Endostapler Study Protocol

Endostapler04

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A proposed study using AEON™ Endostapler Handles and Reloads

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Co-Investigator(s):

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SUMMARY

The goal of this post-market study is to evaluate safety and efficacy of the AEON™ Endostapler when used in VATS or open lung resection surgery (lobectomy or wedge resection). Patients eligible will be over the age of 18 and undergoing planned lobectomy or wedge resection. The study will include 30 total consecutive patients that meet eligibility criteria. The procedures will be performed according to institutional standard-of-care and all subjects will undergo standard preoperative evaluation as well as postoperative care. Relevant data will be collected using the Case Report Form which should be filled out following each procedure by a member of the surgical or nursing team.

Enrollment: 80 Subjects Meeting Inclusion/Exclusion Criteria

Investigator Masking: None (Open Label)

Device: 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 are CE certified per Certificate No. G1 003029 0001 Rev. 00. The AEON™ Endostapler devices were cleared by the United States Food and Drug Administration (FDA) under the 510(k) process. Pertinent applications numbers are K171589 and K173443.

The AEON™ Endostapler has previously been proven as safe and effective for bariatric surgery as presented by Cleveland Clinic at SAGES 2019. The AEON™ Endostapler also has been evaluated for superior hemostasis against the Ethicon stapler with research led by Dr. James Redmann, as referenced inclinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT04149925?term=AEON+or+%27Lexington+medical%27&draw=2&rank=1.
This study aims to demonstrate safety and effectiveness for thoracic surgery.

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 table contains the available AEON™ Endostapler Reloads as well as their specifications. The surgeon should read and follow the Instructions for Use and use their own clinical judgement when determining the 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
Gray (Curved Tip)	45 mm	AESC45G	2.0 mm	0.75 mm	12 mm
White	45mm	AESR45T	2.5mm	1.0mm	12mm
White (Curved Tip)	45 mm	AESC45T	2.5 mm	1.0 mm	12 mm
White	60mm	AESR60T	2.5mm	1.0mm	12mm
Orange	45mm	AESR45R	3.25mm	1.5mm	12mm
Orange (Curved Tip)	45mm	AESC45R	3.25mm	1.5mm	12mm
Orange	60mm	AESR60R	3.25mm	1.5mm	12mm
Purple	45mm	AESR45P	4.0mm	1.8mm	12mm
Purple (Curved Tip)	45mm	AESC45P	4.0mm	1.8mm	12mm
Purple	60mm	AESR60P	4.0mm	1.8mm	12mm
Black	60mm	AESR60B	5.0mm	2.2mm	15mm

STUDY DETAILS

Patients satisfying the inclusion and exclusion criteria will be consecutively evaluated. Enrollment will be contingent on meeting these criteria, and the use of the AEON™ Endostapler.

Patient Inclusion and Exclusion Criteria:

Inclusion Criteria:

- Patients undergoing planned VATS or open lung resection surgery (lobectomy or wedge resection)

Exclusion Criteria:

- Active bacterial or fungal infection
- Prior history of VATS or open lung surgery
- Use of staple line reinforcement material (buttress)
- Patients under the age of 18 on the date of the surgery
- Any female patient who is pregnant
- Scheduled concurrent surgical procedure other than lobectomy or wedge resection (central venous access - e.g., port placement, mediastinoscopy with lymph node sampling, and VATS lymphadenectomy are allowed)

Primary Outcome Measure:

- Incidence of reported device-related adverse events through 30-day post-operative evaluation period

Secondary Outcome Measures:

- Incidence of product malfunction during procedure

Steps and Procedures:

The study will include 80 total procedures on consecutive patients which will be performed by either Dr. André Dutly or Dr. Alexandru Has using the AEON™ Endostapler.

All patients will undergo the standard preoperative evaluation pathway.

On the day of surgery, the surgeon will elect to use the AEON™ Endoscopic Stapler Reloads. The surgeon should read and follow the Instructions for Use and use their own clinical judgement when determining the appropriate products to use. If the reloads are used, and it is clinically appropriate, reloads from other manufacturers should not be used for that case. However, in the event of unavailability of a clinically appropriate AEON™ Endoscopic Stapler Reload, a similar reload from another manufacturer is

allowed. At the end of each case, a member of the surgical or nursing team will fill out the Case Report Form.

All typical post-operative care will continue, including during the immediate post-operative period prior to hospital discharge. Regularly scheduled follow up appointments will be scheduled based on the preference and practice pattern of the surgeon and institution.

Surgery Locations:

Surgeries will all take place at Kantonsspital St. Gallen (Rorschacher Str. 95, 9001 St. Gallen, Switzerland).

Statistics:

This is an open-label study. 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. Mean and standard deviation will be used for continuous data.

Appendix A – Case Report Form

Surgery Date: _____ Surgeon: _____ Hospital: _____

Surgery Type: _____

Patient Gender: _____ Patient Age: _____

AEON Endostapler	Black 60mm	Purple 60mm	Purple 45mm	Orange 60mm	Orange 45mm	White 60mm	White 45mm	Gray 45mm
Quantity Non-Curved Tip Reloads Used								
Quantity Curved Tip Reloads Used								

Intraoperative Outcomes		
Product malfunction during stapling? (circle one)	Yes	No
Blood transfusion due to staple line bleeding? (circle one)	Yes	No

If yes to any above, please specify:

30 Day Postoperative Outcomes		
Reported device-related adverse events? (circle one)	Yes	No

If yes to any above, please specify:

Investigator Signature: _____

Date: _____