PATIENT APPLICATION
CMF™ OL1000™ Bone Growth Stimulator

USING YOUR CONTROL UNIT

This is your control unit—this control unit consists of an LCD display and a button. To begin your treatment, press the "push button" below the LCD screen, holding it down until it beeps. A record of your treatment will be displayed until it beeps.

The 30-minute treatment countdown will begin as shown here. When using the device, the LCD screen will continue to show the time remaining on your daily treatment. You should complete your entire 30-minute treatment in one session.

After 30 minutes, the "treatment complete" icon will appear as a smile face on the display—the device will beep twice and automatically shut off.

At any time, you may check your treatment record by pressing the push button once, quickly, before it beeps. The LCD screen will show you two numbers. The number in the upper left-hand corner is the number of days you have successfully treated. The number in the upper right-hand corner is the number of days since you first used the device.

If your daily treatment has already been completed for that day, the treatment record will be shown followed by the treatment complete smile face.

INSERTING/REPLACING YOUR BATTERIES

When it is time to replace your battery, the treatment screen on your control unit will show a picture of a low battery. Never change the batteries when the device is running. Your carrying case will contain additional 9V batteries for your use. Remove any plastic from the new battery before replacing. Remove the battery cover from the back side of the control unit. The battery compartment has been designed to prevent the incorrect installation of the batteries. It is labeled with the correct polarity configuration to ensure proper insertion. Install the battery as shown and replace the battery cover on the control unit. Your device is now ready for use.

You should only use batteries supplied by DJO®. Additional information about the proper handling of batteries can be found in your user manual provided by your representative or found in your device carrying case.

WARNING: Battery operated device (9V alkaline battery), not to use lithium batteries.

APPLYING YOUR DEVICE

Remove the device and control unit from the case. The OL1000™ bone growth stimulator may be applied to a number of different fracture types. Your representative will choose the device suited best to your injury.

Place device centered around your broken bone. If you have a cast, brace or external fixator, you may remove the foam pads from the OL1000 for a better fit. A strap can be used but is not necessary for the device to function. Close the strap if you have chosen to use one.

It is recommended, though not necessary, that you remain stationary for the duration of your treatment.

It is important to ensure the device is positioned properly over your fracture for the duration of your treatment. You are now ready to operate your device.

Additional information about the OL1000 & OL1000SC can be found in your user manual provided by your representative or found in your device carrying case.

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 cardiovertor 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™ SC1, 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.

CMF™ OL1000™ Postmarket Patient Registry Data

CMF™ OL1000™ Bone Growth stimulator Post market Patient Registry Data: As of June 30, 1998, the CMF™ OL1000™ had been applied to 5300 patients with physician diagnosed nonunion with varying times from injury, two months or greater. Patient registry data was collected from December 1994 to December 1998. At the time of database closure, we expected follow-up on 4100 patients and received follow-up on 2370 patients (57.8%). Physician diagnosed healing determined patient outcome in the patient registry. All patients were treated for 30 minutes per day, and devices were programmed to provide a maximum of 270 days of treatment. The results of these 2370 patients are presented above.

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