

**Innovative** solution and fully secured  
for treating **Herniated Discs**

Technical administration of **DISCOGEL®**



CE 0459



This procedure must be performed by a health practitioner used to percutaneous disc punctures

## REFERENCES

**Nucléolyse a l'éthanol gélifié dans le traitement des névralgies cervico-brachiales par hernie discale cervicale a propos de 44 cas.**  
Thèse n°3045 Dr. Stephen BINSSE ; Faculté de Caen en 2004.

**Percutaneous Treatment of Lumbar Intervertebral Disk Hernias With Radiopaque Gelified Ethanol: A Preliminary Study. 202 cas.**  
Journal of Spinal Disorders & Techniques. 20(7):526-532, October 2007.

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## SUMMARY OF THE PRESENTATION

- Indications
- Herniated disc definition
- Kind of hernia
- Symptomatology
- Active agent, mechanism of action
- Medical imagery

## **ANY non excluded\*disc hernia:**

- Cervical
- Thoracic
- Lumbar

\*Showing a connection with the intradiscal space.

This procedure must be performed by a health practitioner used to percutaneous disc punctures

**DEFINITION :**

Inter vertebral disc rupture which is prominent in the spinal canal and corresponds to a nucleus backward expulsion, (*nucleus pulposus*).

The disc hernia can lead to a root compression provoking a quality of life degradation.

The clinical evidence of a disc hernia can  
be confirmed by medical imagery

## **KIND OF HERNIA:**

- In axial plane, we describe:
  - Median
  - Postero lateral or Para median
  - Foraminal
  - Extra foraminal herniated discs
- In sagittal plane, we describe:
  - Ascendantes
  - Descendantes herniated discs
- Herniated discs can be:
  - Excluded (with regard to posterior longitudinal ligament)
  - Extruded (by definition)
  - Protruded (incomplete form of herniated disc)

## **SYMPTOMATOLOGY :**

- Sometime non-expressive
- Lombalgia, Back pain, cervicalgia
- Paresthesia, paresia
- Amyotrophy, motrice trouble

Be careful, medical imagery may put the lying patient in loading simulating conditions to induce the hernia expulsion in the spinal canal

## ACTIVE AGENT , MECHANISM OF ACTION:

- Gelified ethanol (radio opaque)
- Quite spontaneous decompression (conservation of the annulus) :
  - intradiscal migration of liquid toward the middle of the disc (*nucleus pulposus*)
  - simultaneous deposition of a prosthesis at the injection site.





