Redefining your Recovery experience

Patient's Guide to Understanding Bone Growth Therapy for Spinal Fusion Healing

ORTHOFIX® | SPINE

Tamie, a triathlete, wears her SpinalStim device.
On the cover: Laura Wilkinson, an Olympic Gold Medalist and CervicalStim device patient, enjoys playing in the park with her family.

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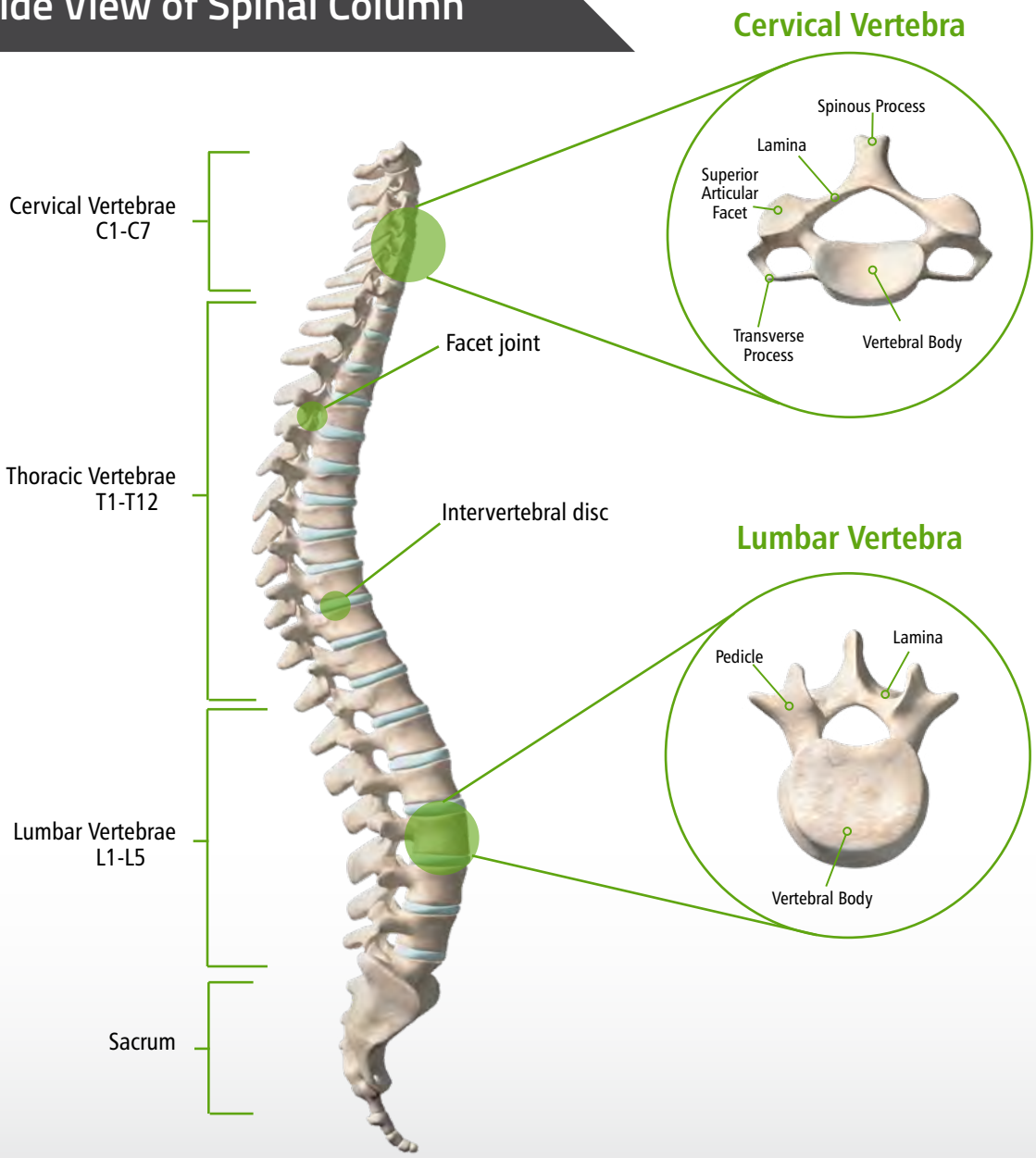
CERVICALSTIM® SPINAL FUSION THERAPY | SPINALSTIM® SPINAL FUSION THERAPY

Side View of Spinal Column



What is Spinal Fusion Surgery?[1,2]

Spinal fusion surgery involves using bone graft in order to fuse two vertebral bodies together into a single, solid bone. Bone graft can be harvested from cadaver bone (allograft), taken from the patient's hip bone during the fusion surgery (autograft), or manufactured (synthetic bone graft). Metal plates, rods or screws can also be used to help hold the vertebrae together.

There are many reasons for spine fusion surgery. Some common causes are vertebral fractures, deformity correction, elimination of pain from motion, treatment of instability, degenerative disc disease, spondylolisthesis, spinal stenosis, tumors, and treatment of some disc herniations. Fusions are typically the last resort and should be considered after other conservative (nonsurgical) measures have failed.

There are different surgical approaches and techniques that can be used to fuse the spine. The spine may be accessed from the back (posterior approach), from the front (anterior approach) or a combination of the two. For a cervical fusion an anterior approach is most common, while lumbar and thoracic fusions are usually performed posteriorly.

A few common surgical techniques are listed below.

- **Cervical Fusion/ACDF (Anterior Cervical Discectomy and Fusion):**
  First, an incision is made to the front of the neck. Muscles and other soft tissue structures are gently pushed away from the vertebrae. An incision is made in the outer coating of the intervertebral disc and most of the damaged disc is removed, but a small portion may be left intact. Next, the anterior cervical fusion is performed, in which a bone graft or a cage is inserted into the space where the disc used to be to prevent the disc space from collapsing. Metal plates, rods or screws may be used to help hold the vertebrae together. This allows the bone to grow together to set up a bony bridge, or fusion, between the upper and lower vertebrae.

What is Spinal Fusion Surgery?[1,2]

- **PLIF (Posterior Lumbar Interbody Fusion):**
  A PLIF starts with an incision in the midline of the back. Next, the lower back muscles are moved off the lamina. The lamina is removed, which allows the nerve roots to be visible. Directly over the nerve roots are the facet joints, which can be trimmed to give the nerve roots more room. The nerve roots are then moved to the side and the intervertebral disc material is removed. A cage is then inserted into the disc space to prevent the disc space from collapsing. Bone graft is placed inside the cage and along the sides of the spine. Metal plates, rods or screws may be used to help hold the vertebrae together. This allows the bone to grow together to set up a bony bridge, or fusion, between the upper and lower vertebrae.

- **ALIF (Anterior Lumbar Interbody Fusion):**
  This type of lumbar fusion is done from the front and may be combined with a posterior approach, if additional stability is needed. It starts with an incision on the abdomen. Next, the abdominal muscles are moved to the side. In contrast to a posterior approach, the abdominal organs and large blood vessels that sit on top of the spine must be moved to the side. In most cases, a vascular surgeon will usually be part of the surgery to move the blood vessels. The intervertebral disc material is then removed. Then a cage is inserted into the disc space to prevent the disc space from collapsing. Bone graft is placed in and around the cage. Metal plates, rods or screws may be used to help hold the vertebrae together. This allows the bone to grow together to set up a bony bridge, or fusion, between the upper and lower vertebrae.

What is Spinal Fusion Surgery?[1,2]

- **TLIF (Transforaminal Lumbar Interbody Fusion):**
  This technique is very similar to a PLIF except that the disc space is only accessed from one side of the vertebra. It starts with an incision in the midline of the back. Next, the lower back muscles are moved off the lamina. The lamina is removed only on one side, which allows the nerve roots to be visible. Directly over the nerve roots is the facet joint, which can be trimmed to give the nerve roots more room. The nerve roots are then moved to the side and the intervertebral disc material is removed. A cage is then inserted into the disc space to prevent the disc space from collapsing. Bone graft is placed inside the cage and along the sides of the spine. Metal plates, rods or screws may be used to help hold the vertebrae together. This allows the bone to grow together to set up a bony bridge, or fusion, between the upper and lower vertebrae.

- **XLIF (Lateral Lumbar Interbody Fusion):**
  This technique is the least invasive because the surgeon accesses the vertebrae from the side of the body therefore leaving the back muscles and nerves mostly undisturbed. This procedure is performed through one or more small incisions and an instrument known as a retractor is used to spread the tissues so that the surgeon can see the spine. The intervertebral disc material is then removed. A cage is then inserted into the disc space to prevent the disc space from collapsing. Bone graft is placed inside the cage and along the sides of the spine. Metal plates, rods or screws may be used to help hold the vertebrae together. This allows the bone to grow together to set up a bony bridge, or fusion, between the upper and lower vertebrae.

What to Expect After Fusion Surgery?

Recovery following a spinal fusion surgery differs from patient to patient. Generally, the hospital stay after a fusion surgery only lasts for a few days, but longer stays aren't uncommon. Before being discharged from the hospital, your doctor will give you specific instructions about how to continue your recovery at home. It usually takes longer to return to a normal active lifestyle following fusion surgery as opposed to other surgeries. Depending on the person, it could take up to a year to completely heal. This is why taking an active role in your recovery is very important. There are several rehabilitation options that your doctor might prescribe for you. Some of the more common options are detailed below.

- **Cervical collar/lumbar brace:**
  Some patients might be prescribed a brace to wear following surgery. It helps to immobilize the spine while healing. Wear times can differ anywhere from four weeks to six months.

- **Rehabilitation facility:**
  A short stay in a rehabilitation facility is sometimes recommended for patients who have had a substantial surgery, are debilitated, or are elderly. The goal is to improve the function of daily activities in order to improve recovery and quality of life. Progress is tracked until symptoms have stabilized or resolved. The length of stay will be at the discretion of your surgeon.

What to Expect After Fusion Surgery?

Physical therapy:
Following a prescribed physical therapy program can aid in the recovery process. While there are precautions to keep in mind, staying active can help restore function, relieve pain, and improve mobility. Activities are customized to each individual's needs and new techniques are added as the patient improves. Therapy will explore new ways to walk, sit, stand, and lie down. Safer ways to lift, pull, or push objects are also covered. Physical therapy is usually started at least six weeks after surgery and could last two to three months or more.

Bone growth therapy:
This type of therapy assists in bone healing at the fusion site. While there are several types of stimulators available, they are all different. They range from being surgically implantable to being worn externally. The Orthofix SpinalStim™ and CervicalStim™ devices are examples of external bone growth therapy devices. The technology by which these stimulators work is the differentiating factor compared to other bone growth therapy devices. These therapy devices use a low-level pulsed electromagnetic field to the injury or fusion site.

"I believe that it helped me heal. I would recommend it. I'm glad my doctor prescribed it."

- Rick, a CervicalStim patient

What is Bone Growth Therapy?

Some patients who experience a spinal fusion may have difficulty healing. In many of these cases, there are certain health factors that may have impaired the natural healing process of the bones. Factors such as smoking, obesity, osteoporosis, diabetes and prior failed fusion(s) can negatively impact the recovery process and clinical success of the fusion surgery. To help overcome these healing challenges, doctors commonly prescribe a treatment called bone growth therapy, also known as bone growth stimulation.

Electrical currents have been used to heal bones since the mid-1800s. However, it wasn't until the1950s when scientists discovered that if a bone is bent or broken, it generates an electrical field. This low-level electrical field activates the body's own repair mechanism which, in turn, promotes bone healing. When this healing process fails to occur naturally, bone growth therapy can be used to help the process.[3-5]

Orthofix bone growth therapy devices have been prescribed since the late 1980s and provide a safe, noninvasive treatment that helps promote healing in spinal fusions that have not healed or have difficulty healing. The devices stimulate the bone's natural healing process by sending low-level pulses of electromagnetic energy to the fusion site.[6-11]

"I was so excited when I first heard about the Orthofix bone growth stimulator because this was a product that would help the body heal noninvasively. "

- Joanie, a SpinalStim device patient

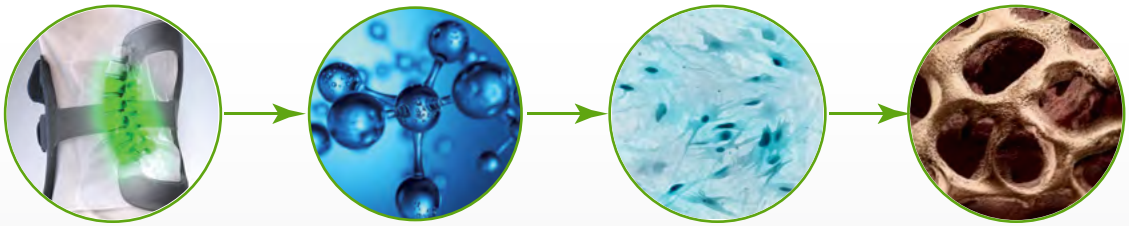
How Does a Pulsed Electromagnetic Field (PEMF) Work?

