circular, stainless steel ruler with a 10 mm radius and 10 mm central spoke length.
- Used during the procedure to measure a safe distance between the sacral foramina and the electrode.

6. Patient Selection

Candidates for sacroiliac joint neurotomy must have a history of chronic sacroiliac joint complex pain for at least 6 months, and meet the selection criteria. It is important to adhere to these criteria for the safety of the patient and success of the treatment. The physician must be trained to diagnose sacroiliac joint complex mediated pain.

Selection Criteria

Candidates for the Sacroiliac Joint Neurotomy procedure must meet the following inclusion criteria.

- Predominantly axial pain below the L5 vertebrae
- Greater than 80% pain relief from two separate intra-articular blocks with no more than 2cc of injectate per block. It is recommended to use higher concentration anesthetic such as 0.75% bupivacaine or 4% lidocaine for a more effective block.
- Chronic axial pain lasting for longer than six months.
- Age greater than 18 years.
- Failed to achieve adequate improvement with comprehensive non-operative treatments, including but not limited to: activity alteration, non-steroidal anti-inflammatory, physical and/or manual therapy, and fluoroscopically guided steroid injections in and around the area of pathology.
- All other possible sources of low back pain have been ruled out, including but not limited to: the intervertebral discs, the zygapophyseal joints, the hip joint, symptomatic spondylolisthesis, and other regional soft tissue structures.

Candidates for the Sacroiliac Joint Neurotomy procedure will be excluded if they meet any of the following criteria:

- Pregnancy
- Systematic infection or localized infection at the anticipated introducer entry site
- History of coagulopathy or unexplained bleeding
- Irreversible psychological barriers to recovery
- Active radicular pain / radiculopathy
- Immunosuppression

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7. *Setup Instructions*

Overview

The following section outlines the procedure for setting up the Pain Management SInergy System. We have provided two set-up guides:

- Quick Start Equipment Set-Up designed for users who have previously handled the equipment.
- Detailed Equipment Set-Up designed for users who are using the system for the first time.

Equipment Set-Up Diagram

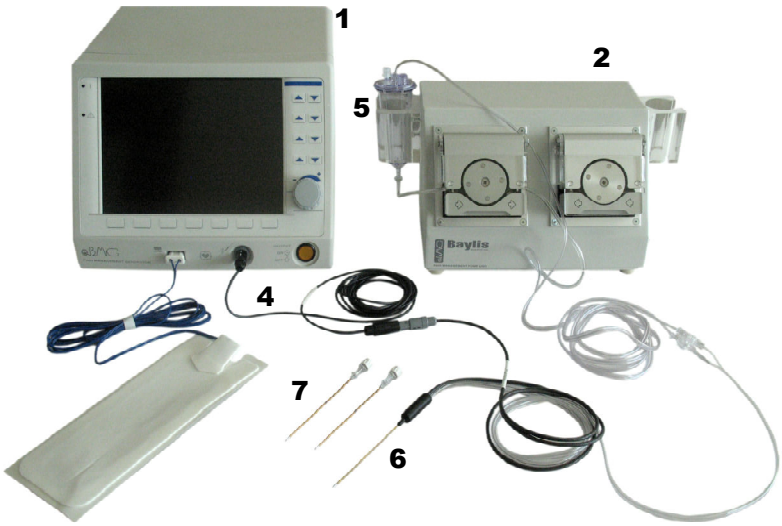
The Pain Management SInergy System consists of:

Reusable Equipment:

1. Pain Management Generator V2.2A or higher
2. Pain Management Pump Unit
3. Pump Connecting Cable (not shown)
4. Pain Management Cooled RF Connector Cable

Disposable Kit:

5. One Pain Management Tube Kit
6. One Pain Management SInergy Probe
7. Two Pain Management SInergy Introducers
8. Two Pain Management Epsilon Rulers (not shown)



Quick Start Equipment Set-Up

1. Connect the Generator to the Pump Unit
2. Plug in the Generator and turn it on
3. Insert one Pain Management Tube Kit into the Pain Management Pump Unit
4. Fill the burette with sterile water
5. Connect the Cooled RF Connecting Cable to the Generator
6. Place the introducer and probe in the patient.
7. Connect probes to Pain Management Tube Kit
8. Connect the probe to the Cooled RF Connecting Cable

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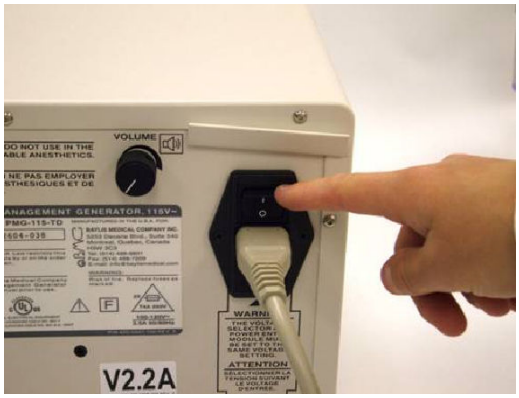
Detailed Equipment Set-Up

1. **Connect the Generator to the Pain Management Pump Unit**
   - Connect the male connector of the Pain Management Pump Connector Cable to the generator.
   - Connect the female connector of the Pain Management Pump Connector Cable to the Pump Unit.
   - Push the connectors as far in as possible, and then tighten by turning the collar clockwise.

2. **Plug in the Generator**
   - Plug the power cord into the Pain Management Generator, and connect the generator directly to a grounded receptacle.
   - Turn the generator on.



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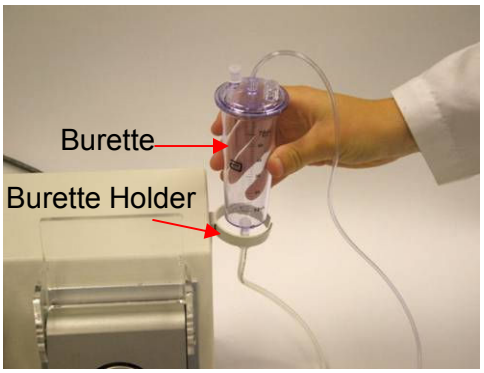
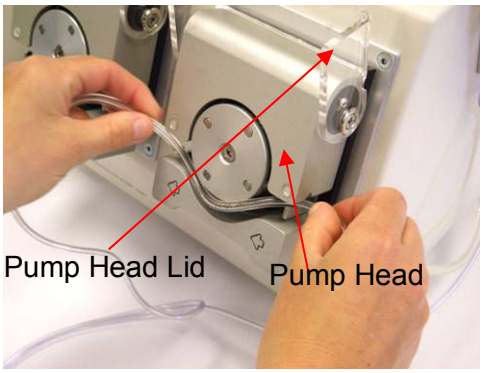
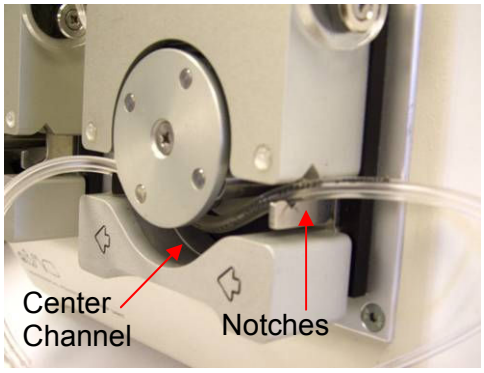
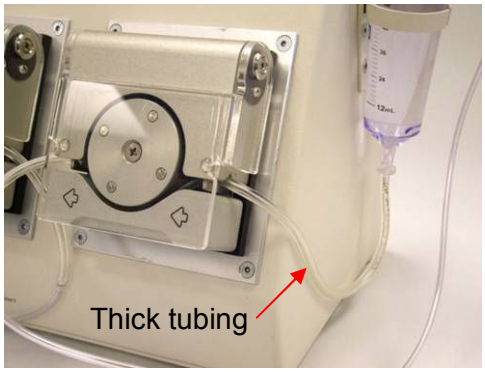
3. **Insert Tube Kits into the Pain Management Pump Unit**
   - Remove the Pain Management Tube Kit from the sterile package.
   - Put the burette into the Pump Unit's burette holder.
   - Open the pump head lid and thread the thicker tubing from the <u>bottom</u> of the burette into the pump head tube holder.
   - Ensure that the tubing is properly placed between the notches and along the center channel beneath the pump head. Improper positioning of the tubing can pinch the tube and restrict the water flow.
   - Close the lid in order to hold the tubing in place. Leave the luer lock caps on the tubing until you are ready to connect the probes so the inner pathway of the tube kit remains sterile.









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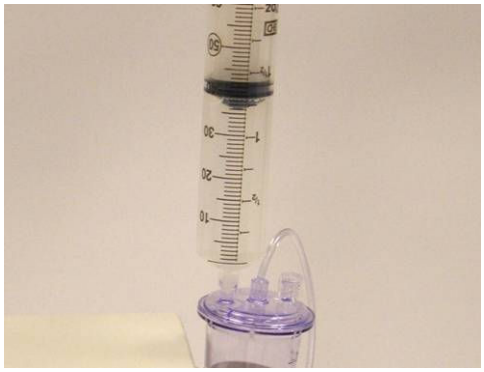
4. **Fill the burette with sterile water**

Fill the burette to the 70 mL mark with room temperature sterile water by a) injecting through the port in the lid or b) removing the lid and pouring the sterile water into the burette.

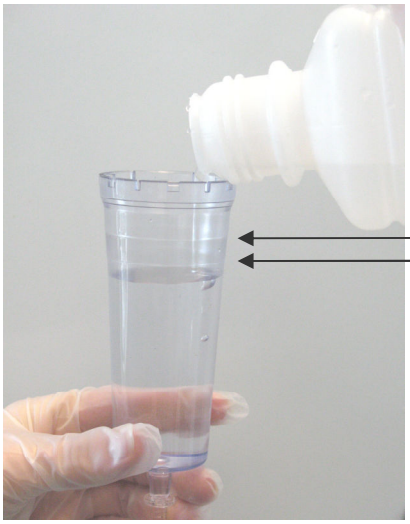
a) Inject sterile water through the port in the lid

- Remove the cap of the burette.
- Using a sterile syringe, fill the burette with 70 ml of sterile water at room temperature.



b) Remove the lid and pour sterile water into the burette

- Open the lid by pressing in and up with your thumbs around one of the three petals.
- Observe proper sterile handling technique while filling the burette; do not place the lid of the burette down on a non sterile surface.
- The fill lines on the burette represent 70mL and 80mL respectively.
- After filling to between the lines, snap the lid back into place on the burette.
- Note that not all burettes have removable lids. In this case, fill the burette by injecting water through the port in the lid.



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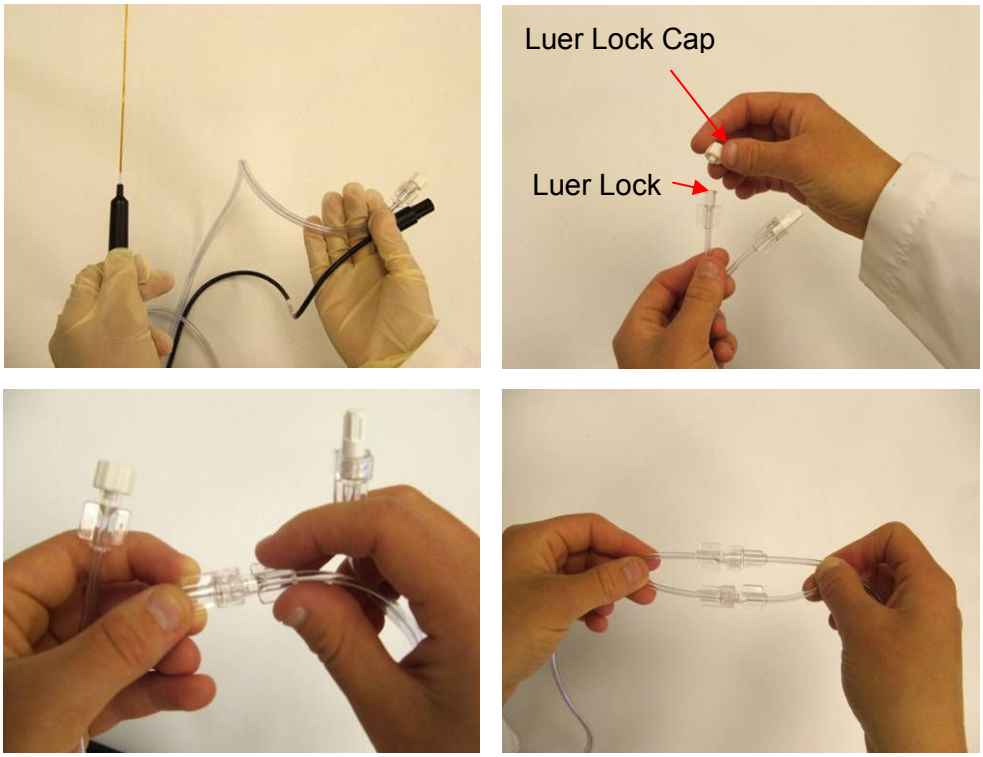
5. **Place the introducer and probe in the patient**
   - Prepare the patient and place the SInergy Introducer and Probe– See Section 8 for Placement Guidelines.

6. **Place the Dispersive Electrode on the patient**
   - Place the Dispersive Electrode on the patient according to the Instructions for Use provided with the kit.

7. **Connect probes to Pain Management Tube Kits**
   - Pass the tubing and electrical connections on the probe out of the sterile field.
   - Remove the caps from the two luer locks on the SInergy Probe and the Tube Kit. Connect the luer locks snugly. Maintain sterility of the tubing's inner pathway so in case water is accidentally spilled in the sterile field, sterility will not be compromised.



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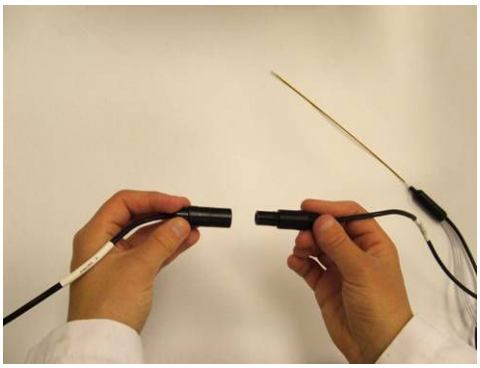
8. **Connect the probes to the Cooled RF Connecting Cable**
   - Connect the male connectors on the SInergy Probes to the female connectors on the Cooled RF Connecting Cable.
   - Connect the Cooled RF Connecting Cable to the generator



9. **Connect the Dispersive Electrode to the Generator**

Now the equipment set-up is complete!

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8. *Procedure Guidelines*

Overview

This section describes the positioning of the introducers and probe within the patient. In this section you will learn:

- The general safety guidelines for placement
- Brief lumbar-sacral anatomy with fluoroscopic and photographic images
- Step-by-step placement technique

General Safety Guidelines

For safe and effective tissue heating and safe anatomical access abide by the following guidelines:

- For L5 dorsal ramus neurotomy the electrode should be directed at the dorsal surface of the notch between the sacral ala and the superior articular process of the sacrum. On a lateral fluoroscopic view, the introducer should be no further ventral than the anterior-posterior midline of the superior articular process (SAP). Placement more superior/ventral to the target point brings the electrode closer to the segmental nerve root, and increases the risk of inadvertent heating of this structure.

- For S1 – S3 lateral branch neurotomy, the electrode should be placed such that the active tip is at least 7 mm from the edge of nearest posterior sacral foramina. This electrode placement will ensure that there is no heating at the sacral canal. Electrode depth should be confirmed with lateral fluoroscopy prior to lesion creation. This will verify that the electrode is located superficial to the sacral surface, and confirm that it has not slipped into the nearest posterior foramen.

