THE FUTURE OF STAPLING IS IN YOUR HANDS. TODAY.

The world’s first smart stapler
Signia™ Stapler
Product Information Guide
# TABLE OF CONTENTS

**PRODUCT OVERVIEW** 03  
- Introduction  
- Technology Overview  
- Features & Benefits

**PRODUCT COMPARISON** 09

**MATERIALS MANAGEMENT** 10  
- 510(K) Clearance  
- Instructions For Use  
- Cleaning, Sterilization & Storage  
- Ordering Information
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.¹²³

The Signia™ stapler gives you:

- Fully powered articulation, rotation, clamping, and firing, which provides greater precision and maneuverability compared to manual staplers¹⁴
- Push-button powered firing that decreases the strain of operation when stapling, compared to firing manually¹
- 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.
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.\(^1\)
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. 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 tissue1,2,3
■ Sets firing speed based on clamp force measurement6
■ Continuously measures force during firing and slows firing speed based on those measurements6

Three force zones with one objective: consistent staple lines1,2,3

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

Malformed Staple % In Variable Tissue vs. Firing Speed1,2
Malformed Staple Percentages (per firing)

<table>
<thead>
<tr>
<th>Increasing Speed During Fire</th>
<th>Increasing Tissue Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>25%</td>
<td>8%</td>
</tr>
<tr>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>8%</td>
<td>4%</td>
</tr>
<tr>
<td>0%</td>
<td>4%</td>
</tr>
</tbody>
</table>

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

Three force zones with one objective: consistent staple lines1,2,3

<table>
<thead>
<tr>
<th>Zone 1:</th>
<th>Zone 2:</th>
<th>Zone 3:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicates the stapler will start firing at its regular speed to deliver optimal staple formation6</td>
<td>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 formation6</td>
<td>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 formation6</td>
</tr>
</tbody>
</table>

† 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

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
POWERED ROTATION, ARTICULATION, & FIRING. WITH ONE HAND.\textsuperscript{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\textsuperscript{1}
- Push-button powered firing reduces strain of operation compared to firing manually\textsuperscript{4}
- Enhanced ergonomics create a well-balanced feel in the hand during use\textsuperscript{1}
- Easy-to-reach controls accommodate a range of hand sizes\textsuperscript{1}
- Easy-to-understand display screen\textsuperscript{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\textsuperscript{7}
- Allows greater perfusion into the staple line\textsuperscript{8}
- Delivers outstanding performance in variable tissue thicknesses
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 motor mating 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.
# Competitive Comparison

<table>
<thead>
<tr>
<th>Feature</th>
<th>Signia™ Stapler</th>
<th>EES Echelon Flex™ Powered Stapler</th>
<th>EES Echelon Flex™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compatible with Signia™ loading units and Tri-Staple™ 2.0 cartridges and reloads</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Single, powered handle compatible with 30 mm, 45 mm, and 60 mm reloads</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Compatible with Endo GIA™ reloads with Tri-Staple™ technology</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Extra-thick reload with tissue indications up to 3 mm</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Integrated real-time feedback display</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Features Adaptive Firing™ technology</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Power source</td>
<td>Lithium ion, 14.8 V, 2150 mAh</td>
<td>4 single-use batteries per handle, single use, disposable</td>
<td>-</td>
</tr>
<tr>
<td>Reusability</td>
<td>Reusable, reposable system comprised of disposable and reusable components</td>
<td>Single use, disposable</td>
<td>Single use, disposable</td>
</tr>
<tr>
<td>Points of articulation with the 45-degree maximum range</td>
<td>Unlimited</td>
<td>3 on each side (left, right)</td>
<td>3 on each side (left, right)</td>
</tr>
<tr>
<td>Articulation</td>
<td>Powered</td>
<td>Manual; second instrument or lateral pressure against body structure</td>
<td>Manual; second instrument or lateral pressure against body structure</td>
</tr>
<tr>
<td>Rotation</td>
<td>Powered and manual</td>
<td>Manual only</td>
<td>Manual only</td>
</tr>
<tr>
<td>Clamping</td>
<td>Powered</td>
<td>Manual only</td>
<td>Manual only</td>
</tr>
<tr>
<td>Firing</td>
<td>Powered</td>
<td>Powered</td>
<td>Manual only</td>
</tr>
<tr>
<td>Jaw Opening</td>
<td>Powered</td>
<td>Manual only</td>
<td>Manual only</td>
</tr>
</tbody>
</table>
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

der 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

## Indications for Use

**Device Name:** Sigma™ Stapler

**Indications for Use (Summary):**

The Sigma™ 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 Sigma™ 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 anastomoses. 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 Sigma™ stapler, when used with Endo GIA™ curved tip single-use reloads or Tri-Staple™ 2.0 curved lip single-use reloads, can be used to blunt clamps or resect large tissues from other certain tissues.

The Sigma™ stapler, when used with Endo GIA™ single-use Radial Reload with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for transection of tissue and creation of anastomoses, as well as application deep in the pelvis, i.e., left 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 Sigma™ stapler, when used with Endo GIA™ single-use reinforced reloads with Tri-Staple™ Technology preloaded with polyglycolic acid staples line reinforcement or Tri-Staple™ 2.0 single-use reinforced reloads preloaded with polyglycolic acid staples line reinforcement, has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue and creation of anastomoses. 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):**

- [X] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

---

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

"DO NOT SEND YOUR COMPLETED FORM TO THE PMA STAFF EMAIL ADDRESS BELOW."

The burden hour for this collection of information is estimated to average 29 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. For comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, write to:

**Department of Health and Human Services**
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRA3388@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

---

**PMA Form 391 (871)**

**Page 1 of 1**

---

**Coviant:** Sigma™ Stapler

**Date:** January 22, 2016

**Page 66**
INSTRUCTIONS FOR USE

INSTRUCTIONS

1. The Signia™ power handle is a reusable, battery-powered stapling handle that is designed as part of the Signia™ system, 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 universal sealed rechargeable Li-ion battery in a universal packet. The product is intended for use in a sterile operating room or scenario for surgical procedures where staple placement is indicated.

PRECAUTIONS AND WARNINGS

1. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

2. The Signia™ power handle is a reusable, battery-powered stapling handle that is designed as part of the Signia™ system, 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 universal packet. The product is intended for use in a sterile operating room or scenario for surgical procedures where staple placement is indicated.

3. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

4. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

5. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

6. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

7. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

8. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

9. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

10. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

11. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

12. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

13. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

CLEANING THE POWER HANDLE

1. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

2. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

3. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

4. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

5. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

6. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

7. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

8. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

9. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

10. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

11. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

12. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.

13. The power handle is a reusable device and will deactivate after reaching the end of its service life. The device will not activate when the power handle is inserted into a sterile power shell during storage or transportation. 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 bay until tactile confirmation is established. The device will then be activated and ready for use. NOTE: The power handle unit is shipped in the OFF mode.
INSTRUCTIONS FOR USE

Covidien
Signia™ Power Shell

PDD0032748

Page 1 of 2

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

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

The device was designed, tested and manufactured for single patient use only. Failure to reprocess this device may lead to failure and subsequent patient injury. Reprocessing and/or recondition of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or recondition 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 shell, Signia™ power shell and Signia™ adapter. The sterile power shell covers the non-sterile Signia™ power handle to create an aseptic control insertion and universal adapter connector. It also provides a communications interface for single-use reunits, loading units and cartridges.

For operation of power shell, refer to the Signia™ stapler system’s user manual. Refer to each component’s instructions for use for detailed product descriptions and associated indications, contraindications, warnings and precautions.

The products are to be used by medical professionals qualified in the treatment, preparation, and use of surgical devices. The Signia™ stapler 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™ adapter, becomes the Signia™ system. Refer to the Signia™ stapling systems user manual for compatible single-use clamping tools, loading units and cartridges including curved-tip reunits, radial reunits and reconditioned reunits.

INDICATIONS FOR USE
The Signia™ stapler is a component of the Signia™ system. It is composed of the Signia™ power shell, Signia™ single use power shell and Signia™ reusable linear adapters. It may be used with compatible single-use reunits, reconditioned reunits, loading units and cartridges. This system has applications in abdominal, gynecologic, pediatric, and thoracic surgery for resection, transection, and resection of anatomies. It may be used to treat lesions and resections of the liver, kidneys, spine, and bile structures and for transection and resection of pancreas.

The Signia™ stapler component of the Signia™ reusable power shell, Signia™ single use power shell and Signia™ reusable linear adapters, when used with compatible curved-tip single use reunits, can be used to treat lesions or resect target tissue from other tissue.

