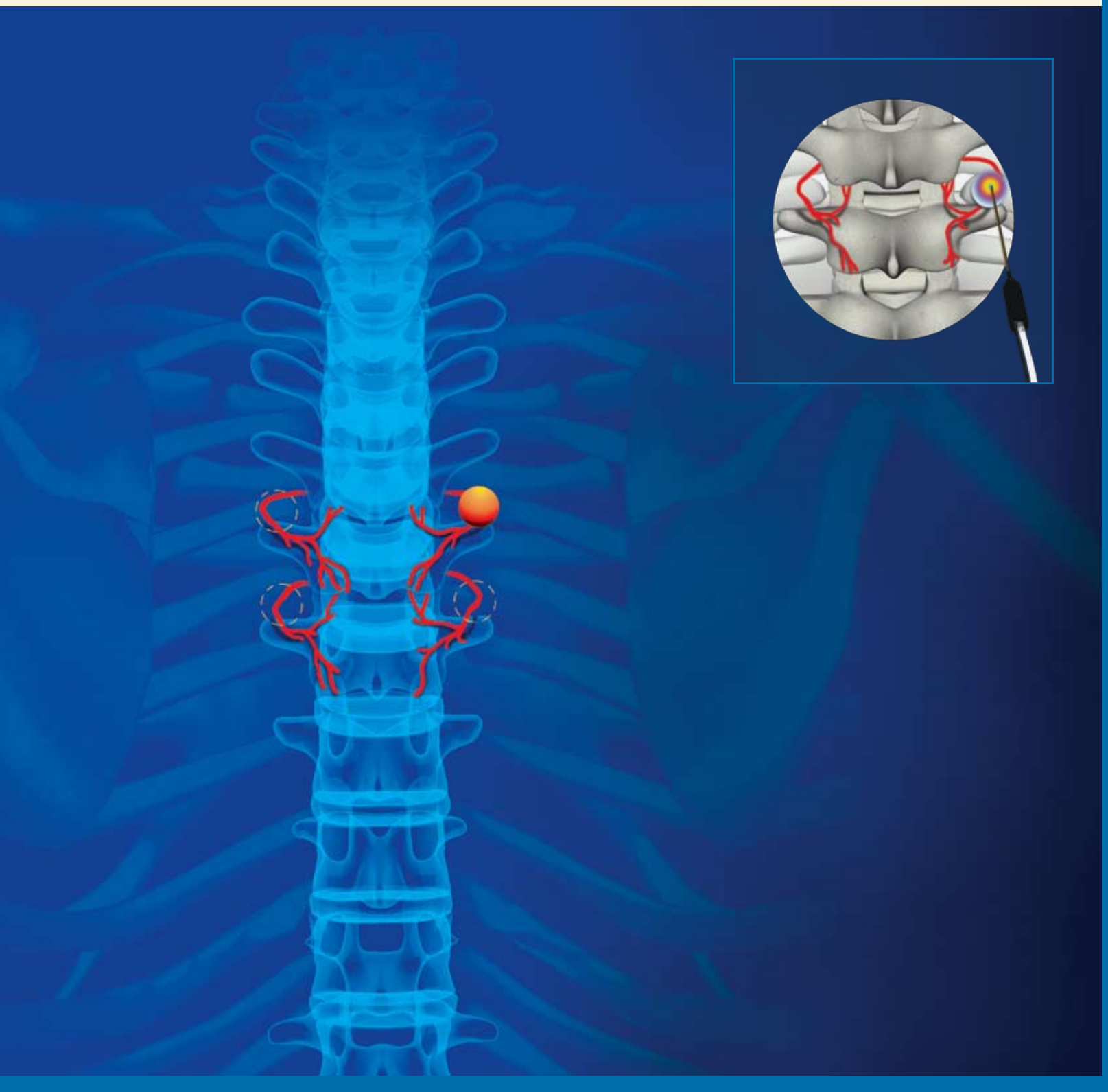
Baylis MEDICAL

FOR THORACIC MEDIAL BRANCH NEUROTOMY

ThoraCool™ Pain Management System



ThoraCool™ Pain Management System

ThoraCool™ Probe:

- Internally water-cooled radiofrequency (RF) probe allows for the creation of optimal, large-volume, spherical lesions.
- Cooling maintains the desired temperature at all times, and produces the desired lesion shape and size, while eliminating tissue charring at the probe tip.
- The temperature sensor at the end of the probe tip ensures an appropriate thermal gradient in the target tissue.
- A radiopaque marker is located at the proximal end of the active tip. This marker defines the lesion location under fluoroscopy, confirming position and enhancing visualization.

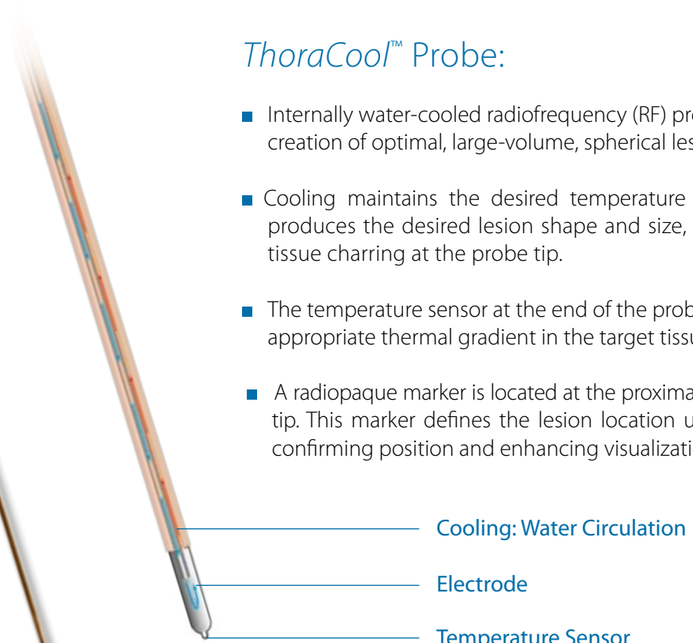


Figure 1 : Water-cooled probe

A major challenge in treating chronic, thoracic facet pain comes from the variable course of the medial branch nerve, particularly in the mid-thoracic levels.

