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## CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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**PROJECT #: 1208434**

**STUDY TITLE – PICO: A PROSPECTIVE, RANDOMIZED, CONTROLLED CLINICAL STUDY TO ASSESS THE PREVENTION OF POSTSURGICAL INCISION HEALING COMPLICATIONS IN PATIENTS UNDERGOING PRIMARY OR REVISION KNEE ARTHROPLASTY (KA) OR TOTAL HIP ARTHROPLASTY (THA), TREATED WITH EITHER SINGLE-USE NEGATIVE PRESSURE WOUND THERAPY (NPWT) OR STANDARD POSTSURGICAL DRESSINGS.**

### INTRODUCTION

**This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.**

This is a clinical trial. Clinical trials include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you are scheduled to have either a knee or hip replacement.

This study is being sponsored by Smith and Nephew, a medical technology company.

The Principal Investigator, James Stannard, is a paid consultant for the company sponsoring this research. If you have questions regarding this conflict of interest please ask the principal investigator.

In order to participate in this study, it will be necessary to give your written consent.

### WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare standard dressing and Single-Use Negative Wound Pressure Therapy System in the prevention of postsurgical incision healing complication in patients undergoing knee and hip replacement.

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This research is being done because we want to know which bandage best improves blood flow, manages fluid like pus, reduce swelling, and provide a “splinting” effect on your surgical incision.

We do not know which of these two commonly-used wound bandages is better.

### **HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

About people will take part in this study 1000.

### **WHAT IS INVOLVED IN THE STUDY?**

If you agree to participate you will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being given either type of bandage.

You will receive either a standard dressing or a PICO dressing. The standard dressing will be a type of absorbent gauze. The PICO dressing is an absorbent adhesive dressing that is connected to a pump. The pump creates a continuous negative pressure (suction) at the incision site. The pump is battery operated, and is about the size of a deck of cards. The pump is attached to the dressing by a flexible tube, and the pump can be kept in your pocket, or you can lay it beside you. There is typically no pain associated with the negative pressure produced by the PICO system. The pump does make an intermittent buzzing sound. Both types of dressing are routinely used for the type of surgery you are having.

If you take part in this study, you will have the following tests and procedures:

Pre-Trial	Investigator discusses study with the patient and provides the patient with a Patient Consent Form  Patient provides written consent to participate in the study  Patient functionality and quality of life assessment (SF12)  *The SF12 assessment (referenced above) is a questionnaire that is designed to evaluate your opinions about your health and quality of life.
Day 0	Patient provides written consent to participate in the study (if not done prior to day 0)  Complete eligibility checklist, relevant medical history and concomitant medication data collection  Patient functionality and quality of life assessment (SF12) (*if not done at Pre-Trial visit)

	<p>ASA level (American Society of Anaesthesiologist (ASA) Physical Status classification system) - The ASA level is documented in your medical record prior to surgery as part of standard of care. It is a classification system used to determine your level of health or illness related to having surgery.</p> <p>BMI (Body Mass Index – which is a measure of your body fat based on height and weight – recorded in your medical record as part of standard of care)</p> <p>Operative procedure (Knee replacement or total hip replacement)</p> <p>Incision assessment following procedure</p> <p>First dressing application</p>
Days 1-7 (following surgery)	<p>Daily communication with the subject (in person or phone contact) to collect the following information:</p> <ul style="list-style-type: none"> <li>○ Drainage amount</li> <li>○ User-friendliness for subject (including ease of use and subject’s opinion of the noise associated with the PICO device.</li> <li>○ Assessment of Complications</li> <li>○ Assessment of return to OR</li> <li>○ Assessment of need for antibiotics</li> </ul> <p>*On the days within this window that fall on a weekend or holiday, the subject will not be contacted, but rather asked for a summary of this information on the next business day. If the subject is unreachable despite the site’s best effort for one or a number of the days in this window, the subject will be asked to give a summary of the “missed” days.</p>
Day 7 (1 week)	Incision appearance: Standard digital photo of the incision (taken by

