AEON™

TECHNICAL BROCHURE

INNOVATING

MINIMALLY INVASIVE

SURGERY WITH

S3 ENGINEERING™

MADE IN USA

LEXINGTON MEDICAL

AEON™

AEON WITH S3 ENGINEERING™

Superior staple lines. Smooth articulation. Multi-speed gear.

Advanced reload architecture

Integrated I-beam assembly, fixed anvil and teardrop shape anvil buckets

High tech manufacturing

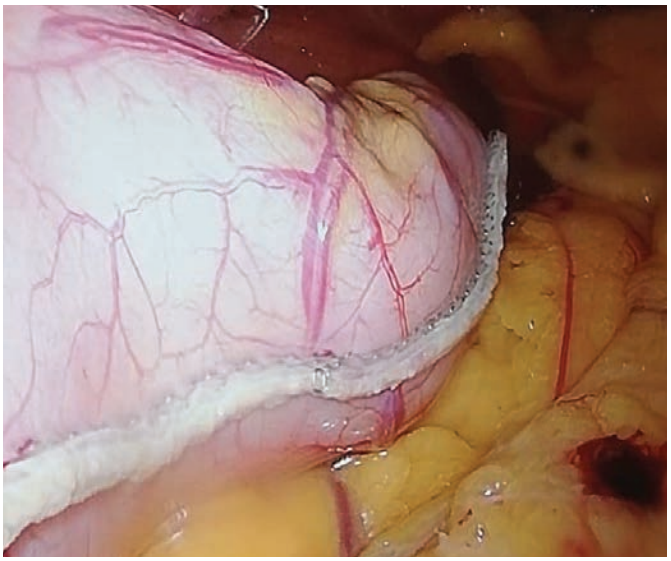
Proprietary manufacturing equipment incorporating AI

Cross compatibility

Cross compatible with Endo GIA™ and Signia™ powered handles

BETTER STAPLE FORMATION IN THICK TISSUE[1]

AEON™ staple lines from a laparoscopic sleeve gastrectomy procedure



SMOOTH RANGE OF MOTION WITH PRECISE ARTICULATION

Precise articulation

Freedom to articulate effortlessly for a more controlled firing

Multi-speed gear

Reduced trigger pull force for thicker tissue

Single-handed grasper

Quick, easy tissue grasping for increased efficiency

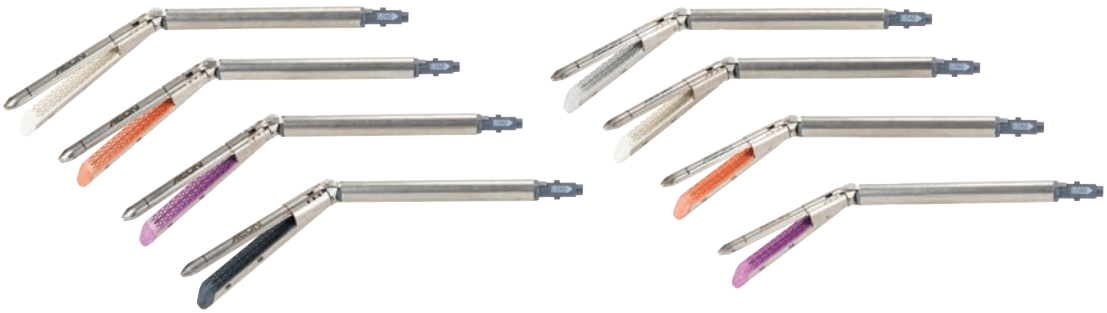
50%

LOWER FIRING FORCE WITH MULTI-SPEED GEAR[1]

