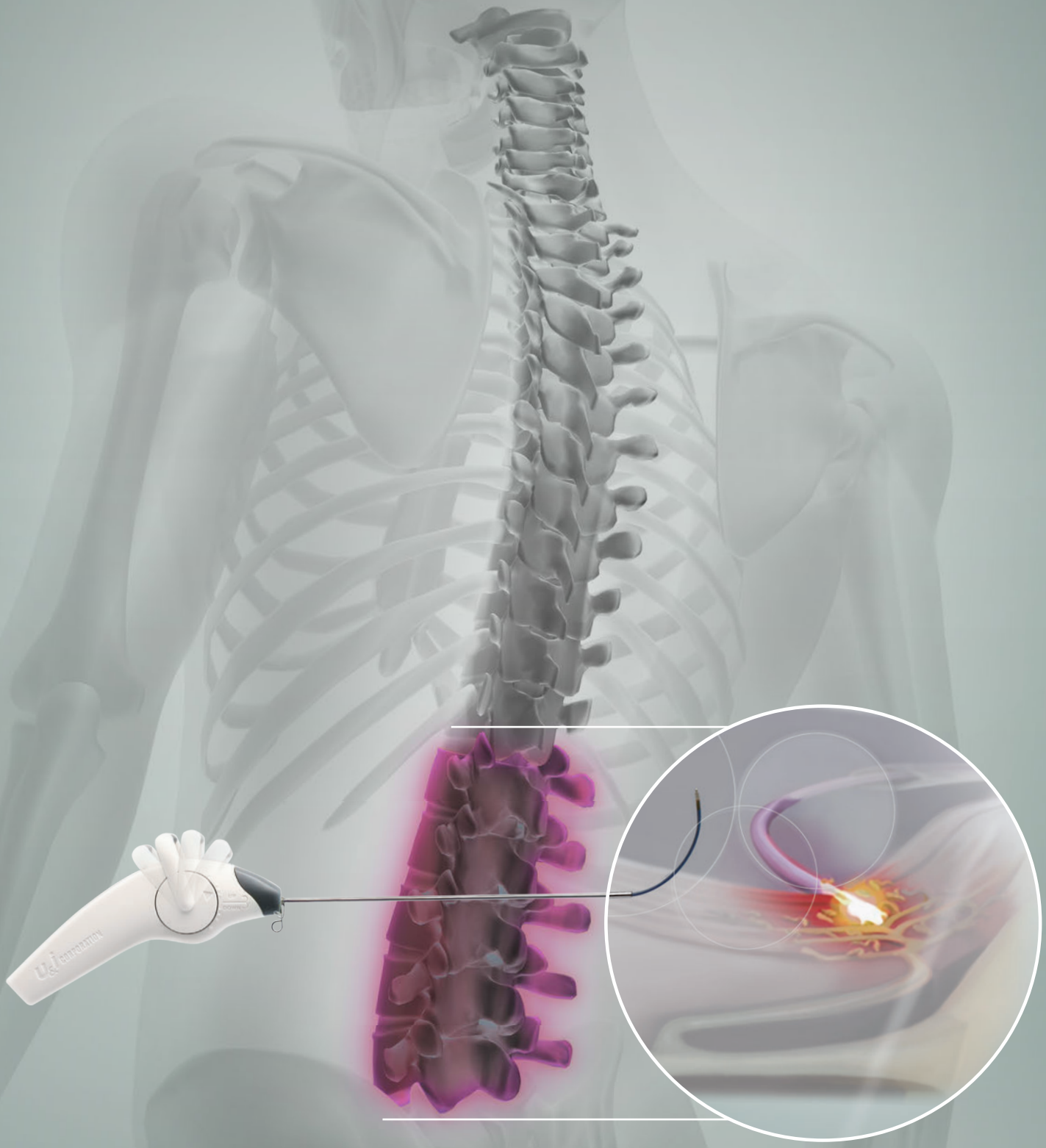
L'DISQ

Minimally invasive disc treatment using
plasma ablation & electro-thermal coagulation



