Wake Forest®
School of Medicine

Department of Plastic and Reconstructive Surgery

EVALUATION OF A NOVEL SUTURELESS DRAIN SECUREMENT DEVICE AND COMPARISON TO STANDARD SUTURE-BASED DRAIN SECUREMENT TECHNIQUES

Informed Consent Form to Participate in Research

Lisa David, MD, Principal Investigator
Adam Katz, MD, Co-Investigator
Cassandra Driscoll, MD, Co-Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate an investigational sutureless drain securement device and compare this device to standard drain securement. You are invited to be in this study because you are scheduled for an operation that will require bilateral drain placement. Your participation in this research will involve no additional clinic visits.

Participation in this study will involve placement of an investigational drain securement device (K-Lock) for one of your drains, and the use of traditional drain securement techniques for the other. All research studies involve some risks. A risk to this study that you should be aware of is possible skin irritation or allergy to the adhesive dressing that is a part of the K-Lock device. You may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include declining participation in the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Lisa David, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is (336) 713-2672.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Wake Forest at 336-716-8372.

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been scheduled for a surgery that will require the placement of at least two (i.e. bilateral) drains. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate the K-Lock, an investigational, sutureless surgical drain securement device designed to alleviate discomfort that may occur at the drain site. The K-Lock attaches with adhesive instead of sutures to relieve any pull on the drain tubing being transmitted to a single focal point on the skin. While this is a new device, it is categorized as a Class I Device and does not require specific FDA approval.

In this study, the sutureless drain securement device will be compared to the use of sutures to secure drains. In this study, you will have two drains. One will be secured with the K-Lock and the other will be secured with sutures.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

40 people at one research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

On the day of your operation, your surgeon will place two drains, one on each side of your body. The exact location of these drains is dependent on the procedure being performed and your surgeon's clinical judgement. One drain will be secured with the K-Lock Device and the other will be secured with sutures. At your planned post-operative visits, you will be asked to complete surveys to evaluate your experience with the drains. This study will require one additional clinic visit for study purposes. This visit will be to assess the drain sites/scars once completely healed. If you have a scheduled follow-up appointment during this time we will plan to meet you then, but if not, we will ask that you come in specifically for scar assessment. This final visit will include photos of the drain sites/scars and one survey to be completed by you and a blinded evaluator.

As part of this research study, you will be videotaped and photographed. Videos of the placement of each of your drains will be taken during your surgery to help us determine the time it takes to place the drain and the ease of drain securement with each method. If the K-Lock device needs to be replaced before your drains are removed, this will be video recorded as well. Photographs will be taken at the time of drain removal to compare the quality of the skin at each drain site. The videos and photos will be only of the drain site. They will not involve/include identifying information or images. You can withdraw your consent to use and disclose the video photograph before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs before they are used in this study. All photos and videos will

be taken with a tablet device that is owned by the Department of Plastic & Reconstructive Surgery and data will be stored on password-protected hard-drives.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the photographs/videotapes/audiotapes of me to be destroyed once their use in this study is finished.

____ The photographs/videotapes/audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?

You will be in the study until all surgical drains are removed and your post-operative follow up is complete.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the device we are studying include skin irritation at the site of device placement, allergic reaction to device adhesive, and the possibility that one site may have better outcomes than another. Early loss of a drain can lead to complications such as abnormal accumulation of fluid or a painful collection of pus due to an infection.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the

information learned from this study will benefit other people in the future. The benefits of participating in this study may be a more comfortable drain securement with the investigational drain device than the sutured drain. Because individuals respond differently to devices, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. Neither you nor your insurance company will be billed for the investigational device.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Department of Plastic and Reconstructive Surgery at Atrium Health Wake Forest Baptist. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. Dr. Adam Katz, one of the study doctors, is the inventor of the K-Lock device being evaluated and has a financial interest in the development of this device. This means it is possible that the results of this study could lead to personal profit for Dr. Katz.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.
If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.
You do not give up any legal rights as a research participant by signing this consent form.
For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call PI's Name at telephone number (also include afterhours number.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes but is not limited to**:**

- Age
- Surgery Type
- Medical conditions like hypertension, diabetes, and tobacco use
- Date of Drain Placement
- Date of Drain Removal
- Any surgical complications
- And post-operative complications

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Lisa David, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Lisa David, MD
Department of Plastic and Reconstructive Surgery
Wake Forest University School of Medicine
Medical Center Blvd
Winston Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because due to circumstances such as, it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Lisa David, MD at (336) 713-2672.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm