

INSURANCE

WILL MY INSURANCE COMPANY PAY FOR THE DEVICE?

Insurance policies are different depending on the plan you have chose. The bone growth stimulator is covered by the majority of health plans and workers compensation plans, including Medicare; specific coverage criteria must be met.

DOES DJO PREAUTHORIZE THE DEVICE WITH MY INSURANCE COMPANY?

If pre-authorization is required, DJO will verify your eligibility and benefit levels to obtain a pre-authorization from the payer of record.

WHAT HAPPENS IF MY INSURANCE COMPANY DENIES THE CLAIM?

In the event the insurance carrier denies coverage, the claim will be forwarded to our appeals processing department on your behalf. Depending upon the outcome, DJO may contact you to arrange payment options.

ADDITIONAL

WHO DO I CALL IF I HAVE A QUESTION?

Customers may call the DJO Customer Care Service line: 1-800-263-6004

Accelerated Fusion in Only 30 Minutes

CMF SpinaLogic® Bone Growth Stimulation



CMF SPINALOGIC® BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION

INDICATION: CMF SpinaLogic® is a portable, battery powered, microcontrolled, noninvasive bone growth stimulator indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels.

CONTRAINDICATIONS: Demand-type pacemaker and implantable cardioverter defibrillator (ICD) operation may be adversely affected by exposure to combined static and dynamic magnetic fields. Physicians should not prescribe CMF SpinaLogic for patients with such devices. The safety and effectiveness of CMF SpinaLogic in pregnant women have not been studied, and the effects of the device on the mother or the developing fetus are unknown. Thus, this device should not be used in pregnant women. If a woman becomes pregnant during treatment with CMF SpinaLogic, treatment should be discontinued immediately.

PRECAUTIONS: The safety and effectiveness of the use of this device on individuals lacking skeletal maturity have not been established. The safety and effectiveness of this device in treating patients with the following conditions have not been established and therefore the safety and effectiveness of the device in these individuals are unknown: osseous or ligamentous spinal trauma, spondylitis, Paget's disease, severe osteoporosis, metastatic cancer, renal disease, and uncontrolled diabetes mellitus. Animal studies conducted to date do not suggest any long term adverse effects from use of this device. However, long term effects in humans are unknown. Compliance with the treatment schedule, timely battery change and proper care of the device are essential. The device will not perform properly and treatment may be unnecessarily prolonged if the patient fails to adhere to the care routine. This device should not be used if there are mental or physical conditions which preclude patient compliance with the physician and device instructions.

ADVERSE EFFECTS: No known significant adverse effects have resulted from the use of this device. Clinical studies, animal studies, and tissue culture experiments conducted with CMF SpinaLogic Bone Growth Stimulator magnetic fields have not indicated any evidence of significant adverse effects.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician. For full prescribing information, contact DJO, LLC.

For more information contact
your local sales representative or call
DJO Customer Service: 800.263.6004
www.djoglobal.com/cmfi

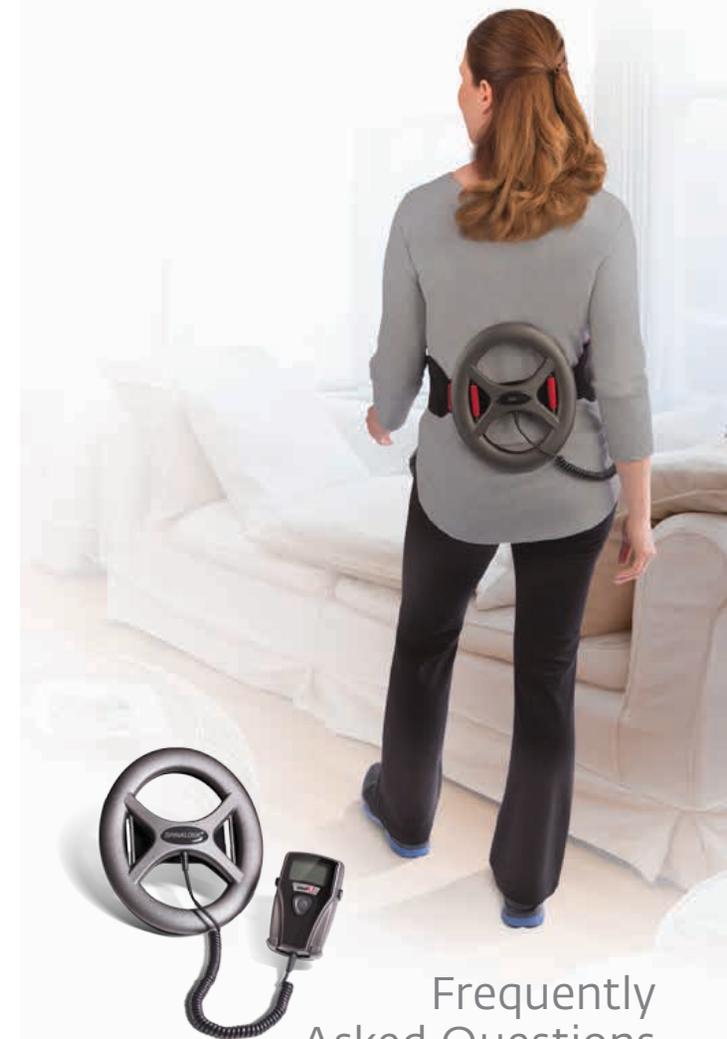


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Accelerated Fusion in Only 30 Minutes

CMF SpinaLogic® Bone Growth
Stimulation



Frequently
Asked Questions



USE

WHAT IS THE CMF SPINALOGIC BONE GROWTH STIMULATOR AND HOW WILL IT HELP ME?

