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<sup>®</sup>  
**stryker**

# **Supplemental Processing Instructions**

**For All Stryker  
Instruments Division  
Power Medical Devices**

**Care Instructions**

**R<sub>x</sub> ONLY**

ENGLISH (EN)

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## Introduction

This manual is intended to give supplemental information and guidance on how power medical devices (equipment) supplied by Stryker Instruments Division may be processed and prepared for use.

**ALWAYS** consult the instructions for use and/or care instructions manual supplied with your device for initial proper care and use. This manual does not supersede the instructions for use and/or care instructions manual supplied with your device, but provides instructions for additional device processing methods and equipment.

This manual may be used by in-service trainers, biomedical equipment technicians, and central supply/sterile processing technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. **ALWAYS** comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. **ALWAYS** comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information or in-service training is required, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

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## Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

SYMBOL	DEFINITION
	General warning sign



## User/Patient Safety



### WARNINGS:

- Only individuals trained and experienced in the processing of reusable medical devices should process this equipment.
- Before processing any equipment, read and understand the instructions. Pay particular attention to **WARNING** information. Become familiar with the equipment prior to processing.
- **DO NOT** reuse, reprocess, or re-package single use cutting accessories. All cutting accessories are intended for a single use only. Reuse may create a serious risk of contamination and lead to infection or cross-infection. Reprocessing may compromise the structural integrity of the cutting accessory and result in fragmentation during use. Critical product information may be lost if the cutting accessory is re-packaged.

## Accessories



**WARNING:** Use only Stryker-approved system components and accessories, unless otherwise specified. **DO NOT** modify any system component or accessory.

**NOTE:** For a complete list of accessories, contact your Stryker sales representative. Outside the US, contact your nearest Stryker subsidiary.

## Processing Instructions

Processing equipment, operators, detergents, and procedures all contribute to the efficacy of medical device processing. The healthcare facility should make sure that the combination used results in a medical device that is safe for use. Alternative methods of processing may be equally suitable.

### 1.0 Point of Use

**CAUTION:** DO NOT use saline to wet or soak the equipment before transport to the decontamination processing area.

**NOTE:** If transport to the decontamination processing area is delayed, cover the equipment with a damp cloth or spray the equipment with a pre-cleaning foam. The pre-cleaning foam will minimize the drying of soil and facilitate later decontamination processing.

1. Separate reusable equipment from disposable waste.
2. Discard waste into an appropriate container; use a puncture-resistant container for sharps.
3. Remove gross soil from the equipment using absorbent wipes.

### 2.0 Transport to Decontamination Processing Area



**WARNING:** During transport, pay particular attention to sharp, cutting edges to avoid injury.

**CAUTION:** Avoid mechanical damage during transport. DO NOT mix heavy devices with delicate devices.

**NOTE:** Clean the equipment as soon as practical, typically within two hours, to preclude extended or repeat cleaning procedures.

## 3.0 Preparation for Cleaning

### 3.1 Detergents



#### **WARNINGS:**

- Read, understand, and follow the indications, instructions, and WARNING information supplied with the detergent for correct handling and use of the product. Pay particular attention to the concentration used and the total dispersion of the detergent. Prepare the detergent solution according to the manufacturer's recommendations.
- ALWAYS provide personal protective equipment (PPE) for processing personnel according to the instructions and material safety data sheets (MSDS) supplied with the detergent.
- To clean the equipment, use specifically formulated detergents only.

#### **CAUTIONS:**

- To clean the equipment, a mild alkaline agent (neutral up to pH 10.5) is preferred. If a washer-disinfector is used, see the instructions supplied with the washer-disinfector machine to select the recommended detergent.
- ALWAYS use a detergent that is suitable for use on aluminum surfaces if aluminum surfaces are present.

### 3.1 Detergents (continued)

#### NOTES:

- The table entitled *Validated Detergents* lists the detergents used by Stryker during the validation of the manual and automated (washer-disinfector) cleaning processes described in these instructions.
- Stryker does not recommend these detergents in preference to other products. Other products may perform equally well or better. However, alternative detergents must be verified by referencing the information provided by the product supplier and/or physical testing.

#### VALIDATED DETERGENTS

Supplier	Designation	Suitability	Process
Stryker	ProClean Instrument Detergent	All materials	Manual Cleaning
Steris	Polystica 2x Concentrate Enzymatic and Polystica 2x Concentrate Neutral	Stainless steel, aluminum, soft metals, and plastics	Automated Cleaning

### 3.2 Water Quality



**WARNING:** Use filtered water for diluting detergents and for rinsing the equipment. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.

