



# Extentrac<sup>®</sup> Elite

Innovative Spine Care Technology



- Operating in compliance with ISO 13485:2016
- US FDA 510 (k) K031996, K980021
- Approved patient weight 300 lbs.
- Protected under U.S. & international patents
- Additional patents pending

# Extentrac<sup>®</sup> Elite

Extentrac<sup>®</sup> Elite is a patented, FDA cleared, multi-functional therapeutic device for treatment of patients suffering from severe low back pain and sciatica due to:

- **Protruding or Herniated Intervertebral Discs**
- **Acute Facet Problems**
- **Degenerative Disc Disease**

## The World's Most Versatile Therapeutic Device

Beginning with the concept that no one specific treatment method, patient position, or protocol fits all patient needs, Extentrac<sup>®</sup> Elite has been designed to provide the broadest range of capabilities, including:

- Hands-on manual therapy and/or automated treatments
- M3D<sup>®</sup> Patient Positioning - Vertical or horizontal, in either the prone or supine position, flexion-distraction, extension, lateral flexion, and rotational circumduction
- Axial and multi-directional disc decompression

This unique range of capabilities allows the clinician to decide the best course of treatment, based upon evidence-based single treatment protocols\*, combinations of treatment protocols, and/or M3D<sup>®</sup> protocols developed specifically for the Extentrac<sup>®</sup> Elite.

\*Flexion, Flexion Distraction, Extension, Gravitational, and Decompression Protocols - See website for studies

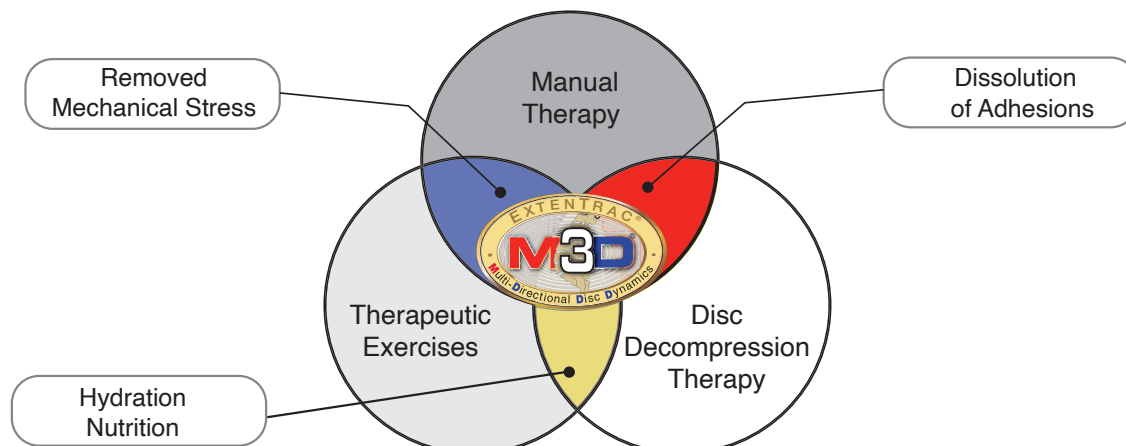
## Innovate with M3D<sup>®</sup> (Multi-Directional Disc Dynamics) Therapy

M3D<sup>®</sup> Therapy provides the clinician the ability to innovate utilizing the appropriate combination of modalities based upon patient needs, in order to provide the optimal clinical outcome.

**Manual Therapy** - Hands-on, one-on-one direct patient contact techniques such as mobilization, range of motion and flexion-distraction.

**Therapeutic Exercises** - Exercises to develop strength and endurance with patient in flexion, extension, and lateral flexion positions.

**Disc Decompression Therapy** - Axial and M3D<sup>®</sup> disc decompression to reduce pain and restore neurological function.



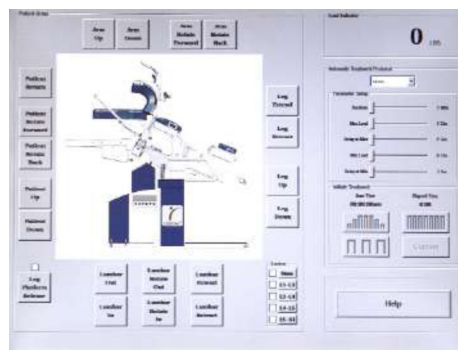
# Hands-On Manual Therapy and Fully Automated Decompression

Unlike traditional devices which are designed solely to be “hands-off”, Extentrac<sup>®</sup> Elite is designed to be a clinician’s tool, allowing for manual “hands-on” therapy as well as automated decompression.

