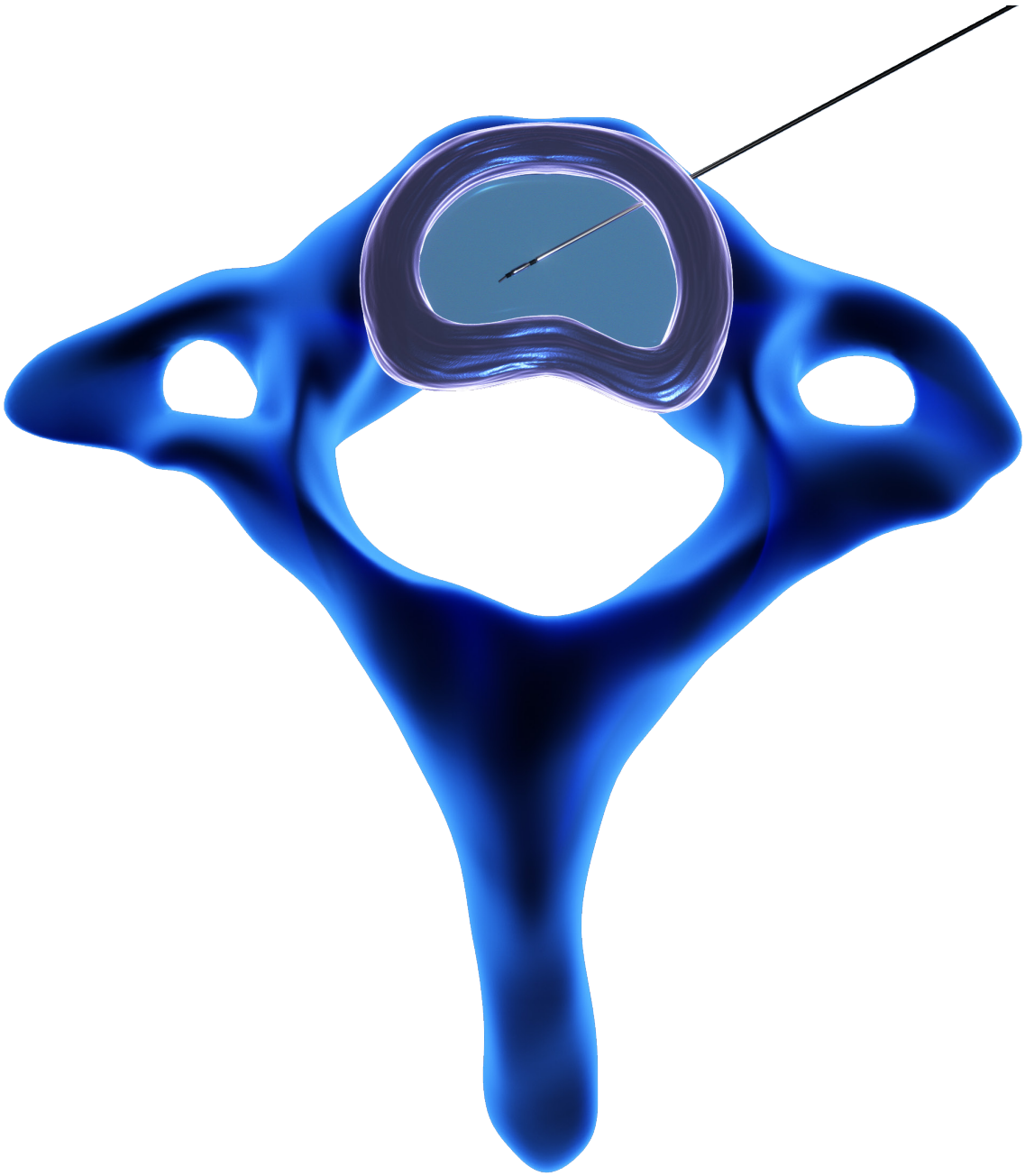
SPINEWAND

TECHNIQUE GUIDE

CIQ DC SpineWand*

Device for use with CIQ Controller



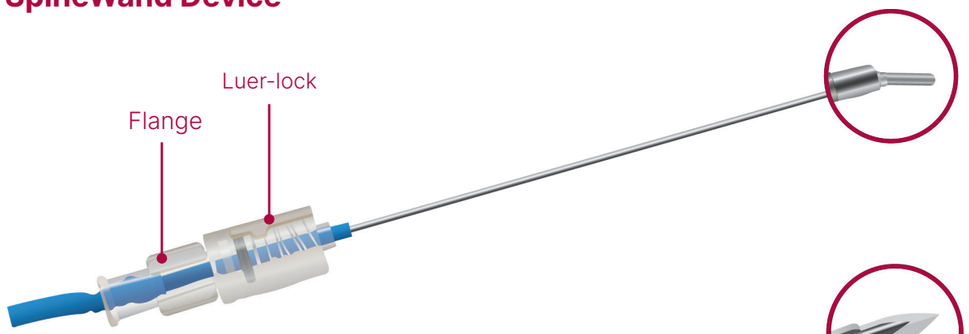
PLASMA DISC DECOMPRESSION

Micro-invasive treatment for contained disc herniation

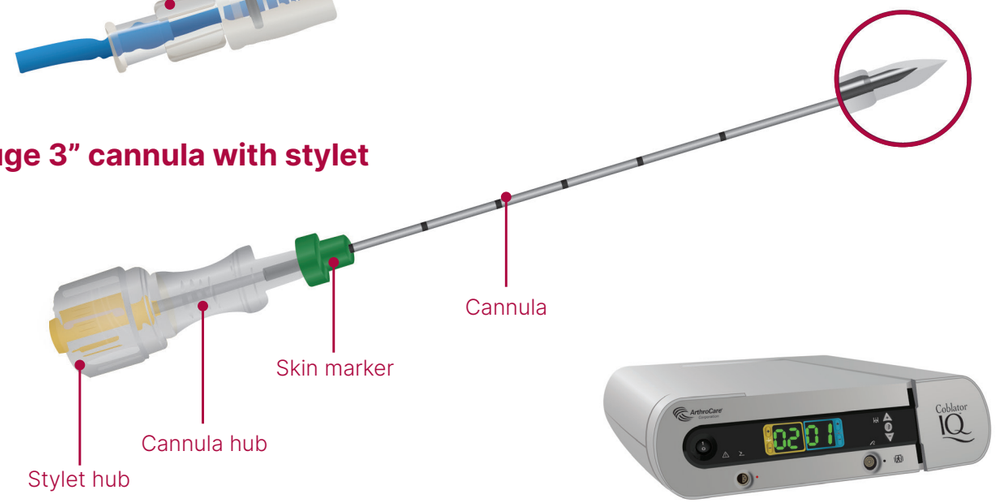
CIQ DC SpineWand* Device

For plasma disc decompression

CIQ DC SpineWand Device



19-gauge 3” 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 plasma ablates tissue through a chemical process as highly energized particles in the plasma break down molecules in the tissue.[1]

***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 for the use of the DC SpineWand* Device and the CIQ Controller is recommended.

Equipment preparation

Materials needed

- C-arm fluoroscope with image intensification
- CIQ Controller with foot control
- DC SpineWand Device and 19-gauge x 3” sterile introducer cannula with trocar tip 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.
- Connect the SpineWand cable connector to the CIQ Controller. Correct connection is indicated by illumination of the ablation and coagulation set point number.
- Ensure the CIQ Controller’s ablation setting is at level 2.
