RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Protocol Title:	Evaluation of standard TED stocking versus Reparel bioactive garment on postoperative leg swelling, pain, and dvt rates after hip replacement surgery.
Protocol #:	
Sponsor:	Reparel
Principal Investigator: (Study Doctor)	**Alexander Sah, MD** Institute for Joint Restoration & Research Washington Hospital Healthcare System 2000 Mowry Ave, Fremont CA 94538
Sub-investigators	Bryant Bonner MD, Meena Mistry PA, Joseph Gomez PA, Kayla Cook PA, Petra Nicolas PA
Study-Related Phone Number(s):	(510) 818-7284 or (510) 818-7249

Why am I being asked to volunteer?

You are being invited to take part in a research study because you are having hip replacement surgery. Standard and traditional protocols after hip replacement surgery include swelling control and deep vein thrombosis formation with compression leg stockings. Literature has been mixed on the effectiveness and comfort of these traditional compression stockings. Alternative leg garments are available, and may provide advantages in pain and swelling relief, and blood clot prevention. **Your participation is voluntary,** which means you can choose whether or not you want to participate. Your decision will not result in any loss of benefits to which you are otherwise entitled. You do not have to participate in this study to have surgery or other treatment from Sah Orthopedics.

Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to collect information and evaluate how patients do after hip replacement surgery in the recovery period in regards to leg swelling and discomfort and blood clot formation. The purpose of this study is to compare new material garments to the traditional stockings. The results of this study may provide information that will add to the knowledge of clinically proven benefits of recovery after hip replacements.

This is a single surgeon, prospective, controlled study consisting of 50 patients with a primary indication of osteoarthritis who are eligible for primary total hip replacement.

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The patients are equally divided in two groups; patients in group 1 will have the reparel garment on the operative leg, and the standard stocking on the nonoperative leg. Group 2 will have the opposite: traditional stocking on the operative leg, and reparel on the nonoperative leg.

What am I being asked to do?

Your doctor has confirmed that this is an appropriate treatment for you during your recovery from hip surgery. You will be in the study from the time you schedule your surgery and enroll until about 2 years following surgery following traditional followup protocols. Prior to surgery, you will be asked about your medical history and undergo a physical exam. You may be asked to complete a questionnaire which will take approximately 5 minutes.

All protocols will be the same even if you are not enrolled in this study. Surgery, recovery protocols, etc. are unchanged in this study; except for the leg garment randomization as described above.

After surgery, with our standard protocols, you will be required to come back to Dr. Sah's office for follow-up visits at 2 weeks, 6 weeks, 12 weeks, 1 year post-surgery as routine. At each follow-up visit you will undergo a physical exam, and xray.

What are the possible risks or discomforts?

There are limited risks with this study. Discomfort, swelling, and blood clots are known potential risks after orthopedic surgery. The reparel leg garment and the traditional compression stocking are both intended to minimize these risks.

The other possible risk of participating in this study is loss of confidentiality and unintended disclosure of your private health information. Measures, as described below, explain how this information is protected.

You cannot participate in this study if you are pregnant. You must confirm that, to the best of your knowledge, you are not pregnant. If you suspect that you have become pregnant, you must notify the study doctor. Pregnancy after the surgery, during the data collection period, does not affect your continued participation in this study.

What are the possible benefits of the study?

You are not guaranteed any benefits for taking part in this study. Your participation may contribute to the knowledge about pain and swelling control and blood clot prevention during the recovery post-surgery. This knowledge in turn may help other patients in the future who require joint replacement surgery.

What are choices do I have if I do not participate?

The alternative to participating in this study is not to participate and to proceed with your surgery and treatment as part of standard care. Your standard care will not be impacted in any way if you do not participate in this research. This knee sleeve product is available outside of the study for patient use, subject to cost by retailer.

Who performs the consent, and are there potential conflicts of interest by research team?

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Informed consent discussion will be performed by Dr. Sah, or one of his research team members, Joseph Gomez, Kayla Cook, Petra Nicolas, Bryant Bonner, or Meena Mistry. The research team may receive research support for the time and effort to perform the study as described. There is no other conflict of interest by the research team.

Who is paying for this study?

The cost of your standard medical treatment will be billed to you and your insurance company. This study has required procedures or examinations that are normally required of patients having joint replacement surgery. You will be responsible for any deductibles or applicable co-pays for routine office visits and x-rays. The study devices are at no cost to you. Neither you nor your insurance company will have any additional financial obligations as a result of participating in the study.

This study is sponsored and funded by Reparel®, the company which makes the leg garment. The study group are supported in their time and effort to execute this study.

Will I be paid for being in this study?

There is no payment to participate in this study.

