RESEARCH SUBJECT CONSENT FORM

Title: Endostapler Hemostasis Study

Protocol No.: Endostapler01

Sponsor: Lexington Medical, Inc.

Investigator: Dr. James Redmann
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Study-Related Phone Number(s): 504-934-3000 (24 hours)

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to compare the performance of two FDA approved laparoscopic staplers for bariatric surgery. Stapler performance will be evaluated primarily by incidence and degree of staple line bleeding.

About 60 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 1 month.

What happens to me if I agree to take part in this research?

You will be put into one of two study groups by chance (like a coin toss/ like drawing straws). The two study groups are (1) stapling performed with the AEON™ Endostapler and (2) stapling performed with the Echelon Flex™ Powered Stapler.

You have an 50% chance of being placed in each group. You cannot choose your study group. This random assignment to your study group in order to compare the performance of these instruments is the investigational aspect of this research.
During your laparoscopic sleeve surgery, after the stomach has been stapled, an image(s) will be captured within the abdominal cavity of the staple lines. The photograph(s) will then be sent to a blinded clinician who will review the image and evaluate hemostasis of the staple lines according to a scale.

What are my responsibilities if I take part in this research?
You have no responsibilities if you take part in this research.

Could being in this research hurt me?

Taking part in this research does not carry any additional risk as laparoscopic staplers are part of the standard of care for this procedure.

The two FDA approved laparoscopic staplers used in this research have similar risks including:

- prolonged surgical procedures
- unplanned, additional surgical interventions
- complications such as bleeding, infection, tearing of internal tissues and organs, and death
- device failure

The types of adverse events observed with surgical staplers and staples may similarly occur with hand sewn alternatives.

There are no risks associated with having an image captured of your abdominal cavity. You will be assigned a study number; therefore, no identifiable information will be associated with your images.

Will it cost me money to take part in this research?

There will be no cost to you to take part in this research.

Will being in this research benefit me?

There are no benefits to you from your taking part in this research.

What other choices do I have besides taking part in this research?

You do not have to be in this research study for your surgeon to use a laparoscopic stapler. Therefore, your alternative is to not take part in the research. There is no penalty if you choose not to participate.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

The research sponsor will not have access to individually identifiable health information (e.g., name, address, date of birth, and social security number).

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-877-366-5414 (toll-free), email@aspire-irb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

The potential risk associated with this procedure will not change because of taking part in this research.

If you are injured or get sick, call the study doctor immediately.

The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment or payment requirements listed on the cash pay agreement form signed prior to surgery will be followed. The sponsor will not pay for medical expenses you may incur for any injuries as a result of your participation in this study, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. For more payment information, please reference the procedure consent form signed prior to surgery and the cash pay agreement if applicable.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You need a treatment not allowed in this research
- The research is canceled by the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

Contact the research team if you decide to leave this research.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date