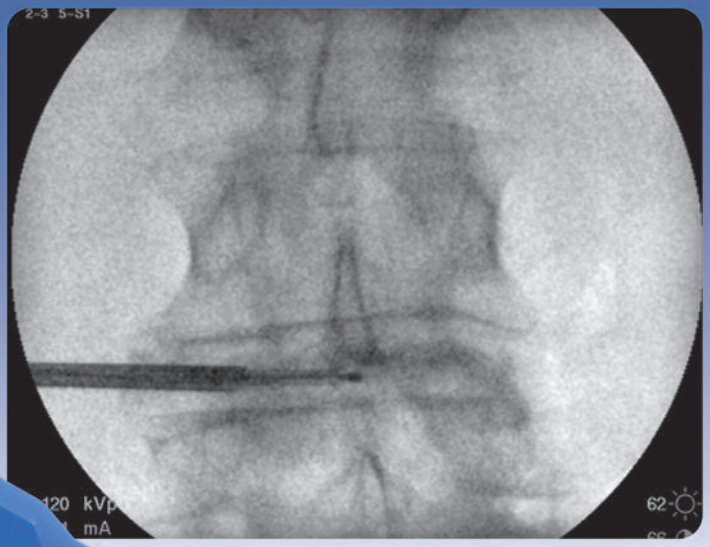
SpineJet®
HydroDiscectomy System

Percutaneous HydroDiscectomy *Surgical Technique*



HydroCision®
The Leader in HydroSurgery®

Equipment

- SpineJet HydroSurgery Power Console
- SpineJet Percutaneous Disposable Access Set
- SpineJet PercResector Handpiece and Direct Connect Tubing Set

Setup Steps

Console, Direct Connect Handpiece

1. Ensure proper voltage alignment between the room's electrical outlet and the switch on the back of the console.
2. Connect Power Cord to back of Power Console and outlet.
3. Connect Foot Switch to front of Power Console (align round pin connector red dot with console connector red dot).
4. Deliver the SpineJet sterile components to the sterile field. Clip the PercResector Handpiece to the patient.
5. Return 3 sterile components to circulating nurse: 1) saline supply hose; 2) pump cartridge; 3) waste evacuation hose.
6. Connect the Pump Cartridge to the Power Console.
7. Connect the saline supply hose to a saline bag.
8. Connect the evacuation hose to an evacuation canister. If using gravity, leave at least one additional port open.
9. Turn on the console and ensure the three lights on the front of the Console are off.
10. Raise Console speed to setting 10.
11. Prime the System by depressing Foot Pedal until saline is flowing through the distal end of the Handpiece and waste hose.
12. Deactivate the Foot Pedal. System is ready for use.

For more information, refer to the SpineJet System Setup.

Access Set

Prior to the surgical procedure separate sterile Access Set Tray from Handpiece tray and place on sterile field.

Access Set Components include in order of use:

- Spine Needle with Stylet
- Guide Wire
- Dilator*
- Straight Cannula
- Optional Curved Cannula

*Inserted, threaded, and locked into the selected cannula.

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 belly in the lumbar area with pillows or use a Kambin Radiolucent Spine Frame to minimize lumbar lordosis.

Warnings & Precautions

- 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 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 must be taken to avoid unintended puncture of the annulus on the contralateral side.
- Attempts to bend the HydroDiscectomy System components may render them unusable or unsafe.
- When using the HydroDiscectomy System components, stop the procedure if patient complains of sudden onset of pain.
- Remove the PercResector hand piece from the patient prior to removing the cannula. Follow standard surgical procedure for post-operative cleaning and closure of the surgical site.
- A thorough understanding of the principles and techniques involved in spinal surgeries is essential to avoid injury to the patient, medical personnel, or damage to the device and 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 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 a local anesthetic (**Figure 2**). Place the tip of the access needle under live fluoroscopy so that it lines up with the center of the disc and the lateral border of the superior articulating process (**Figure 2A**). Advance the access needle under intermittent live fluoroscopy staying as close to the lateral border of the superior articulating process as possible (**Figure 2B**). Once the resistance of the annulus of the disc is felt, stop advancing the needle. (At this time the patient may experience pain if the needle is too close to the nerve. If the pain is radiating down the leg it may indicate nerve pain. If the pain is localized in the back area it may indicate 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 pedicle (**Figures 2C** and **2D**).