Orthofix's bone growth therapy devices create a low-level pulsed electromagnetic field, which helps promote the body's natural healing process.[3-5] Published pre-clinical research shows that PEMF affects bone-healing processes at the molecular, cellular and tissue levels.* [9-13] At the cellular level, the PEMF signal activates bone growth signaling pathways, which enhances bone formation by increasing both the bone building cell population and maturity.* [9,12] At the tissue level this leads to stronger, higher density bone.

The PEMF signal is produced from a coil built into a fabric garment that is worn over the fusion site.*[11,13] The garment can be worn over clothing, casts, or braces.

PEMF and the Healing Process

The result of these molecular, cellular and tissue processes is improved healing rates of a fusion.



PEMF

Creates low-level electrical field[3]

MOLECULAR

Within 10 minutes of PEMF exposure, signaling pathways are activated* [9]

CELLULAR

PEMF stimulates bone cells to proliferate, differentiate and mineralize*[12]

TISSUE

PEMF has been shown to improve the quality of bone tissue and enhance bone preservation*[11,13]

The SpinalStim Device

The SpinalStim device is FDA approved to be used after spinal fusion surgery or to be used to treat a failed fusion from a previous surgery.[7,17,18] For complete prescribing information, please visit our website at BoneGrowthTherapy.com.

This single-piece device is lightweight, flexible and portable, allowing freedom of movement during treatment. The typical prescribed treatment time is two hours per day. An LCD and audible alarm provide important feedback during treatment such as the operational status, treatment time remaining, battery capacity, etc.

Product Features and Benefits:

- Works effectively when worn over clothing or bracing
- 360 degrees of PEMF treatment around the fusion site [15,19]
- Coverage up to 5 vertebral levels[15,19]
- Cordless design enables you to keep moving while healing
- Accompanied by the STIM onTrack Mobile App which provides patients with a treatment calendar, therapy reminder, outcome measurement questionnaires and additional educational resources

STIM onTrack™
Mobile App

The SpinalStim device has an overall clinical success rate of 92 percent (for adjunct use only) in treating spinal fusion surgery patients.[7,18] In addition, the SpinalStim device can be used for treatment of a failed fusion, reducing the need for a revision surgery.[7,17]

"I wore the CervicalStim device religiously every single day. I was not a day without it. I know any kind of small thing that can help and make a difference, that all adds up. So I was all game."

- Laura Wilkinson, Olympic Gold Medalist and Orthofix CervicalStim device patient

The CervicalStim Device

The CervicalStim device has been approved by the FDA to be worn after cervical spine fusion surgery in patients at risk for nonfusion.[8] For complete prescribing information, please visit our website at BoneGrowthTherapy.com.

It is a single-piece device that is lightweight, flexible and portable, allowing freedom of movement during treatment. The typical prescribed treatment time is four hours per day. An LCD and audible alarm provide important feedback during treatment such as the operational status, treatment time remaining, battery capacity, etc.

Product Features and Benefits:

STIM onTrack™
Mobile App

- Works effectively when worn over clothing or bracing
- 360 degrees of PEMF treatment around the fusion site[15]
- Coverage up to five vertebral levels[15]
- Cordless design enables you to keep moving while healing
- Accompanied by the STIM onTrack Mobile App which provides patients with a treatment calendar, therapy reminder, outcome measurement questionnaires and additional educational resources

The CervicalStim device has an overall clinical success rate of 84 percent in treating patients with difficult fusions.[8,16]

"I didn't know about the bone growth stimulator until after my surgery, but when I read the brochure and I saw that it increased the percentage of success rates so much, I closed the brochure immediately and said, let's give this a try. "

- Joe, a SpinalStim device patient

Why Do Physicians Prescribe SpinalStim and CervicalStim Devices?

