THE FUTURE OF STAPLING IS IN YOUR HANDS. **TODAY.**

The world's first smart stapler

Signia™ Stapler
Product Information Guide

Medtronic
Further, Together

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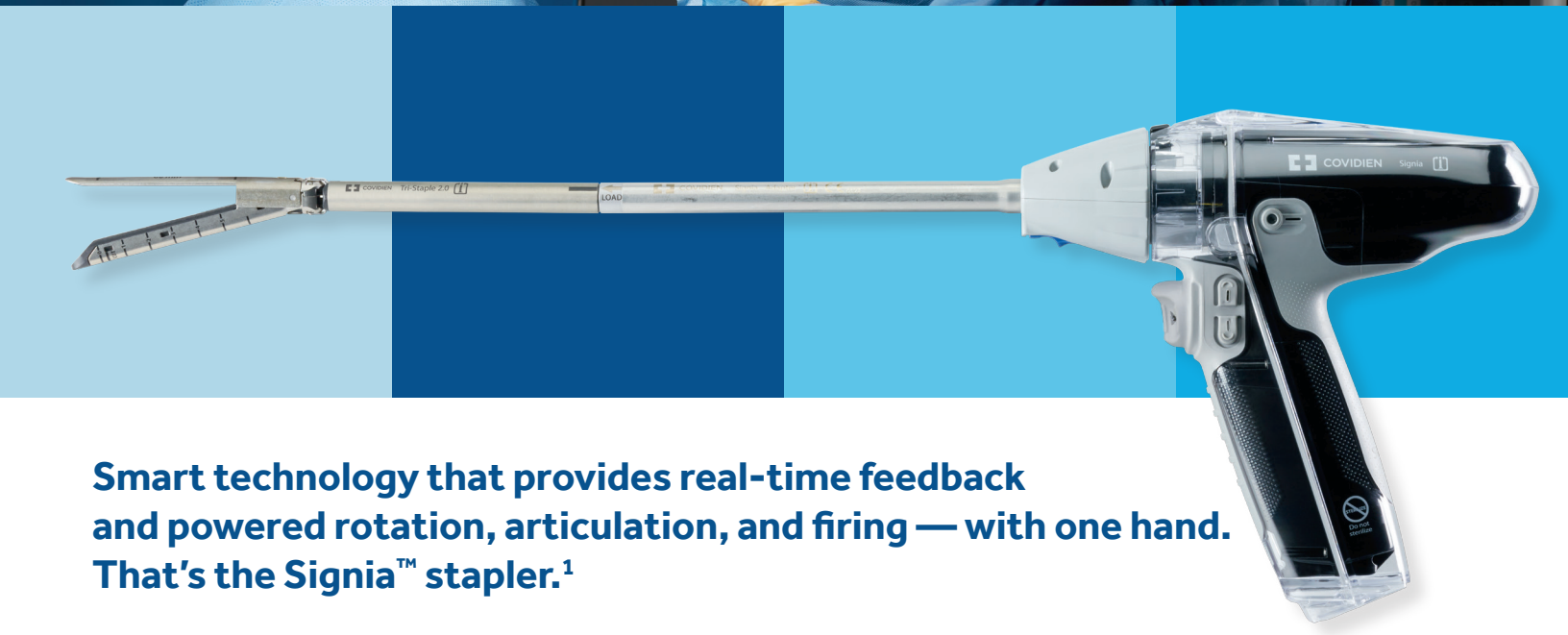
AN INTELLIGENT TOOL FOR **HANDS THAT HEAL.**



Smart technology that provides real-time feedback and powered rotation, articulation, and firing — with one hand. That's the Signia™ stapler.[1]

Your hands and your expertise. They're among your most important tools in the OR. And our new stapler is designed to be the ultimate complement — by providing you real-time feedback and staple line consistency in a true one-handed design.[1,2,3]

The Signia™ stapler gives you:

- Fully powered articulation, rotation, clamping, and firing, which provides greater precision and maneuverability compared to manual staplers[1,4]
- Push-button powered firing that decreases the strain of operation when stapling, compared to firing manually[4]
- Compatibility with our existing reload portfolio featuring the proven performance of Tri-Staple™ technology
- Enhanced performance when paired with Tri-Staple™ 2.0 reloads and Signia™ loading units with Tri-Staple™ 2.0 cartridges

And that's just the beginning.

A POWERED STAPLER **THAT EMPOWERS YOU.**

All the information you need at your fingertips

To help you deliver consistent staple lines, the Signia™ stapler is equipped with state-of-the-art technology that automatically adjusts clamp force and firing speed.[2,3] This information is provided to you in real-time on an easy-to-understand display screen[1] right on the stapler.

How it works

The smart features of the Signia™ stapler are only available when it's paired with Tri-Staple™ 2.0 reloads and Signia™ loading units with Tri-Staple™ 2.0 cartridges. That's because our new loading units have a chip which allow them to communicate meaningful information to the stapler — during your procedure.[1]

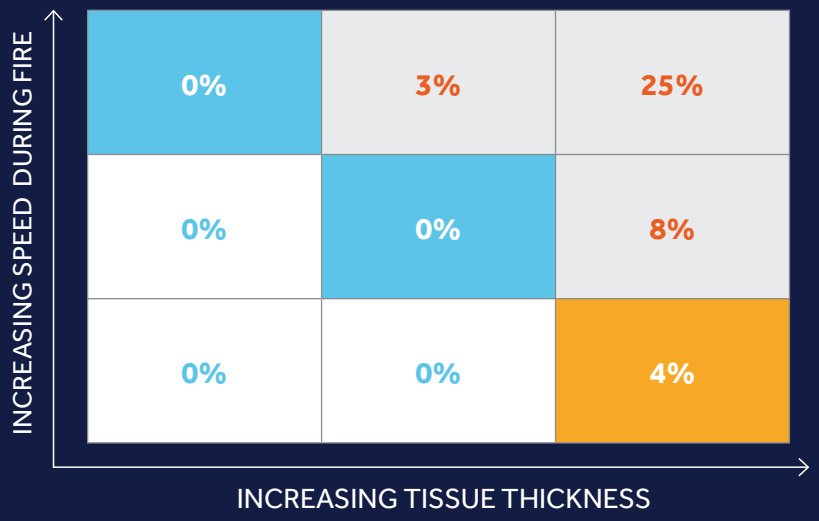
Intelligence Enabled™

NOT ALL TISSUE IS **CREATED EQUAL**

Evidence shows firing more slowly in thicker tissue helps ensure a higher percentage of properly formed B-shaped staples.[2]

Malformed Staple % In Variable Tissue vs. Firing Speed[†,2]

Malformed Staple Percentages (per firing)



Adaptive Firing™ Technology

It's what makes the Signia™ stapler smart. And it's what gives you real-time feedback when clamping on and firing through tissue.[5]

With Adaptive Firing™ technology, we're putting the tactile feedback of a manual stapler into a visual display on a powered device — and we're taking it to the next level.[††]

That's because Adaptive Firing™ technology:

- Measures force and provides feedback when clamping tissue[1,2,3]
- Sets firing speed based on clamp force measurement[6]
- Continuously measures force during firing and slows firing speed based on those measurements[6]

Three force zones with one objective: consistent staple lines[1,2,3]

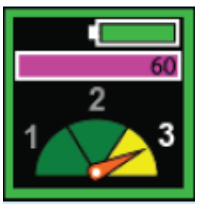
Not only does the Signia™ stapler measure force and adjust firing speed, it lets you know when it does — with visual and audible feedback.[6]

Note: Display feedback provided when using the Signia™ stapler with Tri-Staple™ 2.0 specialty reloads or Signia™ loading units with Tri-Staple™ 2.0 single use cartridges

Signia™ Stapler Operational Use Display Screen Sequence

Zone 1:
Indicates the stapler will start firing at its regular speed to deliver optimal staple formation[6]

Zone 2:
Indicates the stapler will require a higher firing force due to thicker or variable tissue and the device will slow its speed to deliver optimal staple formation[6]



Zone 3:
Indicates the stapler will require the highest firing force due to very thick or variable tissue and the device will adjust to its slowest speed to deliver optimal staple formation[6]

† N=243 firings. Graph represents values based on preliminary ex vivo porcine model data. Represents the various speeds a user can deploy staples using a manual handle. This data was used to develop the optimal firing speeds for the Signia™ System.

†† SAGES Lap Report. Engineering Report Number RE00055515

POWERED ROTATION, ARTICULATION, & FIRING. WITH ONE HAND.[1]

Every piece of the Signia™ stapler is designed to benefit to you and your patients

- Single-handed operation means your other hand is freed to focus on the surgical site[1]
- Push-button powered firing reduces strain of operation compared to firing manually[4]
- Enhanced ergonomics create a well-balanced feel in the hand during use[1]
- Easy-to-reach controls accommodate a range of hand sizes[1]
- Easy-to-understand display screen[1]

The Tri-Staple™ technology advantage

Benefits you — and your patients — can count on. The Signia™ stapler delivers them with the unparalleled performance of Tri-Staple™ technology, which:

Generates less stress on tissue during compression and clamping[7]

Allows greater perfusion into the staple line[8]

Delivers outstanding performance in variable tissue thicknesses

FLEXIBILITY & COMPATIBILITY **WITHIN YOUR REACH.**

Our fully reposable platform offers:

- Pricing flexibility
- Signia™ power handle can be reused
- Signia™ linear adapter can be reused

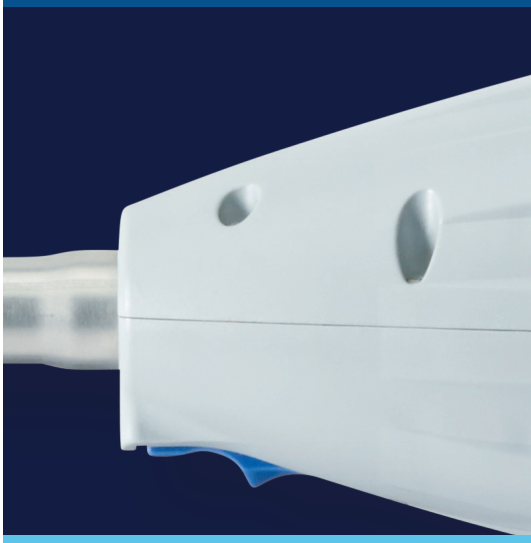
The system is comprised of:

- Signia™ power handle
- Signia™ power shell
- Signia™ adapters
- Various accessories*

And it's compatible with:

- Tri-Staple™ 2.0 reloads
- Signia™ loading units with Tri-Staple™ 2.0 cartridges
- Endo GIA™ reloads
- Endo GIA™ reloads with Tri-staple™ technology

*System accessories include a single-bay battery charging station, reusable insertion guide, and a manual retraction tool.



Signia™ Power Handle

The Signia™ power handle is a reusable handheld battery-powered stapling handle. It includes a microprocessor, electronics, motors, a 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 non-sterile 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

The Signia™ linear 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™ loading units with Tri-Staple™ 2.0 cartridges, Tri-Staple™ 2.0 reloads, and the power handle.
It is provided nonsterile and must be sterilized before use.
NOTE: The linear adapters are reusable devices that deactivate after reaching the end of their service life. They will not deactivate while in use.

