SPINALOGIC®

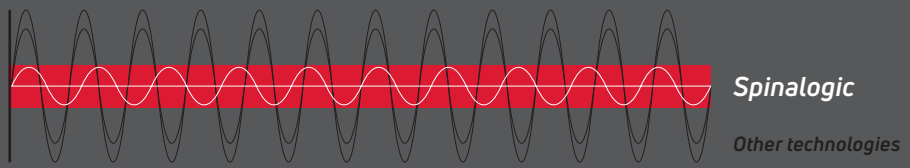
SMARTER TECHNOLOGY

Electrical stimulation helping to drive successful spine fusion

SPINALOGIC®

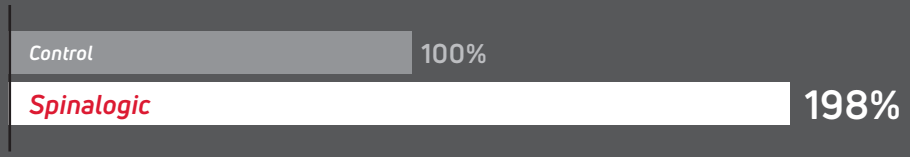
Early researchers determined that maximum bone cell response occurred within frequencies similar to those generated intrinsically by functional activity (0-150Hz). Further research showed 76.6Hz to be the more efficient frequency for bone healing—the frequency offered by the Spinalogic®.[1]

Other 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. Spinalogic is like a steady stream of water focused exclusively on the cup.



FREQUENCY RANGES [2 7]

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.[3 4]

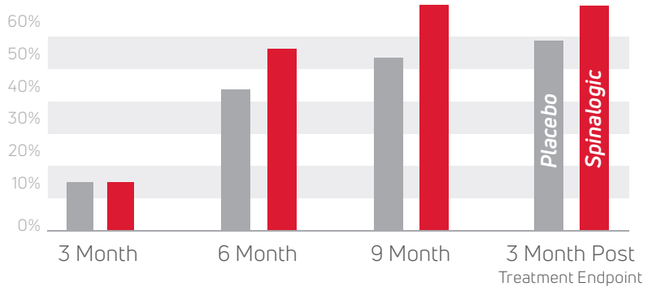


IGF-II S YNTHESIS[3]

PROCEED CONFIDENTLY

There are many variables that can prevent successful spinal fusion—from patient risk factors to post-op treatment compliance. Spinalogic® and its efficient bone growth technology has been shown to help increase the likelihood of lumbar fusions—giving your patients every advantage to support a full recovery.[5]

CLINICAL RESULTS OF SPINALOGIC [5]



97%

Lumbar fusion success observed [6]

21%

Increase in lumbar fusions over placebo device [5]

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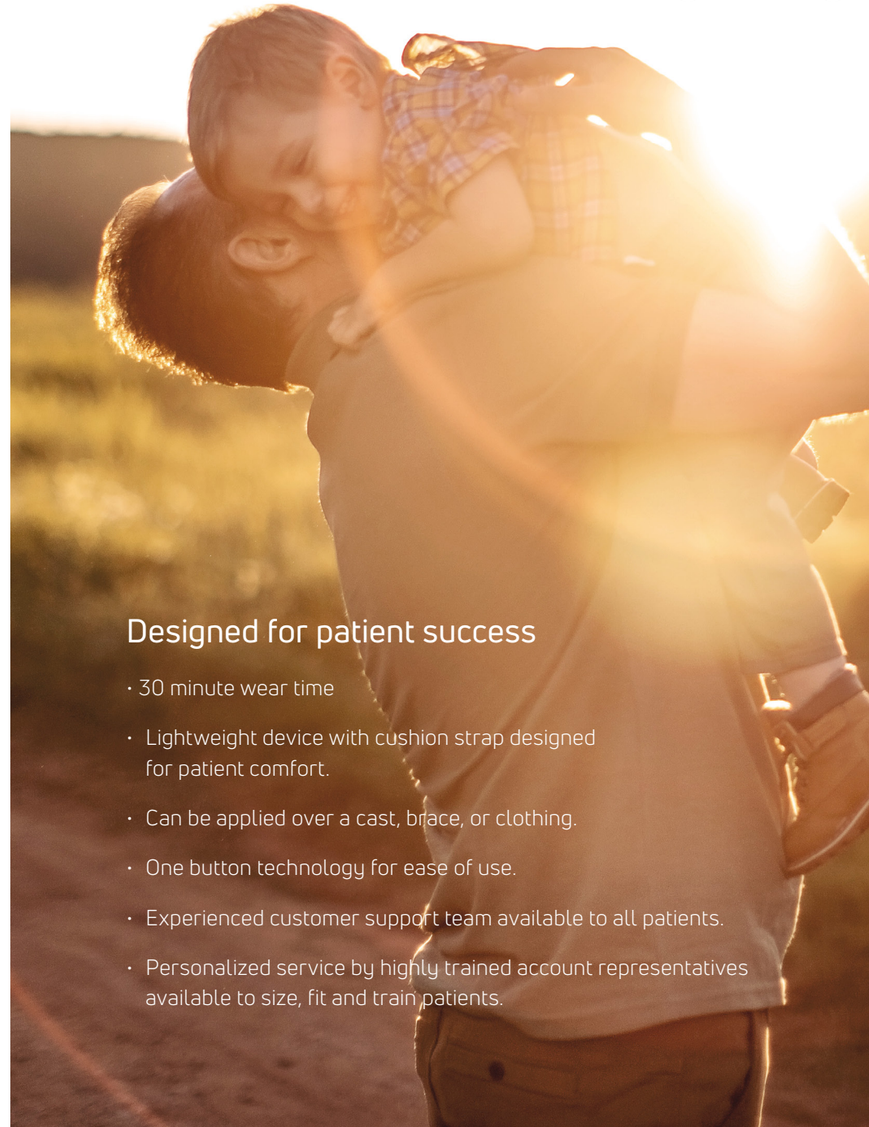

Designed for patient success

- 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.

Spinalogic® BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION

INDICATION: Spinalogic® 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 cardiovertor defibrillator (ICD) operation may be adversely affected by exposure to combined static and dynamic magnetic fields. Physicians should not prescribe Spinalogic® for patients with such devices. The safety and effectiveness of Spinalogic® 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 Spinalogic®, 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 Spinalogic® 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 McLeod, K.J., Rubin, C.T., The Effect of Low Frequency Electrical Fields on Osteogensis. J. Bone Joint Surg., 74A: 920-929, 1992.

2 Signal shown in red represents 76.6Hz frequency emitted by CMF Technology

3 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.

4 Fitzsimmons, R.J., Ryaby, J.T., Magee, F.P. and Baylink, D.J. (1995), IGF-II receptor number is increased in TE-85 osteosarcoma cells by combined magnetic fields. J Bone Miner Res, 10: 812-819.

5 Linovitz R, Pathria M, Bernhardt M, et al. Combined Magnetic Fields Accelerate and Increase Spine Fusion: A Double-Blind, Randomized, Placebo Controlled Study, Spine. 2002 July; 27(13):1383-1388.

6 Raiszadeh, Ramin, et al. "Effectiveness of combined magnetic field bone growth stimulation on lumbar spinal fusion outcomes: a single center retrospective analysis comparing combined magnetic field to no-stimulation." International Journal of Research in Orthopaedics 6.3 (2020): 1. A retrospective study that utilized radiographic fusion criteria, included data from 4 surgeons, consisted of a heterogenous patient population and had minimum 6 months follow up.

7 Based on actual frequencies of other technologies (1-50,000HZ, 60,000Hz)

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