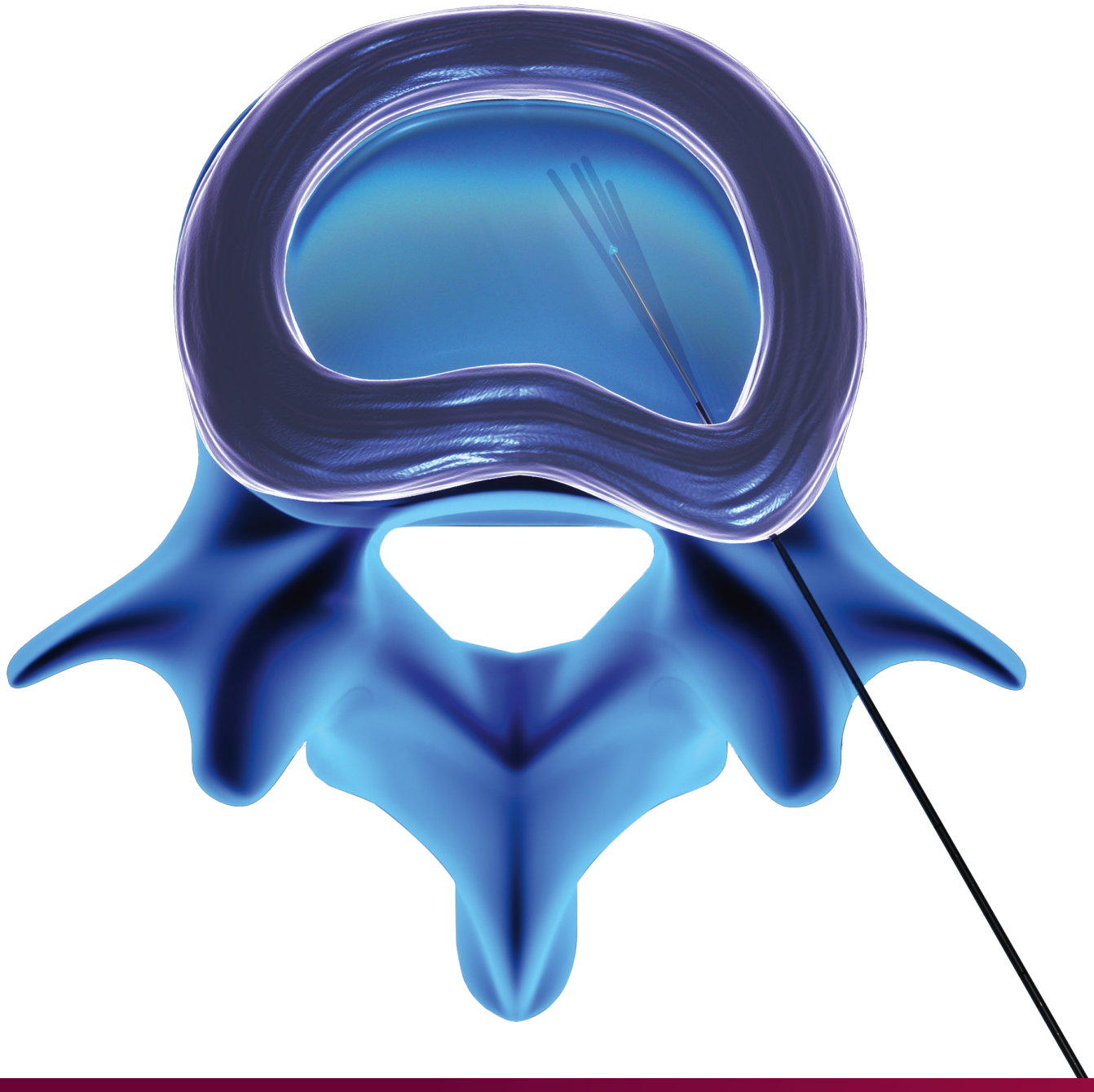
SPINEWAND

TECHNIQUE GUIDE

CIQ DLR/DLG SpineWand*

Device for use with CIQ Controller



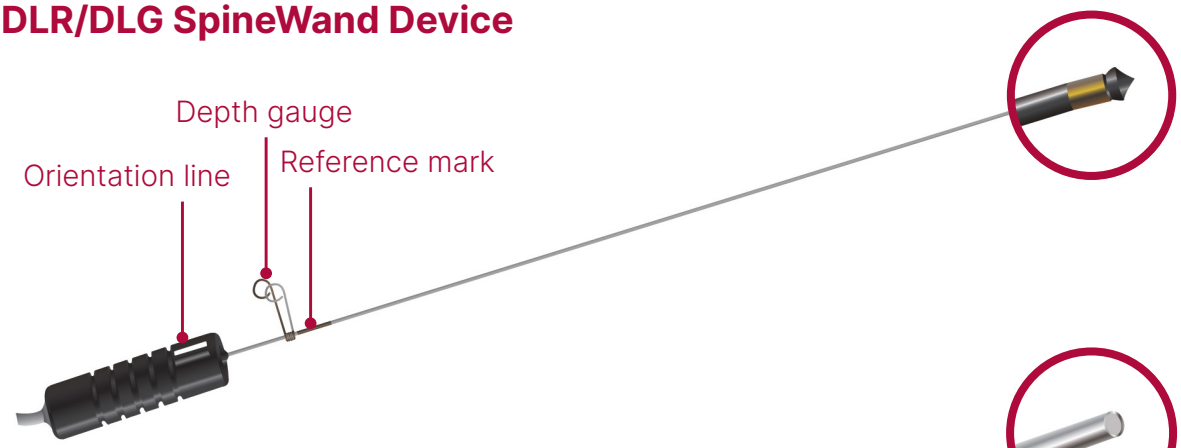
PLASMA DISC DECOMPRESSION

Micro-invasive treatment for contained disc herniation

CIQ DLR/DLG SpineWand* Device

For plasma disc decompression

CIQ DLR/DLG SpineWand Device



17-Gauge CRAWFORD cannula with stylet

CIQ Controller

Controlled Ablation Technology

'Controlled ablation' involves the creation and application of a high-energy field called glow discharge plasma. This low-temperature plasma ablates tissue through a chemical etching process as highly energized particles in the plasma break down molecules in the tissue.[1,2]

***SpineWand is a trademark of Smith & Nephew**

SURGICAL TECHNIQUE

Preparation for use

The operator should be experienced in general and electrosurgical spinal surgery. Additional training from a company representative on the use of the DLR/DLG SpineWand* Device and the CIQ Controller is recommended.

Equipment preparation

Materials needed

- C-arm fluoroscope with image intensification
- CIQ Controller with foot control
- Select appropriate device:
  - CIQ DLR Controlled ablation SpineWand and one 17-gauge, 6" sterile cannula with stylet
  - CIQ DLG Controlled ablation SpineWand and one 17-gauge, 8" sterile cannula with stylet

Note: Recommended use is one cannula per spine level. Cannulas are only packaged and sold separately.

Set-up