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.

Single-Bay Charger

The single-bay charger and power supply charges the power handle.

Non-Sterile Central Sterile Disposable

COMPETITIVE **COMPARISON**

FEATURE	SIGNIA™ STAPLER	EES ECHELON FLEX™* POWERED STAPLER	EES ECHELON FLEX™*
Compatible with 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 Endo GIA™ reloads with Tri-Staple™ technology	■	—	—
Extra-thick reload with tissue indications up to 3 mm	■	—	—
Integrated real-time feedback display	■	—	—
Features Adaptive Firing™ technology	■	—	—
Power source	Lithium ion, 14.8 V, 2150 mAh	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 with the 45-degree maximum range	Unlimited	3 on each side (left, right)	3 on each side (left, right)
Articulation	Powered	Manual; second instrument or lateral pressure against body structure	Manual; second instrument or lateral pressure against body structure
Rotation	Powered and manual	Manual only	Manual only
Clamping	Powered	Manual only	Manual only
Firing	Powered	Powered	Manual only
Jaw Opening	Powered	Manual only	Manual only

510 (K) CLEARANCE

/DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 26, 2016

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

Re: K160176
Trade/Device Name: Signia Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 22, 2016
Received: January 27, 2016

Dear Mr. Gianelli:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

510 (K)
CLEARANCE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160176

Device Name

Signia™ Stapler

Indications for Use *(Describe)*

The Signia™ stapler, when used with Endo GIA™ single-use reloads, Endo GIA™ single-use reloads with Tri-Staple™ Technology, Tri-Staple™ 2.0 single-use reloads and Signia™ loading units with Tri-Staple™ 2.0 single-use cartridges, has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of the pancreas.

The Signia™ stapler, when used with Endo GIA™ curved tip single use reloads or Tri-Staple™ 2.0 curved tip single-use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ stapler, when used with Endo GIA™ single use Radial Reloads with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e., low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of the pancreas.

The Signia™ stapler, when used with Endo GIA™ single use reinforced reloads with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement or Tri-Staple™ 2.0 single use reinforced reloads preloaded with polyglycolic acid staple line reinforcement, has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of the pancreas.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

INSTRUCTIONS FOR USE

COVIDIEN™

Signia™

Power Handle

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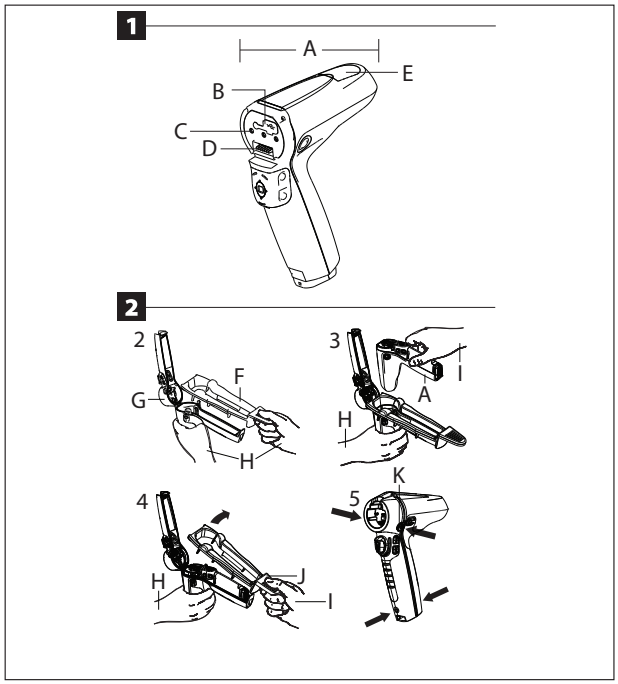

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

DESCRIPTION

The Signia™ power handle is a reusable, battery-powered stapling handle that is designed as part of the Signia™ stapler, which is composed of the Signia™ power handle, Signia™ power shell and Signia™ adapters. The power handle includes a microprocessor, electronics, motors, an OLED display screen and a rechargeable Li-ion battery in a sealed packet.

For system configuration information and Instructions for Use, see the Signia™ stapling system's user manual. Refer to each system component's Instructions for Use for detailed product descriptions and associated indications, instructions, contraindications, warnings and precautions.

The product is to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The Signia™ stapling system is intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

COMPATIBILITY

The power handle, when combined with a power shell and adapter, becomes the Signia™ stapler. Refer to the Signia™ stapling system's user manual for compatible single use stapling reloads, loading units and cartridges including curved-tip reloads, radial reloads and reinforced reloads.

INDICATIONS FOR USE

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use staple reloads, reinforced reloads, loading units and cartridges has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of pancreas.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible curved tip single use reloads can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use radial reloads has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

CONTRAINDICATIONS

Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for specific indications, contraindications, warnings, and precautions.

PRECAUTIONS

1. The power handle is a precise instrument. Care should be taken to avoid dropping, improper cleaning, improper handling or sterilizing the device. These actions may shorten device life and/or lead to device failure.
2. The power handle is provided non-sterile. DO NOT STERILIZE.
3. Ensure the battery is sufficiently charged prior to use. Refer to the Instructions for Use provided with the associated charger.
4. REMOVE the power handle from the used power shell after use.
5. Ensure the power handle is completely dry prior to inserting it into a sterile power shell or charger.
6. Do not hold or carry the stapler by the distal end of the adapter or stapling reload.
7. The Signia™ power handle should be cleaned when it appears dirty or contaminated and following each use the adapter or by the stapling reload.
8. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performing endoscopic procedures, consult the medical literature relative to techniques, complications, and hazards.
9. A thorough understanding of the principles involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to the patient and operators, as well as damage to the instrument.

1 SCHEMATIC VIEW

A) POWER HANDLE

B) DATA CONFIGURATION PORT

C) MOTORS

D) ELECTRONIC CONNECTORS

E) OLED DISPLAY SCREEN

INSTRUCTIONS FOR USE

Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for detailed instructions on set up and use.

SET UP

NOTE: The power handle unit is shipped in the OFF mode.

When receiving a new power handle, turn it on by placing the power handle into a charger terminal facing forward and the base of the handle onto the terminal from back to front until a secure connection is established. The device will turn on and begin initializing.

CHARGING

NOTE: Refer to the charger Instructions for Use or the Signia™ stapling system's user manual for complete information related to charging power handle devices.

1. Insert the power handle into the battery charger, placing it into the battery charger bay facing forward and the base of the handle onto the terminal from back to front until a secure connection is established.
2. Upon its first activation, charge the power handle for a minimum of three hours before clinical use.
3. Recharge the power handle after each use.

2 INSERTING THE POWER HANDLE

PRECAUTION: The non-sterile power handle must be inserted into a sterile power shell with a sterilized reusable insertion guide while maintaining aseptic transfer principles. Use caution when inserting the power handle so as not to contaminate the sterile shell.

PRECAUTION: Ensure the power handle is sufficiently charged before use. See the Instructions for Use provided with the charger.

PRECAUTION: The reusable insertion guide is provided non-sterile. It must be cleaned and sterilized prior to each use. Refer to the Instructions for Use provided with the reusable insertion guide for cleaning and sterilization instructions.

1. SCRUBBED PERSON: After aseptically removing the sterile power shell from the packaging, carefully open the power shell by holding the back handle of the power shell so the front handle is facing up and away from the back handle.
2. SCRUBBED PERSON: Align and fully seat a clean, sterilized reusable insertion guide onto the back handle of the open power shell to provide an aseptic transfer guide when inserting the power handle into the power shell.

F) REUSABLE INSERTION GUIDE

G) POWER SHELL

H) SCRUBBED PERSON

PRECAUTION: Ensure the reusable insertion guide is properly seated onto the power shell before inserting the power handle.

3. CIRCULATING PERSON: Maintaining aseptic transfer techniques, insert the power handle into the reusable insertion guide and power shell.

A) POWER HANDLE

H) SCRUBBED PERSON

I) CIRCULATING PERSON

4. CIRCULATING PERSON: After the power handle is fully seated in the power shell, carefully remove the reusable insertion guide using the extended handle.

J) EXTENDED HANDLE

H) SCRUBBED PERSON

I) CIRCULATING PERSON

5. SCRUBBED PERSON: Taking care not to touch the power handle, close the front portion of the power shell until there is tactile confirmation the base of the power shell is closed and the top secure clips are secured. This confirms the shell is fully closed and securely locked.

K) OP SECURE CLIPS

PRECAUTION: Ensure both top secure clips are secured before use.

Operational Use

Refer to the Signia™ stapling system's user manual for complete information regarding controls and communications.

Removing the Power Handle

1. Release top secure clips, press the secure latch, and carefully open the power shell to expose the power handle.
2. Remove the power handle with a clean glove.

CLEANING THE POWER HANDLE
PRECAUTIONS AND WARNINGS

NOTE: The power handle is made from metal, electronics, and plastic.

NOTE: The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not deactivate during use. The device number of uses remaining indication is provided on the power handle OLED display.

1. The power handle is provided non-sterile. Clean after each use. DO NOT STERILIZE.
2. Do not rinse under running water or submerge. Avoid moisture on the gold electrical contacts on the bottom and front face.
3. Do not use alcohol, quaternary ammonium, and bleach based wipes as they may cause physical deterioration of the handle housing such as discoloration, embrittlement, or cracking. Only use the cleaning methods described in this manual to maximize the physical characteristics of the handle housing.
4. Do not use instrument lubricant on the power handle.

TO CLEAN THE POWER HANDLE

1. Wipe down all exposed surfaces with a slightly water dampened lint-free cloth to completely remove any gross debris from the device.
2. If additional cleaning is required, use a hydrogen peroxide based wipe such as Oxivir™* Tb per the manufacturer's instructions.
3. Ensure the power handle is completely dry prior to inserting it into a sterile power shell or charger.

MAINTENANCE

Inspect the power handle for damage or wear prior to use including bent electrical connectors, buildup of debris in electrical contacts or cracking of the power handle housings.

STORAGE

Return the power handle to a battery charger for charging and storage. Store at room temperatures (50 °F–104 °F or 10 °C– 40 °C) and relative humidity (30%–75%). Avoid prolonged exposure to elevated temperatures.

DISPOSAL

NOTE: Contact Covidien customer service prior to recycling and disposing of to confirm contracted recycling and disposal agreements. Contact customer service at http://www.covidien.com/sales-support or by dialing 1-800-722-8772. Recycle the power handle by returning it to the manufacturer.

