

What is Lysis of Epidural Adhesions?

Lysis of Epidural Adhesions (also know as the Rac[®] Procedure) is a technique involving site-specific catheter placement and fluid injection intended to “open up” the perineural space with various therapeutic medications. The injected medications are designed to free the nerve root from restrictions and reduce inflammation associated with swollen, painful nerve roots exiting the spinal canal in the epidural space. A unique, proprietary, steerable, soft-tip Rac[®] Catheter is guided to the target site where medications are delivered directly to the painful nerve roots. These Rac[®] Catheters are introduced through a specially designed, shear-resistant epidural needle called the RX-2™ Coudé[®] or RX Coudé[®]. They are commonly introduced through the sacral hiatus. They can also be introduced transforaminally.

Also known as:

- Lysis of Epidural Adhesions
- Percutaneous Neuroplasty
- Rac[®] Procedure
- Adhesiolysis

Patient Inclusion Criteria²

- Spinal stenosis
- Facet pain
- Osteophyte causing radiculopathy
- Failed back surgery syndrome
- Multilevel degenerative arthritis
- Disc herniation and radiculopathy
- Spondylosis and radiculopathy (MRI, CT)
- Disc disruption/radicular or non-radicular pain
- Pain unresponsive to spinal cord stimulation and narcotics
- Radiculopathy due to epidural fibrosis (on enhanced MRI)
- Metastatic carcinoma of the spine leading to compression fracture
- Thoracic disc related chest wall and abdominal pain (after mapping)
- Chronic low back pain and failed conservative treatment options
- Radiating lower extremity pain with provocative straight leg raising test

Typically indicated for patients diagnosed with:

- Failed back surgery syndrome
- Spinal stenosis
- Epidural adhesions
- Chronic back pain from excessive scarring in the anterior lateral epidural space
- Radicular pain unresponsive to epidural steroid injections

Patient Exclusion Criteria²

- Spinal instability or spinal cord syrinx
- Pregnant or lactating women
- Arteriovenous malformation
- Arachnoiditis
- Local and or systemic infection
- Uncontrolled or acute medical illnesses including: coagulopathy, renal insufficiency, chronic liver dysfunction, progressive neurological deficit, urinary and sphincter dysfunction, increased intracranial pressure, spinal fluid leak, pseudo tumor cerebri intracranial tumors, unstable angina, and severe chronic obstructive pulmonary disease
- The use of anti-platelet medicants or anti-coagulants including: aspirin, Plavix, NSAID’s, ginkgo, ginseng, vitamin E, coumadin, etc. (laboratory measurements for bleeding and clotting to be in the normal range following discontinuation for appropriate duration)
- Drug addiction and/or uncontrolled major depression of psychiatric disorders
- History of adverse reaction to local anesthetic, steroids, contrast or other injected medications

Standard Injection Volumes for Caudal/Lumbar Lysis of Adhesions

1. Diagnostic: 5-10 mL OMNIPAQUE™240* - outline filling defect and place catheter to target site
2. To show runoff and absence of loculation, contrast 4-5 mL OMNIPAQUE™ 240* injected through the catheter
3. 2-3 mL OMNIPAQUE™240* through catheter for verification of enzyme effectiveness
4. Spreading Factor: Hylenex® 150-300 units (human recombinant) diluted in 10 mL of preservative-free saline
5. Steroid Injection: 4 mg dexamethasone or 40 mg triamcinolone
6. Local Anesthetic: 10 mL 0.2% ropivacaine or 10 mL of 0.25% bupivacaine
7. Depending on the physician's lysis technique, wait 20-30 min. Evaluate for motor block with a voluntary straight leg raise. If no motor block is present, with the patients painful side down, inject 8-10 mL of 10% hypertonic saline over 20-30 minutes. If the patient experiences pain, inject 2-3 mL of local anesthetic.

* **Critical note:** Make sure to use non-ionic water-soluble contrast media. Some physicians also use 5-10 mL of ISOVUE-M 200. Please refer to current literature for volumes and medications used for injections.