- For all targets, the introducer should be directed towards the target site until the tip is in contact with bone. When the stylet is removed and the electrode is inserted, there will be a 2 mm gap between the active tip and bony endpoint. This will achieve the appropriate electrode depth for treatment. Ensure that the probe is seated firmly in the introducer before proceeding.

- The stylet should always be replaced in the introducer prior to repositioning. The electrode is not designed to create new pathways through the dense connective tissue along the surface of the sacrum.

- Ensure that the electrode does not make physical contact with the “finder” needle during RF delivery.

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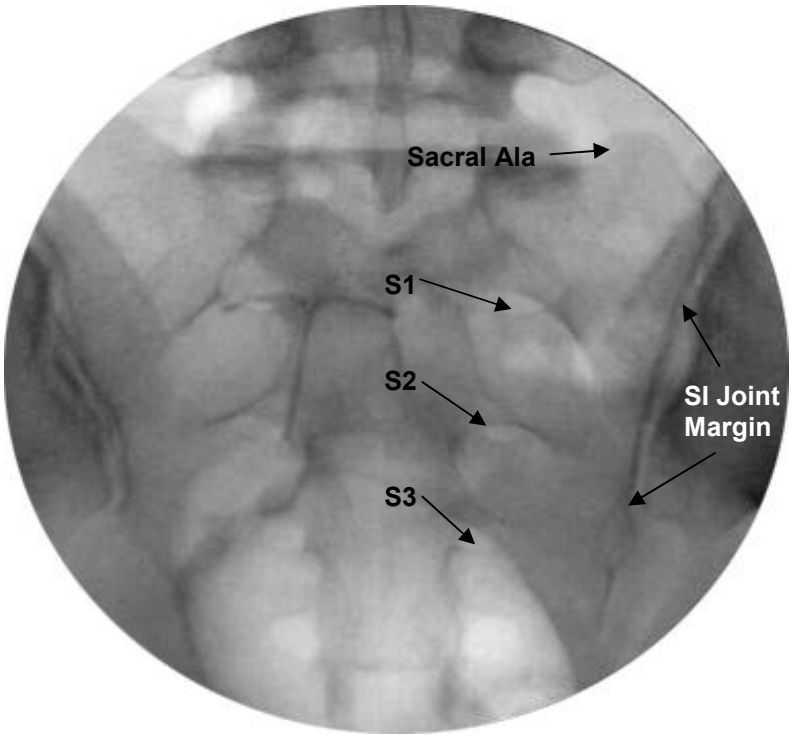
Lumbo-Sacral Anatomy



Fluoroscopic Image: This is an A-P view of a lumbo-sacral spine, showing the SI joint margin, the sacral foramina, and the sacral ala

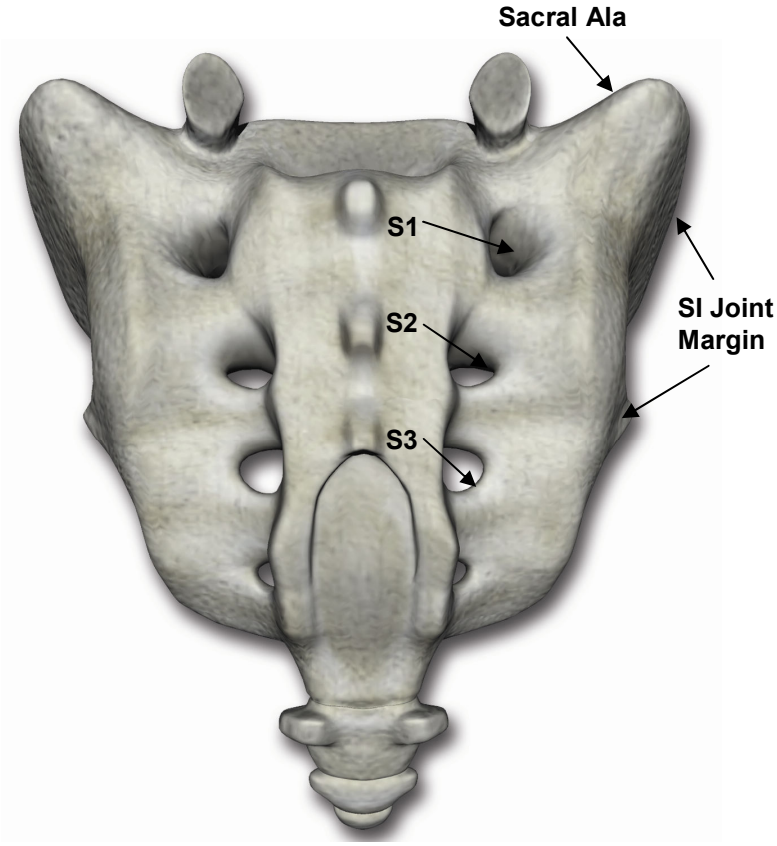


Illustration of Sacrum: Compare the above image with this illustration of the posterior sacral surface.

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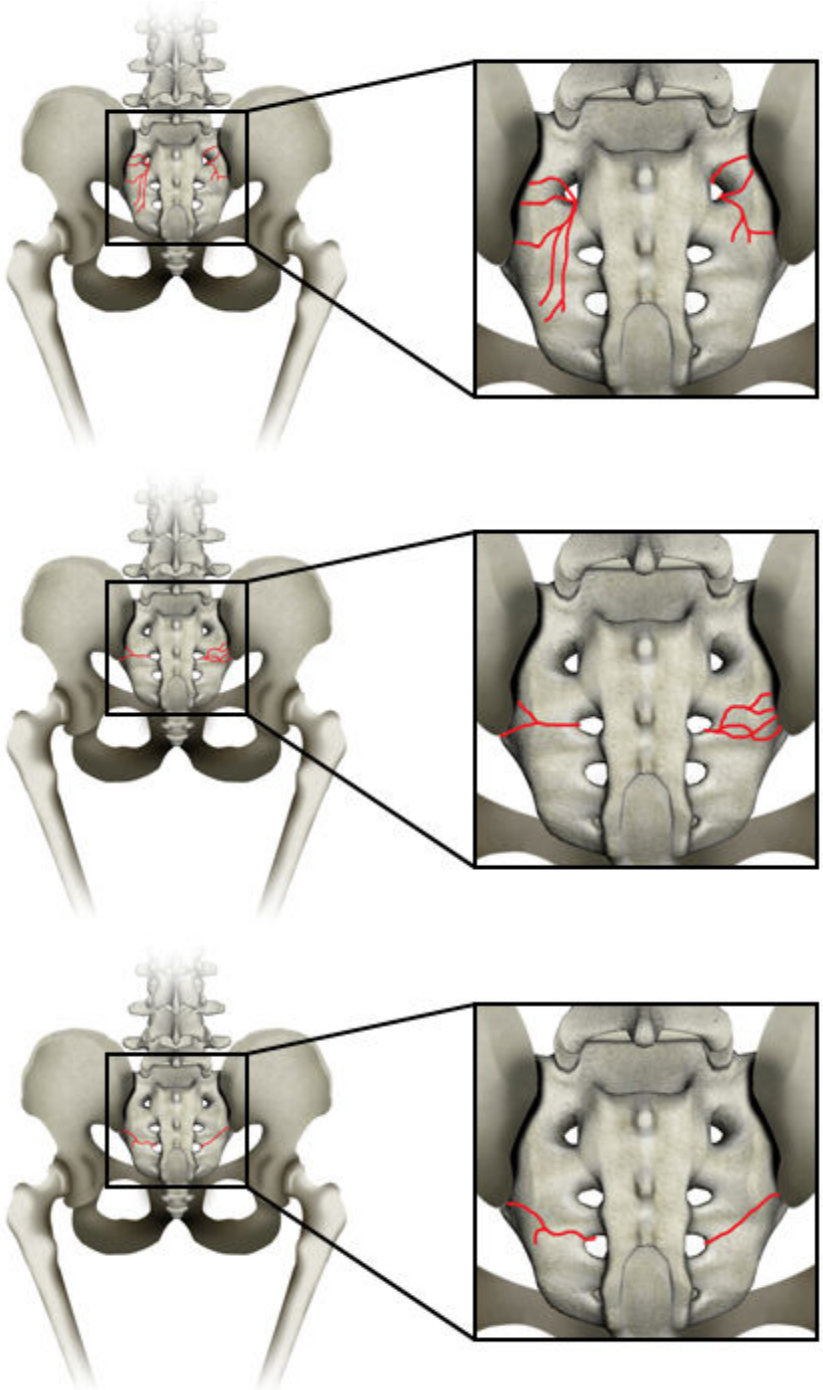
Sacroiliac Joint Innervation

Lateral branches of the posterior rami are responsible for relaying nociceptive signals from the SIJ and the surrounding structures to the CNS. Anatomical studies suggest that the number and running course of these lateral branches is variable[14]. This is demonstrated not only between specimens, but also from side to side, and from level to level. There exists no correlation between nerve location and the bony landmarks identifiable under fluoroscopy. This variability presents a challenge for clinicians seeking to treat sacroiliac joint syndrome.



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Procedure Preparation

- The patient should be N.P.O. prior to the procedure. Bowel prep is encouraged for enhanced imaging quality, but is optional based on physician preference. Prophylactic antibiotics can be administered prior to the procedure based on physician preference. Place the patient in the prone position on the table.

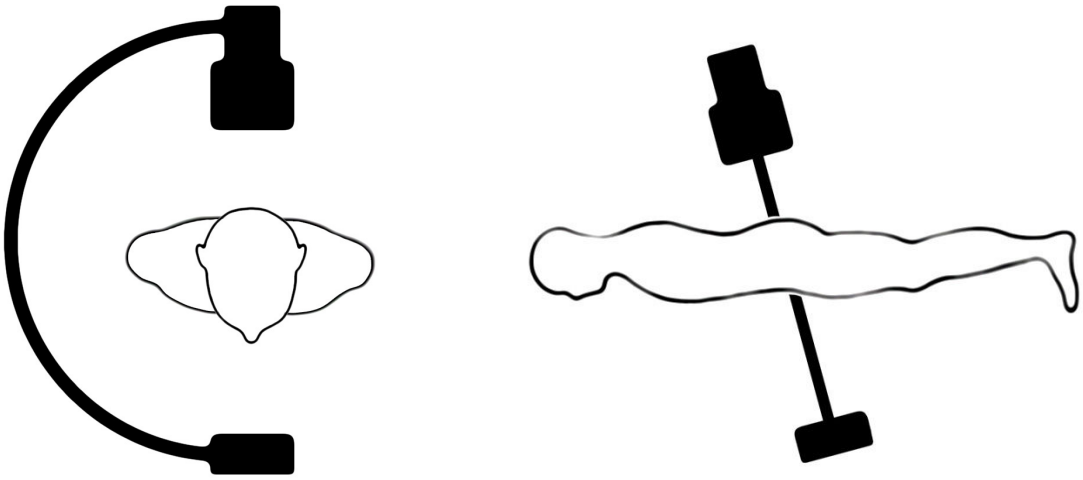
- The patient must be monitored properly throughout the procedure using verbal communication as well as equipment to measure heart rate, blood oxygen level, and blood pressure.

- As with any minimally invasive technique, adhere to sterile procedural practices.

- Prepare the site with sterile draping to maintain sterility of the lower lumbar and sacral area.

- The procedure is conducted with the aid of fluoroscopic guidance. Precautions should be taken to minimize exposure to radiation.

- Ensure the patient is comfortable and the appropriate pharmacological pain therapy has been administered. This may constitute intravenous sedation, oral analgesics, or other methods depending on physician and institution preference. The patient should be relaxed and able to communicate throughout the procedure. General anesthesia should be avoided.



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Sacroiliac Joint Neurotomy: Procedural Technique

A technique for lesioning the lateral branches of the S1 thru S3 dorsal roots using the Pain Management SInergy System is provided.. Subsequent pages detail a technique for lesioning the L5 dorsal ramus using the same equipment.. Fluoroscopic images provided courtesy of Dr. Robert E. Wright, Denver Pain Management, and Dr. Paul Dreyfuss, Washington Interventional Spine Associates.

Sacroiliac Joint Neurotomy: S1 – S3 Lateral Branches

1. Obtain an anterior-posterior (A-P) fluoroscopic image by aligning the L5-S1 vertebral end plates. The S1, S2 and S3 posterior sacral foramina should be identifiable. If not, the image can be rotated 10-15 degrees in the ipsilateral direction, or as required, in order to better visualize the posterior sacral foramina.

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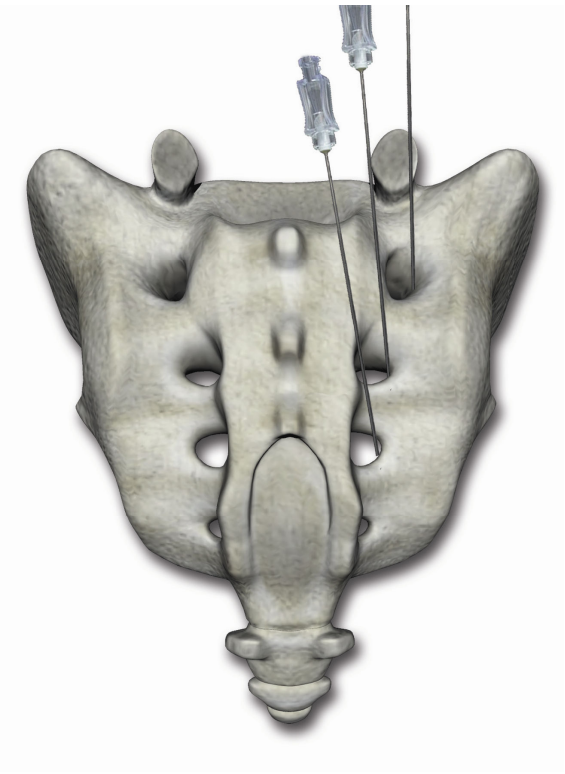
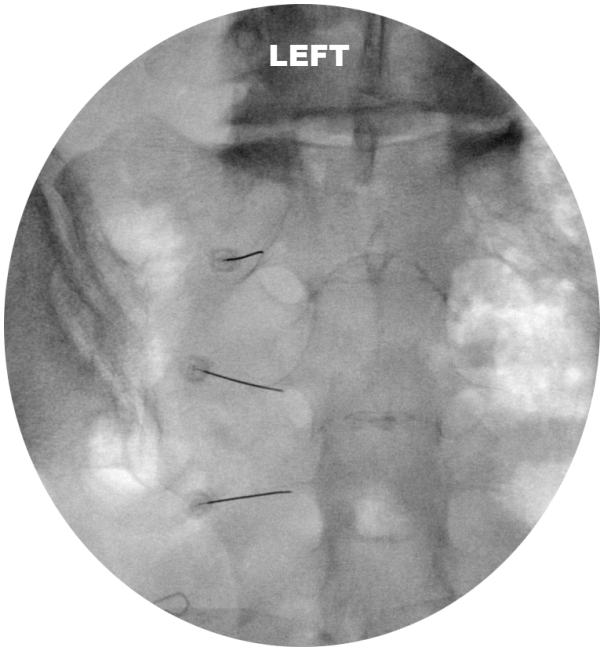
2. A thin-gauge needle is gently placed along the inside lateral aspect of each S1, S2 and S3 sacral foramina until it has entered the posterior aspect of the sacral canal. The purpose of this finder needle is to act as a reference point for the placement of the introducer and the probe in the absence of reliable bony landmarks.





