KEY INFORMATION FOR THE EFFECT OF SHORT TERM PATIENT OUTCOMES WITH THE USE OF INTERFERENTIAL CURRENT THERAPY AFTER TOTAL KNEE ARTHROPLASTY

We are asking you to choose whether or not to volunteer for a research study about the use of interferential current therapy to improve post-surgery outcomes after total knee replacement. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if the use of a novel device during your post-surgical hospital stay improves pain, swelling and range of motion. The device is called interferential current therapy. The device works by producing a painless electric signal above and below the knee. The signal works to block the pain signal being sent from your knee to your brain theoretically improving your pain. This device has not been approved by FDA for treatment after Total Knee Replacement. Your participation in this research will last about 2-3 days while you are admitted post-operatively after your knee replacement surgery.
The purpose of this research is to gather information on the effectiveness of an interferential current therapy device.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By volunteering, you would benefit by potentially improved post-operative pain, swelling and short term outcome leading to use of less opioid medications and faster return to normal functional status. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may decide that you do not want to participate in this study because there is a 50/50 chance of being in the placebo group. If you are in the placebo group, you will use the same device as the treatment group twice a day for two days but the device will not apply the electrical signal necessary to block your pain. If the study computer places you in the test group, there is no guarantee that IFC device will help your pain. Research has not been done to confirm whether it will improve pain treatment. For a complete description of risks, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is your operative surgeon, Dr. SJ Kim. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: sukim@montefiore.org.
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

MONTEFIORE MEDICAL CENTER
Wakefield Division

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called "The effect of short term patient outcomes with the use of interferential current therapy (IFC) after total knee arthroplasty." Your participation is voluntary it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Dr. SJ Kim. You can reach Dr. Kim at:
Montefiore Medical Center
The University Hospital for Albert Einstein College of Medicine
1250 Waters Place Tower 1, 11th Floor Bronx NY 10461
347-577-4410 Office
347-577-4596 Fax
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right-hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by
ORTHO IFC LLC
850 New Burton Road
Suite 201
Dover, Delaware 19904

Why is this study being done?

Interferential current therapy (IFC) is the production of a painless electric signal that block the pain signal being sent from your knee to your brain theoretically improving your pain. This technology has been used in physical therapy as a treatment modality for more than 50 years, has been thoroughly studied, and has been determined to be safe and effective. However, this device with a new therapy program has not been approved by FDA. Moreover, IFC has not been used as an additional treatment for knee replacement surgery aftercare before. Therefore, it is considered experimental for this treatment.
The goal of this study is to determine whether the use of IFC as part of the care after knee replacement surgery results in more rapid recovery. We hypothesize that IFC treatment during the hospital stay after knee replacement surgery will result in a more rapid recovery with less pain, discomfort and swelling, more rapid and effective recovery of muscle strength, joint range of motion, and overall function.

Why am I being asked to participate?

You are being asked to participate in this study because you are going to have a total knee replacement surgery with Dr. Kim.

What will happen if I participate in the study?

When you give consent, you will be enrolled into the study. Your surgery and the standard of care after the surgery will not be altered when you participate in the study. The standard of care regardless of participation in the study includes spinal and local anesthesia prior to surgery followed by oral and injectable pain medication post-operatively to effectively control pain. In addition, you will start working with physical therapy within the first day of surgery and begin the process of recovery.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the Interferential Current Therapy (IFC) group or the Placebo group. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to the IFC treatment group. If you are selected to IFC group, you will receive IFC treatment twice a day before your physical therapy during your hospital stay. If you are selected to Placebo group, the same device will be used however the device will not apply the electrical signal necessary to block your pain. Both study groups will receive standard of care during the hospital stay as mentioned above.

If you participate in the study, you will be asked to fill out few short questionnaires regarding your pain level, amount of pain medication you use and your overall health.

As part of this study we will review your medical records and put the information we collect in our research records.

A description of this clinical trial will be available on 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.

How many people will take part in the research study?

You will be one of about **50** people who will be participating in this study.

How long will I take part in this research?

It will take you about 6 weeks to complete this research study. During this time, we will not ask you to make any extra visits to the hospital or to the clinic, you will only have the standard post-operative office visits at 2 weeks and 6 weeks after your surgery. The current therapy device will be used only during your hospital stay after the surgery.

Information Banking (Future Use and Storage)

Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

Sponsor (IFC Ortho LLC) will be responsible for any medical costs caused by use of study device.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Kim (347-577-4410).

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?

Based on prior research using this IFC, there are side effects of the device including skin irritation and burns related to the electrical stimulation however these are rare.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Questionnaire
You may feel uncomfortable answering questions about use of pain medication or your personal information. You can choose not to answer questions that make you feel uncomfortable.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include improved pain control and function, decreased swelling and opioid use, faster return to better activity level.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you the standard care and treatment that is appropriate for you.

Your other choices are to not be involved in the study and have standardized post-operative total knee replacement care provided by the Orthopaedic surgery team at Wakefield hospital.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and they will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

If you have a complication related to the device, we will not let you continue with the study any more**.** In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date