

HERNIATOME

PERCUTANEOUS DISCECTOMY DEVICE

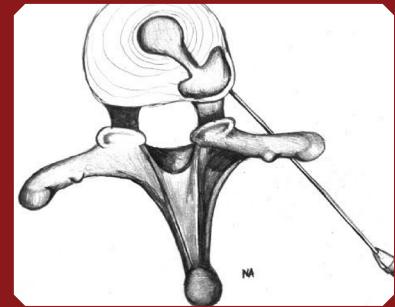


SMALL ACCESS. BIG RESULTS.

HERNIATOME DISC DECOMPRESSION

Physicians using Herniatome should have training and experience with fluoroscopy, discography and other intradiscal therapies.

INTENDED USE: The Herniatome Disc Decompressor is designed to aspirate disc material during percutaneous discectomies in the lumbar, cervical and thoracic regions of the spine.

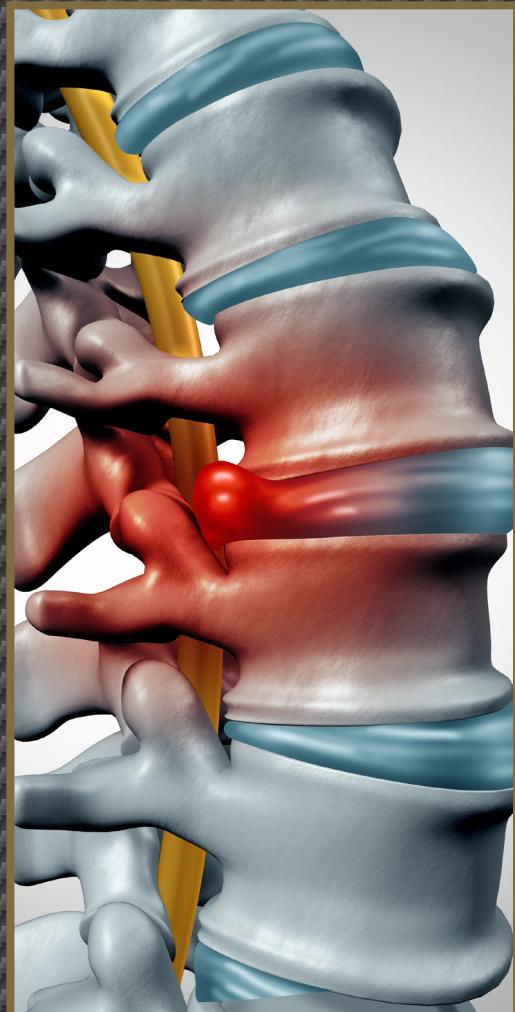


Ideal Patient Selection

- Failed conservative treatment
- Radicular pain with herniated disc
- MRI demonstrating 50% preserved disc height
- MRI consistent with contained disc herniation
- VAS of pain greater than 5/10
- Positive low-volume diagnostic SNRB

Contraindications

- 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
- Performed under local anesthesia or conscious sedation to allow patient monitoring for signs of segmental spinal nerve irritation. General anesthesia is contraindicated
- Traumatic spinal fracture, infection, tumor, pregnancy and severe co-existing medical disease
- Patients with severe and rapidly progressing neurological deficits



PROCEDURE ADVANTAGES

PERCUTANEOUS DISCECTOMY

When conservative treatments fail to relieve lumbar radiculopathy related to disc herniation, only 2 options remain on the table: perpetual opioids or surgery — neither of which is desirable as far as the patient is concerned. The lack of alternative treatments has encouraged the development of new therapeutic options and the Herniatome system has evolved from the combination of surgical decompression and intradiscal guided imaging.

Percutaneous Discectomy using Herniatome is a safe, effective and minimally invasive procedure. Performed with CT and/or fluoroscopic monitoring, the aim of the hernectomy is identical to that of surgery to extract the herniation or a portion of the herniation to reduce the pressure on the nerve root.

Herniatome is a clinically proven alternative to surgical intervention.