- Connect the power cord to the Controller and outlet, press ON/OFF switch to 'ON' (1) position. The Controller will present to default ablation and coagulation settings for each SpineWand.
- Connect the foot control to the Controller.
- Deliver the 17-gauge introducer cannula and SpineWand to the sterile field.
- Connect the SpineWand cable connector to the CIQ Controller. Correct connection is indicated by the illumination of the ablation and coagulation set point number.
- Ensure the CIQ Controller's Ablation setting is at level 2, and Coag setting is at level 1.

CIQ Controller and DLR/DLG SpineWand Device features

- Audible tone after SpineWand ablation is activated every 5 seconds.
- Ablation shut-off time is after 20 seconds of continuous activation.

Note: If the power shuts off, the user must release the ablation foot pedal and re-press to resume ablation (shut-off is not permanent).

Patient preparation

- Prepare the patient pre-operatively in the prone position according to standard surgical procedures.
- Select the proper length CIQ DLR/DLG SpineWand Device and cannula based on patient anatomy.
- Refer to the CIQ DLR/DLG SpineWand Device Instructions for Use (IFU) packaged with the product for more information, and a complete list of Warnings, Precautions and Contraindications.

Prior to procedure

Note: Morgan Steer Orthopaedics recommends a dry run prior to a live case in order to familiarize oneself with the DLR/DLG SpineWand® Device.

