

# Annuloplasty

IntraDiscal ElectroThermal therapy (IDET) or Annuloplasty

## 1) Introduction, Procedure background

Annuloplasty or IDET (IntraDiscal ElectroThermal therapy) was introduced in 1997 by Joel Saal, M.D., and Jeff Saal, M.D., the inventors of the technology. Intradiscal electrothermal annuloplasty is a minimally invasive procedure for the treatment of lumbar degenerative disc disease. This procedure has been used in the lumbar spine of patients who have failed conservative treatment regimens and who might otherwise be candidates for a spinal fusion procedure. IDET is a minimally invasive outpatient procedure developed over the last few years to treat patients with "discogenic" back pain.

If discogenic pain is caused by small nerves within the annulus fibrosus, destruction of these nerves should relieve the patient's pain. During IDET procedure, radiofrequency energy is converted into heat in a thermal-resistive coil that is percutaneously placed into the disk.

## 2) Indications & CI

Patient selection

Annuloplasty or IDET is currently indicated for patients with chronic back pain that does not respond to at least 6 months of conservative treatment.

For those who fail to respond and have significant limitations in their daily function, additional testing such as MRI Imaging and Lumbar Diskography are useful in determining which disks, if any, may be responsible for the chronic pain. Discography is mandatory and should produce severe concordant low back pain.

Candidates for IDET include patients with "diskogenic" pain caused by:

- Internal disk tears
- Mild disk degeneration limited to one or two levels
- Low back pain (diskogenic pain) for at least 6 months without radicular component
- No nerve root disturbance weakness

Exclusion criteria include:

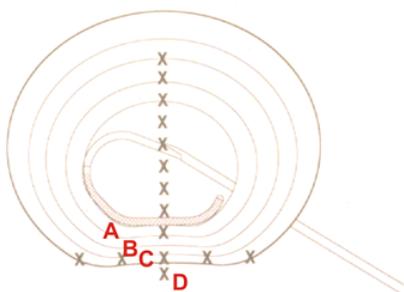
- Radicular symptoms

- Severe disk degeneration with significant narrowing of disk space : disc Height < 50%
- Previous surgery at the same level, significant psychological disorders
- Non diskogenic pathology
- Spinal stenosis, spondylolisthesis
- Neurological symptoms
- Hemorrhagic diathesis
- Local infection of cutaneous or subcutaneous or muscular layers

### 3) Principle of Annuloplasty

Diskogenic pain differs from a ruptured or herniated disk because the pain originates within the disk and does not come from nerves or other structures. Diskogenic pain is confined to the back and does not radiate down the legs. The procedure principle is cauterizing the nerve endings within the disk wall to help block the pain signals. An electrothermal catheter (heating wire) is passed percutaneously through a needle and positioned along the back inner wall of the disk (the annulus), the site believed to be responsible for the chronic pain. The catheter tip is then slowly heated up. It is a procedure made possible by the development of electrothermal catheters that allow for careful and accurate temperature control.

Fig. 1: Smith+Nephew™ ORA-50 S Electro Thermal Spine Generator and the SpineCATH® for IntraDiskal ElectroThermal Therapy (IDET)™ . In Vivo Temperature Mapping. Source: Saal, J.A. and Saal J.S., Operative Techniques in Orthopaedics, Vol. 10, No 4, 2000, pp 271-281.



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

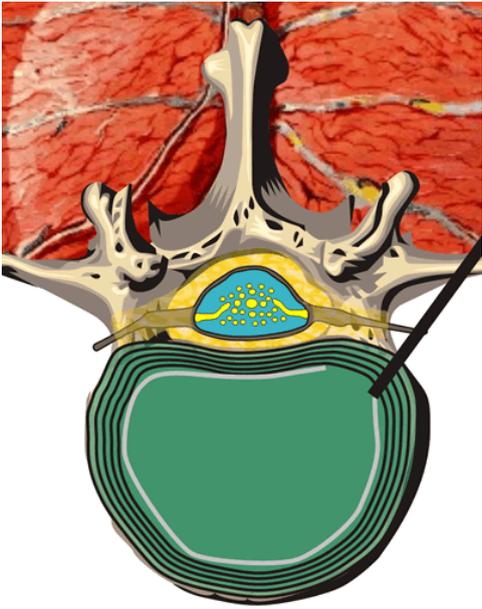


Fig. 2: annuloplasty principle. An electrothermal catheter (heating wire) is passed percutaneously through a needle and positioned along the back inner wall of the disk (the annulus).

