

# The SpineCOR

Pain Relief Back Brace

A new and innovative approach to spinal treatment in adults targets pain relief by providing Postural Rehabilitation and Spinal Offloading



The new SpineCor® Pain Relief Back Brace is a neuro-muscular-skeletal rehabilitation tool for treating abnormal spinal loading and abnormal posture; it is not a simple back support brace.

Modes of Action:

- Corrective movements gently guide the posture and spinal alignment in an optimal direction.
- The elastic corrective bands act to resist the body's movement back to the abnormal position.
- This constant "correction, relaxation, correction, relaxation" is in reality a corrective postural exercise.
- The brace is able to put a patient's body through 10's of 1000's of repetitions per day instead of the 10-50 repetitions that are typical with other rehabilitation techniques.
- It creates dynamic spinal offloading and neuromuscular rehabilitation with the ultimate goal of neuromuscular integration.

The Musculoskeletal Affects of Abnormal Posture and Spinal Alignment:

- Scoliosis and other spinal conditions can affect the "balance" of body posture and spinal alignment.
- A loss of normal spinal balance creates abnormal loading on the vertebra, discs, ligaments, joints, tendons, muscles and nerves.
- Over a relatively short period of time, abnormal loads on the body tissues alter their functions.
- Over a long enough period of time, the structure of body tissues will change in response to the abnormal loading further compromising function.
- These changes can damage the body, i.e. facet joint arthrosis, disc degeneration, nerve root irritation, spinal stenosis, all of which lead to pain.
- Promoting a change in the balance of the posture and the spine can help to correct the abnormal loading.



### Treatment Objectives:

1. Pain: The primary treatment objective of the SpineCor® Pain Relief Back Brace is most often pain relief; however, postural improvement is directly related to pain relief and therefore should also be considered as a secondary objective.
2. Posture: Clinically appraised desirable postural changes will be patient specific and defined by both clinical and radiological features of their condition. Often, the posture changes seen, such as improvements in spinal decompositions, are responsible for stabilization or correction of progression and reductions in pain.
3. Progression: Correction/Stabilization of Spinal Deformities/Misalignments. In such cases, radiological evaluations are advised to optimize treatment. Radiological objectives may include optimization of spinal balance, reduction of spinal decompositions and reduction of Cobb angles. Please note significant correction of Cobb angles in adults will rarely be possible and therefore should not be the primary or only treatment objective.

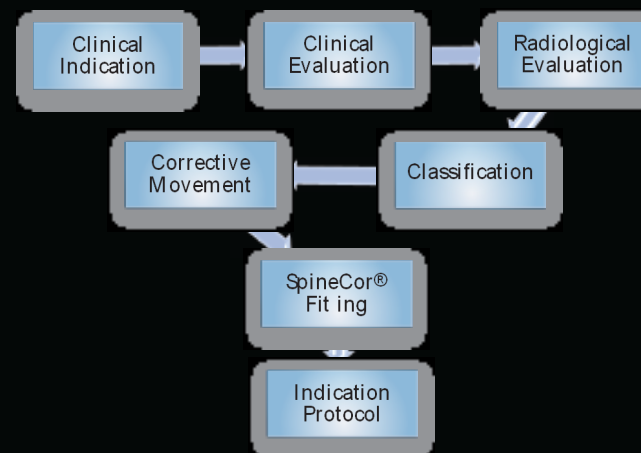
### Indications:

These include but are not limited to the following:

- Adult De-novo Scoliosis
- Degenerative Adult Adolescent Idiopathic Scoliosis
- Hyper Kyphosis
- Postural Scoliosis
- Chronic Antalgic Scoliosis
- Post Traumatic Scoliosis
- Spinal Stenosis related to spinal misalignment
- Poor posture



### Treatment Protocols:



X-rays are required before treatment to determine:

- A. Patient suitability for treatment
- B. Scoliosis/deformity classification
- C. Patient specific treatment objectives

The indications provided are guidelines and not absolute. Co-morbidities must be considered and may contraindicate bracing.

SpineCor® Assistant Software (SAS) is required for scoliosis classification, as well as detailing the appropriate corrective movement and brace fitting. This is the same clinical assistant software used for the SpineCor® (pediatric) Dynamic Corrective Brace.

During treatment, x-rays may be required to optimize treatment in relation to spinal deformity correction/stabilization. Where the primary or only treatment objectives are pain reduction or postural improvement, x-rays of the patient in the brace are not essential.

Initially, the brace is worn 8 – 16 hours per day in order to initiate postural changes. After several months of wear, it is often possible to reduce wearing time while maintaining the same pain relief effect.

Initial follow-up for brace adjustment is recommended at 4 – 6 weeks with further follow-ups at 3 – 6 months dependant on individual patient needs.

The SpineCor® Pain Relief Back Brace should always be prescribed by a doctor, physician or spinal surgeon who can determine that no contraindications exist prior to brace treatment.

### Treatment Outcomes:

During a two-year development process, the SpineCor® Pain Relief Back Brace was clinically tested on over two hundred patients.

