

Endoscopic HydroDiscectomy *Surgical Technique*



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Endoscopic HydroDiscectomy Surgical Technique

The SpineJet Endoscopic HydroDiscectomy System is designed specifically for decompressing and debulking the nucleus during an endoscopic guided procedure. It can be used to decompress the nerve root and to create a working channel for additional endoscopic guided work. The void created by the SpineJet Endoscopic HydroDiscectomy System allows the physician to have additional visibility and facilitates access for other instruments. The SpineJet EndoResector Handpiece can slide down either the scope and/or the working channel of the endoscope. The outer diameter of the SpineJet EndoResector Handpiece is 3.5 mm. Please refer to the Endoscope Manufacturer's instructions for use, including specific dimensions, details, and recommendations.

Equipment

- SpineJet Power Console
- SpineJet Quick Connect
- SpineJet EndoResector 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 EndoResector 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 EndoResector Handpiece to the Quick Connect.
13. Turn the Console speed to 10.

For more information, refer to the SpineJet System Setup.

Patient Preparation

Prepare the patient pre-operatively according to standard procedures. The Endoscopic 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.

Endoscope Placement

Insert the endoscope into the disc space in accordance with the manufacturer's instructions for use.

Warnings

- The SpineJet EndoResector should not come into contact with the spinal cord, nerve roots, or major blood vessels to avoid the possibility of injury.
- Inadvertent movement of the SpineJet EndoResector 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 EndoResector Handpiece may render it unusable or unsafe.
- When using the SpineJet EndoResector stop the procedure if patient complains of sudden onset of pain. Remove the EndoResector Handpiece from the patient prior to removing a cannula, if used. 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 in order 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.
- The SpineJet EndoResector 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. Insertion of the SpineJet EndoResector into the Endoscope

Insert the SpineJet EndoResector Handpiece into the working channel of the endoscope (**Figure 1**). Note if the SpineJet EndoResector Handpiece does not fit down the working channel, it may fit down the scope channel. Before placing it into the scope channel, withdraw the endoscope and utilize the scope channel to insert the EndoResector. If the scope channel is used, confirm initial placement of the SpineJet tip using A/P and lateral fluoroscopic views.

Do not pass the tip of the SpineJet EndoResector more than two-thirds of the way into the disc. Use lateral and A/P views to confirm that the EndoResector tip does not go more than two-thirds of the way into the disc (**Figure 2**). The SpineJet EndoResector tip should be within the endoscopic field of vision at all times (**Figure 3**) and/or placement should be confirmed via live fluoroscopy or an alternative imaging technology.

2. Perform the HydroDiscectomy

Depress the foot pedal to run the SpineJet EndoResector. For approximately one minute, use a gentle piston motion (back and forth) to consume nucleus extending the tip fully (**Figure 4**). The initial resistance encountered will quickly dissipate as the nucleus tissue is evacuated. Utilize fluoroscopy to confirm location of the tip.

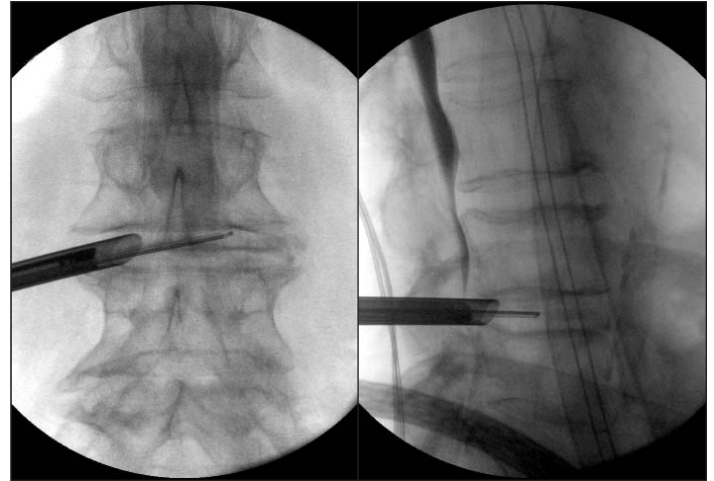


Figure 2

Figure 3



Figure 4



Figure 1

Slowly advance the tip of the SpineJet EndoResector further into the disc as material is cleared (**Figure 5**). During the second minute, while continuing to use the pistoning motion, rotate the SpineJet EndoResector 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. The nucleus pulposus can be visualized in the evacuation tube as it is being removed.

The amount of disc material removed is determined by the length of time the SpineJet EndoResector is activated within the disc (**Figure 6**). 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.

The Safe Zone

Do not pass the EndoResector tip more than two-thirds of the way into the disc. Use lateral and A/P views to confirm that the EndoResector tip does not go more than two-thirds of the way into the disc. Keep the SpineJet EndoResector tip within the endoscopic field of vision at all times and/or confirm placement using continuous live fluoroscopy.



Figure 5

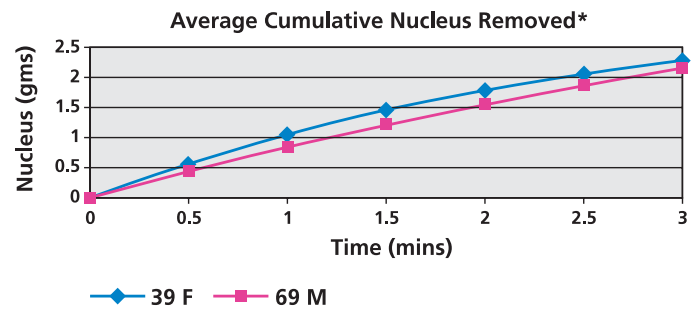


Figure 6

Ordering Information

SpineJet Endoscopic HydroDiscectomy System

Description	Catalog No.
SpineJet EndoResector Handpiece <i>(disposable, supplied sterile)</i>	56110
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 EndoResector Handpiece
#56110

HydroCision Customer Care Line

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*Data on file.

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