Xstim Spine Fusion Stimulator

IGNITE THE HEALING POWER WITHIN

PATIENT'S GUIDE

Xstim Spine Fusion Stimulator utilizes clinically proven capacitive coupling technology for bone growth stimulation, trusted by healthcare experts for over three decades– now updated for today's patient needs.

PROMOTES SPINE FUSION

Targeted Electrical Stimulation

Recovery from spinal fusion surgery can be challenging. One crucial aspect of successful fusion is the growth of new bone that joins the vertebrae together. This process is intricate and may take several months, delaying your ability to resume your normal, active routine.

At Xstim, Inc. we believe in the innate power of the human body to heal itself. However, sometimes it needs some extra help. Certain patients undergoing spinal fusion may encounter challenges in their bone healing after surgery. Often many health factors can reduce your chances of successful fusion such as smoking, obesity, osteoporosis, diabetes, and previous unsuccessful fusion attempts can impede the effectiveness of fusion surgery and delay recovery. To address these obstacles, surgeons commonly recommend bone growth stimulation therapy, like Xstim Spine Fusion Stimulator.

In developing Xstim Spine Fusion Stimulator, we acknowledged the longstanding trust in bone growth stimulation therapy, which has effectively helped heal spine fusions in thousands of patients over 30 years using capacitive coupling technology. The safety and efficacy of the signals produced by Xstim Spine Fusion Stimulator have been well-established. However, recognizing the evolving needs of modern patients, we reimagined bone growth stimulation to meet their contemporary lifestyles. Thus, Xstim Spine Fusion Stimulator was born.

MEET XSTIM SPINE FUSION STIMULATOR

Trusted Signal Technology

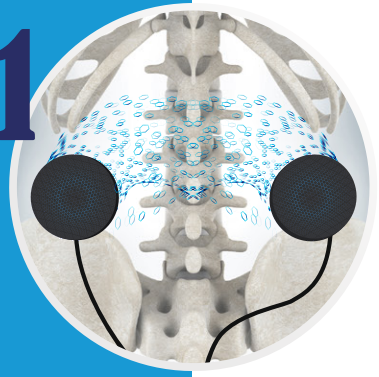
Our flagship product, Xstim Spinal Fusion Stimulator, is a class 3, FDA-approved device whose electrical stimulation signal has been clinically proven to promote bone healing after lumbar spinal fusion surgery for one or two levels (1,4). This proven capacitive coupling technology safely and effectively triggers the body's inherent healing mechanism through the transmission of low-level electrical pulses to the fusion site (1). The system is designed to deliver 270 days of continuous therapeutic treatment for 24 hours daily.

Visit **www.xstimmed.com/patients** to download the patient instructions for use and full prescribing information.

HOW DOES IT WORK?

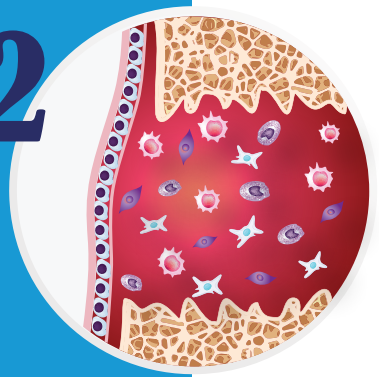
The electrical stimulation signal used in Xstim Spine Fusion Stimulator has been shown to UPREGULATE multiple growth factors to aid in fusion[2]

1



Xstim Spine Fusion Stimulator comfort hydrogel electrodes are placed 4 to 6 inches apart adjacent to the fusion site. The Xstim Spine Fusion Stimulator device sends imperceptible low-level electrical impulses to the spine fusion site through the electrodes, creating a favorable environment for bone regeneration.

2



In an in vitro study, using the same electrical stimulation signal, has shown that multiple bone morphogenetic proteins (BMPs) are upregulated throughout the bone healing phases in as little as 30 minutes of exposure, with optimal upregulation occurring through the day at 24 hours.[2]