**CAUTION:** Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per AAMI TIR 34.



## 4.0 Handpiece and Attachment Cleaning



### WARNINGS:

- Clean the equipment as indicated before first and every use.
- Prior to cleaning, remove all detachable components and single use cutting accessories from the handpieces. Detachable components include cords, handswitches, bur guards, shields, irrigation clips, attachments, and battery packs.
- Use the cleaning methods as indicated in these instructions or the instructions for use and/or care instructions manual supplied with the equipment. Using other cleaning methods may prevent proper sterilization of the equipment.
- Brushes should not be visibly larger or smaller than the diameter of the lumen to be cleaned. Incorrectly sized brushes will not clean all surfaces.
- Use PPE at all times during cleaning.

### CAUTIONS:

- These cleaning instructions are not appropriate for Stryker battery packs. See the *5.0 Battery Pack Cleaning* section for information on how to properly clean battery packs.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.
- DO NOT use ultrasonic cleaning equipment.
- DO NOT immerse or soak any equipment in liquid. DO NOT allow moisture or liquid to soak into electrical plugs, receptacles, or openings. Moisture or liquid may enter the equipment, cause corrosion, and damage the electrical and/or mechanical components.

## 4.0 Handpiece and Attachment Cleaning (continued)

### CAUTIONS:

- Before cleaning and/or sterilizing a handswitch, ALWAYS set the safety switch between the RUN and SAFE positions.
- ALWAYS use a non-abrasive, soft, flexible, nylon-bristle brush in the lumen or nose of an Elite or Saber SD Series attachment or an Impaction Drill Bur Guard. ALWAYS use light pressure and DO NOT force the brush any farther after you feel resistance.
- When cleaning a Bur Guard, DO NOT force a brush or cleaning tool through the bur insert hole.
- DO NOT use pipe cleaners or cotton swabs to clean lumens.
- DO NOT bend connector pins during cleaning.
- Use of compressed air is only recommended for drying of equipment.
- ALWAYS make sure the detergent solution is completely rinsed off before drying the equipment.

### NOTES:

- Equipment may be placed under running water and/or dipped into liquid to ensure thorough wetting and contact with liquid while actuating moving parts.
- Two methods of cleaning are described: a manual cleaning method and an automated cleaning method. Removal of all gross soil is required for both cleaning methods.

## 4.1 Manual Cleaning

### 4.1.1 Recommended Equipment

- Non-abrasive, soft, flexible, nylon-bristle brushes
- Syringe
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F]. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
- Medical-grade compressed air, < 140 kPa [< 20 psi]

### 4.1.2 To Clean Handpieces and Attachments

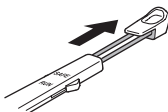
1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
2. Make sure all surfaces of the equipment are thoroughly wetted using warm water.
3. Using suitable brushes, clean the equipment thoroughly. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from brushing, such as details around a trigger or connector. Flush difficult-to-reach areas with a syringe filled with the detergent solution.
4. Use soft brushes of appropriate diameters to clean lumens. If a lumen passes all the way through a device, make sure that the brush cleans the whole length of the lumen. For dead-ended lumens, use light pressure and do not force the brush any farther after you feel resistance.

#### 4.1.2 To Clean Handpieces and Attachments (continued)

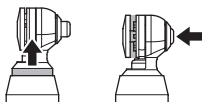
5. Actuate all moving parts of the equipment to clean hidden surfaces.

##### NOTES:

- When removing debris from a handswitch, completely extend the finger rest to access all surfaces.



- When removing debris from a sagittal saw handpiece or sagittal saw attachment, pull out the blade mount, and depress the button to open the blade mount, to access all surfaces.



- When removing debris from an oscillating saw handpiece, actuate the blade mount collar to access all surfaces.



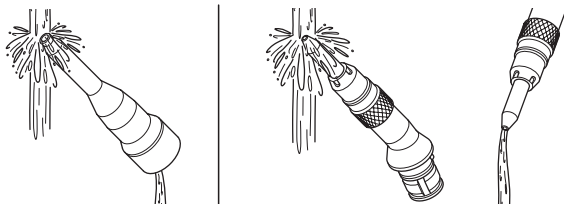
##### CAUTIONS:

- DO NOT allow attachments to remain continuously under running water throughout the cleaning.
- DO NOT orient any attachment vertically under running water.

