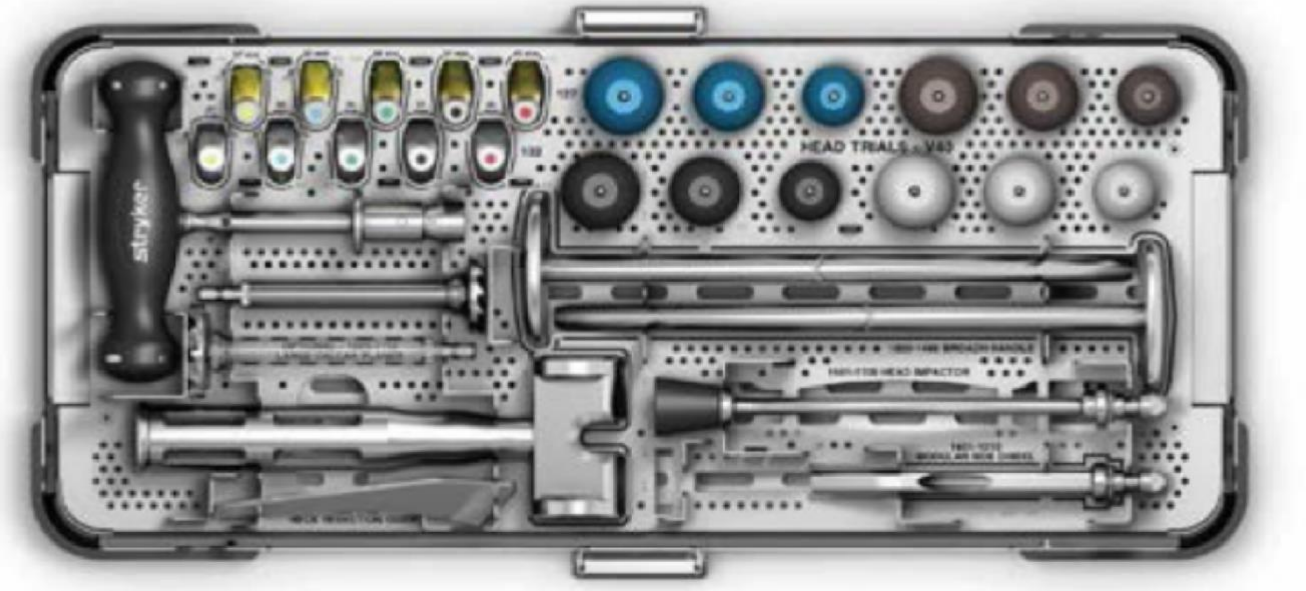
stryker®

Instructions

Cleaning, Sterilization, Inspection & Maintenance of Reusable Medical Devices



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Introduction

All Stryker Orthopaedics reusable instruments must be cleaned and sterilized prior to use. To assist in instrument upkeep, this document will cover the following instructions:

- Sterilizing reusable instruments.
- Determining when an instrument should be replaced.
- Assembling and disassembling for multi-component instruments.

In the event of conflicting national cleaning and sterilizing requirements, such requirements will prevail over Stryker Orthopaedics recommendations.

In accordance with ISO 17664, Stryker Orthopaedics has provided two methods of cleaning reusable instruments:

1. Fully-manual method.
2. Automated washer-disinfector method.

Use automated method whenever possible.

The automated cleaning process is more reproducible and, therefore, more reliable. Additionally, staff are less exposed to the contaminated devices and the cleaning agents used.

Whichever method is used, staff should always use suitable protective clothing and equipment. Adhere to the instructions provided by the cleaning agent manufacturer for correct handling and use of each product.

Equipment, operators, cleaning agents, and procedures all contribute to the efficacy of the process. Stryker Orthopaedics has validated the processes provided in these instructions; however, alternative methods of processing outside the scope of this document may be suitable for reprocessing.

