

[®]
stryker

Heavy Duty

**Battery Powered
and Electric
Heavy Duty Systems**

Processing Instructions

R_x ONLY

ENGLISH (EN)

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Introduction

This processing instructions manual contains information intended to ensure the safe, effective, and compliant sterile processing of your product.

Processing equipment, operators, cleaning agents, 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.

NOTE: The user/processor should comply with local laws and ordinances in countries where processing requirements are more stringent than those detailed in these instructions.

Audience

This manual is intended for in-service trainers, biomedical equipment technicians, and central supply/sterile processing technicians. Keep and consult this reference manual during the life of the product.

Conventions

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.

Contact Information

For additional information, including safety information, in-service training, or current literature, contact your Stryker sales representative or call Stryker customer service at 1-269-323-7700 or 1-800-253-3210. Outside the US, contact your nearest Stryker subsidiary.

Intellectual Property

Trademarks not the property of Stryker Corporation are the property of their respective owners.

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
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General warning sign

Description

This comprehensive reference provides processing instructions and recommendations for Stryker Heavy Duty Systems (Battery Powered and Electric) components and equipment, including battery packs and aseptic battery housings.

Safety Directives



WARNINGS:

- Before processing this equipment, read and understand the processing instructions. Pay particular attention to safety information.
 - Only individuals trained and experienced in the processing of reusable medical devices should process this equipment.
 - DO NOT reuse, reprocess, or repackage a device that is intended for single use only.
 - A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
 - Design features may make cleaning difficult.
 - Reuse may create a contamination risk and compromise structural integrity resulting in operational failure or fragmentation during use.
 - Critical product information may be lost during repackaging.
- Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

Limitations of Processing

Repeated processing has a minimal effect on this equipment. See the *Inspection* section for additional guidance on evaluating device functionality.

Preparation for Cleaning

Equipment and Materials



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

The following equipment is required to process devices per the instructions in this manual:

- Warm water (See the *Water Quality* section.)
- Prepared, specially formulated cleaning agents (See the *Cleaning Agents* section.)
- Absorbent wipes
- Soft, nonlinting cloth
- Syringe
- Non-abrasive, soft, flexible, synthetic bristle brushes
- Washer-disinfector (complies with ISO 15883 series)
- Cleaning agents as required by the washer-disinfector manufacturer
- Instrument air¹ < 140 kPa [< 20 psi]
- Oven

¹ Instrument air is medical gas that falls under the general requirements for medical gases as defined by the National Fire Protection Association (NFPA) Health Care Facilities Code, is not respired, is compliant with the American National Standards Institute (ANSI)/International Society of Automation (ISA) Quality Standard for Instrument Air, and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °C [-40 °F].

Accessories

The following optional equipment may be purchased to aid in processing:

DESCRIPTION	REF
Light Mineral Oil	1605-010-000
Blu62® Pretreatment Foam	3000-00X-000 series
Blu62 Instrument Detergent	3000-00X-000 series
Cordless Driver Sterilization Container	4100-451-000
Cordless Driver Sterilization Cases	4X00-465-000 series
Cordless Driver Aseptic Battery Kit Sterilization Cases	422X-450-000 series
Sports Medicine/Small Bone Trauma (SMT) Sterilization Case	4300-452-000
Battery Powered Micro (BPM) Sterilization Case	4300-462-000
Cordless Driver 4/Sabo®2 Insert Trays	4405-45X-0X0 series
Trauma Insert Tray	4405-451-010
Trauma 3 Handpiece Insert Tray	4607-454-010
System 6 Sterilization Cases	6102-45X-000 series
EZout® Insert Tray	7102-459-010
Insert Trays and Sterilization Cases	7102-45X-0X0 series 7102-55X-0X0 series
Aesculap Rigid Sterilization Containers and Accessories	7102-XXX-XXX series
Hybrid Insert Tray	1900-375-010

NOTE: For a complete list of components or ordering information, contact your Stryker sales representative or call Stryker customer service. See the *Contact Information* section. Outside the US, contact your nearest Stryker subsidiary.

Water Quality



WARNING: Use the appropriate water quality for each stage of the cleaning process. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.

- Use utility water for flushing, washing, and rinsing the equipment. Utility water is water that comes from the tap.
- Use potable water for diluting cleaning agents. Potable water is water that is treated and delivered in a manner so that it meets United States (US) Environmental Protection Agency (EPA) or local guidelines as suitable for drinking.
- Use critical water for final rinsing of the equipment prior to sterilization. Critical water is water that is extensively treated usually by a multistep treatment process that could include a carbon bed, softening, deionization, and reverse osmosis or distillation to ensure that the microorganisms and the inorganic and organic material are removed from the water. A final submicron filtration could also be part of the treatment process.

CAUTION: Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per Association for the Advancement of Medical Instrumentation (AAMI) TIR 34.

Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F] is recommended for manual cleaning. The water should not exceed 60 °C [140 °F] and should be warm to the touch.

Cleaning Agents



WARNINGS:

- To clean the equipment, use specifically formulated cleaning agents only.
- Read, understand, and follow the indications, instructions, and safety information supplied with the cleaning agent for correct handling and use of the product.