The SpinaLogic bone growth stimulator is a safe, nonsurgical treatment which your physician has prescribed to aid the healing of your fusion. The stimulator uses a very low-strength Combined Magnetic Field (CMF) to activate the body's natural healing process. When a human bone is bent or broken, it generates an electrical field. This low level electrical field activates the body's internal repair mechanism, which in turn stimulates bone healing. In some patients, this healing process is impaired or absent. The fusion may not mend properly, and a pseudoarthrosis results. The bone growth stimulation provided by DJO has proven very successful in treating spinal fusions.

HOW DOES THE CMF SPINALOGIC WORK?

The CMF SpinaLogic generates a low level magnetic signal at the fusion site. These very specific electromagnetic fields help stimulate the bone cells at your fusion site. CMF is unlike other bone growth stimulators on the market as the CMF technology operates continuously within the optimal range of electromagnetic frequencies for bone growth stimulation. The unit may be worn over a cast, external fixation, orthopedic brace, or clothing without lessening its effectiveness.

IS CMF SPINALOGIC SAFE?

Yes. The CMF signal emitted by the SpinaLogic is less than the strength of the earth's magnetic field. However, CMF is very specific and potent in its ability to help promote the natural bone growth process at your fracture site. Furthermore, there are no known side effects related to the use of this device. Thousands of patients have worn SpinaLogic to heal their spine fusions. SpinaLogic may be safely used with fixation devices, such as screws, plates, or pins.

HOW OFTEN WILL I NEED TO CHANGE THE BATTERY?

The SpinaLogic will be delivered with approximately 9 months worth of batteries. A low battery symbol will appear on the LCD screen on your remote indicating when the batteries should be changed.

CMF Bone Growth Stimulation spinal fusions provides a proven, convenient solution to accelerate the healing of your spinal fusion



The CMF signal continuously operates within frequencies optimal to heal bone.



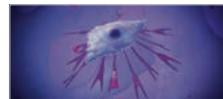
This potent signal allows for a single 30-minute per day treatment.



And is specifically targeted to the osteoblast cell.



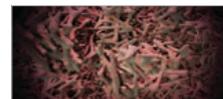
This signal targets the endogenous production of IGF-II, a key growth factor in the formation of bone.



IGF-II protein is recruited through calcium ion channels and receptors on the cell membrane.



The resulting increase in IGF-II growth factor helps promote cell division.



CMF was specifically designed for a once daily treatment to best mimic cell replication.



As the cells continue to divide and regular treatment progresses, the body is able to heal.

WEAR

DO I NEED TO WEAR THE CMF SPINALOGIC AT THE SAME TIME EACH DAY?

The unit will allow one 30 minute treatment per day. You have the flexibility to receive your treatment at any time you choose. It is recommended to be worn approximately the same time each day.

CAN I WEAR THE CMF SPINALOGIC WITH A TENS UNIT OR CARDIAC PACEMAKER?

SpinaLogic can be used with a TENS unit, however, the device may interfere with demand type pacemakers. If you wear a pacemaker, you should consult your doctor before using SpinaLogic.

CAN I WEAR THE CMF SPINALOGIC IF I AM PREGNANT?

The effect of CMF treatment has not been studied during pregnancy or nursing. Therefore, if you are pregnant or nursing, you should consult your doctor before using SpinaLogic.

CAN I BRING MY CMF SPINALOGIC ON AN AIRPLANE?

Yes. In advance of your travel, you may request a letter from our Customer Service Support department that will explain what the device is and how it operates. This letter can be presented to the appropriate airport personnel, though this option will be subject to airline security. You should also keep your user manual available to quickly and easily identify the device for any security personnel. We recommend administering your 30-minute treatment prior to going through security, this will ensure when moving through the x-ray and imaging devices, that the unit cannot be turned on for the magnetic fields to interfere.

TREATMENT

WHAT WILL CMF SPINALOGIC TREATMENT FEEL LIKE? HOW WILL IT AFFECT MY DAILY ACTIVITIES?

You should not feel the CMF therapy during the treatment. The SpinaLogic unit is lightweight and adjustable for a comfortable fit. It is powered with a battery, which allows the unit to be portable. You can sit, stand, sleep, walk, recline, and drive while using SpinaLogic. With your physician's approval, you can resume a normal activity level.

WHAT IS MY DAILY TREATMENT TIME WITH THE CMF SPINALOGIC?

The SpinaLogic treatment is simple, only 30 minutes per day.

HOW LONG WILL IT TAKE TO HEAL USING THE CMF SPINALOGIC?

The healing process determines the duration of the treatment, and your physician will closely monitor your progress. To promote healing, it is very important that you wear SpinaLogic daily as prescribed. Your doctor may require that you bring your unit in on your follow-up visits to check your compliance. Although your treatment may vary, most patients wear the device between four and eight months.

WHAT DO I DO WITH THE DEVICE WHEN I AM DONE USING IT?

After your treatment is complete and your doctor says you no longer need to use your CMF SpinaLogic, you may dispose of the device yourself according to your local governing ordinances and recycling plans. You may also contact our Customer Support department for help with device disposal. The CMF SpinaLogic and CMF OL1000 are not reusable. Each device is for single patient use only and cannot be re-sold or used on multiple patients.

