

SPOTLIGHT™

ACCESS SYSTEM

Surgical Technique



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Introduction

This surgical technique guide describes the SPOTLIGHT™ Access System that provides one-piece reusable ports that are constructed of stainless-steel and fiber optics with a rigid arm attachment and integrated light that allow surgeons to access the spine by dilation of the overlying tissues in a minimally invasive fashion. The SPOTLIGHT Access System ports design is offered in a range of diameters and lengths to accommodate surgeon needs and access depths. Each ports size comes in both a straight and angled anatomic configuration to allow flush ports seating on the lamina and facets. The SPOTLIGHT Access System also contains manual surgical instruments, which are designed with a profile to navigate the narrow diameter of the port's surgical corridor. General discectomy and endplate preparation instruments of appropriate length and width can also be used through the port.



Fig. 1

Surgical Technique

1: Patient Positioning

Position patient in the prone position.

On the contralateral side to the planned incision, position the Rigid Arm clamp on the table rail lateral to the mid or upper thigh to facilitate subsequent placement of the Rigid Arm Assembly.

Once the surgical preparation and draping are completed, the clamp can attach to the bed rail over the drapes and the Rigid Arm can be attached to the clamp — the Rigid Arm Assembly can be adjusted within the sterile field.

- A radiolucent operating room table is needed for AP fluoroscopy/X-ray views. Any radiolucent operating room table appropriate for the planned procedure will suffice. Lateral fluoroscopy/X-ray views can be obtained on any standard operating table.



Fig. 2



2: Anatomical Landmarks

Dilation of the multifidus and longissimus muscles that run parallel to the spine is the primary objective. Fluoroscopy is used to locate the desired level.

- Close attention is paid to keep the targeted surgical site at the center of the fluoroscopic view.

A C-arm with A/P and lateral views provides imaging.



Fig. 3

3: Targeting

An Incision Template is used with fluoroscopic guidance to locate the incision's center over the disc space of the selected level to be operated on. A longitudinal incision slightly larger than the desired port diameter is made, through the skin. Make a small incision in the lumbodorsal fascial layer to facilitate passage of the first dilator.

SPOTLIGHT Retraction Ports sizing is determined by the inner diameter. The incision size should be based on the outer diameter, which is 4 mm larger than the inner diameter.

- Proper targeting is very important to maximize ease of surgery and minimize the need to enlarge the incision. For unilateral lumbar discectomy the center of the target is generally the inferior edge of the lamina and the medial border of the facet joint of the desired disc level. This incision can be positioned lateral to the facet joint for an extraforaminal approach to a far lateral or intraforaminal disc herniation.

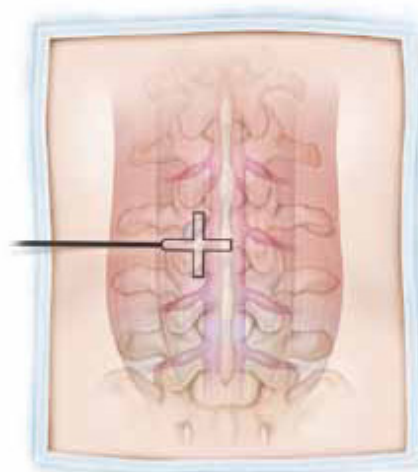
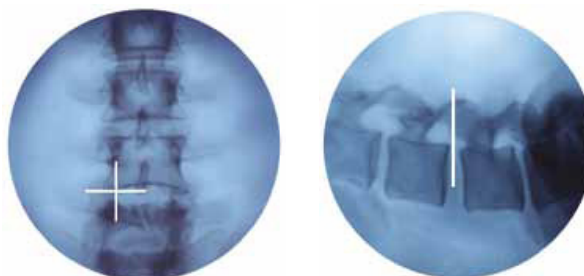


Fig. 4



4: Initial Dilatation

Once the incision is made, the First Dilator is inserted into the incision, through the opening in the fascia to dilate the paravertebral muscle tissue down to the laminar level.