Literature and Scientific Articles

One Day Lumbar Lysis of Adhesions Step by Step: Poster Presentation, 4th Croatian Congress on the Treatment of Pain, Osijek, Croatia, May 2018

1. Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, Veihelmann A, Hauschild M, Wagner K, Al Muderis M, Gollwitzer, H, Diehl P, Toepfer A. Percutaneous Epidural Lysis of Adhesions in Chronic Lumbar Radicular Pain: A Randomized, Double-Blind, Placebo-Controlled Trial. *Pain Physician* 2013; 16: 185-196
2. Rac[®] G, Heavner J, Smith J, Noe C, Al-Kaisy A, Matsumoto T, Lee S, Nagy L. Epidural Lysis of Adhesions and Percutaneous Neuroplasty Rac[®] Procedure. *Intech - Pain and Treatment*; Chapter 10: 289-333
3. Rac[®] G, Day M, Heavner J, Smith J. The Rac[®] Procedure: Lysis of Epidural Adhesions (Percutaneous Neuroplasty). *Comprehensive Treatment of Chronic Pain by Medical, Interventional, and Integrative Approaches (Deer Ed.)* 2013; Chapter 50: 521-534
4. Manchikanti L, Cash KA, McManus CD, Pampati V. Assessment of Effectiveness of Percutaneous Adhesiolysis in Managing Chronic Low Back Pain Secondary to Lumbar Central Spinal Canal Stenosis. *International Journal of Medical Sciences* 2013; 10(1): 50-59
5. Manchikanti L, Singh V, Cash K, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing post lumbar surgery syndrome: 2-year follow-up of a randomized, controlled trial. *Journal of Pain Research* 2012; 5: 597-608
6. Helm II S, Benyamin R, Chopra P, Deer T, Justiz R. Percutaneous Adhesiolysis in the Management of Chronic Low Back Pain in Post Lumbar Surgery Syndrome and Spinal Stenosis: A Systematic Review. *Pain Physician* 2012; 15: E435-E462
7. Park E, Park S, Lee S, Kim N, Koh D. Clinical Outcomes of Epidural Neuroplasty for Cervical Disc Herniation. *Journal Korean Medical Science* 2013; 28: 461-465
8. Dunn A, Heavner J, Rac[®] G, Day M. Hyaluronidase: a review of approved formulations, indications and off-label use in chronic pain management. *Expert Opinion on Biological Therapy* 2010; 10(1): 127-131
9. Veihelmann A, Devens C, Trouillier H, Birkenmaier C, Gerdesmeyer L, Refior H. Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: a prospective randomized blinded clinical trial. *Journal of Orthopaedic Science* 2006; 11: 365-369
10. Manchikanti L, Rivera J, Pampati V, Damron K, McManus C, Brandon D, Wilson S. One Day Lumbar Epidural Adhesiolysis and Hypertonic Saline Neurolysis in Treatment of Chronic Low Back Pain: A Randomized, Double-Blind Trial. *Pain Physician* 2004; 7: 177-186
11. Manchikanti L, Pakanati R, Bakhit C, Pampati V. Role of Adhesiolysis and hypertonic saline neurolysis in management of low back pain: Evaluation of modification of the Rac[®] Protocol. *Pain Digest* 1999; 9: 91-96
12. Heavner J, Rac[®] G, Raj P. Percutaneous Epidural Neuroplasty: Prospective Evaluation of 0.9% NaCl Versus 10% NaCl With or Without Hyaluronidase. *Regional Anesthesia and Pain Medicine* 1999; 24(3): 202-207
13. Gilbert K, Brismée J, Collins D, et al Lumbosacral nerve roots displacements and strain: part 1: A novel measurement technique during straight leg raise in unembalmed cadavers. *Spine* 2007; 32(14): 1513-1520; Phila Pa 1976
14. Rac[®] G, Heavner J. Complications Associated with Lysis of Epidural Adhesions and Epiduroscopy. *Complications in Regional Anesthesia and Pain Medicine*, 2nd Edition; Chapter 33: 373-384
15. Helm S, Rac[®] G, Gerdesmeyer L. Percutaneous and Endoscopic Adhesiolysis in Managing Low Back and Lower Extremity Pain: A Systematic Review and Meta-analysis. *Pain Physician* 2016; 19: E245-E281