PRODUCT CLASSIFICATION PER IEC 60601-1

Type of protection against electric shock: Internally powered (battery)

Battery ratings: Lithium ion, 14.8 V, 2150 mAh

Degree of protection against electric shock: Type CF applied part

Degree of protection against ingress of water: IPX4

Not suitable for use in presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Mode of operation: Continuous mode

INSTRUCTIONS FOR USE

COVIDIEN™

Signia™
Power Shell

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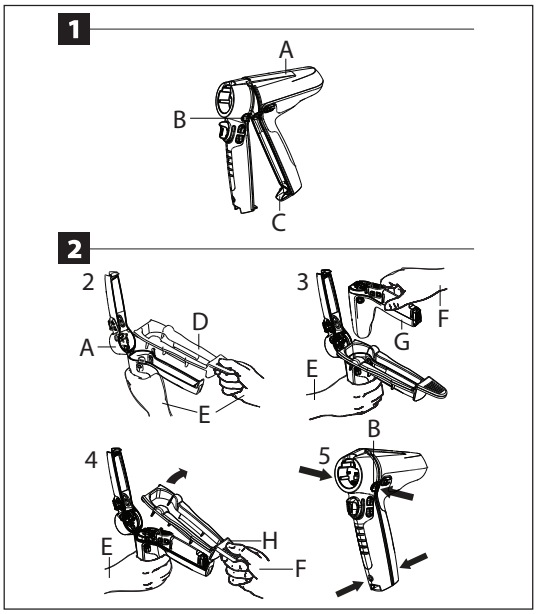

EN

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The Signia™ power shell is a single use, sterile control shell that is designed as part of the Signia™ stapler, which is composed of the Signia™ power handle, Signia™ power shell and Signia™ adapter. The sterile power shell covers the non-sterile Signia™ power handle to create an aseptic control interface and universal adapter connector. It also provides a communications interface for single use reloads, loading units and cartridges.

For system configuration information and Instructions for Use, see the Signia™ stapling system's user manual. Refer to each system component's Instructions for Use for detailed product descriptions and associated indications, instructions, contraindications, warnings and precautions.

The product is to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The Signia™ stapling system is intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

COMPATIBILITY

The Signia™ power shell, when combined with the Signia™ power handle and Signia™ adapters, becomes the Signia™ stapler. Refer to the Signia™ stapling system's user manual for compatible single use stapling reloads, loading units and cartridges including curved-tip reloads, radial reloads and reinforced reloads.

INDICATIONS FOR USE

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use staple reloads, reinforced reloads, loading units and cartridges has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of pancreas.

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The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use radial reloads has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

CONTRAINDICATIONS

1. The Signia™ power shell is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

2. Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for specific indications, contraindications, warnings, and precautions.

WARNINGS AND PRECAUTIONS

1. The power shell is provided STERILE and is intended for use in a SINGLE procedure only.

2. Visually inspect the power shell packaging for damage or wear prior to use. Do not use the power shell if the packaging or device appears damaged.

3. Do not exceed limitations of the hinge when opening the power shell.

4. Do not overly deflect side clips. Replace if clips are broken during set up or use. Jagged edges may tear gloves.

5. REMOVE the power handle from the used power shell after use. DO NOT RESTERILIZE OR REUSE. Resterilized or reprocessed power shells will not function.

6. Ensure the power shell is securely closed before operating the stapler.

7. Insert a power handle into the power shell before attaching an adapter to the power shell.

8. Do not hold or carry the stapler by the distal end of the adapter or by the stapling reload.

9. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performing endoscopic procedures, consult the medical literature relative to techniques, complications, and hazards.

10. A thorough understanding of the principles involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to the patient and operators, as well as damage to the instrument.

1 SCHEMATIC VIEW

A) POWER SHELL

B) TOP SECURE CLIPS

C) SECURE LATCH

INSTRUCTIONS FOR USE

Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for detailed information on power handle insertion techniques and setup instructions. These instructions are not intended as a reference to surgical techniques.

2 INSERTING THE POWER HANDLE

PRECAUTION: The non-sterile power handle must be inserted into a sterile power shell with a sterilized, reusable insertion guide while maintaining aseptic transfer principles. Use caution when inserting the power handle so as not to contaminate the sterile shell.

PRECAUTION: Ensure the power handle is sufficiently charged before use. See the Instructions for Use provided with the charger.

PRECAUTION: The reusable insertion guide is provided non-sterile. It must be cleaned and sterilized prior to each use. Refer to the Instructions for Use provided with the reusable insertion guide for cleaning and sterilization instructions.

1. SCRUBBED PERSON: After aseptically removing the sterile power shell from the packaging, carefully open the power shell by holding the back handle of the power shell so the front handle is facing up and away from the back handle.

2. SCRUBBED PERSON: Align and fully seat a clean, sterilized reusable insertion guide onto the back handle of the open power shell to provide an aseptic transfer guide when inserting the power handle into the power shell.

A) POWER SHELL

D) REUSABLE INSERTION GUIDE

E) SCRUBBED PERSON

PRECAUTION: Ensure the reusable insertion guide is properly seated onto the power shell before inserting the power handle.

3. CIRCULATING PERSON: Maintaining aseptic transfer techniques, insert the power handle into the reusable insertion guide and power shell.

E) SCRUBBED PERSON

F) CIRCULATING PERSON

G) POWER HANDLE

4. CIRCULATING PERSON: After the power handle is fully seated in the power shell, carefully remove the reusable insertion guide using the extended handle.

E) SCRUBBED PERSON

F) CIRCULATING PERSON

H) EXTENDED HANDLE

5. SCRUBBED PERSON: Taking care not to touch the power handle, close the front portion of the power shell until there is tactile confirmation the base of the power shell is closed and the top secure clips are secured. This confirms the shell is fully closed and securely locked.

B) TOP SECURE CLIPS

NOTE: Ensure both top secure clips are secured before use.

DISASSEMBLING THE POWER HANDLE

1. Release the top secure clips, press the secure latch and carefully open the power shell to expose the power handle.

2. Remove the power handle with a clean glove.

3. Discard the power shell.

STORAGE

Store at room temperatures (50 °F-104 °F or 10 °C- 40 °C) and relative humidity (30%-75%). Avoid prolonged exposure to elevated temperatures.

DISPOSAL

Discard or recycle as per local, state, and governmental regulations.

PRODUCT CLASSIFICATION PER IEC 60601-1

Degree of protection against electric shock: Type CF applied part

Not suitable for use in presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Mode of operation: Continuous mode

ELECTROMAGNETIC COMPATIBILITY GUIDANCE (EN/IEC 60601-1-2)

PRECAUTION: The power shell is considered medical electrical equipment. Medical electrical equipment requires special care regarding electromagnetic compatibility (EMC), and needs to be installed and put into service according to the EMC information provided in this document.

PRECAUTION: Portable and mobile RF communication equipment can affect medical electrical equipment.

WARNING: The use of accessories other than those specified and sold by Covidien may result in increased emissions or decreased immunity of the power shell.

WARNING: The power shell should not be used next to other equipment. If adjacent use is necessary, observe the power shell to verify normal operation.

Guidance and Manufacturer's Declaration-Electromagnetic Emissions		
The power shell is intended for use in the electromagnetic environment specified below. The customer or user should ensure it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The power shell uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity			
The power shell is intended for use in the electromagnetic environment specified below. The customer or user should ensure it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	N/A	The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for five cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for five seconds	N/A	The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration-Electromagnetic Immunity			
The power shell is intended for use in the electromagnetic environment specified below. The customer or user should ensure it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the power shell, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitting device. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1. At 80 MHz and 800 MHz, the higher frequency range applies. Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones, and land mobile radios; amateur radio; AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the power handle, adapter and power shell are used exceeds the applicable RF compliance level above, the power handle, adapter and power shell should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the power shell.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

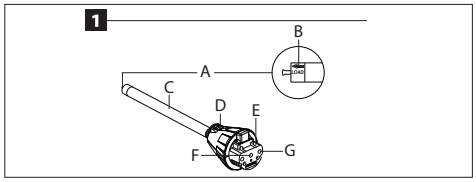
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Power Shell			
The power shell is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the power shell as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

INSTRUCTIONS FOR USE

COVIDIEN™

Signia™
Linear Adapters

PT00048739



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!
This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

DESCRIPTION
The Signia™ linear adapters are reusable instruments that connect with the assembled Signia™ power handle and Signia™ power shell to make up the Signia™ stapler and enable functionality of compatible stapling reloads. The Signia™ linear adapters are composed of motor-mating connectors, sensor gauges and device communications interfaces to provide functionality and communications between compatible stapling reloads and the power handle.

For system configuration information and Instructions for Use, see the Signia™ stapling system's user manual. Refer to each system component's Instructions for Use for detailed product descriptions and associated indications, instructions, contraindications, warnings, precautions.

The product is to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The Signia™ stapling system is intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

COMPATIBILITY
The Signia™ linear adapter is used with the Signia™ stapler. Refer to the Signia™ stapling system's user manual for compatible single use stapling reloads, loading units and cartridges including curved-tip reloads, radial reloads and reinforced reloads. The Signia™ linear adapter is also compatible with the Signia™ manual retraction tool. When using compatible stapling reloads or the Signia™ manual retraction tool, refer to individual Instructions for Use for indications, instructions, contraindications, warnings and precautions.

INDICATIONS FOR USE
The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use staple reloads, reinforced reloads, loading units and cartridges has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of pancreas.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible curved tip single use reloads can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use radial reloads has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

CONTRAINDICATIONS
Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for specific indications, contraindications, warnings, and precautions.

1 SCHEMATIC VIEW
A) PIN

B) LOADING ALIGNMENT ARROW (for Covidien™ compatible stapling reloads)

C) SHAFT

D) SINGLE-USE RELOAD UNLOAD BUTTON

E) LOADING HUB

F) CENTER TRI-LOBE STAPLING DIRECTIONAL CONTROL

G) RIGHT TRI-LOBE ROTATIONAL CONTROL

INSTRUCTIONS FOR USE
Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for detailed information on power handle insertion techniques and set up instructions. These instructions are not intended as a reference to surgical techniques.

WARNINGS AND PRECAUTIONS
1. The stapler and adapters are to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use of surgical devices. Covidien™ stapling reloads are intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

2. Refer to the Instructions for Use provided with the Signia™ stapling system's user manual for specific indications, contraindications, warnings, and precautions.

3. Select the Covidien™ stapling reload with an indicated tissue range that is appropriate for the target tissue. Overly thick or thin tissue may result in unacceptable staple formation.

4. The adapter is a precise instrument. Care should be taken to avoid dropping. Improper handling, cleaning, or sterilization may shorten device service life and/or lead to device failure.

5. The adapter is provided non-sterile. Clean and sterilize before each use.

6. Do not flash sterilize (immediate-use sterilize) the adapter.

7. Use only the sterilization method that is recommended and qualified for the adapter, as described in this document. Do not use hydrogen peroxide gas plasma technology (such as STERRAD™* systems) or gamma sterilization to sterilize the adapter.

8. Clean the adapter immediately after use to prevent blood and other biological materials from drying on the surface of the device. Do not use abrasive agents.

9. Do not hold or carry the stapler by the distal end of the adapter, or by the stapling reload when an adapter is attached to the stapler.

10. Do not attempt to load a stapling reload before the adapter has been attached to the stapler and calibration has been completed. Doing so may lead to improper calibration and/or device damage.