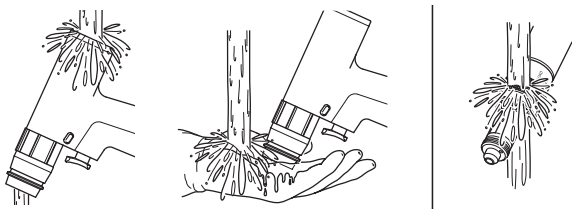
#### 4.1.2 To Clean Handpieces and Attachments (continued)

##### 6. Rinse the equipment:

- 6.1. For attachments only, hold the attachment on an incline, distal end pointing up, and rinse the lumen under warm running water. For dead-ended lumens, once the water comes back out of the attachment, immediately point the distal end of the attachment down to allow the water to drain out. Repeat this step one or two more times until the water draining from the attachment is clear.



- 6.2. For all other equipment, hold the equipment on an incline, distal end pointing down, and rinse the equipment in warm running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces, lumens, hinges, blind holes, and joints between mating parts. Actuate all moving parts to remove any remaining detergent solution.



**NOTE:** A final rinse of the equipment using deionized or filtered water is recommended.

**4.1.2 To Clean Handpieces and Attachments (continued)**

7. Visually inspect the equipment for any remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning and rinsing procedure using fresh detergent solution.
8. Allow the equipment to drain on absorbent wipes.
9. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air.
10. After cleaning, inspect and test the equipment immediately. See the *6.0 Inspection and Testing* section.

## 4.2 Automated Cleaning

### 4.2.1 Recommended Equipment

- Non-abrasive, soft, flexible, nylon-bristle brushes
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Washer-disinfector
- Detergents and rinsing agents as required by the washer-disinfector
- Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F]. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
- Medical-grade compressed air, < 140 kPa [< 20 psi]

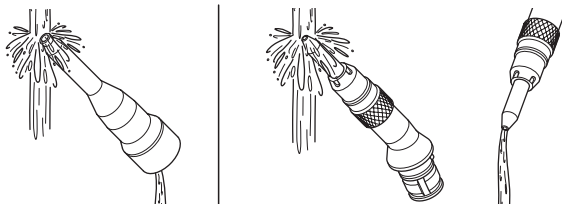
### 4.2.2 To Clean Handpieces and Attachments

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
2. Make sure all surfaces of the equipment are thoroughly wetted using warm water.
3. Using suitable brushes, clean the equipment thoroughly. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from brushing, such as details around a trigger or connector. Flush difficult-to-reach areas with a syringe filled with the detergent solution.
4. Use soft brushes of appropriate diameters to clean lumens. If a lumen passes all the way through a device, make sure that the brush cleans the whole length of the lumen. For dead-ended lumens, use light pressure and do not force the brush any farther after you feel resistance.
5. Actuate all moving parts of the equipment to clean hidden surfaces.

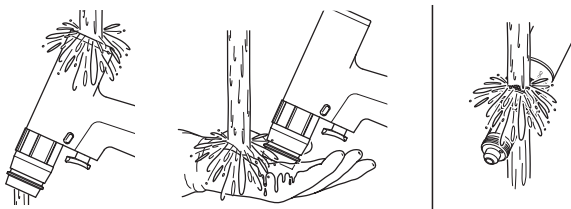
#### 4.2.2 To Clean Handpieces and Attachments (continued)

##### 6. Rinse the equipment:

- 6.1. For attachments only, hold the attachment on an incline, distal end pointing up, and rinse the lumen under warm running water. For dead-ended lumens, once the water comes back out of the attachment, immediately point the distal end of the attachment down to allow the water to drain out. Repeat this step one or two more times until the water draining from the attachment is clear.



- 6.2. For all other equipment, hold the equipment on an incline, distal end pointing down, and rinse the equipment in warm running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces, lumens, hinges, blind holes, and joints between mating parts. Actuate all moving parts to remove any remaining detergent solution.



**NOTE:** A final rinse of the equipment using deionized or filtered water is recommended.



#### 4.2.2 To Clean Handpieces and Attachments (continued)

7. Visually inspect the equipment for any remaining soil and repeat the cleaning steps if necessary.
8. Allow the equipment to drain on absorbent wipes or load the equipment into the washer-disinfector immediately.