CAUTIONS:

- Alkaline agents may be used to clean instruments in countries where required by law or local ordinances, or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. It is critical that alkaline cleaning agents are thoroughly neutralized and completely rinsed from devices.
- ALWAYS prepare the cleaning agent according to the manufacturer's recommendations. Pay particular attention to the concentration used and the total dispersion.
- To clean the equipment, a neutral cleaning agent is preferred.
- An alkaline cleaning agent (neat, up to pH 11) is allowable, but not preferred. Alkaline cleaning agents may cause cosmetic damage or reduce the life of the product.
- If a washer-disinfector is used, make sure the cleaning agent used is suitable for use in a washer-disinfector.
- ALWAYS use a cleaning agent that is suitable for use on aluminum, stainless steel, plastic, rubber, and titanium surfaces.

Stryker validated the manual and automated (washer-disinfector) cleaning processes using the following cleaning agents:

Supplier	Product	Suitability	Process
Stryker	Blu62 Instrument Detergent	All materials	Manual Cleaning
Steris	Prolystica 2x Concentrate Enzymatic	Aluminum, stainless steel, soft metals, and plastics	Automated Cleaning
	Prolystica 2x Concentrate Neutral		

Prepare the cleaning agent according to the manufacturer's recommendations.

Point of Use (Post-Surgery)

CAUTIONS:

- Dry, soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to processing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- DO NOT use saline to wet or soak the equipment before transport to the decontamination processing area.
- Pretreatment foam will minimize the drying of soil and facilitate later processing. DO NOT allow pretreatment foam to dry on the equipment.

1. Separate reusable equipment from disposable waste.
2. Discard waste into an appropriate container; use a puncture-resistant container for sharps. See the *Disposal/Recycle* section.
3. Use absorbent wipes to remove gross soil from the equipment.
4. If transport to the decontamination processing area is delayed, cover the equipment with a damp cloth or spray the equipment with a pretreatment foam as often as necessary to maintain moisture.

Transport to Decontamination 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.

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

Cleaning

NOTE: These cleaning instructions are appropriate for handpieces, attachments, battery packs, cords, aseptic battery housings, sterilization cases, EZout accessories, and non-sterile single use cutting accessories (e.g., K-wires). To properly clean a console, see the instructions for use supplied with the console.

**WARNINGS:**

- Clean the equipment as indicated before first and every use. Use the cleaning methods as indicated in these instructions. Other cleaning methods may prevent proper sterilization of the equipment.
- Prior to cleaning, separate all detachable components and remove single use cutting accessories from the handpieces. Detachable components include attachments, battery packs, and cords. Remove non-sterile batteries from the aseptic housings.

CAUTIONS:

- ALWAYS handle the equipment with care. DO NOT drop the equipment.
- DO NOT use solvents, lubricants, rinse aids, or other chemicals, unless otherwise specified.
- DO NOT use ultrasonic cleaning equipment.
- DO NOT immerse or soak any equipment, including non-sterile batteries, in liquid unless otherwise specified. Equipment may be placed briefly under running water to ensure thorough wetting and contact with liquid while actuating moving parts.
- DO NOT allow moisture or liquid to enter electrical plugs, receptacles, or openings. Moisture or liquid may cause corrosion and damage the equipment.
- DO NOT allow fluid to remain inside the recesses of the aseptic housing.

- DO NOT use pipe cleaners or cotton swabs to clean lumens or connector receptacles.
- DO NOT bend connector pins during cleaning.
- ALWAYS make sure the prepared cleaning agent is completely rinsed from the interior and exterior of the equipment before drying the equipment.
- Use of instrument air is only recommended for drying of equipment.

NOTES:

- 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. Select the desired cleaning method per facility protocol.
- Automated cleaning may reduce the useful life of battery packs. Manual cleaning per these instructions is preferred.

Manual Cleaning

1. Remove the lid and insert tray(s) from the base of the sterilization case.
2. Remove all soiled medical devices from the insert tray(s) and base.
3. Wipe all soil from the external surfaces of the aseptic housing. Unlock the aseptic housing, and remove the non-sterile battery from the aseptic housing. Set aside the non-sterile battery.

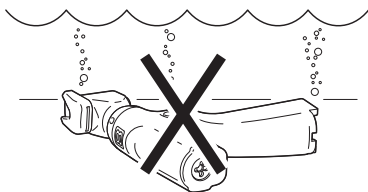
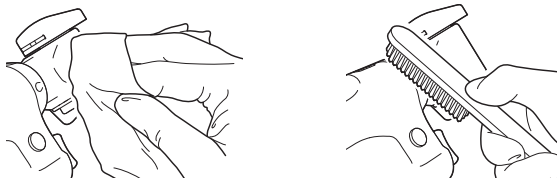
NOTE: The non-sterile battery may be wiped with a clean, dry cloth. Do not rinse, spray, or wipe the non-sterile battery with a saturated cloth.

