XSTIM

Introducing

XSTIM SPINE FUSION STIMULATOR

Advanced Spine Fusion Bone Growth Stimulation,
Powered by Capacitively Coupled Technology

MEET XSTIM

Spine Fusion Stimulator with Trusted Capacitive Coupling 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.[1,5] 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] With an impressive clinical success rate of up to 85% after one- or two-level lumbar fusion surgery[1], Xstim spine fusion stimulation therapy has transformed the way we approach the recovery and rehabilitation process for individuals who have undergone one- or two-level lumbar spinal fusion surgery[1]. By harnessing the body's innate capacity to heal itself, we aim to provide the best possible outcomes for our patients.

TAKE-ANYWHERE DESIGN

Compact, Lightweight & Portable for Discreet Treatment On-The-Go

BACKED BY ROBUST CLINICAL EVIDENCE

Up to 85% Fusion Success Rate in Posterolateral Lumbar Fusions [1]

BACKED BY OUR SIGNATURE CONCIERGE CARE

Xstim Seamlessly Converges Patient Care and Prescriber Satisfaction

TRUSTED SIGNAL TECHNOLOGY

Modernized for Today's Patient

CRAFTED FOR LIFE ON THE MOVE

Sleek modern design makes for a perfect fit on belt or in pocket.

INFORMATION AT YOUR FINGERTIPS

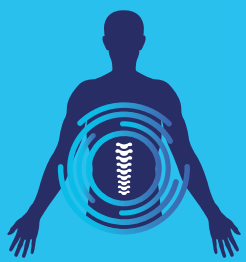
Large on-board color LCD Screen

CLINICALLY PROVEN SIGNAL

Capacitively Coupled signal, trusted by surgeons for over three decades

DISCREET AND LIGHTWEIGHT

Small, flexible comfort-gel electrodes



TARGETED STIMULATION WITH INTEGRATED TECHNOLOGY

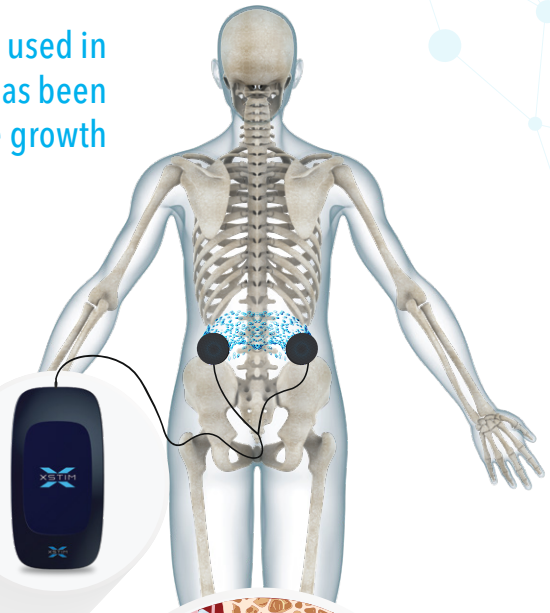
Targeted Stimulation of the Lumbar Spine

PRESCRIBE XSTIM SPINE FUSION STIMULATOR.

PRESCRIBE CONFIDENCE.

XSTIM SPINE FUSION STIMULATOR WORKS

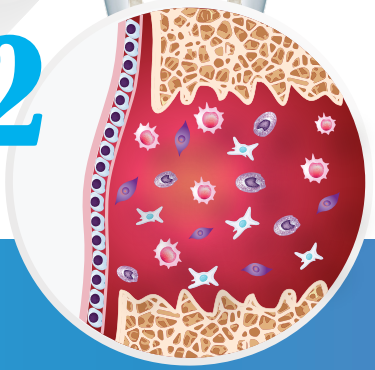
The electrical stimulation signal used in Xstim Spine Fusion Stimulator has been shown to UPREGULATE multiple growth factors to aid in fusion.[2]



