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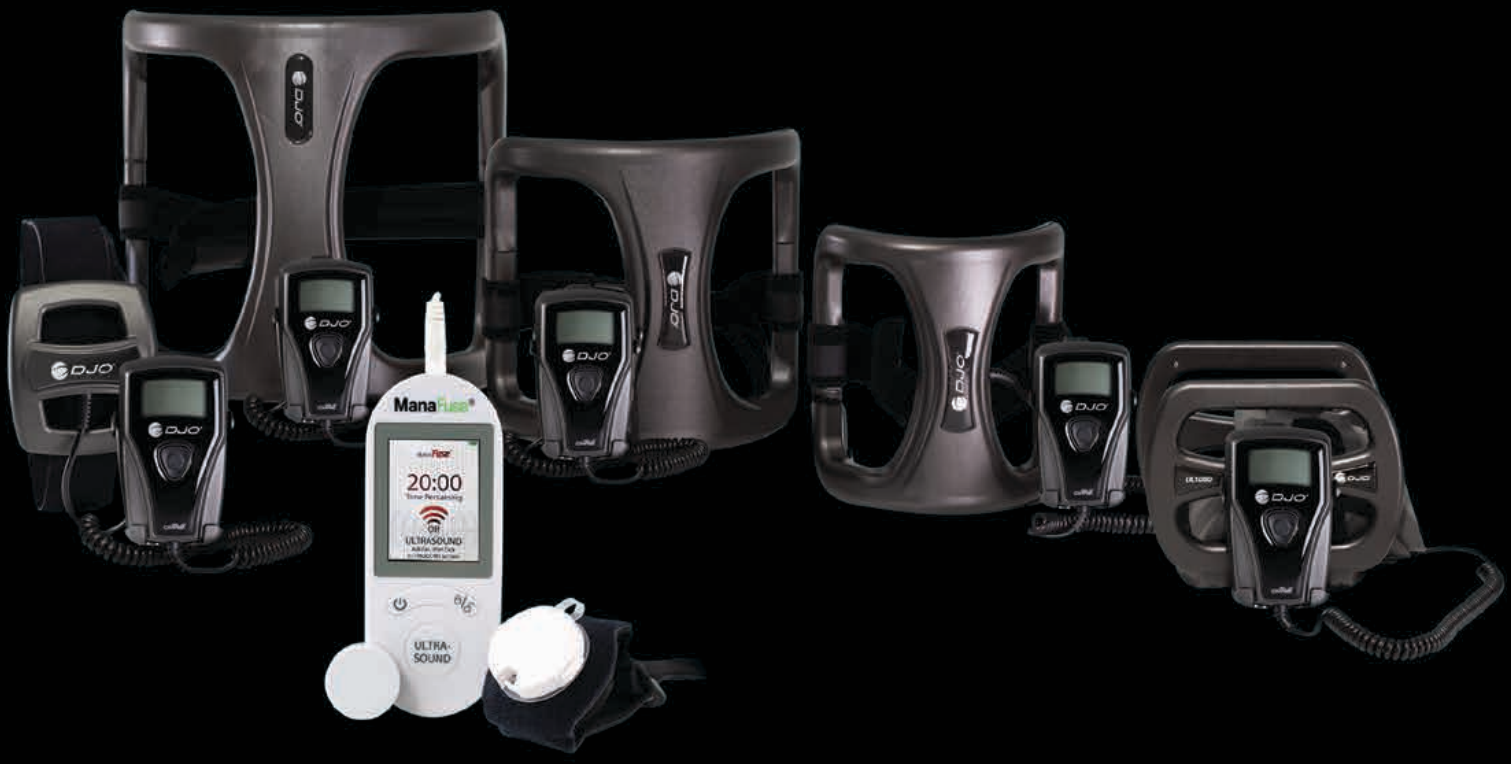
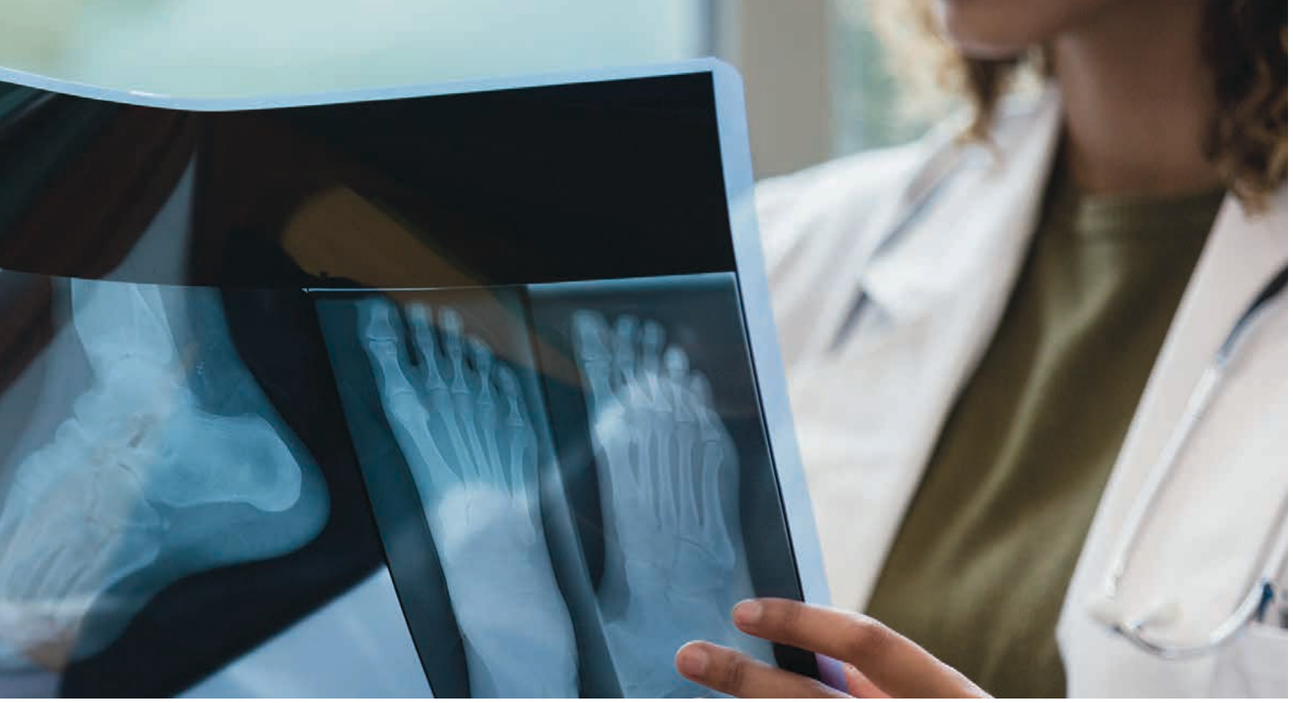
Parent Company of DJO, LLC

