**Endostapler Hemostasis Study Protocol**

September 9, 2019

*A proposed study using AEON™ Endostapler Handles and Reloads*

*(Lexington Medical, Inc., Billerica, Massachusetts)*

**Principal Investigator:**

Dr. James Redmann (surgeon)

**Co-Investigator(s):**

Dr. Thomas Lavin (surgeon)

Dr. Matthew French (surgeon)

**Research Coordinator:**

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**Primary Outcome Evaluator:**

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**SUMMARY**

The goal of this prospective, multi-center, post-market study is to measure AEON™ Endostapler performance with the EASY/THICK MODE feature for laparoscopic bariatric surgery against the Echelon Flex™ Powered Stapler system from Ethicon. Stapler performance will be evaluated primarily by incidence and degree of staple line bleeding through a third-party blinded primary outcome evaluator. The study will include 60 total consecutive cases of individuals undergoing a planned laparoscopic sleeve gastrectomy (LSG). The LSG procedure will be performed according to institutional standard-of-care and all subjects will undergo standard preoperative evaluation as well as post-operative care. Relevant data will be collected using the Data Collection sheet which should be filled out following each procedure by a member of the surgical or nursing team.

**Enrollment:** 60 Subjects Meeting Inclusion/Exclusion Criteria

**Investigator Masking:** None (Open Label)

**Primary Outcome Evaluator Masking:** Yes (Surgeon and Device)

**Devices:** AEON™ Endostapler and Echelon Flex™ Powered Stapler System

**LEXINGTON MEDICAL AEON™ ENDOSTAPLER BACKGROUND**

The AEON™ Endostapler is comprised of a stapler handle and reloads. The handle may accept multiple reloads of single fire cartridges. The AEON™ Endostapler devices were approved by the United States Food and Drug Administration (FDA) under the 510(k) process. Pertinent applications numbers are K171589 and K173443. Devices will be used pursuant to the indications specified in K171589 and K173443, as well as the general guidelines for use of this device on a prescription basis as outlined by the Federal Food, Drug, and Cosmetic Act (1976), and the Code of Federal Regulations Title 21 Part 800-895.

### Approved Indications for Use

The AEON™ Endostapler has applications in general, abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses.

### Available AEON™ Endostapler Reloads

The following two tables contain the available AEON™ Endostapler Reloads, as well as the similar products that they may replace. This is meant as a guide, and the surgeon should read and follow the Instructions for Use and use their own clinical judgment to determine appropriate products to use.

*Table 1. Available AEON™ Endostapler Reloads*

| Reload Type | Cartridge Length | Product Code | Open Staple Height | Closed Staple Height | Minimum Port Size |
|---|---|---|---|---|---|
| Gray | 45mm | AESR45G | 2.0mm | 0.75mm | 12mm |
| White | 45mm | AESR45W | 2.5mm | 1.0mm | 12mm |
| White | 60mm | AESR60W | 2.5mm | 1.0mm | 12mm |
| Orange | 45mm | AESR45R | 3.25mm | 1.5mm | 12mm |
| Orange | 60mm | AESR60R | 3.25mm | 1.5mm | 12mm |
| Purple | 45mm | AESR45P | 4.0mm | 1.8mm | 12mm |
| Purple | 60mm | AESR60P | 4.0mm | 1.8mm | 12mm |
| Black | 60mm | AESR60B | 5.0mm | 2.2mm | 15mm |

*Table 2. Approximate Equivalence for AEON™ Endostapler Reloads*

| AEON™ Endostapler | | | Echelon Flex™ | | |
|---|---|---|---|---|---|
| Cartridge Color | Open Staple Height (mm) | Closed Staple Height (mm) | Cartridge Color | Open Staple Height (mm) | Closed Staple Height (mm) |
| Gray | 2.0 | 0.75 | Gray | 2.0 | 0.75 |
| White | 2.5 | 1.0 | White | 2.5 | 1.0 |
| Orange | 3.25 | 1.5 | Blue | 3.5 | 1.5 |
| Purple | 4.0 | 1.8 | Gold | 3.8 | 1.8 |
| Purple | 4.0 | 1.8 | Green | 4.1 | 2.0 |
| Black | 5.0 | 2.2 | Black | 4.2 | 2.3 |

**STUDY DETAILS**

Patients will be screened based on the inclusion and exclusion criteria below and will be consecutively evaluated for study enrollment. Each case will be randomly assigned to one of the two FDA approved endoscopic staplers. For the purposes of this study, the surgeons will either use the AEON™ Endostapler or the Echelon Flex™ Powered Stapler system from Ethicon. Enrollment will be contingent on meeting these criteria, and the use of either the AEON™ Endostapler or the Echelon Flex™ Powered Stapler system from Ethicon. Study participation will begin once the subject signs the consent form and will end after the one-month postoperative follow up visit.

