A Randomized Phase II Evaluation of Negative Pressure Wound Therapy for Reduction of Postoperative Surgical Site Infection in Patients Undergoing Colorectal and Hepatopancreatobiliary Surgery

Trial: NCT01905397

Consent Forms for

Duke University (August 6, 2020)

&

Indiana University (August 21, 2020)

DUKE UNIVERSITY HEALTH SYSTEM

A Randomized Phase II Evaluation of Negative Pressure Wound Therapy for Reduction of Postoperative Surgical Site Infection in Patients Undergoing Colorectal and Hepatopancreatobiliary Surgery

PI: Dan Blazer, III, MD

You are being asked to take part in this research study because you are having abdominal (colorectal, liver, or pancreas) surgery. Research studies are voluntary and include only subjects who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Dan Blazer III will conduct the study and it is funded by Kinetic Concepts (KCI) USA, Inc. The funding source of this study, Kinetic Concepts USA, Inc. will pay Duke University to perform this research, and these funds may reimburse part of Dr. Blazer's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Dan Blazer or your regular Duke surgeon will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The primary purpose of this study is to investigate whether negative pressure wound therapy (NPWT) helps to lower the rate of surgical site infections (SSI) in patients having abdominal surgery compared to standard conventional post-operative wound care. Surgical site infections may complicate recovery from surgery and may result in longer post-operative hospital stays. NPWT is given via one of two devices, either the Prevena™ Incision Management System (PIMS) or ActiVAC. The choice of device is based on the type of incision, with ActiVAC being used for larger incisions or unusually shaped incisions.

More specifically, records of conventional wound care with sterile dressings following colorectal, liver, or pancreas surgery -- the current standard of care for post-surgery closed wounds for these procedures -- indicate that the surgical site infection (SSI) rate is 10-30%. Studies of two types of abdominal cancer surgery using post-operative standard of care report SSI rates within this range. The only study using the negative pressure wound therapy device being assessed in this study involved surgery in the sternum area and reported no SSIs. Both methods are used routinely in the Duke hospital system depending on the surgeon's judgment as to the patient's needs and the risks involved. The procedure being evaluated involves a dressing with a built-in pressure indicator that enables a closed sterile covering of the closed wound area.

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The dressing is connected by tubes to a suction pump that, as needed, removes fluids that may accumulate in the closed wound and make the patient more vulnerable to infection.

NPWT is routinely used post-operatively as standard of care in the U.S. PIMS and ActiVAC are cleared by the U.S. Food and Drug Administration (FDA) for use over clean, closed incisions following suture or stapled closure.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 180 subjects will participate in this study at Duke University and Indiana University.

WHAT IS INVOLVED IN PARTICIPATING IN THE STUDY?
Once you understand what is involved with participating in this study and all your questions have been answered, you will be asked to sign and date this consent form to show that you are willing to take part in this research study.

SCREENING
The following evaluations (tests or procedures) will be done at your "screening visit" (after you sign this consent and up to 42 days before your surgery).

- A complete physical examination, including vital signs (temperature, blood pressure, pulse and breathing rate).
- A medical and surgical history.
- A review of medication(s) (to be done or confirmed on the day of surgery) you are now taking including any prescription, over-the-counter medications, and/or vitamins and supplements you are currently taking or have taken within 30 days prior to surgery.

A serum or urine pregnancy test will be conducted on women of childbearing potential within 30 days prior to surgery. This test is conducted standard of care and requires no additional blood to be drawn.

Completion of screening
After completing the screening, the study team will check the results to determine whether you can continue on as part of this clinical study.

Randomization and Day of Surgery
If you are eligible to continue in the study, you will be randomized in a 1: 1 ratio (like flipping a coin) up to 5 business days before your surgery to receive either conventional standard of care wound dressing or the NPWT via PIMS or ActiVAC. When you are "randomized" into the

study, this means that you are put into one of the groups or "arms" by chance. A computer program will place you in one of the study arms. Neither you nor your study doctor may choose the group you will be assigned.

- The type of wound care you are assigned will be administered at the completion of your surgery.

All of the other medical care you receive during your hospitalization will be standard of care.

There are no research-related tests or procedures.

Postoperative day 4-5

You have the following take place while still in the hospital:

- Review of any side effects or symptoms you may have from participating in the study.
- Review of any changes in any of medications you may be taking.
- Assessment of your surgical site.

End of study/follow-up Visit:
Approximately 30 +/- 14 days after your surgery, you will come in to see your surgeon for a routine standard of care follow-up visit. The following will take place:

- Review of any side effects or symptoms you may have from participating in the study.
- Review of any changes in any of medications you may be taking.
- Assessment of your surgical site.

HOW LONG WILL I BE IN THIS STUDY?
Your participation will be finished at your first post-operative visit, approximately 30 days after your surgery.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
Your doctor will explain the risks of your surgery and any other are treatments you will receive as part of your standard care.

