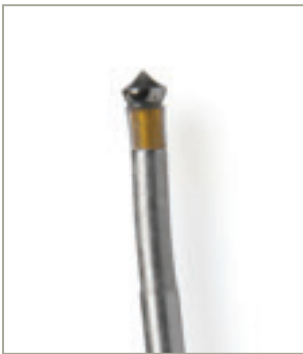


Nucleoplasty®

PERC™ DLR/DLG SpineWand™ Technique Guide

Coblation® uses radiofrequency energy to excite the electrolytes in a conductive medium, such as saline solution, creating a precisely focused plasma. The energized particles in the plasma have sufficient energy to break molecular bonds, excising or dissolving soft tissue at relatively low temperatures (typically 40°C to 70°C), thereby preserving the integrity of surrounding healthy tissue.



DLR SpineWand

Recommended Wand:

Perc DLR or Perc DLG SpineWand

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 SpineWands and the ArthroCare® System 2000 is recommended.

Equipment Preparation:

Materials Needed:

- C-arm fluoroscope with image intensification
- ArthroCare System 2000 Controller with foot control
- ArthroCare Patient Cable (Note: see Instructions For Use for sterilization instructions)
- Select appropriate Convenience Pack:
 - DLR Pack contains DLR SpineWand and 17-gauge x 6" sterile Crawford needle with stylet
 - DLG Pack contains DLG SpineWand and 17-gauge x 8" sterile Crawford needle with stylet
 - Recommended use is one Crawford needle per spine level

Setup:

- Connect the power cord to the controller and outlet
- Connect the foot control to the controller
- Deliver the 17-gauge Crawford needle to the sterile field
- Deliver the SpineWand and patient cable to the sterile field
- Connect the patient cable to the controller, aligning the respective dots
- Connect the patient cable to the SpineWand extension cable, aligning the respective dots
- Set Controller to power level 2

Patient Preparation:

- Prepare the patient pre-operatively according to standard procedures

Nucleoplasty Technique using the Perc™ DLR/DL

1 First time users should verify SpineWand/needle orientation

- A Prior to inserting the needle into the patient, the stylet should be removed and the SpineWand inserted.
- B Advance the SpineWand through the needle until the distal end of the reference mark is positioned at the proximal edge of the needle hub (illustration 1a). This is the proximal limit for creating Coblation channels.
- C The active section of the SpineWand tip will be outside the tip of the needle (illustration 1b).
- D Remove the SpineWand from the needle, and re-insert the stylet.

2 Use a standard posterior-lateral surgical approach

NOTE: Recommended use is one Crawford needle per spine level

- A During insertion of the access needle, target the center of the disc in both the coronal and sagittal planes.
- B Using fluoroscopic imaging, confirm proper needle placement using A/P and lateral views (illustration 2). Use 6" or 8" Crawford needle, 17 gauge, supplied with convenience pack.

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

3 Insert DLR or DLG SpineWand under fluoroscopic guidance

- A Introduce the SpineWand into the access needle, advance the reference mark to the needle hub, then stop. This assures the active section of the SpineWand is deployed in the tissue (illustration 3).
 - B Retract the needle and SpineWand approximately 2 mm (Illustration 4a).
 - C Note the location of the reference mark on the shaft of the SpineWand (Illustration 4b). This mark identifies your proximal channel limit.
 - D Using blunt dissection, advance the tip of the SpineWand into the target tissue. Stop when the SpineWand tip reaches the distal limit (Illustration 5a).
 - E Squeeze the wings of the depth gauge on the shaft of the SpineWand, and advance the depth gauge down the shaft to the proximal end of the needle hub (Illustration 5b). This is the distal limit for creating Coblation channels.
- NOTE: If the SpineWand handle reaches the needle hub before the SpineWand tip reaches the distal limit, the SpineWand handle will serve as the depth gauge.**
- F Withdraw the SpineWand to the reference mark (Illustrations 1a and 4b). You are now ready to begin Coblation channeling.