Ensure that the tip of the first dilator is resting on solid bone.

The First Dilator's position is confirmed fluoroscopically. While holding the first dilator in place, pass the next largest dilator over this dilator. The first dilator can now be removed. With a careful feel for the bony surface, move the dilator in a wanding motion over the lamina and base of spinous process as blunt dissection to free attached muscle. This step will facilitate visualization and ensure that the SPOTLIGHT Retraction Port will seat against the lamina. Further blunt dissection can be performed after the addition of subsequent dilators.

- If desired, the fascia can be incised prior to the insertion of the First Dilator

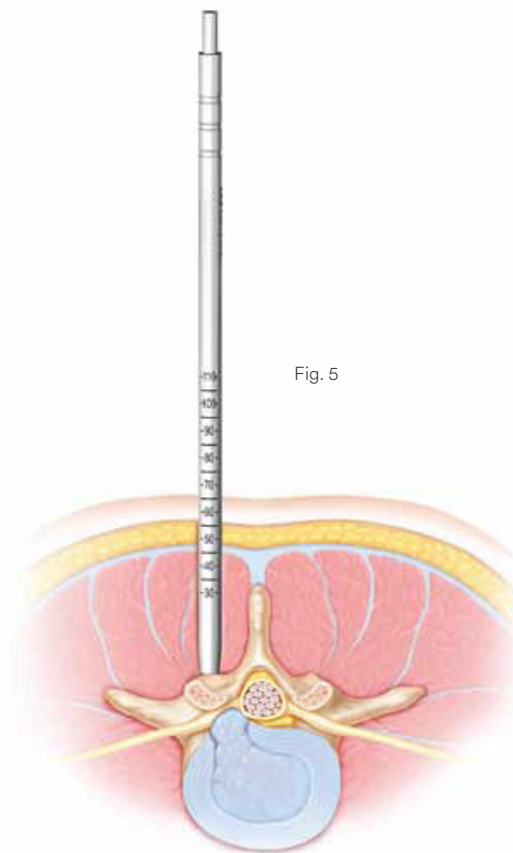


Fig. 5

5: Serial Dilatation and Depth Gauging

Sequential dilation is performed by passing the next largest dilator over the previously inserted dilator.

It is recommended to use the Second or Third Dilator to determine the depth as this will be flush to the bone and provide you with the corresponding depth. The depth should be taken at the point where the skin contacts the dilator.

The Third through the Seventh Dilators correspond to the appropriate port diameters (i.e., use the Third Dilator for placement of the 12-mm port, Fourth Dilator for placement of 15-mm port, etc.).

- The SPOTLIGHT Retraction Ports also come in an angled configuration to provide another option for flush Port seating on the lamina.

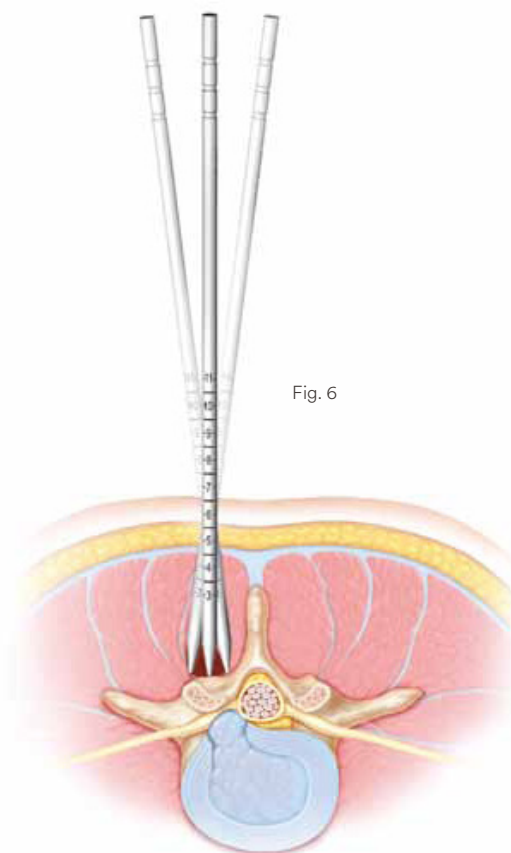


Fig. 6

Port Sizes

Ports are available in lengths ranging from 30 mm to 110 mm in 10-mm increments. Ports are determined by inner diameter.



