The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: A Randomized Controlled Trial of Prevena™ Incisional Negative Pressure Wound Therapy to Reduce Surgical Site Infection in Re-operative Colorectal Surgery.
Sponsor: Cleveland Clinic
PI: Dr. David Liska (Tel: 216 444-9219)
After hours phone contact #: 216-444-2200

You are being invited to participate in a research study. This research study is designed to answer specific questions about new ways to prevent complications of surgery. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- You are being asked to participate in a research study.
- Ask as many questions as needed so you can make an informed decision.
- Carefully consider the risks, benefits, and alternatives of the research.
- Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

Surgical site infection, or wound infection, is a common problem affecting over 20% of patients undergoing colorectal surgery. This can cause problems for patients such as prolonged hospital stay, repeated procedures, prolonged wound dressings and delayed wound healing.

This study will compare standard wound dressing to the Prevena wound management system on the occurrence of surgical site infections within 30 days after surgery on patients undergoing re-operative colorectal surgery. The Prevena™ wound management system is FDA approved for this purpose and involves applying a vacuum sponge over the wound at the end of surgery and leaving it in place for 7 days. You are being asked to participate because you are undergoing a colorectal surgical procedure which puts you at risk of developing a post-operative surgical site infection.

What is involved if you decide to take part in this research study?

If you choose to become involved in this study, you will be randomized to have your wound dressed in the standard manner (control group) at the end of your surgery or have the Prevena™ wound management system applied. Before surgery, we will record information on your general health. At the end of your surgery, we will record information pertaining to your procedure. Following surgery, you will undergo standard post-operative evaluation and assessment by your attending surgeon. A member of the clinical team trained in research will formally assess your

wound on post-operative day 7. If you have been discharged from hospital prior to post-operative day 7, an early outpatient assessment will be scheduled for day 7, as is the standard practice of our department.

A second formal wound review will be performed at approximately 30 days after your surgery in our outpatient clinic as per our routine care. At this visit, you will also complete a post-discharge questionnaire with us to identify any occurrence of wound infection while you were not in hospital. Additionally, we will take photographs of your wound at the end of your surgery, on post-operative days 7 and 30 to assess wound healing.

Your participation in this study will end 30 days after your surgery.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

This is a data collection study; the alternative is not to participate. Your wound care and post-operative management would continue using standard of care. Since the Prevena™ wound management system is part of our standard of care; you may get this dressing option even if you're not participating in this study. However, no data will be collected for research purposes and you will not be asked to complete the questionnaire.

3. RISKS

What are the risks of participating in the research study?

There exists the potential that the Prevena™ could cause wound discomfort, if this occurs then the device would be removed. Please review below detailed risks due to PREVENA ™ Incision Management System.

Risks Due to PREVENA ™ Incision Management System

Risks	Disorders/Conditions
Skin and Subcutaneous Tissue	• Local cutaneous reaction (i.e. redness, rash, significant pruritis, urticaria) • allergic reaction • maceration • minor soft tissue damage • epidermal (skin) stripping • minor bleeding • pain • contusion (bruising)
Other	• bleeding complications (associated with the surgical procedure, concomitant therapies and co-morbidities) • first degree burn (if device gets warm) • exposure related infection • localized infection • physical discomfort • minor desiccation (due to dressing leak) • moderate soft tissue damage (i.e. due to trip hazard, tubing entanglement) • deterioration of the wound (due to lack of visibility of incision site through dressing)

Furthermore, there is a potential risk to the confidentiality of your data. To protect your data, the following safeguards have been initiated: the data obtained for this study will be stored on an electronic database called REDCap (Research Electronic Data Capture). The software features of REDCap ensure HIPAA compliance including password restricted access, user-based privileges and a full audit trail. The databases are stored in a secure computer, operated by the Cleveland Clinic. Your information is stored in a de-identified manner, representing only your medical registration number, not your name.

4. BENEFITS

What are possible benefits of participating in the research?

You may experience no direct benefit from participating in the research. The resultant knowledge gained will likely benefit future patients.

5. COSTS

Are there any costs to study participation?

There are no additional costs to you to participate in this study, the cost of the Prevena™ is part of the DRG bundle.

6. COMPENSATION

Will I receive any compensation for participating in the study?

You will receive no financial reimbursement for your participation in this study.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

The Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information. Only people on the research team will know your identity and that you are in the research study. However, sometimes other people at the Cleveland Clinic may see your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing (Dr Jean :David Liska, Dept of Colorectal Surgery, Cleveland Clinic). If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study or your future care.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the overall study results. You can search the Website at any time.

8. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?

This is an investigator-initiated trial and neither we the researchers nor institution have any conflicts of interest relating to this study.

9. QUESTIONS

Who do you call if you have any questions or problems?

Dr David Lisak, Cleveland Clinic Main Campus (A30), 9500 Euclid Avenue, Cleveland, OH 44195 (Tel: 216-444-9219) during normal business hours. After hours phone contact #: 216-444-2200 and ask the operator to page the colorectal fellow on call.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

11. SIGNATURES

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date