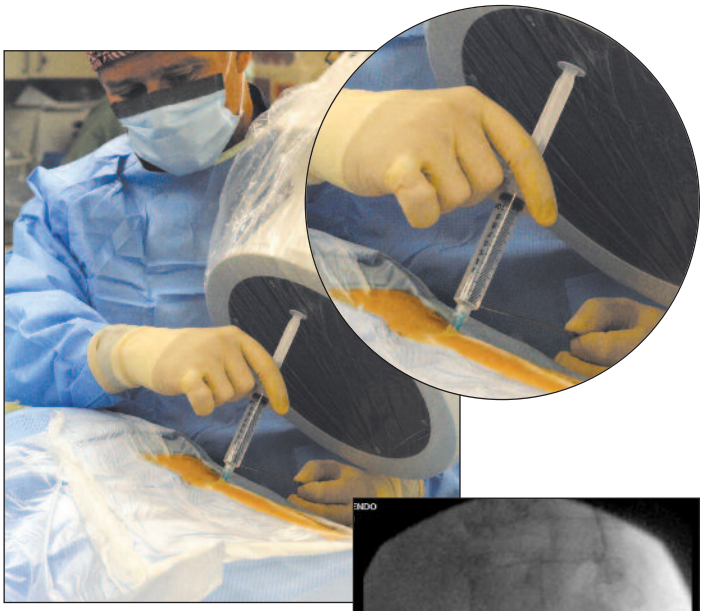


Figure 2

Figure 2A

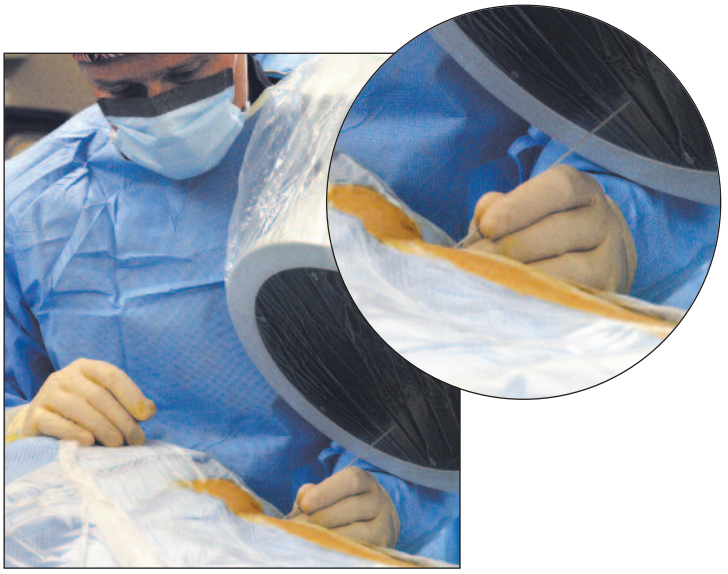


Figure 2B

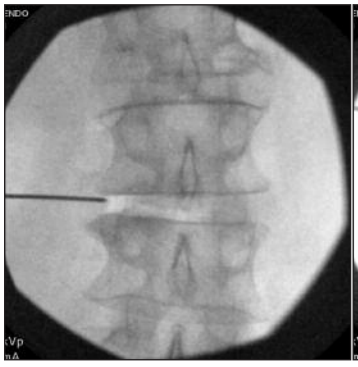


Figure 2C – A/P view

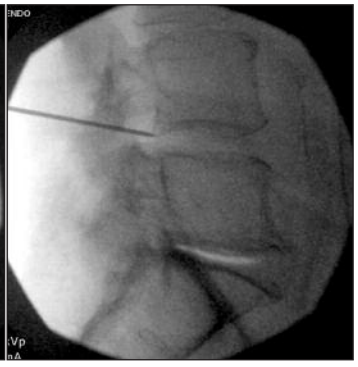


Figure 2D – lateral view

2. Needle Insertion (continued)

Advance the needle into the disc first using lateral views (**Figure 2E**), then intermittent A/P (**Figure 2F**) and lateral views. Continue to advance the needle until it is approximately in the center of the nucleus, midway between either endplate. Confirm placement with A/P and lateral fluoroscopic views. Once placement is confirmed, remove stylet from needle taking care to maintain placement of the needle in the center of the nucleus (**Figure 2G**).