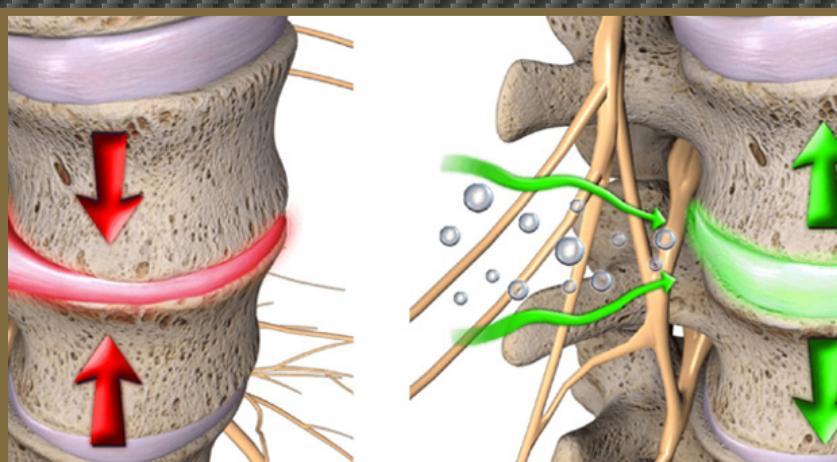
The duration of the procedure varies between 15 and 30 minutes and doesn't require an extended hospital stay.

FOR THE CLINICIAN:

- Retain patients within your practice
- Minimal invasiveness
- Outpatient setting
- Short procedure (15-30 min.)
- Quick recovery time
- High success rates, low complication rates
- Automated device does the heavy lifting (less complicated, less effort and less risk compared to surgery)
- Similar to discogram, epidural steroid injection, vertebroplasty procedures
- Does not complicate subsequent surgical procedures in case of failure

FOR THE PATIENT:

- Minimal scarring
- Less painful & less traumatic
- No overnight hospital stays
- Rapid return to activity
- Relief of pain
- High success rates
- Low complication rates
- Reduces need for major surgery
- Avoidance of general anesthesia

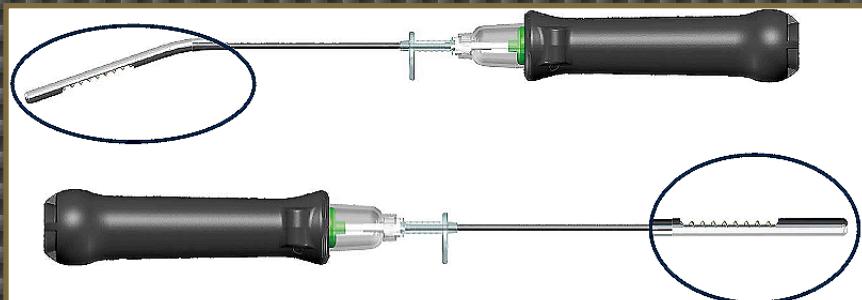


DEVICE SPECIFICATIONS

More Effective & Less Expensive System Advantages

- » **Needle is threaded from end-to-end** (users of competitor devices reported clogging due to needle only being threaded towards the tip)
- » **Lateral Window and Curved Cannula** provide a wider extraction range of the herniation with minimal movement
 - Device collects disc material from distal tip and side (other devices only collect material from distal tip)
 - Allows tissue collection by rotating the needle, which requires less motion and manipulation of the device
- » More effective and thorough disc decompression
- » Real-time evaluation – qualitative and quantitative – of the decompression
- » 17ga device needle
- » 20ga Introducer Needle that ensures safe and correct positioning of device (only necessary for curved distal end)

Curved distal end with lateral window



Straight distal end with lateral window

Lumbar Type

Order Code	Size	Description
5091715	17ga - 15cm	Curved distal end, lateral window
5091745	17ga - 15cm	Straight distal end, lateral window

Cervical Type

Order Code	Size	Description
5091709	17ga - 9cm	Curved distal end, lateral window
5091749	17ga - 9cm	Straight distal end, lateral window

SURGICAL TECHNIQUE

CURVED CANNULA:

>> STEP 1: After local anesthesia, use standard discography approach to insert introducer needle at exact level of the herniation (Fig. 1)

>> STEP 2: Remove inner stylet and detach hub at location indicated by the score on the cannula (Fig. 2 & 3)

>> STEP 3: Carefully introduce distal curved cannula over the introducer needle (Fig. 4)

>> STEP 4: Remove introducer needle from the curved cannula (Fig. 5)

>> STEP 5: Insert Herniatome device. Attach and lock the collection chamber to the luer fitting on the cannula (Fig. 6)

>> STEP 6: Activate device with button. Apply rotating and back/forth movements to facilitate tissue removal at specific areas of the disc (rotate 90 degrees/minute). Monitor probe tip under live fluoroscopy to avoid contact with annulus.

>>> The procedure is completed when the decompression is sufficient to reduce the resistance felt. Active portion of procedure should not exceed 10 min.

STRAIGHT CANNULA:

>> STEP 1: After local anesthesia, use standard discography approach to advance introducer needle at exact level of the herniation

>> STEP 2: Remove inner stylet and advance Herniatome probe tip into the introducer cannula

>> STEP 3: Attach and lock the collection chamber to the luer fitting on the cannula

>> STEP 4: Activate device with button. Apply rotating and back/forth movements to facilitate tissue removal at specific areas of the disc (rotate 90 degrees per minute)

>> STEP 5: Monitor probe tip under live fluoroscopy to avoid contact with annulus.