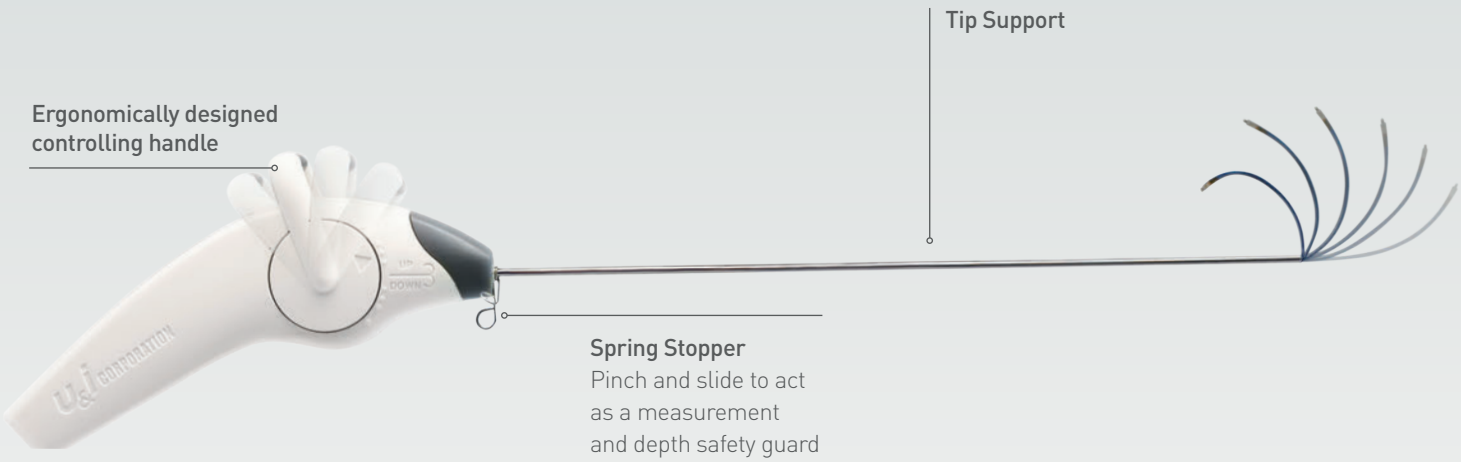
U&I CORPORATION

CE 0434

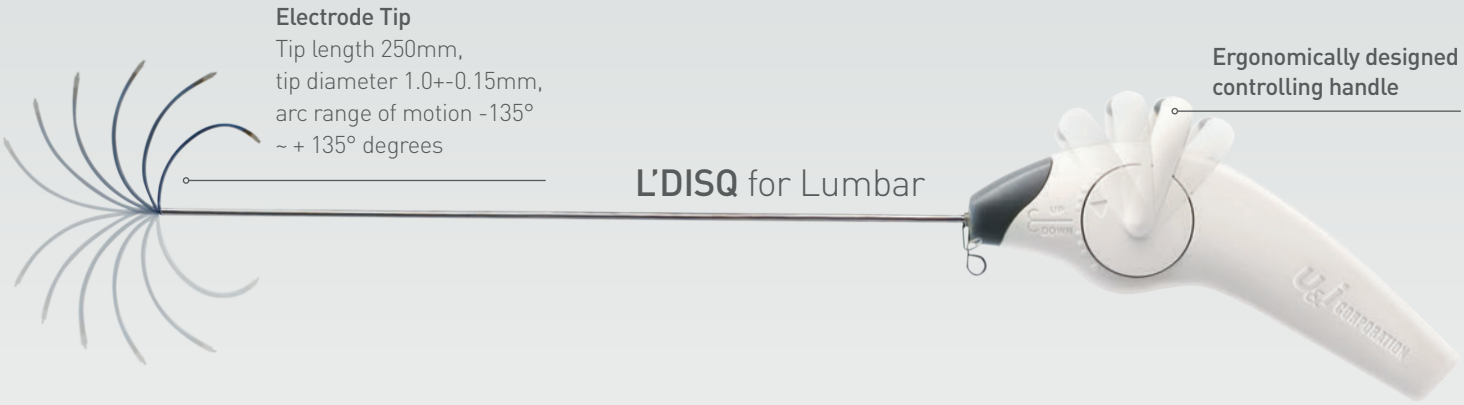
Surgical Technique Manual

FDA Approved

Contents



L'DISQ is a minimally invasive device for percutaneous disc decompression and electro-thermal coagulation using mono/bipolar radio frequency energy, effectively treating herniated discs with or without internal disc disruption.



Before treatment with L'DISQ the patients should undergo diagnostic imaging with Computed tomography (CT) scanning and/or magnetic resonance imaging (MRI).

Provocation discography may also be indicated to diagnose a painful, internally disrupted disc.