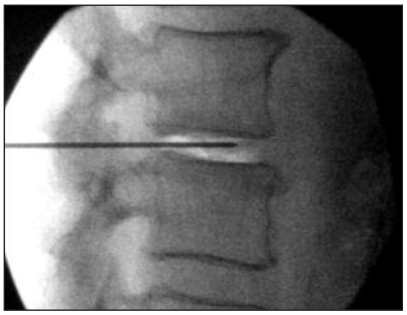


Figure 2E – lateral view

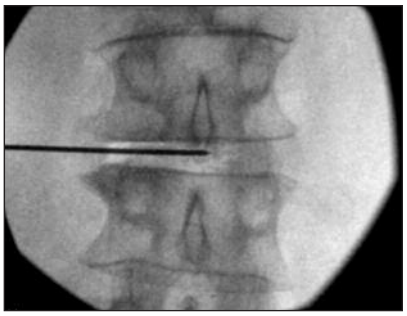


Figure 2F – A/P view

Figure 2G

3. Guide Wire Insertion

Thread the Guide Wire (**Figure 3**) through needle first using lateral views (**Figure 3A**) then intermittent A/P (**Figure 3B**) and lateral views until the Guide Wire is approximately in the center of the nucleus midway between either endplate. Confirm placement with A/P and lateral fluoroscopic views.

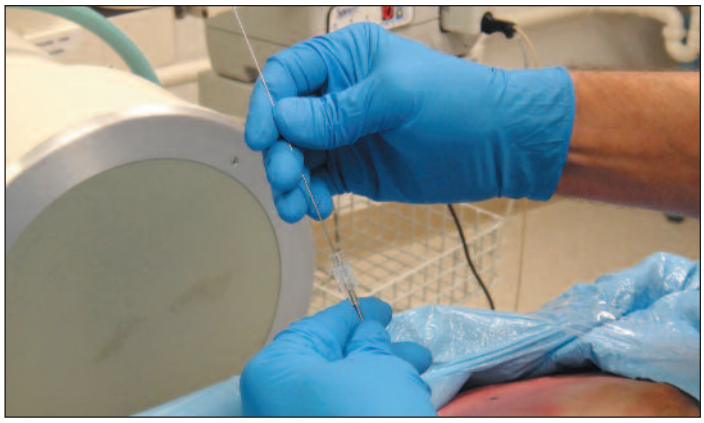


Figure 3

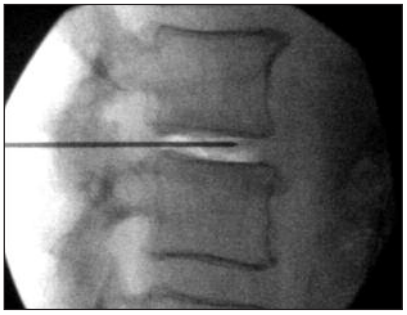


Figure 3A – lateral view

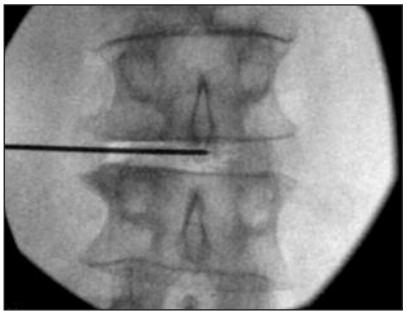


Figure 3B – A/P view

4. Dilator and Cannula Insertion

Use a # 11 blade scalpel to make a nick along the parallel access of the needle to allow room for the Cannula and Dilator Set **(Figure 4**). Thread Dilator through either Straight or optional Curved Cannula and lock into place by rotating the proximal, blue end of Dilator clockwise one quarter turn (**Figures 4A** and **4B**). Ensure proper distal alignment of Dilator and Cannula by making sure the Dilator is fully inserted into the Cannula and turned until resistance is felt.