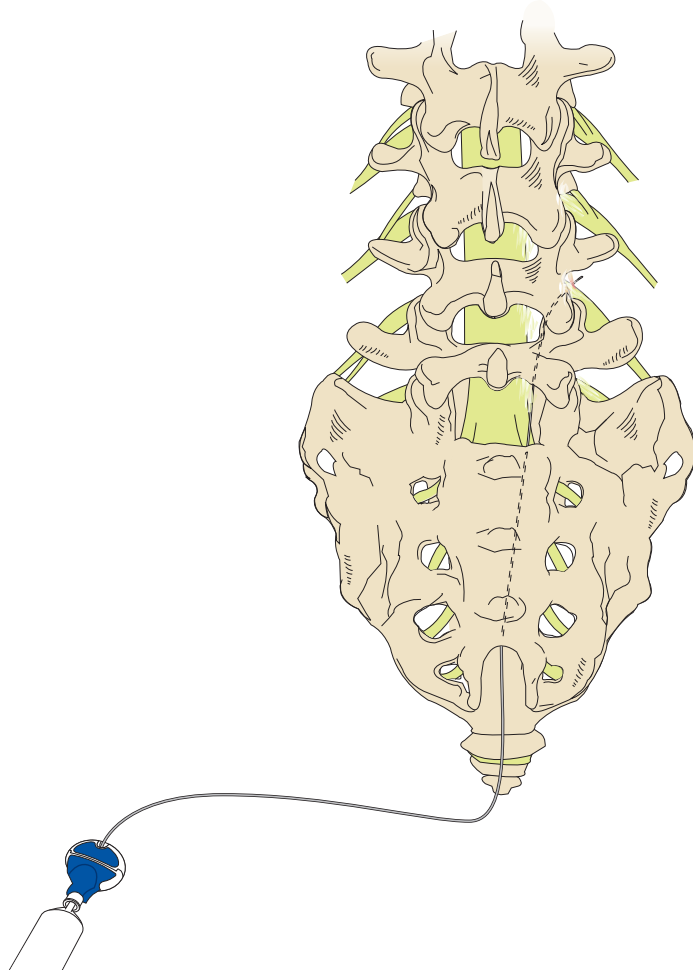
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NOTE: Although this step-by-step guide is based on the technique and clinical experience of a physician, the information contained in this guide is for general guidance on matters of interest only and shall not be substituted for or assimilated to legal or medical advice. You should always consult current literature for appropriate techniques, volumes, and medications used for injections and procedures.
Before using any medical device, read all the instructions for use supplied with the product. This guide and its contents are not a substitute for the operator's manual of any medical product, which include important warnings and precautions. This white paper does not instruct on the proper medical use of this equipment. It is the responsibility of the physician and/or support staff using the described equipment to decide the suitability of the procedure for each patient, and to refer to current literature for appropriate techniques, volumes, and medications used for injections and procedures.