Post-discography CT scan can also be used to define the internal morphology of the disc (including annular tears, disc protrusions, contained herniations, etc).

Preparation for use

Equipment set up

1. Connect power cable to RF Generator and run self-system safety check
2. Connect RF Switch – Foot to the front connector on RF Generator
3. Connect the Manipulator Connector Cable (4-pin) to front RF Generator connector

Equipment shut down

1. Depress the power switch on RF Generator. All lights on the RF Generator should turn-off
2. Disconnect every cable and connector from RF Generator
3. DO NOT CLEAN or STERILZE, or RE-USE any single-use consumable as this may damage or compromise the performance of the device and may expose patient to risk of contracting an infectious disease

Equipment caution

1. L'DISQ consumables and capital equipment are only indicated to be used in a clean interventional surgical suite or operating room
2. Connect components only with indicated and compatible parts supplied by U&i corporation
3. If an instrument malfunctions, do not try to fix any parts, return the machine to a validated service center for a complete evaluation
4. The physician should use recommended output level during each procedure to achieve the desired result

Patient preparation

During treatment, sedation should be optimised to allow communication between the patient and surgeon (clinician), as well as keeping the patient comfortable and safe for the procedure. It is recommended that all procedures be performed utilising sterile conditions with sterile scrubs, sterile drapes and double gloves.

Discitis is a potential complication for any intra-discal procedure, therefore use of prophylactic antibiotics is advocated.

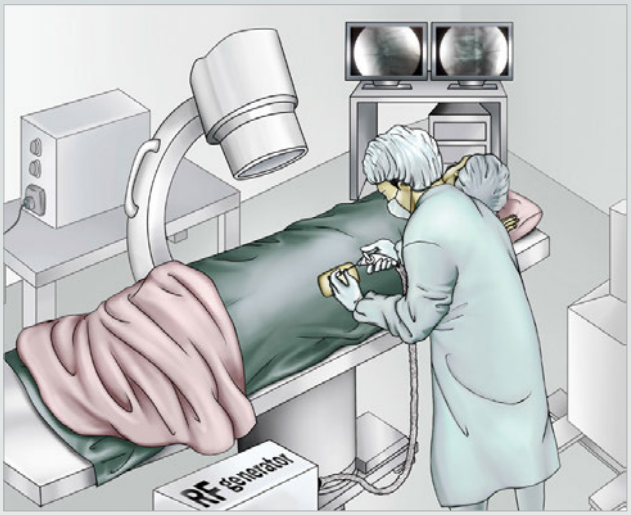
It is recommended that patients be sedated. Midazolam (2-5.0 mg) should be slowly administered intravenously over 3 minutes.

Patient response should be monitored and the dosage titrated to establish a level of sedation permitting the patient to remain clearly conversant and responsive, yet tolerant of procedural discomfort.

Patient position

The patient lies in a prone position on a fluoroscopy table. On the side selected for puncture, a wide area of the skin of the back is prepped and draped from the costal margin to the mid-buttock and from the midline to the flank.

The puncture side recommended is opposite to the side of the disc herniation. The procedure should be performed by an experienced spine interventionalist who has been trained using L'DISQ



Patient in prone position of the fluoroscopy table

Indications

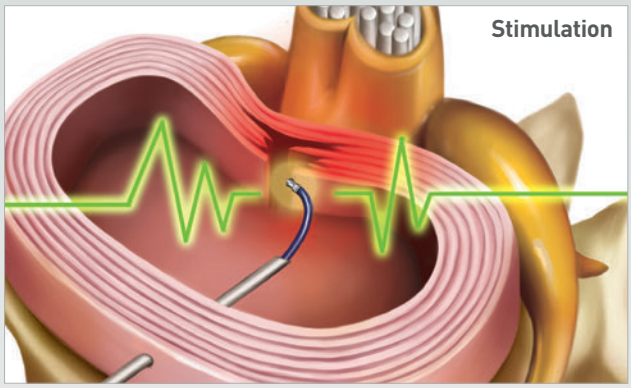
- Herniated nucleus pulposus (including bulging or protrusion morphologies)
- Discogenic pain (internal disc disruption) with/ without protrusion

Contra-indications:

- Patients with cardiac pacemakers or other electronic device implants
- Lactating or pregnant women
- Previously operated discs where integrity of annulus has been compromised by an annulotomy
- Severely degenerated discs with less than 50 % of normal disc height
- Discs with metallic fusion cage implanted at an adjacent disc level
- Annulus herniations with free disc fragments
- Patients with spinal infections, disease, or severe osteoarthritis
- Patients with bony deformities such as spondylolisthesis, stenosis, hermivertebrae, or severe congenital abnormalities