CONTRAINDICATIONS

1. The 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 systems 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 range when opening the power shell.

4. Do not overtighten side clips. Replace clips or reunits before closing or if they are damaged.

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

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

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

8. Do not install or carry the stapler by the distal end of the adapter or by the stapler 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 operator, as well as damage to the instrument.

1. SCHEMATIC VIEW
A) POWER SHELL
B) TRIP SECURE CLIPS

2. INFORMATIONS INSTRUCTIONS FOR USE
Refer to the instructions for use provided with the Signia™ stapling system’s user manual for detailed information on power shell insertion techniques and set-up instructions. These instructions are not intended as a reference to surgical techniques.

3. 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, the caveat when inserting the power shell 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 use. Refer to the instructions for use provided with the reusable insertion guide for cleaning and sterilization instructions.

1. SCRUBBED PERSON
After aspiratically removing the sterile power shell from the packaging, carefully open the power shell by holding the back handle of the power shell in the forward handle is being up and away from the back handle.

2. SCRUBBED PERSON
Align and fully seat the rear, 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
B) REUSABLE INSERTION GUIDE
C) SCRUBBED PERSON

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

1. CIRCUATING PERSON
Maintaining aseptic transfer techniques, insert the power handle into the reusable insertion guide and secure shell.

2. SCRUBBED PERSON

3. SCRUBBED PERSON

PRECAUTION: Ensure the power handle is securely closed after insertion of the power shell.

1. SCRUBBED PERSON

2. SCRUBBED PERSON

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

DISASSEMBLING THE POWER HANDLE

1. Release the top securing clips, grasp the secure lock and carefully open the power shell to expose the power handle.

2. Remove the power handle with a clean glove.

3. Close the used power shell.

STORAGE
Store ambient temperatures (20°F – 77°F or 10°C – 4°C) and relative humidity (30% - 70%). Avoid prolonged exposure to elevated temperatures.

DISPOSAL
Discard as waste 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 (EN60601-1-2)
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 notify normal operation.
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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic Environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic discharge (ESD) IEC 61000-4-2</td>
<td>≤±4 kV contact ≤±4 kV air</td>
<td>≤±4 kV contact ≤±4 kV air</td>
<td>Power shell should be stored, transported, and used in a manner that prevents contact with static sources and that ensures the static shield is electrically connected to the power shell.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>≤±6 kV differential mode ≤±6 kV common mode</td>
<td>N/A</td>
<td>The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions, and voltage surges on power supply input lines IEC 61000-4-11</td>
<td>≤45% (&lt;90% dip/pulse) ≤48% cycle ≤60% dip/pulse ≤75% ≤25 cycles ≤30% dip/pulse ≤75% ≤5 cycles ≤90% dip/pulse ≤75% ≤0.2 seconds</td>
<td>N/A</td>
<td>The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.</td>
</tr>
<tr>
<td>Power frequency (EMI) IEC 61000-6-4</td>
<td>3 A/m</td>
<td>N/A</td>
<td>The power shell is a low-voltage battery-operated device and is suitable for use in all establishments.</td>
</tr>
</tbody>
</table>

Note: The power shell is intended for use in an electromagnetic environment which satisfies the following requirements:

1. 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.
2. 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.
3. 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.

Guidance and Manufacturer’s Declaration of 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic Environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000- 4-6</td>
<td>3 V or 10 V rms for 300 kHz to 30 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used only in areas where the recommended separation distance between equipment and the power shell is greater than the separation distance specified for the frequency of the transmitting device.</td>
</tr>
<tr>
<td>Radiated RF IEC 61000- 4-3</td>
<td>3 V or 10 V rms for 300 kHz to 30 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used only in areas where the recommended separation distance between equipment and the power shell is greater than the separation distance specified for the frequency of the transmitting device.</td>
</tr>
</tbody>
</table>

Note: The power shell is intended for use in an electromagnetic environment which satisfies the following requirements:

1. The power shell is intended for use in an electromagnetic environment which satisfies the following requirements.
2. The power shell is intended for use in an electromagnetic environment which satisfies the following requirements.
3. The power shell is intended for use in an electromagnetic environment which satisfies the following requirements.

