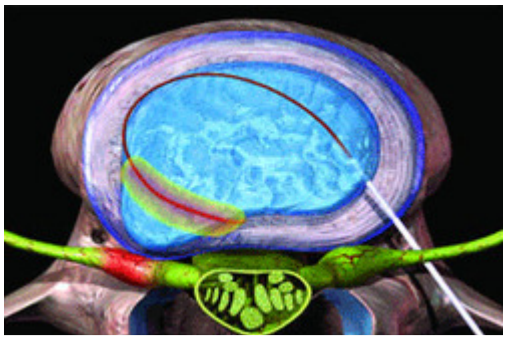
Stryker Multigen – Intradiscal Lesions

Smith and Nephew Acutherm

- A new minimally invasive spinal procedure that treats herniated discs directly at the site, giving patients another chance to do the things that make them smile.



Targeted Disc Decompression (TDD) is possible due to the ACUTHERM◇ Decompression Catheter, a device that features a heating coil designed to treat the herniation directly at the site.

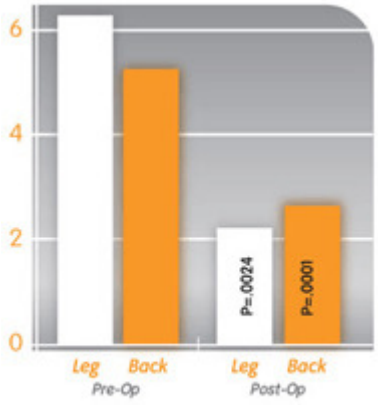
This one of a kind technique offers a more focused treatment as well as improved navigation and placement.

Unlike alternative treatments that target the centre of the affected disc, TDD focuses on the actual herniation itself.

Pre-Operative Post-Operative, 3 months Pre-Operative Post-Operative, 3 months

TDD uses thermal energy to treat patients with contained herniated discs who have failed to respond to more conservative treatments like physical therapy, medication and rest

- VAS Scores



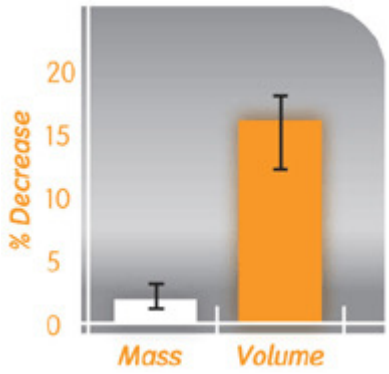
Significant reduction in VAS scores

The chart above illustrates the significant reduction in Visual Analog Pain Scores (VAS) scores for both back and leg pain resulting from treatment with the procedure.

Also pictured (above) are actual pre- and post-operative MRI images showing a noticeable decrease in the size of the herniation. In a clinical study performed at a leading medical institution, the average decrease in disc herniation was 1.7 mm.[3]

The ACUTHERM◦ Decompression Catheter, in conjunction with the Smith & Nephew ELECTROTHERMAL◦ 20S Spine System and Stryker Multigen System, is used to perform Targeted Disc Decompression. Thanks to this system's special features, along with a patented navigation method that ensures close proximity to the target tissue, patients who suffer back and leg pain resulting from contained herniated discs now have an effective, minimally invasive treatment option.

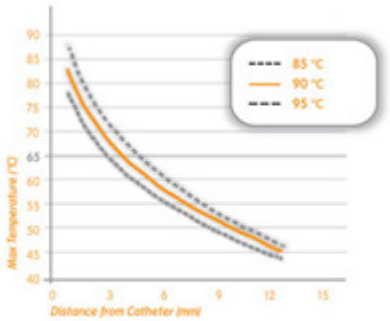
- Clinically Verified



Clinical studies have demonstrated that TDD may result in a reduction of the size of herniations in the disc and a decrease in the severity of back and leg pain suffered by patients.

An analysis of discs following treatment with TDD (right) shows the dramatic decrease in the mass and volume of nucleus pulposus tissue.[2]

- ## Scientifically Sound



Temperatures achieved at various catheter settings

The underlying science of TDD involves the application of heat energy at controlled levels to coagulate the collagen in the disc, causing tissue contraction and a reduced herniation. The ultimate goal is relief of pain for the patient.

Cadaveric studies indicate temperatures of at least 65° C can be achieved in regions up to 5 mm from the catheter. Further data is provided in the chart above.

The result is a reproducible method for collagen contraction.[1]

- ## Optimal patient selection criteria

Inclusion
Contained disc herniation < 6mm
Leg pain greater > back pain
Mixed pattern of back and leg pain
Failed conservative therapy

Exclusion
Extruded or sequestered disc
Disc height < 50%
Spinal stenosis
Spinal fracture or tumour
Segmental instability
Prior surgery at index level

1. Report: Thermal Mapping of Discs Treated with the Smith & Nephew Decompression Catheter.
Data on file with Smith & Nephew.

2. Volumetric Reduction of Bovine Intervertebral Discs with the useof an Intradiscal Decompression Catheter. Michael Schaufele MD, Nigel Andrews PhD, James Huckle PhD, International Spinal Injection Society, 2004. Accepted for presentation.

3. Patient Outcome and MRI findings following treatment of Lumbar Disc Herniations with Electrothermal Disc Decompression. Michael Schaufele, MD, Emory University, Atlanta, GA. and David Appleby, MPH, Smith & Nephew, Andover, MA. Data on file at Smith & Nephew, Andover, MA.