## HANDS-ON THERAPY



## AUTOMATED DECOMPRESSION



## M3D<sup>®</sup> Patient Positioning

Patient positioning for treatment requires more than a “one position, fits all” device. For example, acute patients in severe myospasm may require treatment options that afford flexion-decompression postures in the prone position. Chronic or sub-acute patients may conversely require supine extension-decompression techniques. Some patients may benefit most from gravitational protocols. For this reason Extentrac<sup>®</sup> Elite offers supine and prone, vertical and horizontal positioning, with unlimited angles in between. Patient access, both on and off the device, is made easy by means of the vertical position.

Vertical through horizontal, flexion, extension, lateral flexion, and M3D<sup>®</sup> lumbar positioning is available. All rotational angles in between can be set, and the device may be used to produce rotational circumduction of the legs about the waist.

### VERTICAL



SUPINE



PRONE

### HORIZONTAL



SUPINE



PRONE

### LATERAL FLEXION



### LUMBAR



*Extentrac<sup>®</sup> Elite is the only multi-functional therapeutic device providing this complete range of patient positioning, allowing the clinician to choose the optimum position to apply manual “hands-on” therapy and/or decompression therapy.*

# Clinical Study Summary

## Overview

A practice based prospective study of 31 consecutive patients with low back pain with or without radiculopathy utilizing the Extentrac<sup>®</sup> Elite and M3D<sup>®</sup> therapy. Each patient completed the Oswestry Low Back Pain Disability Questionnaire (ver 2) pre and post treatment. Outcome measurement was based upon the Oswestry Disability Index (ODI).

Oswestry Disability Index (ODI) [0-100%]

81-100% Bed bound (or exaggerating symptoms)

61-80% Crippled

41-60% Severe disability

21-40% Moderate disability

0-20% Minimal Disability

## Pre-Treatment

84% (26 of 31) patients had a minimum ODI of 41% (severe disability or worse)

## Treatment

Based upon each patient's diagnosis, the Extentrac<sup>®</sup> Elite with M3D<sup>®</sup> treatment was applied.

Average number of treatments: 11

## Post-Treatment Summary of Data

The following table provides the number of patients within pre-treatment ODI ranges, and the number of patients within each post-treatment ODI range per each pre-treatment ODI range.

		Post-treatment ODI							
Pre-treatment ODI		81-100%	61-80%	41-60%	21-40%	0-20%	Mean abs $\Delta$ ODI* (pts)	Mean $\Delta$ ODI** (%)	
81-100%	1	0	0	0	1	0	52.0% pts	59.1%	
61-80%	10	0	0	2	5	3	40.7% pts	59.1%	
41-60%	15	0	0	3	5	7	22.1% pts	46.0%	
21-40%	3	0	0	0	1	2	15.3% pts	48.9%	
0-20%	2	0	0	0	0	2	13.0% pts	72.2%	
Total	31	0	0	5	12	14	27.8% pts	53.0%	

\*Mean (average) absolute percentage point change in ODI [ Pre ODI – Post ODI]

\*\* Mean (average) percentage change in ODI [ (Pre ODI – Post ODI) / Pre ODI]

## Outcomes

- 94% (29 of 31) patients experienced an improvement of at least 6% points, where 6% points is defined to be the Minimum Clinically Important Difference (MCID)<sup>1</sup>
- Mean (average) absolute % improvement in ODI was 27.8% points (greater than 4.5X the MCID)
- Mean (average) percent improvement in ODI was 53.0%

1. Julie M Fritz and James J Irrgang. A Comparison of a Modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. PHYS THER. 2001; 81:776-788.



