INSURANCE

WILL MY INSURANCE COMPANY PAY FOR THE DEVICE?

Insurance policies are different depending on the plan you have. The CMF™ SpinaLogic® bone growth stimulator is covered by the majority of health plans and workers compensation plans, including Medicare; specific coverage criteria must be met.

DOES DJO® PREAUTHORIZE THE DEVICE WITH MY INSURANCE COMPANY?

If pre-authorization is required, DJO® will verify your eligibility and benefit levels to obtain a pre-authorization from the payer of record.

WHAT HAPPENS IF MY INSURANCE COMPANY DENIES THE CLAIM?

In the event the insurance carrier denies coverage, the claim will be forwarded to our appeals processing department on your behalf. Depending upon the outcome, DJO® may contact you to arrange payment options.

ADDITIONAL

WHO DO I CALL IF I HAVE A QUESTION?

Customers may call the DJO® Customer Care Service line: 1-800-263-6004

Accelerated Spine Fusion in 30 Minutes a Day[1,2]

CMF™ SpinaLogic® Bone Growth Stimulation[3]

For more information contact
your local sales representative or call
DJO® Customer Service: 800.263.6004
www.djoglobal.com/cmf

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: 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™ SpinaLogic® 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™ SpinaLogic® 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: Do not use the CMF™ SpinaLogic® near products that may have strong magnetic fields, such as audio speakers. The device may not work properly around these products.

- **WARNING!** This device is intended only for single patient use. Secondary use can cause serious injury, including infection.
- Care must be taken when operating this device adjacent to other equipment. Potential electromagnetic or other interference could occur with this or other equipment. Try to minimize this interference by increasing the separation between this device and nearby equipment, and by not using other equipment (i.e.cell phones, MRI, electro surgery, defibrillation, etc.) when you are using this device.
- The equipment should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Do not use the CMF™ SpinaLogic® while smoking or near heat, fire or flammable gases because the device may be damaged.
- Do not use the CMF™ SpinaLogic® if there are exposed wires or the device appears damaged.
- Do not modify or repair this device because you may damage it.
- Do not put the device or any of its parts in any liquid.
- Do not drop the device or bend the coils because this may damage it.
- Device is designed to comply with electromagnetic safety standards. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
  - Reorient or relocate the receiving device
  - Increase the separation between the equipment
  - Contact DJO® Customer Care
- Some people, with very sensitive skin, may experience redness. Generally, this redness is totally harmless and usually disappears after 10 to 20 minutes. However, never start another treatment on the same area if the redness is still visible.
- If the performance of the device varies in any way from the described operation, call Customer Care.
- The use of other cables and accessories may affect EMC performance.
- This device and its accessories must be kept out of the reach of children, Pets, and Pests.
- Do not use device in contact with open wounds.
- Contamination by Patient could be sweat, expired gases, saliva, on the CMF™ Spinal Logic®. Clean the applied part of the coil once a week using soap and a damp cloth.
- Do not use device while in bath or shower

CAUTIONS: DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

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 CMF™ SpinaLogic®, which has the same treatment signal as the OL1000™ and OL1000™ SC[1], have not indicated any evidence of significant adverse effects.

DJO, LLC | A DJO Global Company
T 800.336.6569 F 800.936.6569
1430 Decision Street | Vista, CA 92081-8553 | U.S.A.
www.djoglobal.com/cmf

Individual results may vary. This therapy is not for everyone. Please consult your physician. A prescription is required. For more information, please call DJO® at 888-624-5450. Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

MKT00-1029 Rev E

Accelerated Spine Fusion in 30 Minutes a Day[1,2]

CMF™ SpinaLogic® Bone Growth Stimulation[3]

Frequently Asked Questions

USE

WHAT IS THE CMF™ SPINALOGIC® BONE GROWTH STIMULATOR AND HOW WILL IT HELP ME?

The CMF™ SpinaLogic® bone growth stimulator is a nonsurgical treatment which your physician has prescribed to help the healing of your fusion. The stimulator uses a very low-strength Combined Magnetic Field (CMF™) to activate the body's natural healing process. In some patients, this healing process is impaired or absent. The fusion may not mend properly. The bone growth stimulator provided by DJO® has proven to be successful in helping to treat spinal fusions after surgery.[1]

ARE THERE KNOWN SIDE EFFECTS OF CMF™ SPINALOGIC®?

There are no known side effects related to the use of this device. Thousands of patients have worn SpinaLogic® to help heal their spine fusions after surgery. SpinaLogic® may be safely used with non-magnetic fixation devices, such as screws, plates, or metal pins.

HOW OFTEN WILL I NEED TO CHANGE THE BATTERY?

The SpinaLogic® will be delivered with a battery installed. A low battery symbol will appear on the LCD screen on your remote indicating when the batteries should be changed. There are additional 9V batteries included that should last for up to 9 months.

WEAR

DO I NEED TO WEAR THE CMF™ SPINALOGIC® AT THE SAME TIME EACH DAY?

The unit will allow one 30 minute treatment per day. You have the flexibility to receive your treatment at any time you choose. It is recommended to be worn approximately the same time each day.

CAN I WEAR THE CMF™ SPINALOGIC® WITH A TENS UNIT OR CARDIAC PACEMAKER?

SpinaLogic® can be used with a TENS unit. However, the device may interfere with demand type pacemakers, refer to the contraindications for additional information. If you wear a pacemaker, you should consult your doctor before using SpinaLogic®.

CAN I WEAR THE CMF™ SPINALOGIC® IF I AM PREGNANT?

The effect of CMF™ treatment has not been studied during pregnancy or nursing. Therefore, if you are pregnant or nursing, you should consult your doctor before using SpinaLogic®.

CAN I TRAVEL WITH MY CMF™ SPINALOGIC®?

Yes. Although not commonly required, in advance of your travel, you may request a letter from our Customer Service Support department that will explain what the device is and how it operates. You can also keep your user manual available to quickly and easily identify the device for any security personnel. We recommend administering your 30-minute treatment prior to going through security, this will ensure when moving through the x-ray and imaging devices, that the unit cannot be turned on for the magnetic fields to interfere.

TREATMENT

WHAT IS MY DAILY TREATMENT TIME WITH THE CMF™ SPINALOGIC®?

The SpinaLogic® is a simple, 30 minute daily treatment time.

WHAT WILL CMF™ SPINALOGIC® TREATMENT FEEL LIKE?

You should not feel the CMF™ therapy during the 30 minute treatment. The SpinaLogic® unit is lightweight and adjustable for a comfortable fit. It is powered with a battery, which allows the unit to be portable. You can perform activities of daily living as recommended by your physician.

HOW LONG WILL IT TAKE TO HEAL USING THE CMF™ SPINALOGIC®?

You will use your Spinalogic® device as long as your physician indicates. Each device functions for 270 days, should you need additional treatment your physician will prescribe subsequent treatment. Normally, the device is used until your spine fusion has healed. Your physician will closely monitor your progress. To promote healing, it is very important that you wear SpinaLogic® daily, as prescribed. Your doctor may require that you bring your unit in on your follow-up visits to check your compliance with using the device.

WHAT DO I DO WITH THE DEVICE WHEN I AM DONE USING IT?

After your treatment is complete and your doctor says you no longer need to use your CMF™ SpinaLogic®, you may dispose of the device yourself according to your local governing ordinances and recycling plans. You may also contact our Customer Support department for help with device disposal. The CMF™ SpinaLogic® is not reusable. Each device is for single patient use only and cannot be re-sold or used on multiple patients.

CMF™ SpinaLogic® Bone Growth Stimulation as prescribed by your physician provides a proven, convenient solution to help the healing of your spinal fusion

CMF™ SpinaLogic®

1. Baumhauer, et al (2017) J of Long Term Effects of Medical Implants. 26(3): 261-270
2. Baumhauer, et al (2017) J of Long Tearm Effects of Medical Implants. 26(3): 277-284
3. Linovitz, et al. (2002) Spine. 2713:1383-1388