## MEDICAL IMAGERY :

L1-L2 disc: healthy

**DISCOGEL®** inside the disc

L2-L3 Disc: Infraction

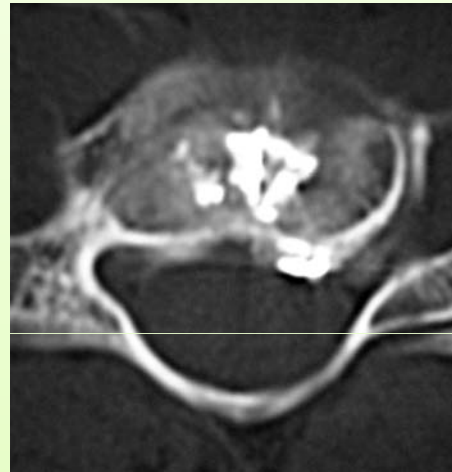
**DISCOGEL®** follows discs infractions

Rachis of a human cadavre

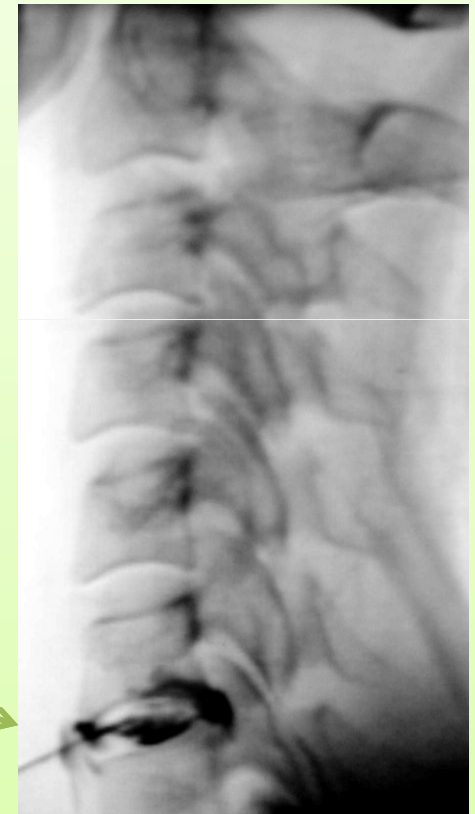


With the courtesy of Pr. THERON – CHU Côte de Nacre - Caen – France  
Plan radiography

## CERVICAL HERNIA :



Injection of **DISCOGEL®**



With the courtesy of Pr. THERON – CHU Côte de Nacre - Caen – France

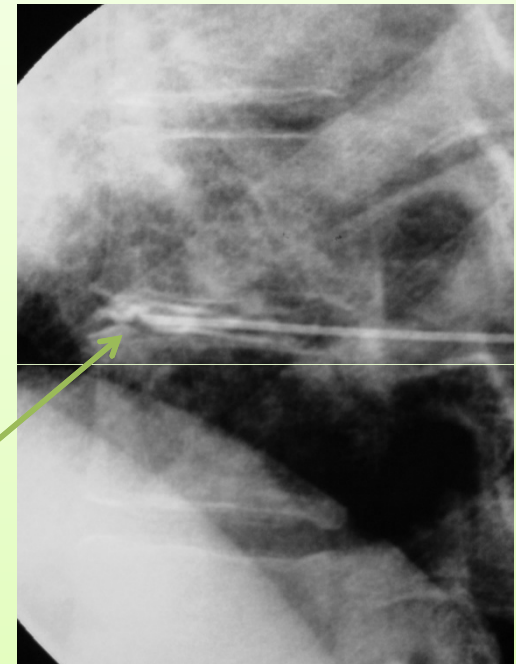
## THORACIC HERNIA:



Thoracic hernia



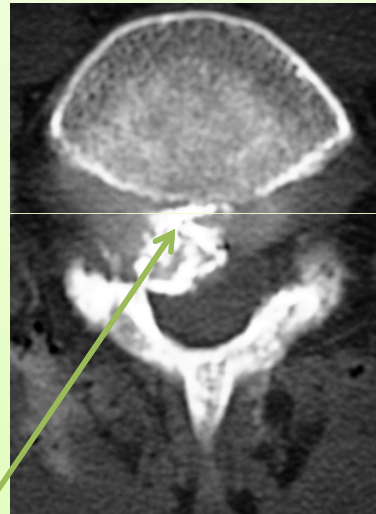
Injection of **DISCOGEL**®



With the courtesy of Pr. THERON – CHU Côte de Nacre - Caen – France

## LUMBAR HERNIA:

Before treatment



Injection of **DISCOGEL**®

6 months after treatment



With the courtesy of Pr. THERON – CHU Côte de Nacre - Caen – France

## STRENGTH OF DISCOGEL® (part 1)

Treatment that can be ambulatory

Minimally invasive treatment (limits risks of infection)

Local anesthetic

Security:

- Gel : follows disc infractions, no leakage
- Radio opaque marker: medical-legal advantage (site seeable after many months)
- Real time control of quantity to inject
- Without any known complication (experience>5years)

Absence known allergy

No inflammation

Absence of pain consecutive to treatment

Absence of interdiscal compression due to a disc collapses

## **STRENGTH OF DISCOGEL® (part 2)**

During a single procedure many discs can be treated with one vial  
High of the disc preserved during life time

Quick results:

- 1 to 3 weeks
- back to work after 3 weeks (instead of 3 months with classical satisfactory surgery)

No recidivism observed (experience>5years)

