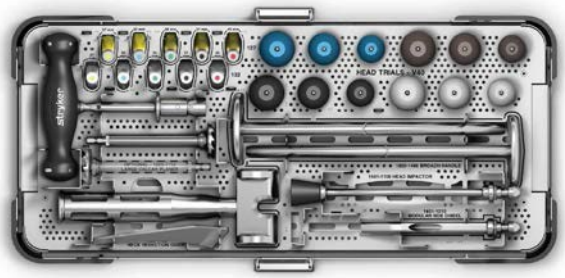
stryker

Instructions for:

Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices

Instructions for Stryker Orthopaedics



Document Number LSTPI_B

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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/or 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, such requirements shall prevail over Stryker Orthopaedics recommendations.

In accordance with ISO 17664, two methods of cleaning Stryker Orthopaedics re-usable instruments are provided in these instructions, a fully-manual method (section 4) and a method using an automated washer-disinfector (section 5). Whenever possible the automated method should be used. 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 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.

Warnings and Precautions

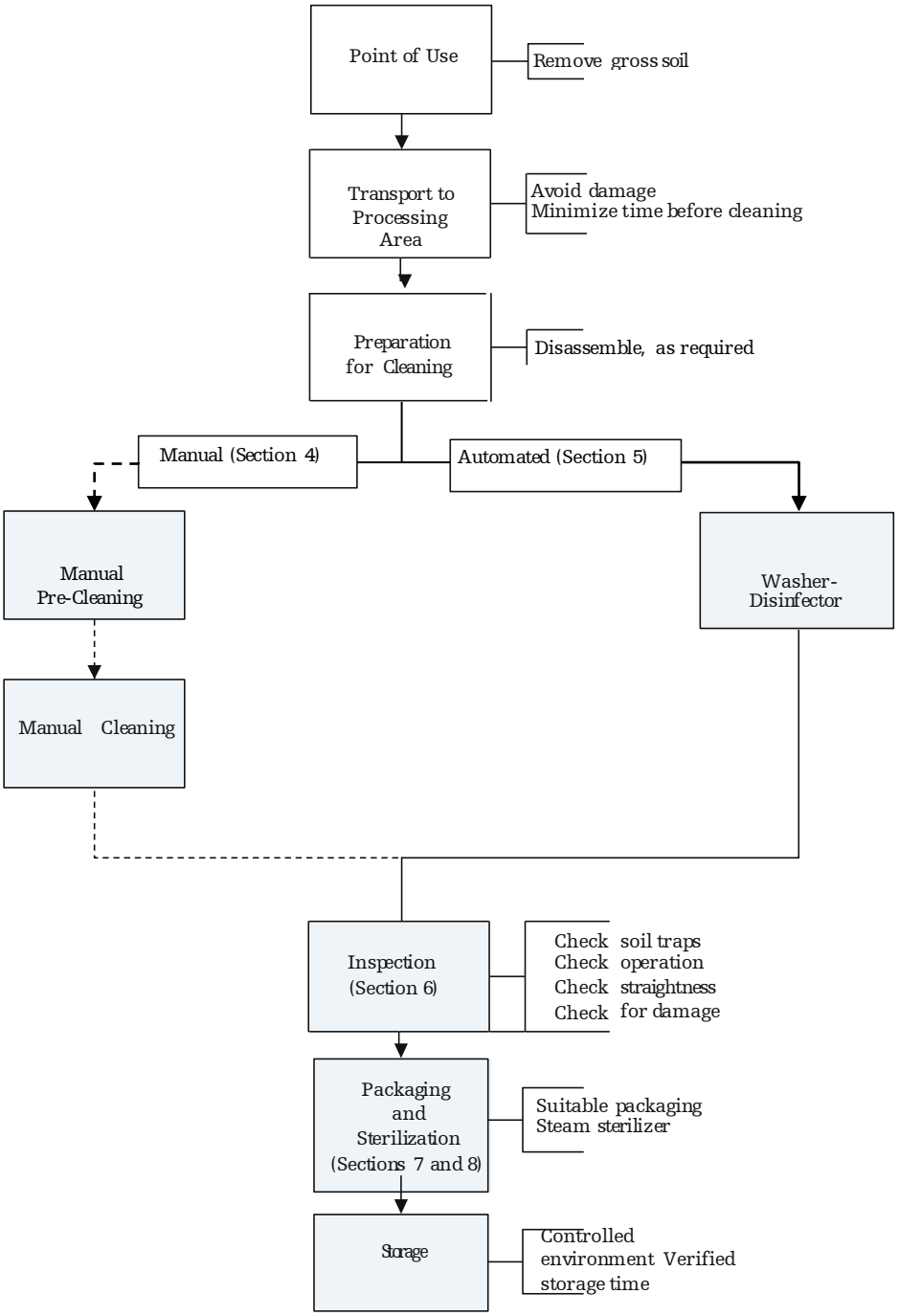
Single use devices must not be reused, as they are not designed to perform as intended after the initial use, unless they are reprocessed by a reprocessor expressly authorized by Stryker Orthopaedics. Only then can it be assured that the device is appropriate for reprocessing and that the correct methods of validation are used. Please refer to the device label to identify single or multiple use devices and components.

