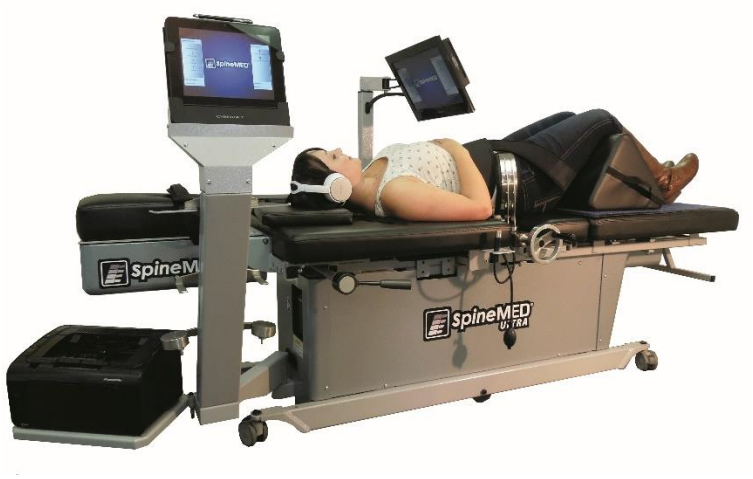
SpineMED Advantages



There are considerable differences between all “Distraction Devices” and SpineMED

There has been enormous confusion in the marketplace due to the popularity of Decompression technology in the 1990’s and early 2000’s, to where all distraction devices then claimed to be decompression technology. Many traction devices simply changed their labelling to “decompression” while the device and its technology did not change whatsoever.

Conventional traction has been around for a very long time. Most medical professionals know that spine surgeons will say that traction is contraindicated for disc patients, as it will most often exacerbate disc pathology. Well seasoned physical therapists will also tell you that they’ve had disastrous results using traction on disc herniation cases.

Original research by the leading surgeons (Nachemson, Andersson and Schultz) demonstrated that intradiscal pressures would INCREASE during treatment on a conventional traction device. This is, of course, causes COMPRESSION of intervertebral discs. This again, is why spine surgeons will often state that traction is contraindicated for disc herniation cases. The researchers concluded that conventional traction forces would cause reflex muscle contraction of the paraspinals.

The original decompression device was developed by Dr. Alan Dyer in the mid-1980’s. A study was published in 1994 by two Neurosurgeons in Texas, that demonstrated the device’s ability to REDUCE intradiscal pressures during treatment on the decompression device. So, while both conventional traction devices and decompression devices apply distraction forces to the spine, the scientific results are INVERSE.

The simple answer to the question as to how they differ, is that conventional traction most often results in triggering reflex muscle contraction, causing the paraspinal muscle and ligaments to fire/contract, which reduces intervertebral space, compressing the discs.

Decompression devices are designed to bypass the body's neurological response to the force, and not cause the paraspinals to fire and contract. Without causing the paraspinals to contract, the distraction forces then increase intervertebral space, unloading or 'decompressing' the intervertebral discs.

Spinal distraction devices are intended to increase intervertebral disc segments to "unload" an intervertebral disc, and to hopefully achieve decompression of the intervertebral discs through the reduction of intradiscal pressures into the negative range. The majority of lumbar disc pathology is at L4-L5, or L5-S1, which is a small segment of the spine, perhaps 4-5 cm in length. Successful unloading of a single lumbar spinal segment likely only requires a distraction force of 10 – 12 lbs. if the force is directly applied to the spine. Unfortunately, most distraction devices, or "Decompression Devices" use conventional nylon pelvic harnesses to clamp the lower torso, and a combination of upper harness and axilla bolsters to capture the upper torso to secure and then apply distraction forces to the patient's lumbar spine. These devices apply distraction forces throughout the entire torso, to "eventually" cause distraction of a single lumbar spinal segment. Force on these devices extends through the lumbar harness into the entire lower torso and throughout all adipose tissue within the torso, as the upper torso is restrained through the axilla bolsters. The formula for distraction forces on these devices is typically 60% to 75% of patient body weight. Enormous force is required as it is being applied over the entire torso, so that it will eventually result in distraction of a lumbar segment. Due to these high force requirements, acute or antalgic patients may experience exacerbations or soreness from the treatment, and frail or geriatric patients typically are not suitable candidates on these devices.