4. Remove all traces of pretreatment foam and any remaining gross soil from the equipment using absorbent wipes or a soft, nonlinting cloth moistened with the prepared cleaning agent. Devices may be placed briefly under running water or flushed with a water-filled syringe to assist in the removal of gross soil.
5. Thoroughly clean the equipment.
 - Use suitable brushes and the prepared cleaning agent to clean all surfaces. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from brushing.
 - Use soft brushes of appropriate diameters to clean the entire length of each lumen. For dead-ended lumens, use light pressure and do not force the brush any farther after you feel resistance.
 - Use a syringe filled with the prepared cleaning agent to flush difficult-to-reach areas. For the universal collet, flush the lumen from the back of the collet.
 - Actuate all moving parts to clean hidden surfaces. Actuate all holding, clamping, and latching mechanisms on sterilization cases, lids, and insert trays.

NOTES:

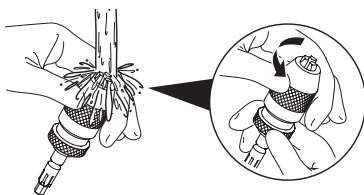
- See the *Special Cleaning Considerations Table* (Appendix A) for critical areas and brush sizes.
- (For System 8 handpieces only): System 8 handpieces may be held under the surface of the prepared cleaning agent during manual cleaning. Do not soak any equipment.

CLEAN THE EQUIPMENT



6. Thoroughly rinse the equipment with warm, running water until all traces of cleaning agent are removed.
- For equipment with lumens, hold the equipment on an incline, distal end pointing up, and rinse the lumen.
 - For dead-ended lumens, once the water comes back out of the equipment, immediately point the distal end of the equipment down to allow the water to drain out. Repeat this step one or two more times until the water draining from the equipment is clear.
 - For all other equipment, hold the equipment on an incline, distal end pointing down.

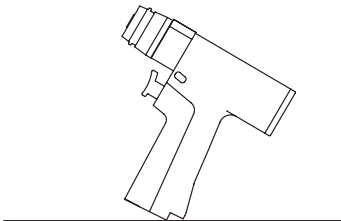
RINSE THE EQUIPMENT



- Pay particular attention to rough surfaces, lumens, hinges, blind holes, battery contacts, and joints between mating parts.
- Actuate all moving parts to rinse hidden surfaces. For sterilization cases and insert trays, actuate all holding, clamping, and latching mechanisms.

NOTE: A final rinse of the equipment using critical water is recommended.

7. (For System 6 handpieces only): If water leaks into the handpiece, tip the handpiece back as shown to allow drainage from the small opening in the battery pack contact area.



8. Visually inspect the equipment for any remaining soil or cleaning agent. If soil or cleaning agent remains, repeat the cleaning procedure using freshly prepared cleaning agent.
9. Allow the equipment to drain on absorbent wipes. If possible, orient the equipment vertically to assist in drainage.
10. After manual cleaning, dry the equipment immediately (see the *Drying* section), or proceed with step 2 in the *Automated Cleaning* section.

Automated Cleaning

CAUTIONS:

- Automated cleaning may reduce the useful life of battery packs. Manual cleaning is preferred. See the *Manual Cleaning* section.
 - ALWAYS ensure the aseptic housing lid stays open during automated cleaning.
 - DO NOT immerse or sterilize non-sterile batteries.
1. Perform the following pre-cleaning steps:
 - Remove the equipment from the insert trays.
 - Remove all visible soil from the equipment using the prepared cleaning agent. Pay particular attention to lumens and moving parts, using brushes as necessary.
 - Rinse the equipment to remove all excess cleaning agent.



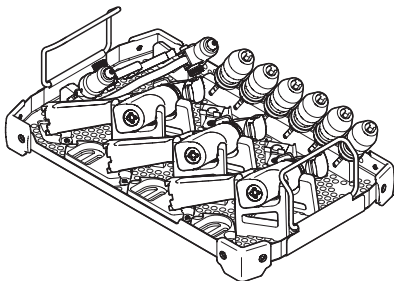
WARNINGS:

- ALWAYS load the equipment carefully to prevent movement that may inhibit proper cleaning during the automated washer-disinfector cycle.
- Only System 7 (7102-45X-0X0), Cordless Driver 4 (4405-45X-0X0), EZout (7102-459-010), and Trauma 3 Handpiece (4607-454-010) insert trays may be used to hold equipment in the washer-disinfector (see the *Accessories* section). All other insert trays and sterilization cases are for use with the sterilization process only and must be washed separately.
- When using the Trauma Insert Tray, the Hybrid Insert Tray, or the Trauma 3 Handpiece Insert Tray during automated washing, be sure the top and bottom trays are separated when placed in the washer-disinfector to ensure products receive adequate exposure to the washer-disinfector cycle.

- ALWAYS separate the sterilization tray components before loading into the washer-disinfector. Load each tray component separately.

NOTE: The equipment illustrated is representational only and may not reflect the actual configuration. See the instructions for use supplied with the insert tray for device-specific loading configurations.

2. Load the equipment into the washer-disinfector in an appropriate insert tray (see the *Accessories* section).
 - Avoid contact between components.
 - Orient the handpieces vertically or at an angle to assist in drainage.
 - Place moving parts in the open position.