11. Do not attach an adapter to the power shell prior to inserting a power handle into the power shell.

12. Do not load a reload onto the adapter prior to attaching onto a power handle. The stapler will not allow the stapling reload to fire until the reload is removed and the adapter completes its calibration.

13. Do not use the adapter if the packaging or the device appears damaged.

14. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performance of any endoscopic procedures, consult the medical literature relative to techniques, complications, and hazards.

15. Depending upon the potential failure mode for the stapler, an alternate opening procedure described in the Signia™ stapling system's user manual may or may not be successful in retracting the knife and opening the stapling reload. Professional experience should be used to assess patient status when deciding the best course of action.

SET UP AND DISSASSEMBLY
Refer to the Instructions for Use in the Signia™ stapling system's user manual for complete set up, operation, and disassembly instructions.

NOTE: If a stapling reload is attached to the adapter before the adapter is attached to the stapler, the adapter will not calibrate for use.

SET UP
1. Align the proximal end of the adapter with the quick release button facing up and in the same orientation as the assembled stapling handle.

2. SIMULTANEOUSLY, PRESS THE TWO COMPONENTS TOGETHER UNTIL THE ADAPTER IS FULLY SEATED INTO THE STAPLING HANDLE AND TACTILE FEEDBACK IS REGISTERED.

LOADING A STAPLING RELOAD

IMPORTANT: When using compatible stapling reloads, refer to the indications, contraindications, warnings, and precautions described in the associated Instructions for Use.

1. Insert the pin located at the distal end of the adapter into the stapling reload. Ensure the LOAD alignment indicator on the reload aligns with the LOAD alignment indicator on the shaft.

2. Lock the reload in place by pushing it in and twisting clockwise 45° (relative to the adapter).

NOTE: When the reload is loaded properly into the adapter, the reload unload button is seated in place without any red showing underneath.

UNLOADING A STAPLING RELOAD
1. Once rotation and articulation is centered and the jaws are open, pull the blue UNLOAD button back to release the stapling reload, twist the reload counterclockwise 45°, and pull the reload from the shaft of the adapter to remove it.

2. Dispose of the single use reload per local procedures and regulations for biohazard waste materials. Do not attempt to reuse or resterilize single use reloads.

CLEANING, DISINFECTION, AND STERILIZATION

NOTE: The adapter is made from metals and plastic.

WARNING AND PRECAUTIONS
1. The adapter is supplied non-sterile. It must be cleaned and sterilized prior to use.

2. Clean the adapter immediately after use to prevent blood and other biological materials from drying on the surface of the device. Do not use abrasive agents.

3. Remove and dispose of the stapling reload (if attached) from the adapter prior to cleaning and sterilizing as described in the Disassembly: Unloading a Stapling Cartridge section of the Instructions for Use provided with the Signia™ stapling system's user manual.

During Use
Remove excess soil on reusable instruments with disposable wipes.

After Use
The adapter should be cleaned thoroughly after every use to remove all traces of blood and debris. Reprocess as soon as possible following use. If reprocessing cannot be performed immediately, cover the adapter with a moist towel.

NOTE: The adapter is a reusable instrument and will deactivate after reaching the end of its service life. The number of uses remaining is indicated on the power handle display. These indications are described in the Signia™ stapling system's user manual.

MANUAL CLEANING
1. Remove the adapter from the assembled stapler according to the Instructions for Use provided with the Signia™ stapling system's user manual.

2. Wipe down the adapter with a separate lint-free cloth soaked in a 32-40 °C pH-neutral detergent solution diluted per the manufacturer's specifications.

3. Under 32-40 °C running water, scrub all reachable exterior surfaces with a general instrument soft nylon bristle brush for 1-2 minutes to remove surgical debris. Hold the distal end of the adapter under running water and flush for 1-2 minutes. Do not insert the brush into the distal end shaft. While brushing, pay particular attention to the grooves on the pin (A). Also pay particular attention to the grooves and sides of the reload unload button (D).

4a. For enzymatic detergents (Validated with Steris Prolystica™* 2X Concentrate): Hold the adapter at a slight angle to allow the detergent solution to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter in a 32-40 °C enzymatic bath diluted as specified by the manufacturer's Instructions for Use and soak for 10-20 minutes.

4b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less than 10.8) (Validated with neodisher MediClean forte™*): Hold the adapter at a slight angle to allow the detergent solution to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter in a 32-40 °C alkaline bath diluted as specified by the manufacturer's Instructions for Use and soak for 10-20 minutes.

5. Manually agitate the adapter in the bath for 1-2 minutes.

6. Invert the adapter until all fluid has completely drained.

7. In a clean 32-40 °C water bath, hold the adapter at a slight angle to allow the water to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter and soak for 2-3 minutes.

8. Manually agitate the adapter in the bath for 1-2 minutes.

9. Invert the adapter until all fluid has completely drained.

10. Repeat step 3.

11. Rinse under 32-40 °C running tap water for 1-2 minutes.

12. Perform a final rinse under purified water for 1-2 minutes.

13. Dry with a clean, soft, lint-free cloth.

14. Inspect the adapter. If not visibly clean, repeat the above steps.

PRECAUTION: Do not use instrument lubricant on the power handle or the adapter.

AUTOMATIC CLEANING

NOTE: The Signia™ adapter should be placed in such a manner to avoid contact with other devices to prevent damage from occuring in result of movement during the wash cycle. It is recommended that the adapter be placed with reload unload button (D) facing downward to assist drainage.

1. Remove the adapter from the stapler according to the Instructions for Use provided with the Signia™ stapling system's user manual.

2. Wipe down the adapter with a lint-free cloth soaked in 32-40 °C pH-neutral detergent solution diluted per manufacturer's instructions.

3. Under 32-40 °C running water, scrub all reachable surfaces with a general instrument soft nylon bristle brush for 1-2 minutes to remove surgical debris.

Hold the distal end of the adapter under running water and flush for 1-2 minutes. Do not insert the brush into the distal end shaft. While brushing, pay particular attention to the grooves on the pin (A). Also pay particular attention to the grooves and sides of the reload unload button (D).

4. Rinse under 32-40 °C running tap water for 1-2 minutes.

5. Perform the automatic cleaning cycle, following the parameters in the table below:

NOTE: Place the adapter into the washer-disinfector in a manner that will protect it from unwanted motion or potential mechanical damage during the automated wash cycle.

Treatment	Time (MM:SS)	Temperature	Chemicals
Pre-Wash	00:45	Cold Tap Water	N/A
Enzyme Wash	04:00	Hot Tap Water	Enzymatic[1] or Alkaline[2] Detergent Diluted per the manufacturer's specifications
Rinse	0:15	Hot Tap Water	N/A
Wash	03:00	Hot Tap Water	Enzymatic[1] or Alkaline[2] Detergent Diluted per the manufacturer's specifications
Rinse	00:15	Hot Tap Water	N/A
Thermal Rinse	05:00	Hot Purified Water heated to 203 °F (95 °C)	N/A
Dry	06:00	High Setting 203 °F (95 °C)	N/A
1. Validated with Steris Prolystica™* 2x concentrate 2. Validated with neodisher MediClean forte™*			

6. Dry with a clean, soft, lint-free cloth.

7. Inspect the adapter. If not visibly clean, repeat the above steps.

NOTE: The adapter has been tested for material compatibility with cleaners that have pH ranges from neutral to 10.8. Refer to the cleaner's manufacturer for information on the microbiological effectiveness of the cleaner.

DISINFECTION
See the instructions in the automatic cleaning section.

STERILIZATION
The following process parameter information are the sterilization methods recommended and qualified for the Signia™ adapter to achieve a minimum sterility assurance level of 10^{-6}.

STEAM STERILIZATION
The adapters are provided non-sterile. They may be sterilized by steam autoclave by placing the instruments in a standard hospital wrap or other suitable container. Put the adapters and accessories into the inserts provided, on their side, in an approved sterilization tray. Follow the process parameters as described:

Steam Autoclave Sterilization:
132°C Pre-vacuum (Hi Vac) Steam Cycle
Exposure temperature: 270°F (132°C)
Exposure time: 4 minutes
Vacuum dry time: 20 - 40 minutes

134°C Pre-vacuum (Hi Vac) Steam Cycle
Exposure temperature: 273°F (134°C)
Exposure time: 3 minutes
Vacuum dry time: 20 - 40 minutes

Outside USA (OUS)				
	Minimum recommended			WHO[1] Cycle
Pre-vacuum Steam Cycle	Cycle	Cycle	Cycle	
Exposure temperature (°C)	132	134	134	134
Exposure time (minutes)	4	3	5	18
Vacuum dry time (minutes)	20-40	20-40	20-40	20-40
1. World Health Organization (WHO) steam sterilization cycle.				

NOTE: When sterilizing multiple instruments in one autoclave cycle, ensure the sterilizer manufacturer's stated maximum load is not exceeded.

WARNINGS AND PRECAUTIONS
1. For steam autoclave sterilization, the Signia™ adapter has been tested to a maximum exposure temperature of 137°C and a maximum exposure time of 18 minutes without degradation in functional performance and service life of the device.

Therefore, do not expose the device to temperatures in excess of 279°F (137°C), and/or exposure time in excess of 18 minutes as this may shorten device service life and/or lead to device failure.

2. Place the adapter on its side during sterilization.

3. Allow a 20 minute cool down period at room temperature post sterilization. Do not leave the instrument in the autoclave for cool down. Remove from the autoclave immediately after the sterilization cycle completes.

4. Do not use flash steam sterilization. Use of flash steam sterilization will damage the device, and may lead to malfunction.

EtO Sterilization
EtO sterilization can be followed in replace steam sterilization methods using one of the following methods:

Hot Cycle:
- Temperature Set Point: 130 °F (54 °C)
- Ethylene Oxide Gas Concentration: 600-650 mg/L
- Relative Humidity: 40-60%
- Exposure Time: 2 hours minimum
- Condition: Wrapped

Cold Cycle:
- Temperature Set Point: 100 °F (38 °C)
- Ethylene Oxide Gas Concentration: 650-700 mg/L
- Relative Humidity: 40-60%
- Exposure Time: 6 hours minimum
- Condition: Wrapped

MAINTENANCE
Inspect the adapter for damage or wear prior to use, including bent electronic connectors or distal tip components, buildup of debris in electronic contacts or cracking of the adapter housings.

STORAGE

Store at room temperatures (50 °F-104 °F or 10 °C- 40 °C) and relative humidity (30%-75%). Avoid prolonged exposure to elevated temperatures.

DISPOSAL

Discard or recycle as per local, state, and governmental regulations.

PRODUCT CLASSIFICATION PER IEC 60601-1

Type of protection against electric shock: Internally powered (battery)

Battery ratings: Lithium ion, 14.8 V, 2150 mAh

Degree of protection against electric shock: Type CF applied part

Not suitable for use in presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Mode of operation: Continuous mode

ELECTROMAGNETIC COMPATIBILITY GUIDANCE (EN/IEC 60601-1-2)

PRECAUTION: The adapters are considered medical electrical equipment. Medical electrical equipment requires special precaution regarding electromagnetic compatibility (EMC), and needs to be installed and put into service according to the EMC information provided in this document.