ONE DAY LUMBAR LYSIS OF ADHESIONS

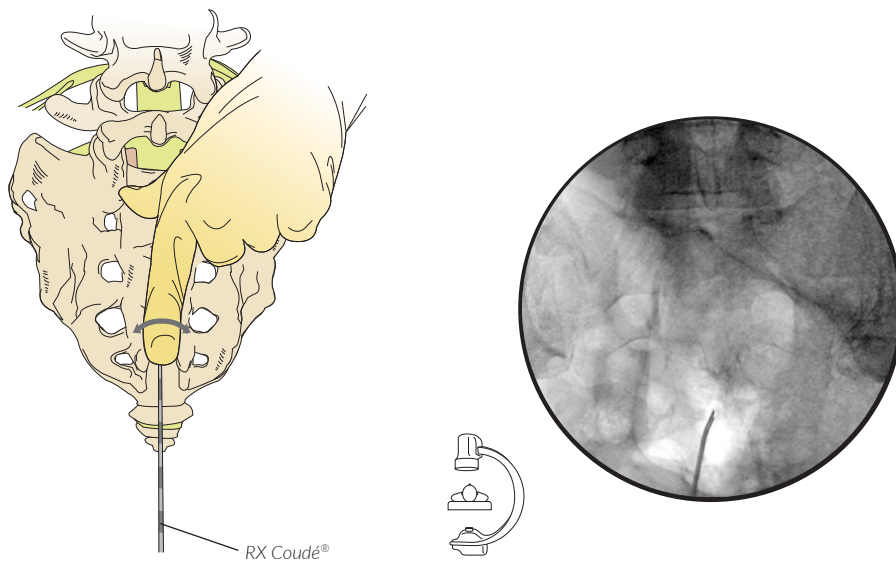
A Step-By-Step Guide On Rac[®] Catheter-Based Procedure Via Caudal Approach

A White Paper Series by Gabor B. Rac[®] M.D., DABPM, FIPP, DABIPP



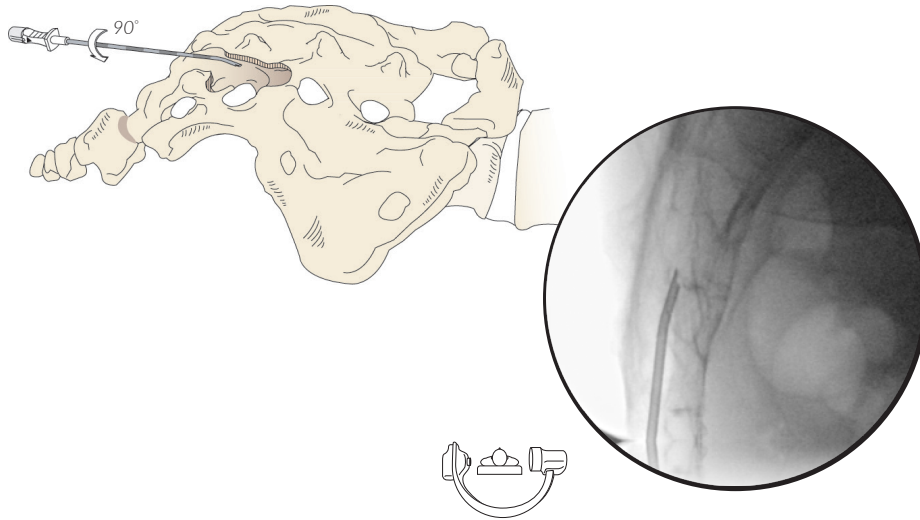
1 RX Coudé® Needle Entry Site

Tuohy and other epidural needles, including the conventional spinal cord stimulator needles, are oval-tipped which increase the chances of shearing as well as other complications. The recommended needle for this procedure is the RX-2™ or RX Coudé®. Both needles have a wide open tip allowing for multiple passes of the catheter and are designed to reduce the chance of catheter shearing. Have the patient lie prone with a pillow placed beneath the lower abdomen to create slight flexion in the lumbar spine and reduce lumbar lordosis. Ask the patient to rotate their legs internally, i.e., toes touching. This internal rotation will relax the gluteal muscles to allow easier identification of the sacral hiatus. Start with the skin wheal needle technique to numb the entry point area of the introducer needle. The skin entry point for the introducer needle is midline and 2" caudal from the sacral hiatus.