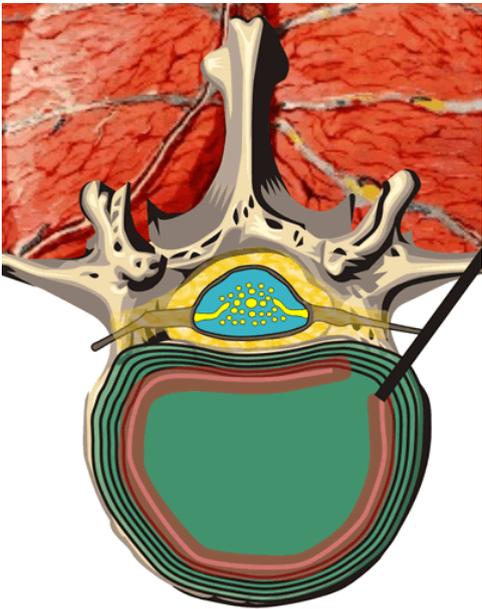


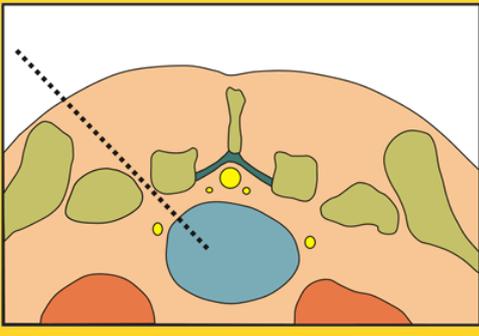
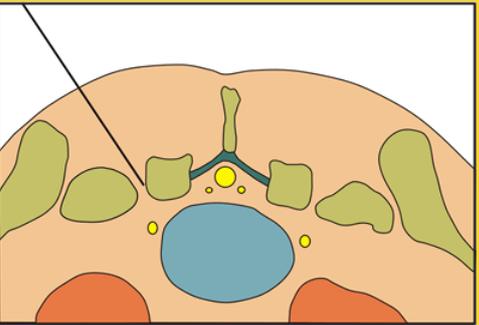
Fig. 3: annuloplasty principle. An electrothermal catheter (heating wire) is passed percutaneously through a needle and positioned along the back inner wall of the disk (the annulus). The catheter tip is then slowly heated up.

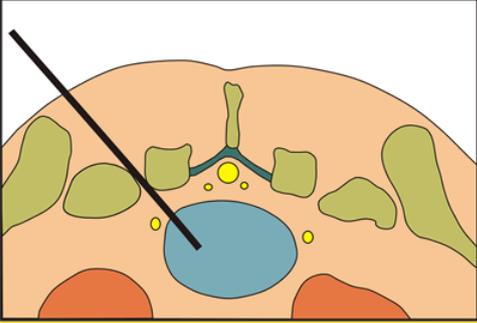
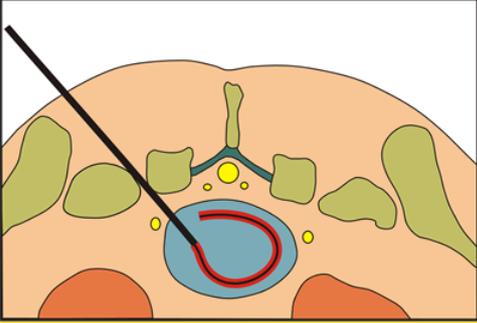
Play movie of the principle (avi divx-mepg4 movie)

pr-idet-mepg4.avi



#### 4) Annuloplasty: procedure description

|   |   |                  |
|---|---|------------------|
| 1 |    | Placement        |
| 2 |   | Materials        |
| 3 |  | Dual guidance    |
| 4 |  | Local anesthesia |

|   |   |   |
|---|---|---|
| 5 |  | Disk puncture                             |
| 6 |  | Annuloplasty<br>or<br>IDET                |
| 7 |   | Follow-up<br>Placement<br>See discography |

## 5) Annuloplasty: technique

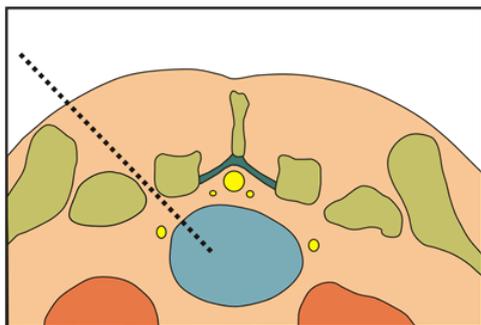


Fig. 1: IDET, CT pathway.