postoperative, +/- 3 days)	<p>the subject, family member, friend, or caregiver). Subject will submit this photo to the site.</p> <p>VAS (Incision Healing Assessment Form) will be completed based on photo of incision.</p>
Day 14 (+/- 7 days)	<p>Incision appearance: Physician exam; VAS (Incision Healing Assessment Form); Drainage amount; Assessment of complications; Assessment of return to OR; Assessment of need for antibiotics.</p> <p>(If the subject will not be returning 2 weeks postoperatively as standard of care, they will be asked to take another standardized digital image at 2 weeks, and the 2 week follow-up will be done over the phone.)</p>
Day 35 (+/- 14 days)	<p>Incision appearance: Physician exam; VAS (Incision Healing Assessment Form); Drainage amount; Assessment of complications; Assessment of return to OR; Assessment of need for antibiotics.</p> <p>Patient functionality and quality of life assessment (SF12)</p>
Study Completion	Reason for Study Completion

All study related tests except for the questionnaires and being assigned to a group would occur even if you do not participate in this research study.

### HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for 5 weeks.

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**You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits.**

### **WHAT ARE THE RISKS OF THE STUDY?**

There is the potential risk that the information you provide on the study questionnaires may not remain confidential.

### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to take part in this study, there will not be direct medical benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other patients who require post-surgical bandages in the future.

### **WHAT OTHER OPTIONS ARE THERE?**

An alternative is to not participate in this research study.

### **WHAT ABOUT CONFIDENTIALITY?**

A copy of this consent will be placed in the medical record. Anyone accessing your record will be able to view the document and see that you have agreed to participate in the study. Medical information produced by this study will become part of your hospital medical record. Information that does not become part of your medical record will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the University of Missouri in a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, the investigator must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this trial.

It is possible that your medical and/or research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies, the University of Missouri Health Sciences Institutional Review Board, or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the University of Missouri will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

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The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

### **WHAT ARE THE COSTS?**

You or your third party payor (insurance company or health plan) will pay for the surgical procedure, and all tests and x-rays that are done as a regular part of your treatment. The PICO device will be provided to you at no cost by the sponsor, Smith and Nephew.

Please note that added costs may include insurance co-payments for doctor visits, transportation, parking, and/or other possible expenses during your participation in this study. Please discuss these issues with the study investigator and/or your doctor.

### **Will I be Paid for Participating in the Study?**

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

### **WHAT IF I AM INJURED?**

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. The sponsor will pay any charges that are a direct result of your participation in this study.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

### **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

**Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate.** If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care in the University of Missouri. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after he has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

You will be informed of any significant new findings discovered during the course of this study that might influence your health, welfare, or willingness to continue participation in this study.

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A description of this clinical trial will be available on [www.ClinicalTrials.gov](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.

## **WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact James Stannard, MD or Thomas Aleto, MD at 573-882-2663.

You may also call a member of the research team at 573-647-6723, or email [umhsorthoresearchgrp@health.missouri.edu](mailto:umhsorthoresearchgrp@health.missouri.edu).

A copy of this consent form will be given to you to keep.

## **WHERE CAN I GET MORE INFORMATION?**

You may also contact the Research Participant Advocate (RPA) at (573) 884-1925 or (888) 280-5002 (toll-free). If you prefer email, you can reach the RPA at [somrpa@missouri.edu](mailto:somrpa@missouri.edu).

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## SIGNATURE

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

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Subject/Patient

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Date

## SIGNATURE OF STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

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Study Representative

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Date

Study Representative is a person authorized to obtain consent. Per the policies of the University of Missouri Health Care, for any 'significant risk/treatment' study, the Study Representative must be a physician who is either the Principal or Co-Investigator. If the study is deemed either 'significant risk/non-treatment' or 'minimal risk,' the Study Representative may be a non-physician study investigator.