Principal Investigator: Kent Higdon, MD Version Date: June 20, 2018
Study Title: Incidence of surgical site infection after irrigation of surgical pocket with 0.05% chlorhexidine compared to triple antibiotic solution in post-mastectomy breast reconstruction
Institution/Hospital: Vanderbilt University Medical Center

Title: Post-Mastectomy Surgical Pocket Irrigation with Triple Antibiotic Solution vs Chlorhexidine Gluconate: A Randomized Controlled Trial Assessing Surgical Site Infections in Immediate Tissue Expander Breast Reconstruction

NCT# 02395614

Date: June 20, 2018

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

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This informed consent applies to Adults

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

The purpose of the study is to evaluate whether wash out of surgical wounds with 0.05% chlorhexidine gluconate (CHG) solution is superior to washout with triple antibiotic solution in reduction of postoperative infection in patients undergoing placement of breast tissue expanders.

2. What will happen and how long will you be in the study?

You are being asked to take part in this research study because you are having bilateral breast reconstruction with insertion of tissue expanders. This research study will compare two methods of washout of your pocket for the placement of the tissue expander during your operation. The traditional method involves using a triple antibiotic solution containing cefazolin, bacitracin, and gentamicin, all commonly used antibiotics. The use of chlorhexidine gluconate and cefazolin, bacitracin, and gentamicin for this indication is not approved by the FDA. We propose that 0.05% CHG solution is more effective as a solution used to sanitize the wound in reducing risk of postoperative wound infection. CHG is one of the most commonly used antiseptics for hand scrubbing and surgical prep. We will be using a commercially prepared 0.05% CHG solution known as IrriSept® (IrriMax Corporation; Lawrenceville, GA) that is packaged for use in sterile environments such as surgery. A solution of 0.05% CHG will be directed to irrigate one side of your breast and the other side will be irrigated with the triple antibiotic solution. The side to receive the chlorhexidine solution will be randomly selected like the flip of a coin; the opposite side will receive the triple antibiotic solution. The study will assess the frequency and severity of any surgical site infection between the two methods. There will be a total of 110 women entered into the study. You will have your breast reconstruction surgery using tissue expanders as planned. You will not be required to visit the office more frequently because of your participation. Your involvement will last for 6 months following your reconstruction. There will not be anything different in your intraoperative or postoperative care as a result of your participation in this study.

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

We anticipate low risk to you given the history of the safety of chlorhexidine gluconate as there will be minimal systemic absorption since it will be used topically as irrigation.

Side effects with chlorhexidine gluconate include:
Uncommon side effects include local irritation and allergic-type symptoms including erythema or redness of the skin or rash.
A very serious allergic reaction to this drug including severe skin rash, swelling, trouble breathing and possibly death is rare.

5. Risks that are not known:

Although the use of chlorhexidine is FDA cleared for cleansing and irrigation, there may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

6. **Good effects that might result from this study:**

a) The benefits to science and humankind that <u>might</u> result from this study are: If this study shows that the use of chlorhexidine gluconate as irrigation for tissue expander implantation provides increased antimicrobial coverage, many other women may benefit from this procedure in the future.
b) The benefits you might get from being in this study are: there is no known benefit to you for your being in this study.

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8. Other treatments you could get if you decide not to be in this study:

You do not have to participate in this study to receive treatment for your condition. Alternatives include standard of care with the current triple antibiotic irrigation used for both sides of your reconstruction.

9. Payments for your time spent taking part in this study or expenses:

There will be no payment for participation in this study

10. Reasons why the study doctor may take you out of this study:

You may be taken out of the study without your consent by the study doctor, for example, if the doctor finds out you are allergic to chlorhexidine. If you are taken out of the study, you will be told the reason why.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Kent Higdon, MD

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. Confidentiality:

Data will be collected and stored in a pass-word protected computer database. Only your study doctor and study personnel will have access to the database. Upon completion of the study, the database will be kept by the study physician under the same password protection and will oversee along with the study coordinator adherence to the study protocol, protection of patient confidentiality, and reporting of all adverse events to the IRB according to IRB policies and procedures.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Higdon and *his* staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy

rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. *Higdon and his* study team may share the results of your study and/or non-study linked information including laboratory results as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, the Food and Drug Administration. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Higdon in writing and let him know that you withdraw your consent. *His* mailing address *is D-4207 MCN, Nashville, TN 37232.* At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

Time