Ordering Information

Dekompressor Kits

Includes: One percutaneous discectomy probe, one introducer cannula with bevel stylet, one probe cleaner

407-265-000	6” 13 Gauge Straight Dekompressor Kit
407-266-000	6” 15 Gauge Straight Dekompressor Kit
407-250-000	6" 17 Gauge Straight Dekompressor Kit
407-251-000	6" 17 Gauge Curved Dekompressor Kit
407-260-000	9” 17 Gauge Straight Dekompressor Kit
407-280-000	6” 19 Gauge Straight Dekompressor Kit

Includes: One percutaneous discectomy probe, one introducer cannula with bevel stylet, one blunt stylet, one probe cleaner

407-281-000	3” 19 Gauge Straight Dekompressor Kit

Cannulae

Sterile; 5 per pack. For use with 6" 17 gauge straight or curved Dekompressor kits 407-250-000 and 407-251-000

407-253-000	6" 17 Gauge Straight Introducer with Stylet
407-254-000	6" 17 Gauge Curved Introducer with Stylet
407-255-000	6" 17 Gauge Blunt Introducer with Stylet

Contraindications

1. Traumatic spinal fracture, infection, tumor, pregnancy, and severe co-existing medical disease are contraindications.
2. The probe is not appropriate for treating patients who present with pain originating from structures other than contained herniated discs. Patients presenting with free fragments, severe bony stenosis, or severely degenerative discs should be excluded.
3. The procedure should be performed under local anesthesia or conscious sedation to allow patient monitoring for signs of segmental spinal nerve irritation. General anesthesia is contraindicated.
4. Patients with severe and rapidly progressing neurological deficits should be excluded.

Special Notes

1. The probe should only be used by physicians who have received training and have previous experience in discography and intradiscal therapies.
2. The probe is designed only for use with the introducer cannula provided in the kit.
3. Never bend or straighten the preferred introducer cannula. Failure to comply may result in patient injury.
4. The probe and introducer cannula are single use disposable items provided sterile. DO NOT ATTEMPT TO RE-STERILIZE OR REUSE.
5. Disc space infection is a rare but potentially serious complication. The procedure should be performed under sterile technique. Intradiscal and parenteral antibiotics are recommended unless contraindicated. If there is an infection present in the vicinity of the spine, especially near the treatment area, it is mandatory to treat the infection before attempting the procedure.
6. Placement of the introducer cannula and probe requires direct visualization of a safe approach to the posterolateral disc annulus. Fluoroscopy, or an alternate imaging technology, is essential to the safe conduct of the procedure.

Caution

1. Read all instructions carefully prior to use.
2. U.S. Federal law restricts this device to sale by or on the order of a physician.
3. For single intervertebral disc access only, do not use on multiple intervertebral levels. Do not immerse in liquids.

Complication

Potential complications include: infections, bleeding, nerve damage, worse pain, failure of technique, paralysis, idiosyncratic reaction, anaphylaxsis, and death.

For complete product information and instructions, please refer to the Dekompressor Instructions For Use.

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DD Disc Decompression

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Operative Technique Guide

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Disc Dekompressor

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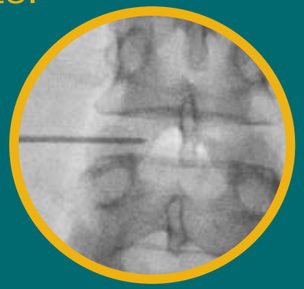
Intended Use

The Stryker Disc Dekompressor is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.

Note: Physicians using the Disc Dekompressor should have training and experience with fluoroscopy, discography, and other intradiscal therapies.



Above. *AP View of 17 Gauge Cannula in symptomatic disc*

Ideal Patient Selection

- Radicular pain
- MRI consistent with contained disc herniation
- MRI demonstrating 50% preserved disc height
- Failed conservative treatment
- Facet pain excluded
- Positive low-volume diagnostic SNRB
- Discogram and post-disco CT consistent with the above (optional)

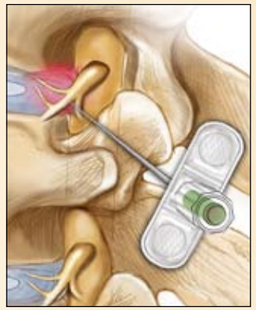
Preparation

- Prepare the patient pre-operatively according to standard procedures
- Prior to opening the package, verify that it is not damaged in a way that could compromise sterility of the probe
- Using sterile technique, remove the probe and stylet from the tray and place in a sterile field
- In a sterile fashion, remove the introducer cannula from the probe collection chamber by rotating cannula wings to loosen
- Flush the introducer cannula with sterile saline
- Insert stylet into the introducer cannula and tighten hub

Discontinue use when any of the following occurs:

- Physician believes sufficient material has been removed
- The collection chamber becomes full
- No material is present on the probe following three minutes of activation
- A maximum of 10 minutes of operation has expired

Surgical Technique

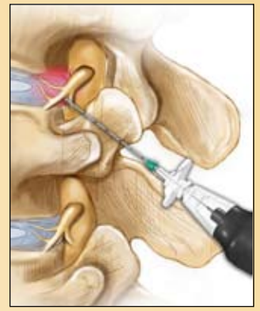


Step 1. *Introducer cannula and stylet introduced into disc.*

Step 1
Using a standard discography approach, advance the introducer cannula and stylet via fluoroscopic guidance into the disc.

Step 2
Confirm radiological position in the disc using AP and lateral views.

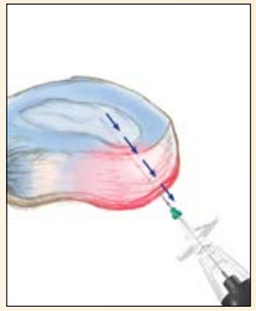
Step 3
Once confirmed, remove stylet and carefully advance the probe tip into the introducer cannula. Gently attach the probe collection chamber to the luer fitting on the cannula.



Step 3. *Probe advanced into cannula.*

Step 4
Visually confirm under fluoroscopy that at least one full-thread turn of the probe tip extends beyond the cannula. If it does not, gently tighten the cannula to the collection chamber.

Step 5
Activate the probe switch to begin discectomy procedure.



Step 6. *Tissue is removed.*

Step 6
Very slowly advance (approximately 1cm per 10 seconds) the probe during activation to facilitate tissue removal and to access specific areas of the disc.
Note: The range over which the probe is to be operated can be visually defined by adjusting the green depth marker to the surface of the skin when the cannula tip is at the anterior annulus nucleus boundary.

Step 7
Monitor activation of the probe tip under live fluoroscopy to avoid contact with the annulus.

Step 8
After 3 minutes, the probe may be removed from the cannula and inspected for the presence of nucleus pulposus tissue along its length.

Step 9
Remove any visible tissue from the probe using the plastic probe cleaner before reinserting it into the cannula and continuing the procedure.
Note: Do not kink the probe while cleaning.

Step 10
Remove the probe and introducer cannula once the desired amount of tissue is removed from the disc.
Note: Disc material may be sent to pathology if desired.

** For complete instructions please refer to the Dekompressor Instructions for Use 0407-280-706*

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