



SIMPLICITY™ RADIOFREQUENCY  
DENERVATION PROBE  
**TECHNIQUE GUIDE**



**Simplicity™**  
Radiofrequency (RF)  
Denervation Probe

# CONTENTS

Overview	3
Design Principle	3
Procedure	4
L5 Primary Dorsal Ramus Radiofrequency Lesioning	6
Using the Simplicity™ Probe with the NT2000iX™ RF Generator	7
FAQ	10

# OVERVIEW

The Abbott Simplicity™ probe revolutionizes sacroiliac joint (SIJ) region radiofrequency (RF) denervation. It incorporates three independent, active electrodes into one device—facilitating fast and easy device positioning and enabling you to create a continuous strip lesion of the lateral branches of the posterior sensory nerves exiting the sacral foramen (S1-S4). The novel design of the Simplicity probe may reduce procedure time by eliminating the need for multiple introducers or needles.

## REVOLUTIONARY SIMPLICITY™ PROBE DESIGN

Figure 1.



- 1 Ergonomic handle designed to maximize push and twist maneuverability to navigate ligaments around the SIJ.
- 2 Proprietary, three-electrode configuration creates large lesions without the need for multiple needle placements.
- 3 Curved probe and diamond-shaped tip provide flexibility for placement in difficult-to-reach anatomical areas and are intended to promote easy, efficient placement.

## PATIENT SELECTION

SIJ pain is highly prevalent, affecting an estimated 15–30% of patients with lower back pain.<sup>1</sup> Patients diagnosed with persistent lumbosacral pain who have had positive temporary response to SIJ injections may be candidates for treatment using the Simplicity probe.

Correct diagnosis is critical to a successful outcome with the Simplicity probe, and is typically accomplished with image-guided SIJ blocks. Two consecutive blocks are often recommended or required, after which patients should experience at least 50% pain relief to be considered a candidate for treatment.<sup>2,3</sup>

# DESIGN PRINCIPLE

**Although RF has been a widely accepted application for denervation, treatment of lumbosacral pain associated with the SIJ is complicated due to the difficulty in locating and ablating multiple sacral nerves.<sup>4</sup>**

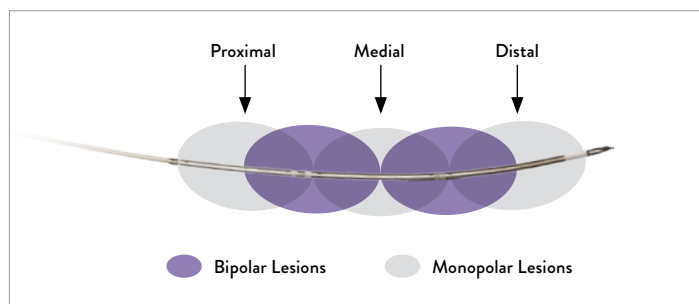
Historically, physicians have primarily used two techniques:

- With the single-needle technique, the physician locates relevant nerves using traditional sensory stimulation and ablates only if the SIJ pain is reproduced. This approach has been shown to offer some pain relief (> 50% pain relief in 64% of patients at 6 months).<sup>5</sup>

- With the “leap-frog” technique, the physician creates bipolar lesions in a leap-frog fashion to create an ablation line long enough to cross all sacral nerves. Sensory stimulation is unnecessary, and the electrodes must be spaced  $\leq 5$  mm apart to ensure complete ablation between electrodes.

Unlike those traditional approaches, the unique, sequential heating algorithms of the NT2000iX™ and NT1100™ RF generators enable the Simplicity probe to create five separate lesions, resulting in a true strip lesion (Figure 2).

Figure 2. Five lesions are created with three independent electrodes.



### HEATING SEQUENCE:

1. A bipolar lesion is made between the distal and medial electrodes.
2. A bipolar lesion is made between the medial and proximal electrodes.
3. A monopolar lesion is made at the distal electrode.
4. A monopolar lesion is made at the medial electrode.
5. A monopolar lesion is made at the proximal electrode.

# PROCEDURE\*

This reference document is intended as an outline for procedures involving SI denervation with RF lesioning to the L5 dorsal ramus and the lateral branches of S1, S2, S3 and S4. It is not intended to replace the clinical judgment or decision-making of the treating physician, nor should it be interpreted as a clinical directive from Abbott.