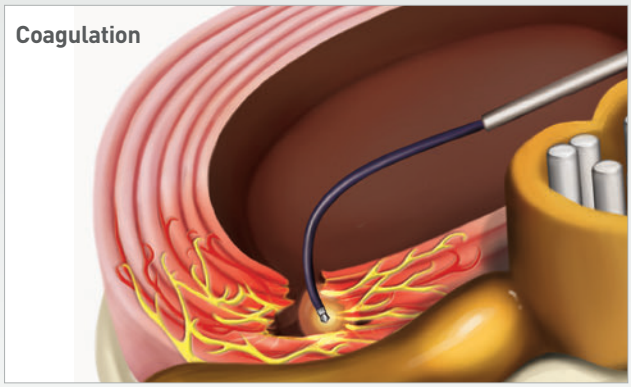
RF Generator treatment process

L'DISQ treats and decompresses contained herniated discs with 3 different modes:



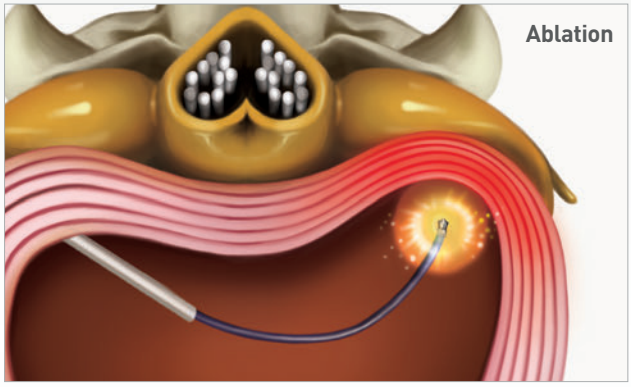
Stimulation

Stimulation = Nerve Location, Frequency Control and Voltage Control identifying the nociceptors and target area of damaged disc material.



Coagulation

Coagulation = Thermal Heating, Effective in IDD (Internal Disc Disruption), Mono and Bipolar Modes coagulating damaged disc material in the area of a painful annular tear, neo-innervation or sensitised nociceptors .



Plasma Ablation

Ablation = Plasma Generation, Tissue Removal and Minimal thermal Injury, remove nucleus pulposus by molecular diassociation.

Surgical approach

1 Prior to injection, a fluoroscopic examination of the spine is performed to confirm segmentation and determine the appropriate level for needle placement.

2 Obtain AP view, with fluoroscopic beam parallel to the inferior vertebral endplate of the index level.

3 Mark insertion point on the skin.

4 Prior to needle placement, infiltrate the subcutaneous tissues and deep muscular tissues along the needle trajectory with 1% Lidocaine.

5 To avoid potential neural injury, the needle should be directed into the **safe triangle**.

6 Depending on the disc level, entry angle will be variable. (See Table below)

7 Insertion of needle

8 When the needle contacts the disc, confirm position with AP and lateral views (contact with the annulus fibrosus should give the perception of firm but still resilient resistance) and the patient frequently experiences a momentary, sharp, or sudden aching sensation in the back or the buttock.

9 Resistance is suddenly decreased after passing the annulus fibrosus. The needle is then stopped when it reaches the borderline of the annulus fibrosus and nucleus pulposus.

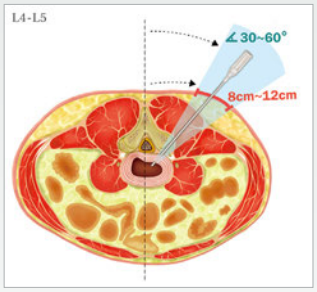
* Try to avoid placing the catheter too deep into the disc as it prohibits the device's ability to articulate its tip (Recommended to place it close to inner wall of annulus fibrosus)

10 Obtain final fluoroscopic images to confirm proper needle placement on AP and lateral views.

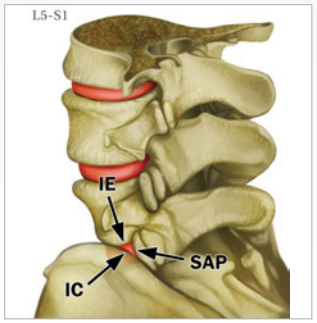
11 Remove the Trocar.

