Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices
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1. Introduction

This document is intended to provide detailed instructions for processing reusable surgical instruments manufactured by Stryker Orthopaedics. All Stryker Orthopaedics reusable instruments must be cleaned and sterilized to prepare them for use. This document also gives instructions for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

This document provides assembly and disassembly instructions for multi-component instruments which must be disassembled prior to cleaning and sterilization.

Stryker Orthopaedics has validated the processes provided in these instructions to be capable of being effective. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing. The healthcare facility should ensure that the selected processing steps are safe and effective.

Alternative methods of processing outside the scope of this document may be suitable for reprocessing; however, these must be validated by the end user. In the event of conflicting national cleaning and sterilization requirements, these shall prevail over Stryker Orthopaedics recommendations.

Warnings and Precautions

 ☢ Single use devices should not be reused, as they are not designed to perform as intended after the initial use, unless they are reprocessed by a reprocesseor expressly authorized by stryker. Only then can it be assured that the device is appropriate for reprocessing, and that the correct method and validation is used.

Some devices may develop changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization that may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label to identify single or multiple use devices and components.

Stryker Orthopaedics reusable instruments are not normally used in surgical procedures where they contact TSE infective tissue (Transmissible Spongiform Encephalopathies) as defined by the World Health Organization (WHO). Therefore decontamination procedures with highly aggressive agents [i.e. sodium hydroxide(NaOH) or sodium hypochloride (NaOCl)] are not necessary and, for normal processing, are not recommended because material degradation may occur. The sterilization parameters recommended in this document are not intended and not suitable for inactivation of prions.
The sequence of steps required to prepare re-usable instruments for re-use or to prepare new devices for initial use are summarized in the chart below. More detailed instructions for each step are given on the following pages.

2. Processing Instructions

- Point of Use
  - Remove gross soil

- Transport to Processing Area
  - Avoid damage
  - Minimize time before cleaning

- Preparation for Cleaning
  - Disassemble as required

Manual Pre-Cleaning
- Soak in enzymatic solution
- 15 minutes (minimum)
- Rinse using agitation under the water level

Manual Cleaning
- Soak in ultrasonic bath
- 20 minutes (minimum)
- Brush, Operate
- Rinse using agitation under the water level

Pre-Cleaning
- Soak in ultrasonic bath
- 20 minutes (minimum)
- Brush, operate
- Rinse using agitation under the water level

Washer Disinfector
- Wash
- 93°C (200°F)
- 10 minutes (minimum)
- Rinse
- Dry

Inspection
- Check soil “traps”
- Check operation
- Check straightness
- Check for damage

Sterilization
- Suitable packaging
- Steam sterilizer

Storage
- Control environment
- Control storage time
Two methods of cleaning Stryker Orthopaedics re-usable instruments are provided in these instructions, a manual method and a method using an automated washer disinfector. Whenever possible the automated method should be used. The automated cleaning process is more reproducible and, therefore, more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used.

Whichever method is used, staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.

For cleaning or disinfecting re-usable instruments, only specifically formulated cleaning agents and/or disinfectants should be used.

As not all cleaning agents and disinfectants may be available around the globe, Stryker Orthopaedics does not recommend any specific cleaning and/or disinfection agent.

The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing re-usable instruments should be carefully considered. Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes with less than 100 cfu/ml and 0.5 EU/ml is highly recommended. Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in staining of the device or prevent effective cleaning and decontamination.

### 3. Cleaning

#### Caution:
Stryker Orthopaedics trays and cases are intended for transport and storage of re-usable instruments. They are not designed for cleaning and disinfection in the fully assembled state. The instruments must be removed from the tray for adequate cleaning results.

