Cleveland Clinic
Consent to Participate in a Research Study

Study Title: A PROSPECTIVE RANDOMIZED TRIAL OF BIOLOGIC MESH VERSUS SYNTHETIC MESH FOR THE REPAIR OF COMPLEX VENTRAL HERNIAS

Principal Investigator: Michael Rosen, MD. (216) 445-3441

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are being asked to participate in a clinical research study because you are scheduled to undergo a repair of your abdominal hernia with a reinforcement material (mesh) as part of your needed medical care.

Why Is This Study Being Done?

The purpose of this research study is to compare open abdominal incisional hernia repair using either a biologic reinforcement material (made from pig tissue)or a synthetic reinforcement material (made from plastic materials) to provide some support during wound healing at the site of your hernia defect where your tissue is weakened. Using materials to reinforce tissue defects is standard of care and both the synthetic mesh SoftMesh™ (CR Bard, Murray Hill, NJ) and the biologic mesh Strattice™ (Lifecell, Branchburg NJ) are some of the many standard mesh materials that are used. You may have a complicated history of hernia and it is known before your surgery that you have a contaminated wound. The use of biologic and synthetic mesh in contaminated fields is considered experimental. Your planned open abdominal incisional hernia repair can be repaired with either reinforcement material. The study will also evaluate early and

long-term recovery effects of both materials in the quality of life and the rate of hernia recurrence as well as the occurrence of complications.

You are being offered the opportunity to take part in this research because you have been diagnosed with a complex ventral incisional hernia (the skin, muscle and tissue layers of the abdomen are weak and bulge or tear and an organ has pushed through the weakened area to form a balloon-like sac). Your surgeon has decided to repair your hernia with a reinforcement material (mesh). This surgery will be an "open" surgical procedure and reinforcing your tissue with material is necessary for your type of hernia repair.

A separate standard operative consent will be provided relative to your surgery or if applicable other conditions being treated. This is standard of care. You will receive a reinforcement material even if you decide not to participate in the study. You will receive standard postoperative care which includes your length of stay in the hospital and postoperative follow-up visits.

How Many People Will Take Part In The Study?
About 253 people will take part in this study at approximately 5 hospitals and medical facilities in the US. Approximately 103 people will take part at Cleveland Clinic.

There is a possibility that the investigators may become aware of new findings that may affect your willingness to continue participation. You will be informed of these new findings so that you may choose to continue or discontinue your voluntary participation.

What Is Involved In The Study?
If you agree to be in this study, you will be asked to sign this consent form. You will have the following tests and procedures to make sure that you can participate:

You will be evaluated preoperatively at a screening visit to ensure that you qualify to participate in the study. If you choose to participate in the study, information on your activities and quality of life experience will also be collected and documented on questionnaires before surgery. These short questionnaires will take approximately 15 minutes to complete. The study staff will also collect additional personal and medical information including your age, gender, height, and weight, surgical history, preoperative symptoms and information relating to your current hernia.

Your active participation in this study will last for 24 months and will involve one preoperative evaluation visit, one operative procedure visit, and 4 follow up visits.

Visit 1: Screening

If you agree to participate by signing the informed consent, you will have Screening assessments completed. At this study visit, the doctor will ask about your past medical and surgical history and any medications you are taking and you will have a brief physical examination. An

abdominal pelvic CT scan (a picture of your abdomen) will be obtained preoperatively in all patients based on our standard approach and your physician will review these and any test results that are used to diagnose your hernia. If you qualify for study participation, you will be asked to join the study. If you choose to participate in the study, the study staff will collect additional information such as your gender, age, height, weight, your medical and surgical history, and information relating to your current hernia. You will be asked to fill out and complete two brief survey questionnaires that ask about your activities and how your hernia impacts what you can do. The questionnaires will take approximately 15 minutes to complete. Prior to surgery photos may also be taken of your abdominal hernia. Your face will not be photographed and no identifying information will be attached to the photo.

You will receive routine pre-operative care, which will vary depending upon any additional procedures that may be performed during your hernia repair. This may include lab work, a special diet, and bowel cleansing. This routine care is not part of the study.

Randomization

If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. This means that half of the people in this study will have their hernia repaired with the standard biological mesh, Strattice™. The other half of the people in the study will have their hernia repaired with a synthetic mesh, SoftMesh™. Neither you nor the study staff will select the group to which you will be assigned. However, this information can be obtained if you have a medical emergency.

Visit 2: Day of Surgery

On the day that your hernia is repaired, you will be randomized to receive either the biological reinforcement mesh or the synthetic mesh if you meet the inclusion criteria of the study. This surgical mesh will be used to support the tissue around the area of your hernia repair. Your surgery will be performed in the usual open manner. As part of standard of care drains may be placed around the mesh. As part of the study your doctor will collect information about your hernia or your surgery such as the size of your hernia, how long the surgery took, how much blood you lost during the surgery, antibiotics and IV fluids that are given, and where and how many drains were placed.