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 W (≥95% in UT)</td>
<td>≥70 m (≥95% in UT)</td>
</tr>
<tr>
<td>0.1 W (≥95% in UT)</td>
<td>≥100 m (≥95% in UT)</td>
</tr>
<tr>
<td>0.01 W (≥95% in UT)</td>
<td>≥250 m (≥95% in UT)</td>
</tr>
</tbody>
</table>

The power shell is intended for use in an electromagnetic environment in which sub-harmonic isolations are provided. 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.

Note 1: The power shell is intended for use in an electromagnetic environment which satisfies the following requirements.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects, and people.
INSTRUCTIONS FOR USE

Signia™
Linear Adapters

PT00048739

NOTE: The adapter is made from metal and all metal parts after each cycle of cleaning and sterilization. The number of cycles remaining is indicated on the power handle display. Re-calibrations are done on the adapter by the Signia™ cleaning/sterilization service.

WASHERING:
1. Remove adapter from assembled stapler using field tools for the specific adapter (See page 2/2 for linear adapters and page 2/3 for radial adapters). Make sure to remove reusable and single use reloads from the adapter.
2. Scrub the assembled adapter using field tools for the specific adapter (See page 2/2 for linear adapters and page 2/3 for radial adapters). Make sure to remove reusable and single use reloads from the adapter.
3. Rinse under 32-40 °C running tap water for 1-2 minutes.
4. Manually agitate the adapter in the bath for 1-2 minutes.
5. Rinse under 32-40 °C running tap water for 1-2 minutes.
6. Dry with a clean, soft, lint-free cloth.

WARNING AND PRECAUTIONS
The following process parameters are the sterilization methods recommended and qualified for the Signia™ adapter to achieve a minimum sterility assurance level (SAL) of 10^-9.

1. Dry the adapter. For reusable, refer to the above steps.
2. Inspect the adapter. If not visibly clean, repeat the above steps.
3. Using the instructions provided, setup the adapter for cleaning and sterilization. See page 2/2 for linear adapters and page 2/3 for radial adapters.
4. Choose a cleaning cycle appropriate for the signia™ adapter. See page 1/2 for linear adapters and page 2/4 for radial adapters.
5. Check the orientations of the disposable and compatible single use linear reloads. See page 2/2 for linear adapters and page 2/3 for radial adapters.
6. Clean the adapter with a single use radial reload. See page 2/2 for linear adapters and page 2/3 for radial adapters.
7. Inspect the adapter. If not visibly clean, repeat the above steps.

WARNING AND PRECAUTIONS
The following process parameters are the sterilization methods recommended and qualified for the Signia™ adapter to achieve a minimum sterility assurance level (SAL) of 10^-9.

1. Dry the adapter. For reusable, refer to the above steps.
2. Inspect the adapter. If not visibly clean, repeat the above steps.
3. Using the instructions provided, setup the adapter for cleaning and sterilization. See page 2/2 for linear adapters and page 2/3 for radial adapters.
4. Choose a cleaning cycle appropriate for the signia™ adapter. See page 1/2 for linear adapters and page 2/4 for radial adapters.
5. Check the orientations of the disposable and compatible single use linear reloads. See page 2/2 for linear adapters and page 2/3 for radial adapters.
6. Clean the adapter with a single use radial reload. See page 2/2 for linear adapters and page 2/3 for radial adapters.
7. Inspect the adapter. If not visibly clean, repeat the above steps.

NOTE: When selecting multiple instruments in one surgical suite, recirculate the drug solution in each instrument at least two times before use.

WARNING AND PRECAUTIONS
The following process parameters are the sterilization methods recommended and qualified for the Signia™ adapter to achieve a minimum sterility assurance level (SAL) of 10^-9.

1. Dry the adapter. For reusable, refer to the above steps.
2. Inspect the adapter. If not visibly clean, repeat the above steps.
3. Using the instructions provided, setup the adapter for cleaning and sterilization. See page 2/2 for linear adapters and page 2/3 for radial adapters.
4. Choose a cleaning cycle appropriate for the signia™ adapter. See page 1/2 for linear adapters and page 2/4 for radial adapters.
5. Check the orientations of the disposable and compatible single use linear reloads. See page 2/2 for linear adapters and page 2/3 for radial adapters.
6. Clean the adapter with a single use radial reload. See page 2/2 for linear adapters and page 2/3 for radial adapters.
7. Inspect the adapter. If not visibly clean, repeat the above steps.