Some device materials may develop changes in mechanical, physical or chemical characteristics 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.

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 (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.

2. Reprocessing Overview

The sequence of steps required to prepare reusable instruments for reuse 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.



Note: 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 sterilization.

3. Preparation for Cleaning
(Point-of-Use for All Instruments)

Point of use

After use (within a maximum of 2 hours post-operatively) remove gross soil using absorbent paper wipes. Intensive rinsing of the reusable 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 reusable instruments. Transport the reusable 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 instruments with a damp cloth to avoid drying of soil.

Preparation for cleaning

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

Caution:
Stryker Orthopaedics trays and cases are intended for transport and storage of re- usable instruments. 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.

4. Manual Cleaning

Pre-Cleaning

Remove gross soil using wipes and solution of cleaning agent.
Immerse reusable instrument in solution of cleaning agent.

Ensure that all surfaces are thoroughly wetted. Use a syringe or pipette 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.

Using suitable soft bristle brushes, clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.

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.

Operate articulating devices and those with moving parts.

Rinse in running water until all traces of cleaning solution are removed.

Pay particular attention to cannulations and blind holes,as well as hinges and joints, between mating parts.

Visually inspect for any remaining soil and repeat the steps above if necessary.

Allow to drain on absorbent paper or transfer immediately to cleaning step.

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

Manual Cleaning

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

• 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.

Instructions:

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.

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.

Note: The guidance provided by the cleaning agent manufacturer concerning concentrations and temperatures should be followed. 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 end user should verify the selected cleaning agent is appropriate for use on reusable surgical instruments.

Manual Disinfection

Equipment Required:

• Bath large enough to allow complete immersion of the reusable instrument with temperature setting according to detergent manufacturer's instructions.

• Disinfectant intended for manual disinfection and compatible with the applied cleaning detergent prepared in 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 grade compressed air (if available) or clean, lint- free single use wipes.

Instructions:

Prepare a bath with a disinfection 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, using a syringe, if needed.

Dry the reusable 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.

5. Automated Cleaning and Disinfection

EquipmentRequired:

• Washer-Disinfector with demonstrated efficiency (e.g. CE mark or FDA clearance and validated in accordance to ISO15883), properly installed, qualified and regularly subjected to maintenance and testing.

• Approved thermal disinfection program with sufficient rinsing steps (A_0 value > 3000 or application of at least 1 minute at 90°C).

• Cleaning agent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.

Instructions:

Load the re-usable instruments into the washer-disinfect or per required loading configuration.

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 reusable instruments so that cannulations are not horizontal and blind holes incline downwards to assist cleaning and 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.

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.

Caution: Cleaning agents with high pH (>8.5) are not recommended for Stryker Orthopaedics reusable instruments and cases/trays/lids. Exposure to excessive pH will cause damage to polymer components and will strip protective coatings from metals, especially aluminum.

6. Inspection

Before preparing for sterilization, all reusable 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, rotating gears, and lumens;

- Recessed features (holes. Textured surfaces, and 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.

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 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 test of the instrument before use is the best method of determining the end of serviceable life.

7. Packaging (Preparation for Sterilization)

For Blue Wrap:

Stryker Orthopaedics case/tray configurations should be double wrapped according to 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 System.

For a complete list of rigid container compatibility details, reference Appendix 2 and Appendix 3.

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.

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

Warning: 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}.

8. Sterilization

The process parameters shown at the right 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.

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

Compatibility with rigid container systems is provided in Appendix 2and Appendix 3. Instruction for Outside USA is provided in Appendix 4 and Appendix 5.

Single instruments, properly double wrapped or double pouched, can be sterilized using the same parameters.

USA

Method	Moist heat sterilization according to ANSI/AAMI ST79
Cycle	Pre-Vacuum (Dynamic air removal)
Temperature	132°C (270°F)
Exposure Time[1]	4 minutes
Drying Time[2]	30 minutes (in chamber)

Outside US

Method	Moist heat sterilization according to ISO 17665
Cycle	Pre-Vacuum (Dynamic air removal)
Temperature	134-137°C (273-279°F)
Exposure Time[1]	3 minutes (minimum)
Drying Time[2]	30 minutes (in chamber)

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

Caution: Longer cycles, such as those recommended for control or elimination of Transmissible Spongiform Encephalopathies, may be utilized; however, instruments should be expected to have reduced functional life.

Warning: Implants and instruments which are supplied STERILE must not be re-sterilized as this process has not been validated.

[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.

9. Storage Before Use

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 manufacturer.

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

10. 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 re-usable 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

16. United States Pharmacopoeia(USP)

17. European Pharmacopoeia (EP)

18. Japanese Pharmacopoeia (JP)

19. HTM-01-01: Decontamination of surgical instruments

Appendix 1: Instructions for Cleaning

Hip Instruments

Instructions For Instruments that **require** disassembly

Catalog Number	Instrument Name	Surgical System	Instructions
6278-1-100	Version Control Stem Inserter	Restoration Modular	Depresses the circular button on the body and pull away from stem inserter
6260-4-070	Proximal Body Steady Handle		Unthread the white plastic tip in a counter-clockwise manner to separate the tip and handle
6278-9-070	Body/Stem Inserter		1) Unthread the split collet from the puller by twisting the collet clockwise; 2)Unthread the jackscrew from the puller by twisting counter-clockwise
6266-0-140	Head Impactor	Restoration Modular Accolade	Unthread the white plastic tip in a counter-clockwise manner to separate the tip and handle
1104-1000	Femoral Head Impactor	Cutting Edge Advantage	Unthread the black plastic tip in a counter-clockwise manner to separate the tip andhandle
1235-0-008	ADMPress	ADM	
2102-0410	Acetabular Reamer Handle	Trident	Remove white plastic sleeve by pulling up and over the end of the metal shaft
1126-xxxx	Cutting Edge Broach	Cutting Edge Advantage	Unthread the cylindrical or tapered distal extensions from the broach by turning counter-clockwise

Instructions For Instruments that **Do not require** disassembly

Catalog Number	Instrument Name	SurgicalSystem	Instructions
7003-0000	Trial Insert Hex Containment Screw	Trident II	**Do Not Disassemble***
2230-0010	Acetabular Insert Trial Containment Screw Kit	Cutting Edge Advantage	**Do Not Disassemble***

* If disassembly occurs- Place the Hex screw in the middle of Insert Trial and secure with Retaining Ring.

Appendix 1: Instructions for Cleaning

Knee Instruments

Instructions For Instruments that **require** disassembly

Catalog Number	Instrument Name	Surgical System	Instructions
6776-8-210	Stem Punch Extractor	Duracon Xcelerate	Remove the hammer from the handle
6778-6-xxx	Offset Adaptor Trials	Scorpio TS	Remove the jam nut by turning counter-clockwise to separate from body
8200-0043	Tibial Offset Fixture		Disassemble locking knob by turning it counter-clockwise to separate
6776-8-010	Tibial Impactor	MRH	Disassemble plastic tip by turning counter-clockwise
6633-9-995	Tibial Offset Fixture	DuraconTS	Disassemble locking knob by turning it counter-clockwise to separate
8050-1060 L or R	MIS Tibial Resection Guides	Scorpio MIS	Disassemble locking knob by turning it counter-clockwise to separate

Dall- Miles Cabling Instruments

Instructions For Instruments that **require** disassembly

Catalog Number	Instrument Name	Surgical System	Instructions
6704-9-320	Single-Sided Tensioner	Dall-Miles	1) Turn the knob clockwise(as indicated by the arrow) until it spins freely; 2) Twist nose silver portion threaded into green body)counter- clockwise to remove
6704-9-350	Double-Sided Tensioner		1) Turn knob clockwise to release the jaws in the tensioner head from the studs; 2) Turn the tensioner heads clockwise until they are removed
6704-9-720	Grip Impactor		Unthread the white plastic tip by turning counter- clockwise
6704-9-420	Cable Cutter		1) Using a wrench, turn the retaining nut to remove; 2) Twist the tip counter- clockwise to unthread the plunger to remove from outer sleeve

Appendix 2: Rigid Container Compatibility for Complete Instruments Sets

Stryker Orthopaedics has validated steam sterilization of complete, fully loaded reusable instrument trays with Aesculap's SterilContainer System. All trays are screen printed with the words RIGID CONTAINER COMPATIBLE. Other rigid container systems may be suitable for use, but must be evaluated by the end- user. Refer to Aesculap Instructions for Use for Care & Handlingof Aesculap SterilContainer Systems (JN442).

Hip Instruments	Accolade II Basic	Tray: 6147-1-101 Lid: 6147-0-100	Aesculap Configuration Base: JN442 Lid: JK48x
	Accolade II Broaches	Tray: 6147-1-102 Lid: 6147-0-100	
	Modular Dual Mobility	Tray: 6147-2-101 Lid: 6147-0-100	
	Acetabular Reamers (36-66mm)	Tray: 6147-3-101 Lid: 6147-0-100	
	Trident and Tritanium General Tray	Tray: 6147-3-102 Lid: 6147-0-100	
	Acetabular Reamers (67-80mm)	Tray: 6147-3-103 Lid: 6147-0-100	
	Trident and Tritanium Insert Trials	Tray: 6147-3-104 Lid: 6147-0-100	
	Trident Window Trials	Tray: 6147-3-105 Lid: 6147-0-100	
	Tritanium Window Trials	Tray: 6147-3-106 Lid: 6147-0-100	
	Trident Tritanium Window Trials	Tray: 6147-3-107 Lid: 6147-0-100	
	Exeter Broach Tray*	Tray: 0585-9-900 Lid: 6147-0-100	
	Exeter Plug Trial Tray*	Tray: 0585-9-901 Lid: 6147-0-100	
	Exeter Retractor Tray*	Tray: 0585-9-902 Lid: 6147-0-100	
	Exeter Extension Broach Tray*	Tray: 0585-9-903 Lid: 6147-0-100	
	ETS Instrument Tray*	Tray: 0585-9-904 Lid: 6147-0-100	
	General Femoral Tray*	Tray: 0585-9-905 Lid:6147-0-100	
	Trident Constrained Insert Trials Tray	Tray: 6147-3-108 Lid:6147-0-100	
	Trident Offset Reamer Tray	Tray: 6147-3-110 Lid:6147-0-100	

*Not available in the USA.

Appendix 2: Rigid Container Compatibility for Complete Instruments Sets

Hip Instruments	Trident II Core Reamers (38-66) mm Tray	Tray: 7000-0100	Aesculap Configuration Base: JN442 Lid: JK48x
	Trident II General Instruments Tray*	Tray: 7000-0101	
	Trident II Core Trials Tray*	Tray: 7000-0102	
	Trident II Auxiliary Trials Tray*	Tray: 7000-0103	

* The compatible Trident II Implant system is not CE marked and is not available outside of the USA.

Appendix 3: US Parameters Rigid Container Compatibility for Legacy Instrument Sets

Stryker Orthopaedics has conducted validation testing for compatibility of specific instrument sets developed prior to January 2017. These instrument sets are referred to as 'legacy instrument sets.' As these sets *were not designed* to be compatible in total with rigid container technology, configurations are required to be modified in order to achieve the required sterility assurance (SAL) of 10^{-6}.

In order to be properly sterilized in rigid containers, all trays must be removed from the outer transportation/storage case. Any instrument sets that consist of two stackable trays must be separated (i.e.: trays must be sterilized in separate containers). Certain instrument/tray configurations have only been validated for use in a rigid container when the instruments have been removed from the tray and placed into a basket. The validated configurations and tray specific instructions are detailed in the following tables.

All validated configurations utilize the following Aesculap SterilContainer part numbers and sizes. Other rigid container systems may be suitable for use, but must be evaluated by the end-user.

Name	Part Number	Description
Container Base	JN441	5½ inch height, perforated bottom with retention plates and 2 round filters
Lid	JK48x Series	Aluminum SterilContainer 2000 Lid (any color) with 2 round filters
Basket	JC224R	Basket with rounded corners 21¼ x 10 x4(inches)

Single instruments or groups of instruments that must be sterilized separately may be placed in a double pouch, blue wrap, or rigid container configuration. In these situations, take care to ensure that all instruments are made available at the time of surgery.

Refer to Aesculap Instructions for Use for Care & Handling of Aesculap SterilContainer Systems.