Thread Dilator and Cannula Set over the proximal end of the Guide Wire. Dilator and Cannula Set advancement must be done under live fluoroscopic lateral view keeping an eye on the distal end of the Guide Wire and ensuring no forward advanced movement (dorsal to ventral or lateral to contralateral, depending on approach) of the Guide Wire (**Figure 4C**). At this point the Dilator and Cannula Set may be advanced through the annulus no farther than approximately one quarter of the way into the nucleus (**Figures 4D** and **4E**). Once placement has been confirmed, maintain placement of the Cannula and unscrew the Dilator (counter clockwise one quarter turn) and remove both the Dilator and Guide Wire, leaving cannulated access to the disc nucleus (**Figures 4F** and **4G**).

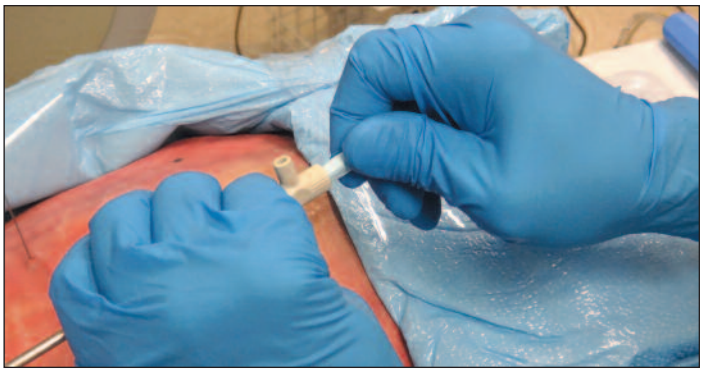


Figure 4B

Figure 4C

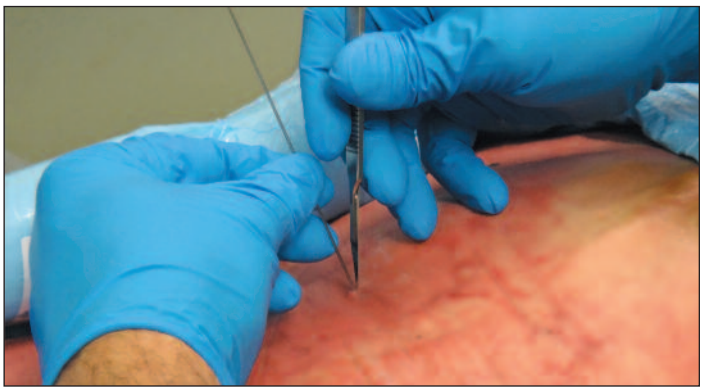


Figure 4

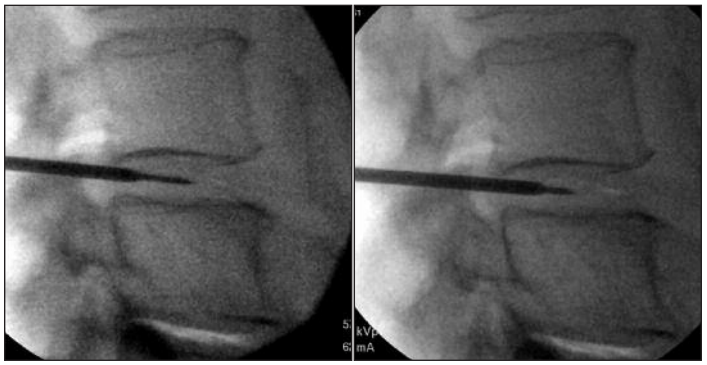


Figure 4D

Figure 4E

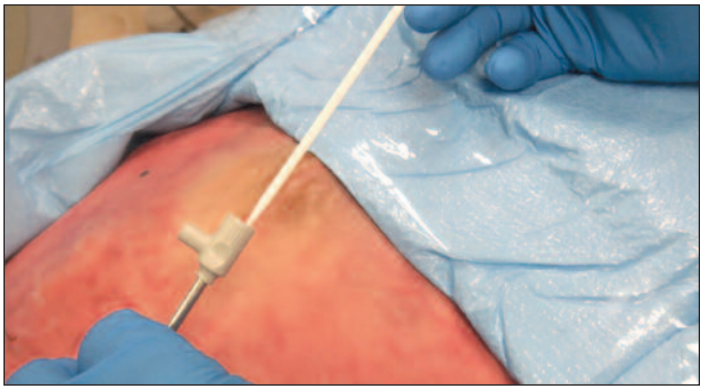


Figure 4A

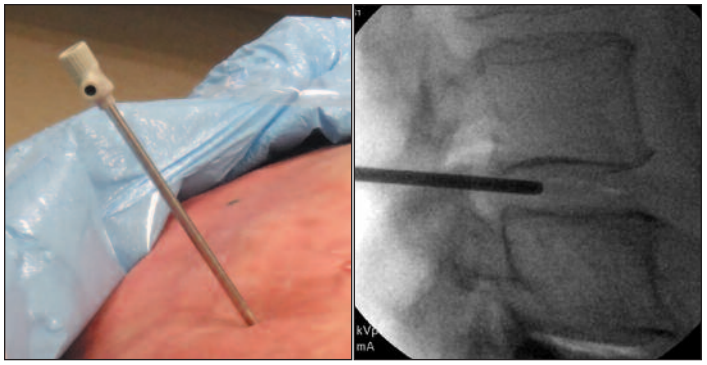


Figure 4F

Figure 4G

5. SpineJet PercResector Insertion

Hold on to the cannula knob taking care not to cover the vent hole. Rest your hand on the patient's back to prevent the cannula from backing out or advancing. (**Figure 5**). Insert the SpineJet PercResector through the working cannula using A/P and lateral fluoroscopy (**Figures 5A** and **5B**). Upon initial introduction into the disc space, resistance will be encountered. The resistance will be felt as the distal tip of the PercResector begins to enter the nucleus. Confirm location of the tip with lateral and A/P views.

