

one of the SpineMED™ Health care professionals at four weeks for re-assessment and instruction of an exercise program. A review of your exercises will be done within 2 months or earlier, if required. Individual issues will be addressed. The Health Care professional will schedule you for a 6 month and one year follow-up at the SpineMED™ clinic.

The majority of patients that recover on SpineMED™ Therapy generally remain in remission. Some individuals with severely degenerative discs, or whose lifestyle or work environment exposes them to higher risk factors have found that a maintenance program consisting of occasional treatment sessions is necessary. This will be determined by the clinician, and the schedule of these treatments will be decided upon at that time. Generally these treatments are performed at one or two week intervals. The purpose of them is to serve as a measure of protection against disabling episodes of low back pain syndrome. Patients in this category develop their own rhythm of maintenance visits that keeps them free from problems.

SUCCESS DEPENDS ON YOUR COMMITMENT

To attain maximum success from the SpineMED™ Disc Program, commitment is crucial. The SpineMED™ team will do everything possible to ensure your recovery, however, the key to success is in the commitment to the entire program and follow through with the required and recommended guidelines.

Here is to a better pain-free and active life!

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SpineMED[®] Therapy

Patient Handbook

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1. INTRODUCTION

Now that the necessary medical reports have been reviewed and screening has taken place, it has been established you are an appropriate candidate. The information provided in this patient handbook will serve as a guide in preparation for the SpineMED™ Disc program. It includes what is required and what is recommended in order to achieve optimal healing and maximum benefits from the program.

The program is designed to recreate the circumstances where your disc(s) can efficiently and naturally heal. The protocol focuses on the ability of the body to heal itself. It is therefore essential that each person participating in the program also be focused on the healing that will be taking place during the next 4 to 8 weeks.

Details of each component of the treatment program, sequencing and expectations are found in this handbook. Some of the features and benefits of the SpineMED™ table are also reviewed.

Being aware and monitoring the response of your body to the treatment, is part of the process. Before and after each individual session, feedback is requested and recorded. The operator of the SpineMED™ table needs to assess the effect of each treatment. The treatment is designed to be comfortable at all times and any discomfort should be reported immediately.

After reading the handbook a discussion with the clinician will take place. The individual condition and underlying problems of your spine being treated will be discussed. It is essential to have a clear understanding of the program and expected outcome before starting the program.

2. PREPARATION FOR TREATMENT

of treatment, the patient will be instructed in proper body mechanics, posture, and the correct way of using your back to avoid re-injury.

Exercise Programs and Activities Post SpineMED™ Program. Experience has shown that patients treated for posterior facet syndromes are usually able to resume full activities immediately following remission of their symptoms with SpineMED™ Therapy. However, those who have achieved remission from more serious lumbar dysfunction that involve intervertebral discs such as herniations and/or degenerative disc disease, need to realize that their lumbar structures and tissues need to be allowed time to heal. Follow up of post program patients indicate that this resolution period requires at least one to two months, before individuals can safely engage in body contact sports or strenuous work and recreational activities. This depends on the severity of the underlying lesions and needs to be discussed with the clinician.

In the immediate post treatment period when a patient is in remission and relieved of pain, there is a tendency to return to a level of activity at work or play that is too strenuous. If this is done, the patient is at risk of experiencing a relapse. Therefore, it is especially important to allow time for resolution and healing of decompressed lumbar discs and the surrounding structures and tissues.

Following a course of SpineMED™ Therapy, patients in remission should be cautioned to slowly increase their exercise program after the 4-week healing period. If their low back pain has caused them to restrict their activities in the past, their muscle strength might be decreased. In some cases, muscles are smaller (atrophied) and weak as a result of nerve compression. For at least one-month post treatment, exercises that cause flexion, extension or rotation of the lumbar spine need to be avoided.

Follow up and Maintenance Therapy. After completion of a minimum of twenty sessions, there will be regular follow-up by

9. Monitoring the Effects of Each Individual Treatment

The advantage of this advanced technology, is that it is extremely comfortable, and while on the table a person does not feel there is a great deal of distraction taking place. The need for the spine to be distracted without discomfort is achieved.

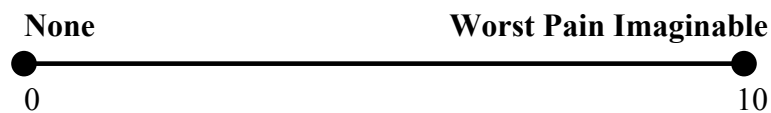
Immediately following the treatment there is a period of 2-3 hours when the spine is re-stabilizing and could be considered to be uncomfortable by some patients. This feeling should not last longer than 2-3 hours and if it does, this must be reported.

The monitoring of your response to the treatment each day, is very important in determining the amount of tension that will be applied to distract the level of the spine that is affected. Each day there is a request for the pain levels, level of function and response to treatment are recorded.