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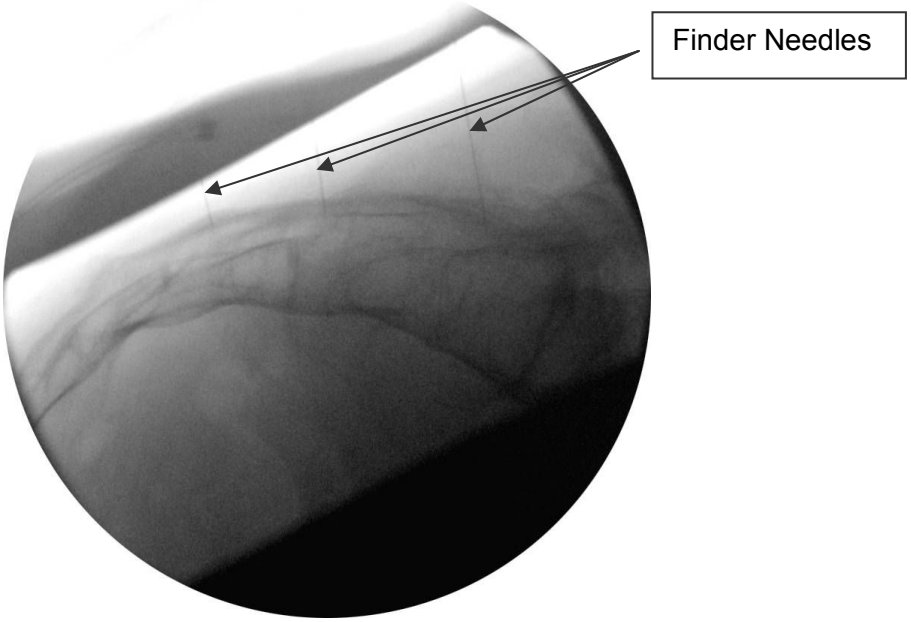
3. It is important to confirm that the finder needles are in the sacral foramina by rotating to a lateral fluoroscopic view. The tip of the needle should be visible in the sacral canal. The finder needles are then withdrawn until the tip of each needle is marking the posterior aspect (or opening) of the sacral canal.



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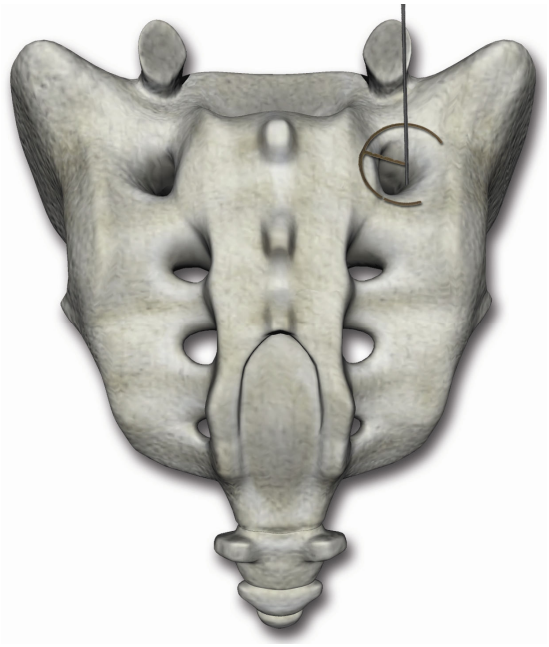
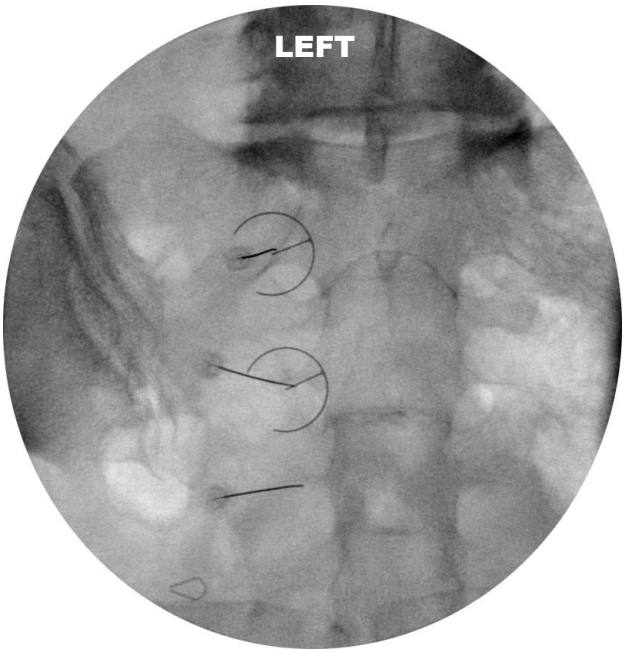
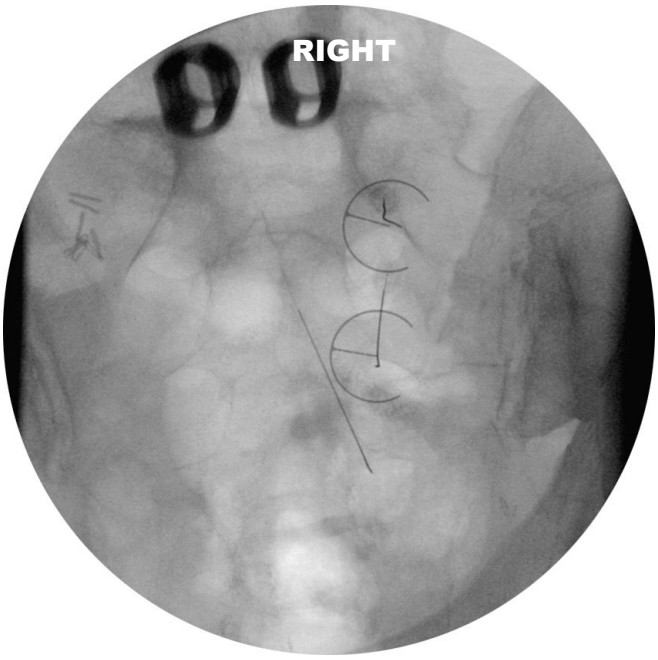
4. Obtain an A-P fluoroscopic image. Place an Epsilon ruler on the skin near the insertion site such that the central spoke is aligned with the lateral border of the S1 foramen, as marked by the tip of the finder needle. The Epsilon ruler is a small stainless steel ruler which projects linear distance onto the sacrum and provides a reference for appropriate lesion spacing. Surgical tape can be used to help secure the Epsilon to the surface of the skin. Consider the tip of the marker needle as representing the center of a clock face. Rotate the Epsilon ruler around this point such that the upper spoke is marking a location equivalent to 2:30 for right sided treatment, or 9:30 for left sided treatment.







IMPORTANT NOTE: Similar to other fluoroscopic measurement techniques, the Epsilon ruler will experience some degree of parallax error. This is because the sacrum and the Epsilon are at different 'depths' with respect to the image intensifier. To minimize y-parallax error (experienced as distortion of the shape of the ruler when it is tilted) both the Epsilon ruler and the patient's sacrum should be perpendicular to the beam of the emitter during placement. In other words, the Epsilon should be flat on the patient's skin, and the image should be A-P.

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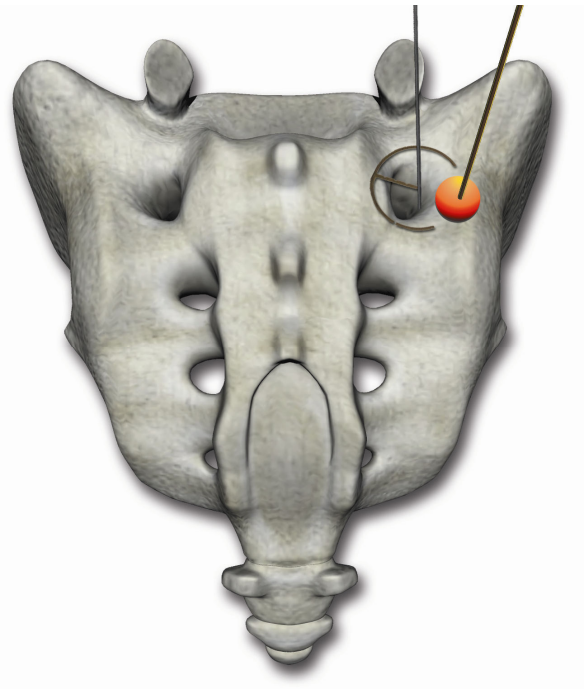
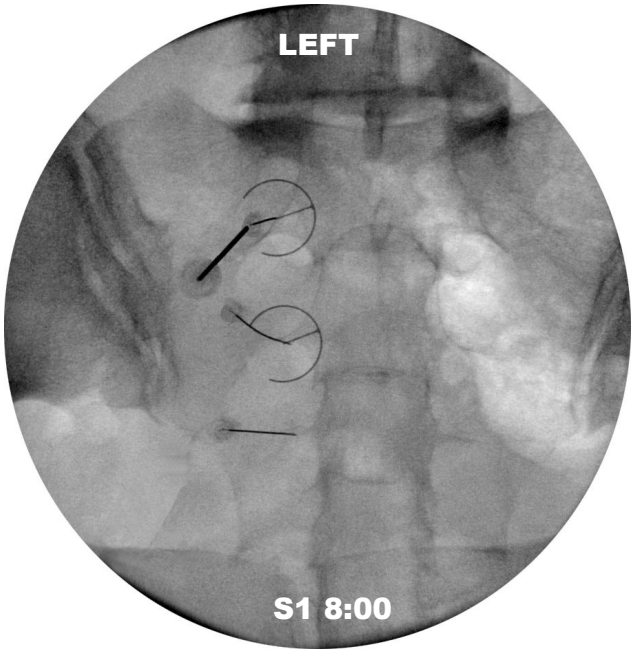
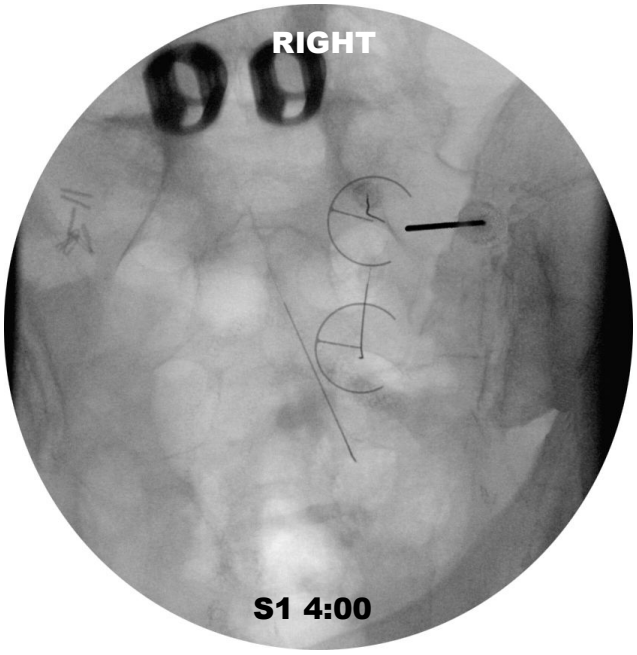
5. The first target location with the Cooled-RF probe is 7 to 10mm lateral and slightly inferior to the S1 finder needle. On the clock face, this corresponds to a 4 o'clock position (8 o'clock for left sided treatment). With the use of the Epsilon ruler as a guide, direct the introducer perpendicularly, "down the beam" until the stylet has made firm contact with the dorsal sacral surface. Note that the ligamentous tissue along the surface of the sacrum can be dense and difficult to penetrate.







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6. Confirm the depth of the stylet and introducer by rotating the image to a lateral view. The stylet and introducer should be at the sacral surface and must not have slipped into the sacral foramina. Not infrequently, especially at S1, one needs to advance further through very tough tissue to obtain the target position.

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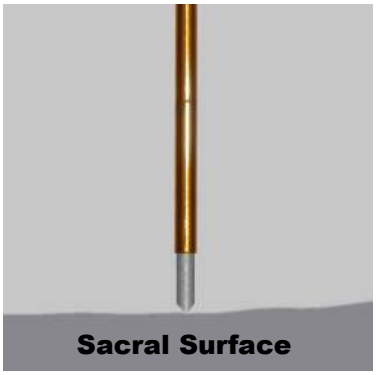
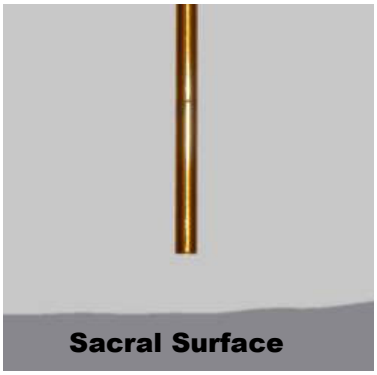
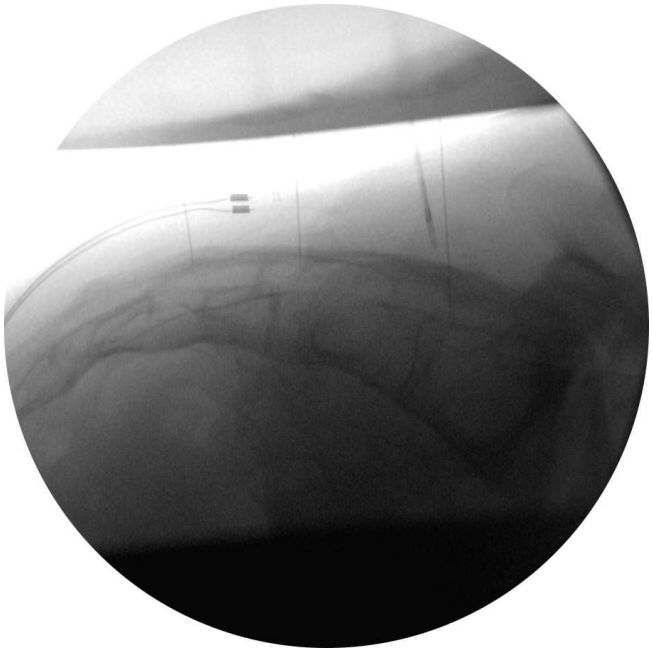
7. Rotate the C-arm back to an A-P view. Remove the stylet from the introducer. A small volume (less that or equal to 1cc) of local anesthetic is optionally administered to the target site through the introducer. Place the SInergy Probe into the introducer, ensuring that it is seated snuggly in the hub. Note that the SInergy Probe is 2 mm shorter that the stylet. The probe is designed to sit 2 mm off of the dorsal sacral surface to ensure that the thermocouple is not shielded in bone, and that the lesion does not extend unnecessarily into the periosteum. The impedance displayed on the screen of the Pain Management Generator should not exceed 500 ohms. Impedance values exceeding 500 ohms may indicate that the probe is positioned in tissue not suitable for lesioning, or that the probe is not fully seated in the hub of the introducer. The position of the probe is secured by sliding the green 'depth' stopper down to the surface of the skin.