The SpineMED utilizes a patented capture and force application system that captures the skeletal structure directly, through the patient's pelvis. With direct capture and application of distraction forces to the skeletal structure, only 12% to 15% of the patient's body weight is required to unload lumbar spinal segments. This patented system eliminates the nylon pelvic harnesses, ropes and seat belts utilized by all other Decompression Systems, which are incredibly inefficient in the capture and application of distraction forces. The very precisely targeted and much lower forces utilized on SpineMED virtually eliminate all of the side effects and exacerbations which can occur on devices utilizing nylon harnesses, ropes and seat belts. Patient suitability for treatment on SpineMED is much wider, due to its very efficient and gentle distraction.

Additionally, most devices will apply a flat, linear pull to the lumbar or cervical spine, to apply distraction forces. This flat, linear pull will distract the entire lumbar or cervical spine, with the greatest distraction being applied to L5-S1 in the lumbar spine, with diminishing distraction and force upwards in the spine, from L4-L5 to L3-L4, etc. In the cervical spine during this flat, linear pull, the greatest distraction force will be at C1-C2, and gradually diminish "down" the cervical spine through C2-C3, C3-C4, etcetera. In these systems, it is not possible to target specific spinal segments, and most often, a non-symptomatic level will be distracted more than a symptomatic level, due to the inability to target specific spinal segments. As an example, it is more common for a patient to have disc pathology at L4-L5, however, treatment on a typical distraction device will apply more distraction force at L5-S1, before any distraction force is applied to L4-L5. The similar problem occurs on the cervical spine, where a flat, linear pull to the cervical spine will apply the greatest distraction force at C1-C2, when the most common levels of pathology are C5-C6 and C6-C7.

The SpineMED System has a patented "Pelvic tilt" and "Cervical tilt" mechanism with places the lumbar spine or cervical spine into flexion during the decompression treatment. The flexion of the cervical spine or lumbar spine,

moves the focal point of distraction forces, so that individual spinal segments may be targeted. With SpineMED, the operator simply selects which spinal segment they wish to target, and the SpineMED software will cause flexion of the patient's lumbar spine between zero and 25 degrees, or between zero and 30 degrees in the cervical spine to target the patient's specific level of pathology. This dramatically improved efficiency with the SpineMED System results in a much more efficient and comfortable treatment without exacerbating patients due to adverse force application.

All "Decompression Devices" are designed to reduce intradiscal pressures in order to promote an increase in the osmotic diffusion gradient across the endplates of the intervertebral discs. This increase in the diffusion gradient promotes the influx of oxygen, water and nutrients into the disc. This diffusion gradient is a differential in pressures; the pressure within the intervertebral disc, and the pressure surrounding the disc. Therefore, the greater the differential in pressure between the interior of the disc in comparison to the surrounding area, the greater the diffusion gradient and subsequent influx of nutrients, water and oxygen.

The position of the body will dramatically alter the internal pressure of the intervertebral discs. The greatest 'natural' creation of osmotic diffusion into the intervertebral disc is during the body position of laying supine, which is commonly during the period of sleep. While lying supine, the pressure within the intervertebral discs (lumbar) is typically about 75 mm/HG. While the typical pressures surrounding the lumbar intervertebral discs (IVD) is approximately 80 mm/HG, there is a very slight diffusion gradient of 5 mm/HG that promotes the influx of nutrients, oxygen and water. When a body is in the standing position, IVD lumbar discs have an approximate internal pressure of 100 mm/HG. When sitting, IVD internal pressures are typically 220 mm/HG +.

Based on the varying IVD internal pressures with different body positions, almost all Decompression Technology position the body in a supine position for treatment. This is largely due to the natural reduction of IVD pressures in a lying supine position. This position then creates a beneficial 'starting point' for further reduction of IVD pressures, to create significant diffusion gradients across the endplates of the discs and promote the influx of nutrients, oxygen and water.

