

Percutaneous HydroDiscectomy *Surgical Technique*



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Percutaneous HydroDiscectomy Surgical Technique

Equipment

- SpineJet HydroSurgery Power Console
- SpineJet Quick Connect
- SpineJet Percutaneous Access Set
- SpineJet PercResector handpiece

Setup Steps

Console, Quick Connect and Handpiece

1. Check to assure proper voltage alignment between the outlet and the switch on the back of the console.
2. Connect power to Power Console and outlet.
3. Connect Foot Switch to Power Console.
4. Deliver the SpineJet PercResector handpiece to the sterile field.
5. Deliver the SpineJet Quick Connect to the sterile field.
6. Connect the saline supply hose to a saline bag.
7. Connect the evacuation hose to an evacuation canister.
8. Connect the Pump Cartridge to the Power Console.
9. Turn Console speed to 3.
10. Prime the System by covering the end of the Quick Connect with a towel or 4x4 and activating Foot Pedal until saline reaches end of Quick Connect.
11. Deactivate the Foot Pedal.
12. Connect the SpineJet PercResector handpiece to the Quick Connect.
13. Turn the Console speed to 10.

For more information, refer to the SpineJet System Setup.

Access Set

- Prior to the surgical procedure, sterilize the SpineJet Percutaneous Access Set through a facility-approved process for stainless steel surgical instruments.
- On the sterile field, lay out the pieces in order of use:
 - Needle
 - Dilator with knob on
 - Cannula
- Before placement of the access needle during the procedure, test to assure that the needle slides through the dilator without resistance.
- Before placement of the dilator, test to assure the dilator slides through the cannula without resistance.

Patient Preparation

Prepare the patient pre-operatively according to standard procedures. The Percutaneous HydroDiscectomy technique is performed under conscious sedation to allow monitoring of the patient for signs of nerve root irritation

Patient Positioning

Place patient in the prone position elevating the knees under the belly in the lumbar area with pillows or a Kambin Radiolucent Spine Frame to minimize lumbar lordosis.

Warnings

- None of the SpineJet Percutaneous HydroDiscectomy System components should come into contact with the spinal cord, nerve roots, or major blood vessels to avoid the possibility of injury.
- Inadvertent movement of the SpineJet Percutaneous HydroDiscectomy System components outside the field of vision or without adequate assurance of device placement via fluoroscopy or an alternate imaging technology may result in patient injury.
- Care should be taken to avoid unintended puncture of the annulus.
- Attempts to bend the SpineJet Percutaneous HydroDiscectomy System components may render them unusable or unsafe.
- When using the SpineJet Percutaneous HydroDiscectomy System components, stop the procedure if patient complains of sudden onset of pain.
- Remove the SpineJet PercResector handpiece from the patient prior to removing the cannula. Follow standard surgical procedure for post-operative cleaning and closure of the surgical site.

Precautions

- A thorough understanding of the principles and techniques involved in spinal surgeries is essential to avoid injury to the patient and medical personnel, and damage to the device or other medical instruments.
- Read all instructions carefully. Failure to properly follow instructions may lead to electrical, mechanical, or thermal injury and cause improper functioning of the device.
- SpineJet Percutaneous Access Set is supplied non-sterile and must be sterilized through a facility-approved process for stainless steel surgical instruments prior to the surgical procedure.
- The SpineJet Percutaneous HydroDiscectomy System components should be inserted, manipulated, and withdrawn carefully from the operative site to avoid possible damage to the device and/or injury to the patient or surgical personnel.
- A transdural approach should not be used under any circumstances.
- Do not apply excessive force in any direction during the procedure to avoid patient injury.

Surgical Technique

1. Visualize the Disc

Visualize the disc under fluoroscopic guidance using an A/P view. Line up the spinous process in the center. Rotate the C-Arm cephalad or caudal in order to line up the endplates to have maximum visualization of the disc. Oblique the fluoroscope keeping the endplates parallel to each other. The degree of the oblique angle depends on the position of the herniation. The more lateral the herniation the less oblique the angle. The more central the herniation the more oblique the angle. (Refer to the MRI axial view for the position of the herniation).