PRECAUTION: Portable and mobile RF communication equipment can affect medical electrical equipment.

WARNING: The use of accessories other than those specified and sold by Covidien may result in increased emissions or decreased immunity of the stapler and adapter.

WARNING: The adapter should not be used adjacent to other equipment. If adjacent use is necessary, the stapler and adapter should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The adapter is intended for use in the electromagnetic environment specified below. The customer or the user should ensure they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The adapter uses RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The adapter is a low-voltage battery-operated device and is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The adapter is intended for use in the electromagnetic environment specified below. The customer or the user should ensure they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	N/A	The power handle, adapter and power shell are low-voltage battery-operated devices and are suitable for use in all establishments.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	The power handle, adapter and power shell are low-voltage battery-operated devices and are suitable for use in all establishments.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_t (>95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for five cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for five seconds	N/A	The power handle, adapter and power shell are low-voltage battery-operated devices and are suitable for use in all establishments.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	The power handle, adapter and power shell are low-voltage battery-operated devices and are suitable for use in all establishments.

Note: U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The adapter is intended for use in the electromagnetic environment specified below. The customer or the user should ensure they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the power handle, adapter and power shell, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitting device. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1. At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones, and land mobile radios; amateur radio; AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the stapler and adapter are used exceeds the applicable RF compliance level above, the power handle, adapter and power shell should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the power handle, adapter and power shell.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Stapler and Power Adapter

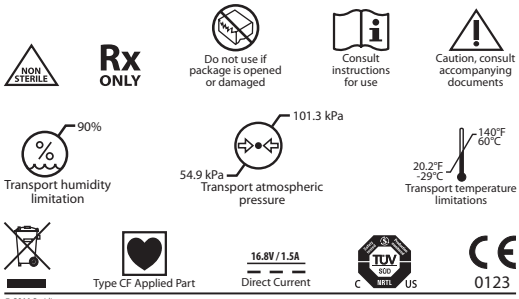
The adapter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the power handle, adapter and power shell as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com

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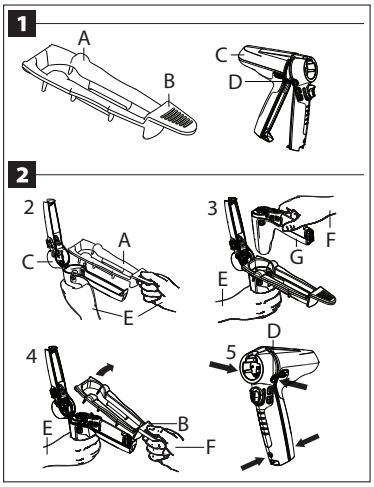
INSTRUCTIONS FOR USE

COVIDIEN™

Signia™

Reusable Insertion Guide

PT00048741



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

DESCRIPTION

The Signia™ reusable insertion guide is designed for use with the Signia™ stapler, which is composed of the Signia™ power handle, Signia™ power shell and Signia™ adapters. The reusable insertion guide is intended to be used to help maintain the sterility of the Signia™ power shell during insertion of the non-sterile Signia™ power handle. It is provided non-sterile and must be sterilized prior to each use.

For system configuration information and instructions for use, see the Signia™ stapling system's user manual. Refer to each system component's instructions for use for detailed product descriptions and associated indications, instructions, contraindications, warnings, and precautions.

The product is to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The Signia™ stapling system is intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

INDICATIONS FOR USE

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single-use staple reloads, reinforced reload, loading units and cartridges has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of pancreas.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible curved tip single use reloads-can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with-compatible single use radial reloads has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

1 SCHEMATIC VIEW

A) REUSABLE INSERTION GUIDE

B) EXTENDED HANDLE

C) POWER SHELL

D) TOP SECURE CLIPS

INSTRUCTIONS FOR USE

Refer to the instructions for use provided with the Signia™ stapling system's user manual, power handle or power shell for detailed information on power handle insertion techniques and set-up instructions. These instructions are not intended as a reference to surgical techniques.

2 INSERTING THE POWER HANDLE

PRECAUTION: Maintain aseptic transfer principles when inserting the power handle into a sterile power shell with a sterilized reusable insertion guide. Use caution not to contaminate the sterile shell during power handle insertion.

PRECAUTION: Ensure the power handle is sufficiently charged before use. See the instructions for use provided with the power charger.

PRECAUTION: The reusable insertion guide is provided non-sterile. It must be cleaned and sterilized prior to each use.

1. SCRUBBED PERSON: After aseptically removing the sterile power shell from the packaging, carefully open the power shell by holding the back handle of the power shell so the front handle is facing up and away from the back handle.

2. SCRUBBED PERSON: Align and fully seat a clean, sterilized reusable insertion guide onto the back handle of the open power shell to provide an aseptic transfer guide when inserting the disinfected power handle into the power shell.

A) INSERTION GUIDE

C) POWER SHELL

E) SCRUBBED PERSON

PRECAUTION: Ensure the reusable insertion guide is properly seated onto the power shell before inserting a power handle device.

3. CIRCULATING PERSON: Maintaining aseptic transfer techniques insert the power handle into the reusable insertion guide and power shell handle.

E) SCRUBBED PERSON

F) CIRCULATING PERSON

G) POWER HANDLE

4. CIRCULATING PERSON: After the power handle is fully seated in the power shell, carefully remove the reusable insertion guide using the extended handle.

B) EXTENDED HANDLE

E) SCRUBBED PERSON

F) CIRCULATING PERSON

5. SCRUBBED PERSON: Taking care not to touch the power handle, close the front portion of the power shell until there is confirmation the base of the power shell is closed and the top secure clips are secured. This confirms the power shell is fully closed and securely locked.

D) TOP SECURE CLIPS

CLEANING, DISINFECTION, AND STERILIZATION

NOTE: The reusable insertion guide is made from plastic.

Warnings

Detergents and solutions should have a pH between neutral and 10.8.

Sterilization temperature should not exceed 279 °F (137 °C).

The reusable insertion guide is supplied non-sterile. Prior to use it must be cleaned and sterilized.

Before Use

Clean and sterilize the reusable insertion guide prior to each use following the instructions provided.

During Use

Remove excess soil on reusable instruments with disposable wipes.

After Use

The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and debris. Reprocess as soon as possible following use. If reprocessing cannot be performed immediately, cover the device with a moist towel.

MANUAL CLEANING

1. Wipe down the device with a lint-free cloth soaked in 32-40 °C pH-neutral detergent solution diluted per manufacturer's instructions.

2. Under 32-40 °C running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the grooves on the extended handle and indentations on the underside of the tool.

3a. For enzymatic detergents (validated with Steris Prolystica™* 2x Concentrate): immerse the device in a 32-40 °C enzymatic bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

3b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less than 10.8) (validated with neodisher MediClean forte™*): immerse the device in 32-40°C alkaline bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

4. Manually agitate the device in the bath for at least 1 minute.

5. Repeat step 2.

6. Rinse under warm running tap water (32-40 °C) for at least one minute.

7. Perform a final rinse under purified water for a minimum of one minute.

8. Dry with a clean, soft, lint-free cloth

9. Inspect the device. If not visibly clean, repeat the above steps.

AUTOMATIC CLEANING

NOTE: The Signia™ reusable insertion guide should be placed in the washer-disinfector with the logo facing up to avoid water collecting in the crevices on the underside of the tool.

NOTE: The Signia™ reusable insertion guide should be placed in the washer-disinfector in such a manner to avoid contact with other devices (damage may occur as a result of movement during the wash cycle).

1. Wipe down the reusable insertion guide with a lint-free cloth soaked in 32-40 °C pH-neutral detergent solution diluted per manufacturer's instructions.

2. Under 32-40 °C running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the grooves on the extended handle and indentations on the underside of the tool.

3. Rinse under running tap water (32-40 °C) for at least 1 minute.

4. Perform the automatic cleaning cycle, following the parameters in the table below:

Treatment	Time (MM:SS)	Temperature	Chemical
Pre-wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent diluted per the manufacturer's specifications
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent diluted per the manufacturer's specifications
Rinse	00:15	Hot tap water	N/A
Thermal rinse	05:00	Hot purified water heated to 203 °F (95 °C)	N/A
Dry	06:00	High Setting 203 °F (95 °C)	N/A

1. Validated with Steris Prolystica™* 2x concentrate
2. Validated with neodisher MediClean forte™*

5. Dry with a clean, soft, lint-free cloth.

6. Inspect the device. If not visibly clean, repeat the above steps.

NOTE: The reusable insertion guide has been tested for material compatibility with cleaners that have pH ranges from neutral to 10.8. Refer to the cleaner's manufacturer for information on the microbiological effectiveness of the cleaner.

DISINFECTION

See the automatic cleaning section.

STERILIZATION

The following process parameter information are the sterilization methods recommended and qualified for the Reusable Insertion Guide to achieve a minimum sterility assurance level of 10^{-6}.

STEAM STERILIZATION

The Reusable Insertion Guide is provided non-sterile. It may be sterilized by steam autoclave by placing it in a polyethylene breathable pouch, standard hospital wrap, or other suitable container. Put the reusable insertion guide into the inserts provided, on its side, in an approved sterilization tray. Follow the process parameters as described:

Steam Autoclave Sterilization:

132°C Pre-vacuum (Hi Vac) Steam Cycle

Exposure temperature: 270°F (132°C)

Exposure time: 4 minutes

Vacuum dry time: 20 - 40 minutes

134°C Pre-vacuum (Hi Vac) Steam Cycle

Exposure temperature: 273°F (134°C)

Exposure time: 3 minutes

Vacuum dry time: 20 - 40 minutes

Outside USA (OUS)				
	Minimum recommended			WHO[1] Cycle
Pre-vacuum Steam Cycle	Cycle	Cycle	Cycle	
Exposure temperature (°C)	132	134	134	134
Exposure time (minutes)	4	3	5	18
Vacuum dry time (minutes)	20-40	20-40	20-40	20-40
1. World Health Organization (WHO) steam sterilization cycle.				

NOTE: When sterilizing multiple instruments in one autoclave cycle, ensure the sterilizer manufacturer's stated maximum load is not exceeded.

WARNINGS AND PRECAUTIONS

1. For steam autoclave sterilization, the Reusable Insertion Guide has been tested to a maximum exposure temperature of 137°C and a maximum exposure time of 18 minutes without degradation in functional performance and service life of the device.

Therefore, do not expose the device to temperatures in excess of 279°F (137°C), and/or exposure time in excess of 18 minutes as this may shorten device service life and/or lead to device failure.

2. Allow a 20 minute cool down period at room temperature post sterilization. Do not leave the instrument in the autoclave for cool down. Remove from the autoclave immediately after the sterilization cycle completes.

3. Do not use flash steam sterilization. Use of flash steam sterilization will damage the device, and may lead to malfunction.

