Combined magnetic field for successful fracture healing.**

- Five different-sized coils to address anatomical variability.
- Can be applied over a cast, brace, or clothing.
- Built in compliance tracking.
- One button technology for ease of use.
- Experienced customer support team available to all patients.
- Personalized service by highly trained account representatives available to size, fit and train patients.

CMF™ OL1000™
Bone Growth Stimulation

Business Card Here

DJO, LLC | A DJO Global Company
T 800.336.6569 | F 800.936.6569
1430 Decision Street | Vista, CA 92081-8553 | U.S.A.
www.djoglobal.com/cmf

Individual results may vary. This therapy is not for everyone. Please consult your physician. A prescription is required. For more information, please call DJO at 888-624-5450. Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

MKTOO-6545 Rev A

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 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, longterm 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.

** The success rate of 51/84 patients in pre-marketing clinical data was 60.7% and was maintained at 2 years post treatment with 90% follow-up of all healed fractures. In the pre-marketing clinical data was 60.7% and was maintained at 2 years post treatment with 90% follow-up of all healed fractures. In the pre-market study non-union was considered to be established when a minimum of nine months had elapsed since injury and the fracture site showed no visibly progressive sighs of healing for a minimum of 3 months. Patient success was defined as three out of four corticies bridged on radiographic and no pain or motion at the fracture site. For additional detailed information on pre-market prospective study, contact DJO.

A technology designed to encourage the

MOST ACTIVE LIFESTYLE...

30 MINUTES
USE PER DAY

- The **MOST** current electrical bone growth stimulation technology.[1]
- The **MOST** relevant scientific evidence.[2]
- The **MOST** clinically effective electrical stimulator at 30 minutes use per day.[3]

DJO Global's® CMF™ Bone Growth Stimulator Offers

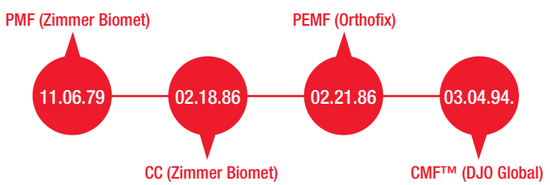
THE MOST CURRENT ELECTRICAL BONE HEALING TECHNOLOGY ON THE MARKET.

CMF™ technology entered the bone healing market in March of 1994 at 30 minutes wear time per day.

The most current electrical technology means that researchers used previous technologies in order to optimize the signal used for bone healing.

Several other electrical technologies require longer wear time to achieve successful results.

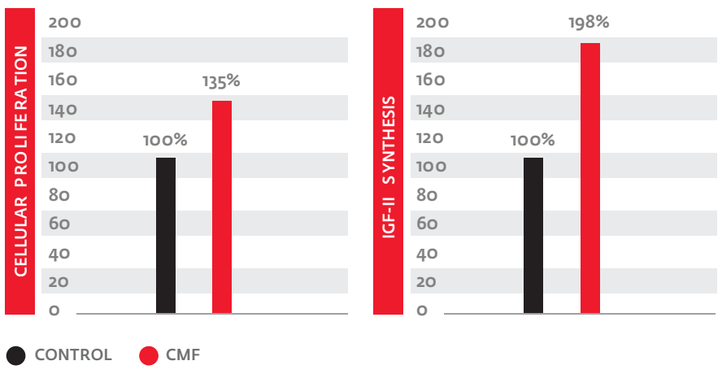
CMF™ operates within the optimal range for bone healing, meaning that patients need only wear their device for 30 minutes per day to achieve clinical benefits.



[1]Based on comparison of FDA approval dates for all electrical stimulators. [2]Based on and compared to all evidence supporting 30 minutes CMF™ weartime.[3] CMF™ OL1000™ is the only electrical stimulation technology indicated for 30 minutes use in the noninvasive treatment of an established nonunion fracture acquired secondary to trauma, excluding all vertebrae and flat bones. [4] Dates represent first FDA approval of technology – technology may have been approved for other products at later dates. [5] McLeod, K.J., Rubin, C.T., The Effect of Low Frequency Electrical Fields on Osteogenesis. J. Bone Joint Surg., 74A: 920 – 929, 1992. [6]Ryaby, J.T., et al., The Role of Insulin-like Growth Factor in Magnetic Field Regulation of Bone Formation, Bioelectrochemistry and Bioenergetics, 35: 87-91, 1994. [7]The only technology approved and with clinical evidence at 30 minutes per day. [8] FDA-approved DonJoy OL1000™ postmarket Patient Registry Data, P910066/S013, April 1999.

Scientific evidence supporting CMF™ is often considered the MOST relevant...

After testing multiple hypotheses, researchers determined that maximum bone cell response occurred within frequencies similar to those generated intrinsically by functional activity. They noted, "Resorption of bone is lowest and new-bone formation is greatest when the power of the induced electric fields is concentrated in the very low-frequency range" (15Hz -150Hz).[5]



Further research in various frequencies impact on bone cell response showed the optimal frequency for bone healing to be 76.6Hz, the frequency now offered by the CMF™ bone growth stimulator system.[6]

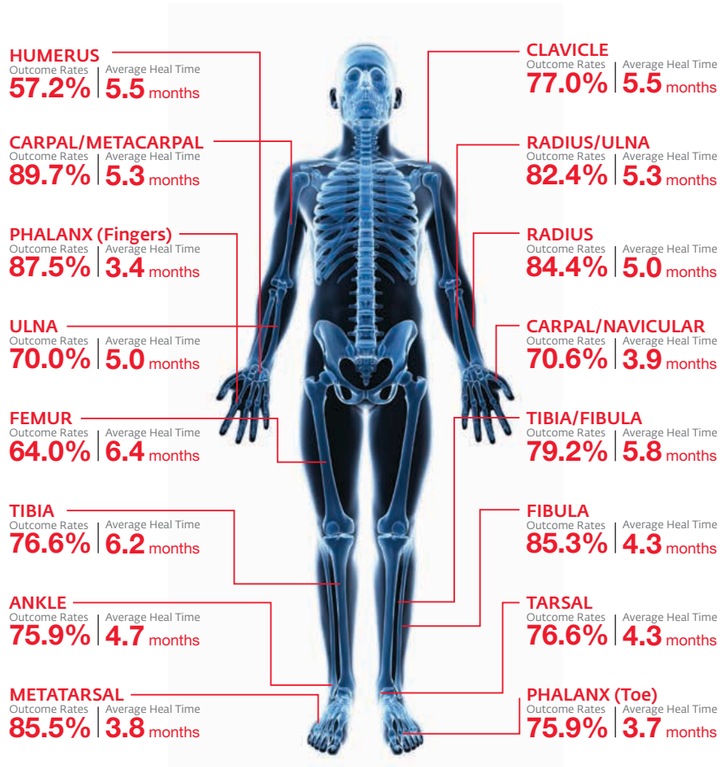
Just 30 minutes exposure to 76.6Hz increased the volume of IGF II molecules and receptors. An increase in both have been correlated to an amplified increase in cell proliferation.

Increase in cell proliferation and IGF Synthesis when exposed to 30 minutes 76.6Hz (CMF™).

CMF™ OL1000™ POSTMARKET PATIENT REGISTRY DATA

CMF™ Technology is the most clinically effective electrical bone growth stimulator at 30 minutes per day.[7]

CMF™ OL1000™ has proven success rates as high as 89% in 30 minutes of treatment per day.[8]



TOTAL (Postmarket) | Outcome Rates: **75.1%**