INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Safety and efficacy of a suction-based cervical stabilizer compared to the standard tenaculum for intrauterine procedures in the clinic setting

IRB #19699

Sponsor: Aspivix

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 this study to help you decide whether you want to participate. It is your choice whether you want to be in this research study or not. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

An intrauterine procedure is a medical procedure that takes place inside the uterus. When intrauterine procedures are performed, often the cervix needs to be stabilized to facilitate intrauterine entry. The standard approach for cervical stabilization uses an instrument called a tenaculum. This leaves two punctures on the cervix, which can cause pain and bleeding, and can prolong any intrauterine procedure (IUD insertion, endometrial biopsy, etc.). Aspivix™ has created a suction-based atraumatic cervical stabilizer for use with such intrauterine procedures. The purpose of this study is to evaluate **patient-reported pain and provider-reported bleeding, ease of use and efficiency** after using the device, called Carevix™, to hold or stabilize the cervix for intrauterine, as compared to Tenaculum (standard of care device). This Carevix™ device is approved by the FDA as of January 2023.

The study is being conducted by Alissa Conklin, MD and Jeffrey Peipert, MD, PhD through Indiana University School of Medicine. It is funded in part by Aspivix, the company that makes Carevix™, the suction-based cervical stabilizing device used in this study.

We are asking you if you want to be in this study because you will undergo an intrauterine procedure.

WHAT WILL HAPPEN DURING THE STUDY?

You will undergo your planned procedure. If cervical stabilization is required, instead of using the traditional instrument called the tenaculum, you will have the Carevix™ suction-based cervical stabilizer used instead. After the completion of your procedure, you will then be asked to complete a questionnaire about your experience. This takes, on average, about 1 minute to complete.

This procedure is performed as a one-time only event and your participation in this study is a one-time only event.

You will not receive the results of any of the survey questions because it is being done only for research purposes.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Like any instrument that holds your cervix, it is possible to have some bleeding on the cervix. Although this has not yet occurred, it is possible that the suction from the device could not release and would require an additional few second to release the suction. It is possible that the suction could cause pain during the procedure, though this is anticipated to be less pain than the traditional tenaculum.

You may be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.

There is a risk someone outside the study team could get access to your research or medical information from this study. More information about how we will protect your information to reduce this risk is below.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured because of participating 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. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We do not know if you will have any personal benefits from taking part in this study, but there may be a possibility of decreased pain and bleeding. We hope to learn things to help others in the future.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making sure you meet the inclusion criteria for the study and the date and type of your intrauterine procedure or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include:

- Age
- Marital status
- Education level
- Employment status
- Date of procedure

- Type of procedure

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians OB/GYN

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US governments or agencies as required by law
- The following research sponsors: Aspivix
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in the consent. Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies.

This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions. 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.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

HOW WILL MY INFORMATION BE PROTECTED?

Since this study includes the collection of information about you, one risk to you is a possible loss of confidentiality, although we will do everything possible to protect your information. Efforts will be made to keep your personal information confidential, but 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, 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, funding research sponsors, and any state or federal agencies who may need to access your medical and/or research records allowed by law.

The survey results for those who receive Carevix™ will be stored in a secure database through Indiana University called RedCap.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

If you have questions about this study or encounter a problem with the research, contact the primary researcher, Dr. Alissa Conklin at 509-808-7049 or at alconkli@iu.edu.

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

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with your IU Health OB/GYN provider.

If you change your mind and decide to leave, the study team will help you withdraw from the study safely. If you decide to withdraw, please call Dr. Alissa Conklin at 509-808-7049 or email her at alconkli@iu.edu. You would need to provide your name and date of birth and that information would be utilized to find the survey recorded from the date of your procedure.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so verbally or in writing by notifying Dr. Alissa Conklin at 509-808-7049 or alconkli@iu.edu. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

PARTICIPANT'S CONSENT

In consideration of all the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name: _____

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

Participant's Address:_____

Printed Name of Person Obtaining Consent:_____

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