Title of Study: Auricular Percutaneous Electrical Nerve Field Stimulation for Postoperative Pain Control in Adults

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Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

Auricular Percutaneous Electrical Nerve Field Stimulation for Pain Control in Adults

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You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, possible risks and benefits to you, your choices, and other important information. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are being invited to participate in this research study because you will undergo surgery on your colon. Because of your condition, you may be eligible for a research study on a device that is placed on your ear that may help improve your pain control.

A total of about 50 people are expected to participate in this study at the Medical College of Wisconsin/Froedtert Hospital and the Clement J. Zablocki VA Medical Center.

The Director of the study is Carrie Y. Peterson, MD in the Department of Surgery, Division of Colorectal Surgery. A study team works with Dr. Peterson. You can ask who these people are.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A research study is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to determine if the BRIDGE device, a small device that fits onto your ear similar to a hearing aide, can help improve pain control after colon surgery.

While the medical device that we are studying, the BRIDGE device, has been approved by the U.S. Food and Drug Administration for acupuncture, and can also be used as an aid to reduce the symptoms of opioid withdrawal, we will be using the same device for a different purpose. For this reason this use must be considered experimental.

We want to compare how patients treated with this device do when compared to an inactive form of the device.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Screening procedures:

If you decide to join the study, some screening tests will be done first to see if you are eligible.
If you have:

- a history of chronic pain issues or anxiety, you may not be eligible to participate in this study.

If the screening information shows that you meet the requirements, and you agree to participate, you will be able to start the study.

If the screening information shows that you cannot be in the research study, the study doctors will continue to treat your disease as appropriate.

Research study groups

Because no one knows if the device actually decreases pain, you will be “randomized” into one of the two study groups. One group will receive an active device, and one group will receive an inactive device. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Neither you nor the study doctor can choose what group you will be in.

Since the expectations of patients and doctors can influence the results of a study, neither you nor your study doctor can know which device you will get until the study is over. A computer program chooses which group you are in, and the devices in each group will look the same.

In an emergency, your doctor can find out which device you are using.

Summary of Study Procedures:
As part of the study, you will be given a device on the date of your surgery and it will be fitted on your ear prior to surgery in the pre-operative area.

Prior to the device being fitted, you will be asked about your pain, anxiety and nausea before surgery, along with collecting a vial of blood and saliva sample up to twice daily.

This device should be worn for 5 continuous days.

After your surgery and while you remain hospitalized, we will collect blood and saliva samples. In addition, you will be asked to rate your pain, anxiety, and nausea during the time you wear the device.

- If you are discharged from the hospital before day 5, you will receive an information sheet regarding the device telling you: 1) how to remove the device after 5 days, 2) explaining what to do if the device becomes dislodged, and 3) providing you with contact information for the study team. You will be contacted by the study team on Day 5 to follow up on your pain, anxiety and nausea.

After completing the active part of the study, we will continue to follow up to ask you about your pain, anxiety, and nausea at your first follow-up visit post-surgery and again 30 days post-surgery.

B2. HOW LONG WILL I BE IN THE STUDY?
You will be in this research study for 5 days. After the study is finished, we want to keep in touch with you to follow your health over time. We will follow up with you in clinic, and then again by phone in 30 days, to ask about your pain, anxiety, and nausea.

B3. CAN I STOP BEING IN THE STUDY?
You are free to withdraw from the study at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please let the study team know by contacting Dr. Peterson at 414-955-5783 or Kathryn Hoffman, Clinical Research Coordinator, at 414-955-1479.

The study investigator may take you out of this study at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the study rules.
- The whole study is stopped.

If this happens, the study doctor will tell you.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE STUDY?
Please cover your device with a washcloth or plastic covering while showering. Please replace electrodes if they come loose. If your device completely falls off, do not replace

it. These instructions, along with our contact information, are included on your patient information sheet. You may contact any of the study team members at any time with questions.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

There are risks to taking part in any research study. There is a risk that you may get a device that does not help your pain or may make it worse. There also may be problems (side effects) we do not know about yet from the device itself. If we learn about new important side effects, we will tell you. It is possible that the application of the device may cause bleeding or dermatitis (skin irritation), though this risk is very low.

We watch everyone in the study for problems (side effects). **You need to tell the study doctor or a member of the study team immediately if you experience any problems, side effects, or changes in your health.** If you have increased pain or discomfort, call Dr. Peterson immediately at 414-955-5783. In an emergency, call Froedtert Hospital at 414-805-3000 and ask to speak with the general surgery resident on call. You may also page Jacqueline Blank, study team member, with any emergent questions: 414-557-8481.

Another risk may be loss of confidentiality. Every effort will be made to keep your study records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your study information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

C2. RISKS OF THE ACTIVE BRIDGE DEVICE

The research device itself may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away. The side effects that you may experience with the device are discomfort, poor pain control, and sensitivity from the tape used to secure the device to your ear. Some patients may feel uncomfortable after placement of the device. Some discomfort is normal at first but you should report if the discomfort persists or gets worse after a few minutes. You may feel a slight pulsing sensation and perhaps a warming sensation in the ear to which the electrodes are applied. The pulsing and warming sensation may disappear after approximately 5 minutes. If you are too uncomfortable, you may remove the device and withdraw from the study.