Positioning the body in a seated position for Decompression Therapy is counter intuitive to the overall premise of reducing IVD pressures, and subsequently increasing the diffusion gradient. The application of Decompression Treatment to a patient in a seated position would first have to overcome the significant increase in IVD pressure (220 mm/HG+) created during a seated position, before IVD pressures could be reduced into the negative range. Decompression Treatment of a patient in a seated position would limit the subsequent reduction of IVD pressures, and therefore limit the creation of a diffusion gradient across the endplates of the discs. It could be further questioned, as to whether it is at all possible to reduce IVD pressures into the negative range while positioning the patients in a seated position.

It is well known that IVD disc injuries are caused through excessive loading and rotation of spinal segments under load. The rotation of spinal segments and subsequent torque on the annulus has been known to cause shearing (tears) in the annulus. It is also well known that treatment methods or activities that apply rotational torque to spinal segments can further exacerbate existing disc herniation pathology or perhaps cause shearing of the annulus.

The application of lateral distraction forces to IVD disc pathology also has the possibility of exacerbating the underlying condition. The skill level of the operator of a device that allows a wide range of variables must be extremely high. The application of rotational torque, lateral distraction forces, flexion or extension positioning during treatments have the potential for further exacerbating the patient's condition. Therefore, the results of treatments conducted on such a device are directly related to the skill level of the person operating the device. In

addition, devices that operate manually and with a wide variable of treatment parameters require the highly skilled practitioner to be operating the device throughout the entire treatment sessions. The physician subsequently becomes the operator of the device.

SpineMED has been designed such that it can be operated by virtually any clinical staff, while still delivering optimal treatment results. The very high outcomes through SpineMED therapy are not directly related and dependent on the skill level of the person operating the device, due to the sophisticated control mechanisms and very high repeatability incorporated into the SpineMED.

The SpineMED produces repeated high outcomes and is often operated by clinic support staff (sometimes the receptionist), with the physician simply overseeing the progress of the patient. This allows the physician to continue to see and treat patients through other modalities rather than spend their valuable time operating a Decompression Device.

Harness style devices, such as the Antalgic Trak (or DRX9000) on the other hand, requires a VERY high skill level to operate, due to the significant number of variables in the hands of the operator. The Antalgic Trak device should only be operated by a highly skilled physician, who understands what they are doing with distraction AND rotation or lateral distraction of the spinal column simultaneously. In many clinics with Antalgic Trak, the physician may be reluctant to allow their staff to operate the Antalgic Trak, due to questionable treatment outcomes through these variables. Therefore, the doctor is spending all of THEIR valuable time operating a machine, rather than treating patients in their traditionally used methods. Due to the operation of the Antalgic Trak, the physician is usually at the device during the entire time of the treatment.

The SpineMED has been designed to produce very high results on a consistent basis, regardless of the skill level of the person who is operating the device. It has also been designed to be the most clinically efficient device on the market, to where it has virtually no impact on existing clinical staff. The SpineMED has been designed to operate completely unattended, with staff involvement of less than two minutes for patient setup. This allows the device to be integrated into a medical office without the need to hire additional staff, or to rely on highly skilled medical staff for its operation. Almost all other devices require dedicated staff to operate and oversee the treatments in operation due to the time requirement and inefficiency of nylon harnesses. This factor alone increases operating costs of a relatively cheap device into a significant ongoing overhead expense. With SpineMED's patented systems, the distraction forces required are typically ¼ of what is required by other decompression devices. These low forces with SpineMED virtually eliminate all of the side effects and exacerbations experienced by clinics using other decompression devices.

With treatment results ranging from 85% to 93% through SpineMED's proven technology, one would ask why you would wish to add the variables of rotational distraction forces, or lateral distraction forces to a patient's treatment? Adding these variables are highly unlikely to improve treatment results, but do have a strong likelihood to exacerbate patient conditions.

While many distraction devices claim to be "just like SpineMED", none have any published literature proving the results of their device and rely simply on conjecture.

There really is no comparison between SpineMED and competitor technologies.