Favorable pharmaco economic interest

Better Medical act service

No scary

Local Anesthetic

Surrounding tissues preservation



## DISCOGEL® KIT

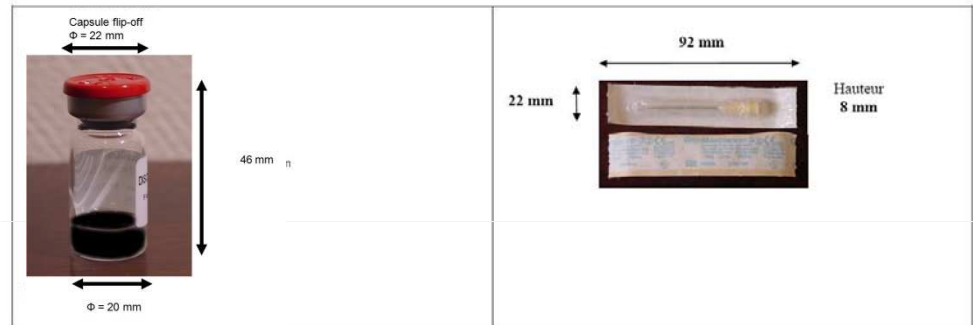


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### Dimensions des divers éléments d'un Kit DISCOGEL®

- 1 Flacon 5ml utilisé pour le DISCOGEL®
- 1 Aiguille « pompeuse Beckton Dickinson Microlance 3, 19G5 (1,1X40mm) - Référence : 301500
- 2 Aiguilles d'injection Beckton Dickinson pour le disque lombaire : Spinal Needle 18 GA 6.00 in. (1,2X152 mm) - Référence : 408360
- 2 Seringues de chez MERIT Medical : Seringue « Medallion » 1,0 ml +/- 5% - Référence : MSS011-R (piston de couleur rouge) (pas d'exemple)
- 1 notice



Shelflife: 2 years

## ADMINISTRATION TECHNIQUE OF **DISCOGEL**®

### ○ Fluoroscopy:

- Real time imagery
- Multiplan observation

### ○ Scanner:

- Not necessary in routine
- Better evaluation of soft tissues
- **DISCOGEL**® may underline the disc infraction



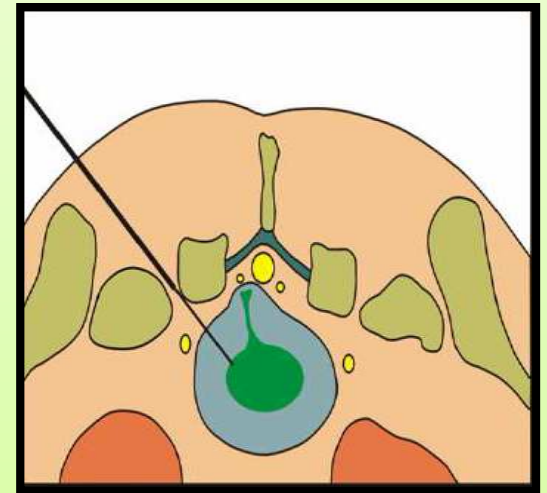
## PATIENT POSITIONNING – ADMINISTRATION OF DISCOGEL®

### Lumbar hernia:

- Patient in position of *decubitus* side
- Sterile environment
- Medical imagery Centre