EtO Sterilization

The following sterilization instructions apply to the use of EtO sterilization:

	Hot Cycle	Cold Cycle
Temperature Set Point	130 °F (54 °C)	100 °F (38 °C)
Ethylene Oxide Gas Concentration	600-650 mg/L	650-700 mg/L
Relative Humidity	40-60%	40-60%
Exposure Time	2 hours minimum	6 hours minimum
Condition	Wrapped	Wrapped

MAINTENANCE

Inspect the reusable insertion guide for damage or wear prior to use. If the device is warped or broken in any way, replace with a new reusable insertion guide.

STORAGE

Store at room temperature. Avoid prolonged exposure to elevated temperatures.

DISPOSAL

Discard or recycle as per local, state, and governmental regulations.

NON STERILE

Rx ONLY

Do not use if package is opened or damaged

Consult instructions for use

Caution, consult accompanying documents

CE

Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com

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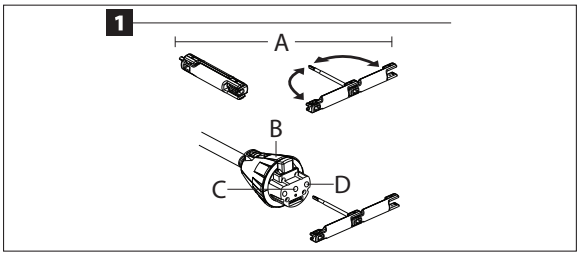
INSTRUCTIONS FOR USE

COVIDIEN™

Signia™

Manual Retraction Tool

PT00048743



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

DESCRIPTION

The Signia™ manual retraction tool is a reusable instrument accessory for the Signia™ stapler, which is composed of the Signia™ power handle, Signia™ power shell and Signia™ adapters. The Signia™ manual retraction tool is designed for use with Signia™ adapters to provide manual operational control of the stapling reload and articulation controls in the event of a malfunction during operation. It is intended to be used only to complete a firing that has been initiated, to retract the knife, and open the jaws and to de-articulate a stapling reload. It should not be used to initiate a new firing of the stapling reload. It is provided non-sterile and must be sterilized before use.

For system configuration information and Instructions for Use, see the Signia™ stapling system's user manual. Refer to each system component's Instructions for Use for detailed product descriptions and associated indications, instructions, contraindications, warnings, and precautions.

COMPATIBILITY

The manual retraction tool issued with the Signia™ adapter which is part of the Signia™ Stapler. Refer to the Signia™ stapling system's user manual for compatible single-use stapling reloads, loading units and cartridges including curved-tip reloads, radial reloads and reinforced reloads.

INDICATIONS FOR USE

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single-use staple reloads, reinforced reloads, loading units and cartridges has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and billiary structures and for transection and resection of pancreas.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible curved tip single use reloads can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ stapler composed of the Signia™ reusable power handle, Signia™ single use power shell and Signia™ reusable linear adapter, when used with compatible single use radial reloads has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

CONTRAINDICATIONS

1. The manual retraction tool is contraindicated for initiating a new firing with a stapling reload.

2. Refer to the Instructions for Use provided with the selected stapling reloads for specific indications, contraindications, warnings, and precautions.

3. Refer to the Instructions for Use provided in the user's manuals for the stapling system for specific indications, contraindications, warnings, and precautions.

1 SCHEMATIC VIEW

A) MANUAL RETRACTION TOOL

B) PROXIMAL END OF ADAPTER

C) CENTER TRI-LOBE STAPLING DIRECTIONAL CONTROL

D) RIGHT TRI-LOBE ROTATIONAL CONTROL

INSTRUCTIONS FOR USE

These instructions are not intended as a reference to surgical techniques.

WARNINGS AND PRECAUTIONS

1. The Signia™ stapler and manual retraction tool is to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use of surgical devices. Covidien™ single-use reloads are intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

2. The manual retraction tool can only be used as a back-up means for operating the adapter controls. Should a malfunction occur in either the stapling reload or the adapter, the stapling reload may not respond to inputs from the tool.

3. Inspect the manual retraction tool before use to ensure functionality.

4. Retracting the knife and opening a fully fired stapling reload using the manual retraction tool may take up to 8 minutes. The user should consider this when deciding on the best course of action in the event of a failure of the stapler.

5. The manual retraction tool is provided non-sterile. Clean and sterilize before each use.

6. Use only the sterilization method that is recommended and qualified for the manual retraction tool as described in this document. Do not use hydrogen peroxide gas plasma technology (such as Sterrad™* systems) or gamma sterilization to sterilize the tool.

7. After firing and removal of the instrument, always inspect the staple line and the surrounding site for hemostasis and/or leakage. Minor bleeding or leakage may be controlled by electrocautery or sutures.

8. When dividing major vascular structures, be sure to adhere to the basic surgical principles of proximal and distal control.

9. Failure to completely fire the stapling reload will result in an incomplete cut and/or incomplete staple formation, which may result in poor hemostasis and/or leakage.

TROUBLESHOOTING

Prior to using the manual retraction tool, review these troubleshooting scenarios related to firing of the reload.

The stapler is designed to stop firing a stapling reload if any of the following events occur:

- The DOWN / FIRE button is released and the UP / OPEN button is pressed during the firing process.
- The stapler senses a firing load that is in excess of the mechanical design limit of the stapling reload.
- The stapling reload completes firing.

If the stapler stops while firing a stapling reload, the following should be assessed:

1. Release the DOWN / FIRE button, and any other button or toggle that may be pressed.

2. Inspect the stapling reload for an obstruction, excessively thick tissue, or for completion of firing.

3. If continued firing is desired, attempt to complete the firing by pressing and holding the DOWN / FIRE button until firing is finished.

If the stapler is unable to complete the firing of the stapling reload:

1. Press the UP / OPEN button. The device will retract the knife to the fully clamped position, but the jaws will remain clamped on the tissue. Press up and hold the UP / OPEN button to open the jaws of the instrument.

PRECAUTION: When dividing major vascular structures, adhere to the basic surgical principles of proximal and distal control.

2. If successful in removing the stapling reload from the tissue, refer to the user manual for the Signia™ stapling system to remove the stapling reload. If unsuccessful, refer to the Removing the Stapling Reload section below.

REMOVING THE STAPLING RELOAD

If the stapler fails to remove the reload from the tissue, the following procedures may be used to attempt to retract the knife and open the jaws of the stapling reload.

WARNING: Depending upon the failure, the procedures described below may or may not be successful in retracting the knife and opening the stapling reload. Professional experience should be used to assess patient status when deciding the best course of action.

NOTE: The alternative opening procedures can be performed utilizing the existing power stapler in use or with a new power stapler if a replacement power handle and sterile control shell are available. Insert a charged power handle into a sterile control shell, following the Power Handle Insertion Steps section of the Signia™ stapling system's user manual.

POWERED OPENING APPROACH

PRECAUTION: Care should be taken to support the adapter and clamped reload during disassembly to prevent distal tip movement and/or tissue damage.

1. Stabilize the adapter and remove the stapling handle by pressing the QUICK RELEASE button on the top of the adapter while simultaneously pulling the stapling handle off of it.

2. Reattach the existing stapling handle or a new stapling handle onto the adapter and connected reload. Upon connection to the adapter, the device will run through a calibration process and recognize if a reload is attached. It will then attempt to reverse the knife blade, forcing the knife to retract and open the stapling reload.

3. Once the stapling reload is disengaged from tissue, remove the power handle from the patient and inspect the staple line and surrounding tissue for hemostasis and/or leakage.

POWER HANDLE REBOOT APPROACH

PRECAUTION: Rebooting the power handle during a firing or incomplete firing will stop the firing process.

1. To force a reboot, simultaneously press and hold both SAFETY buttons for up to 10 seconds. Release the buttons and the device will reboot.

NOTE: Upon reboot, the device will run through a calibration process and recognize if a reload is attached. It will then attempt to reverse the knife blade, forcing the knife to retract and open the stapling reload.

2. Once the stapling reload is disengaged from tissue, remove the stapler from the patient and inspect the staple line and surrounding tissue for hemostasis and/or leakage.

MANUAL OPENING PROCEDURE

Use the following manual retraction tool procedure if another power stapler is not available to perform the above powered opening approaches.

WARNING: The manual retraction tool is intended to be used as a back-up device for the Signia™ stapler should the stapler experience a failure during operation. It can be used to complete a firing that has already been initiated, or to retract the knife and open the jaws to remove a reload from tissue. It should NOT be used to initiate a new firing of a stapling reload.

WARNING: The manual retraction tool is provided non-sterile. Clean and sterilize before each use.

1. Remove the power stapling handle from the adapter by pressing the black QUICK RELEASE button on the adapter while pulling the handle off of it.

PRECAUTION: Care should be taken to support the adapter and clamped reload during disassembly to prevent distal tip movement and or tissue damage.

2. To control the firing, insert the manual retraction tool into the center hole marked with the number 1 on the proximal end of the adapter.

3. To continue firing the stapling reload, turn the manual adapter tool counterclockwise.

4. To retract the knife and open the jaws of the stapling reload, turn the manual adapter tool clockwise and in the direction of the arrow indicator.

PRECAUTION: Retracting the knife and opening a fully fired stapling reload using the manual retraction tool may take up to 8 minutes. The user should consider this when deciding on the best course of action in the event of a failure of the power stapling handle.

NOTE: If the reload is articulated, insert the manual retraction tool into the hole marked with the number 2 on the proximal end of the adapter. Center the reload, and remove the instrument from the patient. Refer to the instructions in the Disassembly section of the Signia™ stapling system's user manual.

NOTE: When the stapling reload is orientated so the lower clamp cover is up and the anvil is down, turning the manual adapter tool counterclockwise will articulate the reload to the right. Turning it clockwise will articulate the reload to the left.

WARNING: If a device malfunction occurs during a procedure or the manual retraction tool is used, do not attempt to reuse the power stapler, power handle, adapter, or the stapling reload. Contact Covidien for return instructions.

PRECAUTION: After firing and removing the Signia™ stapler from the patient, always inspect the staple line and the surrounding site for hemostasis and/or leakage. Minor bleeding or leakage may be controlled by using electrocautery or sutures.

CLEANING, DISINFECTION, AND STERILIZATION

NOTE: The manual retraction tool is made from metal and plastic.

Warnings

Detergents and solutions should have a pH between neutral and 10.8.

Sterilization temperature should not exceed 279 °F (137 °C).

The manual retraction tool is supplied non-sterile. Prior to use it must be cleaned and sterilized.

Before Use

Clean and sterilize the manual retraction tool prior to each use following the instructions provided.

After Use

The manual retraction tool should be cleaned thoroughly after every use to remove all traces of blood and debris. Reprocess as soon as possible following use. If reprocessing cannot be performed immediately, cover the instrument with a moist towel.

MANUAL CLEANING

NOTE: The Signia™ manual retraction tool should be cleaned in the open position; with external and internal handles in either an open V shape (45° angle relative to the shaft) or T shape (90° angle relative to the shaft).

1. Wipe down the device with a lint-free cloth soaked in 32-40 °C pH-neutral detergent solution diluted per manufacturer's instructions.

2. Under 32-40 °C running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the indentations on the interior of the handles.