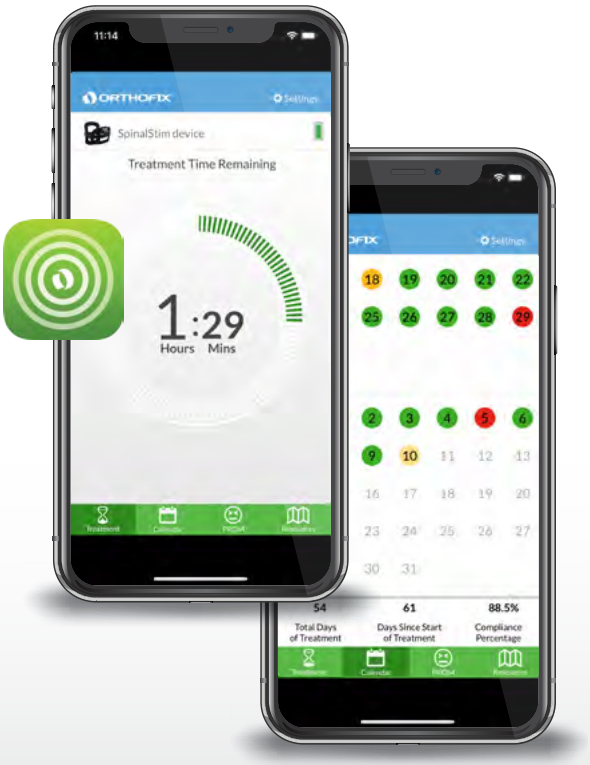
- Increase success rates in high-risk spinal fusion patients[7, 8,16,18]
- Statistically significant results for patients who smoke or have a multi-level fusion
- PEMF signal covers 360 degrees around the fusion site[15,19]
- Coverage up to five vertebral levels[15,19]
- Supported by the North American Spine Society's coverage recommendations[20]
- The STIM onTrack Mobile App and Orthofix Proprietary Physician Portal enables physicians to remotely view patient adherence to prescribed treatments.

STIM onTrack Mobile App

The STIM onTrack™ Mobile App is a patient-friendly accessory available for you to use with your Orthofix Bone Growth Therapy device that encourages you to adhere to treatment sessions prescribed by your physician. It features a daily treatment reminder and a device usage calendar to help you take an active role in your bone healing recovery. Studies show that patients who are more involved with their follow-up care have an overall better recovery experience and better outcomes. At the time of device delivery, your Orthofix representative will help you download the application to your mobile device.

Features:

- Daily treatment reminders
- View a duplicate display of the device
- Tracks real-time usage data
- Links to educational patient resources
- Treatment calendars
- Quality of life questionnaire
  -Patient Reported Outcome Measure



Patient Reported Outcome Measure (PROM):

The PROM Tab on the STIM onTrack Mobile App enables patients to complete a specific standardized Patient Reported Outcome Measure (PROM) questionnaire to remotely share measures of their quality of life and/or functional well-being with their physician.

- These questionnaires are validated tools that are widely used by healthcare providers
- The responses may be used by your healthcare provider to assist in understanding your current overall recovery status**
- The questionnaire available to complete is dependent on your type of bone growth therapy device prescribed for use
  - For SpinalStim device - Oswestry Disability Index (ODI)
  - For CervicalStim device - Neck Disability Index

* STIM onTrack mobile app is available as an accessory for U.S. model devices only

** Information collected via the STIM onTrack mobile app is not intended for the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease.

Orthofix Guarantee Program

Orthofix bone growth therapy devices are prescribed with a guarantee program that provides for a refund of the fee paid for the unit to the payer(s) of record if no radiographic progress is shown that the fusion is healing.**

This permits physicians to prescribe and insurance providers to approve your bone growth therapy device with confidence.

**Subject to eligibility requirement.

THE Healing ADVANTAGE® GUARANTEE PROGRAM

Commonly Asked Questions

Below are common questions asked by real patients, just like you! If you have a question that hasn't been addressed, please visit our in-depth FAQ section located at BoneGrowthTherapy.com or by contacting your local Orthofix representative.

Am I a candidate for bone growth therapy?

Doctors may prescribe bone growth therapy for patients who are experiencing bone healing complications or exhibit risk factors that can impede healing. Common bone healing factors include:

- Smoking/tobacco use
- Diabetes
- Obesity
- Multi-level fusions
- Medication that depletes bone
- Spondylolisthesis (Grade 2+)
- Allograft (bone graft) use

What happens after my doctor prescribes a bone growth therapy device?