## Case Studies



**Patient:**

15 Year Old Gymnastics Student

**Symptom:**

Low Back Pain

**Diagnosis:**

Chronic Lumbar Strain/Lumbar Spasms

**Treatment:**

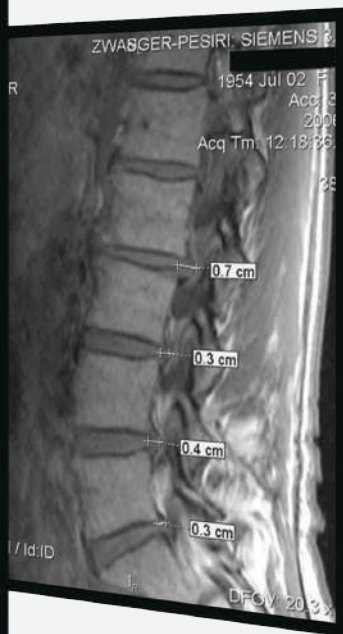
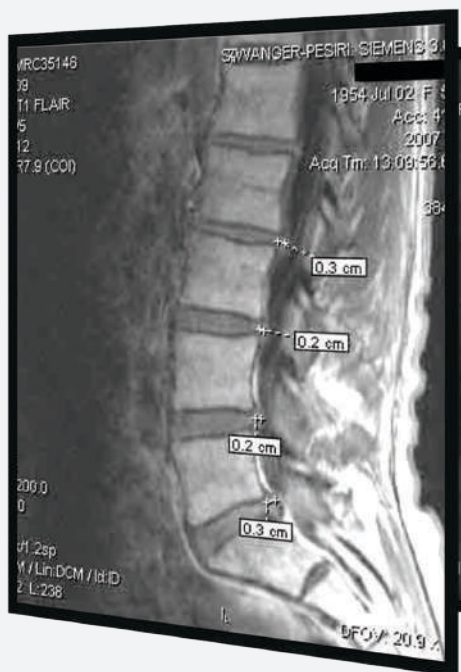
Prone Position, M3D<sup>®</sup> Protocols Utilizing Extentrac<sup>®</sup> Elite

**Number of Visits:**

10 Fifteen Minute Treatments

**Results:**

No More Pain/More Flexibility



**Patient:**

53 Year Old Female

**Symptom:**

Lower Back Pain/Sciatica

**Diagnosis:**

Multi-Level Disc Herniation

**Treatment:**

Supine Position, M3D<sup>®</sup> Protocols Utilizing Extentrac<sup>®</sup> Elite

**Number of Visits:**

18 Fifteen Minute Treatments

**Results:**

Asymptomatic with Reduction in Size of Disc Herniations

See website for more information.

## Innovation



For over 20 years, Dr. David F. Cuccia has worked with spine care specialists from around the world to develop the world's most versatile back therapy device... Extentrac® Elite.

At the heart of the device are its lumbar and leg assemblies which enable the application of precise therapeutic decompression and evidence-based treatment protocols from multiple angles and directions in flexion, extension, lateral flexion, and axial positions prior to decompression.

## Key Features

- 1 15.6" Touchscreen Computer Automated or Manual Treatment Cycles.
- 2 Fully Adjustable Contoured Underarm Supports.
- 3 Cushioned Hand Support.
- 4 M3D Adjustable Lumbar Assembly for Precise Spine Positioning and Lumbar Mediated Decompression.
- 5 M3D Adjustable Leg Assembly for Precise Spine Positioning During Leg Mediated Decompression, Mobilization and Spinal Ranges of Motion.
- 6 Power Adjustable Overhead Exercise Bar with Patient Control Switches for Supervised Participation in Decompression, Therapeutic Protocols and Exercise.
- 7 Adjustable Head/Thoracic Back Support Cushion
- 8 Split Table Design with Friction-Free Lumbar Support.
- 9 Fully Rotatable Patient Treatment Platform for Easy Patient Positioning.
- 10 Patient Hand Control Bar with Control Switches for Supervised Patient Participation in Decompression.
- 11 Practitioner Leg Bar with Control Buttons For Precise Hands-On Manually Applied Therapeutic procedures.



## Accessories

Included : Foot Rest, Ankle Cuffs, Complete Harness set with Belts.

## Frequently Asked Questions

### Q: How much time is taken for each treatment?

A: Unlike devices with limited capability and protocol options, Extentrac<sup>®</sup> Elite's versatility provides for a broad range of treatment options based upon the clinician's determination of the appropriate protocol(s) best suited to individual patient need. Some patients are best treated with manual therapy, some automated decompression, and some both. Treatment times typically vary from 10 minutes to 20 minutes, with the overall average being approximately 15 minutes.

