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NUCLEOTOME® AUTOMATED PERCUTANEOUS LUMBAR DISCECTOMY SYSTEM

As much as 80% of the population may experience low back pain at sometime during their active life (*1*). Although open simple discectomy and partial laminectomy have provided countless patients relief from herniated discs for many years, open surgery is a major traumatic event and can lead to infection, neurological and vascular injury, thrombosis, and even death. One study of 28,395 patients who underwent lumbar discectomy reported a major complication in 1 in 64 patients, serious neurological complication in approximately 1 in 336 patients, and death in 1 in 1695 patients (*2*). One study of 654 microdiscectomy procedures found a 10.8% complication rate, one death, and one major bowel injury (*3*).

APLD is a Safe Alternative to Open Lumbar Discectomy

Clarus Medical's **Nucleotome**® automated percutaneous lumbar discectomy system avoids open surgical decompression and can achieve a 75% or greater success rate in carefully selected patients (*4-9*). The APLD procedure is a safe and effective alternative to open surgery and microdiscectomy for a subset of patients with relatively small, contained herniations.

Meticulous Patient Selection is Key to the Success of APLD

APLD must be reserved for patients whose herniations are contained by the annulus or posterior longitudinal ligament who have failed a trial of conservative treatment. Substantial migration of a disc fragment is an absolute contraindication for APLD, although patients with ≥ 3 mm of migration may still enjoy a good result (*10*). CT discogram is likely the most definitive procedure to identify appropriate patients for APLD (*10*).

Guided by fluoroscopy, the physician advances the Nucleotome probe percutaneously into the nucleus of the disc, where nucleus material is aspirated into a side port near the distal tip of the probe. The small diameter (2.0 mm to 3.5 mm) Nucleotome probe has a rounded tip to avoid serious injury to vessels and structures. The probe is powered by the **Nucleotome Console**, similar in dimension to an RF generator. The Nucleotome Console pneumatically passes saline through the probe, which creates a vacuum effect and sucks the nucleus material through the probe's side port. As the nucleus material is suspended in saline, a reciprocating inner cannula shaves the nucleus at a rate of up to 180 cuts/minute. Nucleus is aspirated through tubing attached to the Nucleotome handle and collected in a filter within an aspiration canister.

Christian Schlicht, MD, PhD, of the VA Medical Center in Albuquerque, NM, has used the APLD system for about two years, performing approximately 20 lumbar and 5 cervical cases. "Overall, the results have been very encouraging, especially when compared to other systems I have used previously [such as Nucleoplasty Wand by Arthrocare; DeKompressor by Stryker, etc.]. I have not had any complete patient failures; most patients have improved over 75% with the procedure. I have not had any complications, not even transient ones," he stated.

Dr. Schlicht added, "The fact that different sizes of Nucleotomes are available is a big plus for me, as I can select depending on the size of the disc, the size of the defect, and the location of the disc. The 2.0-mm device is ideal for the cervical spine for my use. I believe it represents the only device on the market for this use which is safe, effective, and easy to use."

APLD is an outpatient procedure and it should always be performed with the patient under local anesthesia. On average, the hospital cost for APLD is less than half of the cost of microdiscectomy and laminectomy. In one study of 1054 APLD procedures, operative time averaged 1.1 hours and postoperative recovery time averaged 6.5 hours, with 78% of the patients being released the same day (*11*). Another study found that 70% of 200 APLD patients returned to work within 2 weeks of the procedure, as compared with 1 in 66 patients who underwent a laminectomy or microdiscectomy (*9*).

Since its introduction, the Nucleotome Automated Percutaneous Lumbar Discectomy technique has been used in more than 200,000 procedures worldwide. More than 50 published articles documenting APLD procedures have reported no mortality or major nerve injury during a Nucleotome procedure; complication rates are lower than 1%, and most complications are minor (*10*).

The Nucleotome system is manufactured and marketed by Clarus Medical, LLC. For more information concerning The Nucleotome system product line, please write to Clarus Medical, LLC, 1000 Boone Avenue North, Minneapolis, MN 55427; call at 1-763-525-8400; or visit the company's Web site at www.clarus-medical.com.

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