

SpineMED[®]
decompression system

The Most Advanced
Decompression System Available



*Decompression, that is unloading due to distraction and positioning



Effectively Treating Back and Neck Pain

Back and neck pain statistics are as painful as the conditions they represent.

85% of U.S. adults suffer from low back and neck pain at some point in their lives.¹

As the aging population grows, this number is likely to climb even higher. Low back pain is especially prevalent. It's the second most common reason to visit a doctor, the fifth most common reason for admission to a hospital, and the third most common indication for surgery.²

While low back and neck pain can typically be managed through traditional treatment options such as physical therapy, chiropractic care, or pain management, discogenic pain can be more intractable. For many patients, addressing the underlying disc pathology is the only answer. It is widely accepted that the ideal environment to improve disc pathology is to decompress, or reduce the intradiscal pressures of the damaged disc.

The SpineMED[®] Difference

SpineMED[®] is designed to target damaged spinal segments and decompress intervertebral discs in order to promote the body's natural healing abilities.

Medical professionals worldwide use SpineMED[®] to add an entirely new dimension to their practice.

SpineMED[®], the world's leading non-surgical decompression system, is designed to target and decompress injured intervertebral discs through distraction and positioning of the lumbar or cervical spine. It provides a non-surgical, drug-free procedure for patients suffering from bulging and herniated discs, sciatica, spinal stenosis, and disc degeneration.

1 - "Low back pain: an economic assessment in the United States". *Orthopedic Clinics of North America*, Volume 35, Issue 1, Pages 1 - 5 S. Pai, L. Sundaram.

2 - Bigos S, et al. "Acute Low Back Problems in Adults, Clinical Practice Guideline No. 14". Rockville, MD: U.S. Public Health Service, U.S. Dept. of Health and Human Services, AHCPH Pub. No. 95-0642, Dec. 1994.

SpineMED® decompression:



Provides practices with a new procedure for patients suffering from discogenic pain



Differentiates your practice and attracts a new patient base



Can add a revenue stream independent of insurance, with a treatment option that enhances your current patient services

It's easy to
integrate SpineMED®
into *your* practice.

The system offers an unattended modality that improves patient flow and typically does not require additional staff. Additionally, we provide comprehensive training and business support to ensure your ongoing success, allowing you to focus on your patients.



“Prior to beginning use of the SpineMED® technology, my practice was limited in the ability to treat spinal disorders. Since I've added the SpineMED® to my practice, I've been able to make much more efficient use of other modalities used in my office. Over the years I have used several different spinal decompression therapy technologies, and the SpineMED® technology in itself is significantly more effective than the tables I've used in the past. My patient satisfaction outcome results have been dramatically improved with the use of the SpineMED®.”**

- Dr. Richard Bernstein
Physical Medicine & Rehabilitation

The SpineMED® System At A Glance

SpineMED® Console

The SpineMED® Console houses the computer system and provides the operator with a platform to control the parameters of the patient's session as well as digital charts.

Touch Screen Computer
allows for easy operation

Printer
prints patient reports and documentation

UPS System
protects sensitive electronics and provides backup battery power

Casters
allow easy mobility

Built-in Modem
allows for remote updates and system checks

The SpineMED® Table

The SpineMED® Table provides the patient with the most clinically efficient decompression session available.

Cervical Unit
decompresses injured cervical discs

Cervical Restraints
comfortably secure patient for distraction

Cervical Tilt
adjusts to target specific spinal segments

Headphones
provide audio for education materials or relaxation

Upper Restraint
anchors patient's torso to stationary portion



Cervical Unit

Patented Pelvic Restraints

Patented Pelvic Restraints
secures patient's pelvis to moveable section of the table

Patented Pelvic Tilt
adjusts to target specific lumbar pathology

Patient Safety Switch
puts patient in control of the session

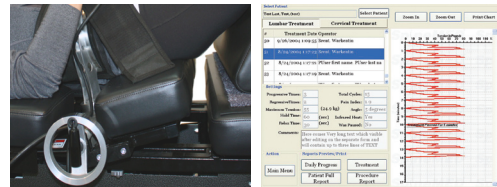
Knee Bolster
adjusts to increase patient comfort