### Materials

The material for annuloplasty of Smith+Nephew™ consists in a needle, an Electro Thermal probe and a generator. This material received FDA 510k clearance in 1998.

- A 17-gauge special needle. Once in appropriate position in the disk, the stylet is removed and the SpineCATH® probe is placed through it in a coaxial fashion,
- The Electro Thermal probe (heating wire) the SpineCATH®,
- The Electro Thermal generator uses the Smith+Nephew™ ORA-50 S Electro Thermal Spine Generator.



Fig. 1: the Smith+Nephew™ ORA-50 S Spine Electro Thermal generator.

## Guidance

See discography

Annuloplasty is performed under dual guidance with a combination of CT and fluoroscopy.



Fig. 1: the patient is placed in prone position. Dual guidance CT + fluoroscopy.



Fig. 2: dual-guidance fluoroscopy.

### Local anesthesia

The procedure is started respecting strict sterility. Local anesthesia is given along the path of the puncture.

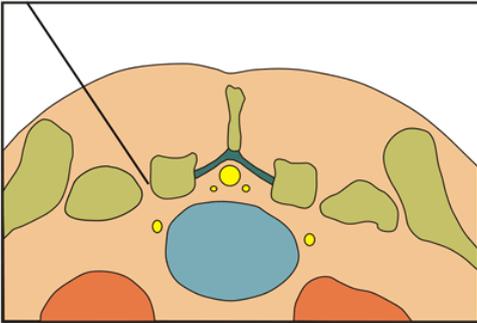


Fig. 1: local anesthesia.

### Disk puncture

#### See discography

- A short scalpel cut is made in the skin.
- Through the skin incision the 17-gauge introducer needle is inserted under continuous lateral fluoroscopy control.
- The tip of the 17-gauge needle must reach the posterior part of the nucleus pulposus. The tip of the introducer needle is placed in the midline third of the disk.

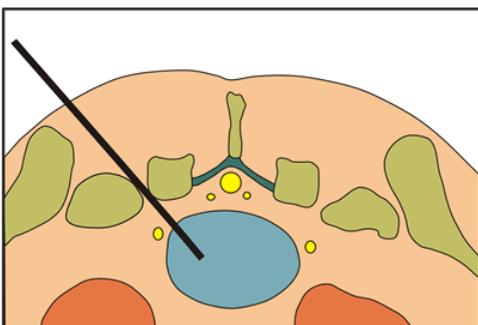


Fig. 1: 17-gauge introducer needle.

## IDET

### IDET (Annuloplasty) Background

- The SpinCATH wire is 30 cm long.
- An electrothermal catheter (heating wire) the SpineCATH® Electro Thermal probe is then passed through the needle and positioned along the back inner wall of the disk (the annulus), the site believed to be responsible for the chronic pain. The catheter should not be heated unless both radiopaque distal markers have exited the introducer needle.
- Under lateral fluoroscopy, the catheter is viewed crossing the anterior midline to the contralateral anterior corner of the disk. The catheter is manipulated until it courses posteriorly. Under anteroposterior fluoroscopy view, the catheter is viewed coursing across the posterior aspect of the nucleus pulposus across the midline and back to the ipsilateral posterolateral disk margin.
- The catheter tip is then slowly heated up to 90 degrees Celsius for 15-17 minutes.

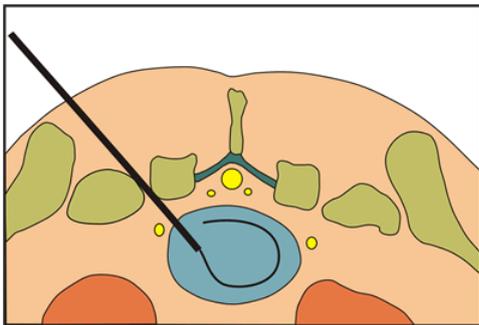


Fig. 1: an electrothermal catheter (heating wire) the SpineCATH® Electro Thermal probe is passed through the introducer needle and positioned along the back inner wall of the disk.

