Processing Instructions

User/Patient Safety

WARNING
- 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.
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

WARNING
- 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.

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.

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Designation</th>
<th>Suitability</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stryker</td>
<td>ProClean Instrument Detergent</td>
<td>All materials</td>
<td>Manual Cleaning</td>
</tr>
<tr>
<td>Steris</td>
<td>Prolystica 2x Concentrate Enzymatic and Prolystica 2x Concentrate Neutral</td>
<td>Stainless steel, aluminum, soft metals, and plastics</td>
<td>Automated Cleaning</td>
</tr>
</tbody>
</table>

Validated Detergents
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 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.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.
- DO NOT use ultrasonic cleaning equipment.
- 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 bend connector pins during cleaning.
- DO NOT use pipe cleaners or cotton swabs to clean lumens.
- ALWAYS make sure the detergent solution is completely rinsed off before drying equipment.
- Use of compressed air is only recommended for drying of 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.
4.1.1 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 Instructions

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.

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.

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 5.0 Inspection and Testing.
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)

Instructions

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with 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 detergent solution.
4. Use soft brushes of appropriate diameters to clean lumens. If a lumen passes all the way through a device, make sure 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.
6. Rinse the equipment:
   - For the 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 on or two more times until the water draining from the attachment is clear.
   - Allow the equipment to drain on absorbent wipes or load the equipment into the washer-disinfector immediately.

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

7. Visually inspect the equipment for any remaining soil and repeat the cleaning steps if necessary.
8. Dry the equipment with medical-grade compressed air or by heating the equipment in an oven below 110°C (230°F).

**WARNING** 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 or System 7 insert tray, when removed from the sterilization tray, may be used to hold System 6 or System 7 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. Place any moving parts, such as chuck jaws, in the open position. Placing the equipment in a horizontal position is also acceptable.

**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.

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

11. On completion, unload the washer-disinfector.

12. Visually inspect the equipment for remaining soil. If soil remains, repeat the cleaning process.

13. Dry the equipment with medical-grade compressed air or by heating the equipment in an oven below 110°C (230°F).

14. After cleaning, inspect and test the equipment immediately. See 5.0 Inspection and Testing.

**VALIDATED AUTOMATED WASHER-DISINFECTOR CYCLE PARAMETERS**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time</th>
<th>Water Temp.</th>
<th>Detergent Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Rinse</td>
<td>2 to 4 minutes</td>
<td>&lt;21°C (&lt;70°F)</td>
<td>Prepared detergent*</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>2 to 4 minutes</td>
<td>43 to 66°C (110 to 150°F)</td>
<td>Prepared enzymatic detergent</td>
</tr>
<tr>
<td>Wash</td>
<td>2 to 4 minutes</td>
<td>60 to 82°C (140 to 180°F)</td>
<td>Prepared detergent</td>
</tr>
<tr>
<td>Rinse</td>
<td>2 to 4 minutes</td>
<td>43 to 82°C (110 to 180°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry Time</td>
<td>15 minutes</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Detergent may be omitted at the pre-rinse stage if the washer-disinfector equipment does not have this capability.
5.0 Inspection and Testing

WARNING: 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.

5.1 Limitations of Processing

Repeated processing has a minimal effect on this equipment. See the 5.2 Visual Inspection and 5.3 Functional Inspection sections for additional guidance on evaluating device functionality.

5.2 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

5.3 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.

6.0 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.

7.0 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.

8.0 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.
- 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.
Sterilization Parameters

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, a minimum dry time of 20 minutes for pre-vacuum cycles, and 15 to 30 minutes for gravity cycles is 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.

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

<table>
<thead>
<tr>
<th>Wrapping Method</th>
<th>Cycle</th>
<th>Sterilization Temp.</th>
<th>Minimum Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped</td>
<td>Dynamic Air Removal (Pre-vacuum)</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>134°C (273°F)</td>
<td>3 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

1 Validation is based on the AAMI protocol.
2 Sterilization parameters for Australia/New Zealand per AS/NZS 4187-2003.
3 Minimum exposure time may be extended to 18 minutes.

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.
### Sterilization Parameters

#### VALIDATED STEAM STERILIZATION CYCLE PARAMETERS

<table>
<thead>
<tr>
<th>Wrapping Method</th>
<th>Cycle</th>
<th>Sterilization Temp.</th>
<th>Minimum Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwrapped</td>
<td>Dynamic Air Removal (Pre-vacuum)</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>No dry time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>134°C (273°F)</td>
<td>3 minutes</td>
<td>No dry time</td>
</tr>
<tr>
<td></td>
<td>Gravity</td>
<td>132°C (270°F)</td>
<td>10 minutes</td>
<td>No dry time</td>
</tr>
</tbody>
</table>

1 Validation is based on the AAMI protocol.
2 Sterilization parameters for Australia/New Zealand per AS/NZS 4187-2003.
Sterilization parameters for Netherlands per Field Standard for Lo aner 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.

### 9.0 Storage and Handling

#### 9.1 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.

### Disposal/Recycle

**WARNINGS**
- ALWAYS follow 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.

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