



Value analysis brochure (VAB)

Powered **by intelligence.**



Confidence for you.
Strength for patients.^{†,1-3}



Signia™ stapling system

[†] Preclinical results may not correlate with clinical performance in humans.

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Introduction

Intelligent stapling – a wise choice.

Experience the intelligent Signia™ stapling system – a powered surgical stapler equipped with Adaptive Firing™ technology to sense tissue thickness and adjust firing speed accordingly.^{†,1,2}

By providing real-time feedback,⁴ the Signia™ stapling system gives you the confidence of consistent, optimally formed staple lines.^{†,1,2} And with a versatile array of reloads backed by the benefits of Tri-Staple™ technology, Signia™ staplers are uniquely adaptable to the needs of you and your patients.

Driven by over 60 years of innovation, the Signia™ stapling system is ready to help you meet your most pressing clinical challenges.

Feel the difference of intelligent stapling.

[†] Preclinical results may not correlate with clinical performance in humans.



Firing that automatically adapts.

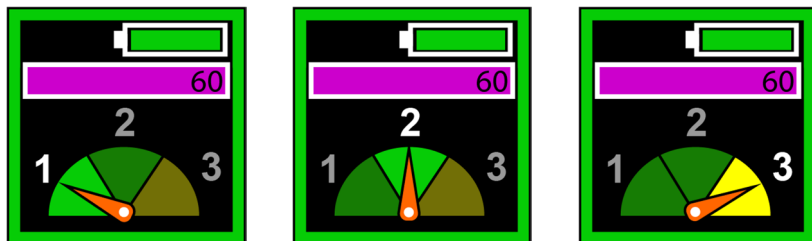
Adaptive Firing™ technology offers a standardized approach to surgical stapling across tissue thicknesses.^{†,1,2}

Why it's important:

- Automatically slowing down firing speed when forces in tissue increase improves staple performance in challenging applications^{†,1,2}
- Adjusting the firing speed when forces are high results in:
 - Reduced percentage of malformed staples by up to **84%**^{†,1-3}
 - More fully formed, B-shaped staples^{†,‡,2,5,6}
 - Up to **21%** stronger, more secure staple lines^{†,1-3}

How it works:

- Initial firing speed is set based on forces that are measured upon clamping^{†,1-3}
- The Signia™ stapler continuously measures force during firing and slows firing speed based on tissue variability and thickness to improve staple performance^{†,1,2}



[†] Preclinical results may not correlate with clinical performance in humans.

[‡] Compared to manual and fixed-speed powered staplers.



Features and benefits: Intelligence

Senses. Measures. Informs. Adapts.

Experience the intelligence of the Signia™ stapling system – a powered surgical stapler that senses tissue thickness and adjusts clamping force and firing speed in real time.

- Deploy Adaptive Firing™ technology to sense tissue thickness and adjust firing speed accordingly^{†,1,2}
- Use force- and tissue-sensing technology to improve staple performance in variable tissue^{†,1,2}
- Get real-time feedback so you can make informed decisions regarding staple reload selection^{‡,7}
- Leverage an easy-to-read display screen^{§,8} to simplify setup and use^{◇,8}



[†] Preclinical results may not correlate with clinical performance in humans.

[‡] Bench test results may not necessarily be indicative of clinical performance.

[§] 23 out of 23 surgeons surveyed agreed.

[◇] 38 out of 38 surgeons surveyed agreed.



Features and benefits: Confidence

Forms the line. Holds the line.

Intelligence powers Signia™ stapling – and Signia™ stapling drives Tri-Staple™ technology. The result is stronger, more consistent staple lines^{†,‡,3,9} that you and your patients can depend on.

- Maximize blood flow,^{§,10} maximize confidence in colorectal procedures
- Tackle variable tissue with confidence in bariatric surgery
- Manage stress, increase confidence in thoracic procedures



Backed by the benefits of Tri-Staple™ technology:

Superior performance^{†,‡,11-15}

Greater perfusion^{§,10}

Less stress on tissue^{§,¶,14,16}

[†] Preclinical results may not correlate with clinical performance in humans.

