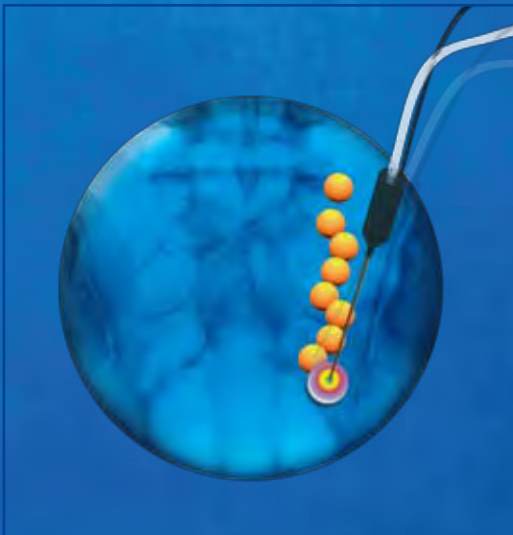
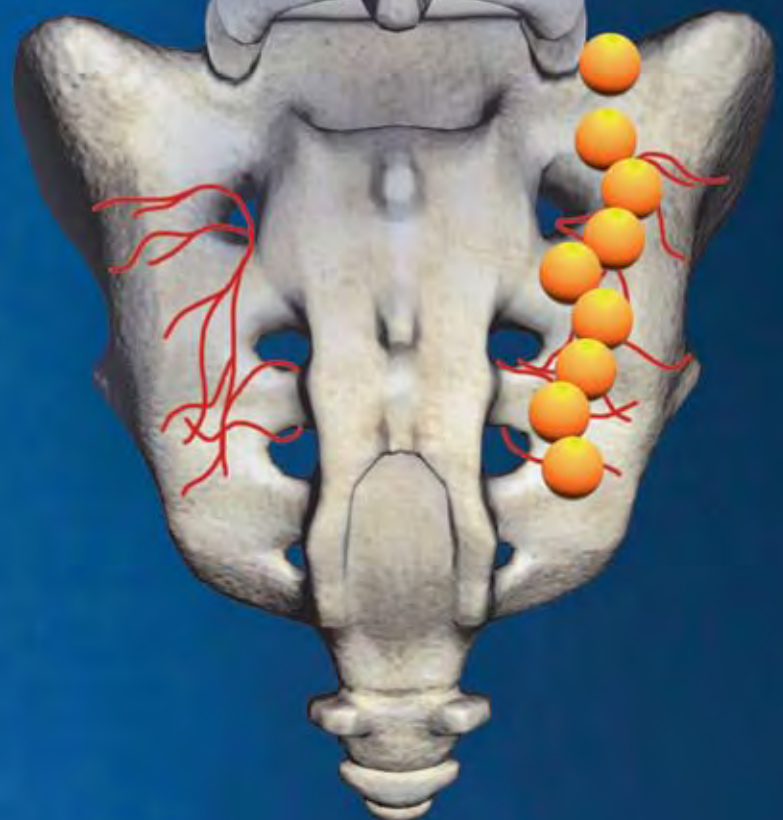