Figure 5

Figure 5A

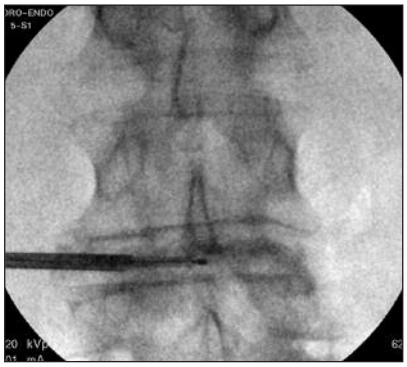


Figure 5B

6. Performing the HydroDiscectomy

Depress the foot pedal to activate the PercResector. At this point begin timing the procedure to gauge rate of nucleus consumption. For the first ten seconds, move the PercResector's distal tip in and out of the Cannula not advancing it more than 0.5 cm beyond the end of the Cannula to create space within the nucleus. The initial resistance encountered will quickly dissipate as the nucleus tissue is evacuated (if the PercResector is initially advanced into the nucleus too far, a vapor lock may occur and the system will not work to its maximum potential). After creating space, use a gentle piston motion (in and out) for approximately one minute to consume nucleus by maximizing the area reached by the tip. Utilizing fluoroscopy to confirm location, advance the tip of the PercResector further into the disc slowly as material is cleared. During the second minute, while continuing to use the pistoning motion, rotate the PercResector 180° clockwise and 180° counterclockwise. During the third minute, the PercResector should be pistoned, rotated, and fanned medially and laterally (parallel to the endplates), taking care not to touch either endplate. The nucleus pulposus can be visualized in the evacuation tube as it is being removed (**Figure 6**).