6: Serial Dilatation (cont'd)

Continue sequential dilation until the desired diameter is achieved.

Ports come in 12 mm, 15 mm, 18 mm, 21 mm, and 24 mm diameters and the selection of these will determine the number of dilation steps required. Dilation steps for the desired SPOTLIGHT Retraction.

Port diameters are as follows:

- 12 mm – Dilators 1 through 3
- 15 mm – Dilators 1 through 4
- 18 mm – Dilators 1 through 5
- 21 mm – Dilators 1 through 6
- 24 mm – Dilators 1 through 7

▲ Precaution

- An Introducer is utilized to insert the largest Dilators. This may be required to overcome the tension of the fascia and to prevent skiving of the dilators.

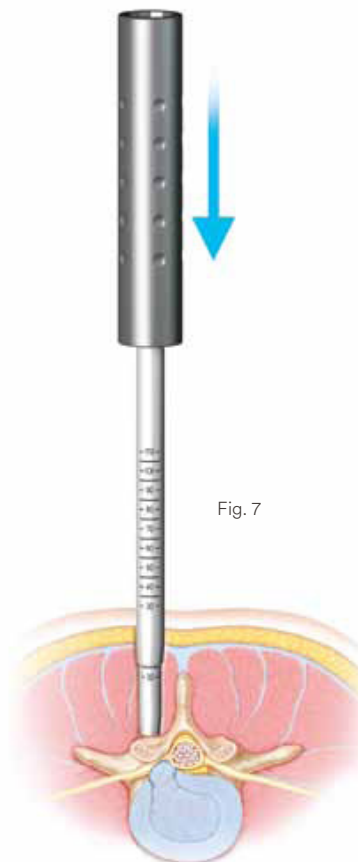


Fig. 7

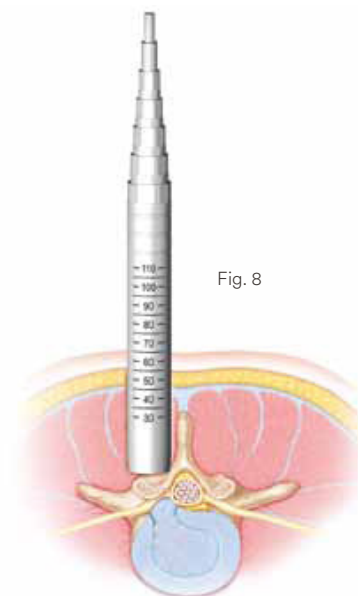


Fig. 8

7: Port Insertion

Once final serial dilation is complete and the proper SPOTLIGHT Retraction Port diameter and length have been determined, the SPOTLIGHT Retraction Port can be inserted.

It is recommended that the surgical assistant hold the Introducer firmly over the dilators to maintain their position against the lamina while the surgeon inserts the SPOTLIGHT Retraction Port to the laminar level.

Irrigating the outer surface of the SPOTLIGHT Retraction Port may assist in inserting the device.