*Slnergy*TM System



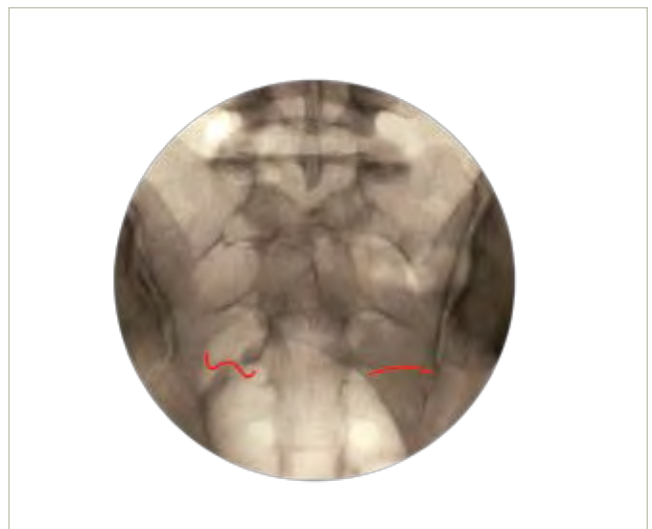
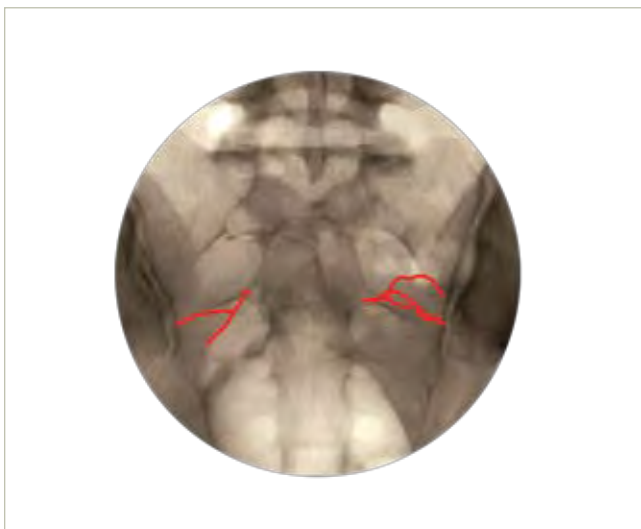
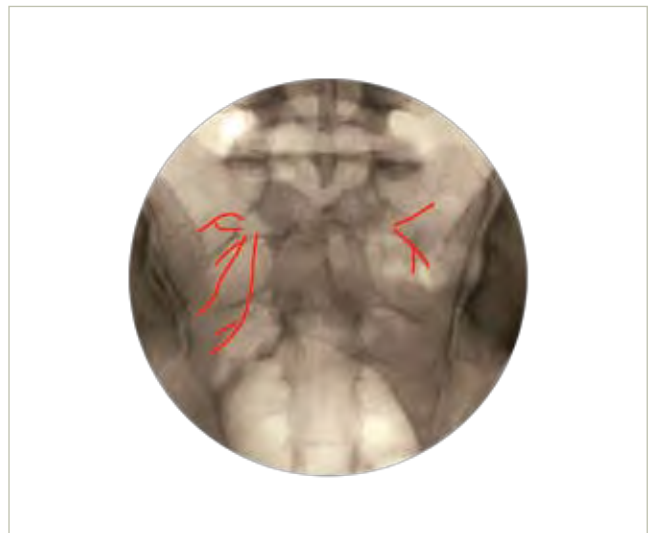
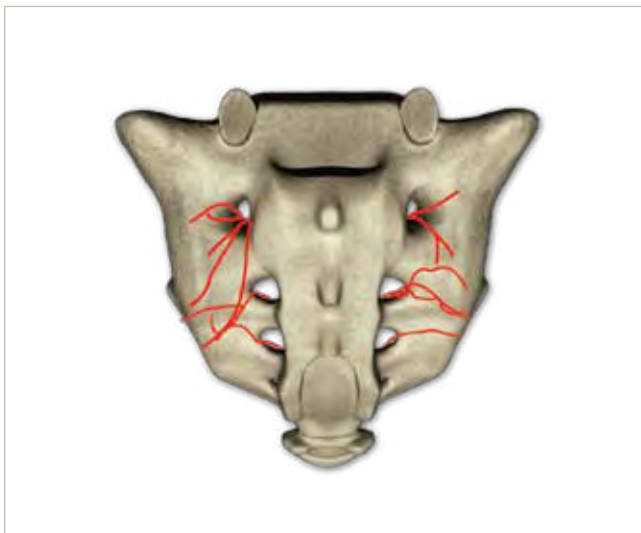
For effective denervation in the treatment of chronic sacroiliac joint pain



SI Innervation

Lateral branches of the posterior rami are responsible for relaying nociceptive signals from the SIJ and the surrounding structures back to the CNS. Anatomical studies suggest that the number and running course of these lateral branches are variable.¹ This is demonstrated not only between specimens, but also from side to side, and from level to level (see figures). There exists no correlation between nerve location and the bony landmarks identifiable under fluoroscopy. This variability presents a challenge for clinicians seeking to treat chronic sacroiliac joint pain.

¹ Yin W. et al. Spine. Sensory Stimulation-Guided Joint Radiofrequency Neurotomy: Technique Based on Neuroanatomy of the Dorsal Sacral Plexus, 2003; 28(20):2419-2425.



The Denervation Procedure

Placement and lesions

The fundamental challenge of treating chronic sacroiliac joint pain is to capture the afferent lateral branches coursing between the painful SI region and the posterior sacral foramina.