NOTE: When selecting multiple instruments in one surgical suite, recirculate the drug solution in each instrument at least two times before use.

WARNING AND PRECAUTIONS
The following process parameters are the sterilization methods recommended and qualified for the Signia™ adapter to achieve a minimum sterility assurance level (SAL) of 10^-9.

1. Dry the adapter. For reusable, refer to the above steps.
2. Inspect the adapter. If not visibly clean, repeat the above steps.
3. Using the instructions provided, setup the adapter for cleaning and sterilization. See page 2/2 for linear adapters and page 2/3 for radial adapters.
4. Choose a cleaning cycle appropriate for the signia™ adapter. See page 1/2 for linear adapters and page 2/4 for radial adapters.
5. Check the orientations of the disposable and compatible single use linear reloads. See page 2/2 for linear adapters and page 2/3 for radial adapters.
6. Clean the adapter with a single use radial reload. See page 2/2 for linear adapters and page 2/3 for radial adapters.
7. Inspect the adapter. If not visibly clean, repeat the above steps.

NOTE: When selecting multiple instruments in one surgical suite, recirculate the drug solution in each instrument at least two times before use.

WARNING AND PRECAUTIONS
The following process parameters are the sterilization methods recommended and qualified for the Signia™ adapter to achieve a minimum sterility assurance level (SAL) of 10^-9.

1. Dry the adapter. For reusable, refer to the above steps.
2. Inspect the adapter. If not visibly clean, repeat the above steps.
3. Using the instructions provided, setup the adapter for cleaning and sterilization. See page 2/2 for linear adapters and page 2/3 for radial adapters.
4. Choose a cleaning cycle appropriate for the signia™ adapter. See page 1/2 for linear adapters and page 2/4 for radial adapters.
5. Check the orientations of the disposable and compatible single use linear reloads. See page 2/2 for linear adapters and page 2/3 for radial adapters.
6. Clean the adapter with a single use radial reload. See page 2/2 for linear adapters and page 2/3 for radial adapters.
7. Inspect the adapter. If not visibly clean, repeat the above steps.
**Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Simplex and Power Adapter**

<table>
<thead>
<tr>
<th>Separation distance (m)</th>
<th>Maximum output power of mobile RF communications equipment (W)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3</td>
<td>0.15</td>
</tr>
<tr>
<td>0.5</td>
<td>0.15</td>
</tr>
<tr>
<td>1.0</td>
<td>0.15</td>
</tr>
<tr>
<td>1.5</td>
<td>0.15</td>
</tr>
<tr>
<td>2.0</td>
<td>0.15</td>
</tr>
</tbody>
</table>

**Limitations**

- The separation distances are not an electromagnetic interference (EMI) limit. Instead, they provide a guide to the range over which equipment is likely to remain compliant when used in a mixed environment.

**Guideline 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>RF emissions test</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admittance (BS)</td>
<td>Conducted RF</td>
<td>Non-broadband signals, in reality. A focus on resonant electrical circuitry should be kept. 25% UT.</td>
</tr>
<tr>
<td>Electromagnetic field</td>
<td>Radiated RF</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (80 MHz-30 MHz)</td>
<td>Voltage dips, short interruptions, and voltage (\pm 6 \text{kV} ) contact; (\pm 8 \text{kV} ) air; (\pm 2 \text{kV} ) common mode</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>LF (30 MHz-300 MHz)</td>
<td>RF emissions</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (300 MHz-3 GHz)</td>
<td>Electrostatic discharge</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (3 GHz-300 GHz)</td>
<td>Electrical fast transient and flicker emissions</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>LF (100 kHz-300 kHz)</td>
<td>Power frequency (50/60 Hz)</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
</tbody>
</table>

** 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.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Immunity test</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A (VDE)</td>
<td>IEC 60601 test</td>
<td>Non-broadband signals, in reality. A focus on resonant electrical circuitry should be kept. 25% UT.</td>
</tr>
<tr>
<td>Electromagnetic field</td>
<td>Radiated RF</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (80 MHz-30 MHz)</td>
<td>Voltage dips, short interruptions, and voltage (\pm 6 \text{kV} ) contact; (\pm 8 \text{kV} ) air; (\pm 2 \text{kV} ) common mode</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>LF (30 MHz-300 MHz)</td>
<td>RF emissions</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (300 MHz-3 GHz)</td>
<td>Electrostatic discharge</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (3 GHz-300 GHz)</td>
<td>Electrical fast transient and flicker emissions</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>LF (100 kHz-300 kHz)</td>
<td>Power frequency (50/60 Hz)</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
</tbody>
</table>

