

Cleaning and sterilization guide

Signia™ system



Cleaning instructions

During use:

Remove excess soil on the reusable instruments with disposable wipes.

After use:

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

Precaution

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

Power shell

Warning

The power shell is single-use only. Discard after use. Do not sterilize. Re-sterilized or reprocessed sterile power shells will not function.

Power handle

Warning and 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 is indicated 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 or a chlorine-based wipe such as Wet Wipe™ Chlorine Disinfection or Wet Wipe™ Triamin Disinfection per the manufacturer's instructions.
- Ensure the power handle is completely dry prior to inserting it into a sterile power shell or charger.

Warning

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

Adapters

Linear

Warning

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

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

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

After use

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

Note

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

Manual cleaning

1. Remove the adapter from the stapler according to the instructions for use provided with the Signia™ stapling system's user manual.
2. Wipe down the adapter with a separate lint-free cloth soaked in a 90-104°F (32-40°C) pH-neutral detergent solution diluted per the manufacturer's specifications.

3. Under 90-104°F (32-40°C) running water, scrub all reachable exterior surfaces with a general instrument soft nylon bristle brush for 1-2 minutes to remove surgical debris. Hold the distal end of the adapter under running water and flush for 1-2 minutes. Do not insert the brush into the distal end shaft. While brushing, pay particular attention to the grooves on the pin. Also pay particular attention to the grooves and sides of the reload unload button.
- 4a. For enzymatic detergents (validated with Steris Prolystica™ 2X Concentrate): Hold the adapter at a slight angle to allow the detergent solution to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter in a 90-104°F (32-40°C) enzymatic bath diluted as specified by the manufacturer's instructions for use and soak for 10-20 minutes.
- 4b. For alkaline detergents (non-enzymatic pH greater than 9.5 but less than 10.8) (validated with neodisher™ MediClean forte): Hold the adapter at a slight angle to allow the detergent solution to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter in a 90-104°F (32-40°C) alkaline bath diluted as specified by the manufacturer's instructions for use and soak for 10-20 minutes.
5. Manually agitate the adapter in the bath for 1-2 minutes.
6. Invert the adapter until all fluid has completely drained.
7. In a clean 90-104°F (32-40°C) water bath, hold the adapter at a slight angle to allow the water to flow into the shaft from the bottom and air bubbles to release from the top. Once all air bubbles are released, immerse the adapter and soak for 2-3 minutes.
8. Manually agitate the adapter in the bath for 1-2 minutes.
9. Invert the adapter until all fluid has completely drained.
10. Repeat step 3.
11. Rinse under 90-104°F (32-40°C) running tap water for 1-2 minutes.
12. Perform a final rinse under purified water for 1-2 minutes.
13. Dry with a clean, soft, lint-free cloth.
14. Inspect the adapter. If not visibly clean, repeat the above steps.

Precaution

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

Automatic cleaning

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

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

4. Rinse under 90-104°F (32-40°C) running tap water for 1-2 minutes.
5. Perform the automatic cleaning cycle, following the recommendations in the table below.

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.

Treatment	Time (min:sec)	Temperature	Chemicals
Pre-wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water	Enzymatic [†] or alkaline [‡] detergent [§]
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic [†] or alkaline [‡] detergent [§]
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

[†] Validated with Steris Prolystica™ 2X Concentrate

[‡] Validated with neodisher™ MediClean forte

[§] 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.

In facilities that require disinfection before sterilization, the thermal rinse cycle during the automatic cleaning process should be programmed for 5 minutes at 95°C (203°F).

Reusable insertion guide

Warnings

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.

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

After use

Initial treatment at point of use: Wipe down the device to remove blood and surgical debris. Reprocess as soon as possible following use. Submerge device in a pH-neutral enzymatic solution or spray with a pH-neutral enzymatic spray per the manufacturer's instructions immediately following completion of the procedure.

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 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the grooves on the extended handle and indentations on the underside of the tool.
- 3a. For enzymatic detergents (validated with Steris Prolystica™ 2X Concentrate): Immerse the device in a 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 11.9 mm soft nylon bristle brush for 1-2 minutes to remove surgical debris. Pay particular attention to the grooves on the extended handle and indentations on the underside of the tool.
3. Rinse under running tap water (90-104°F/32-40°C) for at least 1 minute.
4. Perform the automatic cleaning cycle, following the parameters in the following table:

Treatment	Time (min:sec)	Temperature	Chemicals
Pre-wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water (specified as greater than 43°C/109°F)	Enzymatic [†] or alkaline [‡] detergent [§]
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic [†] or alkaline [‡] detergent [§]
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

[†] Validated with Steris Prolystica™ 2X Concentrate

[‡] Validated with neodisher™ MediClean forte

[§] 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.

In facilities that require disinfection before sterilization, the thermal rinse cycle during the automatic cleaning process should be programmed for 5 minutes at 95°C (203°F).

Manual retraction tool

Warnings

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.

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

After use

Initial treatment at point of use: Wipe down the device to remove blood and surgical debris. Reprocess as soon as possible following use. Submerge device in a pH-neutral enzymatic solution or spray with a pH-neutral enzymatic spray per the manufacturer's instructions immediately following completion of the procedure.

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 (i.e., reverse osmosis (RO), distilled, deionized) for a minimum of 1 minute.
8. Dry with a clean, soft, lint-free cloth.
9. Inspect the device. If not visibly clean, repeat the above steps.

Automatic cleaning

Note

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

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

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

Treatment	Time (min:sec)	Temperature	Chemicals
Pre-wash	00:45	Cold tap water	N/A
Wash	04:00	Hot tap water (specified as greater than 43°C/109°F)	Enzymatic† or alkaline‡ detergent§
Rinse	00:15	Hot tap water	N/A
Wash	03:00	Hot tap water	Enzymatic† or alkaline‡ detergent§
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

† Validated with Steris Prolystica™ 2X Concentrate

‡ Validated with neodisher™ MediClean forte

§ 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

In facilities that require disinfection before sterilization, the thermal rinse cycle during the automatic cleaning process should be programmed for 5 minutes at 95°C (203°F).

Sterilization instructions

Sterilizing

The adapters, manual retraction tool, and the reusable insertion guide are provided non-sterile. They may be sterilized by steam autoclave. Adapters should be placed in standard hospital wrap or other suitable container for sterilization.

Warning

Do not use hydrogen peroxide gas plasma technology (such as STERRAD™ systems), ethylene oxide (although the EtO sterilization will be removed when product transitions to MDR), 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

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Always refer to the instructions for use included with the product for complete indications, instructions, warnings, precautions, and contraindications.

Outside U.S. (OUS)

Pre-vacuum steam cycle	Minimum recommended			WHO† cycle
	Cycle	Cycle	Cycle	
Exposure temperature (°C)	132	134	134	134
Exposure time (minutes)	4	3	5	18
Vacuum time (minutes)	20–40	20–40	20–40	20–40

† World Health Organization (WHO) steam sterilization cycle

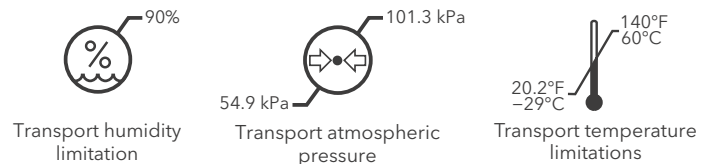
Note

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

Dynamic-air-removal steam sterilizers achieve air removal through a preconditioning phase. Follow the sterilizer manufacturer's instructions for proper preconditioning.

Storage

Store at room temperature.



Disposal

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