2. Needle Insertion

After the patient has been prepped and draped using sterile technique, infiltrate the skin with lidocane (Figure 1). Place the tip of the access needle under live fluoroscopy so that it lines up with the center of the disc and the lateral boarder of the superior articulating process (Figure 2). Advance the access needle under intermittent live fluoroscopy staying as close to the lateral boarder of the superior articulating process

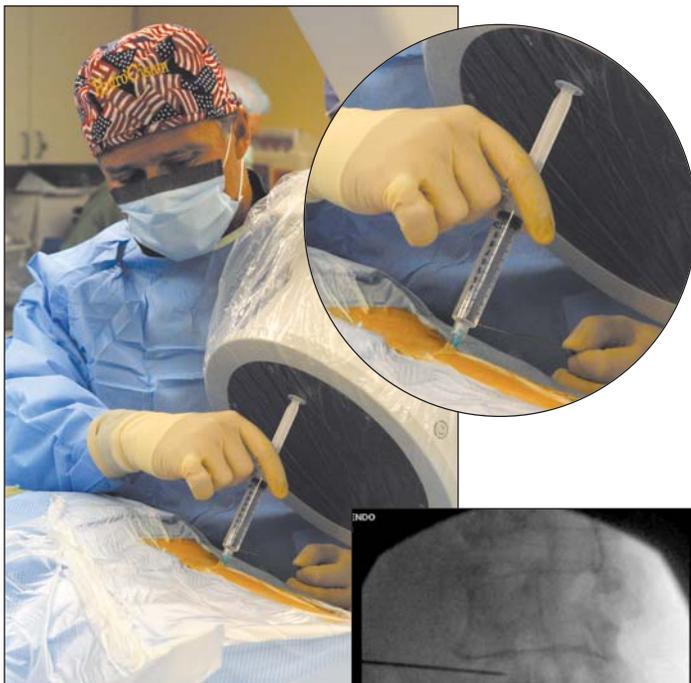


Figure 1

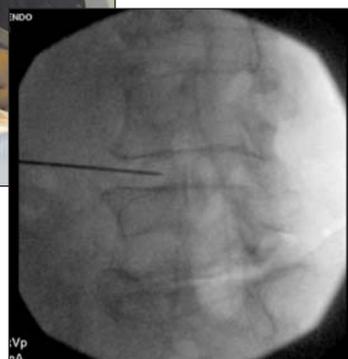


Figure 2

(Figure 3). Once the resistance of the annulus of the disc is felt, stop advancing the needle. (This is the time the patient may experience pain if the needle is too close to the nerve. If the pain is radiating down the leg it usually indicates nerve pain. If it is pain localized in the back area it is usually discogenic pain.) Take an A/P view to confirm the depth of the needle. It should be no further than the medial border of the pedical (Figures 4A and 4B).



Figure 3

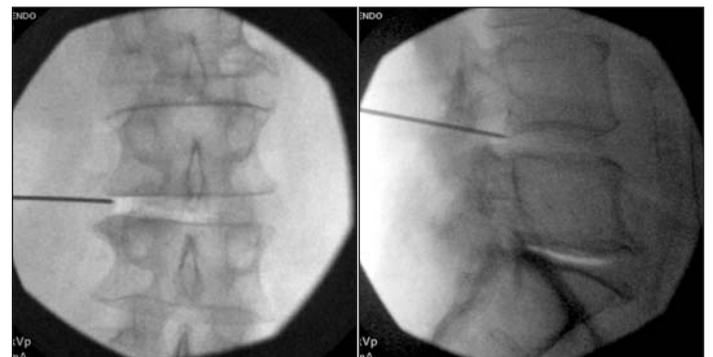


Figure 4A – A/P view

Figure 4B – lateral view

2. Needle Insertion (continued)

Advance the needle into the disc using first lateral views (Figure 5A) then intermittent A/P (Figure 5B) and lateral views until the needle is approximately in the center of the nucleus midway between either endplate. Confirm placement with A/P and lateral fluoroscopic views.