**Guideline 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>RF emissions test</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admittance (BS)</td>
<td>Conducted RF</td>
<td>Non-broadband signals, in reality. A focus on resonant electrical circuitry should be kept. 25% UT.</td>
</tr>
<tr>
<td>Electromagnetic field</td>
<td>Radiated RF</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (80 MHz-30 MHz)</td>
<td>Voltage dips, short interruptions, and voltage (\pm 6 \text{kV} ) contact; (\pm 8 \text{kV} ) air; (\pm 2 \text{kV} ) common mode</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>LF (30 MHz-300 MHz)</td>
<td>RF emissions</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (300 MHz-3 GHz)</td>
<td>Electrostatic discharge</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>HF (3 GHz-300 GHz)</td>
<td>Electrical fast transient and flicker emissions</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
<tr>
<td>LF (100 kHz-300 kHz)</td>
<td>Power frequency (50/60 Hz)</td>
<td>The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.</td>
</tr>
</tbody>
</table>

---

**Note:** 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. The power handle, adapter and power shell shall remain at the same separation level as required for use in an industrial environment.
INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THROUGHOUT.

INSTRUCTIONS: This is a proprietary manual and is for use in conjunction 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 assist in maintaining the sterility of the Signia™ power handle during storage of the non-sterile power handle. It is provided non-sterile and must be cleaned and sterilized prior to each use. The reusable insertion guide is non-sterile and when used with compatible single use radial reloads has been shown to provide an aseptic transfer guide when inserting the disinfected power handle into the reusable power shell with a sterilized reusable insertion guide. The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. This procedure cannot be performed incorrectly, due to the device's internal transfer.

CLEANING, DISINFECTION, AND STERILIZATION: The reusable insertion guide is made from plastic. The Signia™ reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. It cannot be performed incorrectly, due to the device's internal transfer.

CLEANING: The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

DISINFECTION: The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

STERILIZATION: The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

Before Use

Check and that the reusable insertion guide prior to use is following the instructions provided.

During Use

Be sure to use no solution interchanged with disposables.

After Use

The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

HOLDING: The reusable insertion guide has been tested for material compatibility with disposable single use radials and has been found to provide an aseptic transfer guide when inserting the disinfected power handle into the reusable power shell when used with compatible single use radial reloads. The reusable insertion guide is available in the following configurations:

A) REUSABLE INSERTION GUIDE
B) EXTENDED HANDLE
C) POWER SHELL
D) TOP SECURE CLIPS
E) SCRUBBED PERSON
F) CIRCULATING PERSON
G) POWER HANDLE

DESCRIPTION

The Signia™ reusable insertion guide is a device used 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 assist in maintaining the sterility of the Signia™ power handle during storage of the non-sterile power handle. It is provided non-sterile and must be cleaned and sterilized prior to each use. The reusable insertion guide is non-sterile and when used with compatible single use radial reloads has been shown to provide an aseptic transfer guide when inserting the disinfected power handle into the reusable power shell with a sterilized reusable insertion guide. The reusable insertion guide should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

INDICATIONS FOR USE

The Signia™ reusable insertion guide is intended for use in surgical procedures where a device is intended to be used as an aseptic transfer guide when inserting the disinfected power handle into the reusable power shell. The reusable insertion guide is non-sterile and should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

The reusable insertion guide is non-sterile and should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

The reusable insertion guide is non-sterile and should be cleaned thoroughly after every use to remove all traces of blood and biological fluids or any probable following. Performing incorrectly can be performed incorrectly, due to the device's internal transfer.

NOTES:

1. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

2. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

3. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

4. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

5. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

6. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

7. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

8. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

9. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.

10. The disposable instruments that are provided for use with the disposable single use radial reloads are provided for use with the disposable single use radial reloads. They are not intended to be used for reprocessing.
**INDICATIONS FOR USE**

The manual retraction tool is contraindicated for initiating a new firing with a stapling reload or for 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 the adapter, the stapling reload may not respond to inputs from the tool.