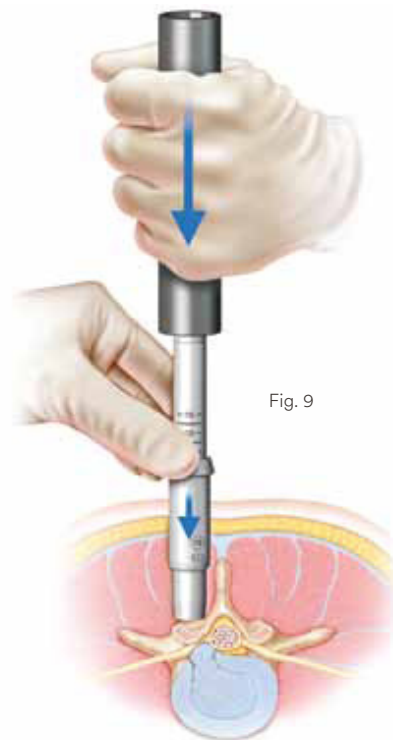


Fig. 9

8: Rigid Arm Attachment

The Rigid Arm Assembly, which was attached to the surgical table during Step 1, is now connected to the SPOTLIGHT Retraction Port to hold it in place for the remainder of the procedure.

Use fluoroscopy to confirm Port positioning.

- When attaching or adjusting the Rigid Arm Assembly care should be taken to maintain the port's position up against the lamina and facet. The Rigid Arm Assembly can be loosened or adjusted at any point during the procedure to allow the SPOTLIGHT Retraction Port to be angled for an alternative field of view and permit exposure of additional portions of the local spinal region.



Fig. 10

9: Removal of the Dilators

Once the SPOTLIGHT Retraction Port has been fully positioned to the laminar level, and the Rigid Arm Assembly has been tightened, the dilators can be removed.

Care should be taken to ensure the SPOTLIGHT Retraction Port remains fully seated during this step.

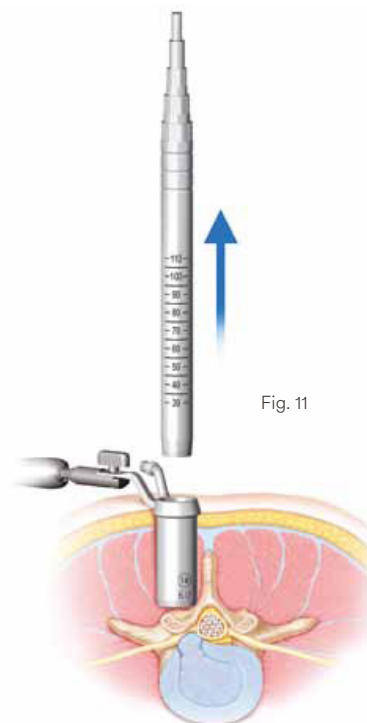


Fig. 11

10: Light Source Attachment

A standard light source with an ACMI connection should be used to illuminate the distal end of the SPOTLIGHT Retraction Port.

Plug in the ACMI connection to the light coupler at the proximal end of the port and turn on the power to the light source.

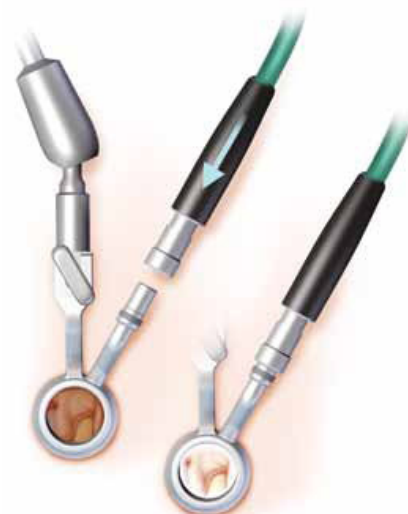


Fig. 12

11: Discectomy

Electrocautery can be used to remove any remaining muscle attached to the bone inside the SPOTLIGHT Retraction Port. This prevents bleeding or oozing from the tissues. Gently palpate the soft tissue with an inactive, extended length Bovie tip or a Penfield 4 to ensure that it is against bone and not in the canal. A pituitary rongeur can be used to pluck the tissue fragments out of the exposure. Irrigation can be used to allow for visualization during these manoeuvres.