Illustration 1

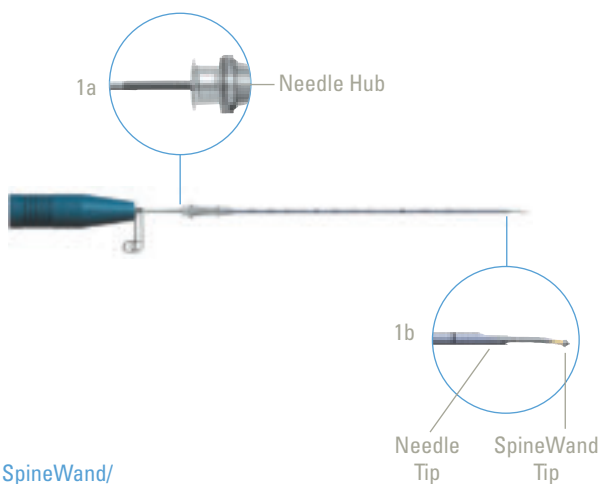


Illustration 2



Proper needle placement
under fluoroscopic imaging

Illustration 3



SpineWand
deployed in tissue

Illustration 4



Identifying proximal
channel limit

G SpineWand

4 After confirming desired placement, create Coblation channels in the following sequence:

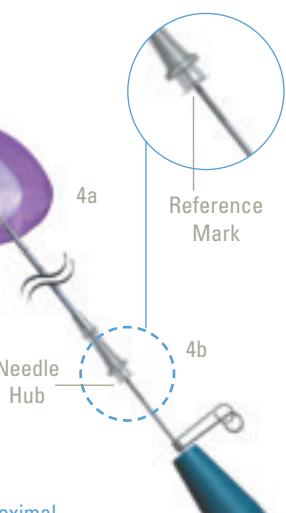
WARNING: If nerve root or spinal cord come into direct contact with the tip of the SpineWand during ablation, then serious nerve injury may result.

- A** Orient the DOT on the SpineWand's handle to the "12 o'clock" position (Illustration 5c).
- B** Using the ablation mode, advance the SpineWand to the pre-determined depth.
- C** Stop advancing the SpineWand, and cease ablation, at the depth gauge.
- D** Withdraw the SpineWand.
- E** Stop withdrawing the SpineWand when the reference mark is adjacent to the needle hub.
- F** Rotate the SpineWand's handle until the DOT is at the "2 o'clock" position, and repeat steps 4b through 4e.
- G** Create additional channels at the 4, 6, 8, and "10 o'clock" positions (Illustration 6).

5 After the Coblation channels have been created, withdraw the SpineWand from the needle, and then withdraw the needle from the patient. Discard SpineWand and needle.

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

6 Follow standard postoperative procedures and shut down system per the Instructions For Use.



Proximal

Illustration 5



Advancing SpineWand to distal limit

Illustration 6

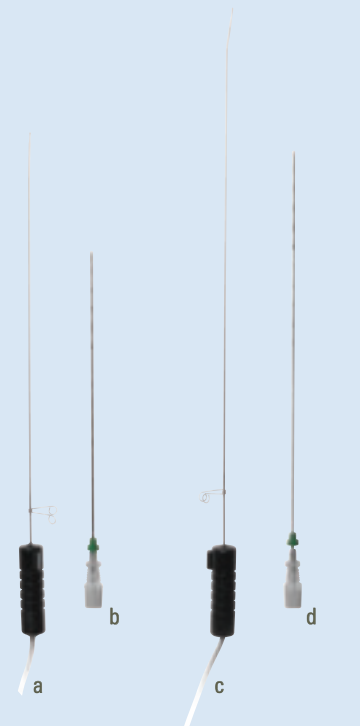


Creating Coblated channels

Special Notes:

- 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 target tissue.
 - 3 **Do not continue** until proper placement of the SpineWand's 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**.
- Refer to the Perc-DLR/Perc-DLG SpineWand Instructions For Use for a more comprehensive listing of Warnings and Precautions.

SpineWand Specifications:		
	PERC DLR	PERC DLG
ANGLE:	8° & 4°	8° & 4°
SHAFT DIAMETER:	1.07 mm / .043 inches	1.07 mm / .043 inches
WORKING LENGTH:	157 mm / 6.20 inches	208 mm / 8.20 inches
MODE:	Plasma ablation	Plasma ablation
DESIGN:	Bipolar multi-electrode	Bipolar multi-electrode
Convenience Pack:		
CATALOG NUMBER:	K 7920-01	K 7925-01
INCLUDES:	Perc DLR SpineWand and Crawford needle, 17 gauge x 6", sterile	Perc DLG SpineWand and Crawford needle, 17 gauge x 8", sterile



a) Perc DLR
b) 17 gauge x 6"
needle

c) Perc DLG
d) 17 gauge x 8"
needle



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CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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