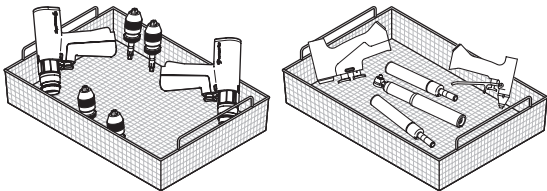
#### WARNINGS:

- ALWAYS load the equipment carefully to prevent movement that may inhibit proper cleaning during the automated washer-disinfector cycle.
- DO NOT use sterilization trays to hold equipment in the washer-disinfector. Sterilization trays are for use with the sterilization process only and must be washed separately.

**NOTE:** A System 6 insert tray, when removed from the sterilization tray, may be used to hold System 6 equipment in place during automated cleaning in a washer-disinfector. See the instructions for use supplied with the sterilization tray.

9. Load the equipment into the washer-disinfector in a wire basket. Always avoid contact between multiple components. If possible, orient the equipment vertically to assist in drainage. Placing the equipment in a horizontal position is also acceptable. Place any moving parts, such as chuck jaws, in the open position.

**NOTE:** The equipment illustrated is representational only and may not reflect the actual equipment configuration.



#### 4.2.2 To Clean Handpieces and Attachments (continued)

**CAUTION:** DO NOT use any type of lubricant in the automated washer-disinfector. Use of additional lubrication is not required and may leave residue on the equipment after cleaning.

- Operate the washer-disinfector. The table entitled *Validated Automated Washer-Disinfector Cycle Parameters* lists the phases that should be included in the cycle.

**VALIDATED AUTOMATED WASHER-DISINFECTOR CYCLE  
PARAMETERS: HANDPIECES AND ATTACHMENTS**

Phase	Time	Water Temperature	Cleaning Agent
Pre-rinse	2 to 4 minutes	< 21 °C [< 70 °F]	Prepared detergent*
Enzyme Wash	2 to 4 minutes	43 to 66 °C [110 to 150 °F]	Prepared enzymatic detergent
Wash	2 to 4 minutes	60 to 82 °C [140 to 180 °F]	Prepared detergent
Rinse	2 to 4 minutes	43 to 82 °C [110 to 180 °F]	–
Dry Time	15 minutes	–	–

\*Detergent may be omitted at the pre-rinse stage if the washer-disinfector does not have this capability.

- On completion, unload the washer-disinfector.
- Visually inspect the equipment for remaining soil. If soil remains, repeat the cleaning process.
- Dry the equipment with medical-grade compressed air or by heating the equipment in an oven below 110 °C [230 °F].
- After cleaning, inspect and test the equipment immediately. See the *6.0 Inspection and Testing* section.

## 5.0 Battery Pack Cleaning



### WARNINGS:

- Clean the equipment as indicated before first and every use.
- Prior to cleaning, remove the battery pack from the handpiece.
- Use the cleaning methods as indicated in these instructions or the instructions for use and/or care instructions manual supplied with the equipment. Using other cleaning methods may prevent proper sterilization of the equipment.
- Use PPE at all times during cleaning.

### CAUTIONS:

- These cleaning instructions are not appropriate for Stryker handpieces and attachments. See the *4.0 Handpiece and Attachment Cleaning* section for information on how to properly clean handpieces and attachments.
- DO NOT use detergent solution with pH levels higher than 10.5. See the detergent MSDS to verify the pH range. Failure to comply may cause the housing material to crack.
- DO NOT leave battery packs in the washer-disinfector for the drying phase. If other devices in the washer-disinfector require a drying phase, the other devices should be processed separately from the battery packs.

## 5.0 Battery Pack Cleaning (continued)

### CAUTIONS:

- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.
- DO NOT use ultrasonic cleaning equipment.
- DO NOT immerse or soak any equipment in liquid. DO NOT allow moisture or liquid to soak into electrical plugs, receptacles, or openings. Moisture or liquid may enter the equipment, cause corrosion, and damage the electrical and/or mechanical components.
- ALWAYS make sure the detergent solution is completely rinsed off before drying the equipment.
- Drying battery contacts with compressed air is recommended. Residual moisture from cleaning may lead to oxidation of the contacts.