1. Place the patient in the prone position with a pillow (or spinal imaging platform) beneath the abdomen to reduce the lumbar lordotic curvature.
2. Apply the grounding pad to a well-vascularized, muscular area in close proximity to the treatment site. Avoid placement over scars, bony prominences, prostheses, hair and ECG electrodes. Do not apply where fluids may pool.
3. Using aseptic technique, prepare and drape the lower lumbar region and buttocks on the operative side.
4. With the C-arm in a vertical position, obtain an anterior-posterior (AP) projection centered on the inferior border of the ipsilateral sacrum (Figure 3).
5. Use a lateral image to identify the ideal entry point at the ipsilateral, lateral and inferior borders of the sacrum (Figure 3).

**TIP:** A technique used by some physicians is to enter the skin approximately 1 cm lateral and inferior to the S4 foramen.

6. Use a 25G spinal needle and local anesthetic to anesthetize the target track of the Simplicity™ probe.

**TIP:** Try to avoid the formation of anesthesia “puddles” on the sacrum, as they may hinder lesion formation.

7. Advance the spinal needle, making contact with the sacral target point lateral to the S4 foramen. Be sure to make contact with the sacrum at an appropriate depth, and ensure the needle has not entered a sacral foramen or ventured inferior to the sacral margin and into the pelvic cavity.
8. Upon contacting the periosteum, advance the needle in a cephalad and slightly lateral direction, staying lateral to the sacral foramen, medial to the SIJ, and in contact with the sacrum. Advance the needle through the ligamentous tissue between the sacrum and ilium.
9. Upon reaching a point where no further cephalad advancement can occur, remove the stylet and inject local anesthetic, with or without corticosteroid, as the needle is withdrawn, anesthetizing the lesion track.

**TIP:** Anesthetize the track in two parts (Figures 4 and 5).

\*One physician’s recommended technique. This document is not intended to replace the clinical judgment or decision-making of the treating physician.

Please consult the Instructions for Use before using the Simplicity™ probe.

All fluoroscopic images courtesy of Dr. J. De Witte, OLV Aalst Belgium.



Figure 3. AP view identifying skin entry point.



Figure 4. Spinal needle placement (from the sacral target point to the mid-SIJ) to anesthetize the track of the Simplicity™ probe (first placement).

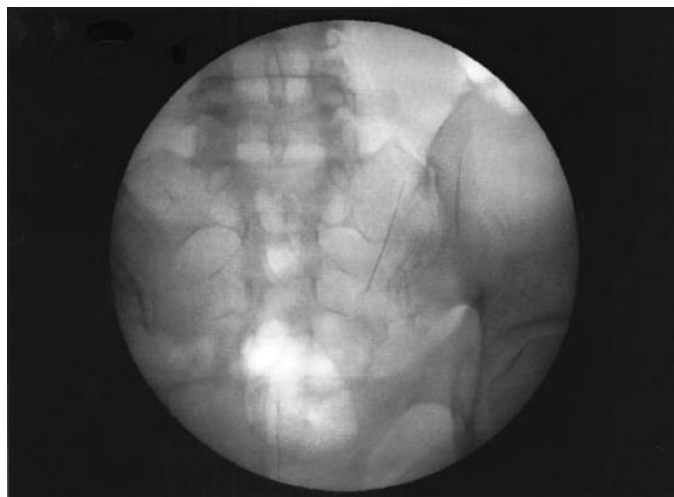


Figure 5. Spinal needle placement (from the mid-SIJ to the sacral ala) to anesthetize the track of the Simplicity™ probe (second placement).

## PROCEDURE (continued)

10. Make additional injections of local anesthetic solution along the intended lesion track as necessary to optimize patient comfort.
11. Insert the Simplicity™ probe through the previously created skin puncture (a scalpel may assist probe entry by making a small skin nick) until it makes contact with the inferolateral border of the sacrum. Verify that the electrode did not enter a sacral foramen or proceed inferior to the inferior border of the sacrum by checking a lateral view.

**TIP:** Place one hand at the entry point and one hand on the Simplicity probe handle, using both hands to insert and gently steer the probe.

**TIP:** Place the probe with the tip curved downward until you reach the periosteum. Always try to touch it tangentially, not under a steep angle. Touch the handle to the skin and steer the probe with your other hand.