Since we don't know if you will receive an active or inactive device, you may desire more options for pain control while in this study. We will treat your pain the same as any other patient with your condition, regardless of study participation.

If you have a sensitivity to tape or adhesives, we ask that you do not take part in the study. If you develop a sensitivity or irritation with the device, we will evaluate you and remove the device if necessary.

C3. OTHER RISKS OF THIS RESEARCH STUDY

We will call you on postoperative day 30 to ask about your pain, anxiety, and nausea. This phone call poses a small risk of loss of confidentiality. If you prefer not to be contacted by phone, you may withdraw from the study. There are also minor risks of blood draws: bruising, bleeding, or pain at access site.

C4. REPRODUCTIVE RISKS

Risks to women who could become pregnant

The device in this study might affect a baby, before or after the baby is born. We do not know if the device causes harm to a baby, so we do not want anyone who might be pregnant to enter the study. You should not become pregnant or nurse a baby while in this study. You must tell the study doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the study.

Birth control methods for all subjects

Check with the study doctor about the birth control methods needed for this study and how long to use them. Some methods might not be good enough for this study. If you are having sex that could lead to pregnancy, you should use birth control while you are in this study.

This may include:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Surgical sterilization (hysterectomy or tubal ligation)
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of diaphragm with condoms (“double barrier”)
- Limiting sexual activity to a male partner who has had a vasectomy

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study may or may not improve your pain control. Your participation in the study can potentially help us improve pain control for future patients. We hope to be able to cut back on the amount of narcotic pain medications that patients use after surgery, and this device may help.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

The medical care that you will receive in this study is considered routine care for your condition and would be recommended whether you join the study or not. Costs for routine care will be billed to you or your insurance carrier.

Use of the BRIDGE device is part of the study will not be billed to you or your insurance company. In addition, the cost of all laboratory tests that are study-related (blood and saliva samples) will be covered by the study and will not be billed to you or your insurance. Some insurers will not pay for drugs, tests or hospitalization that are part of research studies, so check with your insurer before you join this study. If you have questions regarding study costs, please contact Dr. Peterson.

D2. WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

You will not be paid for participating in this study.

D3. WHAT OTHER CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. Whether or not you join this study, your usual medical services will not change.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important new information about the device that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE STUDY?

If you have been following directions, the injury is directly related to the research, and not the result of an underlying condition, then MCW and/or the Sponsor will compensate you for the injury.

If you think you have been injured because of this study, let the study doctors know right away by calling Dr. Peterson at 414-955-5783, Clinical Research Coordinator Kathryn Hoffman at 414-955-1479, or study team member Jacqueline Blank at 414-557-8481. In an emergency, call Froedtert Hospital at 414-805-3000 and ask to speak with the general surgery resident on call.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If you have more questions about this study at any time, you can call Dr. Peterson at 414-955-5783, Kathryn Hoffman, Clinical Research Coordinator, at 414-955-1479, or study team member Jacqueline Blank at 414-557-8481.
- If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To be in this research study, the study team needs your permission to access, collect

and use some of your health information. If you say no, you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); any Froedtert Health Affiliate- Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this study is:
Medical records of the care you receive for this study, including details of the surgery performed, your recovery, medications and treatments given while in the hospital, and demographic information will also be collected along with your contact information so we may call you after you leave the hospital.

E2. Who will see the health information collected for this study?
The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the study team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

Because this study involves the use of drugs and/or devices, the FDA also has the right to inspect all study records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different study without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?
One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to

protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study doctor about whether this could apply to you.

E4. How long will you keep the health information for this study?
If you sign this form, we plan to keep your information for 10 years after the research study ends in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to *Carrie Peterson, MD, Medical College of Wisconsin and Froedtert Hospital, Department of Surgery, Division of Colorectal Surgery, Hub for Collaborative Medicine 6th Floor, 8701 Watertown Plank Rd, Milwaukee, WI 53226*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

E6. Access to clinical records
If you join this study, you will be given one of two devices without knowing exactly which one (a "blinded" study). If you ask to see your health records during this "blinded" study, the study team cannot tell you which device you are being given. This is because the study team also remains "blinded" about which device the sponsor has randomly assigned to you. You would have to wait until the time given below. We cannot do the study unless you agree. However, if the blinded information is needed to treat you, it will be provided to the study doctor.

- What are the blinded options? You will get one of these interventions: active BRIDGE device or inactive BRIDGE device
- When can you find out which intervention you were given? You may find out which intervention you were given no earlier than 1 year after the completion of the study (completion of data collection for all patients).

F1. FOR MORE INFORMATION ABOUT THE STUDY
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can look up this study by referring to the ClinicalTrials.gov number (NCT02892513) or by asking the study team for a printed copy.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document, including Attachment 1 (patient information sheet). All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Witness (if applicable**)** *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date**

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the study team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. In all research study protocols the Principal Investigator is responsible and accountable for the study.*

Attachment 1 – Patient information sheet.