DENERVEX™
ROTATIONAL ABLATION DENERVATION DEVICE

Procedural Reference Guide
Surgical Technique

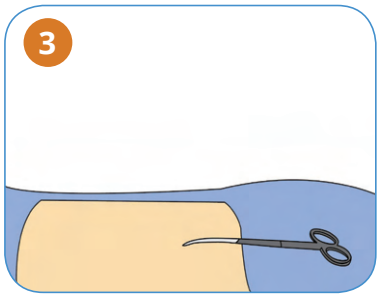


SETUP

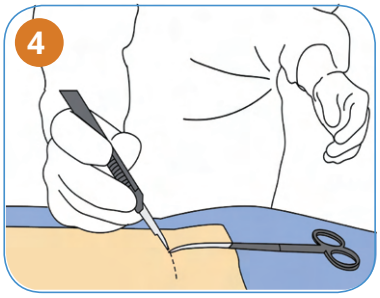
1. **PLACE** the patient in a prone position, **DRAPE** and **PREPARE** the treatment site(s) following standard techniques.

2. **PLACE** a return electrode underneath either the thigh or abdomen ensuring the entire area of the return electrode is reliably attached. **CONNECT** the return electrode cord to the DenerveX™ Pro-40 Generator. **VERIFY** the generator's ground pad light is illuminated in solid green.

LOCATING FACET JOINT WITH FLUOROSCOPY



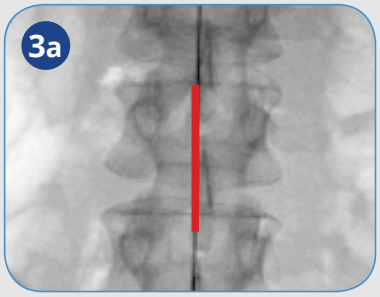
3. **DETERMINE** desired treatment location via fluoroscopy, and **MARK** skin.



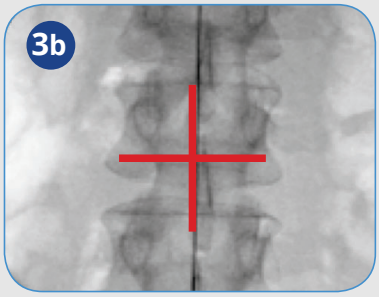
4. **MAKE** a 10-15mm incision in a location that takes into account the angle of approach required to reach the targeted facet joint.

Note: The approach needs to be perpendicular to ensure optimal positioning of the device at the treatment site. This approach differs from a rhizotomy procedure, which typically utilises an approximate 18 ◦ angled trajectory.

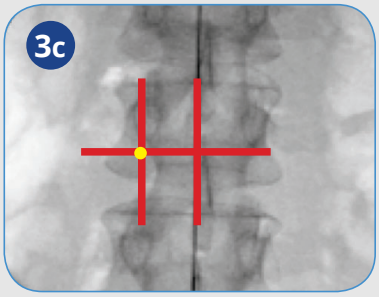
Locating Target Facet Joint for K-Wire Placement



3a. **FIND** the midline of the spine and **MAKE** a line.



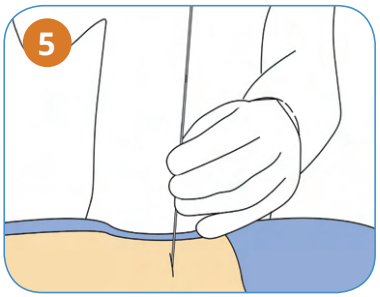
3b. **CREATE** a perpendicular line over intended treatment vertebrae.



3c. **MOVE** about 2 finger widths over from midline of spine, toward intended facet joint treatment, and determine where it intersects with perpendicular line.

Where second vertical line and perpendicular line meet, is your guide for correct treatment area (yellow circle on image).

INSERTING K-WIRE



5. Using fluoroscopic guidance,

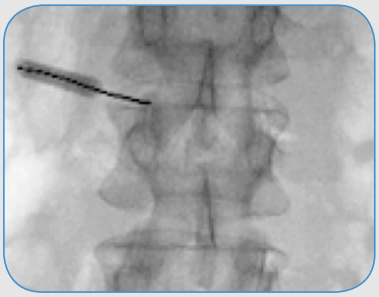
ADVANCE the K-wire **perpendicular** to the incision until it reaches the facet joint. **TAP** the wire gently into the bone using a small hammer. **CONFIRM** via fluoroscopy the correct position of K-wire.