- Deliver the 19-gauge introducer cannula and SpineWand to the sterile field.

CIQ Controller and SpineWand features

- Audible beep tone is heard every 5 seconds after SpineWand is activated.
- Ablation shut-off time is 10 seconds.

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

Patient preparation

- Prepare the patient pre-operatively according to standard surgical procedures.
- Refer to the CIQ DC SpineWand Device Instruction for Use (IFU) package 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 DC SpineWand* Device.

A. Prior to actual procedure, the stylet should be removed and the SpineWand inserted.

B. Advance the SpineWand to the tip of the cannula. There should be only mild resistance upon insertion of the SpineWand.

C. While holding the SpineWand stationary with one hand, pull the cannula back with the other hand exposing the tip and turning the cannula, securing it to the SpineWand's locking mechanism. The active section of the SpineWand tip will be outside the edge of the cannula.

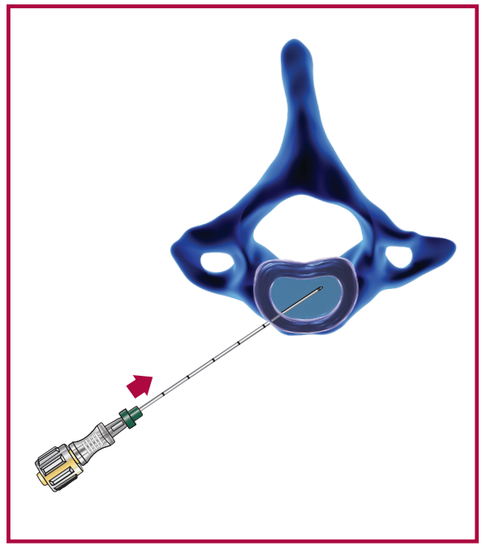
D. Remove the SpineWand from the cannula and reinsert the stylet. You are now ready to begin the procedure.