**Selection of Subjects:**

Inclusion Criteria

- Patients undergoing planned laparoscopic sleeve gastrectomy with signed surgery consent form
- Informed consent for study obtained and signed from each subject

Exclusion Criteria

- Planned open surgical approach
- Prior bariatric operation (i.e. revisional bariatric surgery)
- Use of staple line reinforcement material (buttress)
- Patients taking anticoagulants
- Patients under the age of 18 on the date of the surgery

**Withdrawal of Subjects:**

Subjects are free to withdraw from the study at any time for any reason. Every effort will be made to determine why any subject withdraws from the study prematurely and this information will be recorded in the Clinical Study Report.

In addition, subjects may be withdrawn from the study by the Principal Investigator in consultation with the Sponsor for the following reasons:

- Adverse event
- Protocol violation
- Loss to follow-up

If a subject withdraws prematurely, all data normally collected by study completion should be collected at the time of premature discontinuation or at the scheduled discharge. All subjects who withdraw from the study with an ongoing adverse event must be followed until the event is resolved or deemed stable. At the discretion of the PI, additional follow up visits may be done for subject safety.

Withdrawn subjects will be replaced, until 60 subjects complete the study.

**Primary Outcome Measure:**

- Incidence of intraoperative staple line bleeding as measured by the provided bleeding severity scale

**Secondary Outcome Measures:**

- Incidence of postoperative leakage during one-month monitoring period following procedure
- Incidence of reported device-related adverse events
- Incidence of product malfunction during procedure
- Incidence of intraoperative or postoperative blood transfusion within 72 hours of surgery start time
- Postoperative pain level per standard protocol

**Steps and Procedures:**

The study will include 60 total consecutive cases, randomized for stapler type: 30 with the AEON™ Endostapler and 30 with Echelon Flex™. Surgeries will be performed by either Dr. James Redmann, Dr. Thomas Lavin, or Dr. Matthew French, with at least 5 surgeries of each stapler brand per surgeon.

All patients will undergo the standard preoperative evaluation pathway. Patients must sign informed consent for the operation.

All firings with the AEON™ Endostapler will be done with EASY/THICK MODE for the purposes of this study and shall conform to the AEON™ Instructions For Use (Appendix C). All firings with the Echelon Flex™ should be done according to the Echelon Flex™ Instructions for Use.

In order to measure the primary outcome of incidence and degree of staple line bleeding, a third-party blinded primary outcome evaluator will be used. No sutures, cautery or clips shall be applied to the staple line during stapling, unless required at surgeon's discretion. Following the last firing, a member of the surgical or nursing team or the research coordinator present for the case will count 10 seconds and then capture an image with the laparoscope. The visual should be clear and portray the entire length of the staple line. In the event that bleeding from the staple line requires control prior to the last firing, an additional image should be captured before applying sutures, cautery, clips, etc. These photographs will then be sent by the research coordinator to the primary outcome evaluator either electronically or by mail. The primary outcome evaluator will be blinded to both the surgeon and device of each case. Upon receipt of photographs, the evaluator will evaluate staple line bleeding according to a provided bleeding severity scale and record results in the Bleeding Severity Evaluation Sheet (Appendix B). If a case has more than one image associated with it, the primary outcome evaluator will consider all images when selecting a bleeding severity level.

At the end of each case, the surgical team will fill out the relevant sections of the Data Collection Sheet (Appendix A). Case ID is captured as day/month/year, followed by surgery count for the day – e.g. 071619A for the first surgery performed on July 16, 2019.

All typical post-operative care will continue, including immediate post-operative care prior to hospital discharge as well as the standard one-week and one-month post-operative evaluation. At the end of both the one-week and one-month post-operative period, a member of the surgical or nursing team will fill out the relevant sections of the Data Collection Sheet.