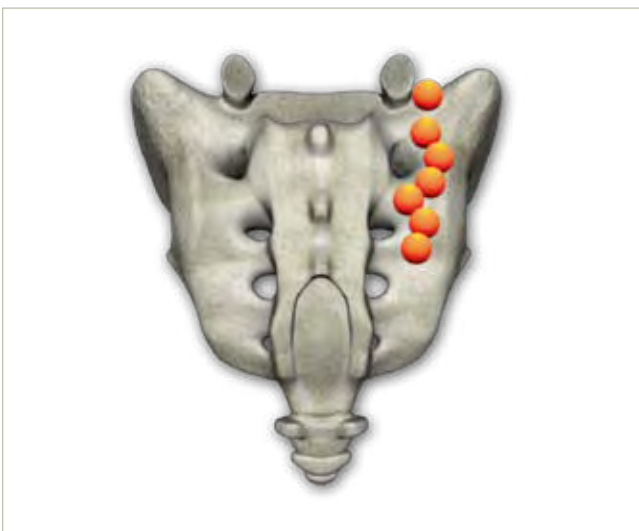
- Using the *Slnergy*™ system, large-volume lesions are created to ablate the targeted neural structures along the sacrum
- Lesions are positioned between posterior sacral foramina and the SIJ (figures 1-4)
- Variability of nerve location and running course are compensated for by lesion size and position
- Pain originating from both the SI joint and the surrounding connective tissue is disrupted
- The consistency of lesion shape and size is precisely maintained by the Baylis Pain Management Generator



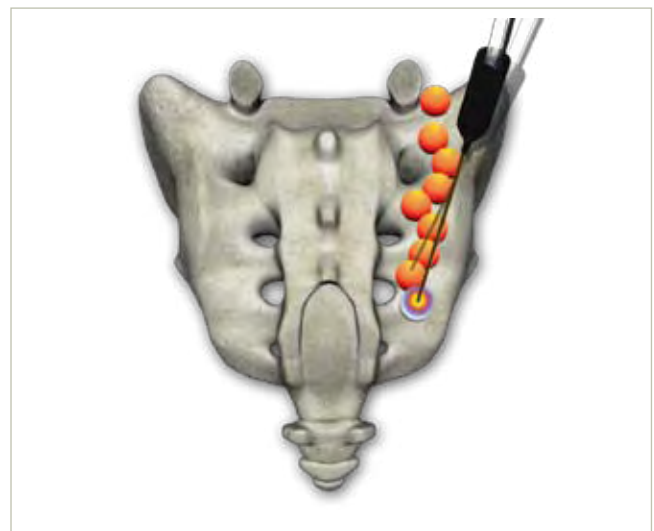
Placement 1 : Lesion L5-S1



Placement 2 : Lesions 1, 2 and 3 at S1 location



Placement 3 : Lesions 1, 2 and 3 at S2 location



Placement 4 : Lesions 1 and 2 at S3 location.
Procedure completed.

The Pain Management *SInergy*[™] Probe

- Cooling tissue adjacent to the electrode allows for higher power delivery and a larger volume of treated tissue
- Cooling eliminates tissue adherence to the probe
- A temperature sensor at the end of the probe tip ensures appropriate thermal gradient in target tissue. The lengths of the stylet and probe ensure precise and reliable placement of the tip thermocouple



