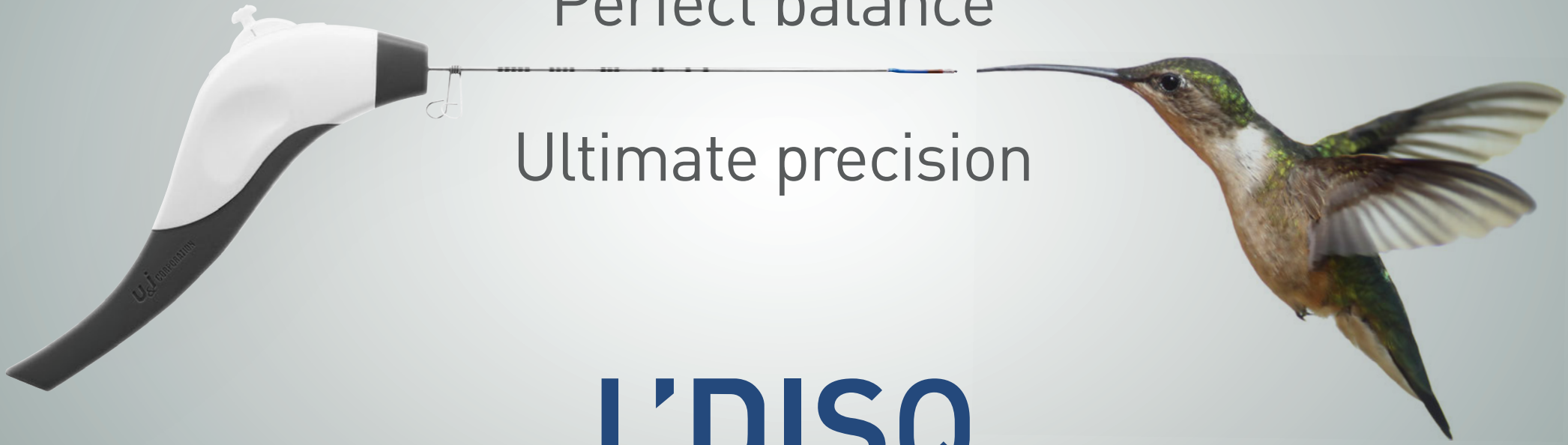
Natural control
Perfect balance



Ultimate precision

L'DISQ

A proven technology and treatment for symptomatic patients with contained herniated discs – Percutaneous Plasma Disc Decompression & electro-thermal coagulation.

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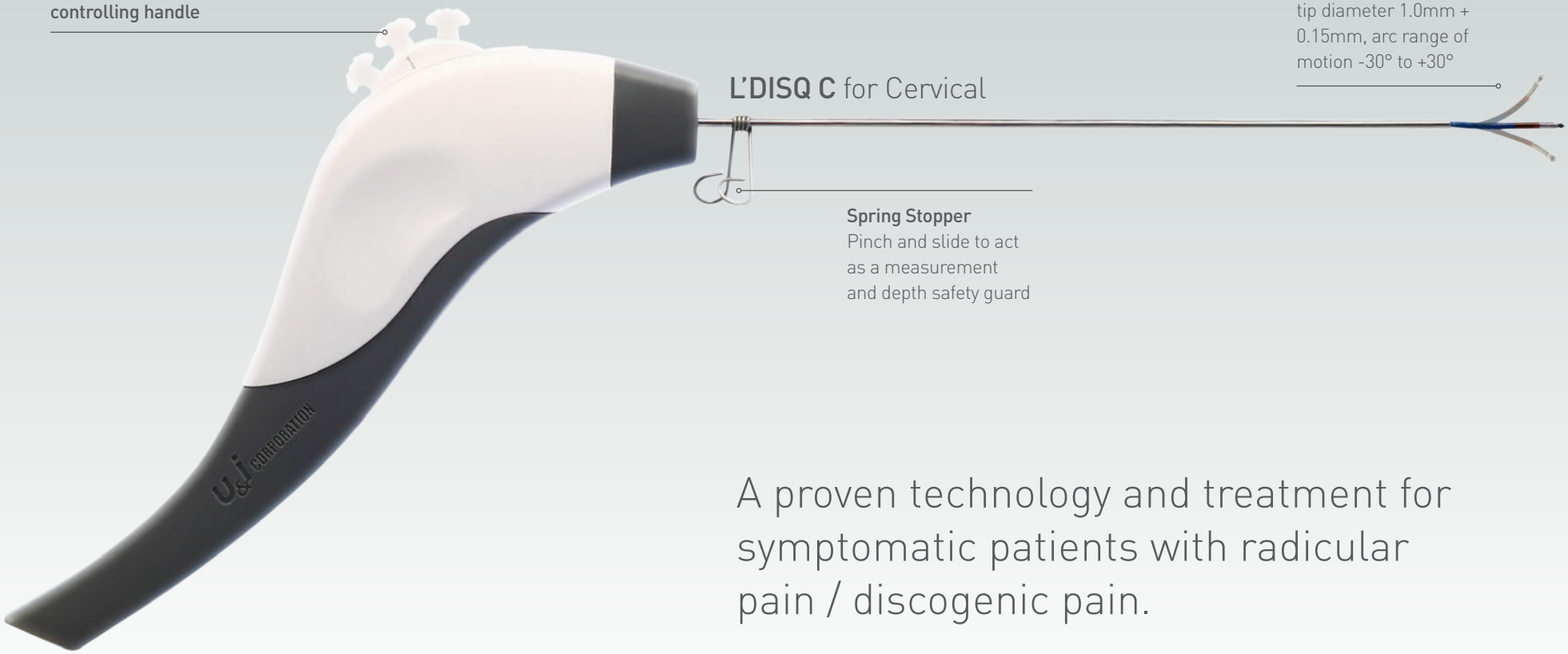
Ergonomically designed controlling handle