A. Prior to inserting the cannula into the patient, the stylet should be removed and the SpineWand inserted.

B. Advance the SpineWand through the cannula until the distal end of the reference mark is positioned at the proximal edge of the cannula hub. This is the proximal limit for creating controlled ablation channels.

C. The active section of the SpineWand tip will be outside the tip of the cannula by approximately 7mm.

D. Remove the SpineWand from the cannula and reinsert the stylet. You are now ready to begin your procedure.

Please refer to the Instructions For Use (IFU) packaged with the products for a complete list of Warnings, Precautions and Contraindications.

Surgical procedure

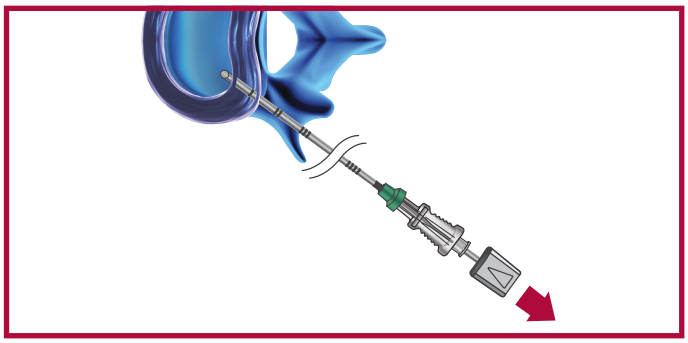
Approach

Note: Recommended use is one cannula per spine level.

1. Use a standard posterolateral approach. Access the disc according to standard methods and confirm proper positioning.

2. Using fluoroscopic imaging, confirm proper cannular placement at the annular-nuclear junction using A/P and lateral views.

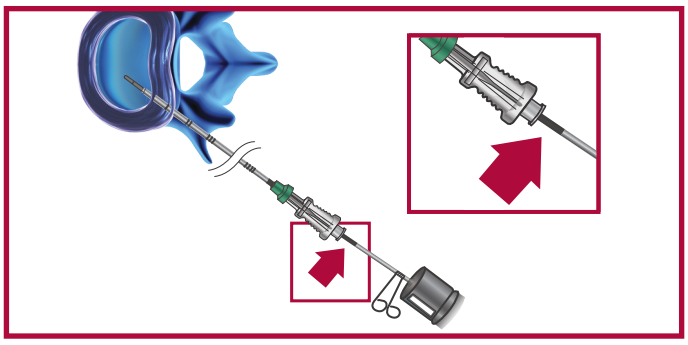
Note: Special care must be taken (clear fluoroscopic imaging of the SpineWand tip in the disc) to avoid ablating too deeply into the tissue or against vertebral body endplates.



SpineWand / cannula orientation

Insert the device

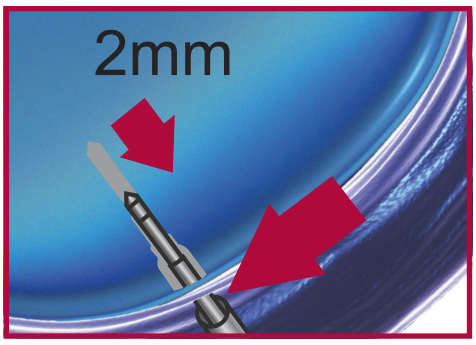
1. Once the disc is accessed and proper positioning is confirmed, remove the stylet and introduce the SpineWand* into the access cannula under fluoroscopic guidance. Advance the SpineWand until the reference mark reaches the cannula hub, then stop. This assures the active section of the SpineWand is deployed into the disc.



SpineWand deployed in disc

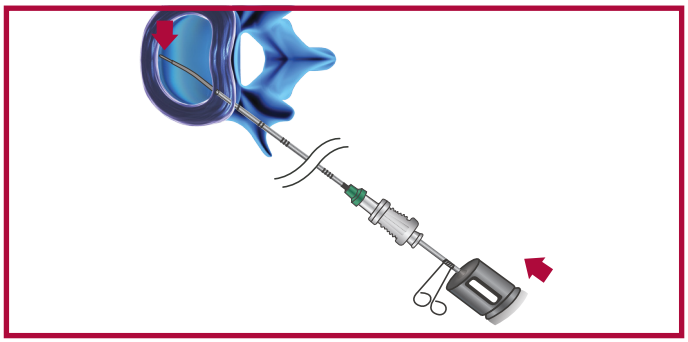
2. Retract the cannula and SpineWand approximately 2mm to ensure the tip of the cannula is located in the annulus, and the tip of the SpineWand is located in the nucleus. This will minimize the occurrence of neural stimulation.