The lamina, ligamentum flavum, and lateral border of the canal can be identified. The spinal canal is entered by dissecting the ligamentum flavum off the caudal edge of the lamina.

- **An up-angled curette is recommended to elevate the ligamentum flavum from the lamina and sweep it from midline laterally.**

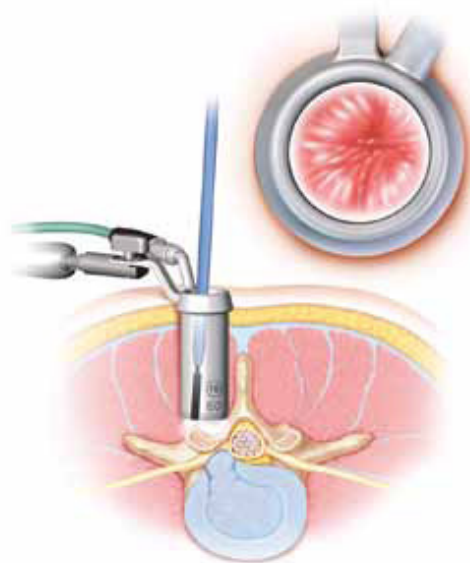


Fig. 13

The ligamentum flavum will act as protection to the dura during hemilaminotomy, until the thecal sac is identified directly.

The ligamentum flavum can be resected with 40 degree or 90 degree angled Kerrison Rongeurs to expose the thecal sac and nerve root, which is retracted medially to expose the annulus fibrosus and the disc herniation.

- If necessary, a high-speed burr can be used to remove hypertrophic bone and thin the lamina or medial facet. Special bayonnetted instruments, such as a Penfield 2 mm, can be used to facilitate visualization of the neuroanatomy and disc.

▲ **Precaution**

- Careful attention to clearing the floor of the spinal canal from epidural vessels with the bipolar electrocautery device prior to incision of the PLL or annulus will decrease bleeding and continue to provide visualization.

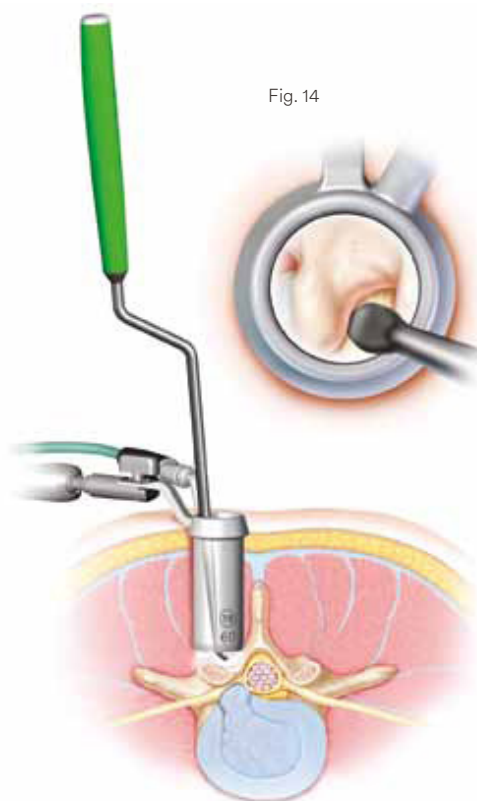


Fig. 14



Fig. 15



12. Removal

Once the decompression is completed and hemostasis of the surgical site is achieved, loosen the Rigid Arm Assembly and slowly pull the port back to remove. Pay attention to bleeding on the surrounding tissues to maintain hemostasis. Turn off the light source and disconnect it and the Rigid Arm Assembly from the port as it is removed.

The fascia is closed with a single suture and the skin is closed with subcuticular sutures.

▲ Precaution

- Connection between light source cable and ACMI connection on port may become warm. Use caution when disconnecting the cable.

Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com.

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