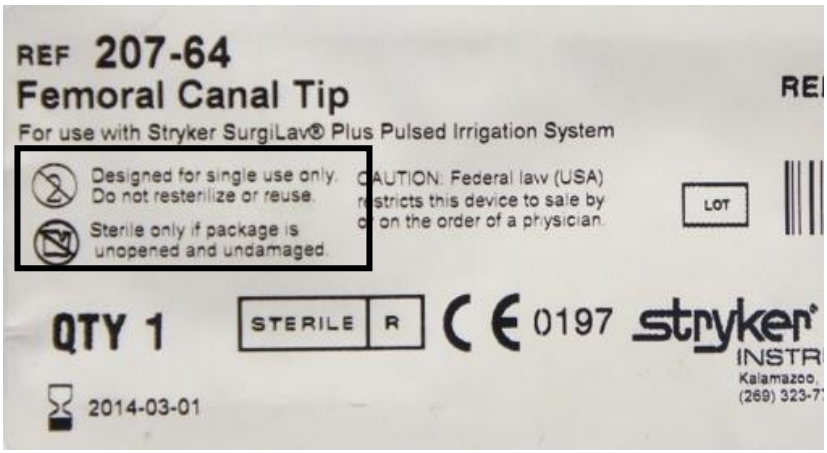
If used, alternative processing methods must be validated by the end user and the healthcare facility should ensure that the selected processing steps are safe and effective.

Warnings & Precautions

Single use devices must **not** be reused.

Single use devices are not designed to perform as intended after the initial use. The only exception to this is if the single use device is reprocessed by a preprocessor expressly authorized by Stryker Orthopaedics. Only then can it be assured that the device is appropriate for reprocessing.

To identify single or multiple use devices and components, refer to the device label on the back of the Stryker product, as shown below.



Identification of single or multiple use devices are located on the back with device labels. Notice how this label is a single use device.

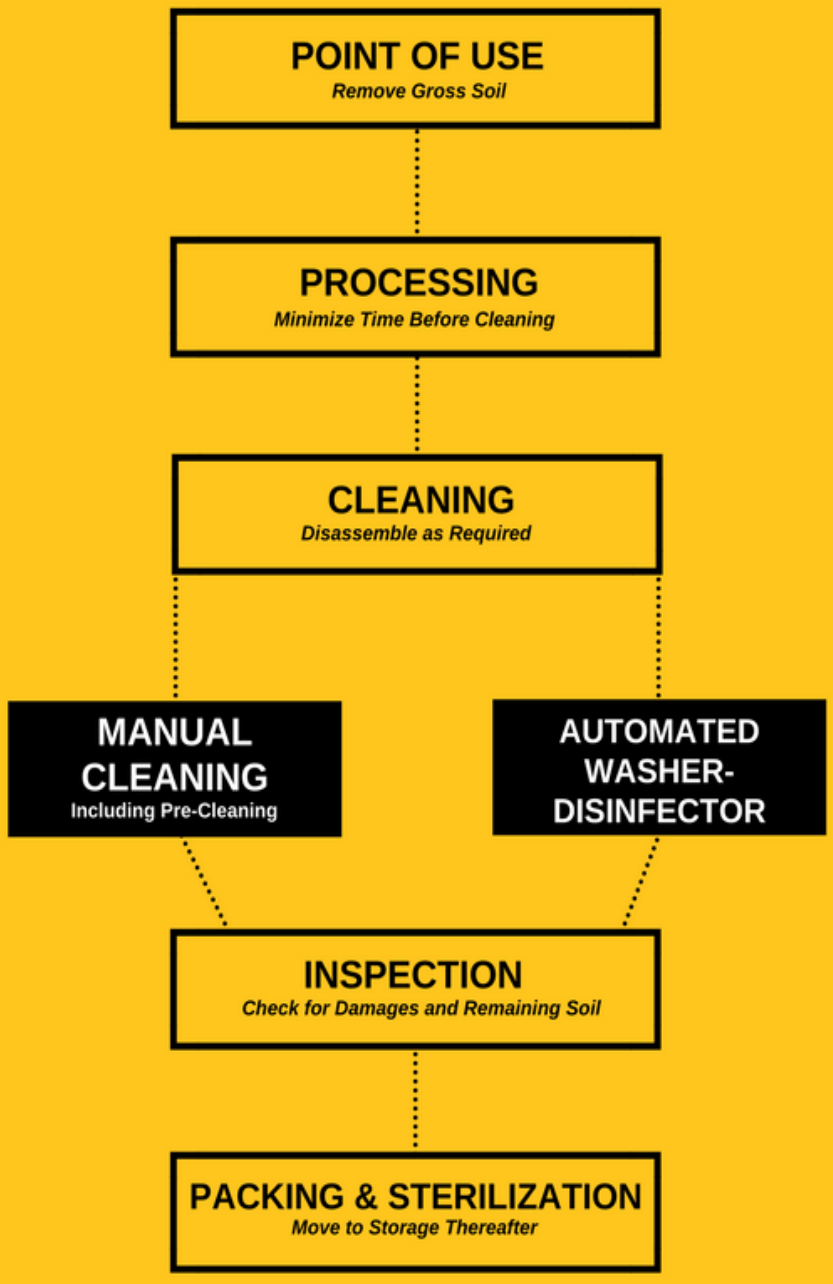
As a result of repeated use, cleaning, and resterilization, some device materials may develop changes in mechanical, physical, or chemical characteristics that may compromise the integrity of the design and/or material. These changes may lead to diminished safety and performance, and/or compliance issues with relevant specifications for the instrument.

