# DJO GLOBAL: CMF LIMITED GUARANTEE PROGRAM

## HEALTH CARE PROFESSIONAL (HCP) ACKNOWLEDGEMENT OF NON-HEALING

If a patient has a non-healing fracture, or fusion of the spine that fails to heal, and the patient meets the requirements of the DJO Limited Guarantee Program, the patient may be eligible for a refund of the patient's payment amount paid to DJO Global for their OL1000 or SpinaLogic bone growth stimulator. Please be advised that if DJO was not the direct supplier of the device to the patient (i.e., it was sold by a physician or another 3rd party), the patient does not qualify under the Limited Guarantee Program. If the patient wishes to participate in this program, the requirements must be met. It is within the sole discretion of DJO to determine if a patient qualifies for this program.

## THIS SECTION MUST BE COMPLETED BY THE TREATING HCP

**Patient Name:** _____ (PRINT FULL NAME) **Patient Date of Birth:** _____ (MM/DD/YYYY)

**CMF Bone Growth Stimulation Device Patient Received** (check one box) **:** ☐ **OL1000** ☐ **SpinaLogic**

**If your patient received a CMF Bone Growth Stimulator device:**

1. Has the patient used the CMF bone growth stimulator device for 9 months? ☐ YES ☐ NO
2. Were radiographs (e.g., CT scan, MRI, etc.) taken within the 30 days before or after the 270th day from the date the patient began using CMF Bone Growth Stimulator device? ☐ YES ☐ NO
3. Do the radiographic reports reflect incomplete healing? ☐ YES ☐ NO

*By my signature below, I confirm that the statements above are accurate and true to the best of my knowledge. I understand that the information indicated above must be supported by documentation in the patient's medical record and that this documentation must be supplied upon request.*

**Physician Signature:** _____ (NO SIGNATURE STAMPS) **Date:** _____

**Physician Name:** _____ (PLEASE PRINT FULL NAME) **NPI#:** _____

**Practice Name:** _____

**CMF 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:** Use of this device is contraindicated in individuals having a synovial pseudarthrosis. Demand-type pacemaker or implantable cardiovertor defibrillator (ICD) operation may be adversely affected by exposure to magnetic fields. Physicians should not prescribe CMF 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). CMF 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 the use of this device on individuals lacking skeletal maturity have 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 have not been established. This device should not be used if there are mental or physical conditions that 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. Clinical studies, animal studies, and tissue culture experiments conducted with the OL1000, which has the same treatment signal as the OL1000 SCI, have not indicated any evidence of significant adverse effects.

**CAUTION:** Federal law (U.S.A. and Canada) restricts this device to sale, distribution or use by or on the order of a physician.

**CMF SPINALOGIC® BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION**

**INDICATION**: CMF 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 CMF SpinaLogic for patients with such devices. The safety and effectiveness of CMF 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 CMF 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 CMF 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.

***Submission of this form in no way guarantees that the patient will qualify for a refund of his or her payment amount under this program.***

***This form along with other required documentation will be reviewed by DJO to determine if the patient qualifies for a refund.***

**Please make a copy of this completed form for your own records.**

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