12 Confirm the position of the herniated disc or annular tear.

13 Insert L'DISQ electrode into the catheter with caution.



Entry point and the angle for L1/L2 ~ L4/L5 Levels



Entry point of L5/S1 Level

Disc Level	Target site	Entry Point (from midline or Spinous Process)	Entry Angle	Note
L1 / L2	-	8 ~ 12 Centimeter	45° ~ 60°	Adjust entry point & angle accordingly
L2 / L3				
L3 / L4				
L4 / L5	Central	12 Centimeter	50° ~ 65°	Contra-Lateral
	Post-Lateral	8 ~ 12 Centimeter	45°	Midline
	Far-Lateral	8 Centimeter	30° ~ 40°	Ipsilateral
L5 / S1	Central	6 ~ 8 Centimeter	50° ~ 60°	Make entry point close to lateral as long as the illiac bone is out of the trajectory line
	Post-Lateral	6 Centimeter	45°	Same as above

* Exact entry point and angle may differ from patient to patient due to anatomical difference.

* Use above table only as a reference

* General guideline – Male: 12cm~up from midline, Female: 9cm~up from midline

L'DISQ Control – Locating the target area

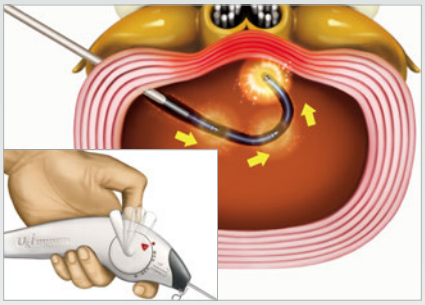
1 Insert L'DISQ electrode until the first indicator meets the entrance of the catheter hub. (The tip comes out of the catheter from this point)

2 Depending on the target site, pull the direction lever as follows.
- Central – pull the lever all the way (4th level)
- Post Lateral – pull the lever up to 2nd or 3rd level
- Far Lateral – pull the lever up to 1st level

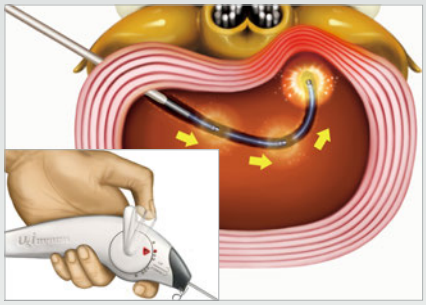
3 Turn on ablation mode (low) then slowly advance L'DISQ toward the target site, confirm the bipolar tip's position with AP and lateral views.

4 After reaching the target area, choose one of the treatment methods.

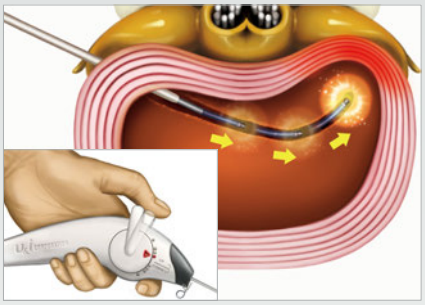
* The reason for controlling the direction before entering the nucleus pulposus is to properly create the channel through ablation, until the bipolar tip reaches the target area - since it is difficult to change direction inside of disc due to the resistance from nucleus pulposus.



Central lever position



Post Lateral lever position



Far Lateral lever position

Treatment Methods

Ablation – for Disc Decompression

1 Using fluoroscopic guidance, with AP and lateral views of the targeted disc, move the bipolar tip to the target area.

When the bipolar tip approaches the target, activate the stimulation mode to apply minimal amount of electric current.

If the patient shows sudden motor reaction to the stimulation or feels sharp pain, or the pelvic limb is contracted

- Reposition the bipolar tip 1-2mm away from the current site
- Activate the stimulation mode again. After checking the end of bipolar tip is positioned at safe and intended point, the spring stopper should be placed at the entrance of the catheter to prevent unexpected movement of bipolar tip towards the nerve.

2 Activate the ablation mode by pressing the footplate
- with the intended power level to remove the pathologic tissue.

Ablation Power Levels:

- Very Low (30W)
- Low (50W) - **Recommended**
- Middle (70W) – Use for discs with calcification or severe degeneration
- High (100W) – **Not recommended**

Ablation Duration:

Recommended ablation duration is between 400 ~ 500 seconds with Low power mode. (Varies by patient's conditions – For example, in case of radiating pain with SLRT of 50 ~ 70 degrees, recommended duration is 400 seconds.)

3 In order to remove surrounding tissues for more decompression, slowly move the handle back and forth (1mm ~ 5mm at a time) and also slowly rotate the handle up to 180 degrees.

IMPORTANT NOTE For more decompression, try to create several channels (pathways) around the target area by pulling the bipolar tip back to the starting point then using ablation again in different direction.

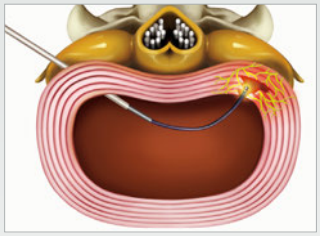
Coagulation – for de-nervation

1 When a putative pain generator is located by electrical stimulation, select the coagulation mode - monopolar or bipolar(Commonly used).

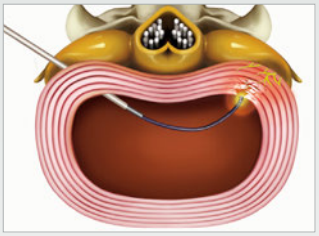
2 Coagulate one target area for approximately 50 seconds – or until patient doesn't feel the concordant pain. At first, patient may experience increased pain from usual symptoms, but it will subside during the course of treatment.

3 Repeat the coagulation procedure for other target sites with a painful annular tear, neo-innervation, or sensitised nocioceptor.

* Total coagulation time is usually between 100 ~ 200 seconds.



Coagulation of nocieceptors



After Coagulation

WARNING
If patient complains of SUDDEN ONSET OF PAIN when ablating and coagulating, stop the treatment then:

- Closely examine the AP and lateral views under fluoroscopy
- Confirm proper placement of spine needle within the disc
- Confirm proper placement of the electrode tip within the centre of the disc
- Do not continue the proceedure until proper placement within the centre of the disc has been confirmed

If the patient again complains of sudden onset of pain during proceedure, then **STOP** the proceedure

WARNING
If nerve root or spinal cord comes into direct contact with bipolar tip during ablation/ coagulation, serious injury may result.

Stimulation – for locating nerves

1 For treatment of discogenic pain, it is necessary to determine the region with neo-innervation or sensitised nociceptors.

2 When the bipolar tip approaches the targeted point, select the stimulation mode.

3 Stimulation strength and type can be controlled by adjusting voltage and frequency

4 Activate the stimulation mode to apply minimal amount of electric current.

5 If the patient shows sudden motor reaction, reposition the bipolar tip to a different site, then activate the stimulation again.

WARNING
If the patient feels a momentary, sharp, or sudden aching sensation in the back or the buttock with very low voltage of electrical stimulation (less than 0.5 ~ 1 V), a pathologically painful area of the disc has been located.

Post Operative Care

Short Term (1 – 2 weeks after procedure)

- Usual pre-procedure symptoms may not disappear immediately after the procedure.
- In the first 2-3 days after the procedure, there could be a slight increase of normal back pain.
- Patient can return to work 1 to 2 weeks after the procedure if the work is sedentary.
- Any symptoms that are unusual or new – such as fever, numbness, or rash – should be consulted with the physician.

Recommendation:

- Rest for 3 days with limited sitting and walking. Use pain medication and anti-inflammatories if necessary (for example, NSAIDs) to minimize possible discomfort. Icing the back may also help to reduce the soreness.
- No driving (~ 3 days)
- Do not bend or twist lower back
- Do not lift more than 5 kgs
- Limit walking and sitting per day to minimize the soreness on the back caused by needle puncture and muscle/annulus trauma.

Mid Term (3 – 6 weeks after procedure)

- Treated disc continues to heal and the patient may start to feel reduced pain. However, some patients may feel reduction in pain over 3 to 4 month period.
- Even if the pain has subsided significantly, the patient should pay extra attention during this period.

Recommendation:

- Pain medication and anti-inflammatories may be prescribed to control discomfort
- Heavy lifting, twisting, or bending should be restricted
- Try to avoid taking flight, driving or riding a long distance if possible.
- May start rehabilitation exercise at a moderate pace

Post Operative Exercises

Sit ups:

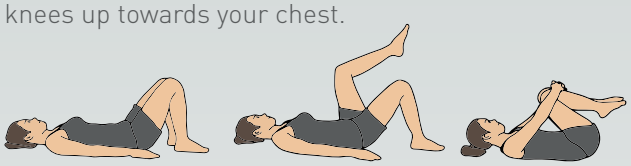
Push your chin down towards your chest and pull up both shoulders until both hands touch your knees.