for controlled firing in thick tissue

1. Data on file

Product Offering



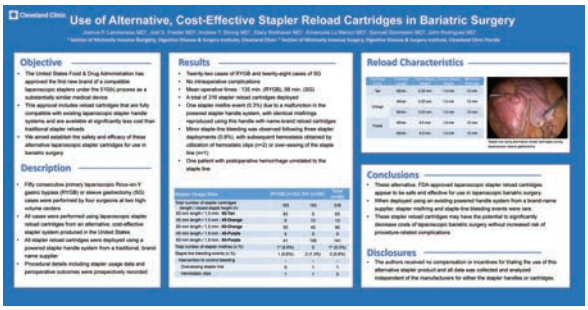
Reload Type	Cartridge Length	Product Code	Open Height	Closed Height	EA/BX
Gray	45mm	AESR45G	2.0mm	0.75mm	6
White	45mm	AESR45W	2.5mm	1.0mm	6
White	60mm	AESR60W	2.5mm	1.0mm	6
Orange	45mm	AESR45R	3.25mm	1.5mm	6
Orange	60mm	AESR60R	3.25mm	1.5mm	6
Purple	45mm	AESR45P	4.0mm	1.8mm	6
Purple	60mm	AESR60P	4.0mm	1.8mm	6
Black	60mm	AESR60B	5.0mm	2.2mm	6

Handle Type	Shaft Length	Product Code	EA/BX
Medium	160mm	AESH160	3
Long	260mm	AESH260	3

Clinical Evidence

Significantly drier staple lines per Surgical Specialists of Louisiana study inital results on clinicaltrials.gov

- Sixty consecutive laparoscopic sleeve gastrectomy procedures; 30 using the AEON™ Endostapler and 30 using the Echelon Flex™ Powered Stapler
- Stapler performance measured by the incidence and degree of staple line bleeding through a third-party blinded primary outcome evaluator
- No intraoperative complications with AEON™ Endostapler

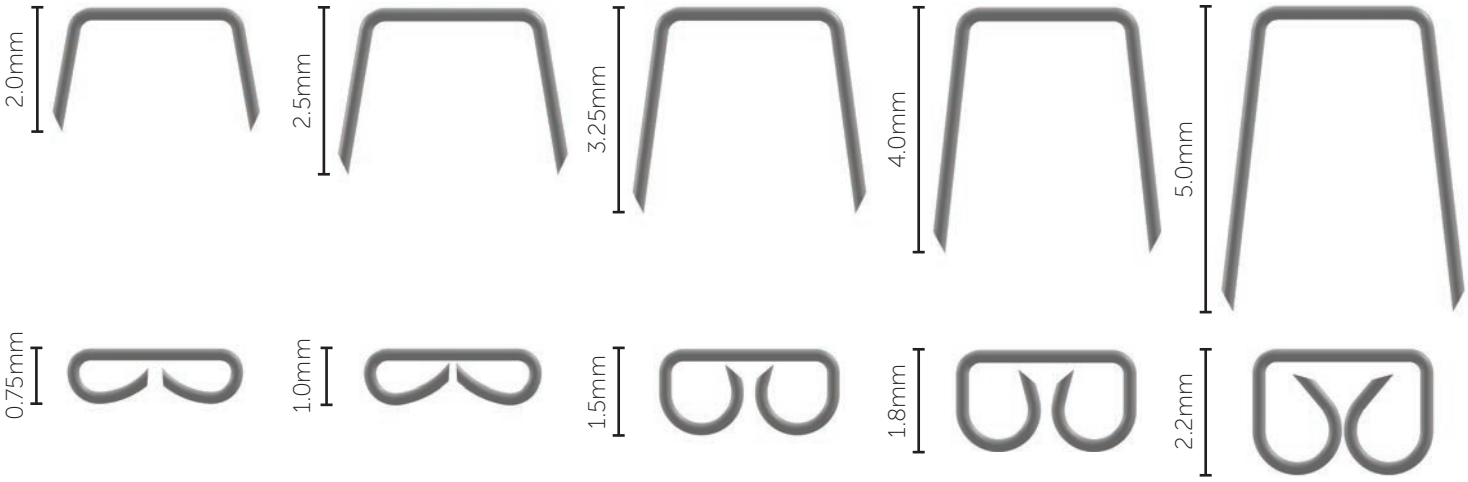


Safe and effective as presented by Cleveland Clinic at SAGES 2019

- No intraoperative complications with 316 AEON™ reloads deployed
- Fifty consecutive patients
- Laparoscopic gastric bypass and sleeve gastrectomy surgeries

