Sponsor: Smith & Nephew

Negative Pressure Wound Therapy-PICO: Cosmesis in Repeat Cesarean Section

Device: PICO-7 Negative Pressure Wound Pump

NCT # 05266053

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Lisa Mims MD, Assistant Professor

Department of Obstetrics & Gynecology

550 N. University Ave Suite 2440

Indianapolis, IN 46202

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH
Negative Pressure Wound Therapy-PICO: Cosmesis in repeat C-Sections
IRB: 2008549700

ABOUT THIS RESEARCH
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Eskenazi Hospital or Indiana University.

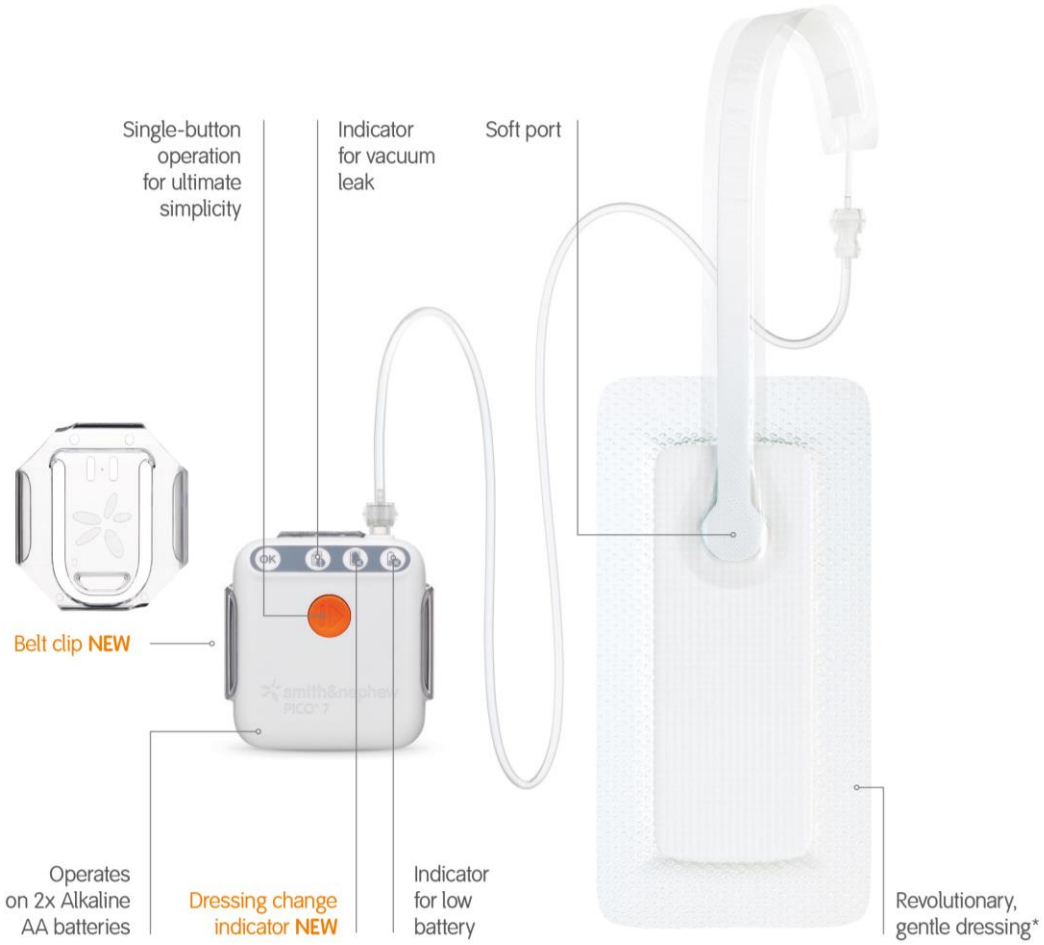
WHY IS THIS STUDY BEING DONE?
The purpose of this study is to compare the appearance (cosmesis) and overall patient satisfaction with C-Section scar at 6 weeks after a repeat C-section in participants who have a negative pressure wound therapy dressing (PICO 7) versus the standard abdominal dressing, which consists of an absorbent pad and Telfa (a material used to prevent the pad from sticking to your wound). This is secured with tape

The PICO 7 dressing is a U.S. Food and Drug Administration (FDA) approved wound dressing used to apply negative pressure to wounds to promote healing. The PICO 7 dressing consists of a negative pressure wound therapy (NPWT) pump connected to an absorbent gentle adhesive dressing that is applied to a wound. When the pump is activated, it acts by pulling excess fluid from the wound. The dressing absorbs this fluid and helps to prevent bacteria from entering the wound. The device has been shown to prevent wound infections and promote healing. Cosmetic appearance will be assessed utilizing the Patient and Observer Scar Assessment Scale (POSAS), which is a scar assessment questionnaire.

You were selected as a possible participant because you are pregnant, you have had a prior C-Section and are undergoing another C-section. Dr. Lisa Mims and Indiana University/OBGYN Department are conducting the study. It is funded by Smith & Nephew, the manufacturer of the PICO 7 dressing.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 100 patient participants taking part in this research. Your postpartum healthcare provider will also be asked to participate in this study. Approximately 50 healthcare providers will participate in this study.