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



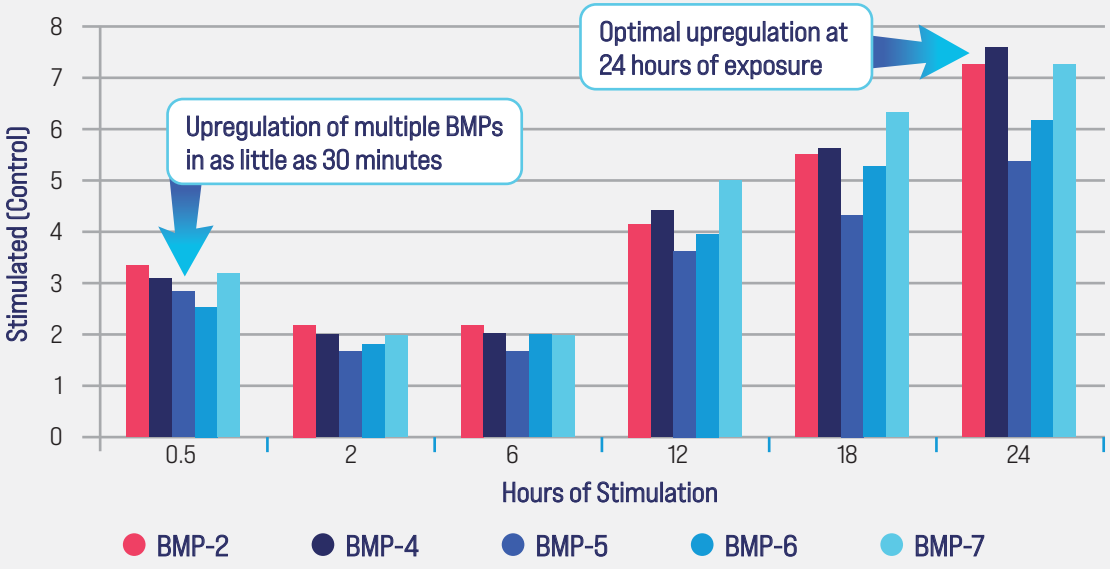
In an *in vitro study*, using the same electrical stimulation signal, has shown that multiple bone morphogenetic proteins (BMPs) are upregulated throughout the bone healing phases in as little as 30 minutes of exposure, with optimal upregulation occurring through the day at 24 hours.[2]

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]

PRE-CLINICAL DATA

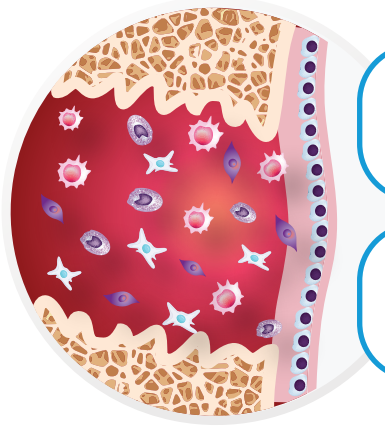
BMP Expression in Response to Capacitive Coupling Stimulation



In an *in vitro study,* upregulation of multiple BMPs occurred in as little as 30 minutes of exposure with optimal upregulation at 24 hours of exposure.[2]

Capacitative Coupling vs. PEMF and CMF

Pre-clinical studies have shown that Capacitive Coupling causes significantly higher levels of cellular proliferation than other electrical stimulation technologies.[4]



63%

CC had a 63% Increase in DNA over CMF (P<0.05)

123%

CC had a 123% Increase in DNA over PEMF(P<0.05)

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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:

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 Spine Fusion Stimulator 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.

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) Brighton CT, Wang W, Seldes R, Zhang G, Pollack SR. Signal transduction in electrically stimulated bone cells. J Bone Joint Surg Am. 2001;83-A(10):1514-1523. (5) U.S. Food and Drug Administration. (2023). PMA P230025 FDA Summary of Safety and Effectiveness Data.

p/n : APM001 Rev A