2 RX Coudé® Needle Placement - LOR - Dye to Confirm Epidural Placement

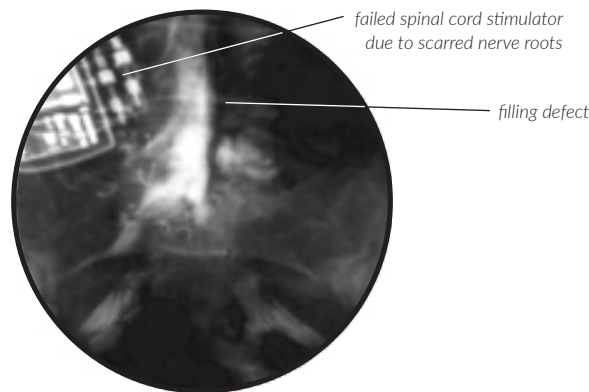
Initial angle of entry through the notch is approximately 45° and then while advancing through the hiatus, this angle is lowered to about 30°. After confirming epidural placement fluoroscopically, rotate the needle 90° towards the target area. Injecting water soluble, non-ionic, radio-opaque contrast media in both A/P and lateral views confirm proper needle placement. Needle tip placement should be below the S3 neural foramen to avoid accidental dural puncture. The RX Coudé® needle allows for multiple passes of the catheter to achieve the optimal tip placement. This is possible because the RX Coudé® tip is completely round allowing for free passage of the catheter.



3 Epidurogram - Inject 5-10 mL of OMNIPAQUE™240

The first injection during the lysis of adhesions procedure is an epidurogram. This is performed to outline the epidural filling defects. This also demonstrates fluid dissection and scar formation while outlining decompression of the affected nerve roots. The epidurogram will also aid in correct catheter tip placement. Use 5-10 mL of OMNIPAQUE™240 to outline the filling defect through the introducer needle. *Use non-ionic water-soluble dye. Some physicians also use 5-10 mL of ISOVUE-M 200.*

This is an image of a patient with L4-L5, S1 radiculopathy treated with spinal cord stimulation. A flare-up associated with radiculopathy pain is effectively treated by the lysis technique.



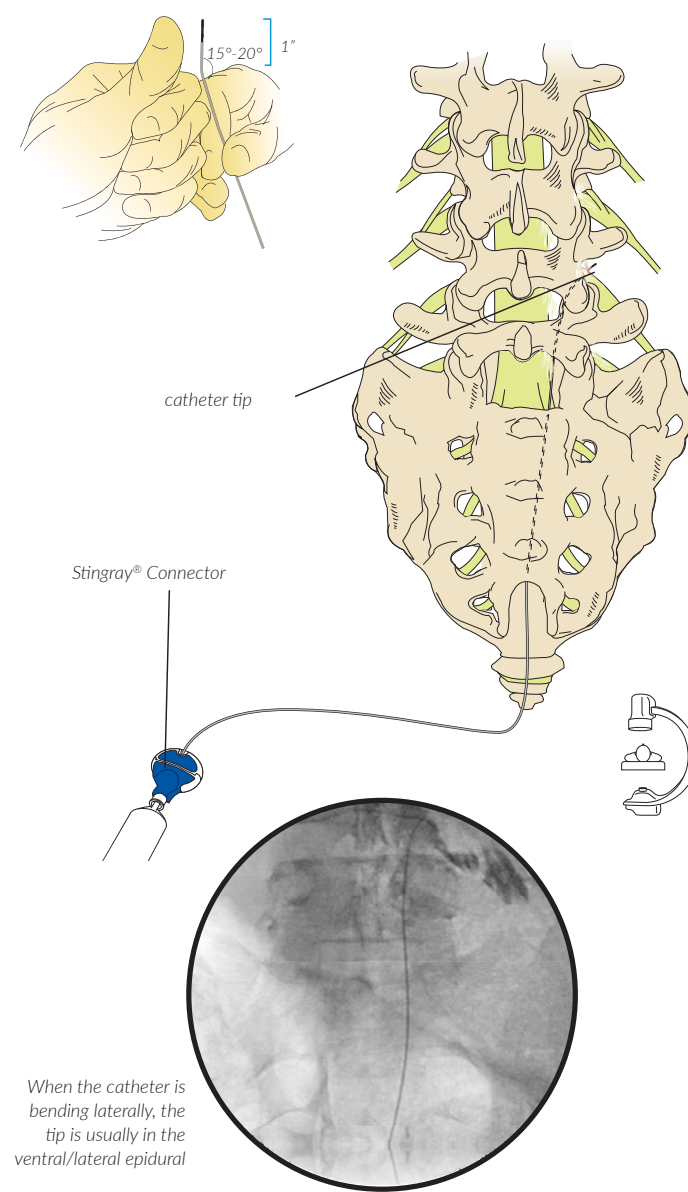
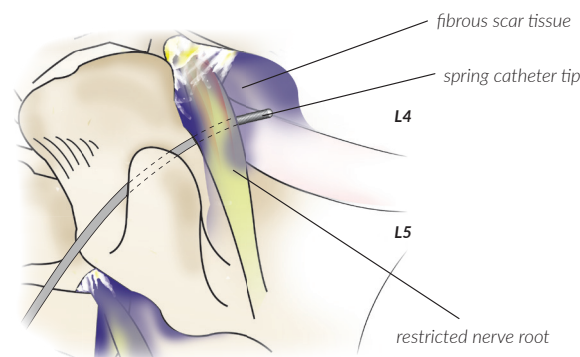
4 Catheter Placement & Visualization of Runoff. Hylenex® 150-300 Units (Human Recombinant) Diluted in 10 mL Preservative-Free Saline - Bolus of Steroid and Local Anesthetic

