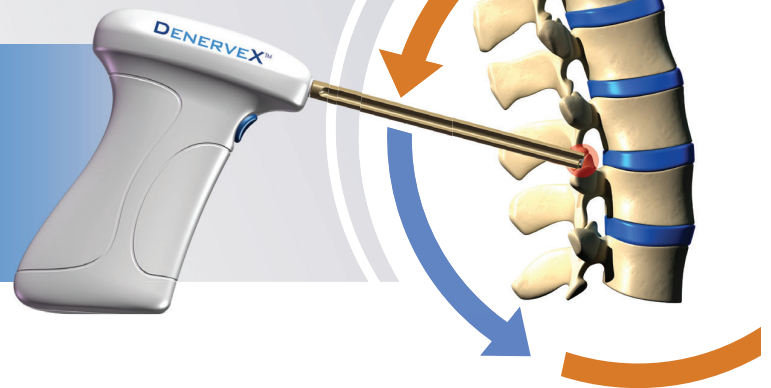


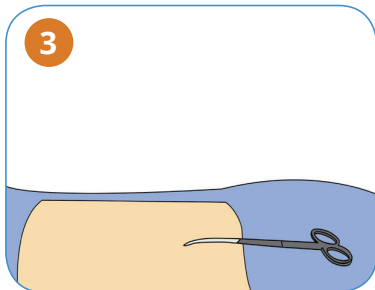
Procedural Reference Guide Surgical Technique



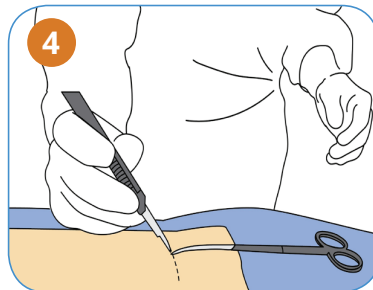
SETUP

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

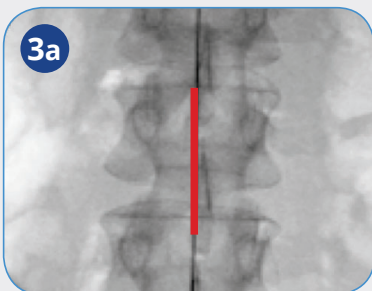


3. **DETERMINE** desired treatment location via fluoroscopy, and **MARK** skin.

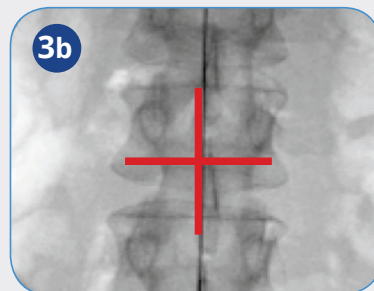


4. **MAKE** a 10-15mm incision in a location that takes into account the angle of approach required to reach the targeted facet joint.

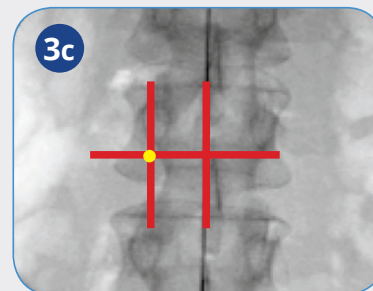
Locating Target Facet Joint for K-Wire Placement



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

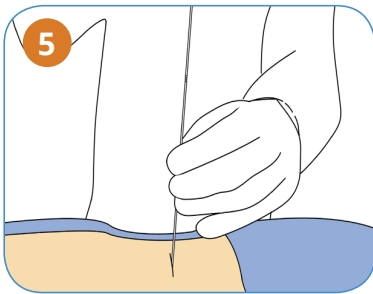


- 3b. **CREATE** a perpendicular line over intended treatment vertebrae.



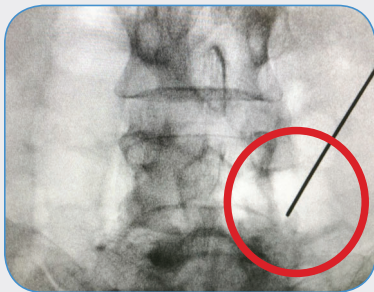
- 3c. **MOVE** about 2 finger widths over from midline of spine, toward intended facet joint treatment, and determine where it intersects with perpendicular line.
Where second vertical line and perpendicular line meet, is your guide for correct treatment area (yellow circle on image).

INSERTING K-WIRE



5. Using fluoroscopic guidance, **ADVANCE** the K-wire into 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.

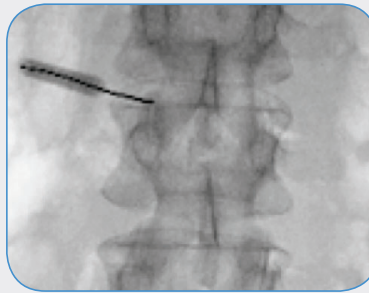
Example of incorrect placement



Tips for K-Wire Placement

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

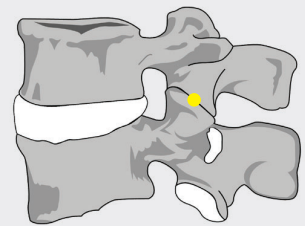
- 5a. **TARGET** the **INFERIOR FACET JOINT** for treatment to prevent slipping off the joint.
- 5b. **USE AP** and **LATERAL** views to confirm positioning on the facet joint.



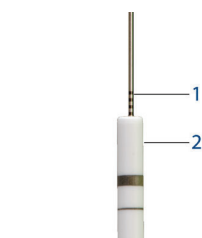
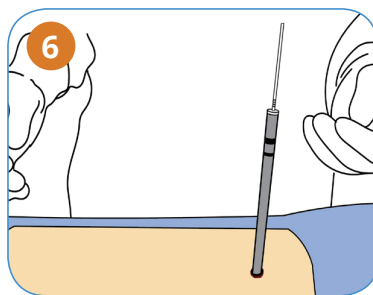
AP
VIEW



LATERAL
VIEW

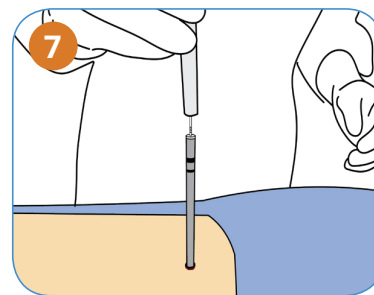


INSERTING PROCEDURE DILATOR AND PORTAL TUBE

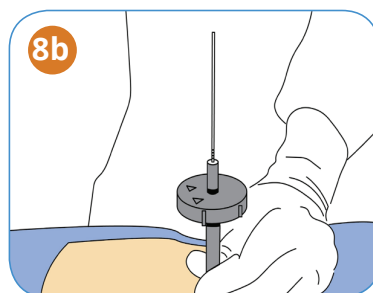
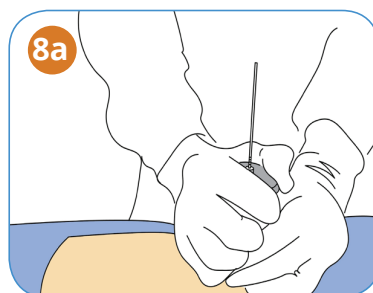


1 - K-Wire Upper Marking Bands
2 - Procedure Dilator

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.



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

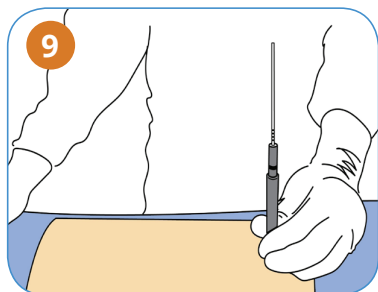


8. **ATTACH** the Portal Driver and further advance the procedure tube as far as possible.

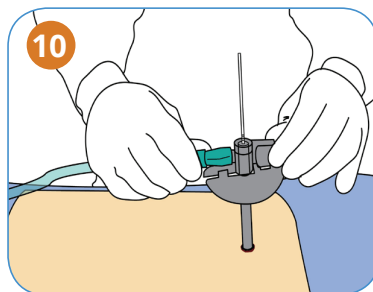
- 8a. **ENSURE** that the large Procedure Dilator marker band is visible, extending past the top face of the driver.

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

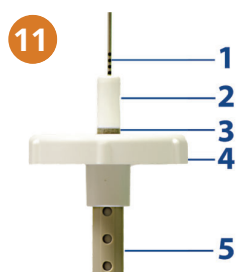
USING THE TISSUE STABILIZER



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.

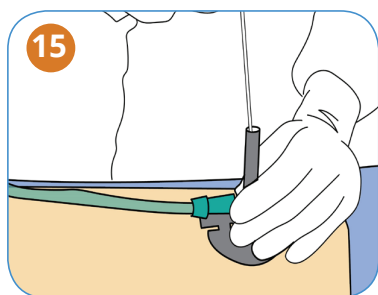
The patient leads should be positioned in such a way that contact with the patient or other leads is avoided.

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.

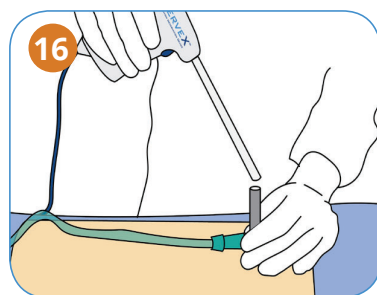
14. RECONFIRM that the K-wire is still positioned over the facet joint and adjust position if necessary.



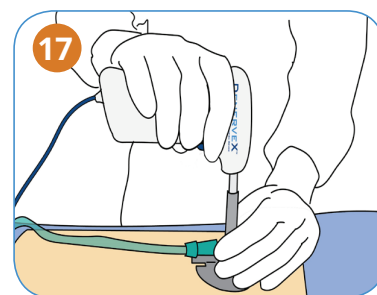
USING THE DENERVEX® DEVICE



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



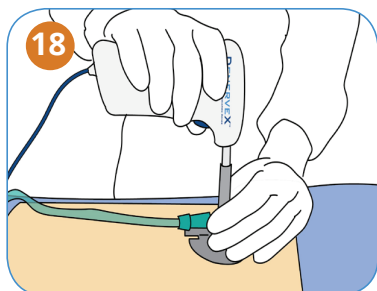
16. INSERT the DenerveX® Device into the Portal Tube.



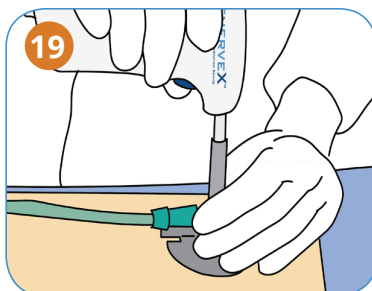
17. DEPRESS and **HOLD** the trigger to activate rotation and delivery of RF energy.

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

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.



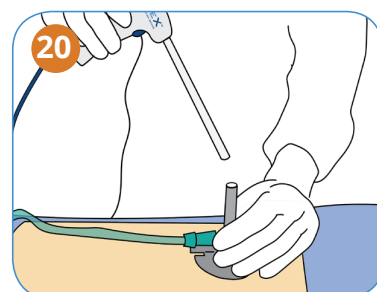
19. **MAINTAIN** gentle downward pressure on the DenerveX® Device for duration of the treatment.

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

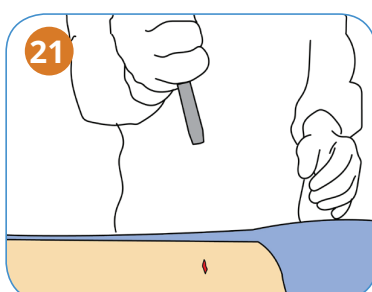
Warning: ⚠ The position of the device should be reconfirmed via fluoroscopy if you feel catching or lateral movement of the device or loss of bone contact. Failure to do so may result in patient injury or reduced treatment effectiveness.

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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 **MEDOVEX**

Unit 1/18 Dequetteville Terrace
Kent Town
SA 50670
Adelaide
Australia

medovex.com