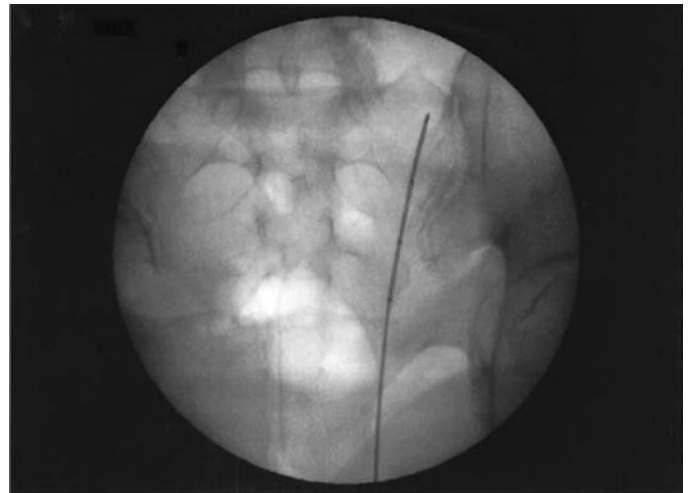
12. Advance the Simplicity™ probe while maintaining continuous contact with the sacrum on a cephalad and slightly lateral line. Stay lateral to the sacral foramen, medial to the SIJ, and ventral to the ilium until contact with the sacral ala prevents further advancement (Figure 6).

**TIP:** While advancing the probe, consider taking a lateral image to ensure you are not advancing over the ilium, but rather advancing into the deep interosseous ligament.

**TIP:** Use the spinal needle as a marker by placing it at the endpoint of the track of the Simplicity probe. It may help as a target for placement of the probe. The needle can also be used as a reference for the probe depth.

13. Confirm appropriate positioning by changing the caudal/cephalad tilt of the C-arm to align the superior endplate of S1. Verify once again that the entire length of the Simplicity probe is advanced to the ipsilateral sacral ala and the three independent, active contacts are positioned parallel to the S1, S2, S3 and S4 lateral branch innervation pathways.

**TIP:** The probe has three radiopaque markers visible under X-ray. Use these to verify placement in relation to the S1, S2, S3 and S4 lateral branch pathways.



**Figure 6.** AP view of the Simplicity™ probe being advanced. Ensure bone contact.



**Figure 7.** Lateral view of the Simplicity™ probe being advanced.

## PROCEDURE (continued)

14. Obtain a lateral view to confirm that the Simplicity™ probe remained in contact with the sacral periosteum, followed the curvature of the sacrum up to the sacral ala, and is in an appropriate position to lesion the lateral branches of S1, S2, S3 and S4. The most proximal contact should be away from the dermis to prevent skin injury.

**TIP:** To determine the proximity of the distal electrode to the skin, place a pointer or metal forceps at the skin entry point and take a lateral image.

15. Connect the Simplicity probe to the RF generator using the Simplicity™ adapter cable (order number AC-SI-III). Align the numbered connectors to the corresponding numbered ports.
16. Perform RF lesioning using the Simplicity™ III heating algorithm in the NT2000iX™ or NT1100™ RF generator. (The heating sequence is described on page 3 of this guide.)
17. Remove the Simplicity probe and follow normal postop protocol.

### L5 PRIMARY DORSAL RAMUS RADIOFREQUENCY LESIONING

After anesthetizing the skin, place an RF needle in contact with the S1 superior articular process, slightly above the groove formed between the superior articular process and the sacral ala. Advance the needle until the active tip crosses the entire width of the superior articular process of S1, parallel to the L5 primary dorsal ramus. Confirm appropriate positioning using AP, ipsilateral, oblique and lateral views. Perform sensory and/or motor stimulation, verifying no motor recruitment in the ipsilateral lower extremity. Perform RF lesioning.

**TIP:** If using IV sedation, lesion the L5 dorsal ramus in the conscious patient first and then start IV sedation at the discretion of the anesthesiologist.

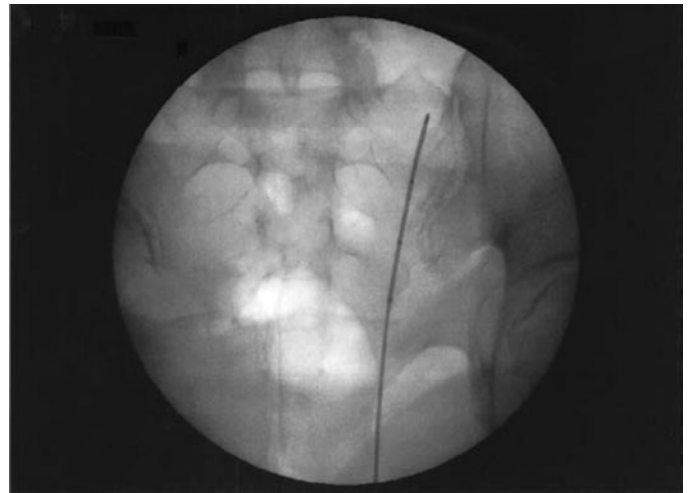


Figure 8. AP view of the Simplicity™ probe placement.