Posterior lateral approach, according to the disco graphic technique

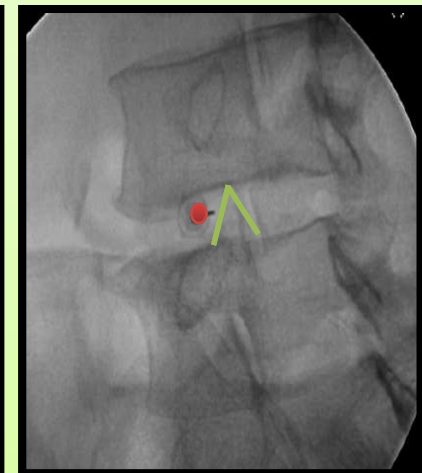
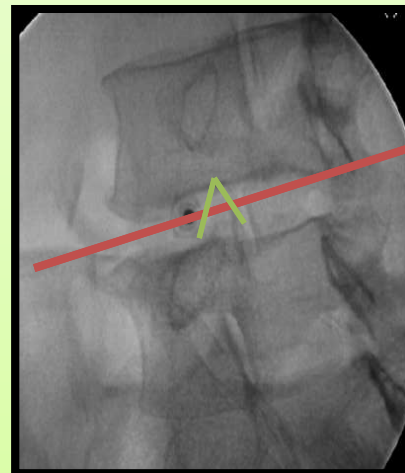
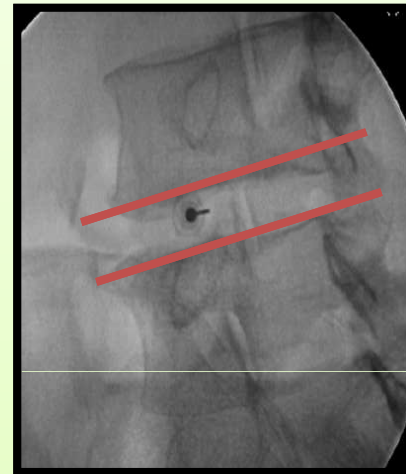
- Scope location of  $\frac{3}{4}$  according to the method " Scotty dog " or,
- Scope location of strict profile with cutaneous marking in 7-8 cm of the median line and the puncture in 45°par report(relationship) to the coronal plan.
- Possibility of bending the needle if the access to the disk L5 // S1 is bothered by the iliac wings



## PUNCTURE TECHNIC– ADMINISTRATION OF DISCOGEL®

### Scotty dog

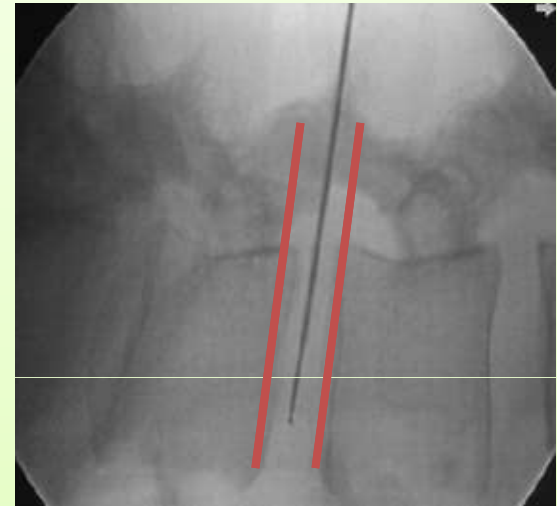
- 1. Parallelism of the vertebral trays
- 2. Scope of  $\frac{3}{4}$  (centering of " the ear of the small dog " )..
- 3. The puncture is made in the axis of shelves, just in front of the posterior articular massif not to touch the nervous root..
- 4. The narrow contact with the posterior articular massif is necessary not to touch the nervous root its release of the foramen



## PUNCTURE TECHNIC– ADMINISTRATION OF DISCOGEL®

### Profile strict view

- 1. Parallelism of the vertebral trays
- 2. Puncture point at 7 to 8 cm of the median lane
- 3. Intersection with the cutaneous projection of the plan of the disk..

