TOUGH BREAK

Smarter electrical stimulation technology to help resolve nonunion fractures
Data estimate of the overall risk of nonunion following a fracture to be up to 12% depending on the anatomical location of the fracture and patient-specific risk factors.

At DJO®, we love solving the difficult problems. It took time and commitment to offer doctors and patients dealing with a tough break another option than additional surgeries or living with the pain. OL1000™ is a bone growth stimulator that is specifically designed to help fractures with a high risk of prolonged union or nonunion and patients with conditions that can inhibit proper bone unionization.

Factors that increase risks of nonunion

The American Academy of Orthopedic Surgeons notes the following factors that increase the risk of nonunion:

- Nicotine/Tobacco use
- Older age
- Severe anemia
- Diabetes
- Low Vitamin D levels
- Hypothyroidism
- Poor nutrition
- Certain medications
- Infection
- A complicated break that is open or compound

Documented tibial nonunion fracture rate 23%

Rate of open nonunion fractures with extensive soft tissue damage 16%

Observed rates of femoral shaft nonunion with the use of IM nailing 8%
Smarter Technology: Early researchers determined that maximum bone cell response occurred within frequencies similar to those generated intrinsically by functional activity (0-150Hz). Further research showed 76.6Hz to be the more efficient frequency for bone healing—the frequency offered by the OL1000™.

Other electrical bone growth technologies claim similar outcomes, but operate across a wider spectrum of frequencies. For example, imagine trying to catch water in a cup with a rotating lawn sprinkler: Ultimately, some of the water finds its way into the cup, but it is extremely inefficient. OL1000 is like a steady stream of water focused exclusively on the cup.

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

Designed for patient success

- 30 minute wear time
- Lightweight device with cushion strap designed for patient comfort
- Can be applied over a cast, brace, or clothing
- 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

djoglobal.com/Regeneration

OL1000™ was designed for success to aid tough fractures
**OL1000™ BONE GROWTH STIMULATION**

**BRIEF PRESCRIBING INFORMATION**

**INDICATION:** OL1000™ 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 OL1000 for patients with such devices. The safety and effectiveness of OL1000 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 OL1000, 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 OL1000 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.

1. DJO CMF PMA P910066/S005, May 1997
7. Signal shown in red represents 76.6Hz frequency emitted by CMF Technology
10. Based on actual frequencies of other technologies (1-50,000Hz, 60,000Hz)