The amount of disc material removed is determined by the length of time the SpineJet PercResector is activated within the disc (**Figure 6A**). Adequate nucleus consumption is typically achieved in a three-minute runtime. Do not apply excessive force in any direction during the procedure to avoid patient injury.

Figure 6

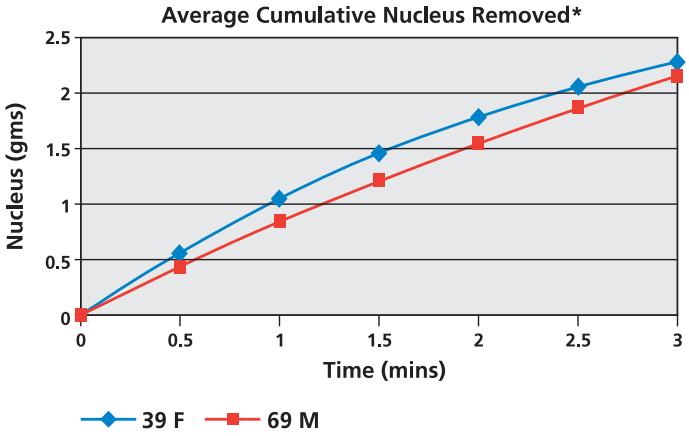


Figure 6A

The Safe Zone

To avoid contact with any neural or vascular structures, do not pass any instruments, including the Access Set components, or the 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 completed, remove the SpineJet PercResector and Access Cannula, leaving a small annular defect. Physicians often recommend performing a transforaminal epidural at each level completed for two reasons: (1) to minimize post-operative pain and (2) to facilitate the recovery of the radicular pain. Close superficial wound according to physician preference.

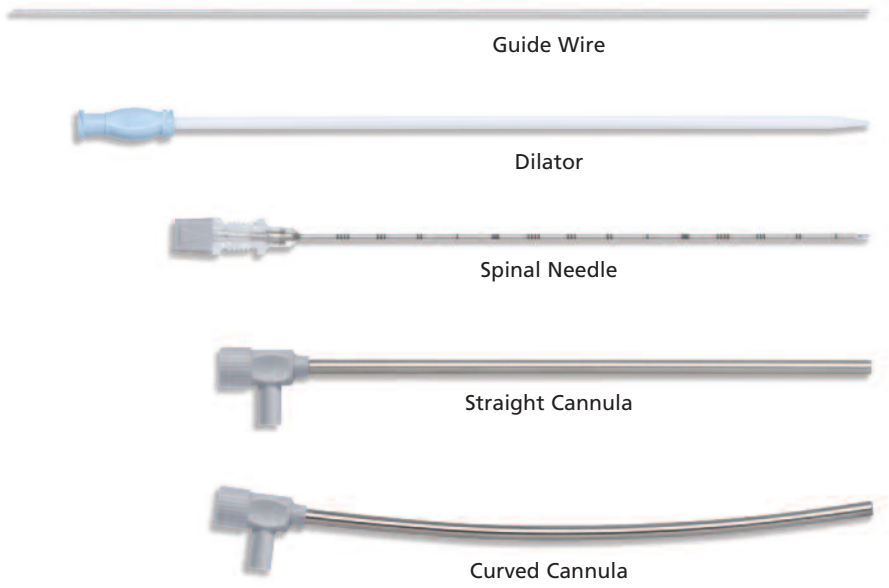
SpineJet®
HydroDiscectomy System

Percutaneous HydroDiscectomy Surgical Technique

Ordering Information

SpineJet Percutaneous HydroDiscectomy System

Description	Catalog No.
• SpineJet PercResector Handpiece and Direct Connect Tubing Set	56000
• SpineJet Percutaneous Straight and Curved Access Set Options *(Includes one access set which can be configured as straight or curved. Set includes one each straight and curved cannula, guide wire, spinal needle with stylet, and dilator. Disposable, supplied sterile.)*	
SpineJet HydroSurgery Console *(Includes Foot Pedal and Power Cord)*	52700
QuicKart Procedure Cart	50300



The HydroCision Percutaneous Hydrodiscectomy System includes both a straight and a curved access cannula.

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