Drive Mechanism
high speed electric actuator—replaces old style traction box

Infrared Heat & Air Bladder
adds to patient comfort and relaxation

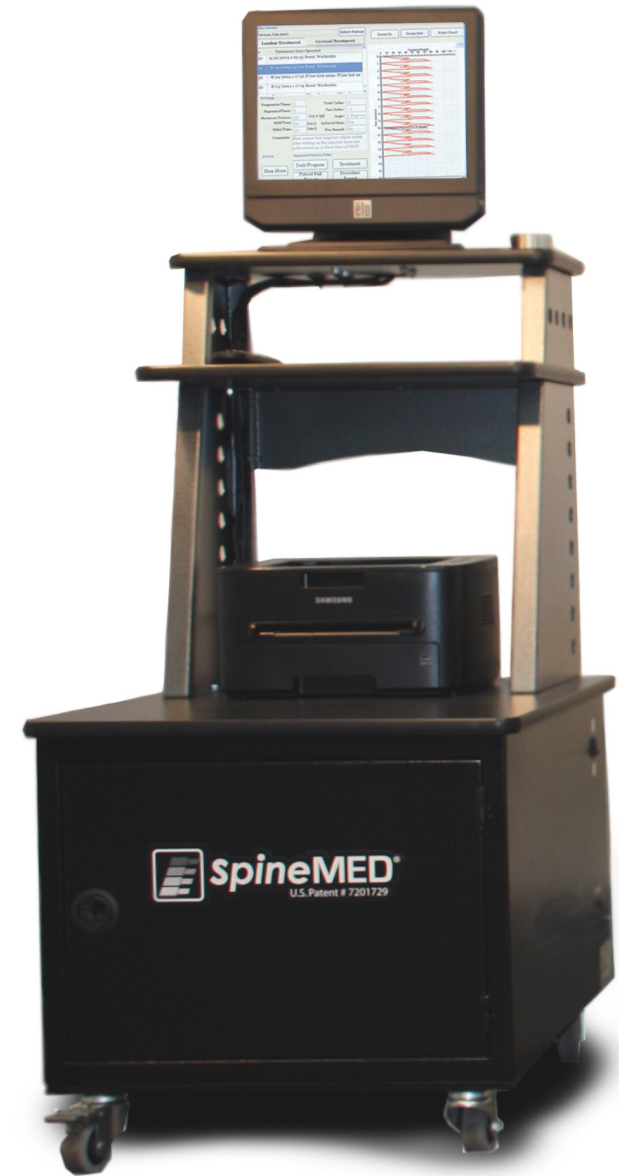
Patient Monitor
allows the patient to view the progress of the current treatment, or to view video through the incorporated DVD Player

CD/DVD Player
provides relaxation music or will display educational or entertainment video



Patented Pelvic Tilt

Proprietary Software





History

The SpineMED® System is the world leader in the modern science of non-surgical spinal decompression.

Prior to becoming involved in the design and manufacturing of the SpineMED® System, the founders of SpineMED® owned and partnered with a number of decompression clinics. They also distributed decompression tables from other manufacturers to physicians around the world.

Based on their years of clinical experience, and feedback gained from healthcare professionals in the field, the SpineMED® System was designed to overcome the limitations and untoward side-effects found with previous devices. Cumbersome nylon harnesses, outdated tower design, and antiquated traction components have been eliminated and replaced with a patented restraint system, exclusive pelvic tilt mechanism and advanced computer controls.

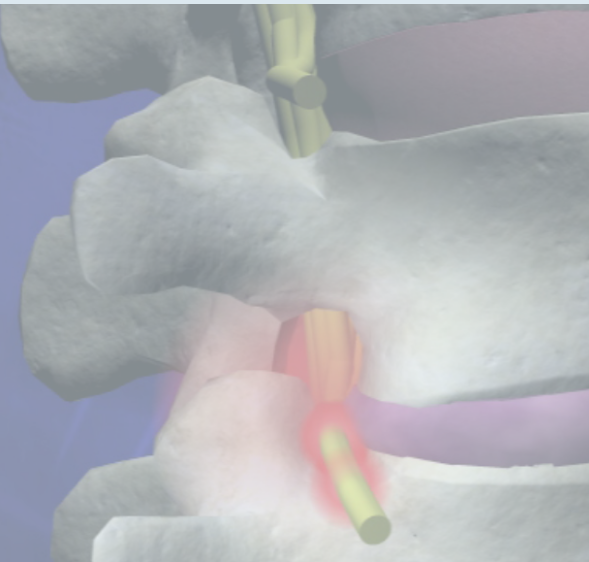
Quality and innovation are the cornerstones of SpineMED®'s philosophy. We are an ISO13485 and CE certified manufacturer of medical devices, and hold numerous patents on SpineMED®'s unique design and key components. The result is a decompression system built to worldwide hospital standards whose quality is unmatched in the industry.