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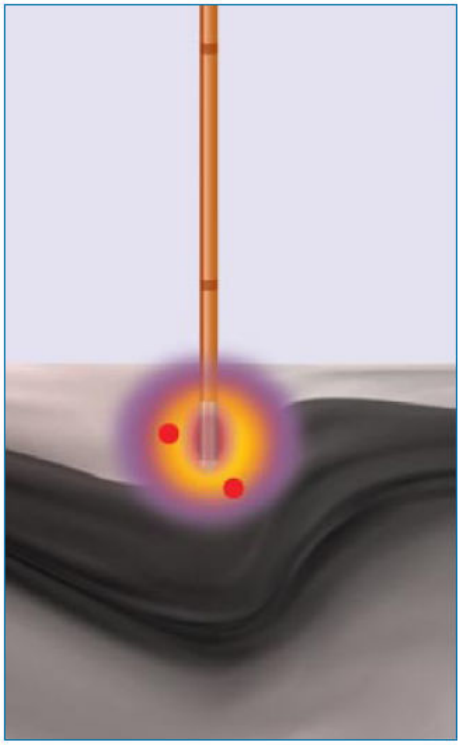
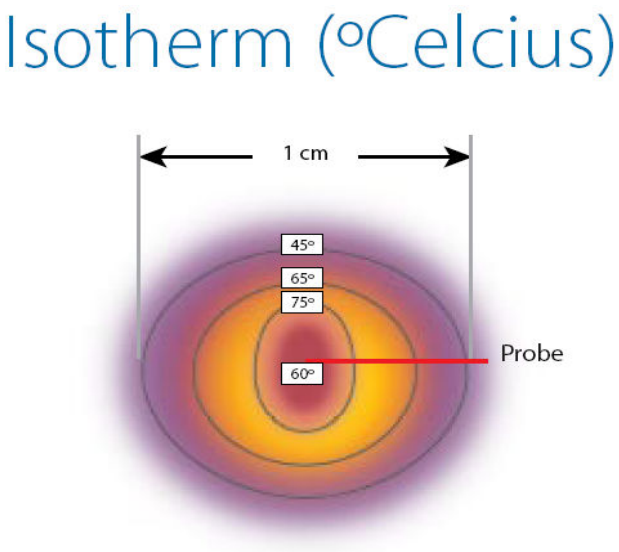
8. Create the first lesion according the parameters outlined in *Lesion Parameters*; Section 9 of this document. Suggested parameters include Set Temperature = 60°C, Time = 2:30. Monitor the patient's response during lesioning for non-concordant pain in the groin, anterior thigh, lower leg, or foot. The lesion can be stopped at any time by depressing the ON/OFF button on the lower right corner of the pain generator.





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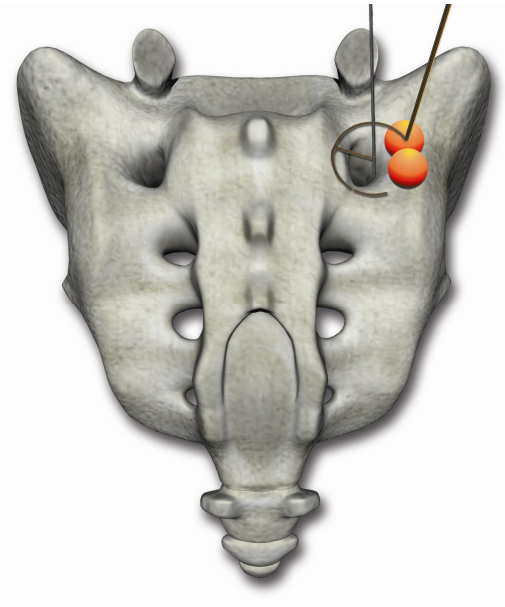
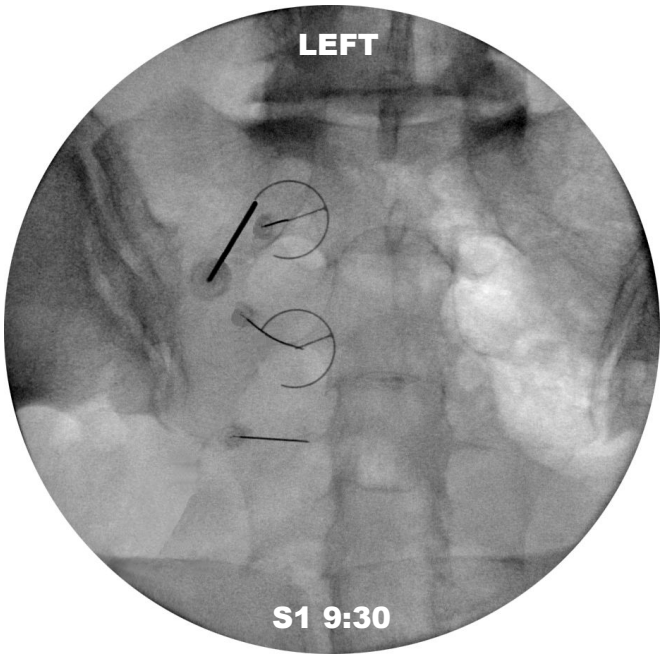
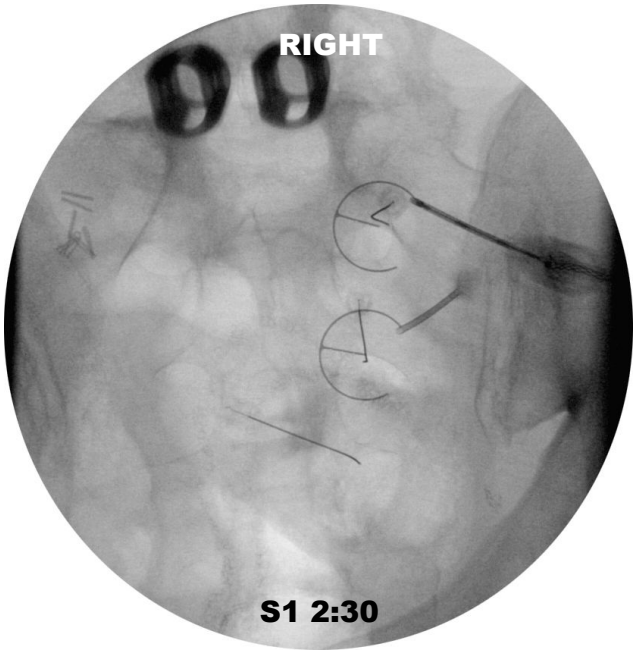
10. After the first lesion is complete, remove the probe from the introducer, and replace it with the stylet. This is important as the probe is not designed to penetrate tough connective tissue. Directing the probe through connective tissue may render it inoperative. The second target site is 7-10 mm superior and lateral to the tip of the S1 finder needle. On the clock face, this corresponds to a 2:30 position (9:30 position on the left side), and should be marked by the upper spoke of the Epsilon ruler. The introducer and stylet are then redirected towards the second target site by withdrawing slightly, and pivoting about the skin. In this manner, the original skin puncture can be used as a pivot point for the second and third targets. Confirm electrode placement and create a lesion using the same procedures described previously.







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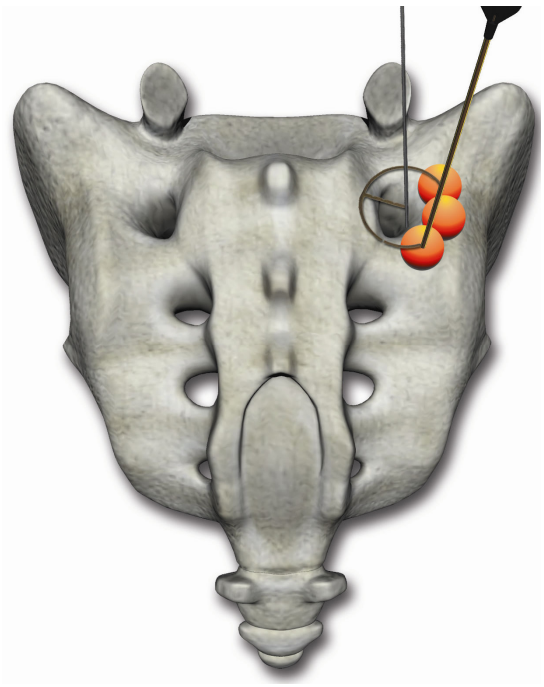
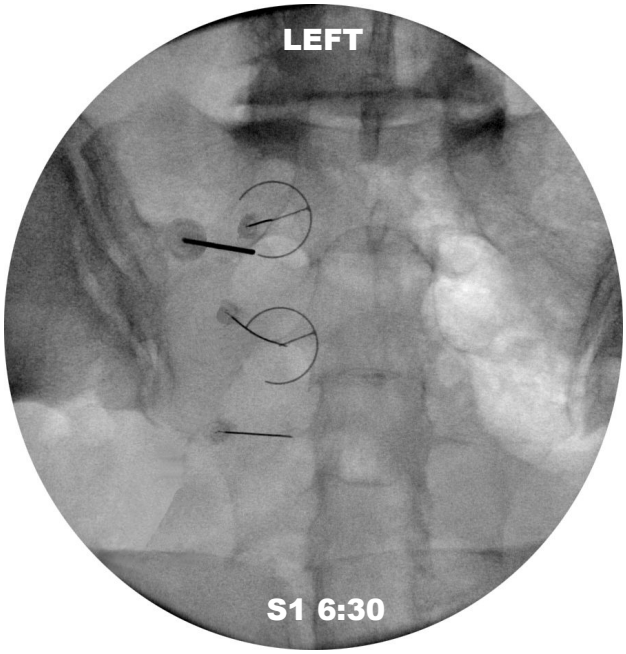
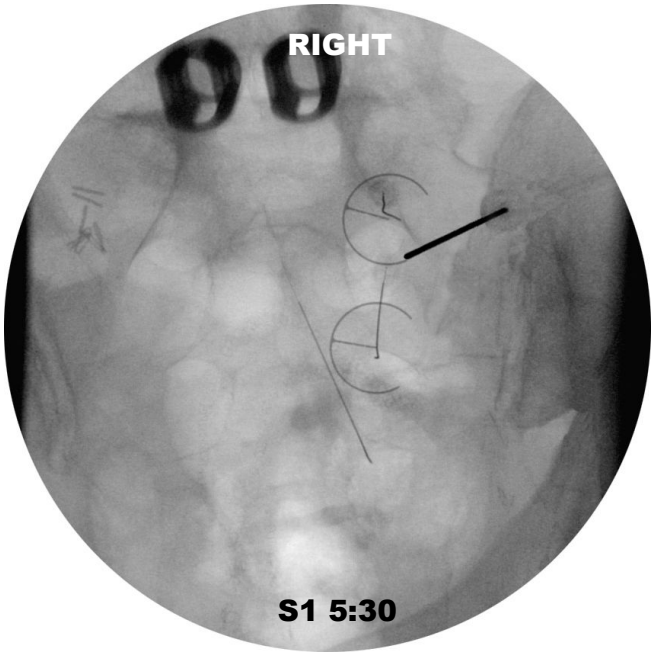
11. Remove the probe and replace the stylet in the introducer. The third target site is 7-10 mm inferior and lateral to the finder needle. On the clock face, this corresponds to a 5:30 position (6:30 position on the left side), and should be marked by the lower spoke of the Epsilon ruler. Once again, the original skin puncture can be used as a pivot point. Withdraw the introducer slightly, and direct it towards the target. Confirm electrode placement and create a lesion using the same procedures described previously.







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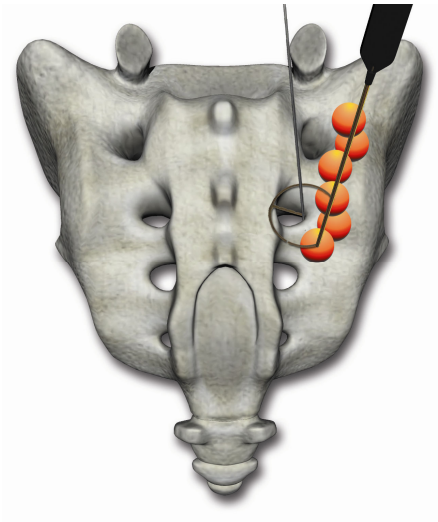
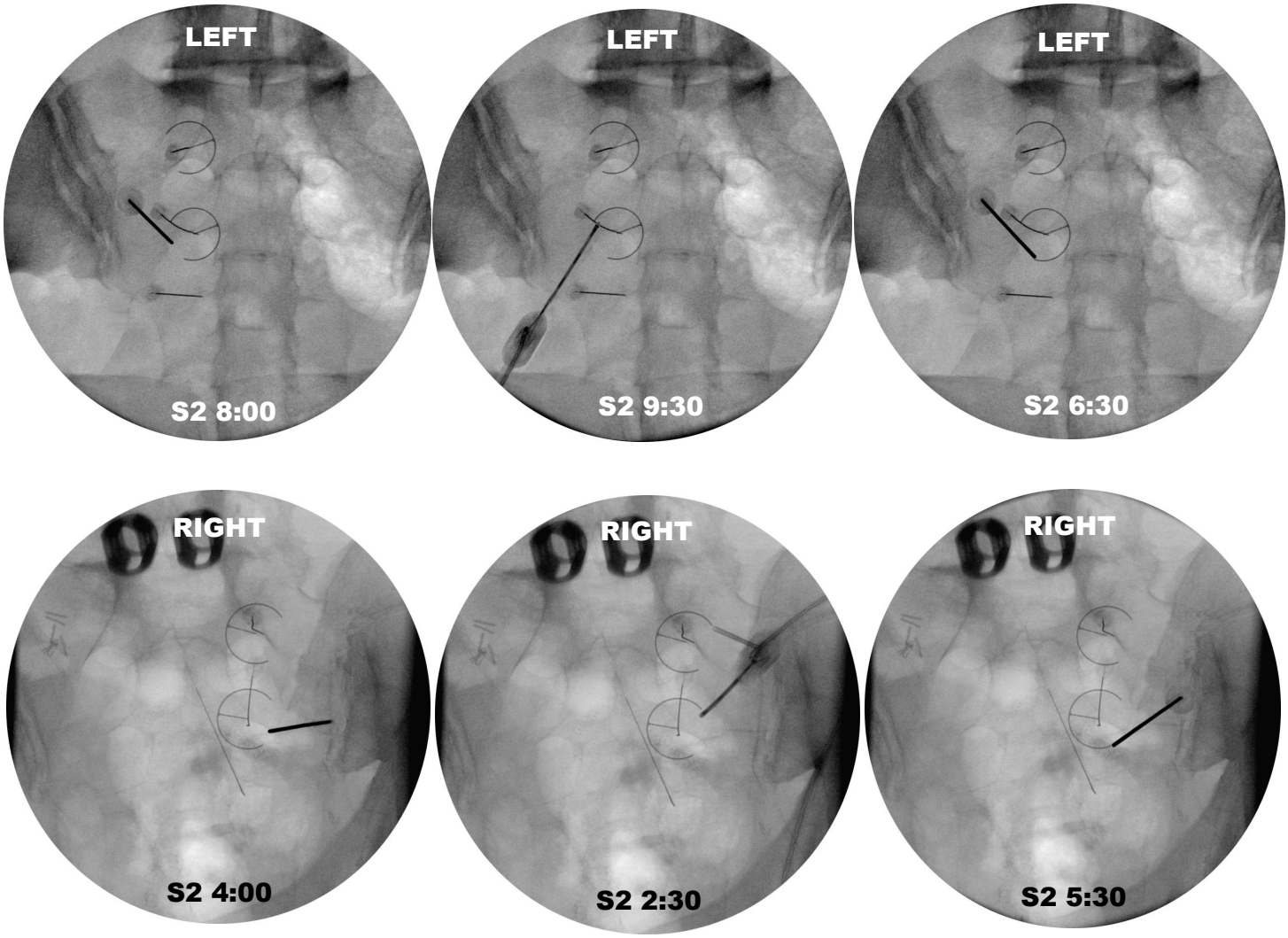
12. The same sequence of steps is repeated to create a lateral arc of treated tissue around the S2 dorsal foramen, lesioning at the 4 o'clock, 2:30 o'clock and 5:30 o'clock positions (8 o'clock, 9:30 o'clock and 6:30 o'clock positions on the left side).