Note: The reference mark on the shaft of the SpineWand identifies your proximal channel limit.



Retract cannula and SpineWand 2mm

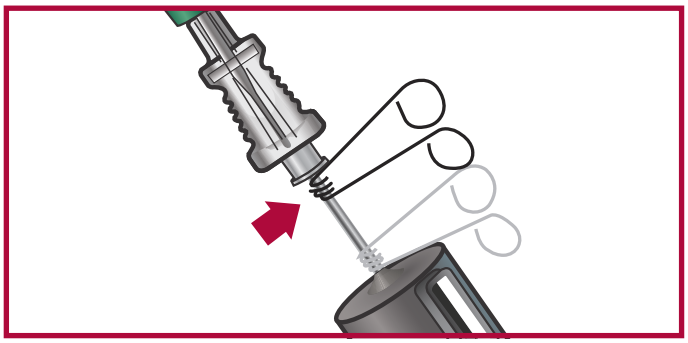
3. Advance the tip of the SpineWand into the target tissue. Stop when the SpineWand tip reaches the distal limit. The distal limit is the annular-nuclear junction on the opposite side of the disc. Confirm positioning using fluoroscopic imaging.



Advance SpineWand tip to distal limit

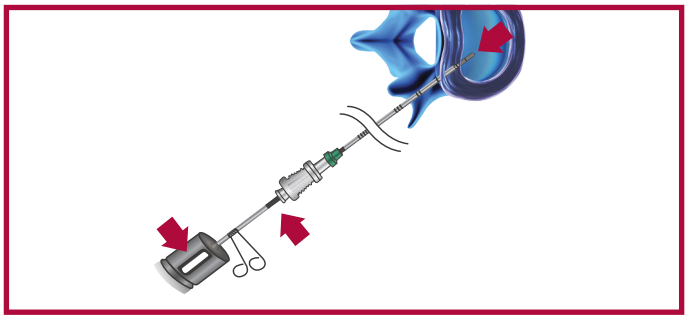
4. Squeeze the wings of the depth gauge on the shaft of the SpineWand and advance the depth gauge to the shaft to the proximal end of the cannula hub. This is the distal limit for creating ablation channels.

Note: If the SpineWand handle reaches the cannula hub before the SpineWand tip reaches the distal limit, it will serve as the depth gauge.



Squeeze wings of depth gauge and advance to the proximal end of the cannula hub

5. Withdraw the SpineWand to the reference mark. You are now ready to create ablation channels.



Withdraw SpineWand to the reference mark

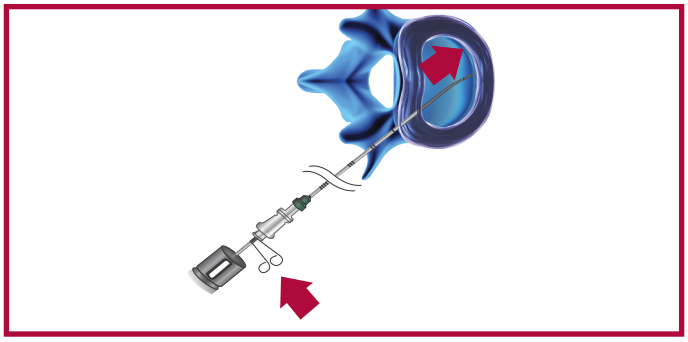
Ablation

Note: If the nerve root, conus or spinal cord come into direct contact with the tip of the SpineWand* during ablation, then serious nerve injury may result.