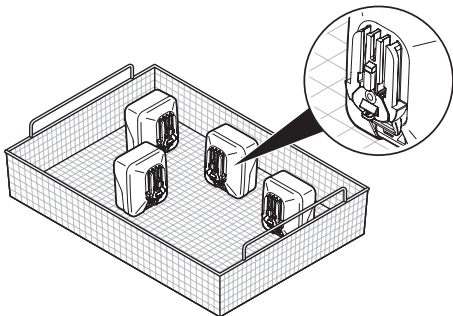


Example tray loading configuration for System 7/System 8

CAUTION: Placing handpieces horizontally in a wire basket or similar holder may increase the potential for trapped moisture.

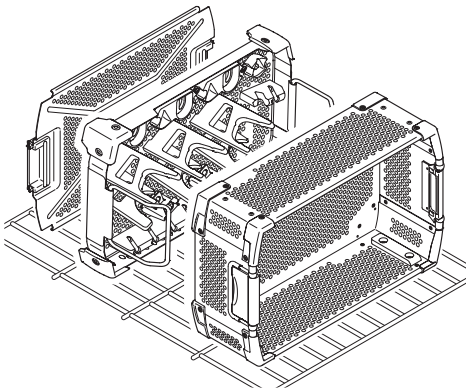
- Orient battery packs on their sides with the battery latches pointing down.

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



Example basket loading configuration for battery packs

- When cleaning an empty insert tray or sterilization case, orient the equipment vertically to assist in drainage.



Example loading configuration for empty sterilization case and insert tray

CAUTIONS:

- DO NOT use any type of lubricant or rinse aid in the automated washer-disinfector. Lubricants and rinse aids are not required and may leave residue on the equipment after cleaning.
- ALWAYS select the lowest possible spray pressure setting when cleaning battery packs in a washer-disinfector. Use a gentle or low impingement setting to prevent damage.
- DO NOT use the dry phase when cleaning battery packs in an automated washer-disinfector. The dry phase will shorten the life of the battery packs. Devices that require a dry phase should be processed separately from the battery packs. If the dry phase must be used, consider an aseptic battery system as an alternative to sterile battery packs.

3. Operate the washer-disinfector. Use the following validated phase parameters as required:

Phase	Time	Water Temperature	Cleaning Agent
Pre-rinse	2 to 4 minutes	< 21 °C [< 70 °F]	Prepared cleaning agent (optional)
Wash ^{1,2}	2 to 4 minutes	60 to 82 °C [140 to 180 °F]	Prepared cleaning agent
Rinse	2 to 4 minutes	43 to 82 °C [110 to 180 °F]	–
Thermal Rinse ^{3,4}	1 minute	90 °C [194 °F]	–
Dry ^{5,6}	15 minutes	–	–

¹ Wash may include enzymatic wash.

² Alkaline cleaning agents may reduce the useful life of battery packs.

³ Thermal rinse is optional. Thermal rinse does not replace sterilization. A thermal rinse phase may be used for up to 5 minutes at a water temperature of not more than 95 °C.

⁴ Thermal rinse may reduce the useful life of battery packs.

⁵ DO NOT use the drying phase for battery packs.

⁶ A temperature of up to 120 °C (248 °F) may be used during the dry phase.

4. Unload the washer-disinfector and visually inspect the equipment for remaining soil or cleaning agent. If soil or cleaning agent remains, repeat the automated cleaning procedure using freshly prepared cleaning agent.
5. Allow the equipment to drain on absorbent wipes. If possible, orient the equipment vertically to assist in drainage.
6. After automated cleaning, dry the equipment immediately (see the *Drying* section).

Disinfection (optional)

Disinfection processes do not ensure the margin of safety associated with sterilization processes. Therefore, disinfection is optional. See the *Automated Cleaning* section and information related to the thermal rinse phase.

Drying

CAUTION: DO NOT dry battery packs in an oven. Drying battery contacts with instrument air is recommended. Residual moisture from cleaning may lead to oxidation of the contacts.

1. Dry the equipment with a soft, nonlinting cloth or instrument air, or by heating the equipment in an oven below 110 °C [230 °F].
2. After drying, inspect and charge battery packs as required. See the instructions for use supplied with the battery pack.
3. After drying, inspect the equipment immediately (see the *Inspection* section).

Inspection



WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect this equipment.
- Perform recommended inspection as indicated in these instructions.
- DO NOT disassemble, modify, or service this equipment, unless otherwise specified.

NOTES:

- If the equipment fails to meet the inspection criteria, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.
- 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 inspection is the best method for determining the serviceable life span of the equipment.

Visual Inspection

Visually inspect the equipment before sterilization and as described in the *Inspection Table* (Appendix B). 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

Lubrication



WARNING: DO NOT lubricate handpieces unless otherwise directed. Handpieces are permanently lubricated. Additional lubrication may cause handpieces to overheat or leak fluid into the surgical site.

Perform the lubrication instructions as described in the *Lubrication Table* (Appendix C).