Stryker Orthopaedics reusable instruments are not normally used in surgical procedures where they contact Transmissible Spongiform Encephalopathies (TSE) infective tissue as instructed by the World Health Organization (WHO).

Decontamination procedures with highly aggressive agents [i.e. sodium hydroxide (NaOH) or sodium hypochloride (NaClO)] 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.

Reprocessing Overview

The sequence of steps required to prepare instruments for initial use and reuse are summarized in the chart below. Instructions moving forward will address the following:



Preparation for Cleaning

Point of Use for All Instruments

Point of Use

After use, remove gross soil from the instrument using absorbent paper wipes. Gross soil *must* be removed a *maximum of 2 hours post-operative*.

Follow with intensive rinsing using fluent water or transfer the medical device into a bath with an aldehyde-free disinfectant solution.

Transport to Processing Area

Transport the reusable instruments to the point where cleaning is to be performed soon thereafter. If the transfer to the processing area is likely to be delayed longer than an hour, consider covering the instruments with a damp cloth to avoid drying of soil.

Avoid damaging the instrument's mechanical use by ensuring that heavy devices do not get mixed with delicate ones. Pay attention to cutting edges, both to avoid personal injury and prevent damage to the reusable instruments.

> **Note:** *Stryker Orthopaedics trays and cases are intended for transport and storage of reusable instruments only. They are not designed for cleaning and/or disinfection in the fully assembled state. The instruments must be removed from the tray for adequate cleaning results.*

Preparation for Cleaning

Appendix 1 provides specific instructions for instruments that require disassembly and for certain instruments that should not be disassembled prior to cleaning.

Manual Cleaning

Pre-Cleaning

When manually cleaning a reusable instrument, first complete the steps for pre-cleaning the instrument:

1. **Remove gross soil.**
   Use wipes and cleaning agent solution.

2. **Immerse in cleaning agent for minimum recommended time**.
   To reach all parts of cannulations, use a syringe or pipette. When immersing in the solution, confirm that air is not trapped within features of the device.

3. **Clean reusable instrument thoroughly.**
   Using suitable soft bristle brushes, clean the reusable instrument thoroughly. Pay particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.

   Note: *Never use metal brushes or steel wool for cleaning*.

   Use a firm bristle brush for cleaning bone-cutting features, such as drill tips, reamer flutes, and the teeth of broaches.

   Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation.

4. **Rinse in running water.**
   Rinse the instrument until all traces of the cleaning solution are removed. Pay attention to cannulations and blind holes, hinges, and joints between mating parts. Visually inspect for any remaining soil and repeat the steps above if necessary.

5. **Drain on absorbent paper and transfer immediately to cleaning step.**

Manual Cleaning

Equipment Required:

- **Ultrasonic bath**
  - Recommended frequency between 25 – 50 kHz.
  - Do not exceed the temperature stated by the detergent manufacturer.
- **Cleaning agent**
  - Use agents intended *only* for manual cleaning and suitable for ultrasonic treatment.
  - Do not exceed the concentration specified by the detergent manufacturer.
  - Stryker Orthopaedics does not recommend any specific cleaning and/or disinfection agent as not all cleaning agents and disinfectants may be available around the globe.
- **Suitable brushes or cleaning wires**
  - Never use metal brushes or steel wool for cleaning.
- **Syringes**
  - Volumes 1 — 50 ml, depending on the size of the channels to be rinsed.
- **Fresh purified water, highly purified water, or sterile water**

Instructions:

1. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified by the detergent manufacturer.