Risks of Study Devices (PIMS and ActiVAC)
All devices may have possible side effects. Each person's reaction to any device can be

different. As a result of your participation in this study, you may be at risk for the side effects listed below and possibly other unexpected side effects. You should talk about these with the study team and, if you choose, your regular health care provider.

Risks Associated with PIMS and ActiVAC (seen in fewer than 1 in 10 subjects):

- Local skin or allergic reactions (redness, rash, significant itching, hives) Systemic allergic reactions, such as difficulty breathing
- Softening and breakdown of the skin
- Peeling or stripping of the skin
- Minor bleeding at the surgical site
- Pain
- More serious bleeding complications (may also be associated with the surgical procedure, other treatments you receive and your overall health)
- Minor skin burn (if device gets too warm)
- Infections of the surgical site or that spread to other parts of the body
- Physical discomfort
- Skin dryness (due to dressing leak)
- Minor to moderate soft tissue damage such as bruising, swelling, or a build-up of fluid at the surgery site
- Worsening of the surgical site/wound (due to lack of visibility of incision site through dressing)

There may be other risks, side effects, or discomforts that are not yet known.

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. If you are pregnant or planning to become pregnant you should not agree to participate in this study.

Financial Risk

There may be financial risk in participating in this study. Not all insurance providers cover the costs of clinical trials. Although Kinetic Concepts is providing the device, they are not paying for your surgery or any other procedures as part of this study. It is your responsibility to contact your insurance provider to discuss your coverage prior to making a decision to participate in this study. Please discuss this thoroughly with your family, doctor and insurance provider(s) to make sure all your questions have been answered.

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CAN I CONTINUE TO TAKE MY CURRENT MEDICATIONS?
For your safety, you must tell the study doctor or nurse about all of the prescribed foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study. Your study doctor will tell you if any of your current medications need to be stopped or changed to allow you to participate in this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There is no guarantee that being in this study will help you. However, we hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of participating in this study, you can receive the standard treatment for your condition, which may include use of a NPWT system. You should talk to your doctor about your choices before you decide if you will take part in this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to Kinetic Concepts, Inc. and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, the National Cancer Institute, the Duke Cancer Institute, representatives and affiliates of Kinetic Concepts, Inc., the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests, x-rays, and/or procedures performed. Some of these tests, x-rays and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the funding source of this study, Kinetic Concepts, Inc. If disclosed by the funding source, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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 ARE THE COSTS?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Blazer. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

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There are no research-related tests or procedures in this study. Please talk with the PI/study team about the device that the funding source will pay for, and the procedures for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

Kinetic Concepts, Inc. will provide the PIMS or ActiVAC system free of charge to you. Your study doctor may request that you return for a checkup before you stop your study participation if he/she thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

WHAT ABOUT COMPENSATION?
You will not be paid to participate in this study.

WHAT ABOUT RESEARCH-RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of the study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

If you are a Medicare, Medicaid or Tricare patient or you have no health insurance, and you are injured as a result of a material manufacturing or design defect in the study device during your participation in this research study and all aspects of the study protocol have been followed correctly, funding source, KCI USA, Inc, will reimburse you or the provider of services for actual and reasonable medical expenses for care you receive for your injuries. Medicare, Medicaid and Tricare will not be billed for these injuries. KCI USA, Inc. has no plans to provide any other form of compensation for study-related injuries.

If you have commercial (private) insurance, and you are injured as a result of a material manufacturing or design defect in the study device during your participation in this research study, and all aspects of the study protocol have been followed correctly, your insurance provider will be billed for medical care you receive for these injuries. For any such costs that are not covered by your insurance provider, funding source, KCI USA, Inc., will reimburse you or the provider of services for the medical care you receive for your injuries. KCI USA, Inc. has no plans to provide any other form of compensation for study-related injuries.

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If you receive Medicare benefits, the funding source, KCI USA, Inc. is required by law to report payments made to you for treatment, complications, and injuries that arise from this research study. Information that you are taking part in the research study, medical treatments received, Medicare claims, and other personal information about you such as your name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

For questions about the study or research-related injury, contact Dr. Blazer at (919) 668-1861 during regular business hours. After hours and on weekends and holidays, page Dr. Blazer by calling (919) 684-8111 (the Duke paging operator), and ask the operator to page Dr. Dan Blazer III.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Participation in this study is voluntary. You are free to withdraw your consent and to discontinue participation in the study at any time.

If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Blazer in writing and let him know that you are withdrawing from the study.