Preparation for Sterilization



WARNINGS:

- DO NOT sterilize any equipment if damage is apparent or the inspection criteria are not met. See the *Inspection* section.
- ALWAYS use a chemical indicator within every sterilization load to make sure the proper sterilization conditions of time, temperature, and saturated steam or hydrogen peroxide are achieved.
- ALWAYS use new sterilization wrap to enclose the equipment. Do not reuse sterilization wrap.
- DO NOT allow any part of a device to be pinched between the sterilization case and the lid when loaded.
- Prior to sterilization, separate all detachable components and remove all single use cutting accessories from the handpieces. Detachable components include attachments, battery packs, and cords.
- If a single use cutting accessory is still attached to the handpiece after cleaning, properly dispose of the cutting accessory and reclean the handpiece. See the *Cleaning* section.

CAUTION: ALWAYS make sure the equipment is clean and completely dry before sterilization.

Equipment and Materials

- Aesculap Rigid Sterilization Container (See the *Accessories* section.)
- Sterilization wrap, grade 600 or lower
- Chemical indicators
- Sterilizer (complies with ISO 17665-1 or ISO 14937)

NOTES:

- Use a sterilizer, sterilization wrap, and rigid sterilization container that are cleared by an applicable regulatory body and that are labeled for use with the specified and validated sterilization parameters.
- The sterilization barrier system (sterilization wrap or rigid sterilization container) will maintain the sterility of the equipment after exposure.

Loading and Packaging

WARNING: ALWAYS follow local, national, or regional guidelines for appropriate sterilization wrapping configurations and chemical indicator placement.

Equipment may be wrapped individually using suitable sterilization wrap, or the equipment may be loaded together as follows:

1. Load the equipment into an appropriate insert tray (see the *Accessories* section).
2. Place the insert tray(s) loaded with devices into the base of the sterilization case or rigid container, and place the chemical indicator(s).
3. Install the lid of the sterilization case or rigid container, and close the latches to secure the lid to the base.
4. Enclose the sterilization case using suitable sterilization wrap.

Stacking and Constraints



WARNINGS:

- DO NOT stack multiple sterilization cases during sterile processing. Stacking multiple cases may damage the sterile barrier provided by the sterilization wrap.
- ALWAYS stack non-sterile cases in a safe and secure manner.
- DO NOT stack wrapped or unwrapped cases during transport.

Sterilization

NOTE: These sterilization instructions are appropriate for handpieces, attachments, battery packs, cords, aseptic battery housings, sterilization cases, EZout accessories, and non-sterile single use cutting accessories (e.g., K-wires).



WARNINGS:

- Sterilize the equipment as indicated before first and every use.
- Use the sterilization methods as indicated in these instructions. 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 and/or damage the equipment.
- After sterilization, allow the equipment to cool to room temperature prior to use. Failure to comply may result in a burn injury and/or damage to the equipment.

CAUTIONS:

- Sterilize only the recommended device types within the sterilization case.
- Prior to sterilization, ensure all non-sterile batteries are removed from the aseptic housings. DO NOT sterilize non-sterile batteries.
- ALWAYS ensure the aseptic housing lid remains open during sterilization.
- DO NOT sterilize a battery pack if damage is apparent (cracks or other damage).
- DO NOT sterilize the console.

NOTES:

- Stryker has validated several sterilization cycles for the sterilization of this equipment. However, sterilizer 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.
- If wet trays or equipment are discovered after sterilization, a change in the product load configuration or a longer dry time may be necessary. See *Extended Dry Time Table* (Appendix D) for configurations known to require longer dry times.
- Validation is based on the AAMI protocol.
- International sterilization parameters are per the following standards:
 - Australia/New Zealand per AS/NZS 4187
 - Europe and the United Kingdom per EN ISO 17664
 - Canada per CSA ISO 17664

Handpieces and Accessories

CAUTION: These instructions are not appropriate for battery packs. See the appropriate *Battery Packs* sterilization section to properly sterilize battery packs.

NOTE: These sterilization instructions are appropriate for handpieces, attachments, cords, aseptic battery housings, sterilization cases, EZout accessories, and non-sterile single use cutting accessories (e.g., K-wires).

Steam Sterilization

NOTE: Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.

Perform one of the following validated steam sterilization cycles:

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Minimum Dry Time
Double Wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	30 minutes ⁴
		134 °C ^{1,2} [273 °F]	3 minutes ³	30 minutes ⁴
Aesculap Rigid Container	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	30 minutes
		134 °C ^{1,2} [273 °F]	3 minutes ³	30 minutes

¹ Sterilization temperature may be extended to 137° C.

² This cycle is for use outside the United States.

³ Minimum exposure time may be extended to 18 minutes.

⁴ Minimum dry time may be extended for certain configurations. See *Extended Dry Time Table* (Appendix D).

Immediate-Use Steam Sterilization



WARNINGS:

- DO NOT place equipment into an insert tray, sterilization case, or sterilization container for immediate-use steam sterilization.
- After cooling to room temperature, ALWAYS immediately use equipment sterilized by immediate-use steam sterilization. Sterility assurance cannot be maintained for unwrapped equipment.

