

## INFORMED CONSENT

**TITLE: POST-MARKET SURVEILLANCE OF CLINICAL AND FUNCTIONAL OUTCOMES WITH POST-OPERATIVE ADJUNCTIVE USE OF CERVICAL-STIM® OR SPINAL-STIM®**

**PRINCIPAL INVESTIGATOR: THOMAS CHEN, MD, PHD**

**DEPARTMENT: NEUROSURGERY**

**24-HOUR TELEPHONE NUMBER: (323) 865-3000**

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We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may also decide to discuss it with your family, friends, or your doctor. You may find some of the language difficult to understand. If so, please ask questions. If you decide to participate, you will be asked to sign this form.

### **WHY IS THIS STUDY BEING DONE?**

This study is about Pulsed Electromagnetic Field (PEMF) treatment.

PEMF has been used in medicine for almost 20 years to help bones heal. ORTHOFIX PEMF bone growth stimulators generate a consistent low-level, pulsed electromagnetic field much like the electrical field produced by the body. Placing the bone growth stimulator directly over the surgery site may help add to the body's own natural healing process. The purpose of this study is to gather additional information on the progress of patients who use these bone growth stimulators.

In other studies, it has been shown that a PEMF bone growth stimulator may speed up bone healing in people at high risk for not healing quickly. You are invited as a possible participant in this study because you are having surgery on your cervical or lumbar spine, your doctor has determined you have at least one high risk factor that may slow down bone healing, and your doctor has prescribed PEMF treatment. Your doctor has explained to you why you are at risk for not healing and why he will prescribe cervical or spinal bone growth stimulator treatment to you after your surgery. The PEMF treatment will be delivered by either the Cervical-Stim® or Spinal-Stim® bone growth stimulator, both of which are made and sold by ORTHOFIX INC. Both of these bone growth stimulators have been approved by the U.S. Food and Drug Administration (FDA) for use in patients who have had cervical or lumbar surgery and are at high risk for inhibited bone healing.

There will be about 1000 participants in different locations across the United States participating in this study. About 50 participants will take part at USC. Each participant will participate in the study for up to nine months.

## **WHAT IS INVOLVED IN THE STUDY?**

If you decide to take part, this is what will happen:

There are no experimental procedures in this study. You will have the same procedures that would be done by your doctor whether you were in this study or not.

While you are in this study, you will follow your study doctor's instructions before surgery and for all your follow-up visits after your surgery. You will wear the bone growth stimulator as prescribed by your study doctor and according to the directions given in the device manual, which may range from 2 to 4 hours every day for up to 9 months. You will be asked to complete study survey forms at two of your study doctor visits. The surveys will ask you questions about your pain and your ability to do daily activities. You will bring the bone growth stimulator with you to each study doctor visit. You will be asked about any problems you may have while using the bone growth stimulator.

Your study doctor's staff will print a device-use report from your bone growth stimulator after your study doctor determines your spine is healed and tells you to stop using your PEMF device, or at nine (9) months after you started PEMF treatment (whichever occurs first). You will need to bring your device with you to your study doctor visits in order to allow your study doctor's staff to print this report.

Only you, the study participant, should use the device. It must be kept out of the reach of children and people who may not be able to read or understand the label.

## **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

Possible risks and discomforts you could experience during this study include the following:

### **Questionnaires**

Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions that make you uncomfortable.

### **Devices**

The devices used in this study are part of your standard of care and their risks include:

Cervical-Stim<sup>®</sup> - Discomforts reported with use of the Cervical-Stim<sup>®</sup> include increased pain, numbness and tingling, headache, migraines and upset stomach. These discomforts should stop when you quit using the Cervical-Stim<sup>®</sup> device.

Spinal-Stim<sup>®</sup> - Discomforts reported with the use of the Spinal-Stim<sup>®</sup> include minor tingling or pain, minor skin rash, sleeplessness, fainting, unsettled stomach, and diarrhea. These discomforts should stop when you quit using the Spinal-Stim<sup>®</sup> device.

There may be risks or side effects which are unknown at this time.

**WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?**

You will not receive any direct benefit from taking part in this study. However, information from this study may help patients who have spinal surgery in the future.

