“Spinal Decompression Therapy”

Spinal Traction, (mechanical) a pulling force applied to the spine to allow for separation between joint surfaces, a longitudinal force applied to the axis of the spinal column, The degree of traction is controlled through the amount of force (pounds per Newtons) allowed, duration (time) and angle of pull (degree) using mechanical means. (CPT 97012)

Non Surgical vertebral axial Spinal Decompression is brought about by applying axial (Y-axis) traction to the spine. It is an "unloading" due to distraction and positioning. Distraction and positioning combined with "unloading creates positive changes in the microcirculation of the disc and nerve roots.

Non-Surgical Spinal Decompression for herniated discs is based on the following theories:

❖**Reduction or elimination of extremity (leg/arm) pain and or numbness, while at the same time decompression of the involved disc creates negative intradiscal pressure which creates a vacuum effect reducing (sucks in) the size of the herniation, and taking pressure off the involved nerve root.**

❖**The pumping motions, of non-surgical spinal decompression, (imbibitions) nutrients to be exchanged at the level of the disc and inflammation around the nerve root to be dispersed resulting in reduction or elimination of pain.**

❖**Decompression is simply proper positioning based upon diagnosis and direction of the HNP, traction that results in spinal unloading resulting in enlivening (imbibition)of the disc and surrounding structures.**

FDA in its April 10, 1996 reply to the VAX D request(Dr. Dyer, PhD, M.D.) that any reference to decompression be defined as "decompression of the intervertebral disc and facet joints, that is , unloading, due to distraction and positioning"

HCPCS code S9090 is the code that is used to report Vertebral axial non surgical spinal decompression and is used per session as a global reporting.

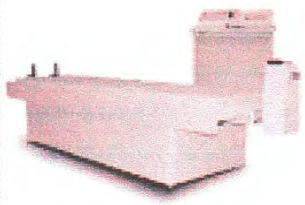
Traction vs. Decompression

Traction can be a devise or a form of therapy but decompression is a desired result, goal or potential outcome of traction, Decompression is an "Event" or a desired result obtained through the use of traction, positioning and unloading resulting in enlivening of the disc.

Typical Equipment cost, purchase, lease, rental, partnering with management company

Motorized Traction / Decompression tables today range in cost from $9000 to $150,000 with most manufacturers arranging finance or friendly lease terms.

VAX-D



Manufacturer
VAX-D Medical Technologies
Oldsmar, Fla.

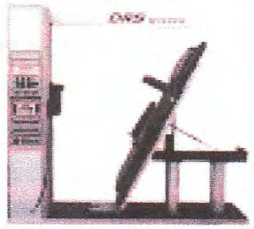
Distributors
DVAD USA

Insiders, past & present
Dr. Allan Dyer
Pres., VAX-D
Steven Brown
CEO, DVAD
Dr. Nicholas Exarhos
Former dir., National Spine Institute (VAX-D distributor, 1994-1996)

Business info.
- Approx. 200 machines currently in use in US
- 2005 sales: $1-2.5 million
- Sales began in 1991
- Manufacturer has 11 employees
- Sales price of machine: $116,400

Treatment instructions
- 15-20 sessions per patient
- Each session: 45 minutes on machine

DRS



Manufacturer
Cluster Technology Corporation
Sarasota, Fla.

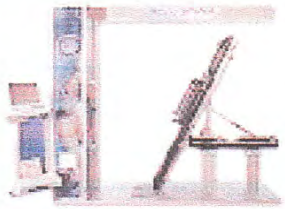
Distributors
Professional Distribution Systems
Universal Pain Technology

Insiders, past & present
Carlos Becerra
Pres. and CEO, Cluster
James J. Gibson, Jr.
Former pres. and CEO, Cluster and former dir., Univ. Pain
Dr. Nicholas Exarhos
Former dir., Univ. Pain

Business info.
- Filed for Chapter 11 bankruptcy in Sept. 2000 and Chapter 7 bankruptcy in Feb. 2005
- Assets: $4,001; liabilities: $3.9 million
- Sales price of machine: $125,000

Treatment instructions
- 15-20 sessions per patient
- Each session: 30-45 minutes on machine

Accu-Spina



Manufacturer
North American Medical (NAM) Corporation
Atlanta, Ga.