**WARNINGS AND PRECAUTIONS**

- **WARNING:** The manual retraction tool is intended to be used as a back-up device for the Signia™ stapler should the stapler fail during operation. It can be used to complete a firing that has already been initiated, to retract the knife and open the jaws from a tissue or from a stapling reload.

PT00048743

**PRECAUTION:** The Stapling reload must be removed from the tissue by the UP / OPEN button to open the jaws of the instrument.

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

- **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.

- **WARNING:** The manual retraction tool is intended to be used as a back-up device for the Signia™ stapler should the stapler fail during operation. It can be used to complete a firing that has already been initiated, to retract the knife and open the jaws from a tissue or from a stapling reload.

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

- **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**

- **WARNING:** The manual retraction tool is made from metal and plastic.

Wear gloves and protection eye wear.

- **WARNING:** The manual retraction tool is intended to be used as a back-up device for the Signia™ stapler should the stapler fail during operation. It can be used to complete a firing that has already been initiated, to retract the knife and open the jaws from a tissue or from a stapling reload.

- **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.

**MANUAL OPENING PROCEDURE**

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.

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 open V shape (45° angle relative to the shaft) or T shape (90° angle relative to the shaft).

3. 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. Do not use solvents, abrasives, phenols, phosphates, or any caustic solutions. Do not use detergents, bleaches, or disinfectants.

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 failure of the power stapling handle.

5. The knife is articulated, insert the manual retraction tool into the hole marked with the number 2 on the proximal end of the adapter. Center the knife, and remove the instrument from the patient. Refer to the instructions in the Disinfection section of the Signia™ stapling system’s user manual.

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

**NOTES:** The Signia™ manual retraction tool should be cleaned by the operator with external and internal handles in either an open shape (45° angle relative to the shaft) or a T shape (90° angle relative to the shaft).

**CLEANING, DISINFECTION, AND STERILIZATION**

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 handle off of it.

2. 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.

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

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 failure of the power stapling handle.

5. The knife is articulated, insert the manual retraction tool into the hole marked with the number 2 on the proximal end of the adapter. Center the knife, and remove the instrument from the patient. Refer to the instructions in the Disinfection section of the Signia™ stapling system’s user manual.

**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**

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 handle off of it.

2. 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.

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

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 failure of the power stapling handle.

5. The knife is articulated, insert the manual retraction tool into the hole marked with the number 2 on the proximal end of the adapter. Center the knife, and remove the instrument from the patient. Refer to the instructions in the Disinfection section of the Signia™ stapling system’s user manual.

**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**

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 handle off of it.

2. 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.

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

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 failure of the power stapling handle.

5. The knife is articulated, insert the manual retraction tool into the hole marked with the number 2 on the proximal end of the adapter. Center the knife, and remove the instrument from the patient. Refer to the instructions in the Disinfection section of the Signia™ stapling system’s user manual.

**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**

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 handle off of it.

2. 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.

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

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 failure of the power stapling handle.

5. The knife is articulated, insert the manual retraction tool into the hole marked with the number 2 on the proximal end of the adapter. Center the knife, and remove the instrument from the patient. Refer to the instructions in the Disinfection section of the Signia™ stapling system’s user manual.

**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**

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 handle off of it.

2. 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.

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

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 failure of the power stapling handle.
Treatment | Time | Temperature | Chemical
--- | --- | --- | ---
Pre-wash | 00:45 | Cold tap water | N/A
Wash | 04:00 | Hot tap water | Enzymatic 1 or Alkaline 2 (diluted per manufacturer’s specifications)
Rinse | 00:15 | Hot tap water | N/A
Wash | 03:00 | Hot tap water | Enzymatic 1 or Alkaline 2 (diluted per 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 10.4. 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

<table>
<thead>
<tr>
<th>Outside USA (2020)</th>
<th>WHO¹ Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum Steam Cycle</td>
<td>Cycle</td>
</tr>
<tr>
<td>Exposure temperature (°C)</td>
<td>132</td>
</tr>
<tr>
<td>Exposure time (minutes)</td>
<td>4</td>
</tr>
<tr>
<td>Vacuum dry time (minutes)</td>
<td>20-40</td>
</tr>
</tbody>
</table>

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.

2. 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.