>>> The procedure is completed when the decompression is sufficient to reduce the resistance felt. Active portion of procedure should not exceed 10 min.

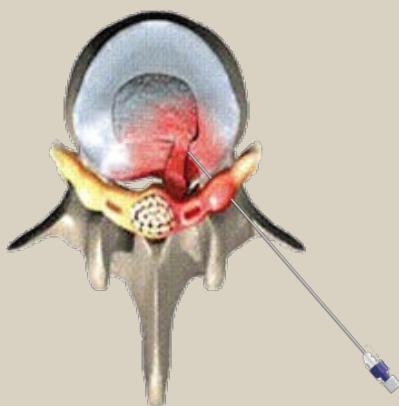


Fig. 1

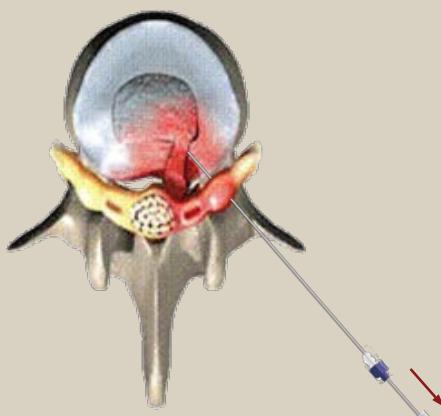


Fig. 2

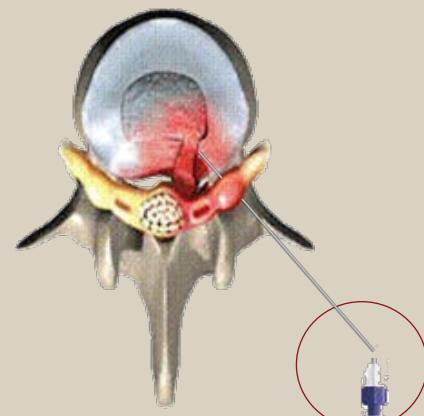


Fig. 3

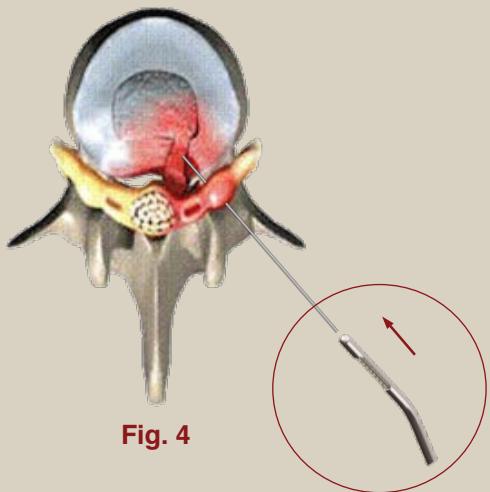


Fig. 4

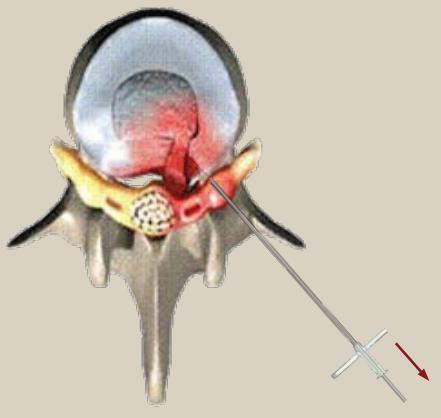


Fig. 5

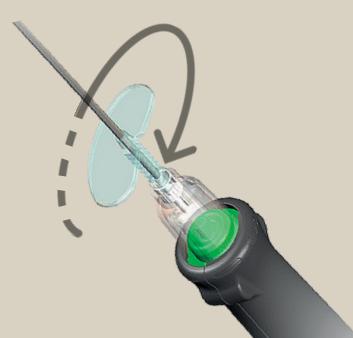


Fig. 6



We at Dumotech strive to provide intuitive and precise surgical instruments that offer reproducible results for successful patient outcomes due in part to less surgery time, less tissue damage, less scarring, less pain, less recovery and less stress. Herniatome is a novel, needle-based tool designed to cut, grind and aspirate disc tissue for lumbar discectomy procedures. This minimally invasive approach allows you to perform safe, rapid and effective manual discectomies for contained herniations.

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University Hospital, Lausanne, SWITZERLAND

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