Visit 3: Post Surgery Care

You will have a physical evaluation every day as part of your routine post-operative care while you are in the hospital. The nature and severity of any wound event and all medical and surgical interventions, including re-operations will be collected. During your hospital stay after your hernia is repaired, information about your stay will be collected such as the return of your bowel function, the length of your stay, and medications you have received.

Follow Up

You will be given instructions to return to the physician's clinic to be examined by the study doctor at 4 weeks, 6 months, 1 year, and 2 years following your surgery. Depending on your doctor's discretion, some of these follow-up visits may be completed using the Cleveland Clinic virtual video visit which is a medically secure platform that is similar to Skype or FaceTime. You will have your abdominal wound evaluated and examined for general health and hernia reoccurrence. You will be asked about any medications you are taking and about any problems you may have had with your hernia repair. Information about any procedures that may be performed during this time will be collected. You will be asked to complete the same surveys that you filled out prior to surgery at each of these visits. You will be informed which mesh you received at your 24 month follow up visit.

If at any time throughout the study period a hernia recurrence is suspected clinically, then an abdominal CT scan will be performed to objectively evaluate the repair as standard of care dictates. All additional procedures, interventions, and adverse events will be collected throughout the final visit at 24 months. The entire length of your active participation in this study will be approximately 24 months after your hernia is repaired.

How Long Will You Be In The Study?

Your participation in this study will last a maximum of 24 months after your hernia is repaired. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, it is important you talk with your doctor first.

2. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

In this study, you will receive routine medical care. As with any routine surgical procedure, there are some risks that are associated and they will be discussed in a separate surgical consent form as applicable. You may experience some pain, bleeding, and discomfort, however this is with any surgical operation. Common occurrences following hernia repair include seroma (accumulation of fluid) or hematoma (blood) around the hernia repair, inflammation, opening of the wound, or infection, and hernia recurrence. You may also experience additional therapies or treatments, including the removal of the reinforcement material (mesh) to treat any of these events. The possible side effects and complications of your surgery relate to the procedure itself and will have nothing to do with data collection. In regards to the surveys you will complete for the study, some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Participation in this study may involve risks that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.

Risks of Drawing Blood and Blood Testing:
Risks associated with drawing blood may include momentary discomfort and/or bruising (small red discoloration) in the area of the IV catheter or blood draw sites. Infection, excess bleeding, clotting, or fainting due to a temporary lowering of blood pressure are also possible, although unlikely.

Unforeseen Risks:
In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this material. You or your legally authorized representative will be informed as soon as possible if new information becomes available that may affect your willingness to continue participation in this study.

Finally, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

3. BENEFITS

Are There Benefits To Taking Part In The Study?
There will be no direct benefit to you by your participation in this research study. Your study participation will help us better understand the usefulness of synthetic versus biologic meshes in a contaminated hernia repair.

4. COSTS

Are there any costs to you if you participate in this study?
You and/or your insurance provider will be responsible for all costs related to your routine medical care, that is, care you would have received whether or not you were part of this study. You may wish to contact your insurance representative to discuss costs further before making your decision about participating in the study.

5. COMPENSATION

You will not be paid for participation in this study.

6. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There

are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?
Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information. The Sponsor will use this study information for research, the stated purpose of the study, and may also use it for submissions related to market approval.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff. If you agree, your personal physician may be informed of your participation in the study.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Michael Rosen MD. 9500 Euclid Avenue Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

8. RESULTS

What will happen to the results of this study?
A description of this clinical trial will be available on 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.

If the results of this study are published, your identity will remain confidential.

9. QUESTIONS

Who do you call if you have any questions or problems?
If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Michael Rosen, MD at 216-445-3441 during regular business hours of 8am-5pm or you may contact the study coordinator at 216-445-3851. After hours please call the clinic operator at 216-444-2000 or 800-223-2273 and ask for the General Surgery Resident on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

In the event of an emergency, dial 911 immediately. If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?
Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

You may refuse to be in or remove yourself from the study at any time without providing a reason and this will not affect the standard of care you receive. To withdraw from the study, tell the investigator you no longer want to participate by contacting Michael Rosen, MD at 216- 445-3441.

If you choose to withdraw from the study, you will be followed based on standard of care at your institution. The investigator or the Sponsor can remove you from the study without your approval. Possible reasons could be if participation appears to be medically harmful to you, if it is discovered that you do not meet eligibility requirements, or if the study is cancelled.

If you are removed from the study or if you decide to stop before completing the study, you may be asked (for your own safety) to undergo final study assessments, examinations, and laboratory tests.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a signed copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date