### NOTES:

- Equipment may be placed under running water and/or dipped into liquid to ensure thorough wetting and contact with liquid while actuating moving parts.
- Two methods of cleaning are described: a manual cleaning method and an automated cleaning method. Removal of all gross soil is required for both cleaning methods.
- Automated cleaning may reduce the useful life of the product. Manual cleaning per these instructions is preferred.

## 5.1 Manual Cleaning

### 5.1.1 Recommended Equipment

- Non-abrasive, soft, flexible, nylon-bristle brushes
- Syringe
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F]. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
- Medical-grade compressed air, < 140 kPa [< 20 psi]

### 5.1.2 To Clean Battery Packs

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
2. Make sure all surfaces of the equipment are thoroughly wetted using warm water.
3. Using suitable brushes, clean the equipment thoroughly. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from cleaning, such as inner and outer crevices of the device. Flush difficult-to-reach areas with a syringe filled with the detergent solution.
4. Actuate all moving parts of the equipment to clean hidden surfaces.
5. Rinse the equipment in warm running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces and the battery contacts. Actuate all moving parts of the equipment to remove any remaining detergent solution.

**NOTE:** A final rinse of the equipment using deionized or filtered water is recommended.

6. Visually inspect the equipment for any remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning and rinsing procedure using fresh detergent solution.
7. Allow the equipment to drain on absorbent wipes.

### **5.1.2 To Clean Battery Packs (continued)**

8. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air.
9. After cleaning, inspect and test the equipment immediately. See the *6.0 Inspection and Testing section*.
10. Charge the battery pack as required. See the instructions for use supplied with the battery pack.

## **5.2 Automated Cleaning**

### **5.2.1 Recommended Equipment**

- Non-abrasive, soft, flexible, nylon-bristle brushes
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Washer-disinfector
- Detergent and rinsing agents as required by the washer-disinfector
- Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F]. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
- Medical-grade compressed air, < 140 kPa [< 20 psi]

### **5.2.2 To Clean Battery Packs**

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
2. Make sure all surfaces of the equipment are thoroughly wetted using warm water.
3. Using suitable brushes, clean the equipment thoroughly. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from cleaning, such as inner and outer crevices of the device. Flush difficult-to-reach areas with a syringe filled with the detergent solution.
4. Actuate all moving parts of the equipment to clean hidden surfaces.
5. Visually inspect the equipment for any remaining soil and repeat the cleaning steps if necessary.

### 5.2.2 To Clean Battery Packs (continued)

6. Rinse the equipment in warm running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces and the battery contacts. Actuate all moving parts of the equipment to remove any remaining detergent solution.
7. Allow the equipment to drain on absorbent wipes or load the equipment into the washer-disinfector immediately.



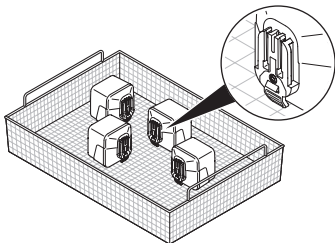
#### WARNINGS:

- ALWAYS load the equipment carefully to prevent movement that may inhibit proper cleaning during the automated washer-disinfector cycle.
- DO NOT use sterilization trays to hold equipment in the washer-disinfector. Sterilization trays are for use with the sterilization process only and must be washed separately.
- DO NOT use insert trays to hold battery packs in the washer-disinfector.

**CAUTION:** DO NOT allow the battery contacts to touch the wire basket or any metal objects inside of the basket. Failure to comply may short circuit the battery pack.

8. Load the equipment into the washer-disinfector in a wire basket. Avoid contact between multiple components. Orient battery packs so that the battery latch is on the side and the latch is pointing down.

**NOTE:** The equipment illustrated is representational only and may not reflect the actual equipment configuration.



### 5.2.2 To Clean Battery Packs (continued)

#### CAUTIONS:

- DO NOT use the drying phase with the automated washer-disinfector. Use of the drying phase may shorten the life of the battery pack.
  - DO NOT use any type of lubricant in the automated washer-disinfector. Use of additional lubrication is not required and may leave residue on the equipment after cleaning.
9. Operate the washer-disinfector. The table entitled *Validated Automated Washer-Disinfector Cycle Parameters* lists the phases that should be included in the cycle.

