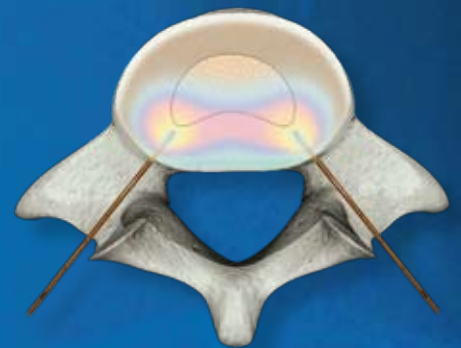


THE NEXT GENERATION IN DISCOGENIC PAIN RELIEF

TransDiscal[™] System



for intervertebral disc biacuplasty

The Baylis TransDiscal[™] System, in combination with the Baylis Pain Management Generator-TD (PMG-TD), is indicated for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs.

TransDiscal™ System

Bipolar, Cooled RF for Intervertebral Disc Biacuplasty

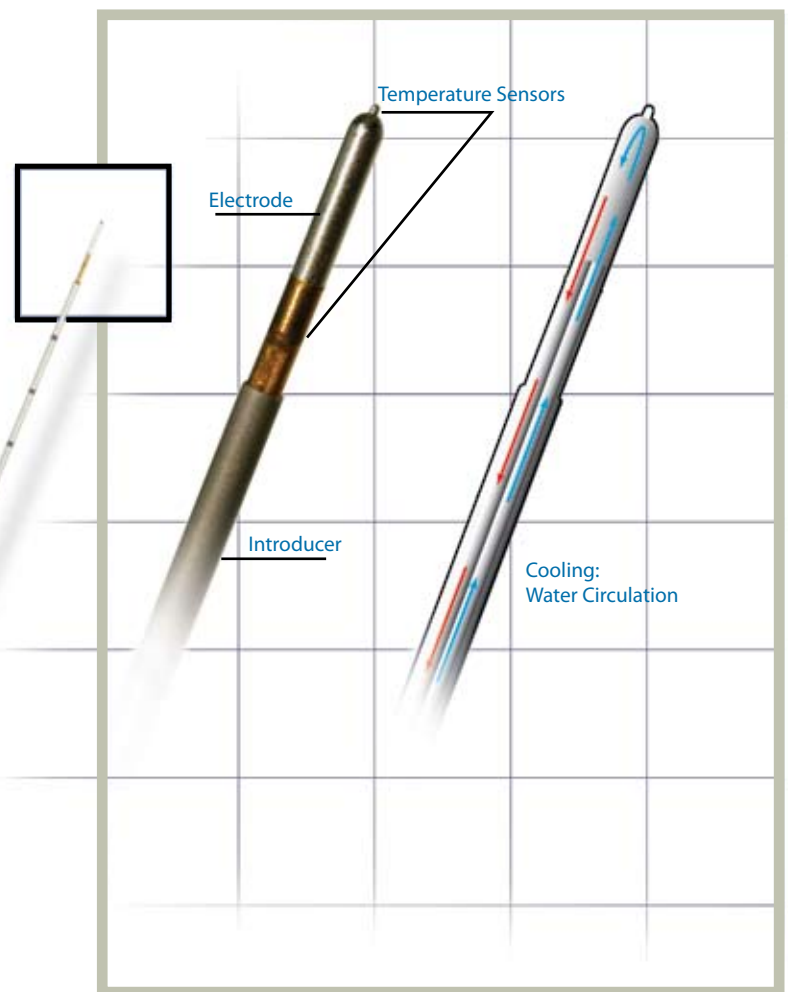
The TransDiscal™ System is taking disc treatments to a new level. It uses a bipolar approach in conjunction with internally water-cooled radiofrequency (RF) probes to coagulate and deactivate nerves in order to treat symptomatic patients with discogenic pain.

Straightforward Probe Placement

The introducers are inserted straight inside the disc without the need for steering a flexible catheter. The stylets provide optional audio-guided impedance monitoring to assist in identifying the annulus and nucleus. Under fluoroscopy, two introducers are placed bilaterally in the posterolateral disc and the TransDiscal™ probes are then inserted into the introducers. This placement procedure is similar to the one used in discography.