Hip Tilt:

Lie down on your back, and rock the pelvis back and forth, arching and flattening your back.

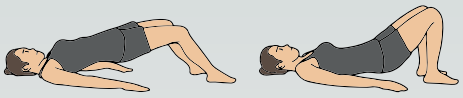
Knee pulls towards the chest:

Hold both knees using both hands and pull your knees up towards your chest.



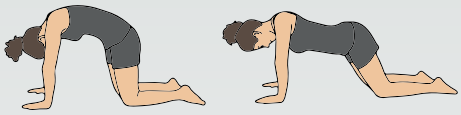
Hip Lift:

Lift your hips with your knees bent, with shoulder and head flat on the floor.



Bending the lower back:

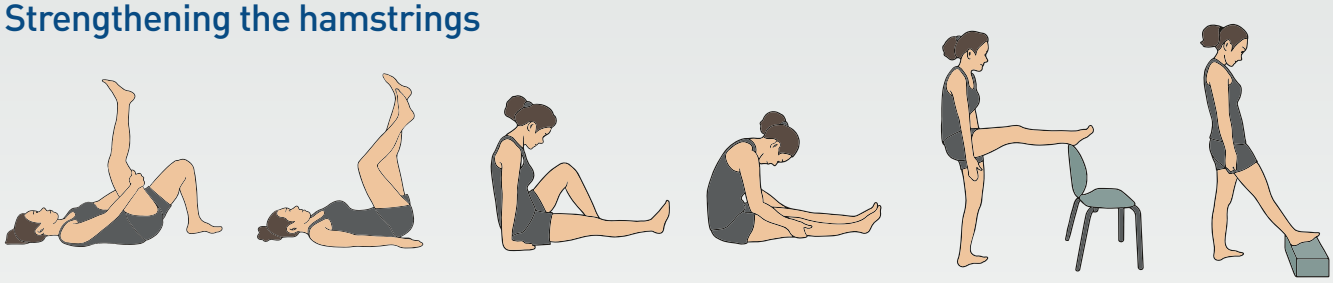
On your palms and knees move your pelvis in circular motion both ways.



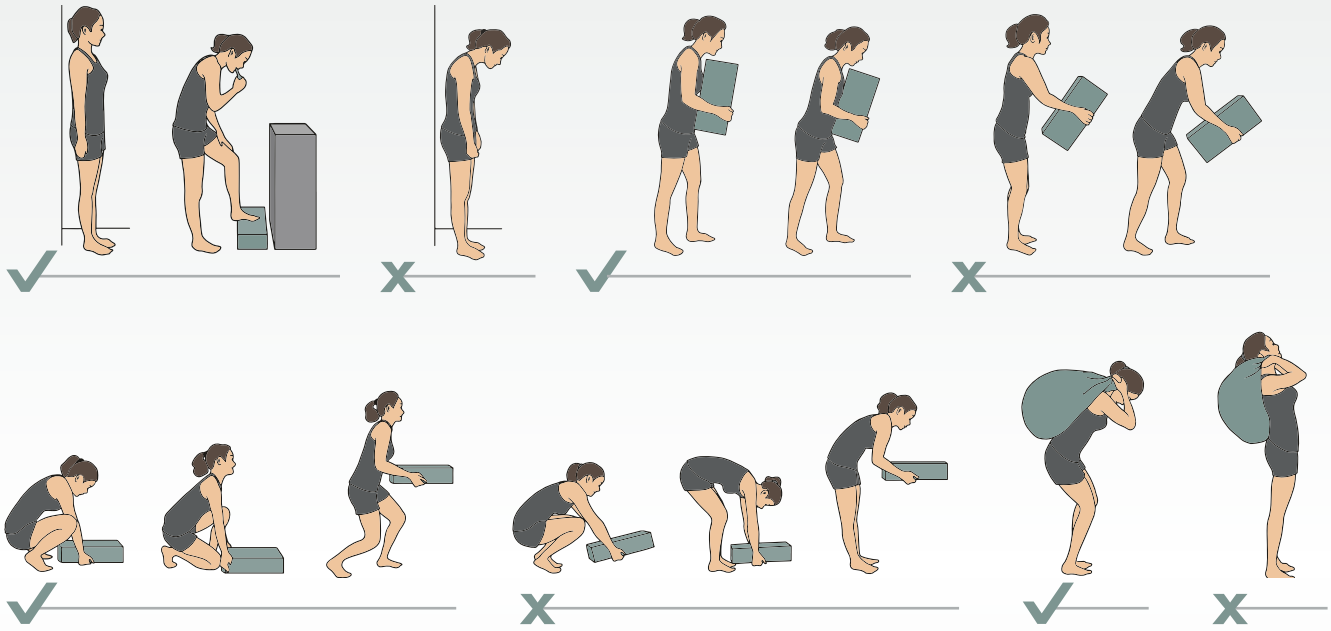
Bend and straighten the knees:

On your palms and knees bend and stretch each knee towards the elbows in turn.

Strengthening the hamstrings



Good Posture / Bad Posture



U&i Corporation

U&i corporation was established in 1993 to develop and manufacture innovative medical devices for orthopaedic and spinal surgical solutions.

U&i contribute to the health of the patients by providing quality products and services to the medical community and industry. All products are under strict quality control in accordance with ISO13485 Quality System Standards, as well as, FDA current Good Manufacturing Practices, to ensure our products are safe and effective to the patients who receive them.

CE 0434

FDA Approved

ISO 13485 : 2003

Best Care and Integrity

Integrity is built upon a culture of best practice, which in a medical environments results in best care. We ensure that these factors stay at the core of our business through all stages of development, manufacture and distribution. The belief we have in our products comes from over a decade of expertise in the medical industry and an acute awareness of the responsibilities we have for the people our products serve.

Best People = Best Results

The best surgical solutions and clinical outcomes come through investment in leading talent and expertise. We seek the best people for every area of our business and provide an environment that encourages constant improvement through research and knowledge share.

Fair and Ethical Community

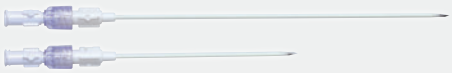
We believe in achieving our goals and setting new standards in medical solutions through fair and ethical business practices. We aim to deliver our promises in a way that helps our community thrive, benefiting patients, clients, partners, employees and stockholders alike.

To purchase L'DISQ for lumbar or cervical surgery please contact your local distributor or email: information@youic.com

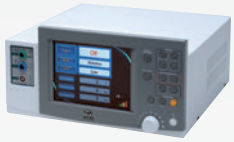
Please refer to the Instructions for use leaflets packaged with each product for essential information including Use, Sterility, Indications, Contraindications, Warnings and Precautions, Potential Adverse Effects and Storage. Additional copies may be obtained from the manufacturer, local distributor or local sales agent.

Product Ordering Information

Consumables - These products are for single use only

Reference Code	Description	
PD01 / PD02	L'DISQ 25mm / L'DISQ 45mm	
PC01	L'DISQ C 17mm	
PDN1010 (PPS-6FR-080) / PDN1010 (PPS-6FR-150)	6Fr (80mm/150mm) electrode catheter (Polymer) incl. catheter tube, catheter-hub, catheter-pin, trocar, trocar-hub, rotor and protection cap - single use only	
PDN1020 (PMS-16G)	6Fr (150mm) electrode catheter (Stainless Steel) incl. catheter tube, catheter-hub, catheter-pin, trocar, trocar-hub, rotor and protection cap - single use only	

Capital equipment

RF Generator	Multi-Purpose-Unit (RF Generator) RF Generator 5W-100W, frequency 380 kHz for Ablation, Coagulation and Stimulation	
PD2021	RFSwitch – Foot (International CE)	
PD2030	Manipulator Connector Cable (4-Pin)	
9571C	ProPlate	
6080	Plate Cable	

* Products manufactured by Duk, woo Medical (find out location and contact details)
35, Hwaseong-ro 1616beon-gil, Bibong-myeon, Hwaseong-si, Gyeonggi-do, Korea. TEL: +82 31 355 9330

** Products manufactured by Union Medical (find out location and contact details)
Indus. zone, 522-6, Younghyun-dong, Uijeongbu-si, Gyeonggi-do, Korea TEL: +82 31 853 1522

L'DISQ

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Local Distributor/Sales Agent for U&i products is:

Disclaimer: Please refer to the Instructions for Use leaflet packed with the L'DISQ for essential information including Use, Sterility, Indications, Contraindications, Warnings and Precautions, Potential Adverse Effects and Storage. Additional copies may be obtained from the U&i Corporation or your local distributor /sales agent.

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