#### Equipment required:
- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning
- Brushes – soft and firm, bottle brushes or cleaning wires for cannulations
- Personal protective equipment as recommended by the cleaning agent supplier
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)

#### Caution:
Never use metal brushes or steel wool for cleaning.

#### Point of use
After use (within a maximum of 2 hours post-operatively) remove gross soil using absorbent paper wipes. Intensive rinsing of the re-usable instruments with fluent water or transfer of the medical devices into a bath with an aldehyde-free disinfectant solution is highly recommended.

#### Transport to processing area
Avoid mechanical damage by ensuring that heavy devices do not get mixed with delicate ones. Pay particular attention to cutting edges, both to avoid personal injury and prevent damage to the re-usable instrument. Transport the re-usable instruments to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the re-usable instruments with a damp cloth to avoid drying of soil.

#### Preparation for cleaning
Disassemble instruments as required. Specific instructions for instruments that require disassembly are provided in Appendix 1.

#### Pre-Cleaning
The pre-cleaning step can be omitted in case of direct subsequent manual cleaning and disinfection. In the event that highly contaminated re-usable instruments are to be subjected to an automatic cleaning process, pre-cleaning in an ultrasonic bath is recommended.
3. Cleaning

Pre-Cleaning

- Remove gross soil using wipes and solution of cleaning agent.
- Immerse re-usable instrument in solution of cleaning agent.
- Ensure that all surfaces are thoroughly wetted.
- Use a syringe to ensure that the cleaning solution reaches all parts of cannulations.
- Ensure that air is not trapped within features of the device when immersing in the solution.
- Soak for minimum recommended time by the detergent manufacturer’s instructions.

Manual cleaning and disinfection

Equipment required:

- Ultrasonic bath large enough to allow complete immersion of the re-usable instrument. (A frequency of 25 – 50 kHz is recommended. Do not exceed the temperature stated by the detergent manufacturer.)
- Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment. Do not exceed the concentration specified by the detergent manufacturer.
- Suitable brushes or cleaning wires to reach all parts of the device.
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)
- Fresh purified water, highly purified water or sterile water for rinsing purposes.

Procedure:

- Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified by the detergent manufacturer.
- Immerse the device completely and activate the bath for minimum of 15 minutes.
- Using suitable brushes or cleaning wires, clean the device paying particular attention to rough surfaces and features that may be shielded from the brushing action.
- Rinse for at least 1 minute in running water until all traces of cleaning solution are removed. Pay particular attention to cannulations, blind holes, hinges, and joints between mating parts. Rinse cannulations at least three times with a syringe (volume 1-50ml).
- If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remains on the device, the cleaning step must be repeated as described above.
3. Cleaning

Disinfection

Equipment required:
• Bath large enough to allow complete immersion of the re-usable instrument, temperature according to detergent manufacturer’s instructions.
• Disinfectant intended for manual disinfection and compatible with the applied cleaning detergent; concentration according to the detergent manufacturer’s instructions.
• Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed).
• Freshly prepared purified water/highly purified water or sterile water for rinsing purposes.
• Filtered medical compressed air (if available) or clean and lint-free single use wipes.

Procedure:
• Prepare a bath with a disinfectant solution at the concentration and temperature specified in the detergent manufacturer’s instructions.
• Immerse the device completely for at least the time specified in the detergent manufacturer’s instructions.
• Rinse cannulations at least three times with a syringe.
• Rinse for at least 1 min in running water of the specified quality until all traces of disinfectant solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse at least five times with a syringe (volume 1-50ml).
• Dry the re-usable instrument using filtered, compressed air or clean, lint-free wipes.
• If additional drying is required, arrange instruments in a clean area or heat in an oven below 110°C.
• Visually inspect and repeat complete manual cleaning and disinfection if necessary.

Automated cleaning and disinfection using washer-disinfector

Equipment required:
• Washer-disinfector with fundamentally approved efficiency (e.g. CE mark or FDA approval according to ISO 15883), properly installed, qualified and regularly subjected to maintenance and testing.
• Approved thermal disinfection Program with sufficient rinsing steps (A0 value > 3000 or application of at least 5 min at 90 °C).