**VALIDATED AUTOMATED WASHER-DISINFECTOR CYCLE  
PARAMETERS: BATTERY PACKS**

Phase	Time	Water Temperature	Cleaning Agent
Pre-rinse	2 to 4 minutes	< 21 °C [< 70 °F]	Prepared detergent*
Enzyme Wash	2 to 4 minutes	43 to 66 °C [110 to 150 °F]	Prepared enzymatic detergent
Wash	2 to 4 minutes	60 to 82 °C [140 to 180 °F]	Prepared detergent
Rinse	2 to 4 minutes	43 to 82 °C [110 to 180 °F]	—

\*Detergent may be omitted at the pre-rinse stage if the washer-disinfector does not have this capability.

10. On completion, unload the washer-disinfector.
11. Visually inspect the equipment for remaining soil. If soil remains, repeat the cleaning process.
12. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air.
13. After cleaning, inspect and test the equipment immediately. See the *6.0 Inspection and Testing* section.
14. Charge the battery pack as required. See the instructions for use supplied with the battery pack.



## 6.0 Inspection and Testing



### WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect and test this equipment.
- Perform recommended inspection and testing as indicated in these instructions.
- DO NOT use any equipment if damage is apparent.
- DO NOT use any system component if the inspection criteria are not met.
- DO NOT service this equipment. If the equipment fails to meet the inspection and testing criteria, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

### NOTES:

- The useful life of this equipment is dependent upon many factors including, but not limited to, the method and duration of each use, and the handling of the equipment between uses.
- Routine and careful inspection and functional testing of the equipment is the best method for determining the serviceable life span of the equipment.

## 6.1 Limitations of Processing

Repeated processing has a minimal effect on this equipment. See the *6.2 Visual Inspection* and *6.3 Functional Inspection* sections for additional guidance on evaluating device functionality.

## 6.2 Visual Inspection

Visually inspect all equipment before sterilization. Pay particular attention to the following:

- Locations where soil may become trapped, such as mating surfaces, hinges, and shafts
- Recessed features, such as holes and lumens
- Features where soil may be pressed into contact with the equipment

## 6.3 Functional Inspection

Perform recommended inspection and testing as indicated in the *Inspection and Testing* and/or *Periodic Maintenance* sections of the instructions for use and/or care instructions manual supplied with the product.

## 7.0 Preparation for Sterilization



**WARNING:** ALWAYS use a chemical indicator within every sterilization load to make sure the proper sterilization conditions of time, temperature, and saturated steam are achieved.

Where appropriate, load equipment into an appropriate sterilization tray.

## 8.0 Packaging

Enclose the equipment using a sterilization wrap that is suitable for the equipment, such as a grade 500 or higher, before sterile processing.

Follow the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN) recommended guidelines for appropriate wrapping configurations.

**NOTE:** The packaging material will maintain the sterility of the equipment after exposure.

## 9.0 Handpiece and Attachment Sterilization



### WARNINGS:

- Sterilize the equipment as indicated before first and every use.
- Prior to sterilization, remove all detachable components and single use cutting accessories from the handpieces. Detachable components include cords, handswitches, bur guards, shields, irrigation clips, attachments, and battery packs.
- Use the sterilization methods as indicated in these instructions or the instructions for use and/or care instructions manual supplied with the equipment. Using other sterilization methods may prevent proper sterilization of the equipment and/or damage the equipment.
- Follow the recommended dry times to prevent moisture from accumulating inside the equipment. Moisture may prevent proper sterilization of the equipment and/or cause the equipment to corrode.
- After sterilization, allow the equipment to cool to room temperature prior to use. Failure to comply may result in burned patient tissue or healthcare staff, and/or damage to the equipment.

### CAUTIONS:

- These sterilization instructions are not appropriate for Stryker battery packs. See the *10.0 Battery Pack Sterilization* section for instructions on how to properly sterilize battery packs.
- ALWAYS make sure the equipment is completely dry before sterilization.
- Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per AAMI TIR 34.

## 9.0 Handpiece and Attachment Sterilization (continued)

### NOTES:

- Steam sterilization (moist heat) is recommended. Stryker has validated several autoclave cycles for the sterilization of this equipment. However, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should verify the process they use, employing the actual equipment and operators that routinely process the equipment.
- The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods and/or various loading configurations.
- The minimum dry time values specified in the following tables were validated using a sterilization configuration of a single handpiece that was wrapped. If an alternate sterilization configuration is used, for example, multiple handpieces are wrapped or processing requires a sterilization case or multiple instrument trays, the dry time values must be increased and verified.
- Dry times vary due to load configurations, tray material, wrapping method, and materials of construction. For Stryker power equipment, minimum dry times of 20 minutes for pre-vacuum cycles, and 15 to 30 minutes for gravity cycles, are required for individual devices. Routine dry times for fully loaded, multiple tray units is 15 to 65 minutes.
- The combination of plastic and metal trays within the same load may present unique challenges depending on the processing equipment and load configurations. If wet trays or equipment is discovered a longer dry time or change in product load configuration may be necessary and can be in excess of 65 minutes.