Figure 5A – lateral view



Figure 5B – A/P view

It is optional to use a number 11 blade scalpel to make a nick along the parallel access of the needle to allow room for the dilator.

3. Dilator Insertion

With the dilator knob attached, advance the dilator over the needle (Figure 6). Needle advancement must be done under live fluoroscopic lateral view keeping your eye on the tip of the access needle assuring no forward advanced movement of the needle (Figures 7A and 7B). At this point the dilator may be advanced through the annulus no further than approximately one quarter of the way into the nucleus. Remove the dilator knob (Figures 8 and 9).



Figure 6



Figure 7A



Figure 7B



Figure 8



Figure 9

4. Cannula Insertion

Slide the cannula over the dilator into the outer annulus using continuous live fluoroscopy in the lateral view (Figures 10 and 11). Refer to the optional trephine step if penetration of the annulus cannot be accomplished with the cannula. Advance the cannula through the annulotomy up to the inner annulus stopping the tip at the nuclear annular junction. Confirm position with A/P and lateral fluoroscopy. Remove the dilator and needle (Figure 12).



Figure 10

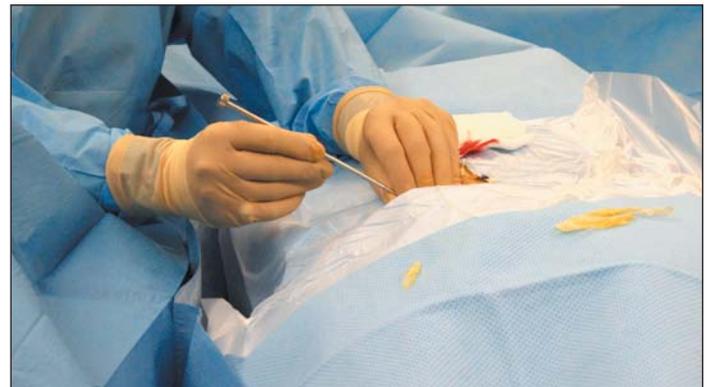


Figure 11



Figure 12

4. Cannula Insertion (continued)

Optional Trepine

Remove the dilator leaving the needle in place. Slide the trephine over the needle up to the outer annulus. Use a twisting motion while pushing gently to core out the annulotomy plug. Remove the trephine and reinsert the dilator with the knob screwed on. Advance the cannula through the annulotomy up to the inner annulus under direct live lateral fluoroscopy. Confirm with A/P and lateral views. Remove the needle and dilator leaving the cannula in place.

5. SpineJet PercResector Insertion

With the bevel of the cannula facing cephalad (left side approach, 8 o'clock position; right side approach, 4 o'clock position) to shield the nerve root, the SpineJet Percutaneous HydroDiscectomy can be safely performed. Hold on to the cannula knob. Take care not to cover the holes on the cannula shaft. Rest your hand on the patient's back to prevent cannula advancement (Figure 13). Insert the SpineJet PercResector through the working cannula using A/P and lateral fluoroscopy (Figures 14 and 15). Upon initial introduction into the disc space, the surgeon will encounter resistance. The resistance felt as the tip of the PercResector just exits the cannula is pressure from the herniated disc. At this point, enter the nucleus under direct live fluoroscopy. Advance slowly until resistance is felt at approximately two-thirds of the way across the disc at the inner portion of the annulus on the opposite side. Do not push through at this point. Do not pass the SpineJet PercResector tip more than two-thirds of the way into the disc. Use lateral and A/P views to confirm that the PercResector tip does not go more than two-thirds of the way into the disc. Note the one centimeter marks on the PercResector shaft (Figure 13).



Figure 13



Figure 14

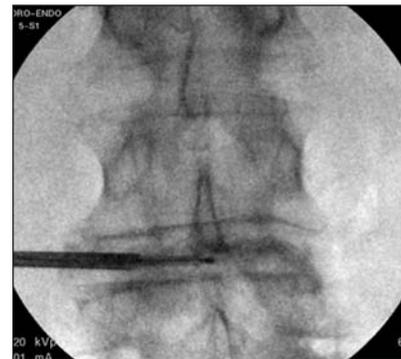


Figure 15

6. Performing the HydroDiscectomy

Depress the foot pedal to run the SpineJet PercResector. Initially, move the SpineJet PercResector tip back and forth and in and out of the cannula not advancing it more than 0.5 cm beyond the end of the cannula for approximately ten seconds to create space within the nucleus. If the handpiece is advanced directly and too far, a vapor lock may occur and the system will not work to its potential.