Distributors
Adagen Medical International
Spina Systems International

Insiders
Carlos Becerra
Pres., NAM
Gidgette Rubin
Vice Pres., NAM
Terence A. Harvey
Pres., Adagen
Donald E. Rhoades
Pres., Spina Systems

Business info.
- Approx. 300 machines currently in use in US
- 2005 sales: $10-20 million
- Sales began in 2001
- Manufacturer has 25 employees
- Sales price of machine: $149,000

Treatment instructions
- 20 sessions per patient
- Each session: 25 minutes on machine, plus thermal applications (1 hour total)

DRX-9000

Manufacturer
Axiom Worldwide
Tampa, Fla.

Distributors
Independently licensed distributors

Insiders
James J. Gibson, Jr.
Pres., Axiom
Dr. Nicholas Exarhos
Vice Pres., Axiom

Business info.
- Approx. 500 machines currently in use in US
- 2005 sales: $2.5-5 million
- Sales began in 2001
- Manufacturer has 20 employees
- Sales price of machine: $95,000

Treatment instructions
- 16 sessions per patient
- Each session: 30-45 minutes on machine

Many manufacturers offer suggested CPT / HCPCS billing codes for submission to 3rd party payers and also arrangements for cash patient financing companies such as Capital One Finance/ ChiroCare Finance etc. where the doctor can get up front treatment plan money.

Revenue Share Programs: A new wrinkle

They install decompression equipment and computer software in a doctor's office free of charge , pay all the marketing fees, advertising fees and arrange patient care financing / billing and pay the treating doctor a fee for treating the patient with the manufacturer / marketing company keeping the balance of the funds.

The management company offer to also cover the cost of related office expenses and guarantee results promising the doctor if not successful with decompression they will simply remove the equipment.

The marketing of decompression units usually centers around a few points.

The marketing of decompression usually begins with a statement that "decompression is not traction"…..the age old treatment with traction they claim doesn't work because it doesn't isolate specific spinal levels and causes the body to react with increased muscle resistance. Some manufacturers claim that the linear pull of traction elicits a proprioceptor response which prevents the traction device from opening the intradiscal space enough to create significant negative intradiscal pressure.

Manufacturers of decompression devices claim that their equipment is capable of isolating the distraction forces to a specific motor unit of the spine and when done on a computer controlled logarithmic curve a "ramping" of the pull (graduated incremental pull without complete reset to origin) can avoid the body's proprioceptive muscle guarding response and resistance. When the disc space is opened with their computer regulated "ramping" algorithm the proprioceptive muscle contraction is avoided and the intradiscal pressure is significantly lowered resulting in enlivenment or imbibitions of the disc.

A few manufacturers of decompression devices claim they can target specific spinal segments with their state of the art computerized tables changing the angle/degree of pull on the spine, some with and without a special tower.

Infomercials:

Produced by marketing consultants, usually contain testimonials from satisfied patients and other physicians, describe the table, how it works and alleged research showing efficacy (NASA had nothing to do with any of the research and 86% effective is a propriatory in house research figure produced through manufacturer funding)

Typical costs associated with advertising:

typically a doctor can budget between $1500 and $10,000 per month for advertising that can include anything from newsprint to radio and TV spots/ infomercials

Patient care financing:

Capital One Finance, ChiroCare, Care Credit Inc., Care First Inc., HelpCard, Patient Source.net, etc gets the doctor money for care up front as the treatment plan is sold and allows the patient to amortize their care with payments over an extended period of time, monthly payments with interest….

Patient Selection Protocols:

usually related to treatment of reported diagnosis within the 722.0 series.

Conditions often treated with IDD therapy include:

Herniated Discs, Bulging discs, Fragmented Discs, DDD, Pinched Nerve, Sciatica, Spinal Stenosis, Arthritis, Facet Syndrome, Spondylolisthesis

Safety issues

Patients must be carefully evaluated and assessed. The benefit of repeated movements on pain centralization, intensity and location with flexion, extension and spinal distraction must be clinically evaluated and considered *before* onset of decompression. Documentation must exist before the onset of decompression treatment demonstrating a sample period of tolerance testing of the procedure motion prior to the application onset of loading / resistance. Clinical documentation must reflect gradual loading/ resistance, recording of incremental resistance advances and the patient tolerance at each level must also be documented.