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

ETO Sterilization

<table>
<thead>
<tr>
<th>Hot Cycle</th>
<th>Cold Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Setting</td>
<td>110.5 °F (43.6 °C)</td>
</tr>
<tr>
<td>Ethylene Oxide Gas Concentration</td>
<td>600-650 mg/L</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>40-60%</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>2 hours minimum</td>
</tr>
<tr>
<td>Condition</td>
<td>Wrapped</td>
</tr>
</tbody>
</table>

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.
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.

**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.

**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.

**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 occurring 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.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Time (min:sec)</th>
<th>Temperature</th>
<th>Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash</td>
<td>00:45</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>04:00</td>
<td>Hot tap water</td>
<td>Enzymatic¹ or Alkaline² Detergent¹</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>03:00</td>
<td>Hot tap water</td>
<td>Enzymatic¹ or Alkaline² Detergent¹</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Thermal Rinse</td>
<td>05:00</td>
<td>Hot purified water heated to 203 F (95 C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry</td>
<td>06:00</td>
<td>High setting 203 F (95 C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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 than 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 11.9mm 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.
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:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Time (min:sec)</th>
<th>Temperature</th>
<th>Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash</td>
<td>00:45</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>04:00</td>
<td>Hot tap water</td>
<td>Enzymatic¹ or Alkaline² Detergent³</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>03:00</td>
<td>Hot tap water</td>
<td>Enzymatic¹ or Alkaline² Detergent³</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Thermal Rinse</td>
<td>05:00</td>
<td>Hot purified water heated to 203°F (95°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry</td>
<td>06:00</td>
<td>High setting</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Time (min:sec)</th>
<th>Temperature</th>
<th>Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash</td>
<td>00:45</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>04:00</td>
<td>Hot tap water</td>
<td>Enzymatic¹ or Alkaline² Detergent¹</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>03:00</td>
<td>Hot tap water</td>
<td>Enzymatic¹ or Alkaline² Detergent¹</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Thermal Rinse</td>
<td>05:00</td>
<td>Hot purified water heated to 203°F (95°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry</td>
<td>06:00</td>
<td>High setting 203°F (95°C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>Outside USA (OUS)</th>
<th>Minimum recommended WHO† Cycle</th>
<th>Cycle</th>
<th>Cycle</th>
<th>Cycle</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum Steam Cycle</td>
<td>Exposure Temperature (C)</td>
<td>132</td>
<td>134</td>
<td>134</td>
<td>134</td>
</tr>
<tr>
<td></td>
<td>Exposure Time (minutes)</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Vacuum Dry Time (minutes)</td>
<td>20-40</td>
<td>20-40</td>
<td>20-40</td>
<td>20-40</td>
</tr>
</tbody>
</table>

†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.

Disposal

Discard or recycle as per local, state, and governmental regulations.
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.³

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

<table>
<thead>
<tr>
<th>ORDER CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIGPHANDLE</td>
<td>Signia™ Power Handle</td>
</tr>
<tr>
<td>SIGPSHELL</td>
<td>Signia™ Power Control Shell</td>
</tr>
<tr>
<td>SIGADAPTSTND</td>
<td>Signia™ Linear Adapter</td>
</tr>
<tr>
<td>SIGADAPTXL</td>
<td>Signia™ Linear Adapter XL</td>
</tr>
<tr>
<td>SIGADAPSHORT</td>
<td>Signia™ Linear Adapter Short</td>
</tr>
<tr>
<td>SIGSBCHGR</td>
<td>Signia™ Single-Bay Charger</td>
</tr>
<tr>
<td>SIGRIG</td>
<td>Signia™ Reusable Insertion Guide</td>
</tr>
<tr>
<td>SIGMRET</td>
<td>Signia™ Manual Retraction Tool</td>
</tr>
<tr>
<td>SIGTRAY</td>
<td>Signia™ Sterilization Tray</td>
</tr>
<tr>
<td>SIGPCORD1</td>
<td>Signia™ Power Cord 1 – US</td>
</tr>
<tr>
<td>SIGPCORD6</td>
<td>Signia™ Power Cord 6 – JA</td>
</tr>
</tbody>
</table>
References

1. Based on internal test report #RE00024826, Signia™ stapling system summative usability report, January 2016.
2. Based on internal test report #R2146-151-0, Powered Stapling Firing Speed DOE Analysis and ASA Parameters, 2015.
5. Based on claim No. 1 of software requirements specification (SRS) and 510k testing.
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.
9. Based on Software Requirements Specification #R0032596, March 9, 2015