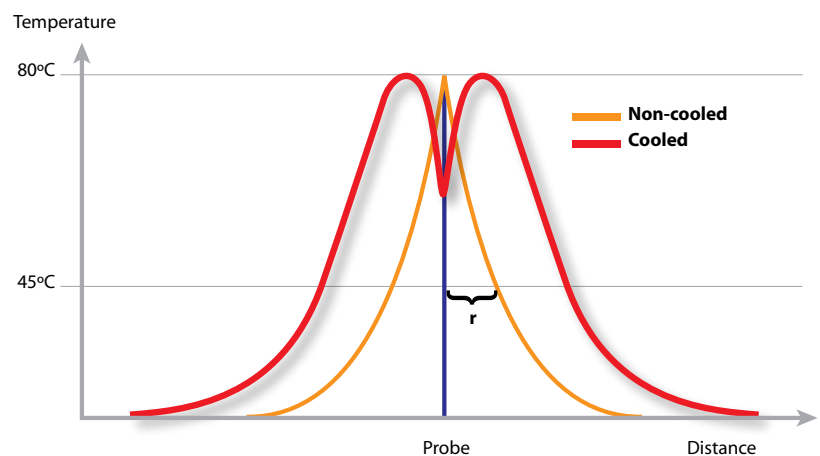
Cooling: Water Circulation

Electrode

Temperature sensor

Ionic Heating of Tissue Using Cooled-RF

- Without cooling, the size of the lesion is limited by the heat generated in tissue adjacent to the electrode
- It is not desirable to raise tissue temperature above 95° C
- Cooling the tissue adjacent to the electrode allows for greater heat dissipation



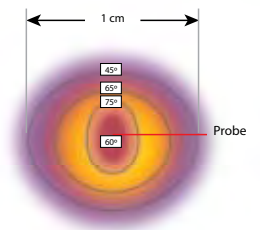
Cooled-RF vs Standard RF Lesioning

- Designed to effectively ablate the posterior lateral branch nerves
- Generates large volume lesions to encompass the known running course of lateral branches between the sacral foramen and the SIJ

Cooled-RF

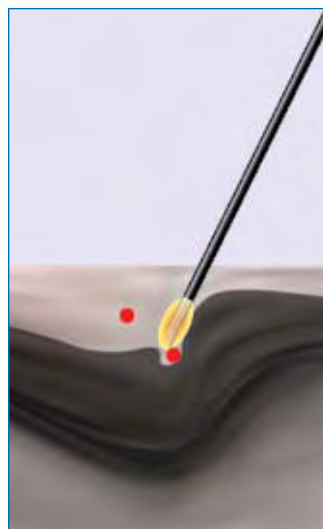
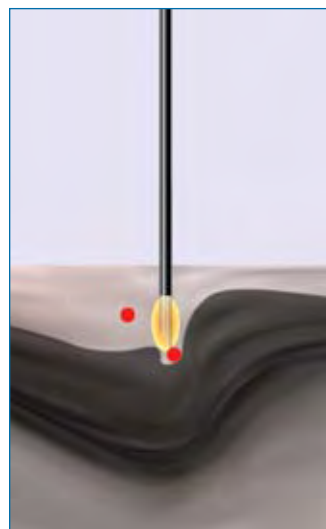
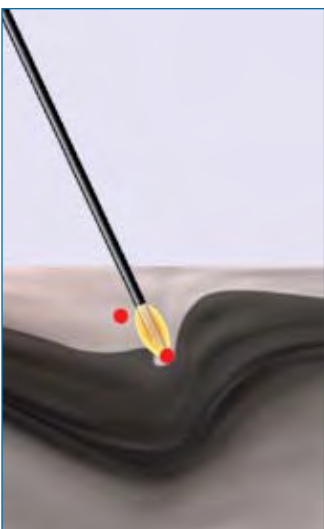


Isotherm (°Celsius)



● Target Nerve

Standard RF



● Target Nerve

Pain Management *SInergy*™ System



Pain Management *SInergy*™ Probe

The disposable probe is 18 gauge with a 4 mm active tip. Probe includes a 4-foot connecting cable and tubing extension to reach out of the sterile field. These are connected to the generator and peristaltic pump unit for RF energy delivery and internal cooling.

Pain Management *SInergy*™ Introducer

The 17 gauge disposable introducer is available in 75 mm and 150 mm lengths. It is insulated and has a luer lock hub that mates with the *SInergy*™ probe of matching length and also to a syringe for injections.



Pain Management Pump Unit

The pump unit is used to circulate cool sterile water during lesion formation. The pump is connected to the generator, which provides power and controls flow rate to the probe.



Pain Management Tube Kit

The disposable tube kit is used as a reservoir and to transport sterile water from the pump to the probe. It consists of a burette to hold water, connected to tubing that is inserted in the pump unit. The tube kit connects to a *SInergy*™ probe with a luer lock.



Pain Management Generator

The PMG-115-TD and PMG-230-TD (V2.2 Advanced unit or higher) are the only generators compatible with the *SInergy*™ system. They are designed with the capability of controlling the peristaltic pump unit.

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PM1010 Rev 04/08

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Caution : Federal Law (USA) restricts the sale of these devices to or by the order of a physician.

Patents Pending and/or issued