Caution:
Chemical disinfection programs are not recommended due to the potential for chemical residues to remain on the instruments. These residues could interfere with sterilization efficacy.

Procedure:
• Load the re-usable instruments into the washer-disinfector.
• Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.
• Avoid contact between devices as movement during washing could cause damage, and washing action could be obstructed.
• Arrange re-usable instruments so that cannulations are not horizontal and blind holes incline downwards to assist drainage.
• Articulating devices should be in the open position.
• Operate the washer-disinfector cycle.
• Upon completion, unload the washer-disinfector. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process. Remaining wetness may be removed with filtered, compressed air or clean, lint-free wipes.
• If additional drying is required, arrange instruments in a clean area or heat in an oven below 110°C.
3. Cleaning

Inspection

Before preparing for sterilization, all re-usable instruments should be inspected. Generally un-magnified visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion.

Particular attention should be paid to:

- Soil “traps” such as mating surfaces, hinges, shafts of flexible reamers.
- Recessed features (holes, cannulations).
- Features where soil may be impacted into the device, such as drill flutes adjacent to the cutting tip and sides of teeth on broaches and rasps.
- Cutting edges should be checked for sharpness and damage.
- For devices that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.

Functional checks should be performed at all times:

- Mating devices should be checked for proper assembly.
- Instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).
- Rotating instruments, such as multiple use drill bits, and reamers, should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface.
- “Flexible” instruments should be checked for damage to the spiral element.

Note: Stryker Orthopaedics does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

4. Packaging

Where appropriate, the cleaned, disinfected, and checked re-usable instruments should be assembled into the dedicated trays provided. Stryker Orthopaedics cases/trays should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized re-usable instruments should meet the following requirements:

- ISO 11607-1
- CE Mark or FDA clearance
- Suitable for steam sterilization
- Grade appropriate for weight of instrument case
Sterilization

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated and maintained in accordance with EN 285, EN 13060, EN ISO 17665, and ANSI/AAMI ST79.

Stryker Orthopaedics has validated an autoclave cycle for sterilization of complete re-usable instrument cases/trays. Instruments shall be sterilized in the assembled state as stored on the tray (i.e.: if the brackets or recessions in the tray are designed to accommodate multi-component instruments in their assembled state, there is no need to disassemble these instruments for sterilization.) The process parameters shown at the right are validated and recommended by Stryker Orthopaedics for sterilization.

Caution: Stryker Orthopaedics does not recommend the use of ‘flash’ sterilization for re-usable instruments.

Warning: Single-use implants and instruments should not be re-sterilized.

Warning: Stryker Orthopaedics does not recommend the use of rigid containers for steam sterilization. This configuration could limit steam penetration and prevent effective sterilization of the instruments.

### USA

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization according to ANSI/AAMI ST 79</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Pre-Vacuum (Pre-Vac)</td>
</tr>
<tr>
<td>Temperature</td>
<td>132°C (270°F)</td>
</tr>
<tr>
<td>Exposure Time(^1)</td>
<td>4 minutes (minimum)</td>
</tr>
<tr>
<td>Drying Time(^2)</td>
<td>30 minutes (minimum, in chamber)</td>
</tr>
</tbody>
</table>

### Outside USA

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization according to ISO 17665</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Saturated steam with fractional forced air removal</td>
</tr>
<tr>
<td>Temperature</td>
<td>132-137°C (270-277°F)</td>
</tr>
<tr>
<td>Exposure Time(^1)</td>
<td>4 minutes (minimum)</td>
</tr>
<tr>
<td>Drying Time(^2)</td>
<td>30 minutes (minimum, in chamber)</td>
</tr>
</tbody>
</table>

\(^1\) Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature.

\(^2\) Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method and material.
After sterilization, re-usable instruments should be stored in the sterilization wrap in a dry and dust-free place. The shelf life is depending on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized re-usable instruments before use should be defined by each health care facility.
7. References

1. ISO 11607: Packaging for terminally sterilized re-usable instruments

2. ISO 17665: Sterilization of health care products, moist heat

3. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities

4. ISO 17664: Sterilization of re-usable instruments - Information to be provided by the manufacturer for the processing of resterilizable re-usable instruments
## Appendix 1: Instruments Requiring Disassembly for Cleaning

### Total Hip Arthroplasty Instruments

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Instrument Name</th>
<th>Surgical System</th>
<th>Disassembly Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>6278-1-100</td>
<td>Version Control Stem Inserter</td>
<td>Restoration Modular</td>
<td>Depress the circular button on the body of the impactor and pull away from stem inserter.</td>
</tr>
<tr>
<td>6266-0-140</td>
<td>Head Impactor</td>
<td>Restoration Modular Accolade</td>
<td>Unthread the white plastic tip in a counter-clockwise manner to separate the impactor tip from the handle.</td>
</tr>
<tr>
<td>6260-4-070</td>
<td>Proximal Body Steady Handle</td>
<td>Restoration Modular</td>
<td>Unthread the white plastic tip in counter-clockwise manner to separate the impactor tip from the handle.</td>
</tr>
<tr>
<td>1104-1000</td>
<td>Femoral Head Impactor</td>
<td>Cutting Edge Advantage</td>
<td>Unthread the black plastic tip in counter-clockwise manner to separate the impactor tip from the handle.</td>
</tr>
<tr>
<td>1235-0-008</td>
<td>ADM Press</td>
<td>ADM MDM</td>
<td>Unthread the black handle in counter-clockwise manner to separate the handle from the press.</td>
</tr>
<tr>
<td>2102-0410</td>
<td>Acetabular Reamer Handle</td>
<td>Trident</td>
<td>Remove white plastic sleeve by pulling it up and over the end of the shaft.</td>
</tr>
<tr>
<td>1126-XXXX</td>
<td>Cutting Edge Broach</td>
<td>Cutting Edge</td>
<td>Unthread the cylindrical or tapered distal extensions from the broach in counter-clockwise manner.</td>
</tr>
</tbody>
</table>
| 6278-9-070     | Body/Stem Separator              | Restoration Modular | 1) Unthread the split collet from the puller by twisting the collet in a clockwise manner  
2) Unthread the jackscrew from the puller by twisting the jackscrew in a counter-clockwise manner. |
| 2199-20xx      | Constrained Liner Inserter       | Trident          | Unthread the metal adapter from the plastic impactor tip by turning it counter-clockwise.        |
| 6278-1-200D    | Distal Stem Inserter             | Restoration Modular | 1) Unthread the handle from the outer sleeve by twisting the outer sleeve in the direction of the arrows laser marked on the instrument while holding the flats on the outer sleeve. Note: Threads between the handle and outer sleeve are left-handed.  
2) Remove the threaded rod from the outer sleeve by holding the hex end and sliding the threaded rod from the outer sleeve. |
Appendix 1: Instruments Requiring Disassembly for Cleaning

Total Knee Arthroplasty Instruments

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Instrument Name</th>
<th>Surgical System</th>
<th>Disassembly Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>6776-8-210</td>
<td>Stem Punch Extractor</td>
<td>Duracon Xcelerate</td>
<td>Remove the hammer from the handle by sliding the hammer off the handle</td>
</tr>
<tr>
<td>6778-6-xxx</td>
<td>Offset Adaptor Trials</td>
<td>Scorpio TS</td>
<td>Remove jam nut by turning it counter-clockwise to separate it from the offset adaptor body</td>
</tr>
<tr>
<td>8200-0043</td>
<td>Scorpio Tibial Offset Fixture</td>
<td></td>
<td>Disassemble locking knob by turning it counter-clockwise to separate it from the fixture body</td>
</tr>
<tr>
<td>6776-8-010</td>
<td>Tibial Impactor</td>
<td>MRH</td>
<td>Disassemble plastic tip by turning it counter-clockwise to separate it from instrument body</td>
</tr>
<tr>
<td>6633-9-995</td>
<td>Tibial Offset Fixture</td>
<td>Duracon TS</td>
<td>Disassemble locking knob by turning it counter-clockwise to separate it from the fixture body</td>
</tr>
<tr>
<td>8050-1060L/R</td>
<td>MIS Tibial Resection Guides</td>
<td>Scorpio MIS</td>
<td>Disassemble locking knob by turning it counter-clockwise to separate it from the fixture body</td>
</tr>
</tbody>
</table>