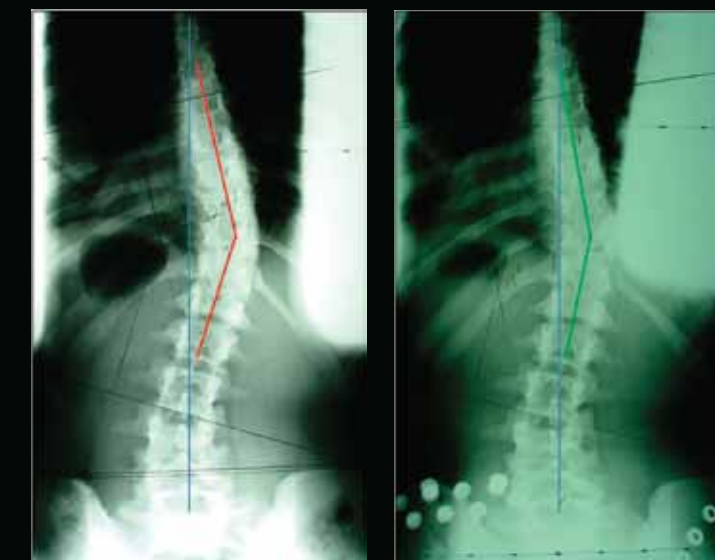
A multi-centre retrospective case series investigating the efficacy of the SpineCor® Pain Relief Back Brace in adult scoliosis patients suffering from back pain is now in progress.

Initial results from the first 26 patients fitting the inclusion criteria at twelve months follow-up demonstrated significant reduction in their numerical pain scores (NPS). 90% of patient's achieved and maintained a mean pain reduction of 70%. In addition, patient's achieved an average Cobb angle reduction of 4.41° ranging from 12° to +3°. There was no statistically significant correlation between Cobb angle reduction and pain intensity.

### Case Studies:

Patient A

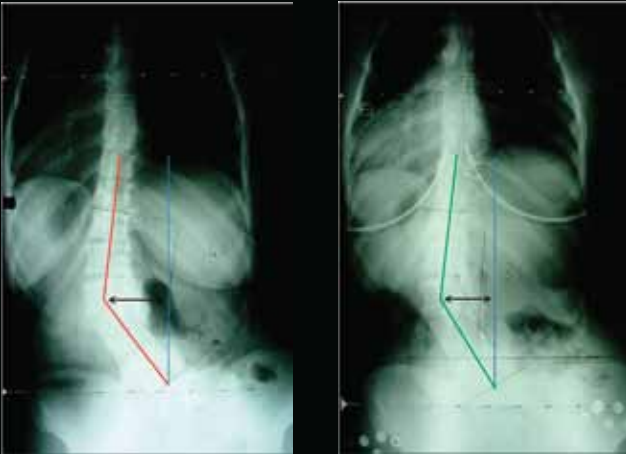
26 year old female with a painful adolescent idiopathic scoliosis as an adult (ASA1). Her pain prior to SpineCor® treatment was rated as an average daily pain of 7/10. Using the SpineCor® Pain Relief Back Brace, daily 8 to 12 hours for 3 months, she had a gradual relief of her pain to an average 2/10. The initial x-ray shows a 32° right thoracic scoliosis. In the SpineCor® Pain Relief Back Brace 1 month after fitting, the x-ray shows an improvement of 8° to 24°. Her pain relief of 1-2/10 and spinal correction have been maintained for over 2 years by using the SpineCor® Pain Relief Back Brace on an occasional basis.



## Case Studies:

### Patient B

47 year old female with a Degenerative De-Novo Adult Scoliosis. Her pain prior to treatment was rated as an average daily pain of 8/10. In the SpineCor® brace she had an immediate relief of her pain to 3/10. The initial x-ray shows a 40° degenerative lumbar scoliosis. In the SpineCor® Pain Relief Back Brace x-rays show an improvement of 7° to a 33° curve. Her pain relief of 0-3/10 and spinal correction have been maintained for over 2 years by using the SpineCor® Pain Relief Back Brace on a daily basis. Note the improved left lateral shift showing “spinal offloading”.



## Training Programs:

Training is in three modules: 0, 1 and 2.

Module 0 - Revision: Optional; depending on the orthotist's experience in treating scoliosis.

- i. Spinal anatomy
- ii. Biomechanics
- iii. Posture and spinal deformity
- ONLINE Training (only 4 hours)

Module 1 - Theory:

- i. Adult Treatment Concept and Spinal Deformity Classification (2 Hours)
- ii. Adult Treatment Protocol and Application (2 Hours)
- iii. Clinical and Radiological evaluation (2 Hours)
- iv. Corrective Movements and Brace Fittings (1 Hour)
- v. SpineCor® Assistant Software (1 Hour)
- ONLINE Training (8 Hours) or ONE DAY Group Training Program (8 Hours)

Orthotists who have already undertaken SpineCor® (pediatric) Dynamic Corrective Brace Training are only required to complete parts i. & ii. of Module 1 online before beginning to treat adult patients.

Module 2 – Practical:

- i. Classification
- ii. Software
- iii. Brace Fitting
- ONE DAY Group Training Program (8 Hours)

## Ordering Information:

The SpineCor® Pain Relief Back Brace is a prefabricated brace customized to the patient's size and condition. Orthotists need to complete an order form detailing the patient's condition, main complaint and treatment objective together with basic measurements including: Spinal lengths (T4-T12 & T1- Coccyx), Chest, Hip and Thigh circumferences.

Each brace ordered will be supplied with one thoracic component (bolero), one set of four corrective bands and three sets of shorts for hygienic and practical reasons.

Orders may only be accepted from orthotists who have completed the necessary training modules.

## Coding Information:

We recommend you consider coding the Adult SpineCor® Pain Relief Back Brace with a base code of L1005. The responsibility for accurate coding lies with the patient care facility that is billing for the product and service. The HCPCS Alpha-Numeric System is subject to revisions and periodic updates and should be consulted prior to billing.

Patented Product US Pat # 5,599,286 Additional Patents Pending.

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