CLINICALLY DRIVEN CHOICES FOR FRACTURE CARE

Combined Magnetic Field Technology

Low Intensity Pulsed Ultrasound





MUSCULOSKELETAL FRACTURES

While most musculoskeletal fractures heal successfully within 6-8 weeks, nonunion fractures typically show no progression toward healing at approximately 3 months. The probability of a patient's fracture progressing to nonunion depends on many factors, including fracture severity and location, disease comorbidity, and medication use.

Nonunion fractures have historically represented about 5-10% of total fractures. However, the rising rate of chronic conditions many of which have the potential to impact bone healing has resulted in an increase of nonunion fractures in recent years.[1]

- In 2018, 51.8% of US adults had at least 1 chronic condition and 27.2% had multiple chronic conditions.[2]
- Chronic disease in the Unites States is expected to worsen in the coming years among all age groups resulting in a higher prevalence and cost of bone fractures.[3]

THE MECHANISM OF BONE HEALING

Understanding the mechanism of bone healing and how non-invasive bone growth stimulation affects the process is critical to successfully treating slow-to-heal fractures.

When placed under mechanical strain and/or in response to injuries, bone generates electrical fields (Wolff's Law[5]). Bone structure adjusts to prevailing mechanical loads by remodeling to accommodate the applied forces. Strain-related electrical potentials in bone arise partly from the piezoelectrical properties of the mineral matrix and partly from the electrokinetic effects of streaming potentials (i.e., the fluidic movement of ions within the bone structure). Piezoelectric currents naturally increase the production of growth factors crucial to bone healing and stimulate cell proliferation and differentiation.