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

Perform one of the following validated steam sterilization cycles:

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 ^{1,2} [273 °F]	3 minutes	No dry time
	Gravity	132 °C [270 °F]	10 minutes	No dry time

¹ Sterilization temperature may be extended to 137° C.

² This cycle is for use outside the United States.

Sterrad Gas Plasma Sterilization

Stryker equipment that is compatible with Sterrad systems is listed on the Sterrad Sterility Guide. Follow the sterilization instructions provided by Sterrad. Contact your Sterrad representative for more information.

Steris Vaporized Hydrogen Peroxide Sterilization

Stryker equipment that is compatible with Steris systems is listed on the Steris Device Compatibility Matrix. Follow the sterilization instructions provided by Steris. Contact your Steris representative for more information.

Battery Packs

NOTE: See the *System 8 Battery Packs* section for sterilization parameters specific to the System 8 battery packs (REF 821X-000-000 series).

CAUTIONS:

- These instructions are not appropriate for handpieces and accessories. See the *Handpieces and Accessories* sterilization section to properly sterilize handpieces and accessories.
- DO NOT sterilize non-sterile batteries used with aseptic housings.
- If the sterilizer requires a dry time setting, ALWAYS use the minimum time allowed by the sterilizer for battery packs.
- 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.
- In countries where law or local ordinance requires steam sterilization parameters outside those listed here, consider using an alternative process, such as low temperature sterilization (Sterrad Gas Plasma or Steris Vaporized Hydrogen Peroxide) or an aseptic battery system.

- If charging is required after sterilization, ALWAYS allow battery packs to cool for at least one hour.
- Dry battery packs before placing them in the charger.

Steam Sterilization (Battery Packs)

Perform one of the following validated steam sterilization cycles:

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Maximum Exposure Time	Dry Time
Double Wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	No dry time
		134 °C ¹ [273 °F]	3 minutes	4 minutes	No dry time
Un-wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	No dry time
		134 °C ¹ [273 °F]	3 minutes	4 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
Aesculap Rigid Container	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	No dry time

¹ This cycle is for use outside the United States.

Sterrad Gas Plasma Sterilization

Stryker equipment that is compatible with Sterrad systems is listed on the Sterrad Sterility Guide. Follow the sterilization instructions provided by Sterrad. Contact your Sterrad representative for more information.

Steris Vaporized Hydrogen Peroxide Sterilization

Stryker equipment that is compatible with Steris systems is listed on the Steris Device Compatibility Matrix. Follow the sterilization instructions provided by Steris. Contact your Steris representative for more information.

System 8 Battery Packs

CAUTIONS:

- These instructions are not appropriate for handpieces, accessories, or Stryker battery packs manufactured prior to System 8 (e.g., REF 721X-XX0-000 series and REF 621X-000-000 series).
 - See the *Handpieces and Accessories* sterilization section to properly sterilize handpieces and accessories.
 - See the *Battery Packs* sterilization section to properly sterilize pre-System 8 battery packs.
- 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.

- In countries where law or local ordinance requires steam sterilization parameters outside those listed here, consider using an alternative process, such as low temperature sterilization (Sterrad Gas Plasma or Steris Vaporized Hydrogen Peroxide) or an aseptic battery system.
- To prevent damage to the battery packs, DO NOT exceed the specified exposure time and/or dry time.
- To prevent wet packs, ALWAYS follow the specified dry time.
- If charging is required after sterilization, ALWAYS allow battery packs to cool for at least one hour.
- Dry battery packs before placing them in the charger.

Steam Sterilization (System 8 Battery Packs ONLY)

Perform one of the following validated steam sterilization cycles:

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Maximum Exposure Time	Minimum Dry Time	Maximum Dry Time
Double Wrapped	Dynamic Air Removal	132 °C [270 °F]	4 minutes	5 minutes	15 minutes ²	30 minutes
	(Pre-vacuum)	134 °C ¹ [273 °F]	3 minutes	4 minutes	15 minutes ²	30 minutes
Aesculap Rigid Container	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	5 minutes	30 minutes

¹ This cycle is for use outside the United States.

² A 15-minute dry time can only be achieved when running a single, wrapped battery alone through this cycle.

Immediate-Use Steam Sterilization (System 8 Battery Packs ONLY)



WARNINGS:

- DO NOT place equipment into a sterilization case or sterilization container for immediate-use steam sterilization.
- After cooling to room temperature, ALWAYS immediately use equipment sterilized by immediate-use steam sterilization. Sterility assurance cannot be maintained for unwrapped equipment.
- To prevent damage to the battery packs, DO NOT exceed the specified exposure time and/or dry time.

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

Perform one of the following validated steam sterilization cycles:

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Maximum Exposure Time	Dry Time
Un-wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	5 minutes	No dry time
		134 °C ¹ [273 °F]	3 minutes	4 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

¹ This cycle is for use outside the United States.

Sterrad Gas Plasma Sterilization

Stryker equipment that is compatible with Sterrad systems is listed on the Sterrad Sterility Guide. Follow the sterilization instructions provided by Sterrad. Contact your Sterrad representative for more information.