There will be no follow up study data collected after this point, however the patients will continue the standard follow up regimen per the physician's practice.

**Surgery Locations:**

Surgeries will take place at Southern Surgical Hospital (1700 Lindberg Dr, Slidell, LA 70458), Crescent City Surgical Centre (3017 Galleria Dr, Metairie, LA 70001), or Avala Hospital (67252 Industry Ln, Covington, LA 70433).

**Termination of the Study:**

The Principal Investigator reserves the right to terminate the study in the interest of subject welfare. The Sponsor may terminate the study for administrative reasons.

Should the study be terminated, all documentation pertaining to the study must be returned to the Sponsor. Any actions required to assess or maintain study subject safety will continue as required, despite termination of the study by the Sponsor.

**Protocol Deviations:**

Deviations from the protocol will be assessed as "minor" or "major" in agreement with the Sponsor. Major deviations from the protocol may lead to the exclusion of a subject from data analysis and will be considered on a case-by-case basis.

The Investigator will not deviate from this protocol for any reason without prior written approval from the Sponsor, except in cases of medical emergencies. The Investigator may deviate from the protocol without prior approval only when the change is necessary to eliminate an apparent immediate hazard to a subject. In that event, the Investigator will notify the Sponsor immediately by phone, notify the IRB, and confirm notification to the Sponsor in writing within 5 working days after the change is implemented.

**Statistics:**

This is an open-label study. Formal sample size calculations were not performed. The number of subjects was chosen based on feasibility and is considered sufficient to meet the study objectives.

Detailed methodology for summary and statistical analyses of the data collected in this study will be documented in the Clinical Study Report.

**Direct Access to Source Data/Documents:**

The Principal Investigator will ensure that the Sponsor, IRB, and regulatory authorities will have direct access to all study sites, source data/documents, and reports for the purpose of monitoring and auditing. In the event that other study-related monitoring should be done by other parties, those parties will be required to sign a confidentiality agreement prior to any monitoring or auditing.

**Appendix A – Data Collection Sheet**

OR Date: _____ Surgeon: _____

Case ID (e.g. 071619A): _____ Hospital: _____

Stapler Type (Circle): AEON™ Endostapler Echelon Flex™ Powered Stapler System

Patient Medications: _____

Patient Gender: _____ Patient Age: _____ Patient BMI: _____

| **AEON™ Endostapler** | Black 60mm | Purple 60mm | Purple 45mm | Orange 60mm | Orange 45mm | Tan 60mm | Tan 45mm |
|---|---|---|---|---|---|---|---|
| Quantity Reloads Used | | | | | | | |

| **Echelon FLEX™** | Black 60mm | Black 45mm | Green 60mm | Green 45mm | Gold 60mm | Gold 45mm | Blue 60mm | Blue 45mm | White 60mm | White 45mm |
|---|---|---|---|---|---|---|---|---|---|---|
| Quantity Reloads Used | | | | | | | | | | |

| **Intraoperative Outcomes** | | | |
|---|---|---|---|
| Product malfunction (circle) | Yes | No | N/A |
| Blood transfusion due to staple line bleeding (circle) | Yes | No | N/A |

| **Surgeon overall satisfaction with the stapler used (circle):** | **Dissatisfied** | **Somewhat dissatisfied** | **Neutral** | **Somewhat satisfied** | **Satisfied** |
|---|---|---|---|---|---|

| **Postoperative Outcomes** | | | |
|---|---|---|---|
| Blood transfusion due to staple line bleeding within 72 hours of surgery start time (circle) | Yes | No | N/A |
| **1 Week** | | | |
| Dysphagia present (circle) | Yes | No | N/A |
| Nausea present (circle) | Yes | No | N/A |
| Weight loss: | | | |
| Pain level per standard protocol: | | | |
| **1 Month** | | | |
| Postoperative leakage during one-month monitoring period following procedure (circle) | Yes | No | N/A |
| Reported device-related adverse events (circle) | Yes | No | N/A |
| *If yes, please specify:* | | | |

**Appendix B – Bleeding Severity Evaluation Sheet**

Evaluation Date: _____ Evaluator: _____

Case ID (e.g. 071619A): _____

| **Staple line bleeding according to Bleeding Severity Scale (circle):** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| | **No bleeding** | **Minimal bleeding** | **Moderate bleeding** | **Excessive bleeding** | **Profuse bleeding** |