### Q: How many treatments are typical for each patient?

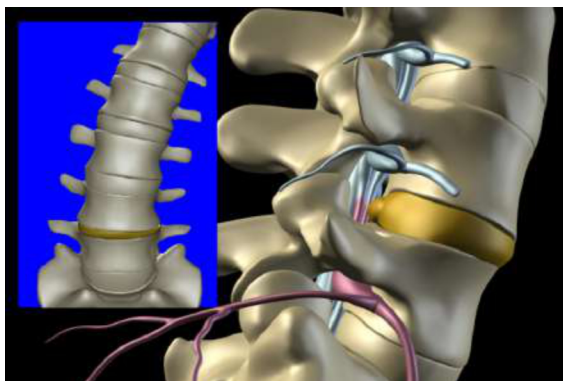
A: Number of treatments is determined by the clinician based upon individual patient need. The typical range is 10-20 treatments per patient, with 20 being for those patients presenting more severe pathology, such as spinal stenosis, multi-level disc herniations, and severe degenerative disc & joint disease. Patients with less severe cases achieve desired results in fewer than 10 treatments. The average for a given clinician will depend upon the patient diagnosis mix with the overall average being approximately 12.

### Q: Why is M3D<sup>®</sup> patient positioning important for disc decompression therapy?

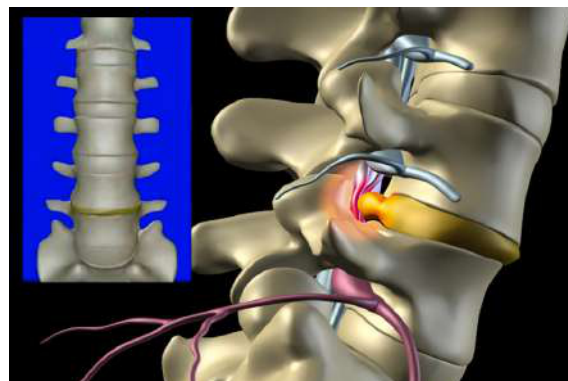
A: With Extentrac<sup>®</sup> Elite, patient positioning for treatment goes beyond the traditional "one position fits all" concept. While the linear axial position is an appropriate treatment position for certain spinal conditions, the vertebral column is a three-dimensional structure housing a network of spinal nerves. In many cases, the typical herniation/protrusion which impinges upon a nerve root is not central, but is lateral or medial. Therefore achieving the optimal antalgia position prior to and during decompression often requires three-dimensional positioning.

For example, a patient presenting a lateral disc herniation impinging upon a descending nerve assumes a position of antalgia, in which flexion and lateral flexion reduces their severe back and leg pain (image on the left). In this case, application of strictly linear axial decompression forces the herniation into the nerve root during treatment, impinging upon the nerve and causing pain (image on the right). Utilizing M3D<sup>®</sup> patient positioning to maintain the antalgia position prior to and during decompression allows for decompression with significantly reduced pain and irritation to the nerve root during treatment.

Antalgia Position (pre and during decompression)



Linear Position (forced by axial decompression)



Over the course of treatment, changes in the patient's position of antalgia can be accommodated for based upon the flexibility of Extentrac's M3D<sup>®</sup> patient positioning.

## Technical Specifications

### Device Dimensions

Maximum Height: 96" (2.5 m)  
(patient bed vertical, full extension)

Maximum Length: 96" (2.5 m)  
(patient bed horizontal, full extension)

Maximum Width: 96" (2.5 m)  
(monitor on left, full lateral flexion right)

### Motion Range

Leg Distraction: 9" (23 cm)

Lumbar Distraction: 9" (23 cm)

Lateral Flexion: 30°  
(each direction)

**Device Weight:** 1,100 lbs. (500 kg)

**Maximum Patient Weight:** 300 lbs. (160 kg)

**Maximum Distraction Force:** 200 lbs. (890 N)

### Electrical Specification

Voltage: 110/120 or 220/240

Amps: 15.0 / 7.5

Frequency: 50/60 Hz Single Phase

**Upholstery:** Naugahyde



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