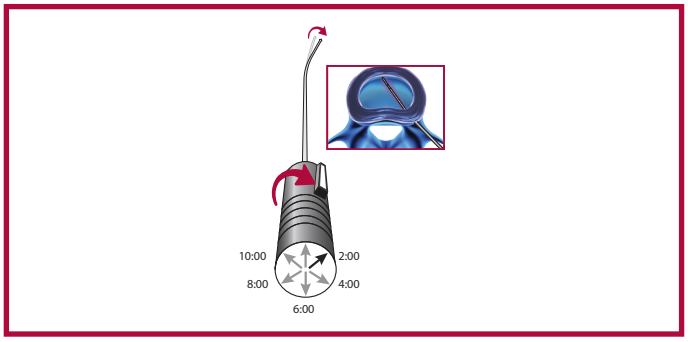
1. After confirming the desired placement of SpineWand and cannula, confirm that the CIQ controller ablation setting (yellow) is at level 2, and Coag setting (blue) is at level 1 to create ablation channels.
2. Orient the white line on the SpineWand handle to the '12 o'clock' position.
3. Depress the ABLATE foot pedal (pedal on far left) on foot controller, while advancing the SpineWand approximately 2mm per second to the pre-determined distal limit, generally 6-8 seconds.

Note: When the SpineWand is activated, the control symbol light on the front of the controller will illuminate and an audible monotone will be emitted.

4. Stop advancing the SpineWand, and cease ablation at the depth gauge.
5. Withdraw the SpineWand to its starting point back to the proximal limit (reference mark adjacent to the cannula hub).
6. Rotate the SpineWand handle until the white line is at the '2 o'clock' position and repeat steps 3 through to 5.
7. Create additional channels at the '4, 6, 8, and 10 o'clock' positions.



Advance the SpineWand



Create additional channels

Remove the SpineWand and cannula

Note: Do not withdraw the SpineWand while power is being applied.

1. After the ablation channels have been created, withdraw the SpineWand from the cannula, and then withdraw the cannula from the patient. Discard SpineWand and cannula.
2. Follow standard postoperative procedures and shut down system per the Instructions For Use.

Special notes about the CIQ DLR/DLG SpineWand* Device technique:

- Local anesthesia should be used to allow for patient monitoring for signs of nerve root irritation.
- When performing ablation with the SpineWand, stop the procedure if the patient complains of sudden onset of pain, then:

1. Closely examine the A/P and lateral views under fluoroscopy.
2. Confirm proper placement of cannula tip within the posterior margin of the annulus.
3. Confirm proper placement of the SpineWand tip within the nucleus.
4. Do not continue until proper placement of the SpineWand tip has been confirmed.

- When subsequently using ablation with the SpineWand, if the patient again complains of sudden onset of pain, you must end the procedure.

Reference
1. Woloszko J, Stalder K.R. and Brown I. G. "Plasma Characteristics of Repetitively-Pulsed Electrical Discharges in Saline Solutions Used for Surgical Procedures" IEEE Trans. On Plasma Sciences, 30(3), June 2002, 1376-1383.
2. Stalder Kenneth R, McMillen Donald F and Woloszko Jean. "Electrosurgical plasmas" J. Phys. D: Appl. Phys. 38 (2005) 1728–1738

Specifications

	CIQ DLR	CIQ DLG
Tip deflection	**3mm**	**3mm**
Shaft diameter	**1.07mm/0.043 inches**	**1.07mm/0.043 inches**
Working length	**219mm/8.63 inches**	**274mm/10.80 inches**
Mode	**Plasma ablation**	**Plasma ablation**
Design	**Bipolar electrode**	**Bipolar electrode**
Cannula inner diameter	**1.35mm/0.053 inches**	**1.35mm/0.053 inches**
Compatible with	**CIQ Controller**	**CIQ Controller**

Ordering information

Reference#	Description
SDLR03-01	CIQ DLR SpineWand Device with integrated cable
SDLG03-01	CIQ DLG SpineWand Device with integrated cable
ES9000-01	CIQ Controller (includes controller, foot control and power cord)
KNS-1706-10	Spine Needle, 17 Gauge Crawford, 6" Straight - pack of 10 (used with DLR SpineWand Device)
SCL600-01	Introducer Cannula, Crawford 17 Gauge 6" Straight - single (used with DLR SpineWand Device)
SCL800-01	Introducer Cannula, Crawford 17 Gauge 8" Straight - single (used with DLG SpineWand Device)

Note: Cannulas for CIQ SpineWands are only packaged and sold separately (SCL600-01 / SCL800-01). Recommended use is one cannula per spine level.

Indications for Use

The CIQ DLR/DLG SpineWands are indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs and are intended to be operated with the CIQ Controller.

NOTES

SPINEWAND

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