Surgical procedure

Approach

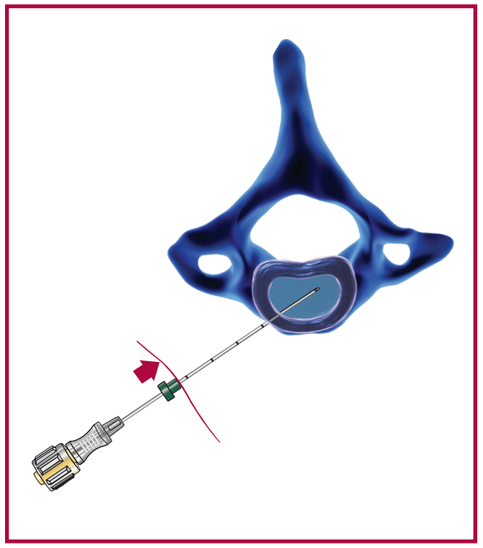
Note: Recommended use is one cannula per spine level.

1. Use a standard right anterior-lateral approach. During insertion of the introducer cannula, target the tip of the stylet to the posterior 1/3 of the nucleus by confirming proper positioning using A/P and lateral fluoroscopic views.



Target the posterior 1/3 of nucleus

2. If desired, reposition the green marker on the cannula shaft down to skin level.



Marker repositioned down to skin level

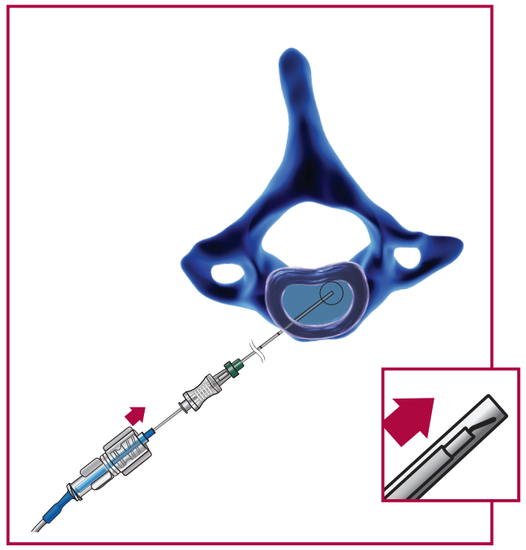
Insert the SpineWand*

Note: Do not use blunt dissection through tissue with the SpineWand tip.

Note: To avoid ablating too deeply into the tissue or against vertebral body endplates, observe the SpineWand tip through clear fluoroscopic imaging.

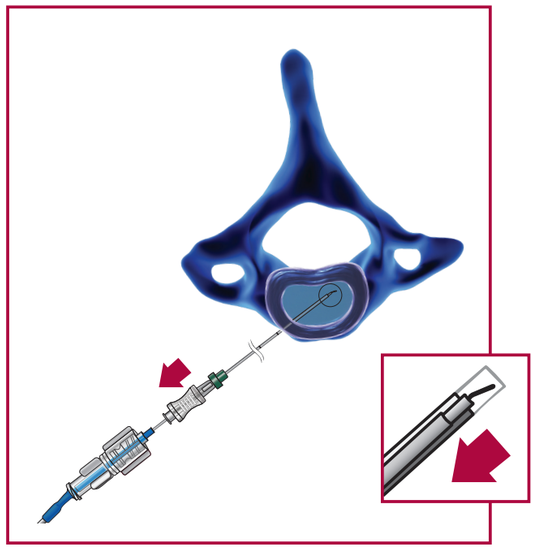
1. Withdraw stylet from cannula and insert the SpineWand under fluoroscopic guidance.

2. Monitor the insertion of the SpineWand to the tip of the cannula using lateral fluoroscopy.



Insertion of the SpineWand monitored under fluoroscopic guidance

3. Once in position, keep the SpineWand stationary with one hand and pull back the cannula with the other hand to expose the tip of the SpineWand which extends 7mm beyond the edge of the cannula.