Staple Heights

GRAY		WHITE		ORANGE		PURPLE		BLACK	
OPEN	CLOSED	OPEN	CLOSED	OPEN	CLOSED	OPEN	CLOSED	OPEN	CLOSED
2.0	0.75	2.5	1.0	3.25	1.5	4.0	1.8	5.0	2.2



Echelon Flex™ Staple Height (mm)		
	OPEN	CLOSED
Gray	2.0	0.75
White	2.5	1.0
Blue	3.5	1.5
Gold	3.8	1.8
Green	4.1	2.0
Black	4.2	2.3

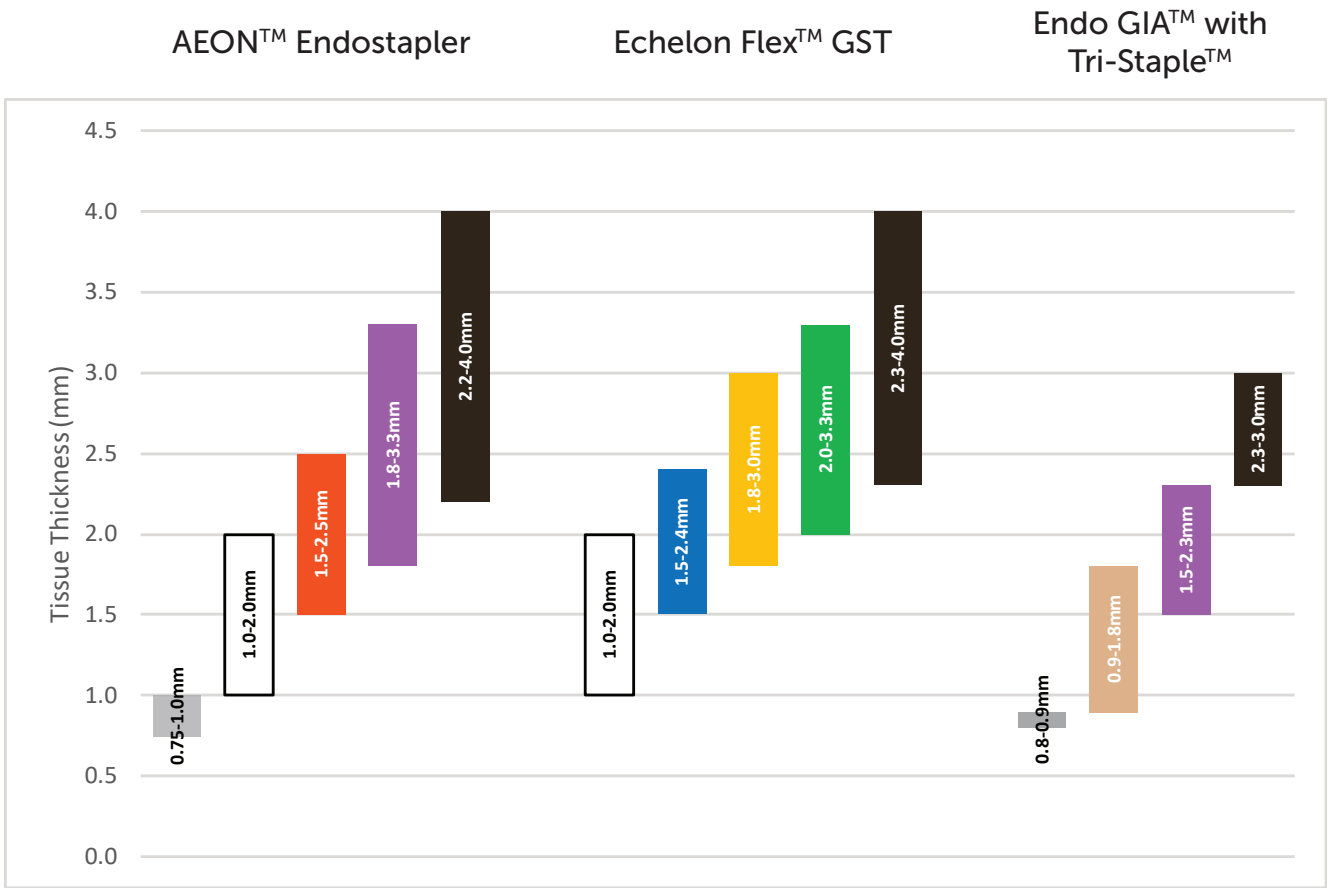
Endo GIA™ Staple Height (mm)		
	OPEN	CLOSED
Gray	2.0	0.75
White	2.5	1.0
Blue	3.5	1.5
Green	4.8	2.0