His mailing address is:

Dr. Dan Blazer, III
c/o Protocol Office
Box 3247
DUMC
Durham, NC 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. If it is discovered that you did not give an accurate medical history or did not follow the instructions for the study given by your Study Doctor and/or study nurse you may be taken off the study at any time. The funding source or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Blazer at (919) 668-1861 during regular business hours. After hours and on weekends and holidays page Dr. Blazer by calling (919) 684-8111 (the Duke paging operator), and ask the operator to page Dr. Dan Blazer III.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

If not signed amongst the person obtaining consent,

_____
Printed Name of Adult Witness

_____ _____ _____
Signature of Adult Witness Date Time

“I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.”

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Evaluation of Negative Pressure Wound Therapy for Reduction of Postoperative Surgical Site Infection in Patients Undergoing Colorectal and Hepatopancreatobiliary Surgery

You are being asked to take part in this research study because you are having abdominal (colorectal, liver, or pancreas) surgery. Research studies are voluntary and include only subjects who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Dan Blazer III will conduct the study at Duke University and it is funded by Kinetic Concepts (KCI) USA, Inc. Dr. Eugene Ceppa will conduct the study here at Indiana University. The funding source of this study, Kinetic Concepts USA, Inc. will pay Duke University to perform this research. Duke University will provide funds to Indiana University to conduct the study here at IU.

If you decide to participate in this study, your surgery will be performed by the surgeons here at IU that would normally have performed your surgery.

STUDY PURPOSE

The primary purpose of this study is to investigate whether negative pressure wound therapy (NPWT) using the Prevena™ Incision Management System (PIMS) or ActiVAC helps to lower the rate of surgical site infections (SSI) in patients having abdominal surgery compared to standard conventional post-operative wound care. Surgical site infections may complicate recovery from surgery and may result in longer post-operative hospital stays. More specifically, records of conventional wound care with sterile dressings following colorectal, liver, or pancreas surgery (the current standard of care for post-surgery closed wounds for these procedures) indicate that the surgical site infection (SSI) rate is 10-30%. Studies of two types of abdominal cancer surgery using post-operative standard of care report surgical site infection rates within this range. The only study using the negative pressure wound therapy device being assessed in this study involved surgery in the sternum (breastbone) area and reported no SSIs. Both methods are used routinely, depending on the surgeon's judgment as to the patient's needs and the risks involved.

The procedure being evaluated in this study involves a dressing with a built-in pressure indicator that enables a closed sterile covering of the closed wound area. The dressing is connected by tubes to a suction pump that, as needed, removes fluids that may accumulate in the closed wound and make the patient more vulnerable to infection. Negative pressure wound therapy (NPWT) is routinely used post-operatively as standard of care in the U.S. PIMS and ActiVAC are cleared by the U.S. Food and Drug Administration (FDA) for use over clean, closed incisions following suture or stapled closure.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of up to 180 subjects who will participate in this study. Up to 57 subjects may participate in the study here at IU.

PROCEDURES FOR THE STUDY

Once you understand what is involved with participating in this study and all your questions have been answered, you will be asked to sign and date this consent form to show that you are willing to take part in this research study.

Screening
The following evaluations (tests or procedures) will be done at your "screening visit" (after you sign this consent and up to 42 days before your surgery).

- A complete physical examination, including vital signs (temperature, blood pressure, pulse and breathing rate).
- A medical and surgical history.
- A review of medication(s) you are now taking including any prescription, over-the-counter medications, and/or vitamins and supplements you are currently taking.

A urine pregnancy test will be conducted on women of childbearing potential on the day of surgery prior to surgery.

Completion of screening
After completing the screening, the study team will check the results to determine whether you can continue on as part of this clinical study.

Randomization and Day of Surgery
If you are eligible to continue in the study, you will be randomized in a 1:1 ratio (like flipping a coin) up to 5 business days before your surgery to receive either conventional standard of care wound dressing or the NPWT using the PIMS or ActiVAC systems. When you are "randomized" into the study, this means that you are put into one of the groups or "arms" by chance. A computer program will place you in one of the study arms. Neither you nor your study doctor may choose the group you will be assigned.

- The type of wound care you are assigned will be administered at the completion of your surgery.

If you are randomized to conventional wound care (control group), you will have your skin incision closed with skin staples or sutures (per the judgment of the operating surgeon), covered with sterile medical gauze and a form of adherent (tape or clear adhesive) for which you do not have any allergy. This dressing will be removed per the treating physician's discretion or current institutional standards.

If you are randomized to the incisional NPWT (experimental group), you will have your skin incision closed with skin staples or sutures (per the judgment of the operating surgeon). A layer of non-adhesive dressing will cover the skin staples or sutures, followed by placement of an adhesive covering only the skin staples or sutures. NPWT will be delivered using either the Prevena pump or the ActiVAC. The incisional NPWT will then be continued for a minimum of 2 days up to a maximum of 7 days, depending on physician preference.

All of the other medical care you receive during your hospitalization will be standard of care. There are no research-related tests or procedures other than the randomization to standard of care wound dressing or negative pressure wound therapy.