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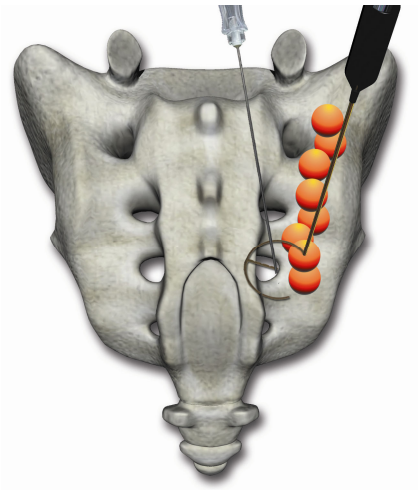
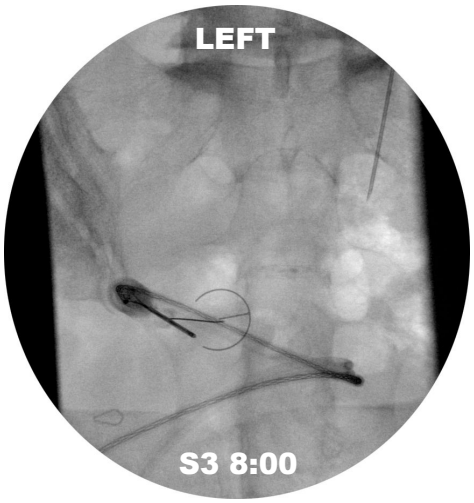
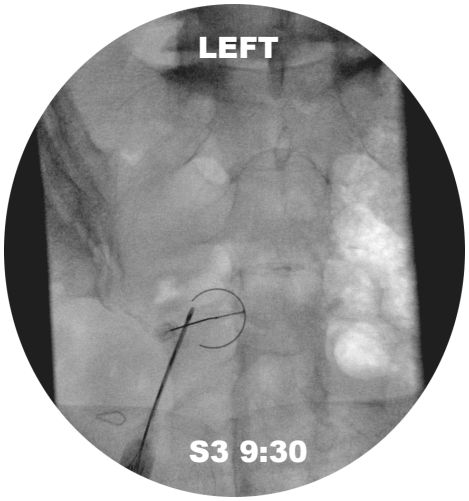
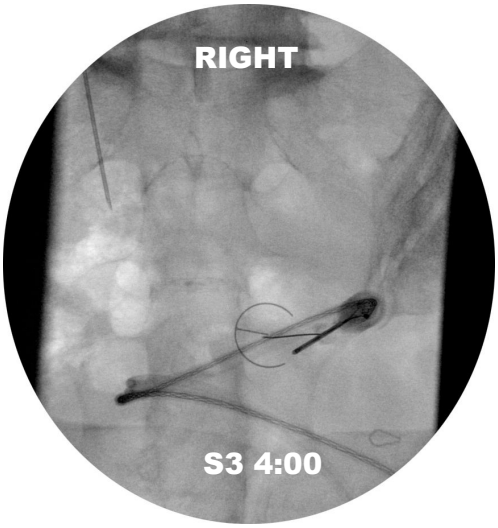
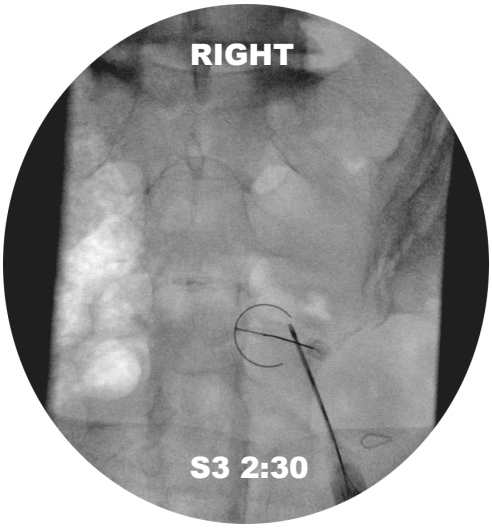
13. The same sequence of steps is also repeated to create a lateral arc of tissue around the S3 dorsal foramen, this time only lesioning at the 2:30 o'clock and 4 o'clock positions (9:30 o' clock and 8 o'clock positions on the left side).











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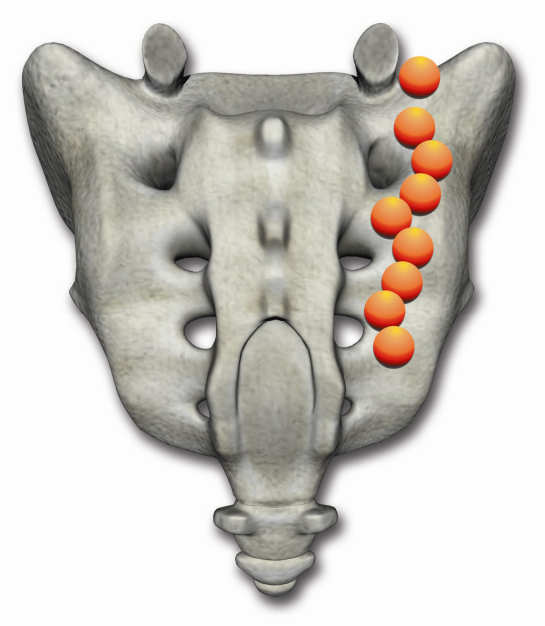
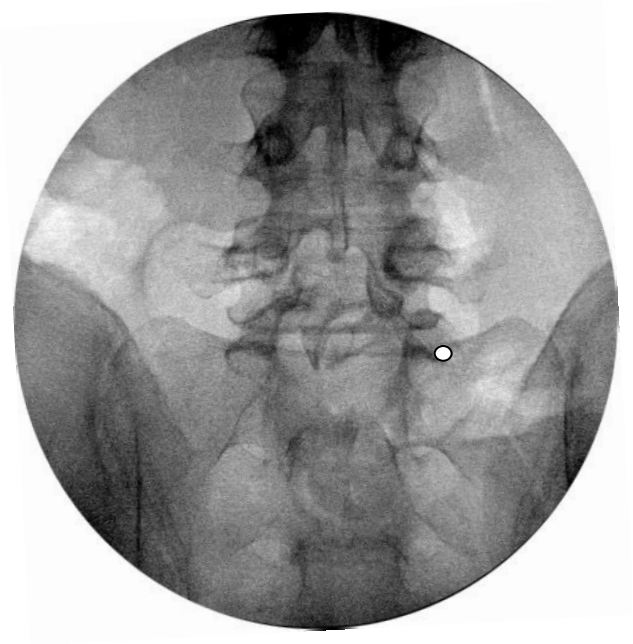
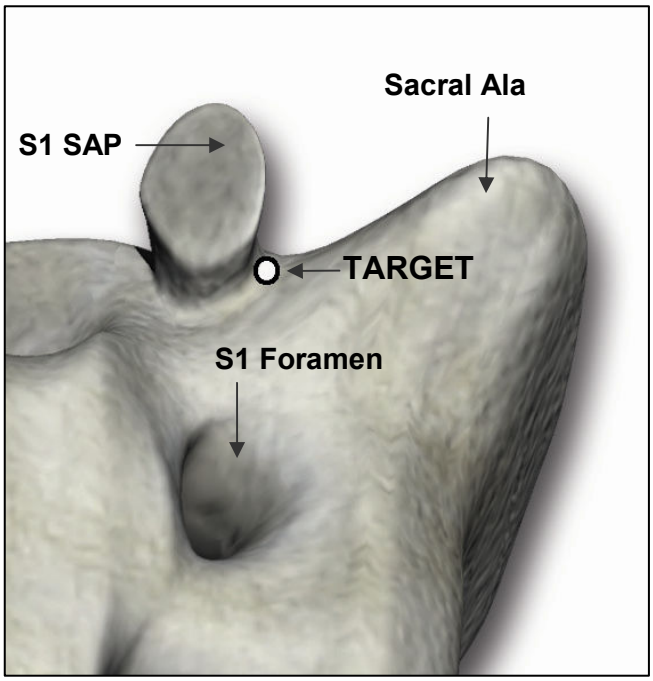
14. After completing the lesions at S3 there is a continuous band of ablative lesions between the sacral foramina and the sacroiliac joint.



L5 Dorsal Ramus Neurotomy

15. Needle placement for this procedure is similar to that for a diagnostic lumbar medial branch block at the same level. The target location is the notch between the ala of the sacrum and the superior articular process (SAP) of the sacrum. This corresponds to the known running course of the L5 dorsal ramus.





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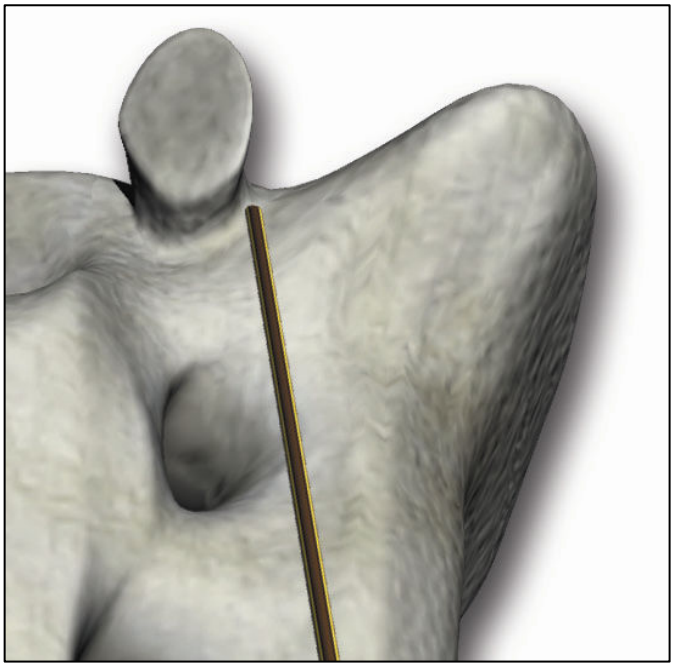
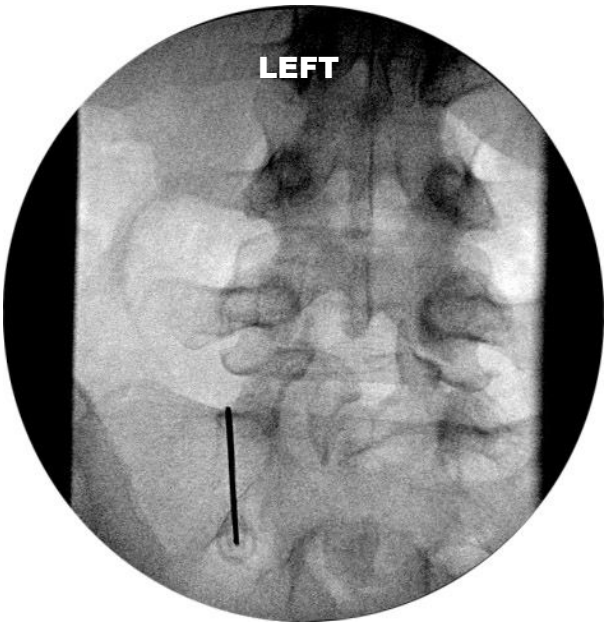
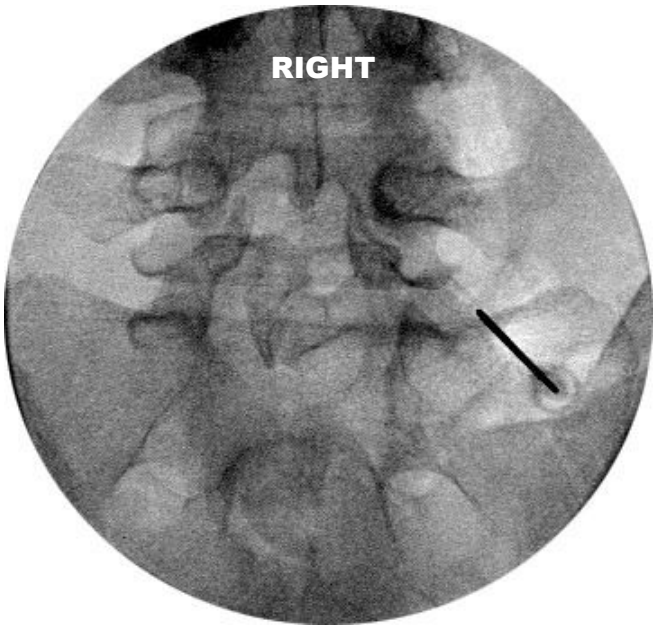
16. The target point lies at the base of the SAP along its lateral midline. This corresponds to a point in the notch where the surface of the bone is still dorsally facing (before it curves ventrally towards the intervertebral foramen). The target point is visualized using an anterior/posterior (AP) fluoroscopic view. The puncture point on the skin is just lateral and inferior to the target. Adjustments to the puncture point can be made to ensure that the needle course is medial to the iliac crest. The introducer is advanced until contact is made with the target bony endpoint. Under AP view, the tip of the needle should be up against the base of the SAP and under its lateral margin.



Note that needle placement is on the dorsal surface of the bone. Placement more superior/ventral to the target point brings the electrode closer to the segmental nerve root, and increases the risk of inadvertent heating of this structure.





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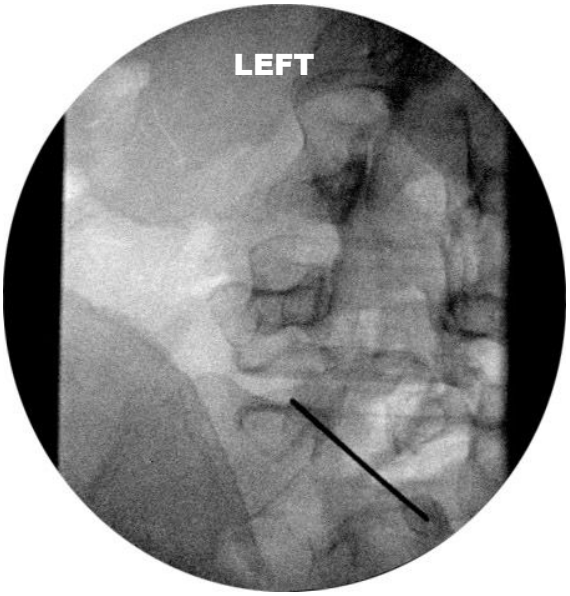
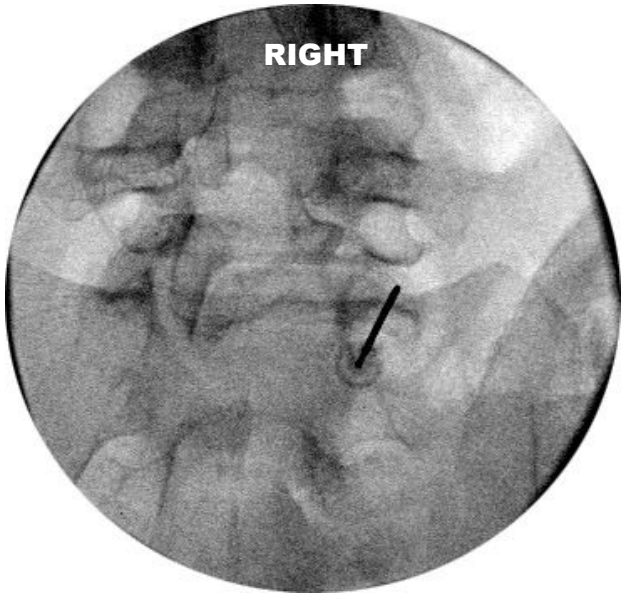
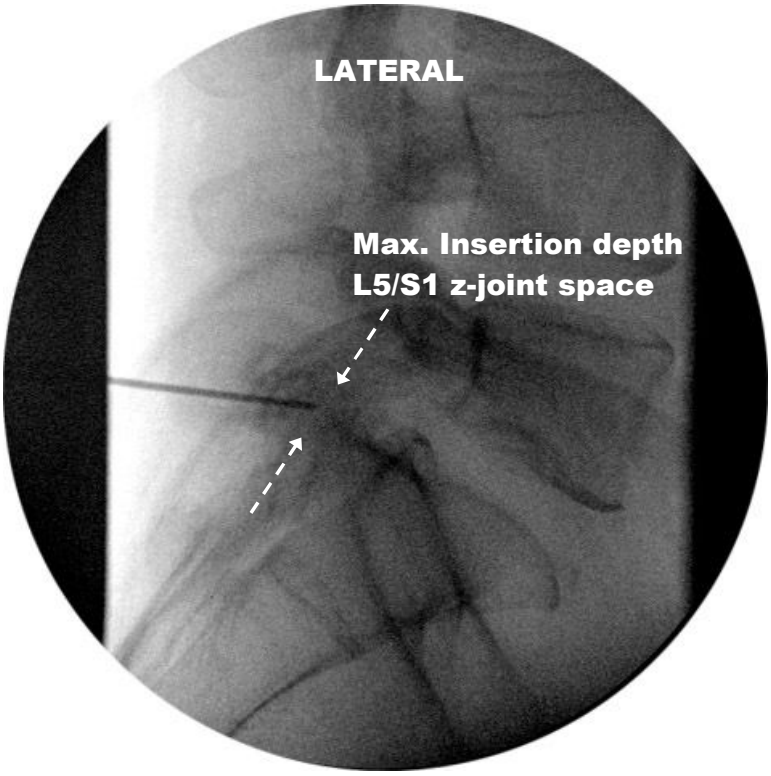
17. Rotation to an oblique view should confirm correct location of the stylet tip at the target point. Reposition as necessary to obtain appropriate needle position.





18. A lateral view is obtained to confirm depth of needle placement. The tip of the stylet should be no deeper than the AP midline of the SAP, which can be approximated by the joint space of the L5/S1 zygopophysial joint.



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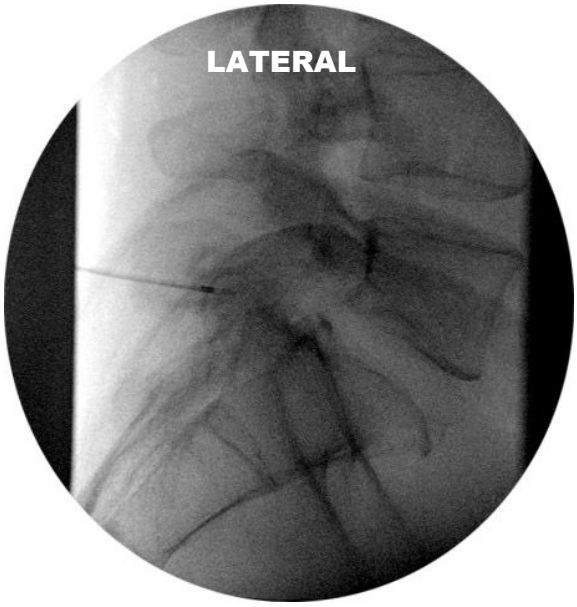
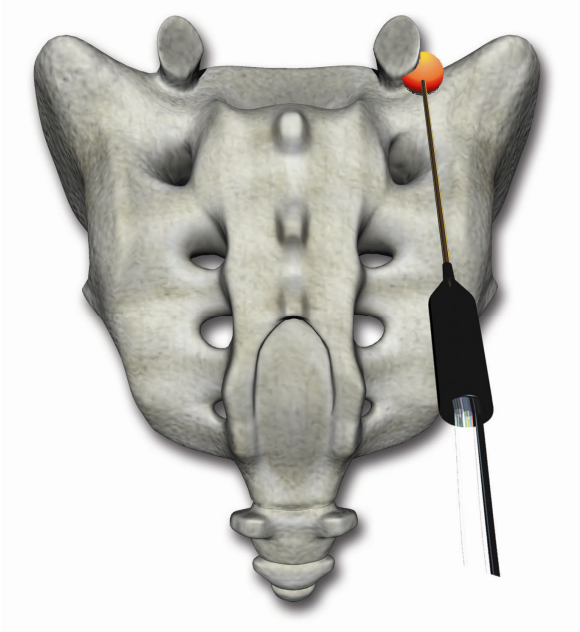
19. Remove the stylet from the introducer. A small volume (less that or equal to 1cc) of local anesthetic is optionally administered to the target site through the introducer. Place the SInergy Probe into the introducer, ensuring that it is seated snuggly in the hub. On lateral view the tip of the probe should be 2 mm proximal to the tip position previously observed for the stylet. This is to accommodate the distal project of the lesion from the tip of the electrode.

Note that there will be up to 4mm of distal lesion projection from the tip of the electrode. Ensure there is adequate distance between the tip of the electrode and the foramen of the L5 segmental nerve root to minimize the risk of inadvertent heating to this structure.



20. A lesion is created around the tip of the electrode as previously described. Suggested lesion parameters remain unchanged; Set Temperature = 60°C, Time = 2:30 Monitor the patient's response during lesioning for non-concordant pain in the groin, anterior thigh, lower leg, or foot. The lesion can be stopped at any time by pressing the ON/OFF button on the lower right corner of the pain generator.



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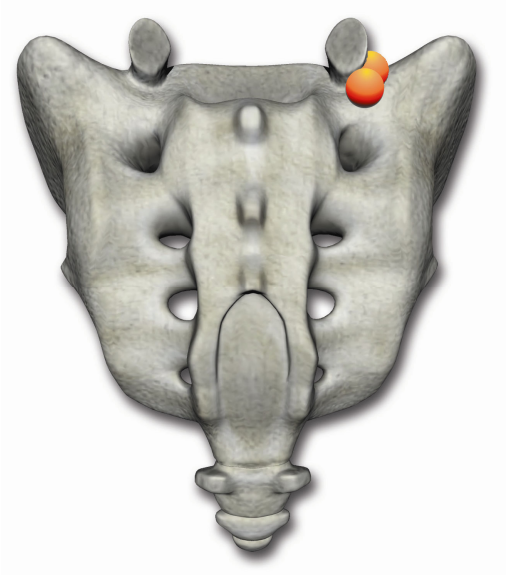
21. Optionally, perform a second lesion at the base of the superior articular process of the sacrum, 6-8mm inferior to the first lesion location.



Post-Procedure Care

Discharge Instructions on the day of the procedure

- Do not drive or operate machinery
- Do not engage in any strenuous activity
- Do not soak in the bathtub, but a shower is okay
- Eat a regular diet
- You may remove bandages the following day
- You may use an ice pack today and warm moist heat tomorrow if you experience discomfort when the local anesthetic wears off.
- If you experience fever, chills or severe pain at accompanied by swelling and redness at the injection site, contact your treating physician.
- If you experience shortness of breath or chest pains go to the nearest emergency room.

Activity Guidelines

- Resume normal activities as tolerated the day after the procedure.
- Avoid excessive activity, lifting, or other forms of increased physical activity for 1-3 days following the procedure.

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9. *Lesion Parameters*

Overview

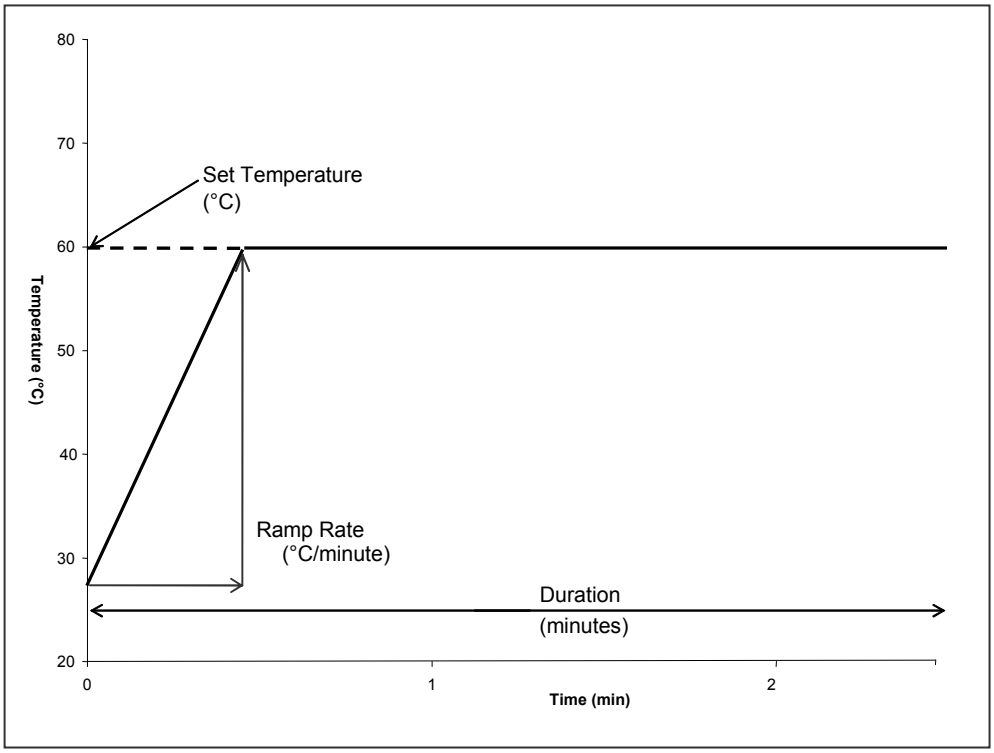
This section describes the parameters used to control the heating profile during the procedure. In this section you will learn:

- What the modifiable parameters are
- How the parameters affect the heating
- Suggested parameters to use

Parameters used to create heating profile

The parameters available to control the heating profile are:

- Ramp Rate
- Set Temperature
- Time



There is a temperature sensor at the tip of the SInergy Probe. The generator will monitor this temperature sensor and automatically deliver the required power to raise the temperature of the target tissue. The shape of the heating profile is determined by the parameters **Ramp Rate**, **Set Temperature**, and **Time**. At the beginning of the procedure the temperature is lower than body temperature because the pumps are running and cooling has begun. The probe temperature will increase at the **Ramp Rate**

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until it reaches the **Set Temperature**. The temperature will remain at the Set Temperature until the **Time** is complete.

Effect of Parameters

Ramp Rate is the rate of increase in temperature per minute (as measured by the probe's temperature sensor). A slower Ramp Rate results in better control of heating, larger volumes of heated tissue, and more consistent temperature profile. A faster Ramp Rate results in shorter procedure time. In conventional non-cooled RF procedures such as a z-joint rhizotomy, the ramp rate is usually about 15 seconds. The optimum ramp rate for the SInergy System is only slight longer, lasting 25 seconds. It must be understood that this time has been optimized to balance procedural speed, and lesion consistency. Ramp Rate can only be changed in the Advanced Settings of the generator.

Set Temperature is the desired temperature of the probe's electrode surface. The temperature will increase at the Ramp Rate until it reaches the Set Temperature which is then maintained. Due to the cooling of the electrodes, the Set Temperature will be 10-15° Celsius lower than the tissue a few millimeters from the electrode. The level of the Set Temperature in combination with the Ramp Rate and Time will affect the temperature throughout the tissue. Set Temperature can be changed at any time before or during the RF delivery.

Time is the duration of radiofrequency energy delivery, including the temperature ramp up and plateau. A longer Time will allow a greater volume of tissue to be heated until thermal equilibrium is reached. The optimum Time is long enough for adequate volume heating without excessive procedure time. Time can be changed at any time before or during the RF delivery.

Power Limit is the maximum power (in Watts) that the generator will output at any time during the procedure. Power output will vary throughout the procedure as required to achieve the desired Ramp Rate and Set Temperature. Typically, power values are higher during the temperature ramp and lower once the probe has reached Set Temperature. If the Power Limit is reached during temperature ramp, the generator will continue to deliver RF at this maximum value. This may increase the Ramp Rate by several seconds, but will ensure that the lesion forms in a safe and consistent manner. If the Power Limit is set too high, it is possible to have irregular lesion shapes or excessive heating.

Refer to the following page for the suggested lesion parameters.

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Suggested Parameters

The suggested parameters used for treating a patient with the SInergy System are:

- Set Temperature = 60 ºC
- Ramp Rate = 80 ºC/min
- Time = 2:30 minutes

These parameters were tested and scrutinized through a series of bench tests and in vivo experiments. The experiments were designed to map temperatures in the tissue and in the surrounding neural structures to ensure that heat was applied in a manner suitable for both efficacy and safety during treatment.

For practical use, set the Advanced Settings on the generator as follows:

- Ramp Rate = 80°C/min
- Post Treatment Cooling = Disable
- Number of Probes = 1
- Power Limit = 12 Watts

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10. Generator Graphs During Treatment

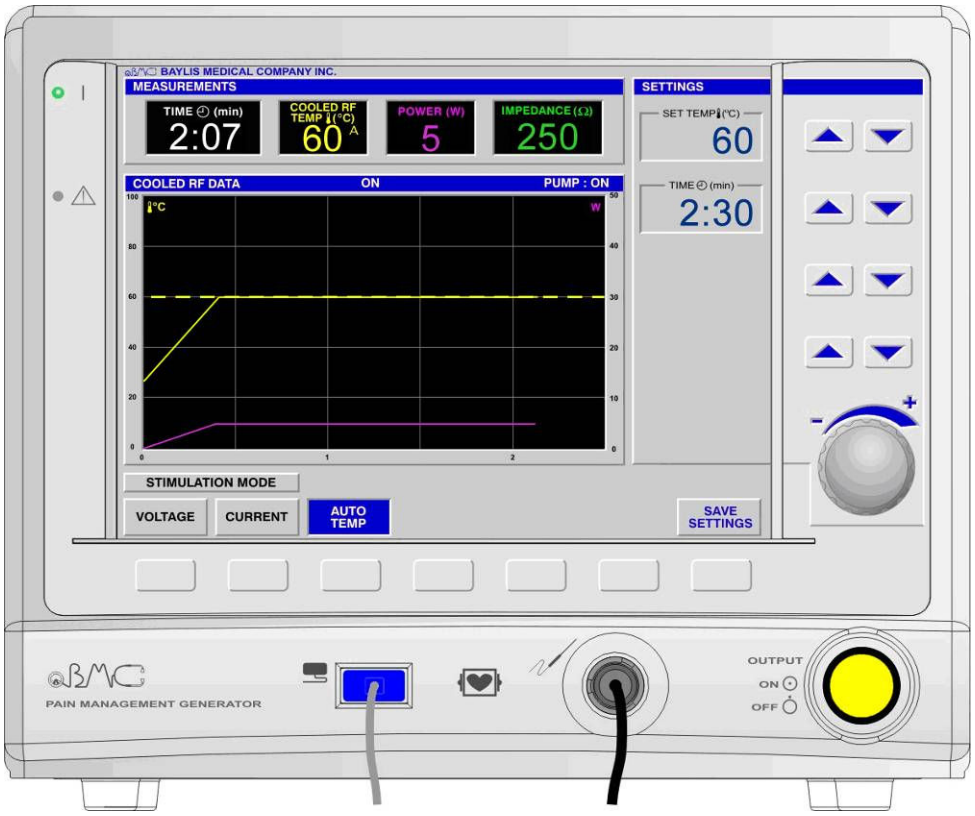
Overview

This section shows images of generator screens to explain what a typical procedure looks like compared to an abnormal procedure. In this section you will learn:

- Appearance of a typical procedure graph.
- Appearance of an abnormal procedure graph.