**WHAT OTHER OPTIONS ARE THERE?**

An alternative is to not take part in this study and to wear the Cervical-Stim<sup>®</sup> or Spinal-Stim<sup>®</sup> following your doctor's standard of care instructions. In that case, information on your use of the product is not collected by Orthofix.

**WILL YOUR INFORMATION BE KEPT PRIVATE?**

The investigator and the Institutional Review Board (IRB) will keep your records private as far as the law allows. The IRB is a research review board that is made up of professionals and community members who review and monitor research studies to protect the rights and welfare of research participants. Officials sent by the Food and Drug Administration (FDA), the sponsor, who is Orthofix, may look at your research records and medical records. Your records will be kept confidential unless the law requires us to share these records.

**WHAT ARE THE COSTS?**

There will be no additional costs to you to participate in this study. You and/or your health plan/insurance company will be responsible for the cost of any standard treatment and diagnostic procedures that you may receive for your spinal problem, including surgery, doctor visits, X-rays and the bone growth stimulator. You and/or your health plan/insurance company/government program will be billed for the standard costs of treatment and diagnostic procedures in the same way as if you were not in a research study. You will also be responsible for any co-payments and deductibles that are standard for your health plan/insurance coverage. Some health plans will not pay these costs for people taking part in studies. Check with your health plan/insurance company/government program to find out what they will pay for.

**ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?**

You will be given a \$25 gift card as compensation for your participation in this study.

**WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?**

It is important that you tell your study doctor, Dr. Thomas Chen, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him at (323) 865-3000.

If you require medical treatment as a result of injury arising from your participation in this study, emergency medical care will be provided. Orthofix will pay for the cost of care/treatment for those injuries related to your participation in the study. No other form of compensation will be provided for injuries resulting from your personal conduct or participation in activities outside of the scope of the study protocol. No financial compensation will be provided for such things as lost wages, disability or discomfort, losses claimed by spouses or family members, medical expenses due to treatment of any underlying or unrelated condition or any other expense arising from or claimed to be due to any research-related injury. However, by signing this form you have not given up any of your legal rights.

**WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?**

During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this information with you. You might change your mind about being in the study based on this information. If new information is provided to you, we will ask for your agreement to continue taking part in this study.

**UNDER WHAT CIRCUMSTANCES CAN YOUR PARTICIPATION BE TERMINATED?**

You may be removed from this study without your consent for any of the following reasons: you do not follow the investigator’s instructions, at the discretion of the investigator or the sponsor, your disease gets worse, or the sponsor closes the study. If this happens, the investigator will discuss other options with you.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?**

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time.

**ARE THERE ANY POTENTIAL CONFLICTS OF INTEREST?**

The investigator is receiving financial support from the study sponsor to conduct the study. He is receiving financial reimbursement to help cover the costs of collecting information on the use of the device. As an investigator Dr. Thomas Chen, your doctor is trying to improve your health condition and conduct good research at the same time. If you wish, you may get a second opinion about your care from another doctor who is not involved with this study. You are free to decide not to take part in any studies you may be offered by your doctor.

**WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?**

You may contact Dr. Thomas Chen at (323) 865-3000 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact Dr. Thomas Chen at (323) 865-3000. If you have questions, concerns, or complaints about the research and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM. (Fax: 323-224-8389 or email at [irb@usc.edu](mailto:irb@usc.edu)). If you have any questions about your rights as a research participant, please also contact the Institutional Review Board Office at the numbers above or write to the Institutional Review Board at the LAC+USC Medical Center, General Hospital, Suite #4700, 1200 North State Street, Los Angeles, CA 90033.

You will get a copy of this consent form.

**AGREEMENT:**

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions were answered. I have decided to sign this form in order to take part in this study.

By signing this consent form, I have not given up any of my legal rights.

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Name of Research Participant	Signature	Date ( & Time) Signed
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I have personally explained the research to the research participant and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

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Name of Investigator/Person Obtaining Informed Consent	Signature	Date (& Time) of Signature
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Study ID: HS-08-00068 Valid From: 3/24/2010 To: 2/1/2011