Endo GIA™ with Tri-Staple™ Staple Height (mm)		
	OPEN	CLOSED
Gray	2.0*	0.75
Tan	2.0, 2.5, 3.0	0.75, 1.0, 1.25
Purple	3.0, 3.5, 4.0	1.25, 1.5, 1.75
Black	4.0, 4.5, 5.0	1.75, 2.0, 2.25

*Per Endo GIA™ brochure, Extra-Thin/Vascular reload contains three rows of 2.0mm staples (non-varied height) and contains all of the other features and benefits of an Endo GIA™ Reload with Tri-Staple™ Technology.

Broadest Range of Tissue

The AEON™ Endostapler accommodates tissue thickness ranging from 0.75mm to 4.0mm, the broadest range among all stapler brands.



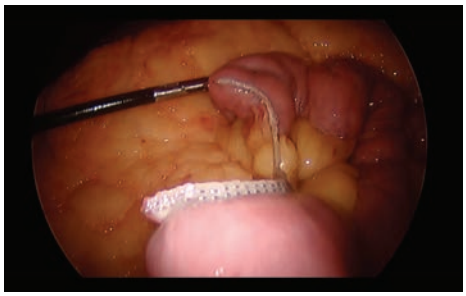
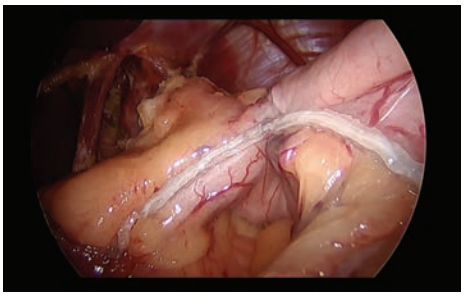
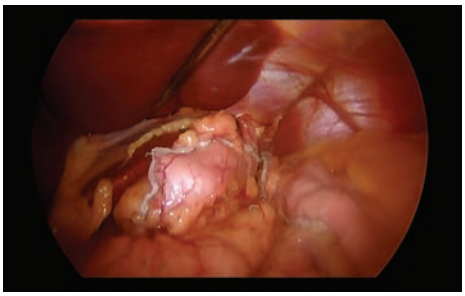
AEON™ tissue thickness ranges per benchtop testing in foam on file. ECHELON FLEX™ GST and Endo GIA™ with Tri-Staple™ values per IFU and materials available on websites.

Endo GIA Comparison

ENDO GIA™ with TRI-STAPLE™	AEON™ ENDOSTAPLER
Gray 2.0mm / 0.75mm	Gray 2.0mm / 0.75mm
Tan 2.0-3.0mm / 0.75-1.25mm	White 2.5mm / 1.0mm
Purple 3.0-4.0mm / 1.25-1.75mm	Orange (for a drier staple line) 3.25mm / 1.5mm
	Purple (for more perfusion) 4.0mm / 1.8mm
Black 4.0-5.0mm / 1.75-2.25mm	Black 5.0mm / 2.2mm