What happens if I am injured or hurt during the study?

Your participation in this study provides no other financial compensation or free medical care. Financial compensation for a research related illness or injury, lost wages, disability or discomfort is not available. However, you do not waive any legal rights by signing this consent form. If you believe you have been injured as a result of participating in this study, you should contact Dr. Sah immediately. Further medical care and hospitalization resulting from injury or illness will be charged to your insurance company, just as it normally would be. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your study doctor, the study Sponsor, or the FDA without your consent because:

- it is in your best interest
- the study doctor thinks it necessary for your health or safety
- you have not followed study instructions
- you do not consent to changes made in the study plan
- the sponsor has stopped the study
- administrative reasons require your withdrawal
- or for any other reason

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care and you will be given a return label to return both devices. If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a final visit for some of the end of study procedures.

What if new information becomes available about the study?

You will be informed as soon as possible of any significant new findings that are discovered during the study that might change your mind about being in the study.

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Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have any questions, concerns, or complaints relating to this clinical study or your participation in it, you may contact Alexander Sah, MD at (510) 818-7284 with questions you might have regarding research-related injuries or the research or procedures involved.

If you have questions on rights of study subjects, complaints, or general questions about what it means to be in a research study, you can call the Washington Hospital Institutional Review Board (Kristin Ferguson, IRB Administrator) at (510) 818-7077 or visit the website at http://whhs.com. The IRB is located at 2500 Mowry Avenue, Fremont, CA 94538.

Authorization to Use and Disclose Information for Research Purposes:

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The Institute for Joint Restoration and Research is required by law to protect your health information. If you sign this document, you give permission to Dr. Sah and staff at the Institute for Joint Restoration and Research, to use your health information that might identify you.

What health information may be used and given to others?

The health information used for this research may include:

- Past, present and future medical records, that may include your name
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Questionnaires
- Records about the study device
- Records about your health care expenses
- Records about your health coverage

Information collection requires the use and release of your current and future health information. This includes your name and any or all portions of your medical and research records during the course of the study.

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

Your information may be given to the sponsor of this research, Reparel®. "Sponsor" includes any persons or companies that work for or with the sponsor or are owned by the sponsor. Health information sent to the sponsor does not usually include your name, address or social security number. The sponsor may see this information at your study doctor's office. Your medical records may be looked at and copied by the sponsor, or government agencies or other groups associated with the study.

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Your health information will be used or released when required by law. The health information listed above may be used by and/or released to:

- Washington Hospital Healthcare System Institutional Review Board
- Reparel® (study sponsor)
- US DHHS
- US FDA

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the study. In addition, the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed. The information may also be used when the sponsor submits required reports to governmental agencies.

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.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study, and sign this consent form, you will not be allowed to look at or copy your research information until after the research is completed.

How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

May I withdraw or revoke (cancel) my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must send a written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

To withdraw this Authorization, you must write to:

Alexander Sah, MD
Institute for Joint Restoration & Research
Washington Hospital Healthcare System
2000 Mowry Ave, Fremont, CA 94538

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. However, information that has already been gathered may

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still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

Your identifiable health information may no longer be protected if you give permission to release it to a person or business. There is a risk that your health information will be released to others without your permission.

Any information in your health records that is fully de-identified will no longer be subject to this authorization and may be used or disclosed for other purposes.

By signing this authorization, I give my permission for the collection, use, and sharing of my persona/protected health information generated and collected in this study by Reparel® (Sponsor), the vendors providing study support services, the study staff, and the regulatory authorities in the U.S. and The Washington Hospital Institutional Review Board.

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Subject Signature Date

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Printed Name of Patient Subject

By signing this consent form, you are acknowledging:

- You have read or someone has read to you this entire informed consent
- You have been able to ask questions about this study
- Your questions have been answered to your understanding
- You have received enough information about this study to make an informed decision
- Your financial questions about this study and your responsibility have been answered
- You understand that you are free to leave this study at any time without affecting your current or future medical care
- You understand the risks and benefits involved with this study as described in this consent form
- You understand your study doctor or designee will answer any future questions
- You understand some study data will be stored at Reparel®, the sponsor of this research study
- You want to take part in this study

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Consent

I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study. I will be provided with a copy of this consent that I am signing.

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

_____ _____

Subject Signature Date

_____

Printed Name of Patient Subject

Statement of Person Conducting Informed Consent Discussion

I attest that the research study has been explained to the above individual by me, including the purpose, the procedures, the possible risks and the potential benefits associated with participation. The individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study. Any questions raised have been answered to the subject's satisfaction.

_____ _____

Person Conducting Informed Consent Discussion Signature Date

_____

Printed Name of Person Conducting Informed Consent Discussion

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