

SpinaLogic®, OL1000®, OL1000 SC®

Bone Growth Stimulation



SPINALOGIC®



OL1000®



OL1000 SC®

The Signal

It's different. It's potent.

The advanced technology of the patented Combined Magnetic Field (CMF) delivers optimal results.

The Science

It's academically recognized.

Research on the role of Combined Magnetic Field regulation of fracture healing is an award recipient from the International Society for Fracture Repair.

Compliance

30-minute daily treatment.

Increased patient compliance.
Improved clinical outcomes.

How is it Different?

The SpinaLogic® and OL1000® utilize state-of-the-art Combined Magnetic Field (CMF) technology, completely different from the Pulsed Electromagnetic Field (PEMF) technology used in other bone growth stimulators.

CMF Technology

CMF technology combines a **dynamic magnetic field** and superimposes it upon a **static magnetic field**. This is in contrast to PEMF technology, which utilizes only an alternating magnetic field.

Lower Energy Magnetic Utilization

The CMF technology utilizes low-energy magnetic fields with a peak amplitude of 0.4 gauss—**1/50th of the PEMF technology**, which utilizes a high-energy electromagnetic field with peak amplitude of greater than 20 gauss.

SpinaLogic®

Indications for use

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 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 has not been established
- The safety and effectiveness of this device in treating patients with the following conditions has not been established and therefore the safety and effectiveness of the device in these individuals is 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 the 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 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 the SpinaLogic Bone Growth Stimulator magnetic fields have not indicated any evidence of significant adverse effects.

OL1000® & OL1000 SC®

Indications for use

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 visible progressive signs of healing.

Contraindications

- Use of this device is contraindicated in individuals having a synovial pseudarthrosis
- Demand-type pacemaker operations may be adversely affected by exposure to magnetic fields. Physicians should not prescribe the 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)
- The 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 this device on individuals lacking skeletal maturity has not been established
- Animal studies conducted to date do not suggest any long-term significant adverse effects from use of this device. However, long-term 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 has not been established

- This device should not be used if there are mental or physical conditions which 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

For full prescribing information, contact VQ OrthoCareSM.

CAUTION

Federal law restricts these devices to sale by, or on the order of, a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

VQ OrthoCare may resell SpinaLogic® in the following markets:
AL, CA (Southern 1/2), CO, GA, IA, LA, MN, MS, NE, NV, OH, PA (Western 1/2), TN (Chattanooga only), UT, WA, WY

VQ OrthoCare may resell OL1000® and OL1000 SC® in the following markets:
AL, AK, AR, AZ, CA (Southern 1/2), CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY (Except Western Upstate), NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WY

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Represented by:



18011 Mitchell South, Irvine, CA 92614
Call 800.266.6969 Fax 800.821.8012
www.vqorthocare.com
customerservice@vqorthocare.com

Manufactured by:



1275 W. Washington St.
Tempe, AZ 85281 USA
t 888.624.5450
www.djortho.com

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