	AEON Endostapler	Endo GIA Tri-Staple with Ultra Handle	Advantage
Smoother firing	✓		Firing gears on the AEON handle facilitate controlled firing with 50% lower firing force*
Uniform staple design	✓		Graduated staple designs are associated with more air leaks than uniform staple designs (Eckert et al. 2018)**
Precise articulation	✓		Continuous articulation for exact angle placement with AEON compared to limited positions with Endo GIA
Advanced reload architecture	✓	✓	Both staplers incorporate an integrated I-beam assembly, fixed anvil and teardrop shape anvil buckets
Cross compatibility	✓	✓	AEON reloads and handles are compatible with Endo GIA and Signia powered handles***

*Data on file
**Eckert, C, Harris, J, Wong, J, Thompson, S, Kassis, E, Tsuboi, M, Ott, H & Force, S, 2018. Preclinical quantification of air leaks in a physiologic lung model: effects of ventilation modality and staple design. *Medical Devices: Evidence and Research*, 11, 433-442 .
***Endo GIA part numbers for proven compatibility listed in the IFU

Gastric bypass procedure with the AEON Endostapler

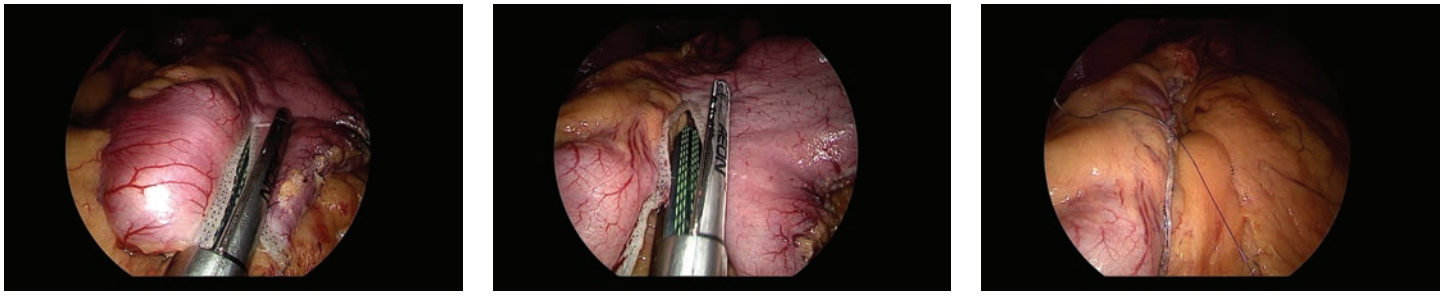
Echelon Flex Comparison

ECHELON FLEX™ STAPLER	AEON™ ENDOSTAPLER
Gray 2.0mm / 0.75mm	Gray 2.0mm / 0.75mm
White 2.5mm / 1.0mm	White 2.5mm / 1.0mm
Blue 3.5mm / 1.5mm	Orange 3.25mm / 1.5mm
Gold 3.8mm / 1.8mm	Purple 4.0mm / 1.8mm
Green 4.1mm / 2.0mm	
Black 4.2mm / 2.3mm	Black* 5.0mm / 2.2mm

*The AEON Black Reload must be inserted through a 15mm trocar

	AEON Endostapler	Echelon Flex GST with Powered Plus Stapler	Advantage
Single use blade	✓		AEON uses a fresh blade for every firing
Universal handle	✓		The AEON handle is compatible with all reload sizes, eliminating the need to open a second handle for different length reloads
Largest staple open height	✓		The AEON black reload has an open staple height of 5.0mm, compared to 4.2mm for Echelon Flex
Articulation control through handle	✓		AEON articulation is controlled by manual lever, without the need to push the distal end against tissue or grasper
Low weight	✓		The AEON stapler weighs 50% less than the Echelon Flex GST stapler*