L'DISQ C for Cervical

Electrode Tip
Tip length 125mm, tip diameter 1.0mm + 0.15mm, arc range of motion -30° to +30°

Spring Stopper
Pinch and slide to act as a measurement and depth safety guard

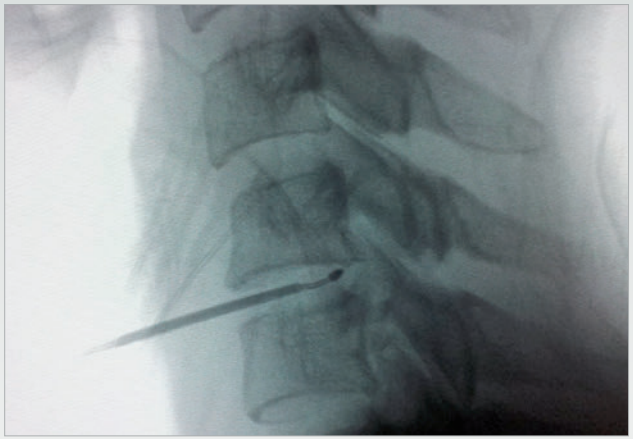
A proven technology and treatment for symptomatic patients with radicular pain / discogenic pain.

L'DISQ and **L'DISQ C** is the worlds most advanced treatment that removes disc lesions that cause pain.

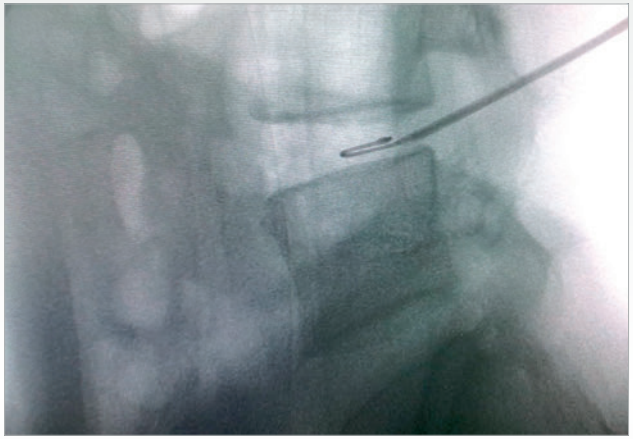
It is a minimally invasive device for percutaneous disc decompression and electrothermal coagulation using mono/bipolar radio frequency energy, effectively treating lumbar and cervical herniated discs.

Minimal Intervention - An Effective Alternative to Major Open Spinal Surgery

Cutting edge technology



Anterior approach for cervical discs



Posterior approach for lumbar discs

L'DISQ utilizes both Monopolar and Bipolar Radio Frequency technology to stimulate, coagulate, and ablate the target discs - by plasma molecular disassociation.

L'DISQ is a minimally invasive percutaneous device used for outpatient procedures for disc decompression and intradiscal thermal coagulation. L'DISQ provides controlled tissue removal with precision to relieve radicular and discogenic pain, giving significant reduction of intradiscal pressure in herniated discs.

Intradiscal thermal change in the treated disc is negligible. The maximum temperature recorded at 1mm distance from the tip of the electrode is 13.25 +- 0.84C°. and it decreases rapidly with distance (11.35 +- 0.61 C° at 5mm).