Make a one inch, 15°-20° bend in the catheter tip for optimum steerability. Some Epimed catheters include Rac2® Bend Marks (RBM) to indicate optimal bend location for lumbar or cervical procedures. For this procedure, use the distal marking (RBM) furthest from the tip of the catheter. Direct the catheter to the anterior-lateral aspect of the affected nerve root by gently twisting the catheter as you advance. Avoid "propelling" the tip in circles, because it can create difficulty in directing the catheter. The target site for the catheter tip is the ventral-lateral epidural space. Most epidural scar formation is symptomatic and located in the ventral and lateral recess.

Once the catheter is placed, inject 4-5 mL of OMNIPAQUE™240 through the catheter to reveal runoff. Once runoff is visualized, inject Hylenex® 150-300 units diluted in 10 mL of preservative-free saline. Fluid injection under pressure opens up the perineural space. This process is called "compartmental filling". Compartmental filling is where the fluid finds the weakest spot in the scar and overflows into the adjoining compartment. Hyaluronidase is used to facilitate spread.^{1,8,12}

The next step is to inject a bolus of steroid and local anesthetic. This bolus includes: 4 mg dexamethasone or 40 mg triamcinolone, local anesthetic, 10 mL of 0.2% ropivacaine or 10 mL of 0.25% bupivacaine.

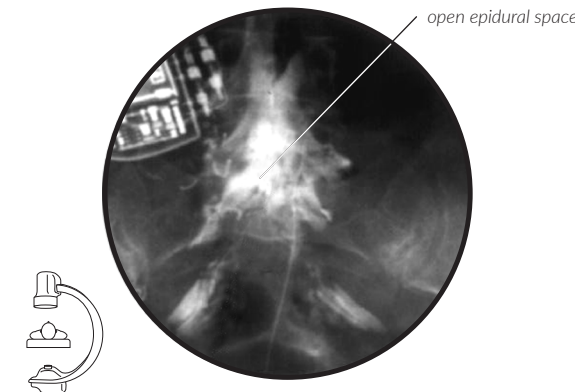
Be aware of allergic and anaphylactic reactions, as any injected material can trigger such reactions. These reactions are very rare, but the physician must be able and ready to treat any and all reactions by having intravenous access, the necessary medications, and monitoring equipment available.