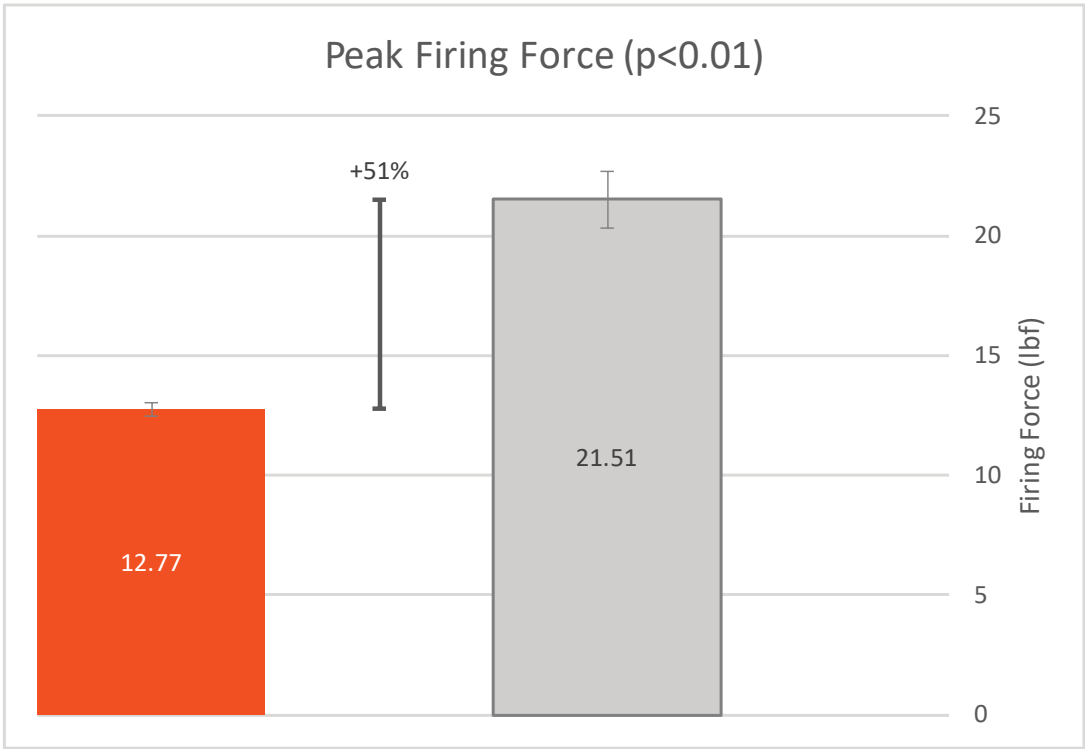
*Data on file



Sleeve gastrectomy procedure with the AEON Endostapler

Lower Firing Force

Reduce the trigger pull force by half with the AEON™ Endostapler.