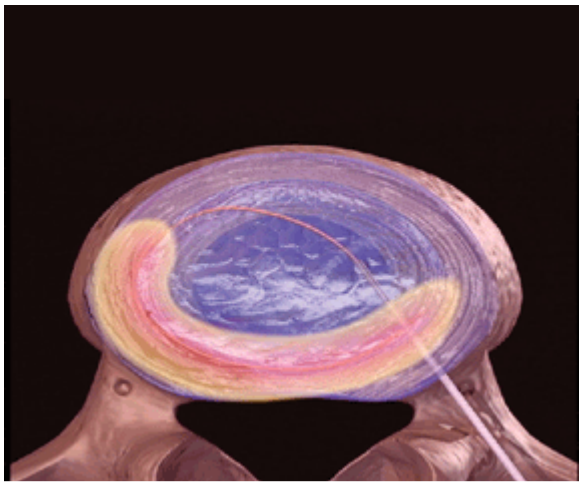
Smith and Nephew Spinecath

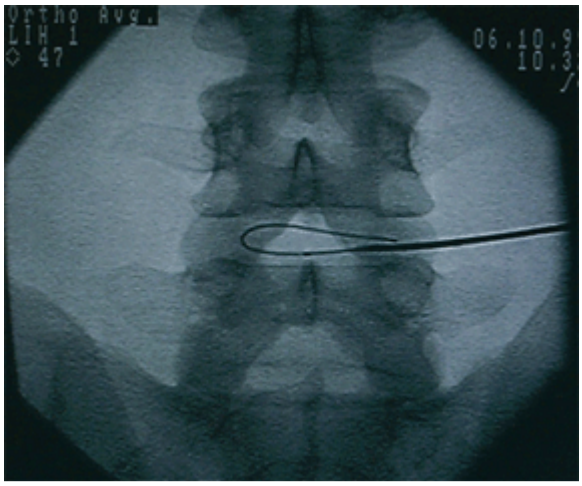
About the SPINECATH◇ Catheter

Novel catheter design for optimal control & precise placement & control of heat

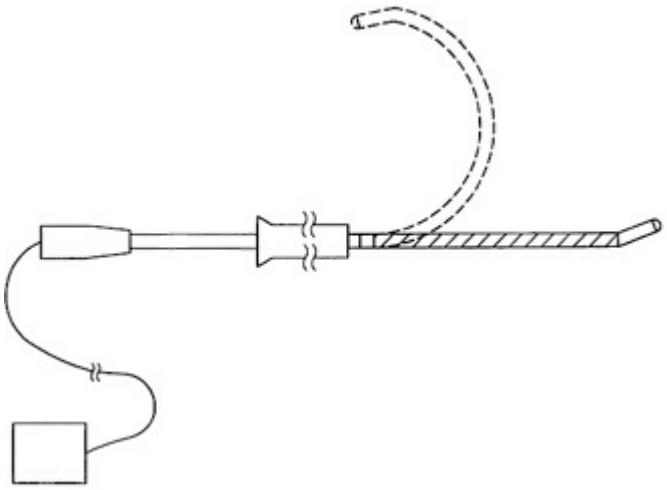
The SPINECATH◇ Intradiscal Catheter is designed to deliver a timed dose of biologically effective heat to the posterior region of the annulus fibrosis—the site of most intradiscal injury associated with chronic low back pain. Features include:

- Five centimetre heating section for thermal conduction over a broad area.
- Unique steering tip provides intradiscal navigation for optimal catheter positioning.
- Temperature monitoring system for controlled delivery of thermal energy.
- 17 gauge introducer needle for unmatched access to the posterior annulus.
- Standard and extra-long lengths available to meet a variety of clinical needs.





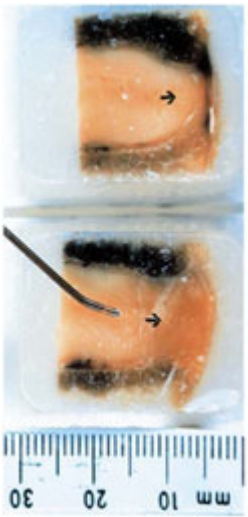
The 5 cm tip of the SPINECATH◇ catheter delivers controlled levels of thermal energy to the intradiscal target region.



As the catheter is pushed into the inner layers of the annulus fibrosis, the flexible tip is guided so that the path of the tip follows the curve of the annulus, and the heating element can be properly positioned.

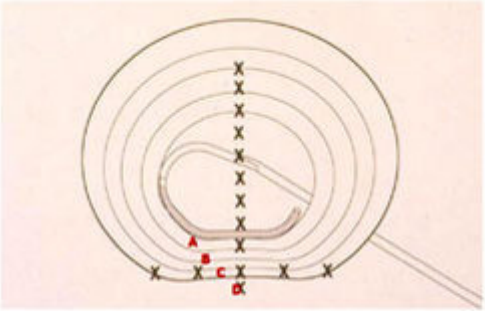
While it may help to understand technical aspects of the SPINECATH◦ catheter, it appears that precise catheter placement is critical for optimal results.

- **Precise** Catheter Placement



Study results suggest that positioning of the SPINECATH◦ catheter during the IDET◦ procedure appears to have an impact on outcomes. The threshold temperatures reportedly needed to achieve therapeutic effects associated with the IDET◦ procedure are 42°-45°C for denervation and 60°-65°C for collagen denaturation.

Only a properly positioned SPINECATH◊ catheter can deliver the right amount of heat to injured areas of the disc



When catheter temperature = 90° C
Tissue adjacent to catheter, A = 69° C
Center of annular wall, B = 60° C
Outer annular wall, C = 42° C
Epidural space, D = 38° C

Tissue modification through collagen denaturation—Gross macroscopic changes are seen in a circumferential area approximately 6x9mm, around the heating probe in the posterior region of the annulus.

Proper catheter placement assures delivery of the requisite levels of heat for denervation and collagen denaturation.