Cleveland Clinic
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A Novel Wound Retractor Combining Continuous Irrigation and Barrier Protection Reduces Incisional Contamination and Surgical Site Infection in Colorectal Surgery

Principal Investigator: Dr. Scott Steele
Regional Site Lead Investigator (Fairview): Dr. David Rosen & Dr. Joseph Trunzo
Study Sponsor: Prescient Surgical, CA

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.
Basic information about this study will appear on http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

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 and repeated procedures. During the operation, two important methods are commonly used to prevent wound infection: 1) Washing the wound with normal saline. 2) Wrapping the wound with a plastic barrier known as wound protector. These two functions are done separately and are considered standard of care. A new type of wound protectors called CleanCision combines

these functions together in one device. It creates a barrier while continuously irrigating the wound. CleanCision is FDA approved for usage in colorectal surgery and we think it can lead to less infection. This study will compare the wound complications after colorectal surgery in patients protected by CleanCision versus the traditional method.

You may qualify to take part in this research study because you undergoing a colorectal surgical procedure which puts you at risk of developing a post-operative surgical site infection.

Funds for conducting this research are provided by Prescient Surgical, the company supplying CleanCision.

Why Is This Study Being Done?

A surgical device that combines continuous wound irrigation and barrier protection will have an important role in preventing wound infections in colorectal surgical procedures. CleanCision is a recently developed apparatus that serves this dual purpose and was found to reduce bacterial wound contamination in preclinical and clinical trials. To date, no study was done to compare CleanCision to the traditionally used wound protector Alexis O after colorectal surgical procedures specifically.

How Many People Will Take Part In The Study?

It is expected that 702 participants will take part in this research study at Cleveland Clinic. A total of 351 participants will be randomized into the arm were CleanCision is used as wound protector. Another 351 participants will be randomized into another arm were Alexis O is used as a wound protector.

What Is Involved In The Study?
If you agree to participate in this research study, the following information describes what may be involved.

All research visits will be conducted at the following locations:

Cleveland Clinic
Department of Colorectal Surgery, Digestive Diseases and Surgery Institute, 9500 Euclid Ave, 3rd floor, A30
Cleveland, Ohio

You will receive surgery at
Cleveland Clinic
9500 Euclid Ave
Cleveland, Ohio

All patients undergoing elective colorectal surgery with a planned resection including open or laparoscopic surgeries qualify to participate in this study. **If you agree to participate in the study**, **you will be randomized to have your wound protected in the standard manner (control group using Alexis O) or have the CleanCision wound protector system**. Either of these systems are only used during the operation. 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 be examined daily by the treating

surgeon or their surgical team as is our traditional practice. We will ask you to kindly email a study team member a photograph of your wound at days 7 and day 30 after the operation to evaluate if there are any symptoms of wound infection. These symptoms include increase redness, swelling, purulent discharge, increasing pain at the site of the wound, and chills. If you have any of these symptoms, we ask you to contact your treating surgeon. If treating surgeon or their team decide to evaluate you at around days 7 or day 30 in outpatient clinic, a study team member will take a photograph of the wound during the visit. A reminder notification will be included in your hospital discharge note. If the study team do not receive any photographs by days 14 or days 37, we may contact you by phone as a reminder. Your duration of your involvement in this study will be end around 37 days after your surgery. The information about your care will be stored securely in an electronic database and in the future, published in an academic journal in an anonymous fashion so that others may learn from our findings. Obtained photographs will be stored in a de-identified manner and will be associated with you via a random study number only known to the study team.

2. RISKS AND DISCOMFORTS

There are risks to taking part in any research study.

All surgical procedures have potential risks (side effects), which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability in risks between individuals. For investigational surgeries, not all of the risks are known at this time. **You need to tell your doctor or a member of the study team immediately if you experience any complications.**
During the research study, you will be notified of newly discovered complications or significant findings, which may affect your health or willingness to participate.

Potential risks to the study subject that may be associated with the use of wound protectors are as follows:

- Infection (a risk associated with any surgical procedure)
- Adverse Tissue Reaction (unlikely)
- Device Failure (unlikely and risk lessened through training and labeling)
- Adverse Interaction with Other Devices (unlikely and risk lessened through training and labeling)
- User Error (risk lessened through training and labeling)
- Wound Damage (risk lessened through training and labeling,) damage to the tissue at the incision site or the abdominal cavity.

3. BENEFITS IN PARTICIPATING

There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

4. ALTERNATIVE PROCEDURES AND TREATMENTS

Participation in the research does not in any way change the treatment options recommended by your doctor.

5. PRIVIACY AND CONFIDENTIALITY

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. Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out 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.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

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. Scott Steele, Digestive Disease Center, at The Cleveland Clinic Foundation, 9500 Euclid Avenue – Desk A30, Cleveland, Ohio 44195***. 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.

6. RESEARCH RELATED INJURIES

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. COST

All the services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your health insurance plan. Examples of these routine services include: workup before surgery, the cost of your surgery, and cost of your hospital stay. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

8. QUESTIONS

Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact the principal investigator of this study Dr. Scott Steele on (216) 444-4715. During non-business hours call (216) 444-2200 and ask the operator to page the Colorectal Surgeon on call. If you have any questions about your rights as a participant you should contact the Institutional Review Board at (216) 444-2924.

9. VOLUNTARY PARTICIPATION

Your Participation in this study is voluntary. Your refusal to participate will not prejudice your future treatment or benefits here at the Cleveland Clinic. You may discontinue participation in the study at any time without fear of penalty or loss of medical care. If you decide to withdraw from the study you can write to the principal investigator of this study, Dr. Scott Steele, Digestive Disease Center, at The Cleveland Clinic Foundation, 9500 Euclid Avenue – Desk A30, Cleveland, Ohio 44195.

10. SIGNATURE

Statement of Participant

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**

_____

Printed name of Witness

_____ _____

Signature of Witness **Date**