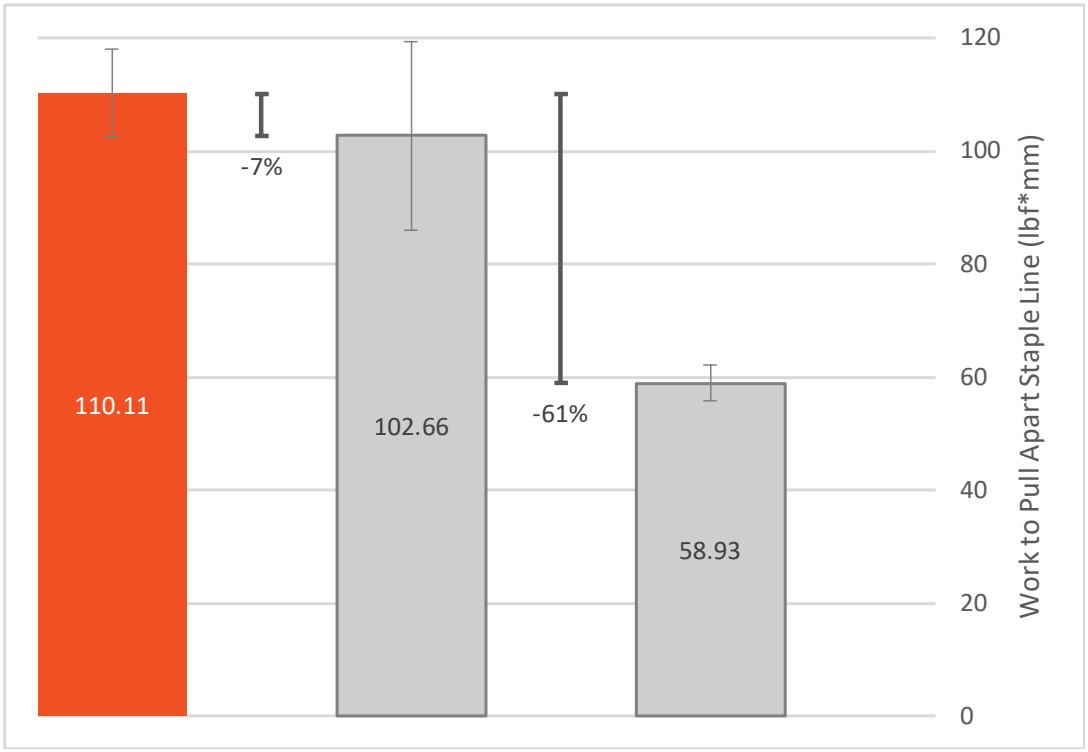
AEON™ Endostapler

Endo GIA™ with Tri-Staple™ and Ultra

Per benchtop data on file.

Stronger Staple Lines

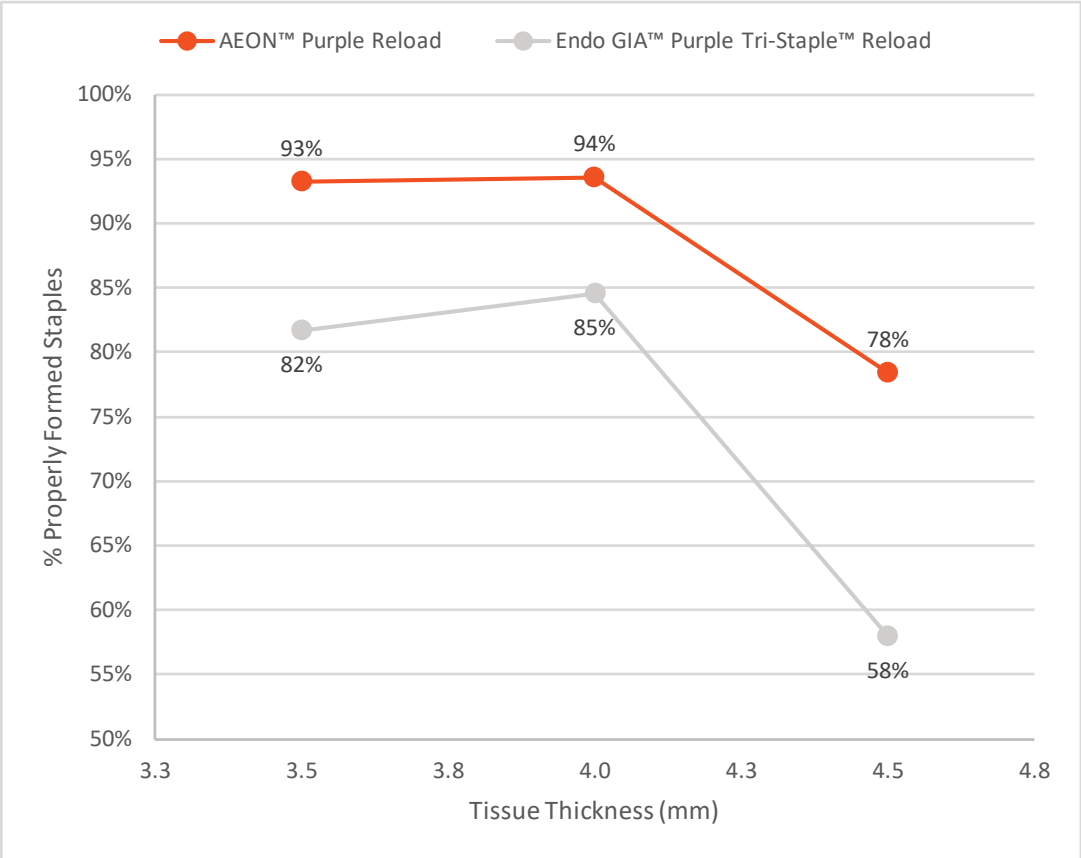
Create staple lines with the greatest resistance to pull apart with the AEON™ Endostapler.