The figures in this section represent screens of a Baylis Pain Management Generator (Model PMG-115-TD and PMG-230-TD, V2.2A). Refer to the generator's user manual for complete details.

The graph on the generator shows the temperature ("COOLED RF TEMP" in yellow), and the power ("POWER" in magenta). An ideal procedure graph, as shown below, has fairly smooth lines with the COOLED RF TEMP rising steadily until the SET TEMPERATURE (dashed yellow line) is reached. The POWER will increase until the COOLED RF TEMP reaches SET TEMPERATURE. Following this the POWER may plateau, or decrease slightly over the remainder of the procedure. Typical POWER values range from 2 to 12 Watts.



Generator graph of an ideal procedure.

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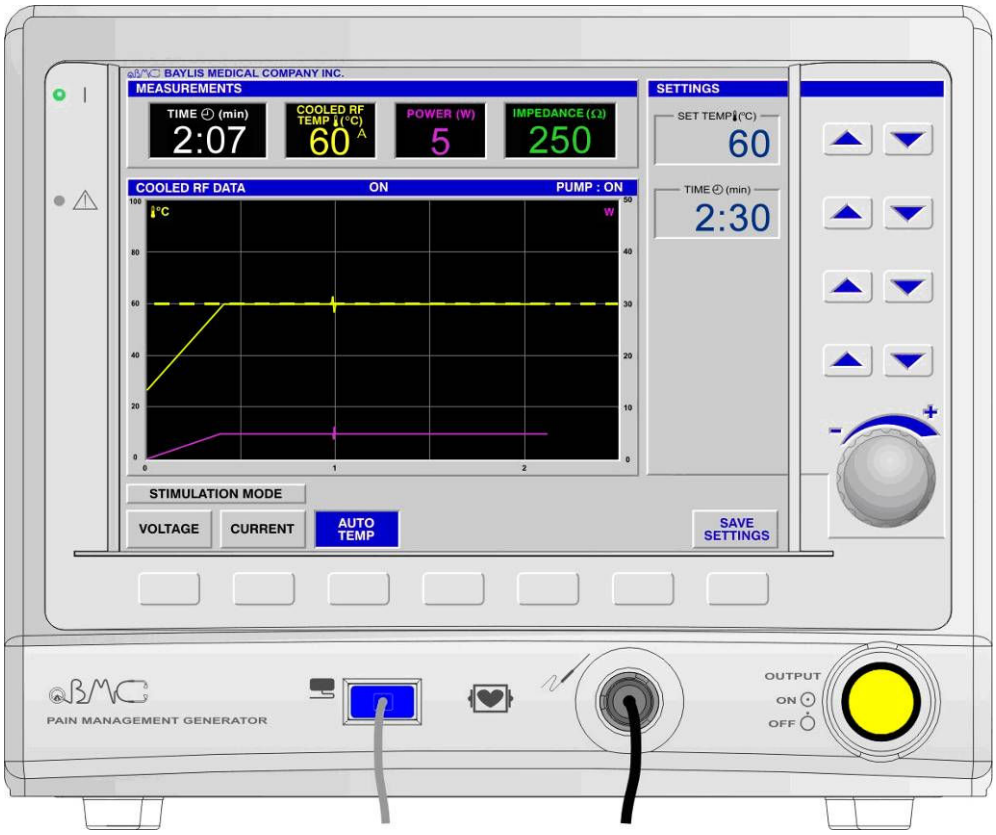
The graph in on this page is similar to the ideal graph except there is a small blip in both lines at about 1 minute. This is commonly seen if the patient moves to get more comfortable or coughs. It may also be seen if the probe is bumped or moved. This is likely not a problem but it is a good idea to check the lateral and AP fluoroscopy views to make sure the probe is still in a desirable position.



Generator graph showing a small blip is okay.

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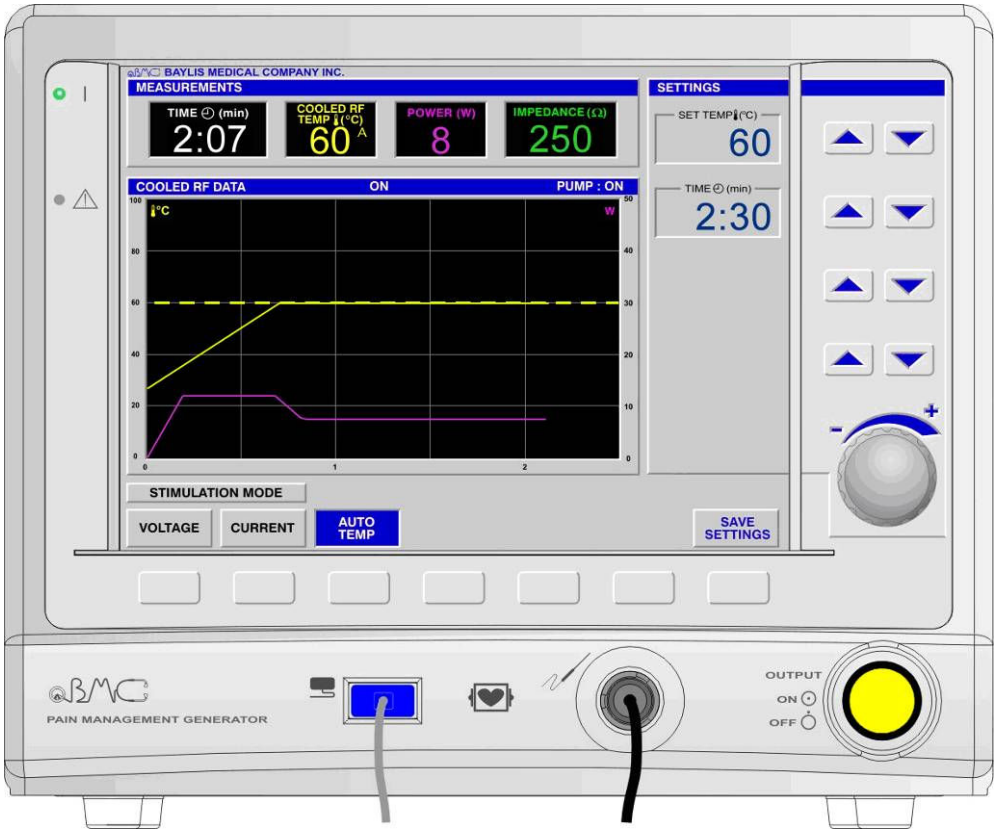
The graph in on this page is also similar to the ideal graph, except that the POWER has reached the power limit of 12W for a short period of time during the beginning of the procedure. As a result, it has taken about 15 seconds longer than usual for the COOLED RF TEMP to reach SET TEMPERATURE. This is periodically seen when the probe has been placed in particularly dense connective tissue. The power limit has ensured that the lesion formed in a safe and uniform manner. If the SET TEMPERATURE is unable to reach SET TEMPERATURE because of this feature, stop the procedure and reposition the electrode.



Generator graph showing that reaching the power limit is okay.

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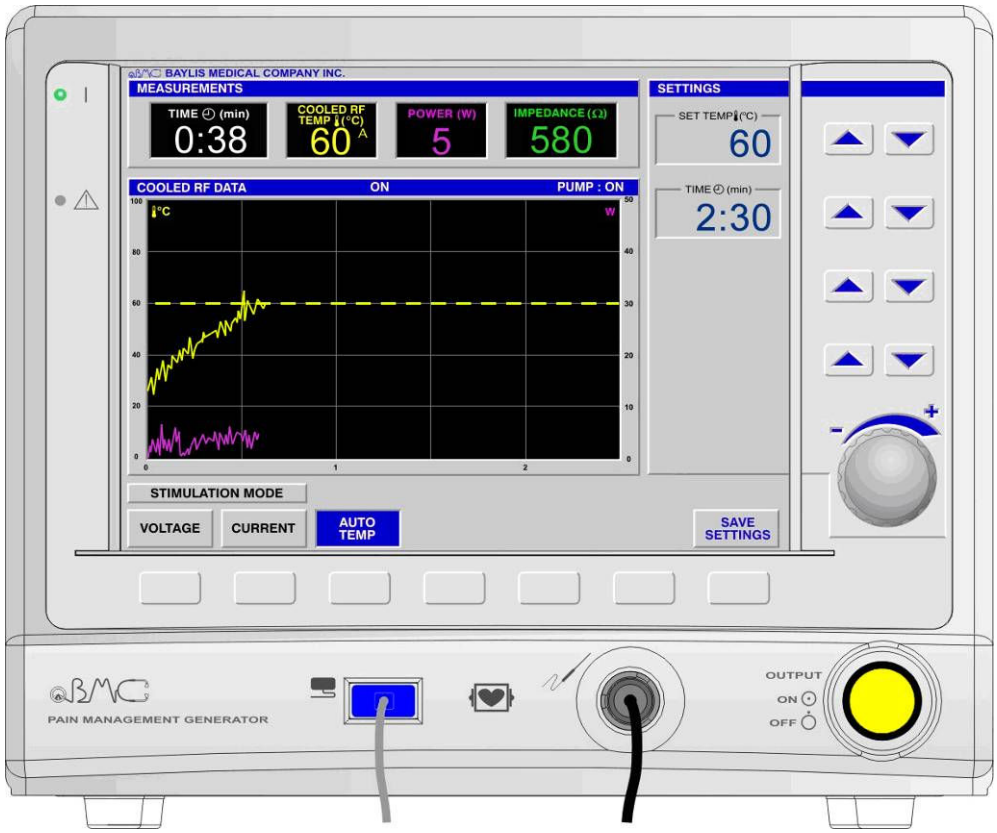
An example of a graph that indicates a poor procedure is shown below. The COOLED RF TEMP and POWER lines have become erratic, indicating that the electrode is not able to deliver RF energy in a consistent manner for this tissue location. This will likely be accompanied by a higher that normal impedance reading (> 500 Ω). This may be caused by tissue inhomogeneity around the active tip of the electrode, or by placing the active tip in dense connective tissue or bone. Immediately stop the procedure and reposition the electrode.



Generator graph of a poor procedure.

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11. Troubleshooting

Overview

In this section you will:

- Learn how to identify potential problems with system components
- Become familiar with the Generator Error and Fault Codes that may appear during a SInergy procedure

Trouble-Shooting Pain Management SInergy System Components

In addition to the information contained within this document, each SInergy Kit has a troubleshooting table in its Instructions for Use to assist the user in diagnosing potential problems.

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SInergy RF System Component Troubleshooting

Troubleshooting during equipment set-up

Problem	Possible Device	Trouble-Shooting Actions
Damage to the packaging of a sterile device	SInergy Introducer, SInergy Probe and Pain Management Tube Kit	Visually inspect the packaging before use. The sterile pouch should not have any holes. Discard the device if packaging has been compromised.
Obvious visual damage to any product.	Cooled RF Connector Cable, Pain Management Pump Unit, SInergy Probes, SInergy Introducers, Pain Management Tube Kits	Visually inspect the products for any damage. Look for damage such as cuts, cracks, breaks, and bends. Do not use damaged equipment.
Electrical connectors do not connect	SInergy Probe and Cooled RF Connector Cable	Check that the connector's keys are lined up in the proper orientation. Turn the connector until it slides in the mating connector. Ensure that the connectors are clean and unobstructed. Check that the connectors being connected have the same number of pins and that the pins are not damaged.
Fluid connectors do not connect	SInergy Probe and Pain Management Tube Kit	Ensure each probe and tube kit has one male and one female luer lock. Remove the white luer lock caps.
The Pump will not accept the Tube Kit tubing	Pump Unit and Pain Management Tube Kit	Fully open the cover for the pump and place the tubing coming from the bottom of the burette of the Tube Kit into (i.e. above) the L-shaped tube Guides (see step 3 in the Equipment Set Up section).
The float ball is stuck on bottom port of the burette when water is injected.	Pain Management Tube Kit	Shake the burette to loosen the ball until it floats. Using a syringe, pressurize the section of tube kit tubing that terminates in a female lure lock.
The lid of the burette can not be removed	Pain Management Tube Kit	Inject sterile water through the port in the lid, rather than removing the lid.
Tube Kit breaks, is leaking or is occluded.	Pain Management Tube Kit	Discard the tube kit.

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Troubleshooting during treatment

Problem	Possible Device	Trouble-Shooting Actions
No Impedance measurement	SInergy Probe, Cooled RF Connector Cable, and Dispersive Electrode	Ensure that all connections are made: - Cooled RF Connector Cable to PMG-TD - SInergy Probe to Cooled RF Connector Cable - Grounding Pad to PMG-TD Check for an error message on the PMG-TD. Possible error codes include W209, W210, E125 and E126. Follow the Troubleshooting Flowchart provided on subsequent pages of this section for trouble-shooting actions. Visually inspect the probe, dispersive electrode and cable for damage. In Treatment Mode ensure the probe is fully inserted into the introducer. Ensure that the devices are dry and at room temperature.
Fluid is not circulating during SInergy Treatment Mode	Pump, Pain Management Tube Kit, SInergy Probe and BMC RF Generator	Check for an error message on the generator. Possible error codes include E101, E103, and E106. Follow the Troubleshooting Flowchart provided on subsequent pages of this section for trouble-shooting actions Follow the fluid pathway along the tubing and probes to see if it is pinched or kinked. For example, if clamps are used to hold the tubing they should not pinch it. Check to see that the tubing is properly placed in the L-shaped tubing guides of the Pump Unit and in the correct direction. Check to see that burette reservoir has been filled. Check to see that the float in the burette is not stuck at the bottom and occluding the flow of water from the burette. Check to the see that the Tube Kit is correctly connected to the luer locks on the SInergy Probes.

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Problem	Possible Device	Trouble-Shooting Actions
		Ensure that the portion of tubing that is in the pump head is the thick tubing coming out of the bottom port of the burette and NOT the thin tubing coming from the top of the burette. Check for leaks or occlusions in tubing and joints of the Tube Kit. Ensure that the pump head lid is closed. Repeat pump priming by initiating the lesion with the ON/OFF button. Gently squeeze the upper and lower jaws of the pump head during priming in order to exert additional pressure on the tubing in the pump.
Pump Unit is making abnormal noises	Pain Management Pump Unit	Check to see that the tube kit is properly inserted in the pump head and in the correct direction.
One pump head stops during Pretreatment Cooling	Pain Management Pump Unit	This is normal. The PMG-TD stops the pumps during pretreatment cooling so the generator can identify which pump head the probe is associated with.
Water is not dripping into the burette.	Pain Management Tube Kit	If water is not dripping into the burette check to see if it is running down the wall of the burette.
The pump is not working when in Cooled RF Treatment Mode (ready, pre-cooling, on, post-cooling states)	Pain Management Pump Unit	Ensure that the Pump Unit is connected to the PMG-TD. Ensure the pump head lids are completely closed. Open and close both pump lids and try again. Check for error messages on the generator. Possible error codes include E101, E103, and E106. Follow flow chart for trouble-shooting actions.
No temperature measurement Or	SInergy Probe, Cooled RF Connector Cable and BMC RF Generator	Ensure that all connections are made: ▪ SInergy Probe to Connector Cable ▪ Connector Cable to the generator. ▪ Generator to power outlet

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Problem	Possible Device	Trouble-Shooting Actions
Erratic temperature reading		Check for an error message on the generator. Possible error codes include E108 and E123. Follow flow chart for trouble-shooting actions. Visually inspect the probe or cable for damage. Ensure that devices are dry and at room temperature. If problem persists discontinue use. Small oscillations or spikes might be seen in temperature during treatment mode. This may be due to the probe or patient moving. Check the fluoroscopy image to confirm the probes have not moved to an unsafe location. If they have moved stop the procedure (press the Output On/Off Button) and reposition the probe. Very large oscillations or spikes (> 15°C) may be seen during RF delivery if the probe is positioned within dense connective tissue or bone. This will likely be accompanied by a higher that normal impedance reading (> 500 Ω). Stop the procedure (press the Output On/Off Button) and reposition the probe. Very large oscillations or spikes (> 15°C) may also indicate that the probe is damaged. Visually inspect the probe and discard if damaged.
Lesion does not reach set temperature after two minutes	Pain Management Generator, SInergy Probe	Check the power output. If it power is consistently equal to the 'Power Limit' (typically 12W as set in Advanced Settings Screen) then the site of the attempted lesion may be unusually thermally conductive. Try repositioning the electrode slightly. Confirm the electrode position with fluoroscopy and repeat the lesion. If the power is below the 'Power Limit', and repositioning and lesioning does not resolve the issue, discontinue use of the probe.