Tips for K-Wire Placement

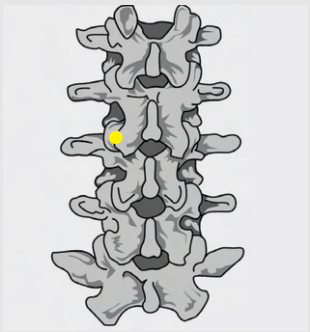
The placement of the K-wire is critical in the process to ensure treatment of the facet joint capsule.

5a. **TARGET** the **INFERIOR FACET JOINT** for treatment to prevent slipping off the joint.

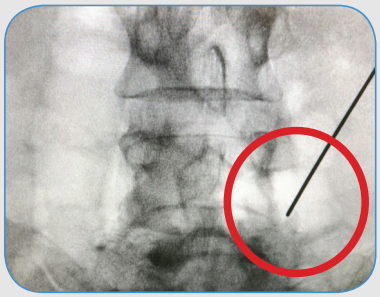
5b. USE **AP** and **LATERAL** views to confirm positioning on the facet joint.

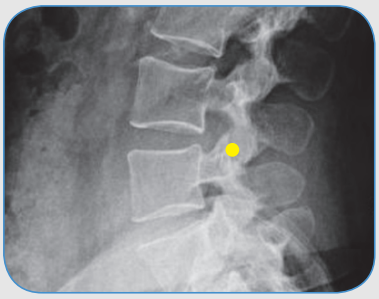


AP VIEW

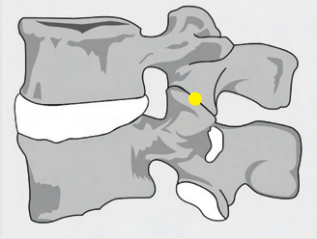


Example of incorrect placement

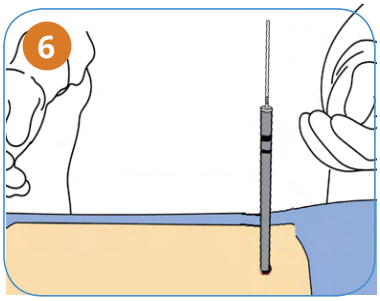


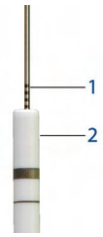


LATERAL VIEW

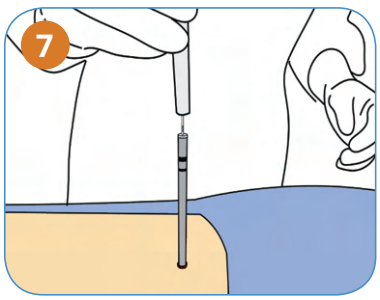


INSERTING PROCEDURE DILATOR AND PORTAL TUBE



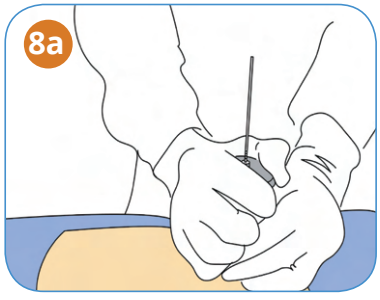


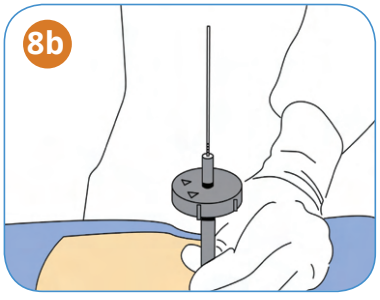
1 – K-Wire Upper Marking Bands
2 – Procedure Dilator



6. **INSERT** the Procedure Dilator over the K-wire until at least two K-wire upper marker bands are visible. **CONFIRM** via fluoroscopy the correct position of K-wire and Procedure Dilator and ensure optimal perpendicular positioning .

7. **INSERT** the Portal Tube over the Procedure Dilator/K-wire.