3a. For enzymatic detergents (validated with Steris Prolystica™* 2x Concentrate): immerse the device in a 32-40 °C enzymatic bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

3b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less than 10.8) (validated with neodisher MediClean forte™*): immerse the device in a 32-40°C alkaline bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

4. Manually agitate the device in the bath for at least 1 minute.

5. Repeat step 2.

6. Rinse under warm running tap water (32-40 °C) for at least one minute.

7. Perform a final rinse under purified water for a minimum of one minute.

8. Dry with a clean, soft, lint-free cloth

9. Inspect the device. If not visibly clean, repeat the above steps.

AUTOMATIC CLEANING

NOTE: The Signia™ manual retraction tool should be cleaned in the open position; with external and internal handles in either an open V shape (45° angle relative to the shaft) or T shape (90° angle relative to the shaft).

NOTE: The Signia™ manual retraction tool should be placed in the washer-disinfector lying flat to assist drainage and in such a manner to avoid contact with other devices (damage may occur as a result of movement during wash cycle).

1. Wipe down the manual retraction tool with a lint-free cloth soaked in 32-40 °C pH-neutral detergent solution diluted per manufacturer's instructions.

2. Under 32-40 °C running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the indentations on the interior of the handles.

3. Rinse under running tap water (32-40 °C) for at least 1 minute.

4. Perform the automatic cleaning cycle, following the parameters in the table below:

Treatment	Time (MM:SS)	Temperature	Chemical
Pre-wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent diluted per the manufacturer's specifications
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent diluted per the manufacturer's specifications
Rinse	00:15	Hot tap water	N/A
Thermal rinse	05:00	Hot purified water heated to 203 °F (95 °C)	N/A
Dry	06:00	High Setting 203 °F (95 °C)	N/A
1. Validated with Steris Prolystica™* 2x concentrate 2. Validated with neodisher MediClean forte™*			

5. Dry with a clean, soft, lint-free cloth.

6. Inspect the device. If not visibly clean, repeat the above steps.

NOTE: The manual retraction tool has been tested for material compatibility with cleaners that have pH ranges from neutral to 10.8. Refer to the cleaner's manufacturer for information on the microbiological effectiveness of the cleaner.

DISINFECTION

See the instructions in the automatic cleaning section.

STERILIZATION

The following process parameter information are the sterilization methods recommended and qualified for the Manual Retraction Tool to achieve a minimum sterility assurance level of 10^{-6}.

STEAM STERILIZATION

The Manual Retraction Tool is provided non-sterile. It may be sterilized by steam autoclave by placing it in a polyethylene breathable pouch, standard hospital wrap, or other suitable container. Put the Tool into the inserts provided, on its side, in an approved sterilization tray. Follow the process parameters as described:

Steam Autoclave Sterilization:

132°C Pre-vacuum (Hi Vac) Steam Cycle

Exposure temperature: 270°F (132°C)

Exposure time: 4 minutes minimum

Vacuum dry time: 20 - 40 minutes

134°C Pre-vacuum (Hi Vac) Steam Cycle

Exposure temperature: 273°F (134°C)

Exposure time: 3 minutes minimum

Vacuum dry time: 20 - 40 minutes

Outside USA (OUS)				
	Minimum recommended			WHO[1] Cycle
Pre-vacuum Steam Cycle	Cycle	Cycle	Cycle	
Exposure temperature (°C)	132	134	134	134
Exposure time (minutes)	4	3	5	18
Vacuum dry time (minutes)	20-40	20-40	20-40	20-40
1. World Health Organization (WHO) steam sterilization cycle.				

NOTE: When sterilizing multiple instruments in one autoclave cycle, ensure the sterilizer manufacturer's stated maximum load is not exceeded.

WARNINGS AND PRECAUTIONS

1. For steam autoclave sterilization, the Manual Retraction Tool has been tested to a maximum exposure temperature of 137°C and a maximum exposure time of 18 minutes without degradation in functional performance and service life of the device.

Therefore, do not expose the device to temperatures in excess of 279°F (137°C), and/or exposure time in excess of 18 minutes as this may shorten device service life and/or lead to device failure.

2. Allow a 20 minute cool down period at room temperature post sterilization. Do not leave the instrument in the autoclave for cool down. Remove from the autoclave immediately after the sterilization cycle completes.

3. Do not use flash steam sterilization. Use of flash steam sterilization will damage the device, and may lead to malfunction.

EtO Sterilization

The following sterilization instructions apply to the use of EtO sterilization:

	Hot Cycle	Cold Cycle
Temperature Set Point	130 °F (54 °C)	100 °F (38 °C)
Ethylene Oxide Gas Concentration	600-650 mg/L	650-700 mg/L
Relative Humidity	40-60%	40-60%
Exposure Time	2 hours minimum	6 hours minimum
Condition	Wrapped	Wrapped

MAINTENANCE

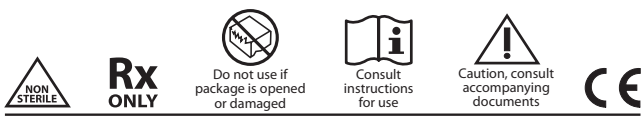
Inspect the manual retraction tool for damage or wear prior to use.

STORAGE

Store at room temperature. Avoid prolonged exposure to elevated temperatures.

DISPOSAL

Discard or recycle as per local, state, and governmental regulations.



Covidien IIc, 15 Hampshire Street, Mansfield, MA 02048 USA.

EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com

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CLEANING INSTRUCTIONS

During use:

Remove excess soil on the reusable instruments with disposable wipes.

After use:

Reprocess the instruments as soon as possible following use. If reprocessing cannot be performed immediately, cover the instruments with a moist towel.

PRECAUTION

Do not use instrument lubricant on the power handle or the adapter.

Power Shell

WARNING

The power shell is single-use only. DISCARD AFTER USE. DO NOT STERILIZE.
Re-sterilized or reprocessed sterile power shells will not function.

Power Handle

WARNING & PRECAUTION

The power handle is made from metal, electronics, and plastic.

NOTE

The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not deactivate during use. The number of uses remaining indication is provided on the power handle OLED display.

1. The power handle is provided non-sterile. Clean after each use. DO NOT STERILIZE.
2. Do not rinse under running water or submerge. Avoid moisture on the gold electrical contacts on the bottom and front face.
3. Do not use alcohol, quaternary ammonium, and bleach based wipes as they may cause physical deterioration of the handle housing such as discoloration, embrittlement, or cracking. Only use the cleaning methods described in this manual to maximize the physical characteristics of the handle housing.
4. Do not use instrument lubricant on the power handle.

To clean the power handle

- Wipe down all exposed surfaces with a slightly water dampened lint-free cloth to completely remove any gross debris from the device.
- If additional cleaning is required, use a hydrogen peroxide based wipe such as Oxivir™* Tb per the manufacturer's instructions.
- Ensure the power handle is completely dry prior to inserting it into a sterile power shell or charger.

WARNING

The power handle is non-sterile and cannot be sterilized. Do not immerse. The power handle will be damaged if sterilization is attempted.

Adapters

WARNING

The adapter is supplied non-sterile. It must be cleaned and sterilized prior to use.

Clean the adapter immediately after use to prevent blood and other biological materials from drying on the surface of the device. Do not use abrasive agents.

Remove and dispose of the single-use reload (if attached) from the adapter prior to cleaning and sterilizing.

After use

The adapter should be cleaned thoroughly after every use to remove all traces of blood and debris. Reprocess as soon as possible following use. If reprocessing cannot be performed immediately, cover the adapter with a moist towel.

NOTE

The adapter is a reusable instrument and will deactivate after reaching the end of its service life. The number of uses remaining is indicated on the power handle display. These indications are described in the Signia™ stapling system's user manual.

Manual cleaning

1. Remove the adapter from the stapler according to the instructions for use provided with the Signia™ stapling system's user manual.
2. Wipe down the adapter with a separate lint-free cloth soaked in a 90-104 F (32-40 C) pH-neutral detergent solution diluted per the manufacturer's specifications.
3. Under 90-104 F (32-40 C) running water, scrub all reachable exterior surfaces with a general instrument soft nylon bristle brush for 1-2 minutes to remove surgical debris. Hold the distal end of the adapter under running water and flush for 1-2 minutes. Do not insert the brush into the distal end shaft. While brushing, pay particular attention to the grooves on the pin. Also pay particular attention to the grooves and sides of the reload unload button.

4a. For enzymatic detergents (Validated with Steris Prolystica™* 2X Concentrate): Hold the adapter at a slight angle to allow the detergent solution to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter in a 90-104 F (32-40 C) enzymatic bath diluted as specified by the manufacturer's Instructions for Use and soak for 10-20 minutes.

4b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less than 10.8) (Validated with neodisher MediClean forte™*): Hold the adapter at a slight angle to allow the detergent solution to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter in a 90-104 F (32-40 C) alkaline bath diluted as specified by the manufacturer's Instructions for Use and soak for 10-20 minutes.

5. Manually agitate the adapter in the bath for 1-2 minutes.
6. Invert the adapter until all fluid has completely drained.
7. In a clean 90-104 F (32-40 C) water bath, hold the adapter at a slight angle to allow the water to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter and soak for 2-3 minutes.
8. Manually agitate the adapter in the bath for 1-2 minutes.
9. Invert the adapter until all fluid has completely drained.
10. Repeat step 3.
11. Rinse under 90-104 F (32-40 C) running tap water for 1-2 minutes.
12. Perform a final rinse under purified water for 1-2 minutes.
13. Dry with a clean, soft, lint-free cloth.
14. Inspect the adapter. If not visibly clean, repeat the above steps.

PRECAUTION

Do not use instrument lubricant on the power handle or the adapter.

Automatic cleaning

1. Remove the adapter from the stapler according to the instructions for use provided with the Signia™ stapling system's user manual.
2. Wipe down the adapter with a lint-free cloth soaked in 90-104 F (32-40 C) pH-neutral detergent solution diluted per manufacturer's instructions.
3. Under 90-104 F (32-40 C) running water, scrub all reachable surfaces with a general instrument soft nylon bristle brush for 1-2 minutes to remove surgical debris.

   Hold the distal end of the adapter under running water and flush for 1-2 minutes. Do not insert the brush into the distal end shaft. While brushing, pay particular attention to the grooves on the pin. Also pay particular attention to the grooves and sides of the reload unload button.
4. Rinse under 90-104 F (32-40 C) running tap water for 1-2 minutes.
5. Perform the automatic cleaning cycle, following the recommendations in the table on the next page.

NOTE

The Signia™ adapter should be placed in such a manner to avoid contact with other devices to prevent damage from occuring in result of movement during the wash cycle. It is recommended that the adapter be placed with reload unload button facing downward to assist drainage.

Treatment	Time (min:sec)	Temperature	Chemicals
Pre-Wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent[3]
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent[3]
Rinse	00:15	Hot tap water	N/A
Thermal Rinse	05:00	Hot purified water heated to 203 F (95 C)	N/A
Dry	06:00	High setting 203 F (95 C)	N/A

1. Validated with Steris Prolystica™* 2x concentrate
2. Validated with neodisher MediClean forte™*
3. Dilute detergents per the manufacturer's specifications

6. Dry with a clean, soft, lint-free cloth.
7. Inspect the adapter. If not visibly clean, repeat the above steps.

PRECAUTION

Do not use instrument lubricant on the power handle or the adapter.

NOTE

The adapter has been tested for material compatibility with cleaners that have pH ranges from neutral to 10.8. Refer to the cleaner's manufacturer for information on the microbiological effectiveness of the cleaner.

Reusable Insertion Guide

WARNING

Detergents and solutions should have a pH between neutral and 10.8.

The reusable insertion guide is supplied non-sterile. Prior to use it must be cleaned and sterilized.

After Use

The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and debris. Reprocess as soon as possible following use. If reprocessing cannot be performed immediately, cover the device with a moist towel.

Manual Cleaning

1. Wipe down the device with a lint-free cloth soaked in 90-104 F (32-40 C) pH-neutral detergent solution diluted per manufacturer's instructions.
2. Under 90-104 F (32-40 C) running water, scrub all reachable surfaces with an 11.9mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the grooves on the extended handle and indentations on the underside of the tool.

3a. For enzymatic detergents (validated with Steris Prolystica™* 2x Concentrate): immerse the device in a 90-104 F (32-40 C) enzymatic bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

3b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less tha n 10.8) (validated with neodisher MediClean forte™*): immerse the device in 90-104 F (32-40 C) alkaline bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

4. Manually agitate the device in the bath for at least 1 minute.
5. Repeat step 2.
6. Rinse under warm running tap water (90-104 F/32-40 C) for at least 1 minute.
7. Perform a final rinse under purified water for a minimum of 1 minute.
8. Dry with a clean, soft, lint-free cloth
9. Inspect the device. If not visibly clean, repeat the above steps.

Automatic Cleaning

NOTE

The Signia™ reusable insertion guide should be placed in the washer-disinfector with the logo facing up to avoid water collecting in the crevices on the underside of the tool.

The Signia™ reusable insertion guide should be placed in the washer-disinfector in such a manner to avoid contact with other devices (damage may occur as a result of movement during the wash cycle).

1. Wipe down the reusable insertion guide with a lint-free cloth soaked in 90-104 F (32-40 C) pH-neutral detergent solution diluted per manufacturer's instructions.
2. Under 90-104 F (32-40 C) running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the grooves on the extended handle and indentations on the underside of the tool.
3. Rinse under running tap water (90-104 F/32-40 C) for at least 1 minute.
4. Perform the automatic cleaning cycle, following the parameters in the table below:

Treatment	Time (min:sec)	Temperature	Chemicals
Pre-Wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent[3]
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent[3]
Rinse	00:15	Hot tap water	N/A
Thermal Rinse	05:00	Hot purified water heated to 203 F (95 C)	N/A
Dry	06:00	High setting 203 F (95 C)	N/A

1. Validated with Steris Prolystica™* 2x concentrate
2. Validated with neodisher MediClean forte™*
3. Dilute detergents per the manufacturer's specifications

5. Dry with a clean, soft, lint-free cloth.
6. Inspect the device. If not visibly clean, repeat the above steps.

NOTE

The reusable insertion guide has been tested for material compatibility with cleaners that have pH ranges from neutral to 10.8. Refer to the cleaner's manufacturer for information on the microbiological effectiveness of the cleaner.

Manual Retraction Tool

WARNING

Detergents and solutions should have a pH between neutral and 10.8.

The manual retraction tool is supplied non-sterile. Prior to use it must be cleaned and sterilized.

After Use

The manual retraction tool should be cleaned thoroughly after every use to remove all traces of blood and debris. Reprocess as soon as possible following use. If reprocessing cannot be performed immediately, cover the instrument with a moist towel.

Manual Cleaning

NOTE

The Signia™ manual retraction tool should be cleaned in the open position; with external and internal handles in either an open V shape (45 degree angle relative to the shaft) or T shape (90 degree angle relative to the shaft).

1. Wipe down the device with a lint-free cloth soaked in 90-104 F (32-40 C) pH-neutral detergent solution diluted per manufacturer's instructions.
2. Under 90-104 F (32-40 C) running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the indentations on the interior of the handles.

3a. For enzymatic detergents (validated with Steris Prolystica™* 2x Concentrate): immerse the device in a 90-104 F (32-40 C) enzymatic bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

3b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less than 10.8) (validated with neodisher MediClean forte™*): immerse the device in a 90-104 F (32-40 C) alkaline bath diluted as specified by the manufacturer's Instructions for Use and soak for 5-10 minutes.

4. Manually agitate the device in the bath for at least 1 minute.
5. Repeat step 2.
6. Rinse under warm running tap water (90-104 F/32-40 C) for at least 1 minute.
7. Perform a final rinse under purified water for a minimum of 1 minute.
8. Dry with a clean, soft, lint-free cloth
9. Inspect the device. If not visibly clean, repeat the above steps.

Automatic Cleaning

NOTE

The Signia™ manual retraction tool should be cleaned in the open position; with external and internal handles in either an open V shape (45 degree angle relative to the shaft) or T shape (90 degree angle relative to the shaft).

The Signia™ manual retraction tool should be placed in the washer-disinfector lying flat to assist drainage and in such a manner to avoid contact with other devices (damage may occur as a result of movement during wash cycle).

1. Wipe down the manual retraction tool with a lint-free cloth soaked in 90-104 F (32-40 C) pH-neutral detergent solution diluted per manufacturer's instructions.
2. Under 90-104 F (32-40 C) running water, scrub all reachable surfaces with an 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the indentations on the interior of the handles.
3. Rinse under running tap water (90-104 F/32-40 C) for at least 1 minute.
4. Perform the automatic cleaning cycle, following the parameters in the table below:

Treatment	Time (min:sec)	Temperature	Chemicals
Pre-Wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent[3]
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic[1] or Alkaline[2] Detergent[3]
Rinse	00:15	Hot tap water	N/A
Thermal Rinse	05:00	Hot purified water heated to 203 F (95 C)	N/A
Dry	06:00	High setting 203 F (95 C)	N/A

1. Validated with Steris Prolystica™* 2x concentrate
2. Validated with neodisher MediClean forte™*
3. Dilute detergents per the manufacturer's specifications

5. Dry with a clean, soft, lint-free cloth.
6. Inspect the device. If not visibly clean, repeat the above steps.

NOTE

The manual retraction tool has been tested for material compatibility with cleaners that have pH ranges from neutral to 10.8. Refer to the cleaner's manufacturer for information on the microbiological effectiveness of the cleaner.

Disinfection

See the automatic cleaning sections.

STERILIZATION INSTRUCTIONS

Sterilizing

The adapters, manual retraction tool, and the reusable insertion guide are provided non-sterile. They may be sterilized by steam autoclave.

WARNING

Do not use hydrogen peroxide gas plasma technology (such as STERRAD™* systems), ethylene oxide, or gamma sterilization. The adapters and accessories are approved for steam autoclave sterilization.

The following information is the sterilization method recommended and qualified for the linear adapter. Do not expose the device to temperatures in excess of 279 F (137 C), as this may shorten device service life and/or lead to device failure.

- Place the adapter on its side during sterilization.
- Allow a 20-minute cool down period at room temperature post sterilization. Do not leave the instrument in the autoclave for cool down; remove it immediately after the sterilization cycle is complete.
- Do not use flash steam sterilization. Use of flash steam sterilization will damage the device, and may lead to malfunction.

Steam Autoclave Sterilization

132 C pre-vacuum (Hi Vac) steam cycle

- Exposure temperature: 270 F (132 C)
- Exposure time: 4 minutes
- Vacuum dry time: 20-40 minutes

134 C pre-vacuum (Hi Vac) steam cycle

- Exposure temperature: 273 F (134 C)
- Exposure time: 3 minutes
- Vacuum dry time: 20-40 minutes

Outside USA (OUS)				
	Minimum recommended			WHO† Cycle
Pre-Vacuum Steam Cycle	Cycle	Cycle	Cycle	
Exposure Temperature (C)	132	134	134	134
Exposure Time (minutes)	4	3	5	18
Vacuum Dry Time (minutes)	20-40	20-40	20-40	20-40
†World Health Organization				

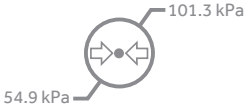
NOTE

When sterilizing multiple instruments in one autoclave cycle, ensure the sterilizer manufacturer's stated maximum load is not exceeded.

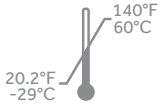
Storage

Store at room temperature.

Transport humidity limitation



Transport atmospheric pressure



Transport temperature limitations

Disposal

Discard or recycle as per local, state, and governmental regulations.

BATTERY LIFE & STORAGE INFORMATION.

Battery Life

Full battery life depends on factors such as tissue consistency and thickness, dwell time, and functionality used during a procedure. At a minimum, the Signia™ stapler is designed to allow for 17 firings, including 10 hours of dwell time. A lockout feature will activate if a minimum of two firings are not possible. And the user will be notified via audible indicator and a yellow signal on the OLED screen.[9]

Storage

Return the power handle to a battery charger bay for safe storage. Always store the device at room temperature (50-104 F or 10-40 C) and relative humidity between 30-75%. And avoid prolonged exposure to elevated temperatures.

PUT THE FUTURE OF STAPLING **IN YOUR HANDS TODAY.**

Ordering Information

ORDER CODE	DESCRIPTION
SIGPHANDLE	Signia™ Power Handle
SIGPSHELL	Signia™ Power Control Shell
SIGADAPTSTND	Signia™ Linear Adapter
SIGADAPTXL	Signia™ Linear Adapter XL
SIGADAPTSHORT (coming soon)	Signia™ Linear Adapter Short
SIGSBCHGR	Signia™ Single-Bay Charger
SIGRIG	Signia™ Reusable Insertion Guide
SIGMRET	Signia™ Manual Retraction Tool
SIGTRAY	Signia™ Sterilization Tray
SIGPCORD1	Signia™ Power Cord 1 – US
SIGPCORD6	Signia™ Power Cord 6 – JA

To try the Signia™ stapler in your next procedure, contact your local Medtronic sales representative or call 800-722-8772.

More information is on our website: medtronic.com/covidien

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4. Based on internal test report #RE00022065, UCONN Biodynamics final report on results focusing on biomechanical exposure related to laparoscopic stapler use, 2012.
5. Based on claim No. 1 of software requirements specification (SRS) and 510k testing.
6. Based on PT00002451 Signia™ Stapler User Manual, Page 13.
7. Based on internal test report #PCG-007. When compared to Echelon Flex™* green reloads as part of an analysis comparing different stapler designs and their performance and impact on tissues under compression using two-dimensional finite element analysis. Sept. 2, 2011.
8. Based on internal engineering report #2128-002-2, Final analysis of staple line vascularity using MicroCT. 2015.
9. Based on Software Requirements Specification #R0032596, March 9, 2015

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