[‡] Compared to manual and fixed-speed powered staplers.

[§] Compared to flat-faced cartridges with single-height staples.

[¶] Bench test results may not necessarily be indicative of clinical performance. Compared to Ethicon Echelon Flex™.

[¶] Compared to Echelon Flex™ green reloads analysis comparing different stapler designs, performance, and impact on tissues under compression using 2-D finite element analysis.



Ergonomic ease. Clinical versatility.

By offering a powered handle with easy-to-reach push-button controls,^{†,8} plus a range of adapters and reloads to fit your specific needs, the intelligent Signia™ stapling system is uniquely adaptable to your cases – and you.



Signia™ power handle

The Signia™ power handle is a reusable handheld battery-powered stapling handle. It includes a microprocessor, electronics, motors, an LCD display screen, and rechargeable lithium-ion batteries in a sealed packet.

Note: The power handle is a nonsterilized device that deactivates after reaching the end of its service life. It will not deactivate while in use.



Signia™ power shell

The Signia™ power shell is a single-use, sterile control shell that covers and seals the nonsterile Signia™ power handle to create a sterile barrier, control interface, and universal adapter connection. It also provides a communications interface for Tri-Staple™ 2.0 single use reloads indicated for use with the stapler.

Precaution: The power shell is single use only.



Signia™ linear adapters

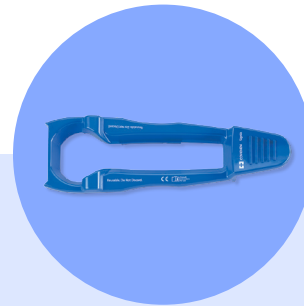
Signia™ adapters are reusable instruments that connect with the assembled Signia™ power shell and power handle to enable functionality of compatible Medtronic stapling reloads. The adapters are composed of motormating connectors, sensor gauges, and device communications interfaces to provide communications between Signia™ and/or Tri-Staple™ reloads and the power handle. They are provided nonsterile and must be sterilized before use.

Note: The adapters are reusable devices that deactivate after reaching the end of their service life. They will not deactivate while in use.



Single-bay charger

The single-bay charger and power supply charges the power handle. It is a nonsterile part of the system.



Signia™ reusable insertion guide

The reusable insertion guide is used to help maintain the sterility of the Signia™ power shell during insertion of the nonsterile Signia™ power handle. It is provided nonsterile and must be sterilized prior to each use.



Signia™ manual retraction tool

The Signia™ manual retraction tool is a reusable, handheld device that can be used to operate adapter controls in the event the stapler malfunctions during operation. The tool can be used to complete a firing, retract the knife and open the jaws, and/or articulate a stapling reload. It is provided nonsterile and must be sterilized before use.

[†] 38 out of 38 surgeons surveyed agreed.



Features and benefits: Versatility

Find the right reload for your case.



Tri-Staple™ 2.0 reinforced reload



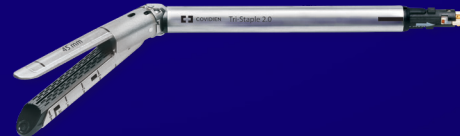
Endo GIA™ curved tip reload with
Tri-Staple™ technology



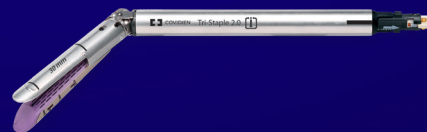
Signia™ small diameter reload



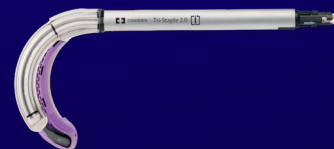
Endo GIA™ black (extra thick)
reload with Tri-Staple™ technology



Endo GIA™ 30 mm reload with
Tri-Staple™ technology



Endo GIA™ radial reload with Tri-Staple™
technology (available in select markets)



Thanks in part to its reposable platform, the Signia™ stapling generates **53%** less medical waste than the SureForm™ 60 stapler arm.¹⁷


Competitive comparison

See the difference of powered intelligence.