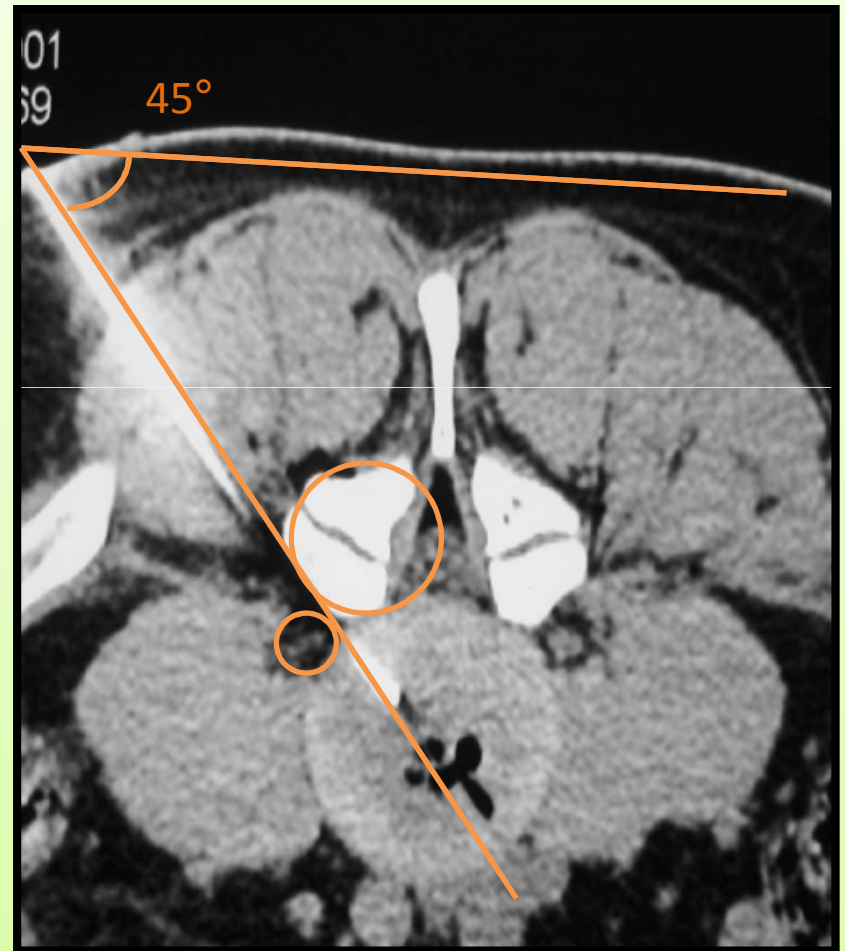
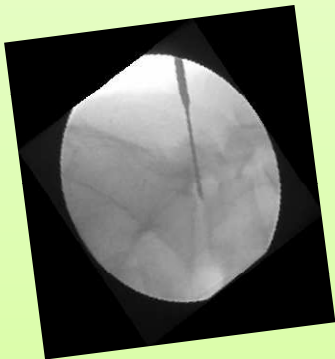


## PUNCTURE TECHNIC – ADMINISTRATION OF DISCOGEL®

### Profile strict view (suite)

- 4. Puncture angle of  $45^\circ$  with the coronal plane.

Initially the needle must touch the articular massif, then slide on its external edge, to come into the disc without any risk to touch the nervous root.



## INSTRUCTION & DOSAGE – ADMINISTRATION OF DISCOGEL®

### INSTRUCTION & DOSAGE

The medical act corresponds to an injection into the spine (the intervertebral space) under radiological control.

The injection into the disc is accomplished, after asepsis and local anesthesia via the post lateral route for lumbar and thoracic discs and via the antero-lateral route for cervical discs.

The re suspension of the metallic contrast agent must be homogeneous at the time of its injection:

**5 minutes of agitation** are necessary.

The quantity of **DISCOGEL®** injected per disc varies between 0,2 and 0,8 ml.

A syringe of 1mL is provided accordingly.

In general, it is recommended to use:

0.2mL of **DISCOGEL®** for cervical discs

0.3 – 0.5mL of **DISCOGEL®** for thoracic discs

0.6 – 0.8mL of **DISCOGEL®** for lumbar discs

### PRECAUTIONS TO BE TAKEN DURING ADMINISTRATION

#### *Injection*

Act takes place in an operating room equipped for radiology and surgery under aseptic conditions. It is recommended that **DISCOGEL®** be injected at room temperature (see chapter “Precautions to observe”). **DISCOGEL®** is directly injected into the spinal disc.

The treatment is ambulatory.

## PRECAUTIONS TO OBSERVE – ADMINISTRATION DU DISCOGEL®

The viscosity of **DISCOGEL®** **depends on the temperature**. Avoid an administration of the product warmed up above room temperature, because gel becomes more liquid and is below optimum viscosity.

To increase its viscosity **DISCOGEL®** can be **refrigerated just prior to injection**.

***Administration to children:*** as the security of this product has not been established for children, extreme caution must be used especially in judging dose.

**DISCOGEL®** should not be blended with other solutions.