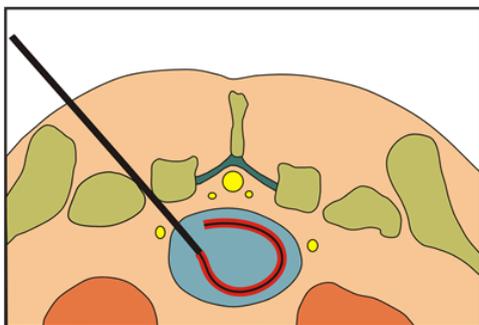


Fig. 2: the catheter tip is then slowly heated up to 90 degrees Celsius for 15-17 minutes.

## Follow-up

The patient is placed at bed rest and observed for 2 hours.

For 2 weeks after the intervention, some positions that could induce hyperkyphosis as well as athletic activities should be restricted. It will still take several weeks for healing to occur. Pain relief is not immediate; pain may actually increase for a day or two after procedure. But gradually the pain from the procedure itself should diminish.

## 6) Advantages of IDET

This minimally invasive technique avoids the drawbacks of classical surgery:

- no significant soft tissue injury
- no risk of fibrosis
- no extensive hospitalization, outpatient basis
- no general anesthesia; IDET can easily be performed under local anesthesia
- minimal recovery time of 6 weeks or less.

### Results

Saal and al. reports, symptoms improvement in 71% of cases on the SF-36 physical function subscale, in 74% of case on the SF-36 Bodily Pain subscale, and 19% of cases did not show improvement on any scale.

The preliminary published clinical data on the efficacy of IDET has been mixed but is generally encouraging; several large, prospective, randomized trials currently under way have yet to be reported. Little morbidity has been documented to date, and use of IDET does not preclude later surgical intervention.

## 7) Case

**Case 1 : IDET annuloplasty at level L4-L5 for chronic back pain not responding to two years of conservative treatment. MR imaging mild loss of signal of the disk without significant loss of height. Discography produced severe concordant low back pain and mild proximal leg pain.**

Play movie of the case (avi 720\*576 hi res divx-mpeg4 movie)

video pr-idet-mpeg4.avi 



Fig. 1: Fluoroscopy control. Disk puncture, 17-gauge introducer needle placement.

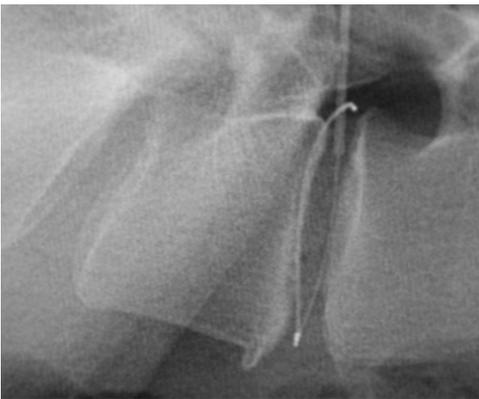


Fig. 2: Fluoroscopy control. An electrothermal catheter (heating wire) the SpineCATH® Electro Thermal probe is passed through the needle and positioned along the back inner wall of the disk.



Fig. 3: Fluoroscopy control. An electrothermal catheter (heating wire) the SpineCATH® Electro Thermal probe is passed through the needle and positioned along the back inner wall of the disk.



Fig. 4: CT control. An electrothermal catheter (heating wire) the SpineCATH® Electro Thermal probe is passed through the needle and positioned along the back inner wall of the disk.

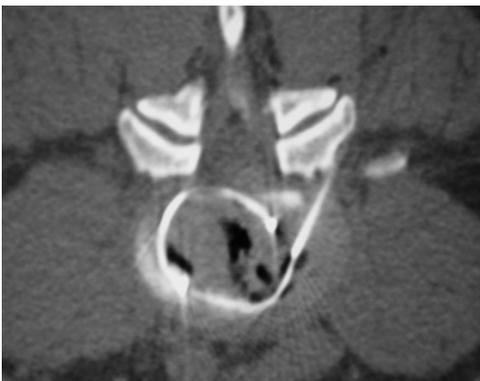


Fig. 5: The catheter tip is then slowly heated up to 90 degrees Celsius for 15-17 minutes.