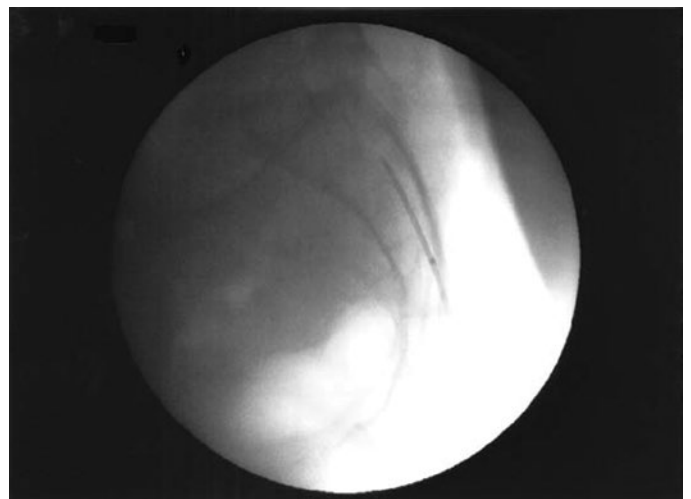


Figure 9. Lateral view of the Simplicity™ probe placement.

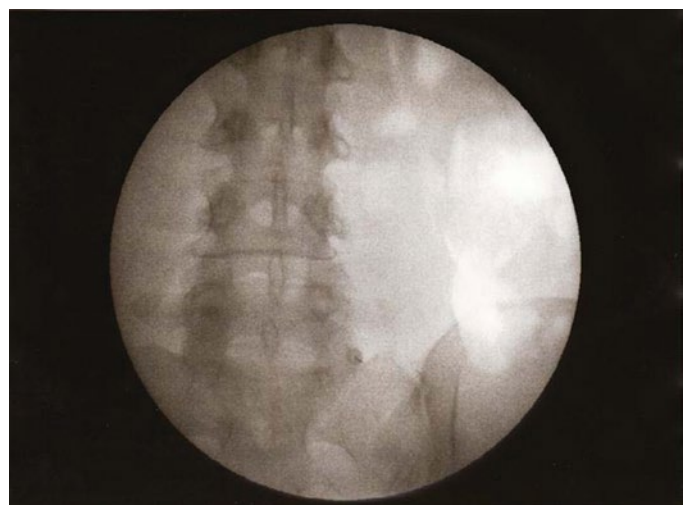


Figure 10. L5 primary dorsal ramus RF lesioning.

# USING THE SIMPLICITY™ PROBE WITH THE NT2000iX™ RF GENERATOR\*

## ELECTRODE CONFIGURATION FOR THE SIMPLICITY PROBE

To use the NT2000iX™ RF generator with the Simplicity™ probe, begin by selecting the appropriate doctor and patient information and then tap **Start** on the Welcome screen. This takes you to the Electrode Configuration screen (Figure 11).

The NT2000iX RF generator has two heating procedures:

- The Simplicity™ II procedure uses two independent electrodes.
- The Simplicity™ III procedure uses three independent electrodes.

The activation buttons for these two procedures are denoted by the II and III buttons found on the bottom right of the Electrode Configuration screen. The button turns white when selected.



NT2000iX™ RF generator

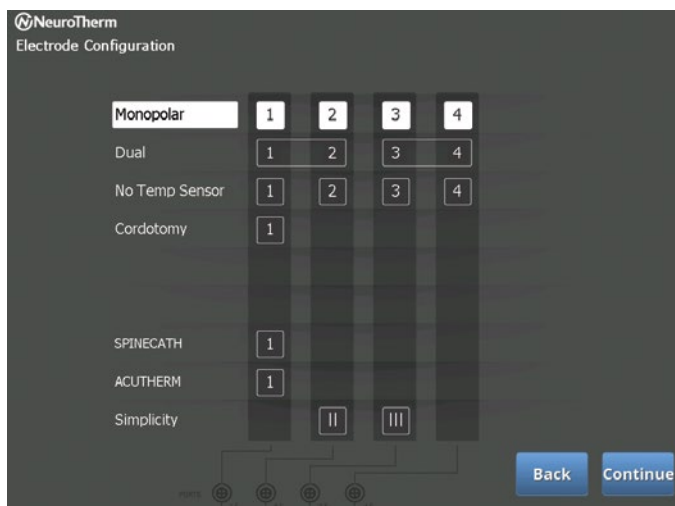


Figure 11. Make the desired selection on the Electrode Configuration screen and tap **Continue**.