Visual analog scale

Mark below on the scale from 0 to 10 your level of pain discomfort with 0 being None and 10 being the worst pain imaginable.

Visual Analog Scale (VAS)



10. POST TREATMENT PROTOCOL

Exercise program: At an appropriate time, approximately 4 weeks following completion of the treatment, an exercise program, specific to the patient's condition will be introduced. It will include stretches to promote flexibility through proper alignment of the healing tissue, stabilization and strengthening exercises and range of motion exercises. Throughout the course

Required Steps to be taken prior to starting the treatment program.

□ Read the Patient Handbook

□ Prescription for a Non Steroidal Anti-Inflammatory (NSAID)

A therapeutic dosage regime should be started 48 hours prior to the first SpineMED™ session in order to develop effective serum levels of anti-inflammatory activity that will help reduce discomfort from the initial mobilization of irritated lumbar structures and tissue. The NSAID should be continued throughout the sessions and for approximately two weeks thereafter.

This will minimize any localized soft tissue inflammation that might occur as a result of the distraction performed by the SpineMED™. With minimal irritation, the body will not trigger any resistance to the distractive force and muscles in the surrounding area of the lumbar spine will relax.

The expertise of a Physician is required to determine which of the NSAID's are suitable. A prescription is required.

□ Bring a lumbar support belt to the first treatment.

The use of an acceptable lumbar support is required for use after each treatment. It serves primarily to prevent movements, which will have a negative effect on the healing that is taking place, and to offer some support to the lumbar spine. This is especially important if there is any travel of a significant distance involved. A support can help to minimize any acceleration or deceleration forces in transit. Also it should be worn when any postural strain is felt or anticipated. If there is the possibility of being involved in activities that might unexpectedly invoke lumbar flexion or rotational movements during the period of time they are on a course of SpineMED™ therapy the support is necessary. Many patients find that wearing a lumbar support belt adds to their comfort level. The ability to remain comfortable and prevent any increase in muscle guarding will encourage healing and tissue relaxation.

The focus is always to keep the stress, strain and loading to the lumbar spine to a minimum during the program.

- ❑ **Taking calcium while on the program** is an essential element in the process of skeletal muscle relaxation. This function is especially important for the "strut"(paravertebral) muscles that have a tendency to react with spasms to lumbar stimuli. Patients seem to benefit with reduced incidence of spasms when they have a daily intake greater than 800 mg. of elemental calcium. The preferred source of elemental calcium is that from the organic salts such as calcium lactate or calcium gluconate (if allergic to lactate).

For this reason it is recommended that the patients on SpineMED™ therapy, who do not consume an adequate quantity of milk each day as a dietary source of calcium, be advised to ingest the tabulated forms of lactate or gluconate in amounts to supply at least 800 mg. of elemental calcium.

- ❑ **Discontinuation of the use of narcotics/ pain killers**
Sometimes patients may already be on analgesics. The goal will be to discontinue the use of any painkillers gradually throughout the program or prior to starting the program. That will be pre-determined by the physician. If required, an appropriate schedule to reduce pain medication will be made. This is particularly important with the use of narcotics, e.g. morphine, percodan, etc.
Narcotics have the capability of suppressing the immune system. Also the program requires feedback on how the body is responding to the treatment; if masked by painkillers, an accurate understanding of the response is not possible.
- ❑ **Discontinuation of active exercise.**
It is necessary to suspend exercise that involves twisting, bending and increased joint compression, such as jogging. While undergoing therapy, activities within tolerance are not discouraged. It is required to follow the guidelines of Do's and

The table slowly releases comfortably and safely. There is an alarm system to notify the operator in the event the safety switch has been depressed. Minor adjustments of positioning can and should be made so that comfort is maintained throughout the treatment.

There is included on the table as a secondary measure, a manual release on the side of the bed that disengages the upper restraint by simply pulling a lever on the side of the table. This is a redundant, secondary safety system.

8. EXPECTATIONS DURING THE SpineMED™ PROGRAM

Patients typically experience relief of pain while undergoing SpineMED™ therapy, however, following a therapeutic session it is sometimes reported that the lumbar spine feels a little "unstable" for 30 to 45 minutes. For this reason, patients are advised to rise from the table slowly and carefully with assistance and are told to avoid postural strain or rapid and rotational movements in the immediate post-treatment period. Stressful movements have a tendency to elicit muscle spasm and should be avoided following SpineMED™ therapy.

The majority of patients can expect to feel a reduction in pain during the second or third week of treatment. It is important to remember that the decrease in pain is usually gradual, like the process of healing, and the effect of the spinal decompression is cumulative. In the case of disc herniation, the correction of the herniation can also specifically mean that there is relief of nerve pressure. If pain relief does occur quickly, it is **essential** not to return to normal activity levels as described in the guidelines of the DO's and DON'T's .