Non-invasive bone growth stimulation is not one-size-fits-all. Both LIPUS (Low-Intensity Pulsed Ultrasound) and electrical stimulation (e-stim) promote bone healing, but the technologies differ in how they assist the process.

- LIPUS emits an ultrasound signal designed to mimic the MECHANICAL STRAIN typically generated in response to injury. By creating mechanical strain, LIPUS signals the body to generate the piezoelectric currents and aid in the bone healing process[1].
- E-stim, including CMF, mimics the PIEZOELECTRIC CURRENTS typically generated after the mechanical strain in response to injury. When applying electrical stimulation like CMF, the need to create enough mechanical stress is not necessary since e-stim is mimicking the effect of that strain[5].

LIPUS EFFICACY AND TREATMENT

LIPUS was originally studied and submitted to the FDA to accelerate the healing of fresh fractures of the distal radius and midshaft tibia. Pre-clinical studies (cell studies) found that mechanical strain via ultrasound during the early application had a positive effect on endochondral bone formation and the clinical data reported a 35% increase in healing in these instances when applied within a week of the fracture. LIPUS has a limited area of influence and must be placed directly on the fracture against the skin. If the patient has a cast, this can be accomplished through a window in the cast[1].

E-STIM EFFICACY AND TREATMENT

E-stim has been studied for years on difficult-to-heal and nonunion fractures. This type of stimulation is typically delivered via a "coil" that can vary in size to deliver a larger field of influence. CMF, for example, offers five size options to treat a wide range of nonunion fracture types including large, comminuted fractures. E-stim technologies were typically studied on high-energy traumatic fractures that had shown no prior healing for up to two years[2]. CMF technology does not require direct skin contact and can be worn comfortably over a cast, brace or clothing.

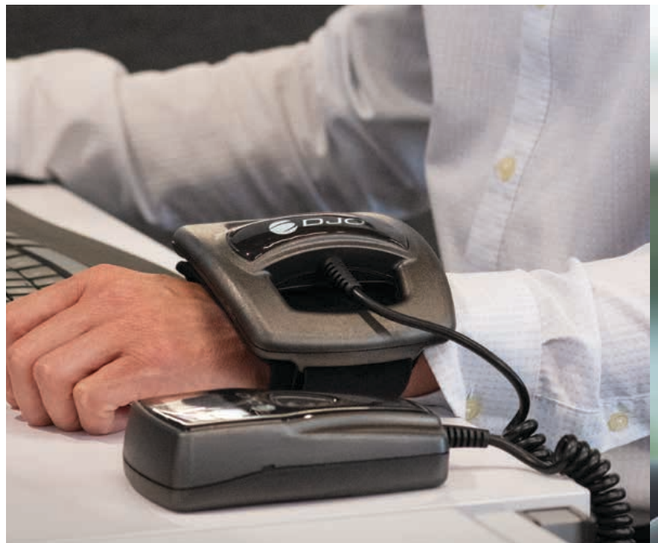
	Ultrasound Stimulation[3]	Electrical Stimulation[4]
Number of nonunion fractures analyzed	29	116
Mean fracture age	14.038 months	29.3 months
Mean number of prior surgical procedures	1.4	2.5
Percent of high energy trauma fractures	0	59.10%
Includes comminuted and/or spiral fractures	NO	YES
Outcomes verified by independent review panel	NO	YES

CHOOSE THE RIGHT TECHNOLOGY FOR THE RIGHT FRACTURE FOR THE RIGHT PATIENT

Data tends to support the use of LIPUS primarily on surface bones and for indicated fresh fractures that can successfully be treated within the product's area of influence. In order to induce healing, LIPUS must be able to create mechanical stress at the fracture site. This may be challenging to achieve with larger, more complex fractures.[3].

E-stim is typically prescribed for the most difficult-to-heal nonunion fractures, those where direct skin contact may not make sense, and those that have undergone surgical procedures with internal or external fixation[4]. Often, larger devices are applied over a fixation given the large area of influence that can be treated with a large e-stim coil[4].