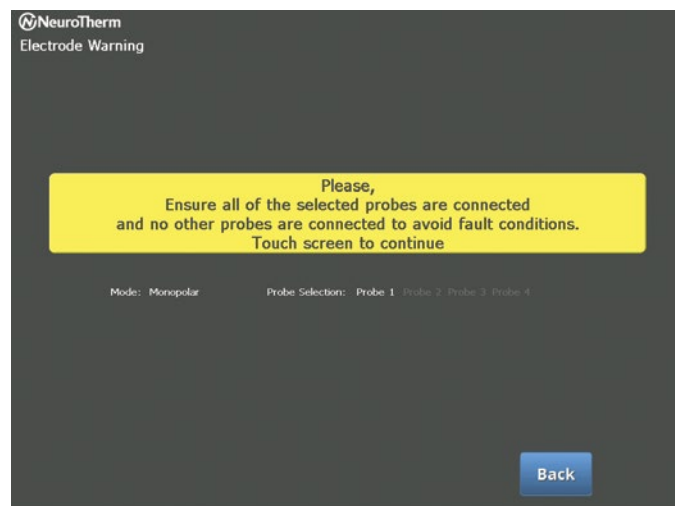
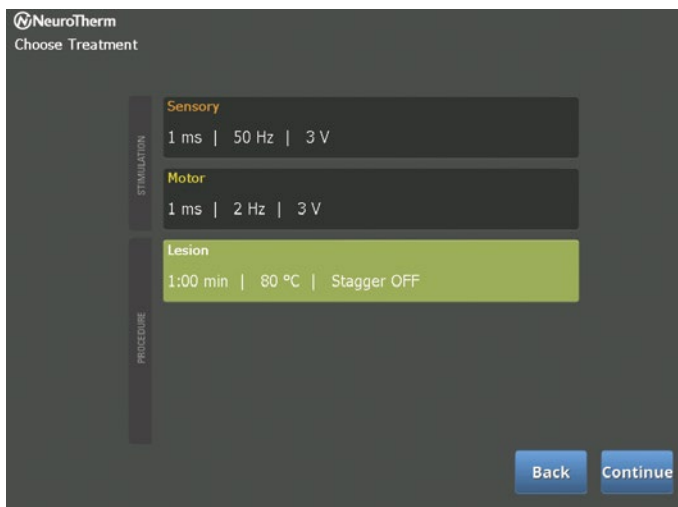


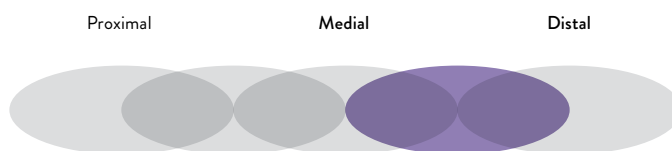
Figure 12. Ensure all of the probes are connected and then tap any part of the screen to continue.

\*One physician's recommended technique. Please consult the *Instructions for Use* before using the Simplicity™ probe.

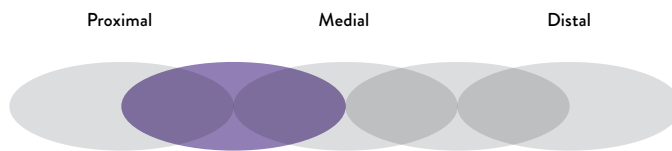
# USING THE SIMPLICITY™ PROBE WITH THE NT2000IX™ RF GENERATOR (continued)



**Figure 13.** You are now at the Choose Treatment screen. Tap **Lesion** to access the Lesion Procedure screen.



**Figure 14.** Tap **Auto** to begin treatment. First, a bipolar lesion is created between the distal and medial electrodes.



**Figure 15.** Next, a bipolar lesion is created between the medial and proximal electrodes.

**NOTE:** Between the two bipolar lesions, the NT2000iX™ generator performs a 20-second cooldown.

**NOTE:** When a bipolar lesion is being created, you may see one electrode reach the desired temperature and the other stay below temperature. This is normal.