The *ThoraCool*™ Pain Management System Overcomes the Challenge of the Variable Nerve Course as Follows:

- With the *ThoraCool*™ pain management system, a large-volume lesion is created to ablate the targeted nerves using patent-pending Cooled-Radiofrequency technology.
- Medial branch variability is compensated for by the lesion size and position.
- The lesion shape and size is repeatable.

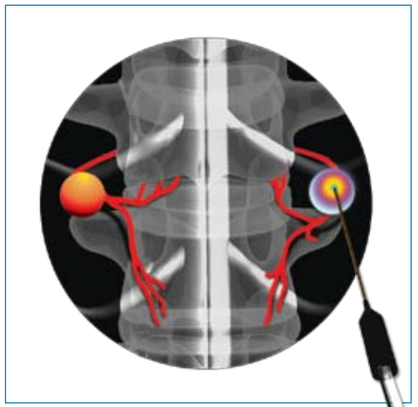


Figure 2 : Cooled-RF lesion

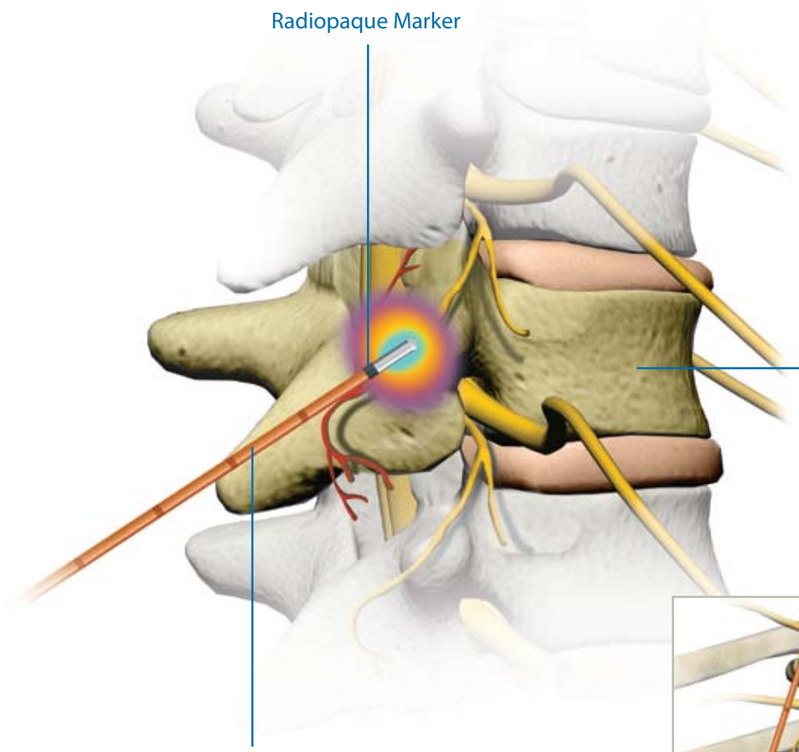
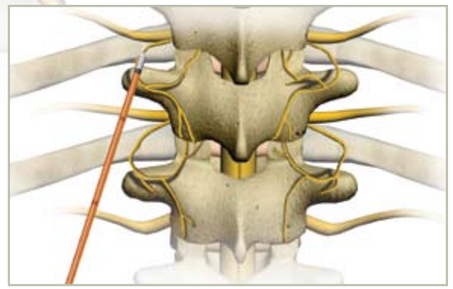


Figure 3 : Medial branch denervation using the *Thora*Cool™ probe



Straightforward Placement:

- Introducer is advanced to the target lesion location under fluoroscopic guidance, using a gun-barrel approach.
- Using an ipsilateral oblique approach, the introducer is advanced toward the "Thoracic Safe Zone" to the target location; the "Thoracic Safe Zone" directs the introducer towards the vertebral body.
- Probe placement is confirmed under fluoroscopy with the radiopaque marker.
- The large, spherical lesions overcome the variability of the medial branch nerve course, disrupting the pain signals.

ThoraCool™ Pain Management System

ThoraCool™ Probe

The disposable probe is 18 gauge with a 5.5 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.

ThoraCool™ Introducer

The 17 gauge disposable introducer has a usable length of 75 mm. It is insulated and has a luer lock hub that mates with the *ThoraCool*™ probe and also a syringe for injections.

Pain Management Pump Unit (sold separately)

The peristaltic pump unit is used to circulate sterile water in the probe during lesion formation. The pump is connected to the PMG RF generator where the software provides power and controls water flow rate to the probe so as to maintain the desired temperature.

Pain Management Tube Kit

The disposable tube kit is used to circulate sterile water to cool the probe electrode. The tube kit consists of a burette to hold water, connected to tubing that is inserted in the peristaltic pump. The tube kit connects to the *ThoraCool*™ probe with a luer lock.

Pain Management Generator

The PMG-115-TD and PMG-230-TD (version V2.2A - Advanced unit or higher) are the only generators compatible with the *ThoraCool*™ pain management system. The software is designed with the capability of controlling both the peristaltic pump unit and the *ThoraCool*™ probe.

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

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Patents Pending and/or issued