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Pain Management Generator Error/Fault Codes for Cooled RF Mode

- If an error/fault condition should occur, a pop-up message will display an error /fault code in the center of the screen.
- The error/fault event, text message displayed [including possible cause], error/fault code, and recoverable/non-recoverable indications regarding Cooled RF Mode are listed in Table 1.

NOTE: For recoverable faults, the error code is displayed for approximately 10 seconds; the Generator will automatically transition back to the previous READY state.

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Table 1: Cooled Error/Fault code interpretation.

LCD Text Message	LCD Text Message
ERROR [E80] **△ Measured Temperature Exceeds Setpoint** Possible high impedance or desiccated tissue at probe tip.	ERROR [E101] **△ Pump Malfunction** Ensure pump lids are fully closed, and cable is securely connected. Pump unit may be defective.
ERROR [E81] **△ Measured Power Exceeds Setpoint** Please check all probe and cable connections. Possible intermittent cable or poor tissue contact.	ERROR [E103] **△ Dynamic Probe-Pump Mapping Failure** Check probe and cable connections; ensure fluid circuitry is connected correctly and free from obstruction. Repeat priming while squeezing the upper and lower jaw of the pump head. Probe(s) or cable(s) may be defective. Contact technical support if problem persists.
ERROR [E82] **△ Excessive RF Current Measured** Possible short between electrodes, or defective probe or cable.	ERROR [E104] **△ Pump Current Limit** Check pump unit and ensure cable is securely connected. Contact technical support if problem persists
ERROR [E83] **△ Excessive RF Voltage Measured** Possible intermittent cable connection or loss of tissue contact.	ERROR [E106] **△ Cooled Temperature Out-Of-Range** Outside 18-34°C expected range. Probe(s), cable(s) or pump unit may be defective.
ERROR [E84] **△ Excessive RF Power Measured** Possible intermittent tissue contact. Possible defective probe(s) or cable(s).	ERROR [E108] **△ Probe A Not Connected** Check probe and cable connections. Probe or cable(s) may be defective.
ERROR [E85] **△ High Impedance Detected** Check probe, cable and dispersive return electrode connections. Possible poor tissue contact. Probe or cable may be defective.	ERROR [E123] **△ Invalid Probe A Temperature Reading** Check probe and cable connections. Probe or cable(s) may be defective. Try new probe and cable(s) if problem persists.
ERROR [E87] **△ Unrecognized Probe Type** See User Manual for a list of valid probes. Please note error code and contact technical support if problem persists.	

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LCD Text Message
ERROR [E125]
△ High Impedance Detected Check probe and cable connections. Possible poor tissue contact. Probe(s) or cable(s) may be defective.
ERROR [E126]
△ Low Impedance Detected Possible short circuit between electrodes, or damaged introducer insulation.
WARNING [W200]
△ High Impedance Detected Check probe, cable, and dispersive return electrode connections. Possible poor tissue contact. Probe or cable may be defective.
WARNING [W209]
△ Low Impedance Detected Possible short circuit between electrodes or damaged introducer insulation.

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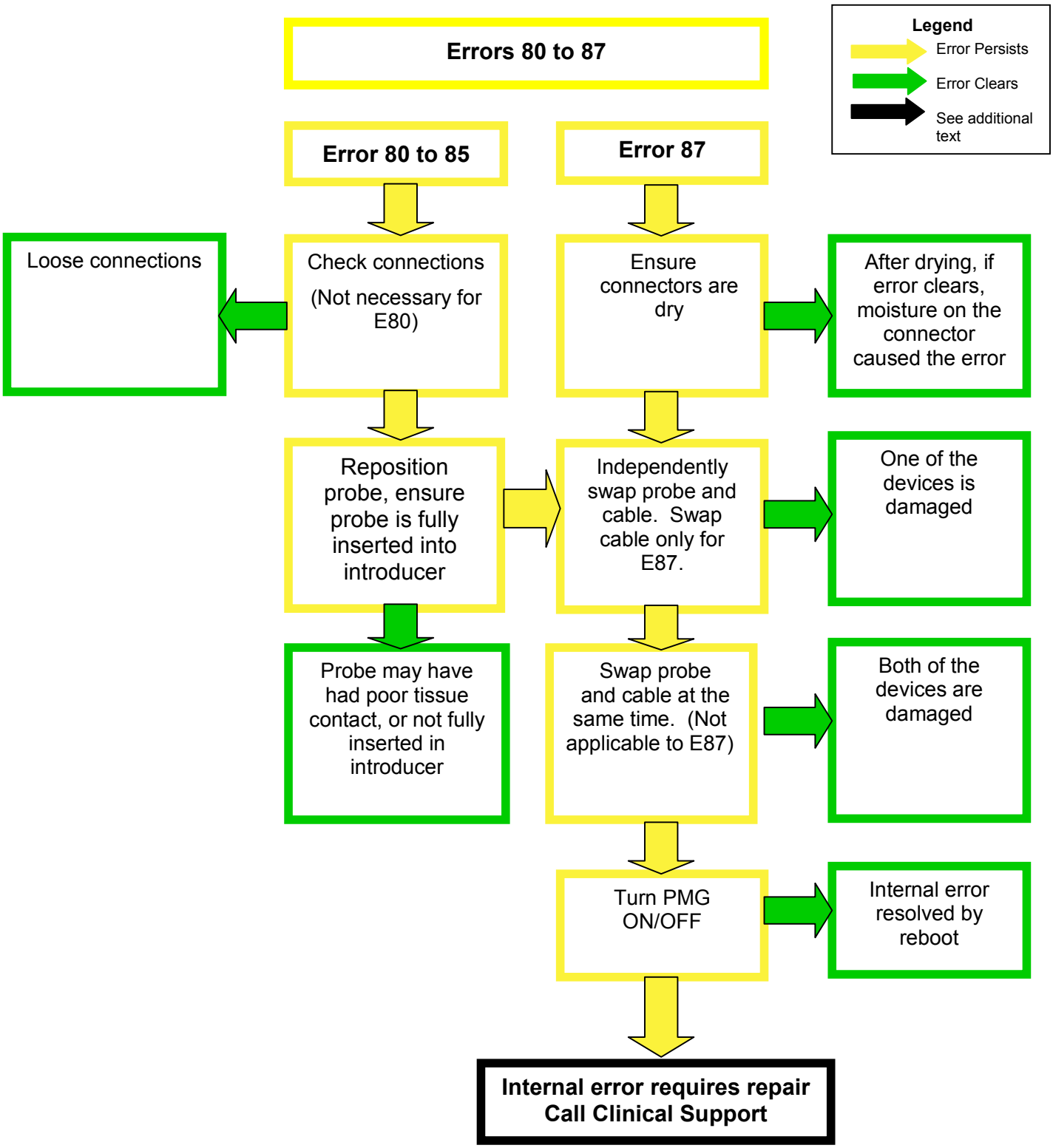
Trouble-Shooting Flow Chart



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Petitioner's Exhibit 1055
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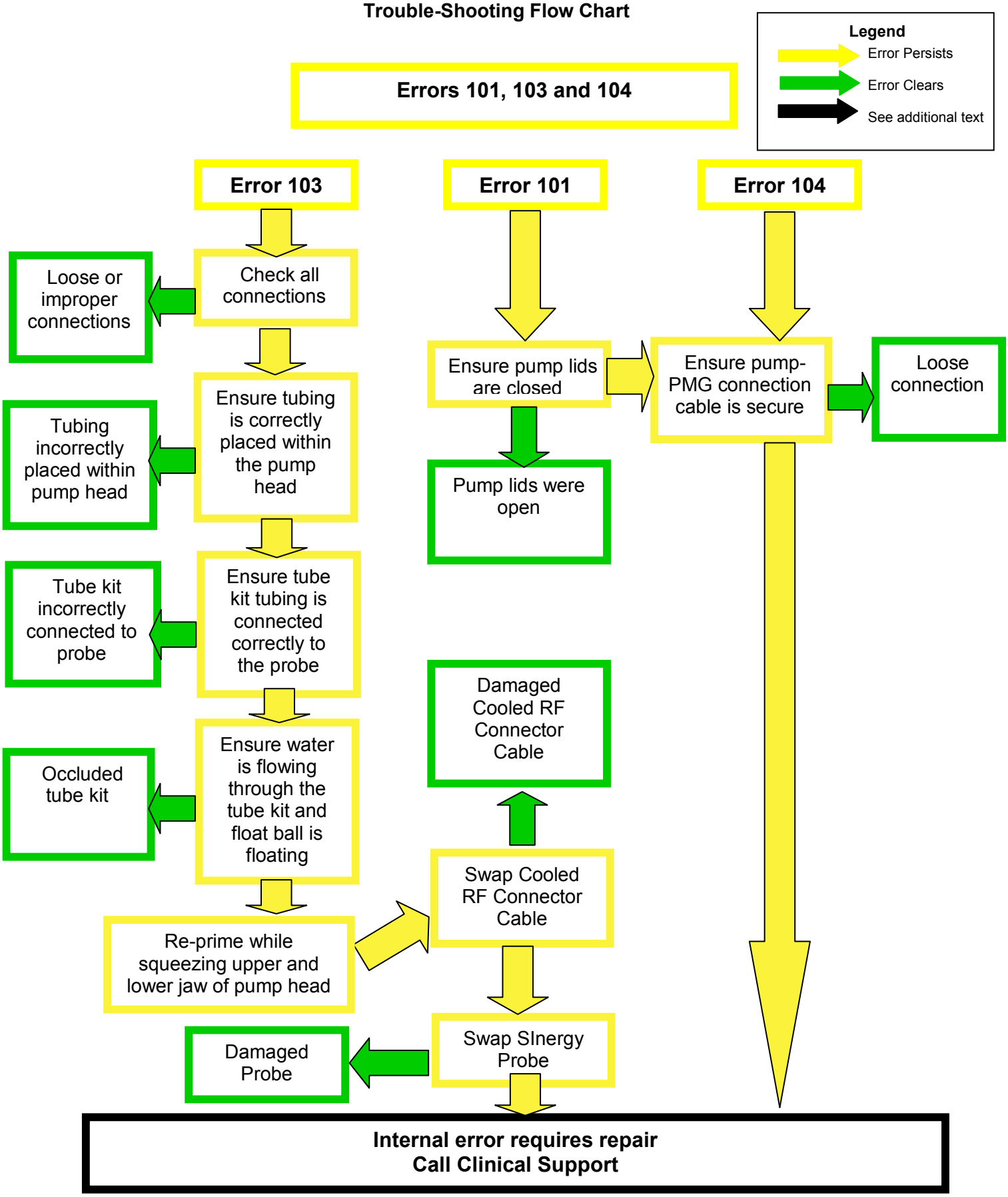
Trouble-Shooting Flow Chart



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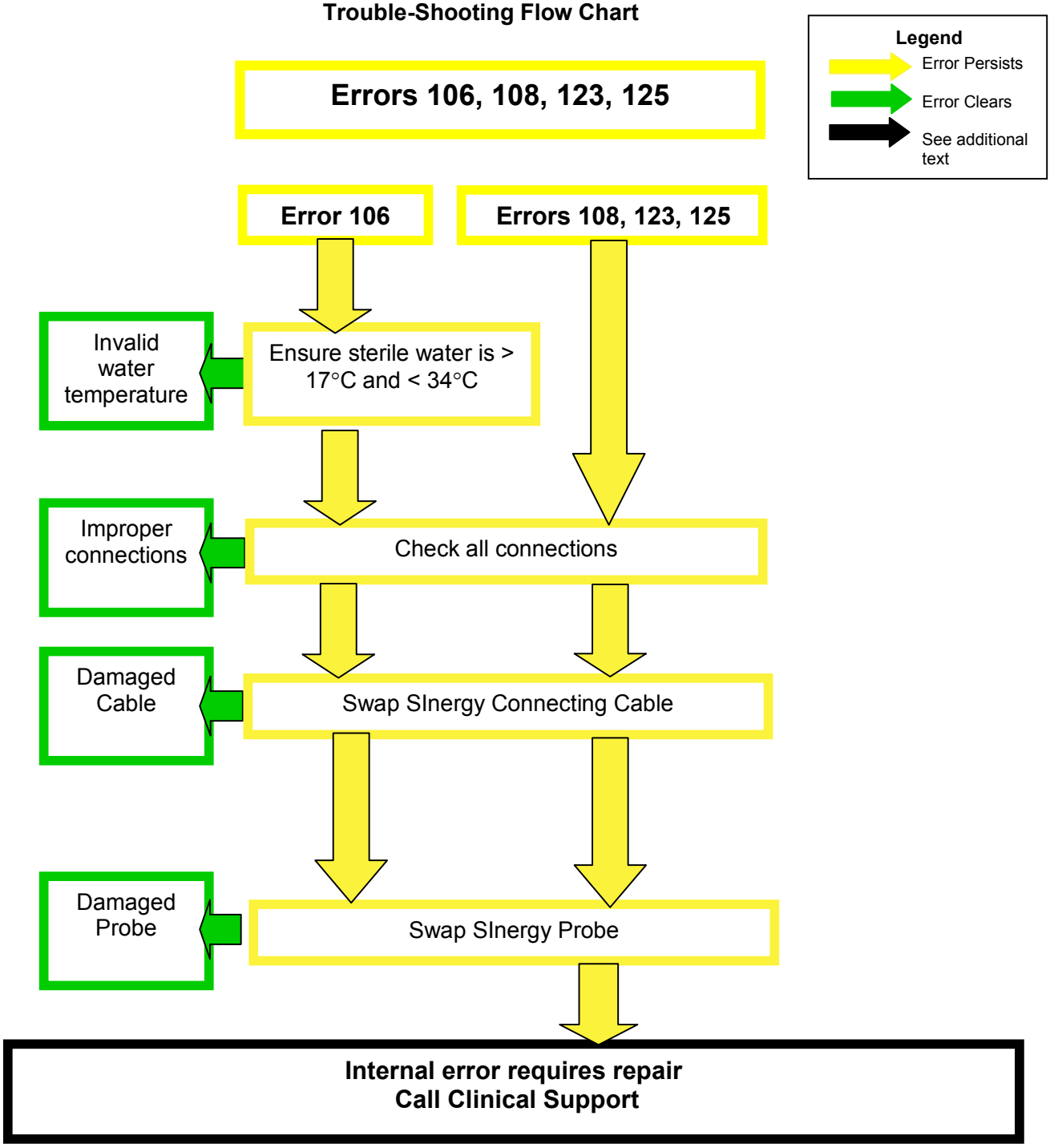
Trouble-Shooting Flow Chart



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