# USING THE SIMPLICITY™ PROBE WITH THE NT2000IX™ RF GENERATOR (continued)

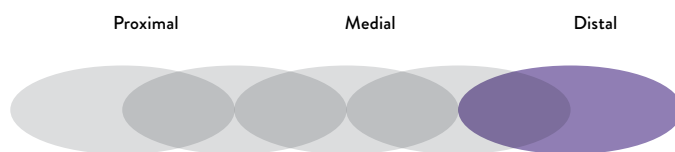


Figure 16. Then, a monopolar lesion is created at the distal electrode.

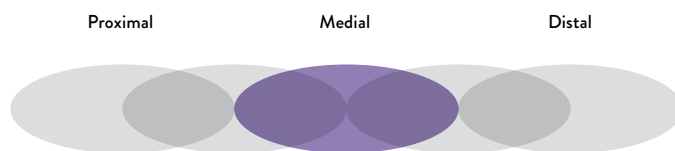


Figure 17. Next, a monopolar lesion is created at the medial electrode.

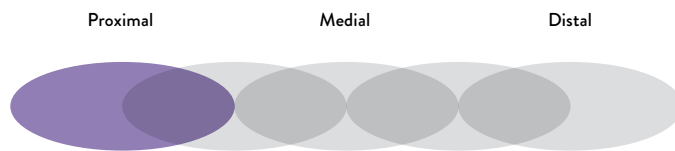
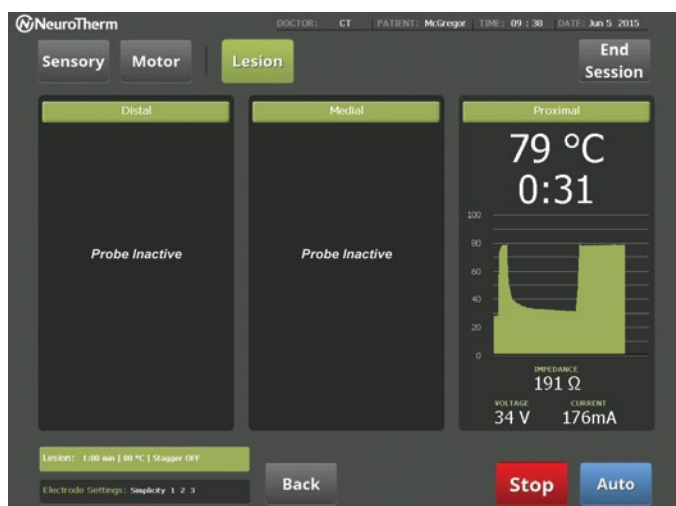


Figure 18. Lastly, a monopolar lesion is created at the proximal electrode.

**NOTE:** When using the Simplicity™ II procedure mode, there will be a bipolar lesion between the distal and medial electrodes, followed by a monopolar lesion at the distal electrode, followed by a monopolar lesion at the medial electrode.

## FAQ

**Q: SINCE THE SIMPLICITY™ PROBE USES DUAL LESIONING, DO I STILL NEED A GROUNDING PAD?**

A: Yes. The Simplicity probe creates both bipolar and monopolar lesions. A grounding pad is required for monopolar lesions, so a grounding pad is still required for use with the Simplicity probe. Please follow the grounding pad instructions for use when placing the grounding pad.

**Q: HOW MUCH ANESTHETIC SHOULD I USE?**

A: Use only as much anesthetic as is necessary, as excess fluid can contribute to irregular and incomplete lesions.

**Q: WHY IS THERE A COOLDOWN PERIOD BETWEEN THE DUAL LESIONS ON THE NT2000IX™ GENERATOR?**

A: The cooldown period allows the medial electrode to cool down to a temperature closer to body temperature.

1. Cohen SP, Chen Y, Neufeld NJ. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. *Expert Rev Neurother*. 2013 Jan;13(1):99-11
2. Cigna Medical Coverage Policy. *Minimally Invasive Treatment of Back and Neck Pain*. July 15, 2014.
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4. Cohen, S. (2005). Sacroiliac joint pain: a comprehensive review of anatomy, diagnosis, and treatment. *Anesthesia and Analgesia*, 101, 1440-1453.
5. Yin, W., Willard, F., Carreiro, J., & Dreyfuss, P. (2003). Sensory stimulation-guided sacroiliac joint radiofrequency neurotomy: technique based on neuroanatomy of the dorsal sacral plexus. *Spine*, 28, 2419-2425.

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St. Jude Medical is now Abbott.

**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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