Postoperative day 4-5
The following will take place while you are still in the hospital:

- Review of any side effects or symptoms you may have from participating in the study.
- Review of any changes in any of medications you may be taking.
- Assessment of your surgical site.

End of study/follow-up Visit:
Approximately 30 (+/- 14) days after your surgery, you will come in to see your surgeon for a routine standard of care follow-up visit. The following will take place:

- Review of any side effects or symptoms you may have from participating in the study.
- Review of any changes in any of medications you may be taking.
- Assessment of your surgical site.

HOW LONG WILL I BE IN THIS STUDY?
Your participation will be finished at your first post-operative visit, approximately 30 days after your surgery. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

RISKS OF TAKING PART IN THE STUDY

Your doctor will explain the risks of your surgery and any other are treatments you will receive as part of your standard care.

Risks of Study Devices (PIMS and ActiVAC)
All devices may have possible side effects. Each person's reaction to any device can be different. As a result of your participation in this study, you may be at risk for the side effects listed below and possibly other unexpected side effects. You should talk about these with the study team and, if you choose, your regular health care provider.

Risks Associated with PIMS and ActiVAC (seen in fewer than 1 in 10 subjects):

- Local skin or allergic reactions (redness, rash, significant itching, hives); Systemic allergic reactions, such as difficulty breathing
- Softening and breakdown of the skin
- Peeling or stripping of the skin
- Minor bleeding at the surgical site
- Pain
- More serious bleeding complications (may also be associated with the surgical procedure, other treatments you receive and your overall health)
- Minor skin burn (if device gets too warm)
- Infections of the surgical site or infections that spread to other parts of the body
- Physical discomfort

- Skin dryness (due to dressing leak)
- Minor to moderate soft tissue damage such as bruising, swelling, or a build-up of fluid at the surgery site
- Worsening of the surgical site/wound (due to lack of visibility of incision site through dressing)

There may be other risks, side effects, or discomforts that are not yet known.

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. If you are pregnant or planning to become pregnant, you should not agree to participate in this study.

Financial Risk
There may be financial risk in participating in this study. Not all insurance providers cover the costs of clinical trials. Although Kinetic Concepts is providing the device, they are not paying for your surgery or any other procedures as part of this study. It is your responsibility to contact your insurance provider to discuss your coverage prior to making a decision to participate in this study. Please discuss this thoroughly with your family, doctor and insurance provider(s) to make sure all your questions have been answered.

CAN I CONTINUE TO TAKE MY CURRENT MEDICATIONS?

For your safety, you must tell the study doctor or nurse about all of the prescribed foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study. Your study doctor will tell you if any of your current medications need to be stopped or changed to allow you to participate in this study.

BENEFITS OF TAKING PART IN THE STUDY

There is no guarantee that being in this study will help you. However, we hope that in the future the information learned from this study will benefit other people with your condition.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of participating in this study, you can receive the standard treatment for your condition, which may include use of a NPWT system. You should talk to your doctor about your choices before you decide if you will take part in this study.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University

Institutional Review Board or its designees, the study sponsor, Duke University, Kinetic Concepts, Inc. or their designees (company who is providing funding for this study), and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA, the National Institutes of Health (NIH), etc., who may need to access your medical and/or research records.

A description of this clinical trial will be available on **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 results. You can search this website at any time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

COSTS

Kinetic Concepts, Inc. (KCI) will provide the PIMS or ActiVAC system, free of charge for use in this study. If you are randomized to the standard of care arm, you and/or your insurance company will be responsible for all costs related to your wound management.

- You and/or your insurance provider will be responsible for all costs related to your surgery and routine medical care including tests and procedures to manage your surgery and other health conditions.
- You should contact your insurance representative to discuss this further before making your decision about participating in the study.
- There are no research-related tests or procedures in this study other than the randomization to standard of care wound dressing or negative pressure wound therapy.

We will carefully monitor your hospital charges as long as you are participating in this study to make sure billing is handled correctly.

PAYMENT

You will not receive payment for taking part in this study.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you at IU and billed as part of your medical expenses. Duke University will be notified of any such treatment. Costs not covered by your health care insurer will be your responsibility. Neither Duke University nor Kinetic Concepts (KCI) USA, Inc. has any responsibility for the cost of such treatment. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are

participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Eugene Ceppa at 317-944-5013. After business hours or in an emergency, please call 317-944-5000 and ask for the general surgeon on call or ask for Dr. Ceppa to be paged.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University or Indiana University Health.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances:

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. If it is discovered that you did not give an accurate medical history or did not follow the instructions for the study given by your Study Doctor and/or study nurse you may be taken off the study at any time. The funding source or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

SUBJECT'S CONSENT

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____ **Date**:_____
(must be dated by the subject)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____