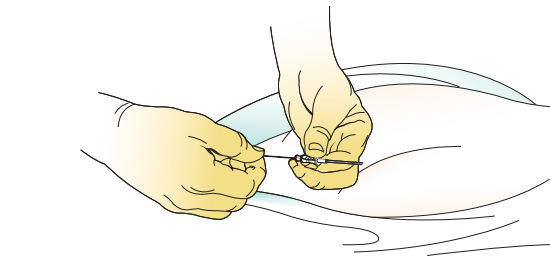
5 Visualization of Opened Up Neuroforamen - Inject 2-3 mL OMNIPAQUE™240

At this point, inject 2-3 mL of OMNIPAQUE™240 to verify filling defect. Inject contrast through the catheter under live fluoroscopic view to verify the absence of intravascular injection and to act as a marker for injection spread in the target area. If the ventral-lateral epidural space does not open up, a second catheter may need to be placed transforaminally.

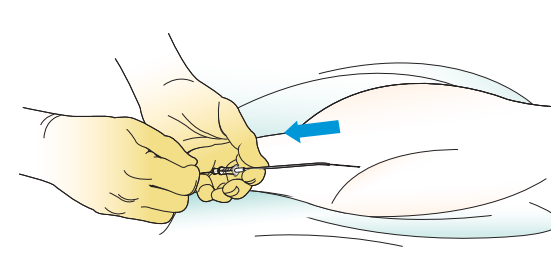
This is an image of an epidurogram performed to identify epidural runoff which indicates an open neuroforamen. Lysis improves the effectiveness of spinal cord stimulation and should be the procedure of choice prior to or whenever spinal cord stimulation fails.



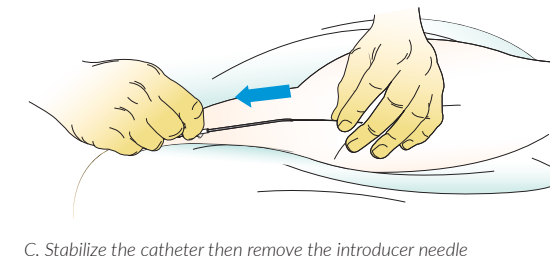
6 Removal of the Needle and Observation Period for the Absence of Motor Block - Followed by Infusion of Hypertonic Saline



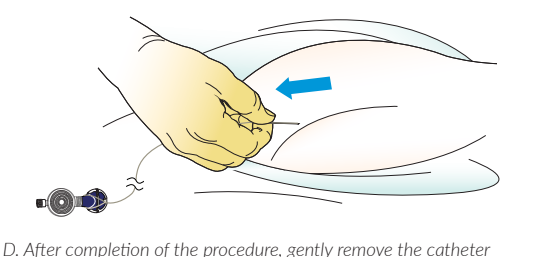
A. Stabilize the catheter to prevent catheter tip displacement



B. Withdraw the introducer needle while holding the catheter in place



C. Stabilize the catheter then remove the introducer needle



D. After completion of the procedure, gently remove the catheter

After the injections have been completed, remove the needle. Next attach the catheter to the bacterial filter to the Stingray® connector, assuring its sterility. The patient should be taken to the recovery room in order to evaluate motor function. This is done with a voluntary straight leg raise. If the patient tests positive for a motor block (i.e. patient is unable to do the straight leg raise), STOP the procedure. This is an indication of a possible subdural spread.

Wait 20-30 minutes and if no motor block is present, place the patient with their painful side down and infuse 8-10 mL of hypertonic saline (10% NaCl) over 5-10 minutes. Most hypertonic saline injections should not be painful. (This volume should be the same or less than the local anesthetic volume previously injected. If pain is experienced during the injection, STOP and inject 2-3 mL of local anesthetic before proceeding with the injection). Hypertonic saline is used for osmotic reduction of edema and disconnection of C fibers (sinuvertebral system) function.³

After injections have been completed, withdraw the catheter from the patient (introducer needle should have been previously removed). Start neural flossing exercises as soon as possible (seen below).

During the one-month follow up visit, it is common to see patients with pain-related facet joint arthropathy. These patients may need a diagnostic block followed by a cryoanalgesia or radiofrequency denervation of the facet joint.

7 Begin Neural Flossing Exercises

After the procedure, have the patient perform the neural flossing exercises as soon as possible.¹³