It is important to emphasize that tissue is healing throughout the program. It is like having a sprained ankle healing. Stress on the tissue needs to be avoided. This same principle applies during the SpineMED™ Disc Program and for 4 weeks following the program.

high frequency electrical impulses to irritable pain receptors can return them to their normal state. The use of the stimulation takes place after the ice application.

It is vital that no other form of therapy/ treatment take place at the same time as the SpineMED™ program. It would not be possible to know what treatment is achieving certain results. Other forms of therapy MUST be discontinued while on the SpineMED™ program.

6. EXPECTATIONS WHILE ON THE SpineMED™ THERAPY TABLE

It is once again stressed that comfort while on the SpineMED™ treatment table is essential. Providing feedback about how your body responds to treatment is extremely valuable. There are guidelines that the clinicians use to determine the tension required for each individual. It is important to use the tension, which gives the best results.

The advantage of this advanced technology, is that it is extremely comfortable, and while on the table a person does not feel that there is a great deal of distraction taking place. The need for the spine to be distracted without discomfort is achieved and is essential to the success of the treatment.

In most cases, there DOES NOT have to be pain for gain. Many patients believe this is true as a result of their past experiences with exercise programs or treatment. Any discomfort while being treated needs to be reported to the technician, as it will be detrimental to your results.

7. SAFETY OF THE SpineMED™ TABLE

At any time, it is acceptable to use the handheld electrical safety switch/ emergency button to discontinue the treatment session if you feel some discomfort. It does not have to be an emergency.

Don'ts for the period of 4 weeks during the treatment and 4 weeks following completion of the treatment. This is the time in which healing of the tissue continues. Exercise and strengthening is essential after the program.

- ❑ **Bed rest is not considered a part of this program.**
- ❑ **Follow the DO's and DON'T s throughout the 4 week treatment period.** Optimal results are achieved when patients follow the do's and don'ts of the SpineMED™ Disc Program.

DO's	DON'Ts
<u>DO</u> rest for at least 1 or 2 hours after each treatment session	<u>DON'T</u> bend forward for the first few hours after treatment
<u>DO</u> be aware of your sitting, standing, and lying posture	<u>DON'T</u> twist your back
<u>DO</u> wear your lumbar back support belt as instructed	<u>DON'T</u> lift heavy objects (over 20 lbs.)
<u>DO</u> wear shoes without laces and use a long handled shoe horn if necessary	<u>DON'T</u> wear high-heel shoes
<u>DO</u> report to the therapist any change in your symptoms at your next visit	<u>DON'T</u> walk long distances after treatment
	<u>DON'T</u> try to engage in those activities that were avoided before therapy too soon after treatment even though you feel relief from treatment.

- ❑ Treatments are administered with patients fully clothed. However, two-piece clothing that separates at the waist would be the most practical and comfortable.
- ❑ To avoid bending immediately after therapy, it is advisable to wear shoes that slip-on rather than lace up.

3. SCHEDULING

It has been shown that optimal results are achieved if the 20 SpineMED™ treatments are performed 5 days a week for 4 weeks. In some cases, two treatment sessions per day may be administered to shorten the total length of time required to undergo a full course of therapy. Please discuss this with the SpineMED™ clinician. Each SpineMED™ treatment takes approximately 30 minutes, with total time for the treatment session taking approximately 60 minutes with the complimentary modalities. The treatment produces a cumulative effect.

Consecutive daily treatments are important. Missing daily sessions will lengthen the time to complete treatment, which will result in an increase to the time it takes to heal. For most cases, 20 treatments will be administered within a 4week period followed by 4 weeks of healing before exercise begins. Difficult cases, such as those with disc involvement at more than one level, might require an additional 5-10 treatment sessions. Progress will be assessed on a daily basis.

4. TREATMENT PROTOCOL

OUTLINE OF EACH SESSION OF THE PROGRAM

Each standard treatment session consists of the following	DURATION
Completion of feedback on pain and functional levels.	5 min.
THERMOTEX InfraRed or Dry Hydrotherapy application	15 min. to 30 min.

Spinal Disc Decompression with SpineMED™ S100A	30 Minutes
Cryotherapy or conventional Ice Pack	15 minutes
Pain Control Device—Interferential Current Unit	15 minutes
Application of Lumbar Support	Continuous
Post treatment completion of self reported V.A.S. and Oswestry.	Variable
Reinforcement of Dos and Don'ts after the Treatment	Continuous

5. COMPLIMENTARY MODALITIES:

Modality of Choice for Tissue Relaxation

Prior to the decompression therapy, the patient might receive far infrared heat or dry hydrotherapy. This is a deep heat that provides relaxation of the muscles and the tissue in the area of the spine that will be distracted by the SpineMED™ table.

Cryotherapy (Ice)

After the SpineMED™ treatment, ice is applied to reduce any immediate irritability of the tissues in the lumbar area that was treated.

High Frequency Electrical Stimulation

The pain receptors that have been stimulated for a long time are irritable and consequently continue to perceive pain. The use of