We are confident that you will find SpineMED® to be the most technologically advanced and clinically effective device available for the conservative treatment of lumbar and cervical disc pathologies.

The Beginning and the End of Discogenic Pain

Intervertebral disc pathology is one of the primary causes of back and neck pain. The discs are prone to degeneration and injury as they are compressed and twisted through daily activities. As the disc degenerates, the gel-like nucleus loses its hydration, reducing disc height and creating the possibility of facet syndrome and lateral foraminal stenosis. Furthermore, disc degeneration causes the pliable outer coating of the annulus to become brittle and susceptible to cracks and tears that can lead to disc herniations. Bulging or herniated discs often press on spinal nerves, causing severe pain and radiculopathy.

Damaged intervertebral discs seldom heal because they remain under constant pressure, even while a person is at rest. It is widely accepted that the ideal environment to improve disc pathology is to decompress, or reduce the intradiscal pressures of the damaged disc. The goal of reducing intradiscal pressure is to enhance the osmotic diffusion of fluids and nutrients across the endplates into the disc, furthering the body's natural healing abilities. Additionally, reduction of intradiscal pressures may help draw the nucleus pulposus of a herniated disc back into the center, thereby relieving pressure on a compressed nerve root—alleviating the problem and the pain.



The SpineMED® Advantages

Offer a more efficient procedure, see more patients, and get better results. With SpineMED®, you're using the most technologically advanced decompression system on the market.

Technology Designed to Overcome Reflex Contractions

It is commonly recognized that achieving decompression depends upon the ability to distract the spine without eliciting reflex muscle contractions or spasms. SpineMED® monitors tension applied to the patient every 2.5 milliseconds and can make adjustments every 20 milliseconds. This ability to almost instantly sense and adjust tensions is a key difference that distinguishes SpineMED® Decompression from other devices and conventional traction.

20 Millisecond Response Time

Use a system that fine-tunes forces almost instantly. SpineMED®'s computer-controlled biofeedback response adjusts distractive forces at an astounding rate of 20 milliseconds (the human neurological response is approximately 50 milliseconds). Old designs simply cannot react and adjust tensions at this incredible speed. While their load sensors and motors are designed to adjust forces in less than a second, the true reaction time is significantly longer as the force is disbursed and absorbed through the traction box, nylon webbing, pulleys, and harness systems.

Built-In Infrared Light Therapy

Enhance your results. A far-infrared light element with an effective penetration depth of 3cm relaxes paravertebral tissues during distraction and promotes increased cellular activity to accelerate healing.

Superior Sessions: Targeted Distraction Using Lower Forces

Get better results with better technology. SpineMED®'s patented pelvic tilt feature is designed to adjust patient positioning to accurately isolate and decompress specific spinal segments. With increased specificity and a more efficient capture, SpineMED® is engineered to achieve optimum decompression. The ability to achieve positive outcomes using lower forces greatly increases patient comfort and suitability, particularly with acute patients and the growing geriatric population.

Focused Distraction

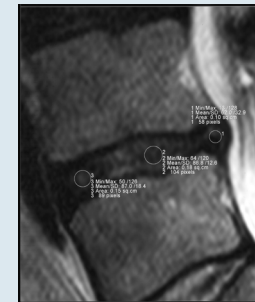
Zero-in and accurately isolate damaged discs. SpineMED®'s pelvic tilt feature rotates the pelvis between 0–25 degrees during lumbar sessions, while the cervical section positions the head between 0–30 degrees of flexion for cervical sessions. Adjustable patient positioning is designed to accurately move the focal point of distraction, allowing SpineMED® to target specific spinal segments. Older technologies attempt this by raising or lowering the traction box within their tower design.



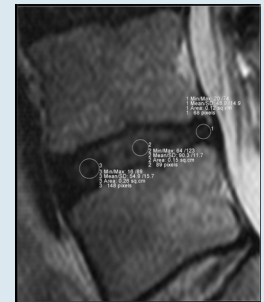


The Significance of Bypassing Reflexes

It is generally recognized that achieving decompression depends upon the ability to distract the spine without eliciting reflex muscle contractions or spasms. The Pre- and Post- MRI's of a SpineMED® patient illustrate the dramatic physiological changes to the damaged disc— both a dramatic reduction in disc herniation and an increase in hydration, as observed through T-2 weighted imaging. These objective changes are not random occurrences in the incidence of disc pathology, and suggest the dramatic reduction of intradiscal pressures and subsequent increase in the osmotic diffusion gradient across the disc endplates.