   Warning: If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials.

2. Immerse the device completely and activate the bath for a minimum of 15 minutes.

3. Use suitable brushes or cleaning wires to clean the device.

4. Rinse for at least 1 minute in running water until all traces of cleaning solution are removed. Ensure cleaning occurs in cannulations, blind holes, hinges, and joints between mating parts.

5. Repeat the cleaning steps above if encrusted soil remains on the device remains.

Manual Disinfecting

Equipment Required:

- **Large bath**
  - Do not exceed the temperature stated by the detergent manufacturer.
- **Disinfectant**
  - Use disinfectant intended only for manual disinfection.
  - Ensure disinfectant is compatible with the applied cleaning detergent.
- **Syringes**
  - Volumes 1 — 50 ml, depending on the size of the channels to be rinsed.
- **Filtered medical grade compressed air**
  - Alternatively, use clean, lint-free single use wipes.
- **Fresh purified water, highly purified water, or sterile water**

Instructions:

1. Prepare a bath with a disinfection solution at the concentration and temperature specified in the detergent manufacturer's instructions.

2. Immerse the device completely for at least the time specified in the detergent manufacturer's instructions.

3. Rinse cannulations at least three times with a syringe.

4. Rinse for at least 1 minute in running water of the specified quality until all traces of disinfectant solution are removed.

5. Dry the reusable instrument using filtered, compressed air or clean, lint-free wipes.

6. Inspect and repeat complete manual cleaning and disinfection if necessary. If additional drying is required, arrange instruments in a clean area or heat in an oven below 110°C.

Automated Cleaning & Disinfecting

Equipment Required:

- **Washer-Disinfector**
  - Ensure washer-disinfector has a CE mark or FDA clearance and is validated in accordance with ISO15883.
- **Thermal Disinfection Program**
  - A_0 value > 3000 or application of at least 1 minute at 90°C.
  - Avoid chemical disinfection programs as they could interfere with sterilization efficacy.
- **Cleaning Agent**
  - Intended for use in washer-disinfector only.
  - Do not exceed the concentration and temperature recommended by the detergent manufacturer.
  - Avoid cleaning agents with high pH (>8.5).

Instructions:

1. Load the reusable instruments into the washer-disinfect or required loading configuration.

2. Connect cannulations to the rinsing ports of the washer-disinfector.
   a. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.

3. Arrange reusable instruments so that cannulations are not horizontal and blind holes are inclined downward to assist cleaning and drainage.
   a. Articulating devices should be in the open position and avoid contact between devices as movement during washing could cause damage and washing action could be obstructed.

4. Operate the washer-disinfector cycle.

5. Upon completion, unload the washer-disinfector.

6. Visually inspect each device for remaining soil and dryness. If soil remains, repeat the cleaning process.

7. Remove remaining wetness with filtered, compressed air or clean, lint-free wipes.

8. Visually inspect and repeat complete manual cleaning and disinfection if necessary. Arrange instruments in a clean area or heat in an oven below 110°C if additional drying is required.

Inspection

Before preparing for sterilization, all reusable instruments should be inspected. Generally, unmagnified visual inspection under good lighting conditions is sufficient. The following inspections are recommended prior to sterilization:

- Check all parts for visible soil and/or corrosion. Pay particular attention to:
  - **Soil traps:** such as mating surfaces, hinges, shafts, rotating gears, and lumens.
  - **Recessed features:** like holes, textured surfaces, and cannulations.
  - **Features where soil may be impacted:** 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.

- Check that mating devices have proper assembly.

- Check "flexible" instruments for damage to the spiral element.

- Operate instruments with moving parts to check for 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 by rolling the instrument on a flat surface.

It should be noted that Stryker Orthopaedics does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on many factors, including the method and duration of each use and the handling between uses.

For devices that are impacted during the surgical procedure, 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.

Careful inspection and functional testing of an instrument before use is the best method for determining the end of serviceable life.