If your doctor prescribes an Orthofix bone growth therapy device, an Orthofix representative will contact you to schedule an appointment – either at your doctor's office or at your home to explain the benefits of the device, how it works, insurance requirements and to ensure that it is properly fitted. For a complete guide of what to expect after a device has been prescribed for you, watch our Patient Fitting Video located under Next Steps on our website at BoneGrowthTherapy.com.

Commonly Asked Questions

Why doctors and patients choose Orthofix bone growth therapy devices:

- High clinical success rates
- Designed for patient comfort and ease of use
- 360 degrees of PEMF treatment
- Effective in the presence of internal and external fixation
- The STIM onTrack Mobile App and Orthofix Proprietary Physician Portal enables physicians to remotely view patient adherence to prescribed treatments

Is bone growth therapy safe?

Yes. Our bone growth therapy devices produce a signal like the one your own body generates to induce normal bone healing. The PEMF therapy emitted by our devices was specially designed with your safety in mind, and is similar in strength to what you're exposed to naturally from the magnetic field of the Earth. Our bone growth therapy devices may be safely used with surgical hardware. The effect of PEMF treatment during pregnancy or nursing has not been studied; consult with your doctor if you suspect you may be pregnant.

More than 800,000 Orthofix patients have worn our stimulators to increase the probability of healing success. For full prescribing information, see the manual that came with your device or visit BoneGrowthTherapy.com

What will treatment feel like? How will it affect my daily activities?

You should not feel the PEMF therapy. The devices are lightweight for a comfortable fit and powered with a rechargeable battery, which allows the unit to be portable. With your doctor's approval, you can resume a normal activity level while wearing the device.

Commonly Asked Questions

Can I wear the device over a brace or collar?

Yes, it can be worn over an orthopedic brace, soft collar or clothing without affecting the PEMF signal as it travels through the body to the fusion site.

How do I know if my device is working?

Both the blue treatment indicator light and the colon between hours and minutes on the display screen will flash to show active status. Once your daily treatment is complete, a check mark will show up on the display screen next to the "Rx".

How long will it take to heal?

The healing process itself determines the duration of the treatment, and your doctor will closely monitor your progress. To promote your healing, it is very important that you wear your bone growth therapy device daily as prescribed. Patients are instructed to wear their device until their doctor confirms they are healed. Although your treatment may vary, most patients wear the bone growth therapy device between three and nine months.

Will my insurance company pay for the device?

Coverage for the device may depend on the insurance plan you have chosen. If prescribing guidelines are met, the bone growth therapy device is accepted and approved by the majority of private and public health plans, including Medicare, Medicaid and workers' compensation plans. In addition, we encourage patients to contact their insurance company for details in regards to health care coverage as some plans may include a deductible, co-payment, or other co-insurance amount.

Commonly Asked Questions

What if I don't have insurance, or I need financial assistance?

Please contact our Patient Care Billing Specialists at 866-543-9340 to discuss payment options.

When I am done with treatments, what do I do with my device?

Orthofix bone growth therapy devices should only be used by the person for whom it is prescribed. Bone growth therapy devices expire after 365 days of treatment. The device is yours to keep once your treatment is complete.

Brief Prescribing Information

Full prescribing information can be found in product labeling on our patient education website BoneGrowthTherapy.com or by calling Patient Services at 1-800-535-4492.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

The SpinalStim Device:

The SpinalStim™ device is indicated as a spinal fusion adjunct to increase the probability of fusion success and as a nonoperative treatment of salvage of failed spinal fusion, where a minimum of nine months has elapsed since the last surgery. Cardiac pacemakers may be adversely affected by exposure to pulsed electromagnetic fields. Use of this device is contraindicated where the individual has an implanted cardiac pacemaker. The safety and effectiveness of this device has not been established for individuals lacking skeletal maturity. The safety of this device for use on patients who are pregnant or nursing has not been established. Rare instances of reversible minor discomfort have been reported.

The CervicalStim Device:

The CervicalStim™ device is indicated as an adjunct to cervical fusion surgery in patients at high risk for non-fusion; there are no known contraindications. Do not use this device if you have a cardiac pacemaker or defibrillator. Remove the device prior to any imaging procedures. The safety of this device for use on patients who are pregnant or nursing has not been established. Adverse effects may include increased pain, numbness and tingling, headache, migraines and nausea; these effects may or may not be directly related to use of the device.

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* The results of preclinical studies may not be indicative of human clinical trials.

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