Taking all of these factors into consideration when choosing a technology will give patients the best opportunity to achieve an improved clinical outcome.



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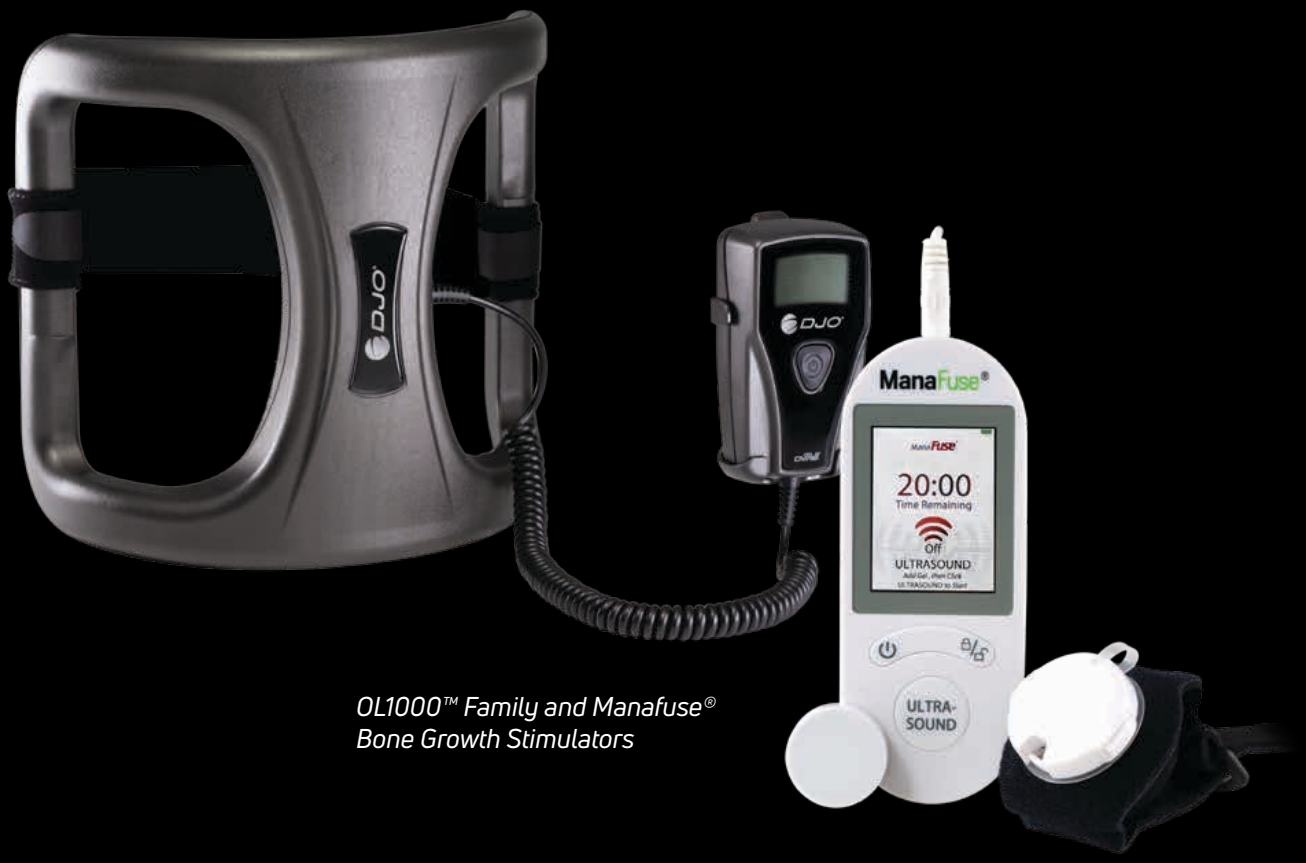

OL1000™ Family and Manafuse®
Bone Growth Stimulators

Enovis is dedicated to helping healthcare professionals choose the right evidence-based technology, for the right fracture, for the right patient. Contact a Sales Representative for more information.

For full prescribing information and indications, please visit:

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