Packaging

Preparation for Sterilization

For Blue Wrap
Using the AAMI/CSR technique.

The packaging for terminally sterilized reusable instruments should be suitable for steam sterilization and the appropriate grade for the weight of the instruments. Additionally, the Blue Wrap should be compliant to the following requirements:

- AAMIST79
- ISO11607
- CE mark
- FDA 510(k) clearance for specified sterilization parameters

For Rigid Containers
Stryker Orthopaedics has validated steam sterilization of complete reusable instrument trays with Aesculap SterilContainer Systems. For a complete list of rigid container compatibility details, reference Appendix 2 and Appendix 3.

Lid/Case/Tray Combinations
For all sterilization packaging configurations, Stryker Orthopaedics recommends the use of biological indicators as described in ISO11138-3 (*Geobacillus stearothermophilus)* and/or chemical indicators as described in ISO11140 for proper monitoring of all sterilization cycles.

Stryker Orthopaedics has only validated the specific lid/case combinations listed to the parameters in Section 8. While other combinations and parameters may be appropriate, the responsibility for validation and evaluation then would be on the end-user.

The use of lid/case/tray combinations in a rigid container system that has not been properly validated in accordance with ISO17665 may result in the inability to meet the required sterility assurance level (SAL) of 10-6.

Sterilization

The process parameters shown in the table below are validated at minimum time and temperature in accordance with ANSI/AAMIST79, EN ISO 17665 and HTM-01-01 and recommended for 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, EN285, EN13060, EN ISO 17665, and ANSI/AAMI ST79.

USA Method	
Method	Moist heat sterilization according to ANSI/AAMI ST79
Cycle	Pre-vacuum (Dynamic air removal)
Temperature	132° C (270° F)
Exposure Time	4 minutes
Drying Time	30 minutes (in chamber)

Stryker Orthopaedics has validated the recommended sterilization cycle for complete reusable instrument cases and trays.

Compatibility with rigid container systems is provided in Appendix 2 and Appendix 3. Instruction for Outside USA methods are provided in Appendix 4 and Appendix 5. Single instruments, properly double wrapped or double pouched, can be sterilized using the same parameters.

Stryker Orthopaedics does not recommend the use of flash sterilization for reusable instruments.

Longer cycles, such as those recommended for control or elimination of TSE, may be utilized; however, instruments should be expected to have reduced functional life thereafter.

> ***Warning***: Implants and instruments that are supplied STERILE must not be resterilized as this process has not been validated.

Storage Before Using

After sterilization, reusable instruments should be stored in the sterilization wrap or rigid container in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions, and handling.

A maximum shelf life for sterilized reusable instruments should be defined by each health care facility based on the recommendations of the wrap or container.

Stryker Orthopaedics recommends storage conditions in accordance with USP (United States Pharmacopoeia), EP (European Pharmacopoeia), and JP (Japanese Pharmacopoeia) guidelines for controlled room temperatures.

References

1 AAMI TIR 12: Design, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for medical device manufacturers.

2 AAMI TIR 30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

3 AAMI TIR 34: Water for reprocessing of medical devices.

4 AAMITIR 55: Human factors engineering for processing medical devices.

5 ANSI/AAMI ST 77: Containment devices for reusable medical device sterilization.

6 ANSI/AAMI ST 79: Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.

7 EN 285: Sterilization - Steam sterilizers - Large sterilizers.

8 EN 13060: Small steam sterilizers.

9 ISO 11138-3: Sterilization of health care products– Biological indicators- Part 3: Biological indicators for moist heat sterilization processes.

10 ISO 11140-1: Sterilization of healthcare products-Chemical indicators- Part 1: General requirements.

11 ISO 11607-1: Packaging for terminally sterilized medical; devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems.

12 ISO 15883-1: Washer-disinfectors- Part 1: General requirements, terms and definitions and tests.

13 ISO 17664: Sterilization of re-usable instruments-Information to be provided by the manufacturer for the processing of resterilizable reusable instruments.

14 ISO 17665-1: Sterilization of healthcare products, moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

15 ISO 17665-2: Sterilization of health care products, moist heat- Part 2: Guidance on the application of ISO 17665-1.