Steris Vaporized Hydrogen Peroxide Sterilization

Stryker equipment that is compatible with Steris systems is listed on the Steris Device Compatibility Matrix. Follow the sterilization instructions provided by Steris. Contact your Steris representative for more information.

Storage and Transportation

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 or rigid container for maximum shelf-life information.

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.

Disposal/Recycle



WARNINGS:

- 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.

- 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 decontaminate a battery pack exposed to infectious material before sending it to a waste treatment facility.



In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) as amended product should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling.



Collect batteries separately for recycling per European Community Batteries Directive.

The Batteries Directive 2006/66/EC introduces new requirements from September 2008 on removability of batteries from waste equipment in EU Member States. To comply with this Directive, this device has been designed for safe removal of the batteries at end-of-life by a waste treatment facility. Infected units should be decontaminated before they are sent for recycling. In the case that it is not possible to decontaminate the unit for recycling, the hospital should not attempt to remove the batteries from waste equipment. Continued disposal of small amounts of portable batteries to landfill and incineration is allowed under the Batteries Directive 2006/66/EC and Member State regulations.

Appendix A: Special Cleaning Considerations Table

HANDPIECES

Component	Moving Parts	Critical Areas	Brush Sizes
Single and Dual Trigger Rotary Handpieces	Yes	Function switch, shift collar, attachment collar, trigger(s), lumen, pin receptacle*	6 mm
Reciprocating Saw	Yes	Function switch, blade collar, trigger, lumen, pin receptacle*	0.75 mm, 2 mm, 3 mm
Sternum Saw	Yes	Function switch, guard collar, blade collar, trigger, lumen, pin receptacle*	0.75 mm, 2 mm, 3 mm
Sagittal Saw	Yes	Function switch, blade mount, blade mount lever, trigger, lumen, pin receptacle*	0.75 mm, 2 mm
Stryker Precision® Oscillating Tip Saw	Yes	Function switch, tabs, drive pins, post, cartridge mount lever, trigger, lumen, pin receptacle*	2 mm
Cordless Driver	Yes	Function switch, lumen, triggers, release button	6 mm
CD NXT™ Handpiece	Yes	Function switch, lumen, triggers, release button, twist collar	8 mm
Sabo Sagittal Saw	Yes	Trigger, blade mount	0.75 mm, 2 mm, 3 mm

HANDPIECES

Component	Moving Parts	Critical Areas	Brush Sizes
EZout Handpiece	Yes	Function switch, trigger, ball retainer, lumen	7.1 mm

*Pin receptacle applies to Electric System 6 only.

ATTACHMENTS AND ACCESSORIES

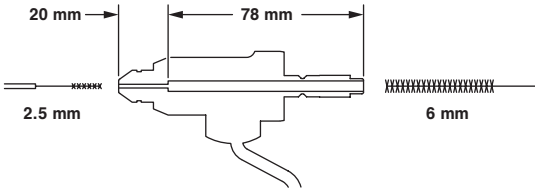
Component	Moving Parts	Critical Areas	Brush Sizes
Sternum Blade Guard	No	Foot	2 mm, 2.25 mm 2.5 mm
		Lumen	19 mm
Wire Collet	Yes	Nose, pre-adjust knob, lever axle, lumen	0.75 mm, 2.5 mm, 6 mm
Pin Collet/Large Collet	Yes	Nose, pre-adjust knob, lever axle, lumen	0.75 mm, 6 mm
1/4 inch Keyed Chuck (POWEReam™)	Yes	Jaws, lumen	0.75 mm, 2 mm, 3 mm
5/32 inch Keyed Chuck	Yes	Jaws, lumen	5 mm, 7 mm
Keyless Chuck	Yes	Jaws, lumen	5 mm, 7 mm
AO® Small Drill	Yes	Retaining collar, lumen	3.3 mm, 5 mm
Hudson®	Yes	Retaining collar, lumen	5 mm, 7 mm, 8 mm

ATTACHMENTS AND ACCESSORIES

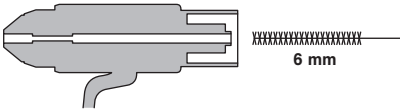
Component	Moving Parts	Critical Areas	Brush Sizes
Hudson/Modified Trinkle	Yes	Retaining collar, lumen	5 mm, 7 mm
Modified Trinkle	Yes	Retaining collar, lumen	5 mm, 7 mm, 8 mm
Trinkle	Yes	Retaining collar, lumen	5 mm, 7 mm
Triathlon®	Yes	Retaining collar, lumen	2 mm, 3 mm, 5 mm
AO Large Reamer	Yes	Retaining collar, lumen	5 mm, 7 mm, 10 mm, 13 mm
DHS/DCS Quick Lock	Yes	Retaining collar, lumen	5 mm, 7 mm, 8 mm
EZout Attachment	Yes	Handle, blade mount, pivots	1.19 mm, 4 mm
EZout Centering Plugs	Yes	Rotating sleeve	9.6 mm
EZout Blade Sizing Tools	No	Lumen	9.6 mm

NOTES:

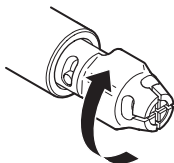
- When removing debris from a wire collet, gently insert a 2.5 mm brush approximately 20 mm deep inside of the nose. Use light pressure to remove debris. Insert a 6 mm brush approximately 78 mm into the back of the collet to clean the rest of the lumen.