Trauma Instruments

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Instrument Name</th>
<th>Surgical System</th>
<th>Disassembly Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>6704-9-320</td>
<td>Single-Sided Tensioner</td>
<td>Dall-Miles</td>
<td>Turn the knob clockwise, as described by the arrow indicating “tighten”, until it spins freely</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Twist nose counter-clockwise to remove. (The nose is the silver portion that threads into the green body)</td>
</tr>
<tr>
<td>6704-9-350</td>
<td>Double-Sided Tensioner</td>
<td>Dall-Miles</td>
<td>Turn knob clockwise to release the jaws in the tensioner heads from the studs. Turn tensioner head clockwise until they are removed from the device</td>
</tr>
<tr>
<td>6704-9-720</td>
<td>Grip Impactor</td>
<td>Dall-Miles</td>
<td>Unthread the white plastic tip in a counter-clockwise manner to separate the impactor tip from the handle</td>
</tr>
<tr>
<td>6704-9-420</td>
<td>Cutter</td>
<td>Dall-Miles</td>
<td>Using a wrench, turn the retaining nut loose and remove. Twist tip counterclockwise to unthread the plunger and outer sleeve from the Cutter body</td>
</tr>
</tbody>
</table>
# Appendix 1: Instruments Requiring Disassembly for Cleaning

## Upper Extremity Instruments

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Instrument Name</th>
<th>Surgical System</th>
<th>Disassembly Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>5901-1111</td>
<td>Extramedullay Resection Guide</td>
<td>ReUnion Primary Humeral</td>
<td>Completely unthread knob from proximal resection guide</td>
</tr>
<tr>
<td>5901-0032</td>
<td>Glenoid Impactor</td>
<td>ReUnion Self Pressurizing Glenoid</td>
<td>Unthread impactor tip from impactor shaft</td>
</tr>
<tr>
<td>5901-0029</td>
<td>Peg Locating Pin</td>
<td></td>
<td>Slide the locating pins along their axis out of the holes in the drill guide</td>
</tr>
<tr>
<td>5900-0060</td>
<td>Humeral Neck Resection Guide</td>
<td>Solar Total Shoulder</td>
<td>Unthread the handle/knob from the resection guide</td>
</tr>
<tr>
<td>5900-0020</td>
<td>Humeral Head Impactor</td>
<td></td>
<td>Unthread the impactor tip from the impactor handle</td>
</tr>
<tr>
<td>5900-8124 5900-8128</td>
<td>Bone Graft Remover</td>
<td>ReUnion Facture Humeral stem</td>
<td>Slide the bone graft remover from the central hole of the bone graft cutting handle</td>
</tr>
<tr>
<td>5100-3600 5100-3601</td>
<td>Torque Limiting Driver</td>
<td>Solar Total Elbow</td>
<td>Pull hex bit from handle</td>
</tr>
<tr>
<td>5100-4402 5100-4403</td>
<td>Humeral Drill Guide</td>
<td></td>
<td>Unthread the smaller diameter knob only from the assembly</td>
</tr>
<tr>
<td>5100-3302 5100-3303</td>
<td>Humeral Cutting Guide</td>
<td></td>
<td>Unthread both knobs from the assembly</td>
</tr>
</tbody>
</table>
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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