L'DISQ offers safe volumetric removal of the nucleus with minimal thermal and no structural change or necrosis to the surrounding tissues.

Clinical studies indicate that the L'DISQ procedure:

- Successfully decompresses the spinal disc
- Reduces VAS pain scores
- Eliminates narcotic usage in 79% patients

Temperature changes in nucleus pulposus and annulus fibrosus during static ablation

	Ablation Sites of L'DISQ	
Sites of thermocouple probe from the tip of the wand	Center of NP	Inner Layer of AF
Without saline infusion		
Outer 1–2mm	13.25 ± 0.84°C	8.25 ± 0.64°C
Outer 4–5mm	11.35 ± 0.61°C	6.36 ± 0.51°C
With saline infusion		
Outer 1–2mm	9.44 ± 0.53°C	6.24 ± 0.12°C
Outer 4–5mm	8.36 ± 0.71°C	5.14 ± 0.86°C

NP = nucleus pulposus; AF = annulus fibrosus.

Statistically significant temperature increases were observed at outer 1–2 and 4–5mm from the wand tip in both the annulus fibrosus and the nucleus pulposus (P <0.01). However, the temperature change did not exceed 13.25 ± 0.84 above the initial temperature at any location.

Patient Selection

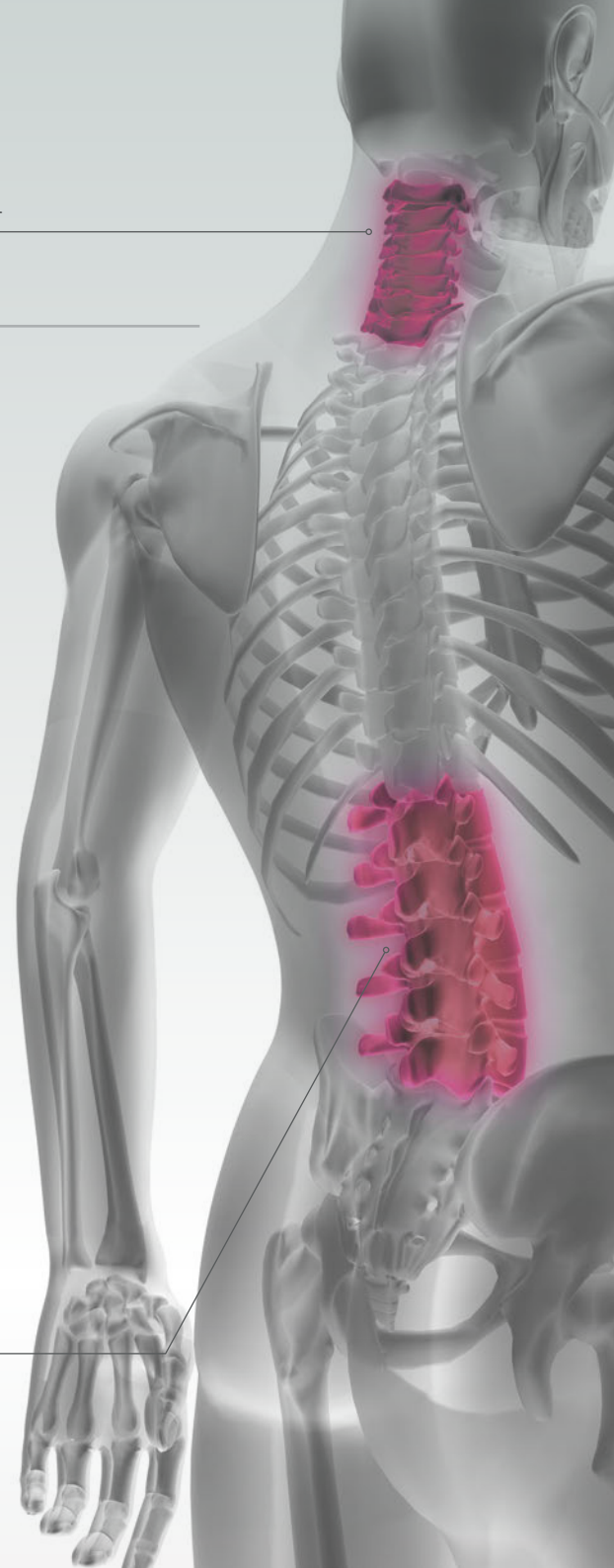
L'DISQ Procedure is recommended for patients who have not responded to conservative management including medications, physical therapy, and epidural steroid injections.