Per benchtop data on file.

Superior Staple Formation

Create staple lines with more properly formed staples in thick tissue with the AEON™ Endostapler.



Per benchtop data on file.

"In over 350 bariatric cases, we have seen excellent staple formation with the AEON endostapler. **The unique dual firing gear allows for slow, controlled firing resulting in the best hemostasis I've seen** and a low risk for post-operative complications for our patients."

Michel Gagner, M.D., FRCSC, FACS, FASMBS
Chief of Surgery, Westmount Square Surgery Center, Montreal, Canada
Professor of Surgery, Herbert Wertheim School of Medicine, FIU
Senior Consultant, Hôpital du Sacre Coeur

"Our patient results have been fantastic in over 400 bariatric cases. Prior to using AEON, we performed testing on excised stomach specimens to evaluate both staple formation and risk of leaks. **The AEON consistently outperformed the other staplers** and we quickly became very comfortable with the product."

Christopher Hart, M.D., FACS
Medical Director, Atlanta General & Bariatric Surgery Center, Atlanta, GA
Bariatric Medical Director, (Emeritus) Chief of Staff, Emory Johns Creek Hospital

"I and my two partners have completed over 200 bariatric cases and been **very satisfied with the clean, beautiful staple lines**. Previously, I was frustrated by other companies for their yearly price increases with no real noteworthy product improvements. With AEON, we are finding **superior hemostasis** as the fresh blade with each reload makes for a much less traumatic, serosal edge."

James Redmann, M.D., FACS
Bariatric Surgeon, Surgical Specialists of Louisiana, Covington, LA
Medical Director, WhyWeight Clinic

"My partner and I operate at a physician-owned facility where we have performed over 600 bariatric cases with the AEON and we have found **the new dual firing gear allows for much smoother, easier firing in the thicker tissue of the stomach**. As an early adopter of the AEON endostapler, we've been fortunate to observe and be part of product evolution over a relatively short period of time."

Greg Walton, M.D., FACS
Bariatric Surgeon, MBS Director, Summit Medical Center, Oklahoma City, OK
Owner, WeightWise Bariatric Program

November 17, 2017

Lexington Medical Inc.
Donna Gasper
Management Representative
11 Executive Park Dr.
Billerica, Massachusetts 01862

Re: K171589
Trade/Device Name: AEON Endoscopic Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 13, 2017
Received: October 17, 2017

Dear Donna Gasper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003029 0001 Rev. 00

Manufacturer:
Lexington Medical, Inc.
11 Executive Park Drive
North Billerica MA 01862
USA

EC-Representative:
Advena Ltd
Tower Business Center, 2nd Flr., Tower Street, Swatar, BKR 4013
Birkirkara, MALTA

Product Category(ies): **Sterile, Endo-mechanical and Abdominal Surgical Instruments**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72133294

Valid from: 2018-10-01
Valid until: 2023-09-30

Date, 2018-10-01

I. Preiß

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003029 0001 Rev. 00

Facility(ies):

Lexington Medical, Inc.
11 Executive Park Drive, North Billerica MA 01862, USA

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DESIGNED, ENGINEERED AND MANUFACTURED IN THE

GREATER BOSTON AREA

LEXINGTON MEDICAL

11 Executive Park Drive Billerica, MA 01862 | www.lexington-med.com | 1-800-418-8281