Pre-SpineMED®



Post-SpineMED®

Many patients, especially those presenting with acute disc pathology, experience a natural guarding reflex under traction. A previous meta-analysis evaluating conventional traction determined that "very few randomized controlled trials reported positive effects on low back pain, and increased pain and intervertebral pressures have been reported after its use."

Additionally, conventional traction has never demonstrated the ability to reduce intradiscal pressures into the negative range. Leading spine researchers Nachemson and Anderson concluded that "when traction is applied so that back muscles contract, then disc pressures will increase."¹

¹ #4. Anderson, G., Schultz, A., and Nachemson, A. (1968) "Intervertebral Disc Pressure During Traction". *Scand. Journal of Rehabilitation Medicine Suppl.* 9. 88-91



Cervical Decompression

Disc degeneration and injury are not limited to the back. Extend SpineMED®'s patented decompression technology to your patients suffering with discogenic neck pathology. SpineMED®'s patented cervical unit seamlessly integrates into SpineMED® and provides you with the same leading edge technology that is incorporated into the lumbar section.



Lower Force Requirements

Reduce the pressure on your patients. With the elimination of outdated harnesses and direct capture of the pelvis with the patented restraints, SpineMED® decompression protocols call for a fraction of the force required with previous devices. In fact, the average distractive force on SpineMED® is $\frac{1}{4}$ body weight, compared with older device recommendations of over $\frac{1}{2}$ body weight. SpineMED®'s lower force requirements dramatically increase patient comfort and tolerance while virtually eliminating any risk of exacerbations or other negative side effects.

Wider Patient Suitability

Attract more patients. SpineMED®'s ability to achieve results using lower forces also increases the scope of suitable patients, especially with acute to sub-acute patients, frail patients, and the growing geriatric population.

Better Patient Capture

You'll see the benefits of the SpineMED® design from the moment you prepare your first patient for the procedure. The patented pelvic restraints comfortably secure the patient's pelvis directly, rendering nylon harnesses a thing of the past. This direct capture provides a secure, comfortable, and repeatable setup, eliminating the variability, slippage, and inconvenience of the nylon harnesses found on older systems.

2-Minute Setup Time

Save time. Save money. With SpineMED®, it's faster and easier to set patients up. SpineMED®'s pelvic restraints, along with other unique technology incorporated in the device, facilitate a patient setup time of less than two minutes. Allowing you to see more patients during the same hours, without impacting your current patient flow or requiring additional staff to operate your SpineMED®.

Secure Patient Capture

Eliminate slippage. With SpineMED®, your patients enjoy uninterrupted sessions, and your staff is relieved of the stopping and starting that come with resetting harnesses. You can set the parameters for the session and leave the patient unattended with full confidence they are receiving a valid session.

Repeatable Sessions

Achieve virtually 100% repeatability from session to session. SpineMED® eliminates the variability or inconsistent positioning of harnesses, regardless of the patient or the operator, with its highly accurate pelvic restraint system.

More Comfortable for Patients

Give your patients a comfortable experience. SpineMED®'s pelvic restraints apply an indiscernible pressure against the pelvis, and an inflatable air bladder supports the patient's natural lordosis to dramatically improve comfort during the procedure.



Accommodate Any Size Patient

Help more patients. SpineMED®'s pelvic restraints comfortably secure patients of virtually any size (70 to 500 lbs.). The restraints effectively displace adipose tissue to capture the skeletal structure without having to rely on different-sized harnesses.

Engineered for Exceptional Clinical Performance

You can depend on SpineMED®. Each system adheres to the highest standards of quality. Extensive computer controls and hospital-grade components ensure superior performance and reliability while the smart design makes SpineMED® easy to operate and practical for your practice.

FDA Cleared and Patent Protected

You will also feel very confident with SpineMED®. The FDA has cleared SpineMED® for both Lumbar and Cervical Decompression (510(k) k051013). The system design and key components are patent protected under US Patent #7201729 and the software systems have been copyrighted.

Smart Design

It's easy to make room for SpineMED®. We've designed the system to fit into existing offices, only requiring a six by nine foot space. Both the console and table have casters for portability, so disassembly is not required to relocate the unit to another room in your office.



"I wish I knew about the SpineMED® therapy two years ago. Surgery was not an option for me, so when I heard about the SpineMED®, I was ready to try anything to help the pain. From about the sixth treatment, I knew I found what was going to work for me without surgery. On a scale from 1 to 10, my pain was a 10. I could not sit or stand for more than 20 minutes without extreme pain. I was walking 5 miles a day before my injury, after my injury I was lucky if I could walk 5 yards. My whole life centered around my back pain. After the SpineMED® Therapy, I feel I have a new lease on life. ... This is the best decision I ever made."**

Kathy Gringling
Westminster, MD





The modular components are easy to replace and have a solid track record. The built-in battery back up and voltage regulator protect the sensitive electronics of the device and provide power in the event of a power outage. This allows the SpineMED® to be plugged into any standard electrical outlet, without the need or expense of adding a dedicated circuit.