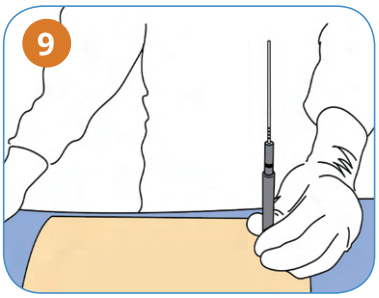


8. **ATTACH** the Portal Driver and further advance the procedure tube as far as possible.

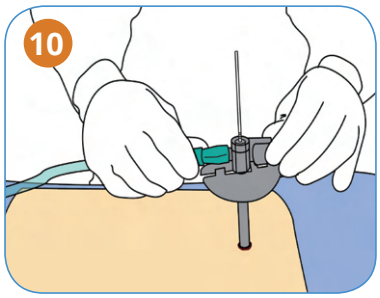
8a. **ENSURE** that the large Procedure Dilator marker band is visible, extending past the top face of the driver.

8b. **CONFIRM** via fluoroscopy the correct position of K-wire, Procedure Dilator and Portal Tube and ensure optimal perpendicular positioning .

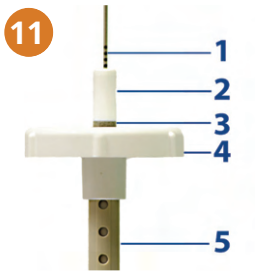
USING THE TISSUE STABILIZER



9. **REMOVE** the Portal Driver and **CHECK** to ensure that at least two K-wire upper marker bands are visible.



10. **CONNECT** standard suction tubing to the side port of the tissue stabilizer.



11. **ADVANCE** the tissue stabilizer with standard suction tubing over the Portal Tube and maintain position using firm hand pressure for the remainder of the procedure. (During all steps from 11-20).

1 – K-Wire Upper Marker Bands
2 – Procedure Dilator
3 – Procedure Dilator Marker Band
4 – Portal Driver
5 – Portal Tube

Note: If the Portal Tube is not fully advanced, the Portal Driver may be reattached and used to further advance the Portal Tube. If full advancement is not possible, a new access point may be necessary.

USING THE DENERVEX® PRO-40 GENERATOR

12. **ESTABLISH** a flow rate of at least 40 LPM.

Warning: ⚠ The DenerveX® Device is designed to work with the DenerveX® Pro-40 Generator (Device rated for 350V peak). Do not use this device without familiarizing yourself with the operation of the generator. For detailed information on the operation of the DenerveX® Pro-40 Generator, see the DenerveX® Pro-40 Generator User Guide. Use of DenerveX® Device with other RF Generators may result in injury to the patient and/or user.

13. **CONNECT** the DenerveX® Device to the DenerveX® Pro-40 Generator and select the desired treatment "Effect" on the Pro-40 Generator.

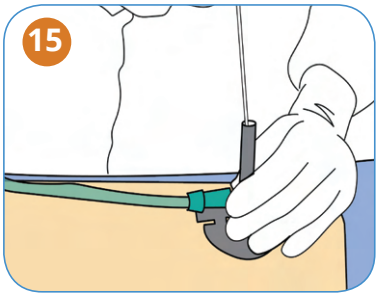
The patient leads should be positioned in such a way that contact with the patient or other leads is avoided.

Note: In general, Effect 3 should be used when treating individuals with High BMI, Effect 2 for those with normal BMI and Effect 1 for low BMI subjects.

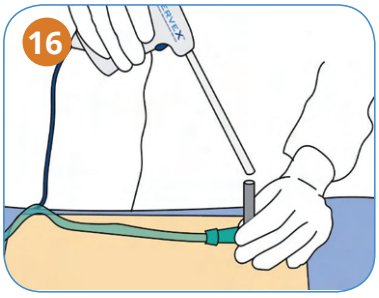
14. **RECONFIRM** that the K-wire is still positioned over the facet joint and adjust position if necessary.



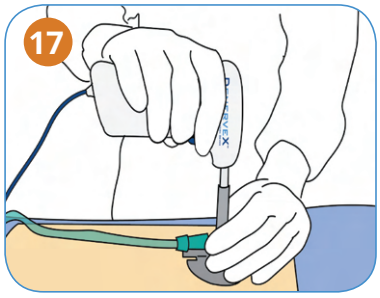
USING THE DENERVEX® DEVICE



15. Gently **REMOVE** the Procedure Dilator and K-wire with one hand, while maintaining the position of the Portal Tube with the other hand.