## 9.0 Handpiece and Attachment Sterilization (continued)

To obtain optimum performance, perform one of the following sterilization cycles validated by Stryker:

### VALIDATED<sup>1</sup> STEAM STERILIZATION CYCLE PARAMETERS<sup>2</sup>: HANDPIECES AND ATTACHMENTS

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Minimum Dry Time
Wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	30 minutes
		134 °C [273 °F]	3 minutes <sup>3</sup>	30 minutes

<sup>1</sup> Validation is based on the AAMI protocol.

<sup>2</sup> Sterilization parameters for Australia/New Zealand per AS/NZS 4187-2003.  
Sterilization parameters for Netherlands per Field Standard for Loaner Instruments, Revision 03.02, April 2008.  
Sterilization parameters for Europe and the United Kingdom per EN ISO 17664.  
Sterilization parameters for Canada per CSA ISO 17664.

<sup>3</sup> Minimum exposure time may be extended to 18 minutes.

### STERRAD GAS PLASMA : HANDPIECES AND ATTACHMENTS

Follow the sterilization instructions provided by Sterrad. Contact your Sterrad representative for more information.

**NOTE:** Stryker equipment that is compatible with Sterrad systems is listed on the Sterrad Sterility Guide website.

- 100NX System Standard Cycle
- NX System Standard Cycle
- 200 System Short Cycle
- 100S System Short Cycle
- 50 System

## 9.0 Handpiece and Attachment Sterilization (continued)



### WARNINGS:

- ALWAYS remove the lid from the sterilization tray during immediate-use steam sterilization.
- ALWAYS make sure handpiece and attachment lumens remain in a vertical orientation during immediate-use steam sterilization.

**CAUTION:** Stryker does not recommend immediate-use steam sterilization for routine sterilization of surgical instruments. Immediate-use steam sterilization should only be used when individual surgical instruments require immediate sterilization and use.

### VALIDATED<sup>1</sup> STEAM STERILIZATION CYCLE PARAMETERS<sup>2</sup>: HANDPIECES AND ATTACHMENTS

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Minimum Dry Time
Unwrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	No dry time
		134 °C [273 °F]	3 minutes	No dry time
	Gravity	132 °C [270 °F]	10 minutes	No dry time

<sup>1</sup> Validation is based on the AAMI protocol.

<sup>2</sup> Sterilization parameters for Australia/New Zealand per AS/NZS 4187-2003.  
Sterilization parameters for Netherlands per Field Standard for Loaner Instruments, Revision 03.02, April 2008.  
Sterilization parameters for Europe and the United Kingdom per EN ISO 17664.  
Sterilization parameters for Canada per CSA ISO 17664.

## 10.0 Battery Pack Sterilization



### WARNINGS:

- Sterilize the equipment as indicated before first and every use.
- Prior to sterilization, remove the battery pack from the handpiece.
- Use the sterilization methods as indicated in these instructions or the instructions for use and/or care instructions manual supplied with the equipment. Using other sterilization methods may prevent proper sterilization of the equipment and/or damage the equipment.
- Follow the recommended dry times to prevent moisture from accumulating inside the equipment. Moisture may cause the equipment to corrode and prevent proper sterilization.
- After sterilization, allow the equipment to cool to room temperature prior to use. Failure to comply may result in burned patient tissue or healthcare staff, and/or damage to the equipment.

### CAUTIONS:

- These sterilization instructions are not appropriate for Stryker handpieces and attachments. See the *9.0 Handpiece and Attachment Sterilization* section for information on how to properly sterilize handpieces and attachments.
- ALWAYS make sure the equipment is completely dry before sterilization.
- Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per AAMI TIR 34.
- DO NOT sterilize a battery pack if damage is apparent (cracks or other damage).
- DO NOT sterilize a battery pack that is not intended to be sterilized, such as an aseptic battery pack, where only the outer housing is intended to be sterilized.

