HOW DOES IT WORK?

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

You should not feel the CMF therapy during the 30 minute treatment. The Spinalogic unit is designed to be 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.

The unit will allow one 30 minute treatment per day, and 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.

Each device functions for 270 days. Your physician will closely monitor your progress, and will indicate when you no longer need to use Spinalogic. Normally, the device is used until your spine fusion has healed. 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.

1 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.

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 Enovis™ 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™ Spinalogic®. 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 Spinalogic® and Spinalogic SC[1], have not indicated any evidence of significant adverse effects.

enovis™

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30 MINUTES. ONCE DAILY.

Bone Growth Stimulation as an adjunct to spine fusion surgery.

Combined Magnetic Field Technology

WILL MY INSURANCE COVER IT?

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

DOES Enovis™ PREAUTHORIZE THE DEVICE WITH MY INSURANCE COMPANY?

If pre-authorization is required, Enovis™ 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 on the outcome, you may contact us at 888-631-9587 option 3 to arrange payment options.

For more information, contact your local sales representative or call Enovis™ Customer Service at **(800) 263-6004**

enovis.com/regeneration

SPINALOGIC®

ARE THERE KNOWN SIDE EFFECTS OF CMF™?

There are no known side effects related to the use of this device. Thousands of patients have been prescribed 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.

CAN I WEAR THE SPINALOGIC IF I AM PREGNANT?

The safety of the Spinalogic is not known if you are pregnant or nursing. Therefore, if you are pregnant or nursing, you should consult your doctor before using the Spinalogic.

CAN I USE THE SPINALOGIC IF I HAVE A PACEMAKER?

The operation of your pacemaker may be affected from exposure to the CMF Spinalogic magnetic fields. Please consult your prescribing physician to see if your device will be placed in close proximity to your pacemaker. Further screening by your attending cardiologist is also recommended such as with an electrocardiogram.

CAN I TRAVEL WITH MY SPINALOGIC?

Yes. Although not commonly required, in advance of your travel, you may request a letter from our Customer Service Support department or your Enovis™ Sales Representative 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.

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. If more are needed, please contact customer service.

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 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 Spinalogic is not reusable. Each device is for single patient use only and cannot be re-sold or used on multiple patients.