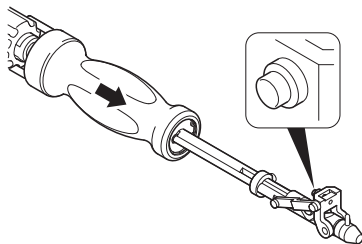
- When removing debris from a universal collet (REF 4500-12X-000 series), gently insert a brush (6.0 mm) into the back of the collet, and continue through the entire length of the lumen. **NOTE:** For the adjustable collet (REF 4500-126-000), set the pre-adjust knob to **L** (Large) before inserting the brush.



- When removing debris from a reciprocating saw or sternum saw, rotate the blade collar to access all surfaces.



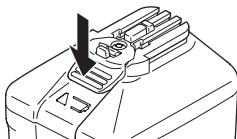
- When removing debris from the EZout Attachment (REF 7202-100-000), actuate the handle and the blade retention mechanism to access all surfaces.



BATTERY PACKS

Component	Moving Parts	Critical Areas	Brush Sizes
Battery Packs	Yes	Battery contacts	3.3 mm
		Screws	5 mm

NOTE: When removing debris from a battery pack, fully depress the battery latch to access all surfaces.

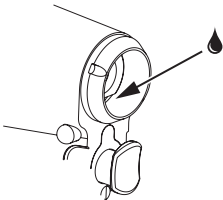


Appendix B: Inspection Table

COMPONENT	INTERVAL	ACTIVITY
Handpiece and Attachment	Before each use	Inspect, operate, and test the equipment to make sure it is working properly. Check all moving parts for free movement. Check for unusual sounds, vibrations and/or bur whip, and note the operating speed.
		Make sure there are no loose or missing components and no nicks, burs, or sharp protrusions that may cause injury or damage surgical gloves.
	Make sure that markings on the equipment are clearly legible.	
	3 Months	<p>NOTE: Applies to Cordless Driver 4 and Sabo2 Saw only.</p> <p>Operate the handpiece for one minute to determine temperature. Make sure the distal tip and/or body of the handpiece are not uncomfortably hot to the touch (approximately 43.3 °C [110 °F]).</p> <p>NOTE: The Cordless Driver handpiece should be checked with the Sagittal Saw attachment (REF 4100-400-000) per the duty cycle specified in the instructions for use supplied with the attachment.</p>

COMPONENT	INTERVAL	ACTIVITY
Cord	Before each use	Inspect for cuts or damage on the surface of the cord. Make sure there are no bent or missing connector pins.
Sterilization Case and Insert Tray	Before each use	Inspect the equipment for visible soil, damage, signs of wear, and/or corrosion.
		Make sure there are no loose or missing components, and no nicks, burs, or sharp protrusions that may cause injury, damage surgical gloves, or tear the packaging material and damage the sterile barrier.
		Test the equipment to ensure lid and base fit together properly, and handles and latches function properly.

Appendix C: Lubrication Table

COMPONENT	INTERVAL	ACTIVITY
Cordless Driver 3 and Attachments	As required	<p>If the operation of the chuck or keyless style attachments become stiff, apply Light Mineral Oil (REF 1605-010-000) to the jaws of the attachment. Wipe off excess oil.</p> <p>If the release button of the Cordless Driver handpiece becomes stiff, apply Light Mineral Oil to the handpiece as indicated. Wipe off excess oil.</p> 

Appendix D: Extended Dry Time Table

The following configurations require an extended minimum dry time when double wrapped for steam sterilization only:

DESCRIPTION	REF	MINIMUM DRY TIME
EZout Insert Tray	7102-459-010	40 minutes
SMT Sterilization Case	4300-452-000	45 minutes
BPM Sterilization Case	4300-462-000	45 minutes
Trauma Insert Tray	4405-451-010	75 minutes
System 6 Sternum Saw Case	6102-453-000	60 minutes
Cordless Driver Sterilization Case	4X00-465-000 series	65 minutes
Hybrid Insert Tray	1900-375-010	75 minutes
System 7 Aseptic Housing Insert Tray	7102-455-010	50 minutes
System 7 Aseptic 2 Handpiece Insert Tray	7102-458-010	50 minutes
Cordless Driver 4/Sabo2 Insert Tray	4405-452-010	50 minutes
Cordless Driver 4/Sabo2 1HP Insert Tray	4405-453-010	75 minutes
Trauma 3 Handpiece Insert Tray	4607-454-010	75 minutes

ES/DE/FR/IT/NL	7200-001-710
JA/ZH/KO	7200-001-720
SV/DA/FI/PT/NO	7200-001-730
PL/EL	7200-001-750
TR	7201-001-760
RU	7201-001-770



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