Easy to Operate

You'll be up and running quickly. SpineMED®'s quick and simple patient setup and intuitive controls provide your practice with an unattended modality that can be operated by virtually anyone on staff. Included with your purchase, a certified SpineMED® specialist will provide you with a day of on-site training. You'll learn how to control the proprietary software with easy touch screen menus. The system automatically calculates many of the patient protocols, and you have the power to limit security access to only those operators with a valid user ID and password, that you assign.

Automated Patient Reporting

Maintain complete record keeping. The SpineMED® system automatically records each session in a permanent electronic patient file, which includes the parameters of the session, the patient's VAS pain score, and any associated SOAP notes or documentation.

You can also access a variety of comprehensive reports at the touch of a digital button. You can save the reports as .pdf attachments, e-mail them, or print them through SpineMED®'s built-in printer.

Solid Reliability with Upgradeable Technology

Stay up-to-date with state-of-the-art equipment. We use hospital grade components to ensure that the SpineMED® system meets the highest standards of quality as outlined by the International Standards Organization. Extensive computerization with a built in modem allows SpineMED® technicians to "dial" into the system, run diagnostics, check calibrations, and even upload software upgrades over the phone line. This ensures your SpineMED® stays current with the latest industry protocols. The system is backed with the best parts and labor warranty in the industry. Once installed, and calibrated there is no scheduled maintenance required for your SpineMED® EVER!

Built-in Audio/Video Entertainment

Make the experience better for your patients. To promote relaxation or provide patient education, SpineMED® includes a DVD/CD player with headphones and an adjustable flat panel monitor. Patients can watch DVDs, listen to music, or monitor the progress of their session.



Post Purchase Support to Ensure Your Ongoing Success



On-site Office Training

At the end of the day you'll be SpineMED® decompression experts. Installation includes a day of on-site training for the doctors and the staff. We install and calibrate the machine, teach you and your staff how to set up a patient for sessions, and provide detailed instructions on protocols and reporting.



Full Marketing Materials Available

With the available marketing package, you'll gain access to a library of marketing materials. When you join the SpineMED® family, we'll work with you to boost patient awareness and attract more patients.



Flexible Patient Financing

Offer more financing options. To increase the acceptance and accessibility of SpineMED®, patients can take advantage of financing packages that eliminate high upfront costs.



Running the Numbers

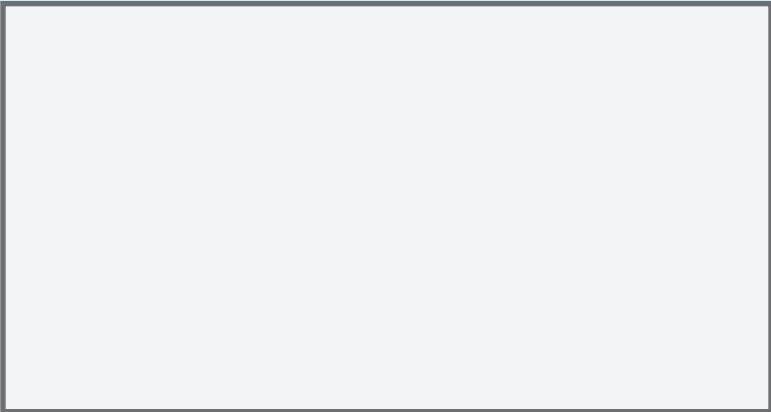
It seems that every year expenses go up and insurance reimbursements go down. Wouldn't it be nice to break free from the insurance squeeze?

Imagine this:

- Set your own price for the services you offer and realize all the revenue.
- Get paid up front. No battling for reimbursements. No late payments.
- Welcome happy patients that don't miss appointments, show up on time, and follow the program through to completion.
- Change the lives of people who are living in pain.

To find out more or place an order, please call **866-990-4444**, email info@spinemed.com, or check out our website at www.spinemed.com.

With SpineMED®, you'll see more patients. And they'll see results.



SpineMED®
decompression system

SpineMED® Decompression System is engineered and certified to worldwide medical standards. FDA 510(k) #k05103, CE, UL, CSA, ISO 13485.



0413