16. **INSERT** the DenerveX® Device into the Portal Tube.



17. **DEPRESS** and **HOLD** the trigger to activate rotation and delivery of RF energy.

Note: Visually verify that the shaft of the device is rotating during activation.

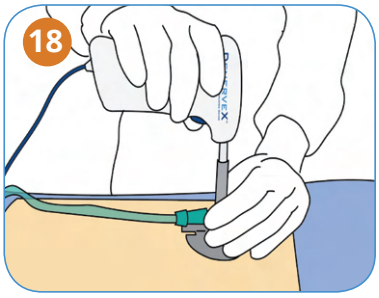
Warning: ⚠ Before triggering the DenerveX® Device, ensure that the DenerveX® Pro 40 Generator parameters have been set and that the plug of the DenerveX® Device has been fully connected to the DenerveX ® Pro 40 Generator.

Warning: ⚠ In the event of an F1 error, ensure that the DenerveX® Pro 40 Generator is switched on before the trigger on the DenerveX® Device is depressed. If an F1 fault occurs, ensure to reset/ switch the DenerveX® Pro 40 Generator off and on. If the problem persists, contact Medovex Support.

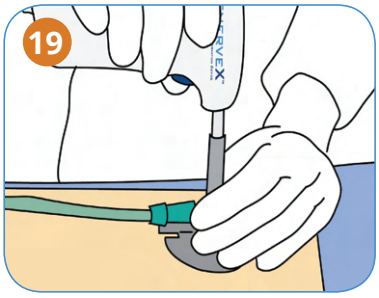
Warning: ⚠ In the event of an F2 error, ensure that the plug of the DenerveX® Device is fully connected to the DenerveX® Pro 40 Generator prior to triggering the device. Unplug the DenerveX® Device and plug it back in fully before depressing the trigger on the DenerveX® Device. If the problem persists, contact Medovex Support.

Warning: ⚠ In the event of an F3 error, select a new DenerveX® Device. This error indicates that the device has reached its maximum usage time.

USING THE DENERVEX® DEVICE *(continued)*



18. Gently **GUIDE** the device through the tissue, without rocking or pivoting, until tactile feedback with the bone is determined.



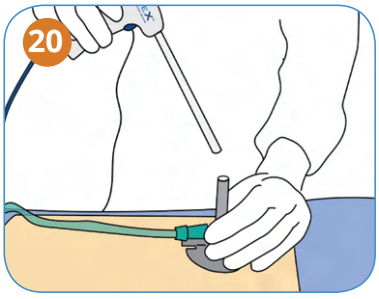
19. **MAINTAIN** gentle downward pressure on the DenerveX® Device for duration of the treatment.

Warning: ⚠ Do not force the device forward as this may result in unintended tissue damage.

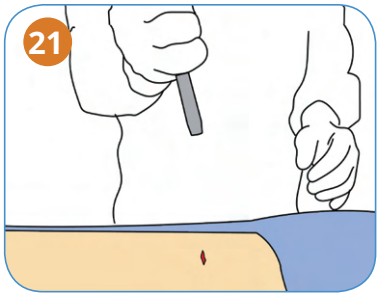
Warning: ⚠ The position of the device should be reconfirmed via fluoroscopy if you feel catching or lateral movement of the device or loss of bone contact. Failure to do so may result in patient injury or reduced treatment effectiveness.

Note: Energy delivery and rotation will stop after 30 seconds or when the trigger is released. An audible Intermittent Activation Tone alarm will sound from the DenerveX® Pro-40 Generator when the 30 second time has been reached. Depressing the Reset Button on the generator is required to allow the generator to activate for the next 30 second period.

COMPLETING THE PROCEDURE



20. **REMOVE** the DenerveX® Device from the Portal Tube.



21. **REMOVE** the Portal Tube and close the incision using standard techniques.

22. **CLEAN** the debris from the hand piece electrode using a standard cautery pad after treatment of each joint.

23. **MOVE** to the next treatment location and repeat steps 1-22.

Note: When not in use, temporarily store the DenerveX® Device in a location isolated from the patient.

Warning: ⚠ Do not reuse or resterilize the DenerveX® Device.

Caution
This DenerveX® guide is for reference only. It is not intended to be a comprehensive instructions for use. For complete details, please see the DenerveX® Instructions for Use included in the DenerveX® Device Kit.

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