Calculation of the amount of pull or force exerted is critical so as not to injure the patient, formula's ranging from 50% of the patient's body weight minus 50 lbs to 50% of the patient's weight -10 lbs are typical.

Proper Examination and Diagnosis

-Complete and thorough medical history

-Thorough and complete Physical Exam

-x-ray of the spine

-CT or MRI of the spine, often times additional Discography or Electrodiagnostic studies

Specific / accurate diagnosis is of paramount importance before onset of non-surgical spinal decompression therapy, to achieve spinal decompression the specific level of disc disease along with direction of HNP must be verified so determination can be made as how best to position the patient on the table and weather flexion or extension is best to achieve the desired disc related spinal decompression.

Equipment maintenance, physician and operator training and equipment emergency shut off features must be considered

Contraindication to Spinal Decompression Therapy

-Severe Osteomalacia or Osteoporosis

-Vertebral Fractures

-Spondylolisthesis (Grade 2 or higher)

-Spondylolysis

-Unstable Post Surgical Conditions

-Any kind of surgical hardware

-Tumor or infection of the spine: Pagets Disease etc.

-Acute Inflammatory Disease, RA, Ankylosing Spondylitis

-Dislocations, ligament tears or ruptures

-Spinal instability or peripheral signs on both flexion and extension

-Neurological conditions e.g. Cauda Equina lesions, Neurological defecits, etc.

-Pregnancy

FDA Filings

510K Clearance for Medical Devices: Section 510(K) of the Food, Drug and cosmetic Act requires device manufacturers who must register, to notify the FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification- also called PMN or 510(K). This allows FDA to determine whether the device is equivalent to a device already placed into one of three classification categories. Thus, "new" devices that have not been classified can be properly identified.

Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process or intended use.

Devices are cleared not approved.

FDA Filings
510K
Manufacturer FDA filing, description and intended use of the devise

Look up each manufacturers 510(k) on the FDA.com website and review the "Device Classification Name", most all are "Equipment, Traction, Powered", "Filing Name" and "Indications for Use"

Remember that when a new device gets a 510(K) decision from FDA it is cleared as SE (Substantially Equivalent) and given a 510(k) Number beginning with a K as in K073132(model D Disc Force), K930691 (Accutrac Traction Unit) aka Kennedy Table, K053503 (Vax D), K060735 (DRX9000), K030060 (Cert-SpineMed),K051938 (Triton) K053223 (Chattanooga)

Regulatory investigative due diligence should involve researching the "intended use" described in the manufacturers FDA 510(k) filing to verify if the manufacturer intended and the FDA cleared the device for use as a decompression or if the doctor or manufacturer is simply marketing a traction device as a decompression unit.

If the device manufacturer does not list decompression as an "intended use" in their 510(k) filing then marketing the device for decompression therapy may be fraudulent.

Coding / Billing for Traction and Decompression, CPT codes, 97012 (Mechanical Traction), 64722 (Surgical Decompression)

Healthcare Common Procedure Coding System (HCPCS) is a set of health care procedure codes based on the AMA Current Procedural Terminology (CPT)

HCPCS was established to provide a standardized coding system for describing the specific items and services provided in the delivery of health care.

-Level I consists of the AMA CPT and is numeric

-Level II codes are alphanumeric and include services and devises not covered by CPT, all Level II alphanumeric codes are single alphabetical letter followed by 4 numeric digits.

CPT codes, 97012 (Mechanical Traction)

CPT 64722 (Surgical Decompression)

CPT 63030, Laminectomy (hemilaminectomy) with decompression of nerve root

HCPCS Code S9090, Global Visit Code for Vertebral Axial Decompression, includes heat, soft tissue work, pre-decompression exercising, EMS/US, core strengthening, etc. performed in conjunction with decompression

Non-Surgical Spinal Decompression is not a covered service under Medicare because there is insufficient scientific data to support the benefits of this technique. (experimental / investigational)

Visit 3rd party payer websites to see their reimbursement information related to non-surgical spinal decompression

www.aetna.com

www.bcbsfl.com, www.bcbsma.com

www.,cigna.com

www.humana.com

www.unitedhealthcare.com

HCPCS Code S9090, Global Visit Code for Vertebral Axial Decompression, includes heat, soft tissue work, EMS/US etc. performed in conjunction with decompression

Most coding irregularities mistakes involve reporting of modalities and or therapeutic procedures and their supervision requirements.