SpineWand tip exposed

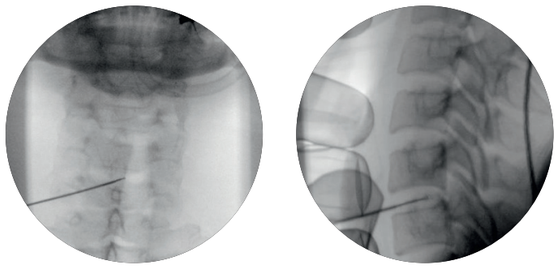
4. Secure the cannula hub on the luer-lock by rotating the cannula onto the SpineWand while keeping the device stationary.

5. Monitor the deployment of the SpineWand beyond the edge of the cannula in lateral fluoroscopy.

6. Confirm the position of the SpineWand tip using fluoroscopic A/P and lateral views.

7. Depress the COAG foot pedal (pedal on far right) on the foot controller for one-half second, to test for neural stimulation.

8. If neural stimulation is observed, stop, and reposition the SpineWand tip.



Fluoroscopic images

Ablation

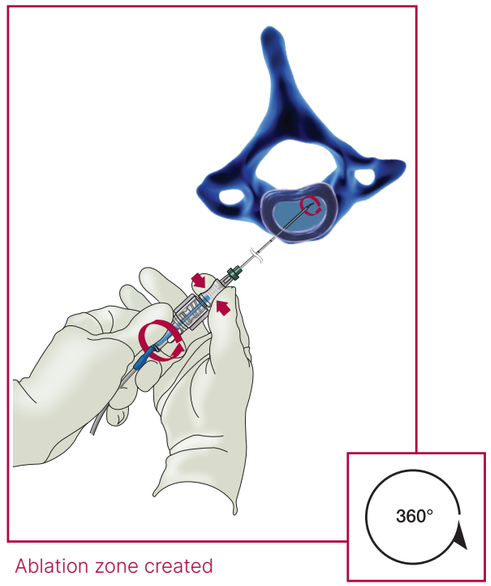
Note: If nerve root or spinal cord come into direct contact with the tip of the SpineWand* during ablation, then serious nerve injury may result.

1. Hold the cannula hub securely with one hand.

2. Grasp the SpineWand flange (proximal to the luer-lock) with the other hand.

3. Depress ablation pedal on the foot controller (pedal on far left of foot control) while rotating the flange in a single, slow and steady 360 degree rotation for 2-3 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.



Ablation zone created

Additional ablation (if desired)

1. Retract cannula and SpineWand 2mm, using fluoroscopic guidance to confirm correct SpineWand deployment.

2. Confirm new position of the SpineWand tip using A/P and lateral views.

3. Repeat ablation steps 1-3.

Remove the SpineWand and cannula

Note: Do not withdraw the SpineWand while it is activated.

1. After the ablation zone has been created, withdraw the SpineWand from the cannula, reinsert the stylet, then withdraw the cannula from the patient. Discard SpineWand and cannula.

2. Follow standard postoperative procedure and shut down system per the Instructions For Use.

Special notes about the CIQ DC SpineWand* Device technique:

- Do not maneuver or advance the access cannula with the SpineWand inserted. Advancing with the SpineWand may damage the tip.
- Controlled ablation pedal is located on the far left of the foot pedal.
- Coagulation is not needed for this procedure except to check for neural stimulation.
- Throughout the procedure, ensure the access cannula is held securely in place to prevent cannula displacement caused by patient movement.
- 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 the cannula tip within the disc.

3. Do not continue the procedure until proper placement of the SpineWand tip has been confirmed. If the patient again complains of sudden onset of pain, you must end the procedure.

- When subsequently using ablation with the DC SpineWand Device, if the patient again complains of sudden onset of pain, you must end the procedure.
- Refer to the CIQ DC SpineWand Device Instructions For Use for a more comprehensive listing of Warnings and Precautions.

Reference
1 Woloszko J, Kwende M, Stalder K. COBLATION in Otolaryngology. *Proc. of SPIE*, Vol. 341. June 2003.

Specifications

	CIQ DC SpineWand Device
Shaft diameter	**0.91mm / 0.036 inches**
Working length	**105.4mm / 4.15 inches**
Mode	**Plasma ablation**
Design	**Bipolar electrode**
Cannula inner diameter	**0.950mm / 0.037 inches**

Ordering information

Reference#	Description
SDC03-01	CIQ DC SpineWand Device with integrated cable
30001 OR ES9000-01	CIQ Controller (includes controller, foot control and power cord)
KNS-1904-10	19-gauge 3” cannulas, 10-pack, individually sealed and sterilized cannulas, trocar tip stylets

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

Indications for Use
The CIQ DC SpineWand Surgical Device is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs and is intended to be operated with the CIQ Controller.

NOTES

SPINEWAND

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