Feature	Signia™ stapling system	Ethicon Echelon Flex™* powered stapler	Ethicon Echelon™* 3000 powered stapler
Compatible with Signia™ adapters, Signia™ loading units, and Tri-Staple™ 2.0 cartridges and reloads	✓	✗	✗
Single powered handle compatible with 30 mm, 45 mm, and 60 mm reloads	✓	✗	✗
Compatible with Tri-Staple™ technology	✓	✗	✗
Extra-thick reload options with tissue indications up to 3 mm	✓	✗	✗
Integrated real-time feedback display	✓	✗	✗
Compatible with Signia™ small diameter reloads for 8 mm trocar access	✓	✗	✗
Features Adaptive Firing™ technology	✓	✗	✗
Power source	Lithium ion, 7.2 V, 2050 - 3000 mAh	4 single-use batteries per handle, single use, disposable	4 single-use batteries per handle, single use, disposable
Reusability	Reusable, reposable system comprised of disposable and reusable components†	Single use, disposable	Single use, disposable
Points of articulation	Unlimited in either direction	3 points of articulation on each side (left, right)	Unlimited in either direction
Articulation	Powered	Manual; second instrument or lateral pressure against body structure	Powered
Rotation	Powered and manual	Manual only	Manual only
Clamping	Powered	Manual only	Manual only
Firing	Intelligent, powered	Fixed speed, powered	Fixed speed, powered
Jaw opening	Powered	Manual only	Manual only

† Power shell is single use

FDA 510(k) clearance letter



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
10801 New Hampshire Avenue, Room 5606-G02
Silver Spring, MD 20910-6002


April 26, 2016

Covidien
Mr. Frank Giunelli
St. Product Specialist Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06471

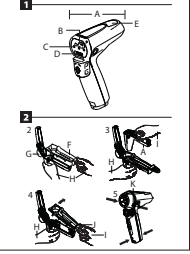
Re: KI16016
Trade Device Name: Signia Stylus
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable stylet
Regulatory Class: Class I
Product Code: GDW
Dated: January 22, 2016
Received: January 27, 2016

Dear Mr. Giunelli:
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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality system (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.


Instructions for use (IFU)



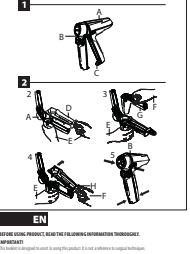
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Signia™
Power Handle
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COVIDIEN
Signia™
Power Shell
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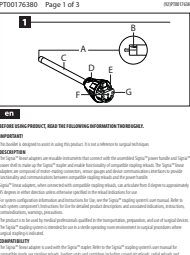
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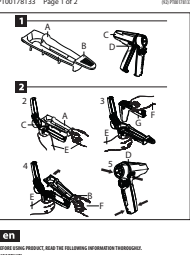
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Ordering information

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	Product code	Description	Quantity
	SIGPHANDLE	Signia™ power handle	1
	SIGPSHELL	Signia™ power shell	1
	SIGSBCHGR	Signia™ single-bay charger	1
	SIGRIG	Signia™ reusable insertion guide	1
	SIGMRET	Signia™ manual retraction tool	1
	SIGTRAY	Signia™ sterilization tray	1
	SIGPCORD1	Signia™ power cord 1 – US	1
	SIGADAPTSTND	Signia™ linear adapter (standard length)	1
	SIGADAPTXL	Signia™ linear adapter (XL length)	1
	SIGADAPTSHORT	Signia™ linear adapter (short length)	1



Meet clinical challenges with confidence.

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