Temperature Sensors

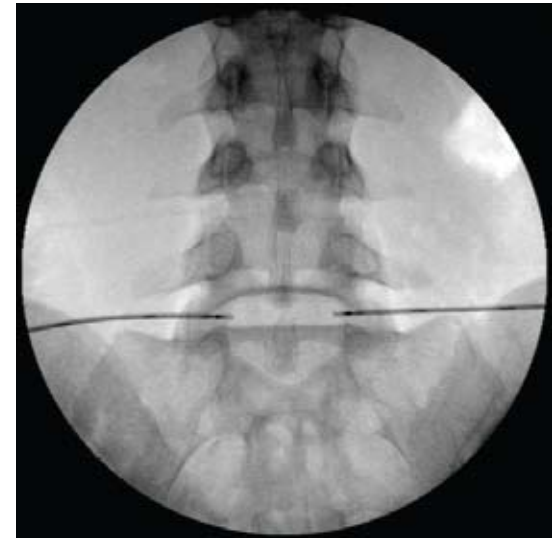
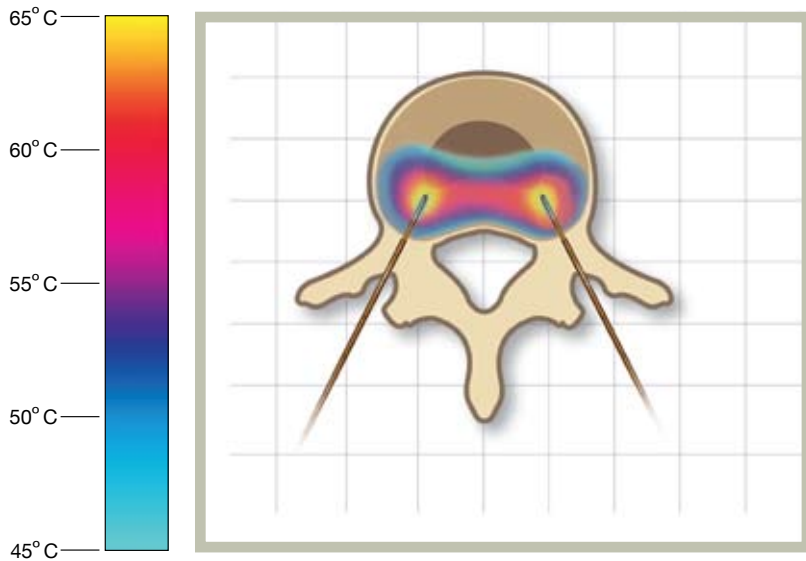
The TransDiscal™ System includes four temperature sensors: two at the end of each probe tip and two located proximally on the probes to monitor peripheral disc temperature.



Water-Cooled RF

Each TransDiscal™ probe is independently and internally water-cooled allowing RF energy to be delivered with greater power to heat a larger volume of disc tissue while eliminating overheating of tissue local to the electrodes. Cooling also eliminates tissue adherence to the probes. The cooling system maintains and balances the temperatures in each probe to the desired set temperature.

TransDiscal™ System



The temperature distribution can be altered by changing the applied parameters which include: set temperature, ramp rate, and procedure time.

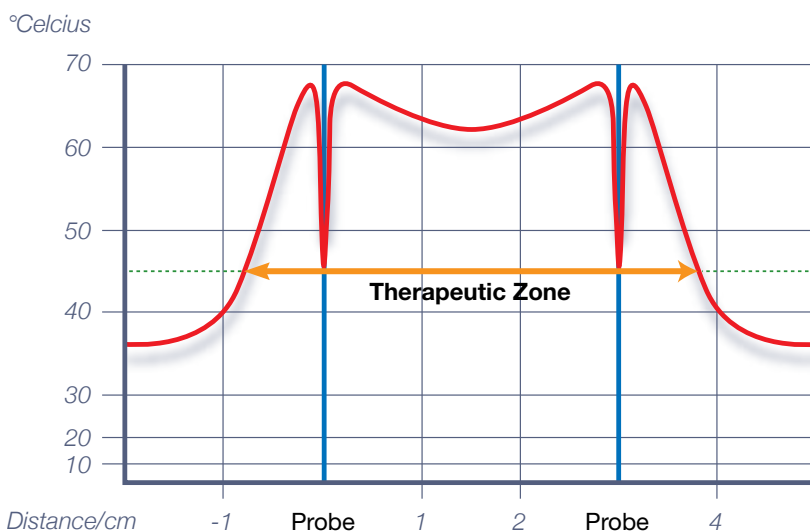
AP fluoroscopic view of TransDiscal™ probes placed in an L5-S1 disc.

Bipolar RF

There are electrodes at the end of the TransDiscal™ probes which are placed bilaterally in the posterior of the disc. The RF energy is applied and directed through the disc between the two TransDiscal™ probes. This concentrated energy results in tissue heating around and between the electrodes.

Ideal Therapeutic Zone

The bipolar RF application combined with internal water cooling allows tissue to be heated within an ideal range for ablating nociceptors and changing the structure of the collagen fibers. The end result is a large, reproducible lesion within a significant volume of the posterior of the disc.



Temperature vs Distance

This graph illustrates the temperature distribution between two probes (placed at 3 cm apart) in the disc at the end of a fifteen minute procedure.

TransDiscal™ System



RF Generator

The PMG-115-TD and PMG-230-TD (Advanced unit) are the only generators compatible with the TransDiscal™ System. They are designed with the capability of monitoring four temperatures simultaneously and controlling the peristaltic pump unit.



TransDiscal™ Probes

The two disposable probes are 18 gauge in size with a 6 mm active tip. Each probe includes a 4-foot electrical 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.

TransDiscal™ Introducers

The 17 gauge disposable introducers are 150 mm long. Each introducer is insulated and has a luer lock hub that mates with the TransDiscal™ probes. Optionally, a model of introducer is available that connects to the generator providing impedance monitoring during placement.



Pain Management Pump Unit

The pump unit includes two independently controlled peristaltic pumpheads and automatically controls the flow rate to each probe.



Pain Management Tube Kit

The disposable tube kits are used to circulate sterile water to cool the probe electrodes. They consist of a burette to hold water, connected to tubing that is inserted in each peristaltic pump. Each tube kit connects to a TransDiscal™ probe with a luer-lock.

Baylis Medical is a world leader in the development and distribution of high-technology pain management products. We conceive, innovate, develop, manufacture, and sell state-of-the-art medical products used around the world. Baylis Medical operates under the ISO 13485:2003 certified quality system.



Baylis Medical Company Inc.
5959 Trans-Canada Highway
Montreal, QC
Canada H4T 1A1

Tel.: (514) 488-9801
Fax: (514) 488-7209
info@baylismedical.com
www.baylismedical.com
www.transdiscal.com



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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