## 10.0 Battery Pack Sterilization (continued)

### CAUTIONS:

- DO NOT leave battery packs in a hot sterilizer for more than the prescribed time as this will shorten battery pack life. If possible, open the sterilizer door and remove the battery packs when the cycle completes to prevent extended exposure to elevated temperatures.
- If the sterilizer requires a dry time setting, ALWAYS use the minimum time allowed by the sterilizer. Failure to comply will shorten battery pack life.
- After sterilization, ALWAYS allow battery packs to cool for at least one hour before recharging. Failure to comply may result in damage and a shortened battery pack life.
- Dry battery packs before placing them in the charger to avoid damage to the battery packs and charger.

### NOTES:

- Steam sterilization (moist heat) is recommended. Stryker has validated several autoclave cycles for the sterilization of this equipment. However, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should verify the process they use, employing the actual equipment and operators that routinely process the equipment.
- The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods and/or various loading configurations.



## 10.0 Battery Pack Sterilization (continued)

To obtain optimum performance, perform one of the following sterilization cycles validated by Stryker:

### VALIDATED<sup>1</sup> STEAM STERILIZATION CYCLE PARAMETERS<sup>2</sup>: BATTERY PACKS

Wrapping Method	Cycle	Sterilization Temp.	Min. Exposure Time	Max. Exposure Time	Min. Dry Time
Wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	No dry time
		134 °C [273 °F]	3 minutes	5 minutes	No dry time
Unwrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	No dry time
	Gravity	132 °C [270 °F]	3 minutes	5 minutes	No dry time
(Riley) FlashPak	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	5 minutes	5 minutes	No dry time
	Gravity	132 °C [270 °F]	5 minutes	5 minutes	No dry time

<sup>1</sup> Validation is based on the AAMI protocol.

<sup>2</sup> Sterilization parameters for Australia/New Zealand per AS/NZS 4187-2003.  
Sterilization parameters for Netherlands per Field Standard for Loaner Instruments, Revision 03.02, April 2008.  
Sterilization parameters for Europe and the United Kingdom per EN ISO 17664.  
Sterilization parameters for Canada per CSA ISO 17664.

## 10.0 Battery Pack Sterilization (continued)

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### STERRAD GAS PLASMA: BATTERY PACKS

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Follow the sterilization instructions provided by Sterrad. Contact your Sterrad representative for more information.

**NOTE:** Stryker equipment that is compatible with Sterrad systems is listed on the Sterrad Sterility Guide website.

- 100NX System Standard and Express Cycles
- NX System Standard Cycle
- 200 System Short Cycle
- 100S System Short Cycle
- 50 System

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### STERIS AMSCO V-PRO: BATTERY PACKS

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Follow the sterilization instructions provided by Steris. Contact your Steris representative for more information.

- Steris Amsco V-PRO 1 Cycle
- Steris Amsco V-PRO 1 Plus Lumen Cycle
- Steris Amsco V-PRO 1 Plus Non-lumen Cycle
- Steris Amsco V-PRO maX Lumen Cycle
- Steris Amsco V-PRO maX Non-lumen Cycle
- Steris Amsco V-PRO maX Flexible Cycle

## 11.0 Storage and Handling

### 11.1 Sterile Equipment



#### WARNINGS:

- ALWAYS transport wrapped equipment with care to prevent damaging the sterile barrier.
- ALWAYS store wrapped, processed equipment in a controlled environment and avoid extremes in temperature and moisture.
- Excessive handling of wrapped equipment will increase the likelihood of damaging the sterile barrier and may lead to contamination.

**NOTE:** See the instructions for use supplied with the sterilization wrap for maximum shelf-life information.

### 11.2 Non-sterile Equipment

**CAUTION:** ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section of the instructions for use supplied with the equipment.

To ensure longevity, performance, and safety, use of the original packaging materials is recommended when storing or transporting this equipment.

## Disposal/Recycle



### WARNINGS:

- ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.
- ALWAYS follow the current local regulations governing the safe handling and disposal of sharps.
- ALWAYS follow the current local regulations governing biohazard waste to safely handle and dispose of surgical waste.

To comply with Batteries Directive 2006/66/EC, battery packs have been designed to be recycled by the end user as a complete unit. Disassembly is not required. Infected battery packs must be decontaminated before they are sent for recycling.

ES/DE/FR/IT/NL 5400-001-710

JA/ZH/KO 5400-001-721

SV/DA/FI/PT/NO 5400-001-731

PL/EL 5400-001-752



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