For approximately one minute, use a gentle piston motion (back and forth) to consume nucleus extending the tip fully. The initial resistance encountered will quickly dissipate as the nucleus tissue is evacuated. Utilize fluoroscopy to confirm location. Advance the tip of the SpineJet PercResector further into the disc slowly as material is cleared. During the second minute, while continuing to use the pistoning motion, rotate the SpineJet PercResector 180° to the left and 180° to the right. During the third minute, the handpiece should be pistoned, rotated, and fanned medially and laterally, taking care not to touch either endplate by moving the cannula. The nucleus pulposus can be visualized in the evacuation tube as it is being removed (Figure 16).



Figure 16

The amount of disc material removed is determined by the length of time the SpineJet PercResector is activated within the disc (Figure 17). Adequate nucleus consumption is typically achieved in a three minute run time. Do not apply excessive force in any direction during the procedure to avoid patient injury.

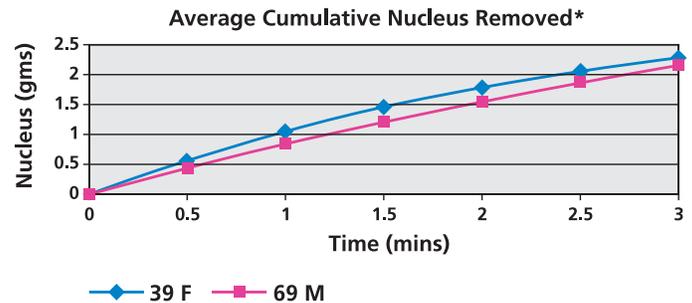


Figure 17

The Safe Zone

Do not pass the SpineJet PercResector tip more than two-thirds of the way into the disc. Use lateral and A/P views to confirm that the PercResector tip does not go more than two-thirds of the way into the disc. Note the one centimeter marks on the PercResector shaft.

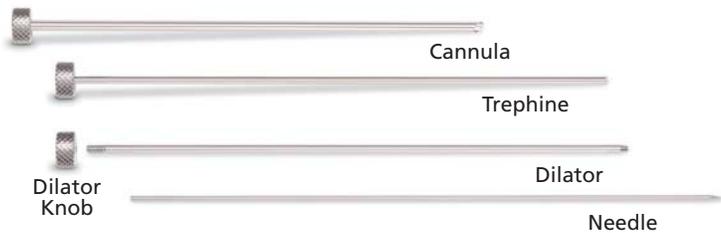
Once complete, remove the SpineJet PercResector and Access Cannula leaving a small annular defect. It is recommended to perform a transforaminal epidural on every level that was worked on for two reasons: (1) to minimize post-operative pain and (2) to facilitate the recovery of the radicular pain. Close wound according to surgeon preference.

*Data on file.

Ordering Information

SpineJet Percutaneous HydroDiscectomy System

Description	Catalog No.
SpineJet PercResector Handpiece <i>(disposable, supplied sterile)</i>	56000
SpineJet Percutaneous Access Set <i>(Includes tray, needle, dilator, dilator knob, cannula and trephine)</i> <i>(reusable, supplied non-sterile)</i>	56983
SpineJet Percutaneous Access Set Replacement Items <i>(reusable, supplied non-sterile)</i>	
Needle	51739
Dilator Knob	52012
Trephine	51711
Dilator	51740
Cannula	51765
Tray	51786
SpineJet Quick Connect <i>(Quick Connect includes tubing set - disposable, supplied sterile)</i>	55400
SpineJet HydroSurgery Console <i>(Includes Foot Pedal and Power Cord)</i>	52700



SpineJet PercResector Handpiece
#56000

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