Time units- 15 minute units,
8-23 minutes for 1 unit,
23 -38 minutes for 2 units.

Modalities: "any physical agent applied to produce therapeutic changes; includes but not limited to thermal, acoustic, light, mechanical or electric energy" (billed in 15 minute intervals)

Supervised modalities (CPT 97010-97028) do not require direct (one on one) patient contact by the provider. (not a time component modality)

Constant Attendance modalities (CPT 97032-97036) require constant one on one patient contact with the provider, (one on one is defined as visual, verbal or manual contact)

Therapeutic Procedures (CPT 97110 – 97546) "effecting change through the application of clinical skills and or services that attempt to improve function." (Exception of group therapy (CPT 97150)) all therapeutic procedures are time based and require direct one on one contact by the physician. Time requirement (one on one) is 15 minutes.

Documentation of treatment is essential to support a claim of decompression because decompression is a desired goal of mechanical traction the selection of CODE CPT 97012 or HCPCS S9090 must be supported by treatment documentation.

Billing non surgical spinal decompression often times involves more than just the modality of traction. A typical non surgical spinal decompression office visit often will incorporate both Physician (one on one) and supervised services. Detailed documentation is necessary to differentiate between those services billed as a supervised modality and those billed as a therapeutic procedure.

Fraudulent billing practices

Often the provider sells the patient course of non-surgical decompression therapy and then bills a third party for numerous related physical therapy adjuncts, core strengthening and nutritional services instead of the decompression treatment.

Common Fraudulent billing practices, “Does my insurance company cover Spinal Decompression?”

-Physician offices informing patients that non-surgical decompression is a covered benefit on their insurance plan and then submitting a claim for therapy services instead of decompression to the carrier.

-Physician office billing insurance carriers for surgical spinal decompression using CPT 64722 or CPT 63030

-Billing Medicare using physical therapy codes CPT 97110, CPT 97112, and CPT 97140 for decompression related services, Medicare considers non-surgical spinal decompression as experimental / investigational

Medicare/ CMS recommends that providers of non-surgical spinal decompression not bill for this service as it is experimental / investigational. Should the patient request the provider bill Medicare and receive a denial the provider must properly report the service using HCPCS S9090 indicating "vertebral axial decompression", obtain a pre care signed ABN (advance beneficiary notice) or if the patient refuses to sign an ABN then the provider submitting a bill must attach the GZ modifier indicating the expectation that Medicare will deny payment for the service as "not medically necessary"

Manufacturer and physician recommended treatment protocols

Plan of care, 20 visit / 40 visit

Treatment Plan costs range from……..$150 per visit to $400 per visit, treatment plans of 20-30-40 visits with costs ranging from $2500 - $15,000

Regulatory history…cases against manufacturers, consultants, doctors, malpractice and safety concerns

-California DC fined $25,000 for using B. A's marketing program

-Georgia DC's sent to federal prison for improper coding

-Numerous DC's around the nation paying fines, refunding money and going to prison for illegal billing /coding

-Numerous DC's around the nation subjected to AG investigations, licensing board review and penalties for billing / coding/ illegal fee plans / advertising abuses

-Spinal Decompression manufacturer offices raided by FBI

-Oregon DOJ found the claim FDA approved and 86% success rate deceptive and statements of NASA research as misrepresented

-Malpractice issues with spinal decompression focusing on patient pre treatment screening, patient placement, harness placement, force/ pounds of pull calculations, doctor / staff training, table safety features, advertising false statements, safety and efficacy research.

Non Surgical Spinal Decompression is not taught in the core curriculum of any CCE educational program.

Most manufacturer training is limited to a video, DVD or online training.

Things we need to pay attention to in the regulatory community:

Is the device cleared by the FDA?

Patient safety, patient selection protocol, calculation of pounds of pull applied

Compliant, Ethical and legal coding, billing and collections procedures

Billing Fraud, what to look for in the doctors notes / billings

Physician billing insurance company for part of treatment and the patient for part of treatment

Clinically based rational for recommendations including the number of sessions recommended and adjunct therapies, medical necessity

Unsupported advertising / marketing claims

Patient care financing, trust accounting, re-pricing of care when discount prepay agreement is terminated, etc.

Physician and assistant training programs, manufacturer based training vs. mandated state board minimal certification