Image of the PICO 7 Wound Dressing



WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

- You will be randomized, like flipping a coin, to one of two groups. One group will continue with their normal standard wound dressing for their postoperative (after C-Section surgery) hospitalization and the other group will have the Negative Pressure Wound Therapy device (PICO 7) applied immediately after C-Section instead of the standard dressing. The standard dressing is removed on approximately postoperative day 1 or 2 and the Negative Pressure Wound Therapy device (PICO 7) is removed prior to discharge (usually postoperative day 3 or 4). If you remain hospitalized for more than 7 days, the dressing will be removed on postoperative day 7.
- You will complete a total of three electronic surveys over a period of 6 weeks. The survey will be sent at approximately 2-week intervals after your discharge from the hospital. The survey will ask you to assess your satisfaction with your scar and its cosmetic appearance. It takes less than 5 minutes to complete. The survey will be sent to you by email or completed over the phone if you do not have access to Internet services.
- Your medical records will be reviewed to obtain demographic, pregnancy, delivery and post-delivery information about you. If your physician treats you for a surgical site infection, your medical records

will be obtained to determine the diagnosis, treatment and possible readmission within 6 weeks of C-Section.

- At your postpartum clinic visit, your healthcare provider will be asked to complete an assessment of your scar similar to the one you completed.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Negative Wound Pressure Therapy Device:

You may experience one or more of the following risks:

- Skin blisters
- Erythema (redness)
- Wound bleeding
- Prolonged (longer than 7 days) wound drainage (fluid that may be red, pink, or clear/yellow in color that drains from the wound).
- In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.
- The PICO 7 pump contains a Magnet that can cause other medical devices that are near the device to fail, which can lead to serious harm, including death. The PICO 7 pump must be positioned at least 4 inches away from other medical devices that could be affected by magnetic interference. These include implantable cardioverter-defibrillator (ICD), pacemakers, insulin pumps, shunt valves, neurostimulators, cochlear implants.
- Excessive bleeding is a serious risk associated with the application of suction to wounds, which may result in death or serious injury.

Standard Abdominal Dressing:

You may experience one or more of the following risks:

- Skin blisters
- Erythema (redness)
- Wound bleeding
- Prolonged (longer than 7 days) wound drainage (fluid that may be red, pink, or clear/yellow in color that drains from the wound).
- In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

A risk of completing the survey is being uncomfortable answering the questions. While completing the survey, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question.

There is a risk of possible loss of confidentiality.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

You may or may not benefit from being in this study. It is possible that you may have a reduced risk of surgical site infection and/or experience more satisfaction and less pain with the device than if you had standard of care wound dressing.

However, we hope that, in the future, other people might benefit from the results of this study because we may have a better understanding of how to improve scar cosmesis for women undergoing a C-Section.

WHAT ARE THE OTHER TREATMENT OPTIONS?

If you decide not to participate in this study, the standard of care is to place an abdominal pressure dressing following surgery and to remove it after 24 hours. There may also be additional incision dressing options; this should be discussed with your doctor.

WILL I RECEIVE MY RESULTS?

None of the activities being done for study purposes only, for example the surveys, will be placed in your medical record. We do not plan to share the results of any of the research activities with you.

HOW WILL MY INFORMATION BE PROTECTED?

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. No information which could identify you will be shared in publications about this study.

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 sponsor, Smith and Nephew, the Indiana University Institutional Review Board or its designees, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law). State and federal agencies may include the Food and Drug Administration (FDA). Some of these records could contain information that personally identifies you.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information from 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.

WILL I BE PAID FOR PARTICIPATION?

You will be paid for being in this research study. You will receive a $10.00 gift card after we have discussed the study with you and answered any questions you may have, and you have agreed to participate in the study. Additionally, you will receive a $15.00 gift card prior to hospital discharge or

during your postpartum clinic visit. It will be sent via mail if we are unable to reach you prior to discharge or at your postpartum clinic visit. If you decide that you do not want the dressing that you are randomly assigned to, then you will not receive payment for participating.

WILL IT COST ME ANYTHING TO PARTICIPATE?

You will not be responsible for these study-specific costs: the PICO 7 device. The rest of your delivery care will be billed to your insurance provider and you/your insurance provider will be responsible for the cost of your care, just as you would be if you were not participating in the study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. 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 at Indiana University. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or research related injury, contact the researcher, Dr. Lisa Mims at 317-880-3960. If you cannot reach the researcher during regular business hours (i.e., 8am to 5pm), please call the on-call OBGYN physician where you have received your prenatal care.

In the event of an emergency, you may call 911 or go to the Emergency Department.

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

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please either notify the team in writing: Dr. Lisa Mims, 550 University Blvd, Suite 2440, Indianapolis, IN 46202 or call 317-880-3960 to withdraw by phone.

Additionally, you may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study procedures.

PARTICIPANT'S CONSENT

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.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

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

Email of Participant:_____

Phone Number of Participant:_____