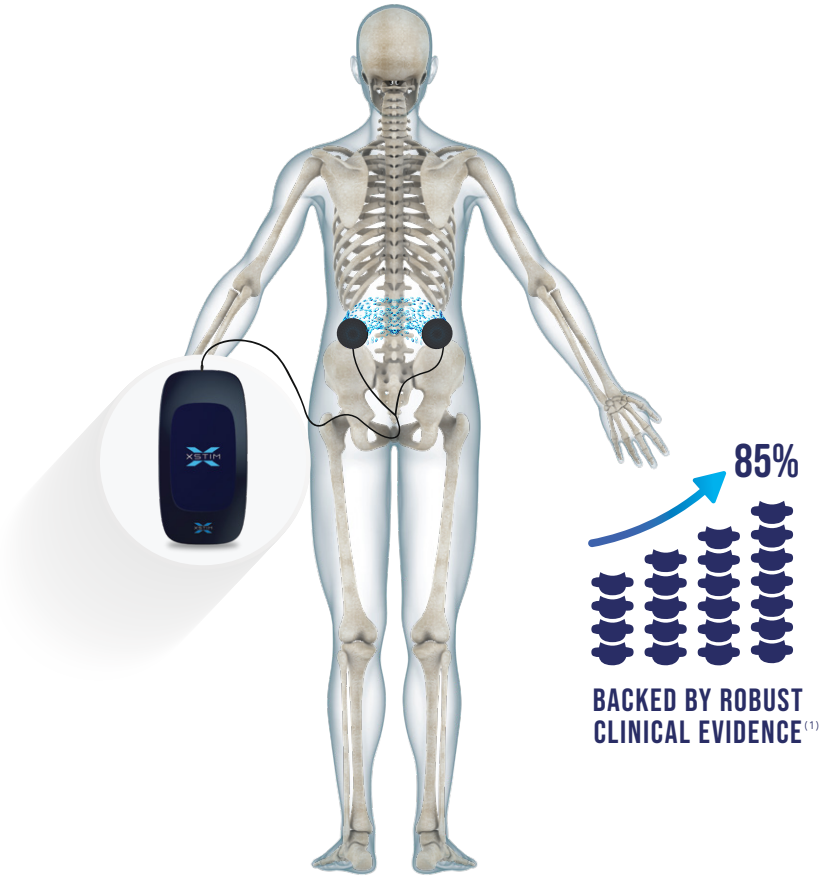
3

As bone remodels over time, the new bone tissue is gradually re-shaped and strengthened by the stresses on the newly formed bone at the fusion site through movement and weight-bearing.[3]

CLINICALLY PROVEN

To Increase Spine Fusion

- In a human clinical trial using the same signal as that of the Xstim Spine Fusion Stimulator the overall success rate (clinical and radiographic healing) for all lumbar fusions was 84.7% in the active capacitively coupled group vs. 64.9% in the placebo group. In this same clinical trial, the active capacitively coupled stimulator achieved statistically significant results in a variety of measurements. [1]
- In posterolateral fusions, the success rate was **89.1%** in the treatment group vs. 64.9% in the placebo group (P=0.006).[1]



COMPACT DESIGN

Convenient Built-In Technology

TAKE-ANYWHERE DESIGN FOR TREATMENT ON THE GO.

100% modern-day wearable so that you can treat with Xstim Spine Fusion Stimulator on the go. The low profile, lightweight, modern design discreetly fits comfortably under your clothes or any spine bracing options you may require after surgery. The large high-definition onboard LCD screen makes reviewing your treatments easy, without having any companion apps to download and manage on your phone.

CONCIERGE CARE

Redefining Medical Device Support

WHAT HAPPENS AFTER MY DOCTOR PRESCRIBES THE DEVICE?

- Once your spine surgeon decides that you could benefit from the Xstim Spine Fusion Stimulator, they will give a company representative a written prescription and any other information your insurance company needs to check if the device is covered under your plan. Xstim, Inc. works with several third-party billers to assist you in determining whether your health plan will cover the Xstim Spine Fusion Stimulator before you receive the device. The pre-authorization process through your health plan might take a few days or even a few weeks. The Xstim Spine Fusion Stimulator is accepted and approved by most major commercial insurance plans, including Medicare, Medicaid, and workers' compensation plans.

- Once your device is approved, a representative authorized by Xstim will reach out to you to arrange a fitting appointment. This can take place either at your doctor's office or in the comfort of your home. During this appointment, they will provide detailed information about the device, its benefits, how it operates, any insurance requirements, and ensure it is properly fitted for you.

COMMONLY ASKED QUESTIONS

CAN I USE THE DEVICE WHILE WEARING A BACK BRACE?

Absolutely! The Xstim Spine Fusion Stimulator was designed to be worn comfortably underneath clothing and a back brace.

HOW OFTEN SHOULD I REPLACE THE ELECTRODES?

If removing the electrode temporarily for any reason, replace the plastic backing material to protect them. Before replacing them on the back, check to see that the surface is still clean and tacky. If not, apply a few drops of water to the skin-facing surface and gently rub into the gel to help rehydrate. If this does not improve the surface properties, use a new pack of electrodes as supplied. Typically, a new set of electrodes may be required after a few days of use (1-7 days). When supplies of electrodes are running low, contact Customer Service at **(844) 228-2067** for additional supplies.

WHAT DOES THE XSTIM SPINE FUSION STIMULATOR'S SIGNAL FEEL LIKE?

One of the advantages of the Xstim Spine Fusion Stimulator is that the capacitively coupled bone growth stimulation signal is imperceptible.

ARE THERE ANY SIDE EFFECTS TO USING THE XSTIM SPINE FUSION STIMULATOR?

There are no known side effects related to the use of the Xstim Spine Fusion Stimulator. It may be safely used with non-magnetic internal fixation devices. Refer to the patient instructions for use for a full list of warnings and precautions.

WHAT DO I DO WITH MY DEVICE WHEN I AM DONE WITH TREATMENTS?

When your treatment is complete, as indicated by the "End of Product Life" message displayed on the device screen, or by the determination of your physician, dispose of the device according to local regulations. You may also contact Customer Support for assistance with disposal.

CUSTOMER SUPPORT

Support Representatives are ready to answer your questions and can be reached at **(844) 228-2067**.

Visit **www.xstimmed.com** for more information or to download patient instructions for use.

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IMPORTANT PRESCRIBING INFORMATION

DESCRIPTION: Xstim Spine Fusion Stimulator passes a specific current between the electrodes in order to promote healing by inducing a therapeutic, low level electrical current at the fusion site. Federal law restricts this device to sale by or on the order of a physician. Prescription (Rx) only. This device is not intended for re-sale.

INDICATIONS FOR USE: The Xstim Spine Fusion Stimulator is a noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. The device is for prescription use only, and intended for single patient use in adult patients only.

CONTRAINDICATIONS: There are no known contraindications.

WARNINGS: Cardiac pacemakers or cardioverters may be adversely affected by Xstim Spine Fusion Stimulator. The concomitant use of Xstim Spine Fusion Stimulator and a pacemaker or cardioverter must be assessed on an individual basis, such as with an electrocardiogram, prior to use. The patient should be referred to a cardiologist for monitoring of pacemaker function while wearing the active stimulator device. If there are any observable adverse changes in the pacemaker rhythm or output, Xstim Spine Fusion Stimulator should not be used. The safety and effectiveness of Xstim Spine Fusion Stimulator in pregnant women have not been studied and the effects of Xstim Spine Fusion Stimulator on the mother or the developing fetus are unknown. A patient who is either pregnant or is intending to become pregnant should be referred to her doctor prior to treatment with Xstim Spine Fusion Stimulator.

PRECAUTIONS: The safety and effectiveness of Xstim Spine Fusion Stimulator in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of Xstim Spine Fusion Stimulator in these individuals are unknown: spondylitis, infection, Paget's disease, cancer, diabetes mellitus, renal disease, osteoporosis, trauma of the lumbar spine. Apply the electrodes after the skin has been cleaned and dried. If erythema develops at the electrode sites, the electrodes should be relocated adjacent to the original sites. If the reaction does not resolve after 48 hours after relocating the electrodes, the patient should be instructed to consult with the physician. Do not submerge or expose Xstim Spine Fusion Stimulator to water. The patient must be instructed to remove Xstim Spine Fusion Stimulator during bathing, showering or swimming. Compliance with the treatment schedule, daily battery pack changes, and replacing the electrodes (1 to 7 days) as needed are essential for proper device function. This system should only be used with components and replacement parts supplied by Xstim. Other components, parts and accessories may not be compatible, and may damage Xstim Spine Fusion Stimulator. If any component does not function properly, contact Customer Service at (844) 228-2067. No attempt should be made to modify or repair Xstim Spine Fusion Stimulator. Patients should be able to use Xstim in accordance with the instructions for use. If a patient cannot comply with these instructions for any reason, use of Xstim Spine Fusion Stimulator is not recommended.

TO LEARN MORE AND FOR FULL PRESCRIBING INFORMATION, VISIT WWW.XSTIMMED.COM OR CALL 844-228-2067.

REFERENCES: (1) Goodwin CB, Brighton CT, Guyer RD, Johnson JR, Light KI, Yuan HA. A double-blind study of capacitively coupled electrical stimulation as an adjunct to lumbar spinal fusions. Spine. 1999;24(13):1349-1356. (2) Wang Z, Clark CC, Brighton CT. Up-regulation of bone morphogenetic proteins in cultured murine bone cells with use of specific electric fields. J Bone Joint Surg Am. 2006;88(5):1053-1065.(3) Wippert PM, Rector M, Kuhn G, Wuertz-Kozak K. Stress and Alterations in Bones: An Interdisciplinary Perspective. Front Endocrinol (Lausanne). 2017 May 1;8:96. doi: 10.3389/fendo.2017.00096. PMID: 28507534; PMCID: PMC5410657. (4) U.S. Food and Drug Administration. (2023). PMA P230025 FDA Summary of Safety and Effectiveness Data.

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