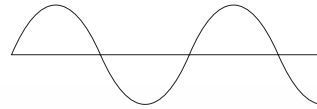




TOUGH BREAK

Smarter electrical stimulation
technology to help resolve
nonunion fractures¹



CHALLENGE ACCEPTED

OL1000™ was designed to help
treat tough fractures¹



OL1000™

89%

Success rate as high as 89.7%
in treating nonunion fractures²

The risk of nonunion following a fracture is estimated to be up to 12% depending on the anatomical location of the fracture and patient-specific risk factors.⁵

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. High risk patients can have conditions that can inhibit proper bone unionization, causing nonunions. OL1000™ is a bone growth stimulator that is specifically designed to help heal nonunion fractures.¹

Factors that increase risks of nonunion⁴

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

23%

Documented tibial
nonunion fracture rate³

16%

Rate of open nonunion fractures
with extensive soft tissue damage⁵

8%

Observed rates of femoral shaft
nonunion with the use of IM nailing³

CHALLENGE ACCEPTED

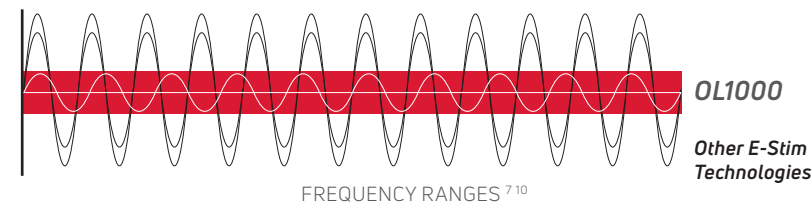
OL1000™ was designed to help
treat tough fractures¹



OL1000™

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™.^{6,9}

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.

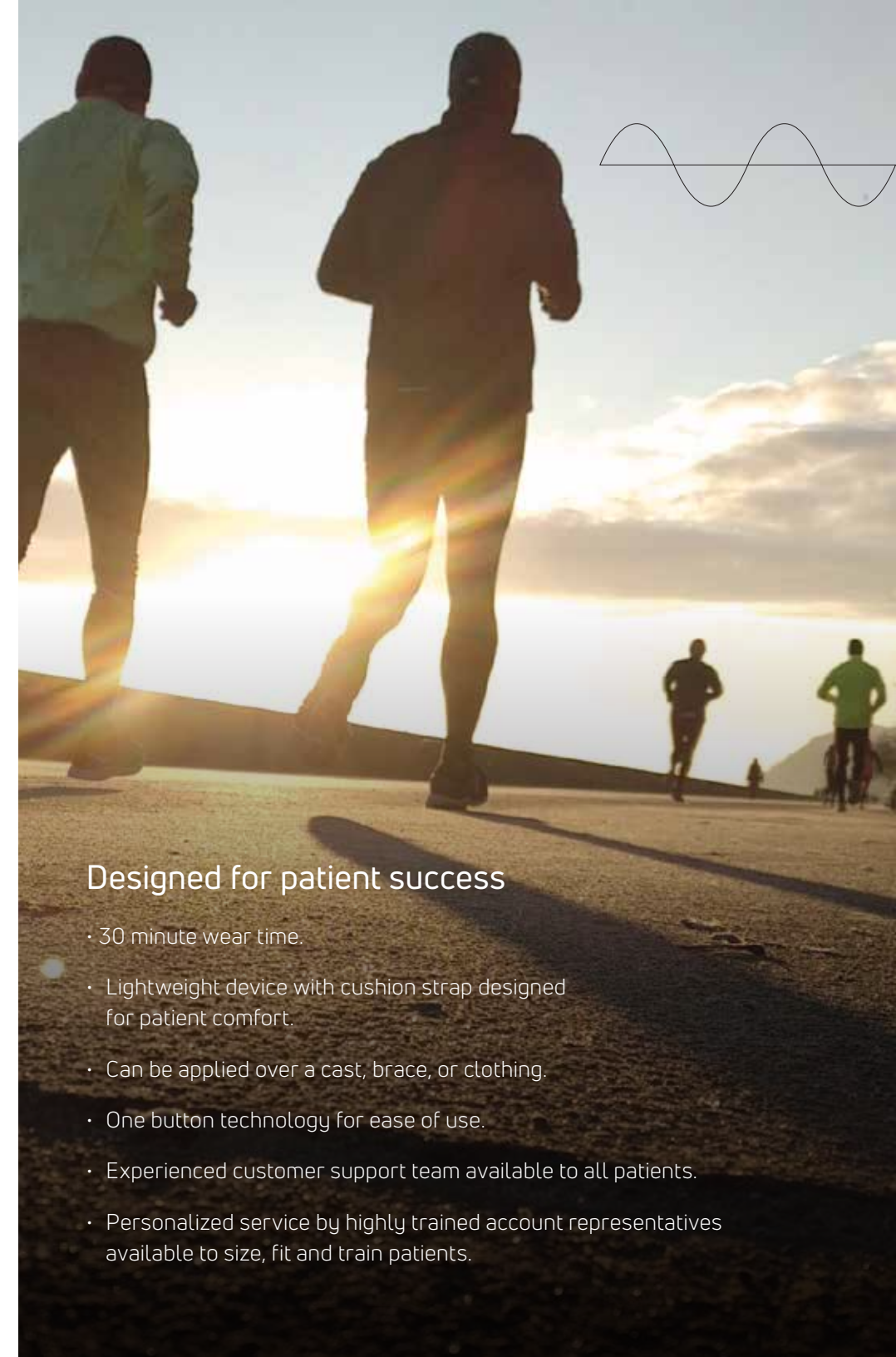


30 minutes of exposure to 76.6Hz increased the volume and number of IGF II molecules and receptors. An increase in both have been correlated to an amplified increase in bone cell proliferation.^{8,9}



Multiple sizes available to accommodate any anatomical variation

djoglobal.com/Regeneration



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.



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: 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
"Tough/Difficult fracture" defined per the following: Success rates obtained on fractures greater than 9 months post injury; Mean time since initial injury = 29.3 months; Mean number of prior surgeries = 2.5
- 2 Baumhauer Phillips M, Baumhauer J, Sprague S, Zoltan J. Use of Combined Magnetic Field Treatment for Fracture Nonunion. J Long Term Eff Med Implants. 2016;26(3):277-284. doi: 10.1615/JLongTermEffMedImplants.2016016818. PMID: 28134611.
- 3 Stewart SK. Fracture Non-Union: A Review of Clinical Challenges and Future Research Needs. Malays Orthop J. 2019;13(2):1-10. doi:10.5704/ MJOL1907.001
- 4 <https://orthoinfo.aaos.org/en/diseases--conditions/nonunions>
- 5 Thomas JD, Kehoe JL. Bone Nonunion. [Updated 2020 May 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK554385/>
- 6 McLeod, K.J., Rubin, C.T., The Effect of Low Frequency Electrical Fields on Osteogenesis. J. Bone Joint Surg., 74A: 920-929, 1992.
- 7 Signal shown in red represents 76.6Hz frequency emitted by CMF Technology
- 8 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.
- 9 Fitzsimmons, R.J., Ryaby, J.T., Magee, F.P. and Baylink, D.J. (1995). IGF-I receptor number is increased in TE-85 osteosarcoma cells by combined magnetic fields. J Bone Miner Res, 10: 812-819.
- 10 Based on actual frequencies of other technologies (1-50,000HZ, 60,000HZ)



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