Indications - Radicular and Axial Symptoms:

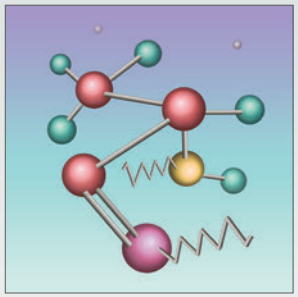
- Herniated nucleus pulposus (including bulging or protrusion morphologies)
- Discogenic pain (internal disc disruption) with/without protrusion

Contra-indications:

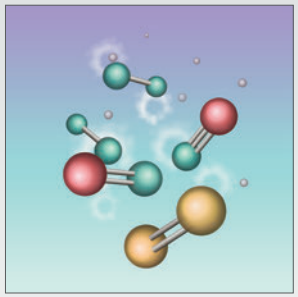
- Patients with cardiac pacemakers or other electronic device implants
- Lactating or pregnant women
- Previously operated discs where integrity of annulus has been compromised by an annulotomy
- Severely degenerated discs with less than 50 % of normal disc height
- Discs with metallic fusion cage implanted 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



Cutting edge technology



Tissue before Plasma

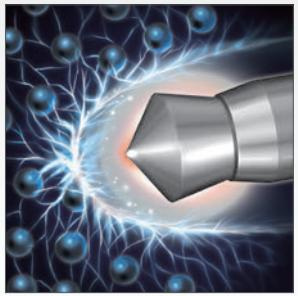


Tissue after Plasma

Bipolar Radio Frequency Energy excites electrolytes in a conductive medium, such as saline, creating focused plasma.

Bipolar Radio Frequency Energy removes the targeted portion of the nucleus tissue via plasma molecular disassociation decompressing the herniated disc to relieve radicular or nerve root compression pain.

Energised particles in the plasma have sufficient energy to break down molecular bonds, vaporising and dissolving soft tissue, such as the disc nucleus, whilst preserving the integrity and health of the surrounding tissue where negligible thermal increase is seen.



Plasma Electric Field generated from Electrode Tip

Clinical in-vitro and in-vivo studies have clearly shown a reduction in intradiscal pressure, positive intradiscal biochemistry changes as a result of Bipolar Radio Frequency Energy and improvements in a number of clinical standardised outcome measures. The procedure also allows for rapid patient recovery.

Radio Frequency Energy has been successfully used in Arthroscopy, ENT, and Spinal surgery for the last 40 years. More than 5 million Radio Frequency procedures to date have been performed including its use for spinal disc herniations.

L'DISQ – Treatment Options

L'DISQ treats and decompresses contained herniated discs using three different functions:

Stimulation (Monopolar/Bipolar)

- Identify nociceptors / nerve roots
- Able to detect motor sensors / sensory sensors specifically
- Safety mechanism prior to ablation/coagulation

Coagulation (Monopolar/Bipolar)

- Electrothermal coagulation (5W / 10W)
- Treatment for painful annulus tear / neo-innervation / nociceptors

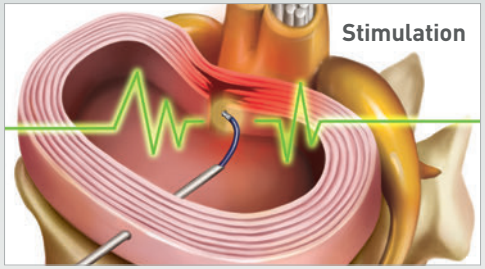
Ablation (Aqua-Plasma)

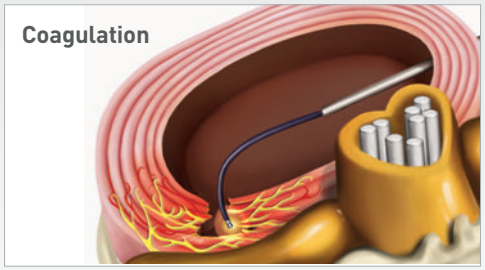
- Decompression of nucleus pulposus
- Molecular disassociation / vaporization
- Minimal damage to surrounding tissues

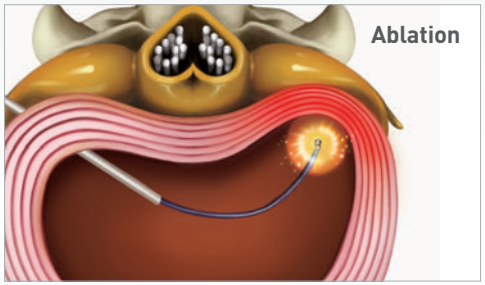
Clinical Benefits - L'DISQ Procedure

L'DISQ is the worlds most advanced treatment that removes disc lesions that cause pain:

- Targeted removal of nucleus tissue with minimal damage to adjacent tissues
- Significant reduction in intradiscal pressure
- Over 80% of patients successfully treated (50% improvement in pain considered successful)
- Sustained improved quality of life and reduction in VAS pain score
- Rapid recovery without the need for bracing (optional for psychological support)
- Local anaesthesia (do not require general anaesthesia)
- Safe procedure with low risk of complication
- 89% patient satisfaction
- More than 5 million patients treated to date with **Bipolar Radio Frequency Energy**







Clinical Data Review – In-Vitro Studies

In vitro studies have investigated Percutaneous Disc Decompression using Bipolar Radio Frequency:

- Temperature of the disc and surrounding tissues
- Optimal surgical approach at different disc levels
- Histology
- Intradiscal Pressure
- Biochemistry of disc material before and after treatment

The outcomes experienced of **Percutaneous Disc Decompression using Bipolar Radio Frequency** and the conclusions drawn from these in-vitro investigations are:

- No evidence of charring or damage to adjacent tissues to the disc with L'DISQ. [1]
- Microscopy of stained tissue samples showed that the posterolateral annulus, the dorsal ganglia and the nerve roots were all in tact after being treated with L'DISQ. [1]
- During ablation temperatures within the nucleus pulposus and inner annulus fibrosis rose less than 1C° with L'DISQ. [1]
- Thermal-mapping data of the L'DISQ electrode wand is a safe procedure with minimal temperature rises 4-5 mm from the wand of 1-2C° and no temperature rise on the outer surface of the disc. [1]
- A lateral approach is recommended for discs within the sacrum for precision targeting with L'DISQ. [1]
- Volumetric and precise removal of target disc tissue. [2]
- No thermal or structural damage to adjacent tissues. [2]
- Reduced intradiscal pressure from 26 to 0 PSI in healthy non-degenerate discs. [3]
- Viable, effective and safe treatment for lower back pain resulting from disc disease. [3]
- Alteration in cytokine expression is consistent with a mechanism of pain relief. [4]
- Significant biochemical changes in the degenerative disc demonstrate Nucleoplasty may be capable of initiating a repair response in the disc. [4]

Clinical Data Review – In-Vivo Studies

In-vivo studies have investigated Percutaneous Disc Decompression using Bipolar Radio Frequency:

- Efficacy, Feasibility, Safety and Clinical Outcomes
- Side Effects and Complications
- Lumbar Clinical Outcomes
- Cervical Clinical Outcomes

The outcomes experienced of **Percutaneous Disc Decompression using Bipolar Radio Frequency** and the conclusions drawn from these in-vivo investigations are:

- Procedure is minimally invasive, low risk, easy to perform. [10]
- Minimal discomfort to patient and effective in short term. [10]
- Reduction of VAS score >50%. A >50% VAS score was measured in 76% of patients at 1 week, 84% at 1 month and 88% at 3 and 6 months post procedure. [8]
- For VAS, ODI, RM points and SF-36 BP scales all patients showed statistical and clinically significant improvement in both pain scores and functional status at each follow up period, with a trend for gradual improvement over 6 months. [8]
- L'DISQ is a safe and efficient device for treating contained herniated discs that ensures the surgeon can access and reach the precise position of the herniated nucleus with the unique curved wand tip and angulation device. [8]
- Bulging reduced or eliminated in over 80 percent of cases. [5]
- Excellent clinical results for contained disc herniations. [5]
- Effective minimally invasive surgical treatment for contained herniated discs. [6]
- Safe low risk procedure causing minimal discomfort to patients. [6]
- Excellent outcomes in carefully selected patients with leg pain caused by radicular encroachment. [7]
- Use for patients with small (<6mm) contained disc herniations with a disc height of >50% and with annular integrity. [7]
- Effective in patients with radiculopathy. Significant reduction in VAS, ODI, and analgesics use. [7]
- Complete resolution of symptoms in 80 percent of patients in Nucleoplasty group. Demonstrated Significant positive results in cases of contained herniated cervical disc/focal protrusions when compared to conservative care. [9]

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

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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.

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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.

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L'DISQ

is manufactured by

U&i CORPORATION

U&i Corporation
20, Sandan-ro 76beon-gil
Uijeongbu-si
Gyeonggi-do
480-859 Korea

+82 31 852 0102
+82 31 852 9025
information@youic.com

www.youic.com | www.ldisq.com

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

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BC-201411-01, Rev.00