Official Title: A Comparison of the Outcomes in Fortiva and Strattice Mesh

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Department of Surgery

BIOLOGIC MESH STRATTICE VS FORTIVA

Informed Consent Form to Participate in Research
Vedra Augenstein, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine if RTI Surgical biologic mesh (Fortiva) is equivalent to Allergan biologic mesh (Strattice) with respect to hernia recurrence rates and mesh related complication rates. You are invited to be in this study because you have a ventral hernia that requires surgical repair. Your participation in this research will involve three (3) visits and last about three (3) years.

Participation in this study will involve the use of RTI Surgical biologic mesh (Fortiva) in your ventral hernia repair. Fortiva is a biologic porcine mesh; meaning the mesh is derived from pigs. All research studies involve some risks. A risk to this study that you should be aware of are surgical or mesh related complications (see below for more detail). You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Other mesh choices will be at the discretion your attending surgeons based on what the surgeon feels is appropriate for your ventral hernia repair. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. RTI Surgical biologic mesh (Fortiva) may also be used in your ventral hernia repair, at the discretion of the surgeon, even if you choose not to participate in the research study.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you have a ventral hernia that requires surgical repair. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words

or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if RTI Surgical biologic mesh (Fortiva) has the same rate of hernia recurrence and mesh related complication compared to Allergan biologic mesh (Strattice). The Study Device (Fortiva) has been cleared for use in soft tissue reinforcement by the FDA. This research study is being done because the Sponsor wants to collect more information about the Study Device.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Two hundred (200) people at this research site will take part in this study. Fifty people will be enrolled to receive the Fortiva mesh and compared to 150 people who have already been surgically repaired with Strattice mesh. To identify the 50 subjects needed for repair with Fortiva mesh, we may need to screen as many as 100 because some people will not qualify or will decline to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

This study will consist of the following steps:
Step 1: You will be seen in clinic for a consultation visit
Step 2: The attending surgeon will introduce the study to you
Step 3: A member of the research team (attending surgeon, fellow, resident, research manager or research associate) will explain the study to you and, if interested, will consent you to participate in the study
Step 4: The attending surgeon will perform your procedure using the Fortiva biologic mesh.
Step 5: NOTE: not all subjects will have step 5. If you had the Fortiva mesh placed without being offered consent previously, you will be introduced to the study and the study will be explained to you by a member of the study team and, if interested, will consent you to participate in the study. This will be the same as step 3 from above but will take place after your surgery has been performed. You will continue on to step 6 as if you were consented prior to your procedure.
Step 6: You may be seen back in clinic as part of our standard of care after a ventral hernia repair or contacted via telephone for a period of 3-years at 2-weeks, 6-months, 1-year, 2-year, 3-year to evaluate your progress and recovery using the mesh, including any hernia mesh complications and if a hernia recurrence occurs.

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

1. Ventral hernia repair using Fortiva biologic mesh (this mesh may be used as part of your ventral hernia even if you choose not to participate in this research study)

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your

personal physician?

[ ] Yes [ ] No _____ Initials

How Long Will I Be in the Study?

You will be in the study for about 3-years. This includes surgical procedure for your ventral hernia and 3-years of follow-up for hernia recurrence and mesh related complications.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the mesh we are studying include:

Anticipated risks are medical problems that are known to be related to ventral hernia repair patients undergoing hernia repairs with or without mesh products. However, all the medical procedures associated with this research study are considered standard treatment for your condition.

Fortiva Biologic Mesh	If you participate in this study, you will be exposed to the Fortiva porcine dermis biologic mesh. The potential risks associated with the use of the Study Device are expected to be similar to the risks associated with all procedures like this. The potential risks may also be the result of disease progression, allergic reaction to porcine (pig) mesh material, multiple medical conditions, surgical technique, hernia closure, and mesh attachment methods. This research study should not pose additional significant risk to you. Unanticipated problems or inconveniences may occur whether you are in the research study or not, so be sure to tell your Study Doctor if you have any health concerns that develop. Possible risks with the use of any hernia procedure may include, but are not limited to: using a mesh that has not previously been studied, potential defect with mesh, need for additional intervention including surgery, adhesions, bowel obstruction, defect recurrence, erosion or extrusion, exposure or

	protrusion, fever, fistula(abnormal connection of two body cavities), Gastroesophageal Reflux Disease (GERD) recurrence, infection, irritation or inflammation, pain, seroma(build-up of fluid) or hematoma(localized bleeding outside of blood vessels), tissue ischemia(restriction of blood flow to tissue), and wound dehiscence(re-opening of surgical incision).
Confidentiality and privacy	Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be as good as standard therapy you could receive without being in the study but with fewer side effects and at a reduced cost for the mesh. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you can choose not to be in the study and have your procedure performed outside of the study. You could be treated with Fortiva biologic mesh even

if you do not take part in the study as this mesh is FDA cleared for this indication.

One of the most commonly used standard of care mesh is Strattice mesh; however, physician preference and availability affect this. This study will compare Fortiva mesh to Strattice to assess the hernia complication and mesh complications associated with each. The potential risks associated with the use of the Study Device are expected to be similar to the risks associated with all ventral hernia repair procedures. The most substantial risks for the Fortiva mesh include mesh related complications and hernia recurrence. This research study should not pose additional significant risk to you. Unanticipated problems or inconveniences may occur whether you are in the research study or not, so be sure to tell your Study Doctor if you have any health concerns that develop.

WHAT ARE THE COSTS?

You or your insurance company will be billed for the medical device. You and/or your insurance company will be billed for the cost of any surgical procedure(s) necessary to implant the Fortiva biologic mesh.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

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

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by RTI Surgical. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Atrium Health - Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for treatment of injuries or illnesses. To the extent research insurance coverage is available under this policy, the reasonable

costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

1. Past and present medical records (physical exams, laboratory, medical imaging, procedures, and other test results)
2. medical and research records created during this research study (physical exams, laboratory, medical imaging, procedures, questionnaires, and other test results, records about the Study Device)
3. Costs of your treatments, procedures, and tests

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Vedra Augenstein, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Vedra Augenstein, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are

enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.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 Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Vedra Augenstein at [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like

to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm