

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



CMF OL1000 BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION

INDICATION: Noninvasive treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

CONTRAINDICATIONS: Use of this device is contraindicated in individuals having a synovial pseudarthrosis. Demand-type pacemaker or implantable cardioverter defibrillator (ICD) operation may be adversely affected by exposure to magnetic fields. Physicians should not prescribe CMF OL1000 for applications that may place the treatment transducers in close proximity to the pacemaker. Further screening by the attending cardiologist is recommended (such as with an electrocardiogram). CMF OL1000 should not be used in the presence of external or internal fixation devices that are constructed from magnetic materials. (NOTE: Almost all fracture fixation devices implanted today are made from non-magnetic materials.)

WARNINGS: The safety and effectiveness of the use of this device on individuals lacking skeletal maturity have not been established. Animal studies conducted to date do not suggest any long-term significant adverse effects from use of this device. However, long-term effects in humans are unknown. Teratological studies have not been performed with this device. The safety of use of this device during pregnancy or nursing in humans has not been established.

PRECAUTIONS: Weight bearing is not advised in the presence of extreme motion at the nonunion site. In the presence of a malaligned nonunion, careful consideration of the use of this device must be undertaken on an individual basis, as treatment with this device is not intended to alter or affect the degree of malalignment. The safety and effectiveness of the use of this device on individuals with nonunion secondary to, or in conjunction with, a pathological condition have not been established. This device should not be used if there are mental or physical conditions that preclude patient compliance with the physician and device instructions. When conditions of atrophy are present or when fractures have remained unhealed for long periods of time, there may be less successful results.

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 the OL1000, which has the same treatment signal as the OL1000 SCI, have not indicated any evidence of significant adverse effects.

CAUTION: Federal law (U.S.A. and Canada) restricts this device to sale, distribution or use by or on the order of a physician.



Fast Track Bone Healing in Only 30 Minutes

CMF OL1000™ Bone Growth Stimulation



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



Frequently
Asked Questions

Fast Track Bone Healing in Only 30 Minutes

CMF OL1000™ Bone Growth Stimulation



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Together in Motion™



USE

WHAT IS THE CMF OL1000 BONE GROWTH STIMULATOR AND HOW WILL IT HELP ME?

The OL1000 bone growth stimulator is a safe, nonsurgical treatment which your physician has prescribed to aid the healing of your fracture. 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 fracture may not mend properly, and a nonunion results. The bone growth stimulation provided by DJO has proven very successful in treating nonunion fractures.

HOW DOES THE CMF OL1000 WORK?

The CMF OL1000 generates a low level magnetic signal at the fracture site. These very specific electromagnetic fields help stimulate the bone cells at your fracture 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 OL1000 SAFE?

Yes. The CMF signal emitted by the OL1000 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 OL1000 to heal their nonunions. OL1000 may be safely used with fixation devices, such as screws, plates, or pins.

HOW OFTEN WILL I NEED TO CHANGE THE BATTERY?

The OL1000 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.

WEAR

DO I NEED TO WEAR THE CMF OL1000 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 OL1000 WITH A TENS UNIT OR CARDIAC PACEMAKER?

OL1000 can be used with a TENS unit, however, based on the location of your fracture, the device may interfere with demand type pacemakers. If you wear a pacemaker, you should consult your doctor before using OL1000.

CAN I WEAR THE CMF OL1000 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 OL1000.

CAN I BRING MY CMF OL1000 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 OL1000 TREATMENT FEEL LIKE? HOW WILL IT AFFECT MY DAILY ACTIVITIES?

You should not feel the CMF therapy during the treatment. The OL1000 unit is lightweight and adjustable for a comfortable fit. It is powered with a battery, which allows the unit to be portable. With your physician's approval, you can resume a normal activity level.

WHAT IS MY DAILY TREATMENT TIME WITH THE CMF OL1000?

The OL1000 treatment is simple, only 30 minutes per day.

HOW LONG WILL IT TAKE TO HEAL USING THE CMF OL1000?

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 OL1000 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 OL1000, 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 OL1000 and CMF SpinaLogic are not reusable. Each device is for single patient use only and cannot be re-sold or used on multiple patients.



CMF OL1000

CMF Bone Growth Stimulation for long bone fracture delivers a quick, convenient solution, helping patients make a fast return to their normal activities.



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.