Appendix 3: US Parameters Rigid Container Compatibility for Legacy Instrument Sets

Hip Instruments

Femoral Hip Instruments	Secur-Fit Advanced Femoral Prep (Single Tray)	1601-5005
	Secur-Fit Advanced Procedure Tray 1 All V40 Head Trials (Part Numbers 6264-x-xxxR) must be removed from the tray and sterilized separately. The remaining instruments may remain in the tray and placed in a rigid container or be placed loosely in a basket inside the rigid container.	1601-5006
	(Secur-Fit) Procedure Tray 2 The Head/Neck Impactor (Part Number 1601-1700) must be removed from the tray and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	1601-5007
	Anato General Instrument Tray All V40 Head Trials (Part Numbers 6264-x-xxx(R)) must be removed from tray and sterilized separately. The remaining instruments may remain in the tray and placed in a rigid container or be placed loosely in a basket inside the rigid container.	4845-7-602
	Anato Bixcut Reamer Tray (Single Tray)	4845-7-603
	Anato Femoral Instruments Tray (Single tray)	4845-7-601
	Direct Anterior Retractor Tray (Single Tray)	1440-2091
	Direct Anterior Femoral Tray The V40 Stem Extractor (Part Number 4845-7-530) and the Quick Connect Handle (part Number 1440-1040) must be removed from the tray and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	1440-2092
	Accolade II Broach Tray (Single Tray)	1020-9002
	(Restoration Modular) Starting Instrument Tray Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-900*
	(Restoration Modular) Conical Distal Reamer Tray 1 13mm-20mm Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-910*
	(Restoration Modular) Proximal Cone Reamer Tray 2 21mm-28mm Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-911*
	(Restoration Modular) Cone Body Trial Tray 1 19mm-25mm Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-940*

* Product is not CE Marked.

Appendix 3: US Parameters Rigid Container Compatibility for Legacy Instrument Sets

Hip Instruments

Femoral Hip Instruments	(Restoration Modular) Cone Body Trial Tray 2 27mm-31mm Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-941*
	(Restoration Modular) Proximal Cone Reamer Tray 19mm-31mm Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-942*
	(Restoration Modular) Finishing Instrument Tray 1 (Upper Half Tray) Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-970*
	(Restoration Modular) Finishing Instrument Tray 1 (Lower Full Tray) Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-970*
	(Restoration Modular) Finishing Instrument Tray 2 Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6278-9-971*

* Product is not CE Marked.

Acetabular Hip Instruments	(Direct Anterior) Straight/Curved Cup Impactor Tray The Universal Impactor/Positioner (Part Number 2101-0200) and the Lateral Decubitus Alignment Guide (Part Number 1440-1370) (both instruments are optional) must be removed from tray and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	1440-2093
	Restoration Anatomic Shell Left Tray (Single Tray)	2107-4005
	Restoration Anatomic Shell Right Tray (Single Tray)	2107-4006

Appendix 3: US Parameters Rigid Container Compatibility for Legacy Instrument Sets

Knee Instruments

Triathlon Primary (PS, CR,and CS)	Size 1, 8 PS Prep & Trialing (Lower Tray)	6541-8-113
	Size 2, 7 PS Prep. & Trialing (Upper Tray)	6541-8-022
	Size 3-6 Femoral & Tibial Prep (Upper Tray) Instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6541-8-002
	Size 3-6 Femoral & Tibial Prep (Lower Tray) The Tibial Alignment Distal Assembly (Part Number 6541-2-610) must be removed from the tray and sterilized separately. Theremaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6541-8-102
	Size 3-6 Femoral & Tibial Trailing (Lower Tray)	6541-8-109
	Size 3-6 Femoral & Tibial Trialing (Upper Tray)	6541-8-009
	Size 1-8 Max PS Tibial Trialing (Single Tray)	6541-8-120
	Size 1, 8 CR Prep. And Trialing (Lower Tray)	6541-8-112
	Size 2, 7 CR Prep. & Trialing (Upper Tray)	6541-8-021
	Size 3-6 CR Femoral & Tibial Trialing (Lower Tray)	6541-8-108
	Size 3-6 CR Femoral & Tibial Trialing (Upper Tray)	6541-8-008
	1-8 CS Tibial Insert Trial (Single Tray)	6541-8-301
	Patella Prep & Trialing (Lower Tray)	6541-8-105
	Patella Prep & Trialing (Upper Tray)	6541-8-005
	Universal Baseplate Prep (Upper Tray) Additional instruments must not be added in the bin.	6541-8-040
	Tibial Augment Trials (Lower Tray) Additional instruments must not be added in the bin.	6541-8-140
	Miscellaneous Instruments (Upper Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	6541-8-004
	Miscellaneous Instruments (Lower Tray) The Slap Hammer (Part Number 6541-4-803) must be removed from the tray and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6541-8-104
	General - Triathlon Precision (Lower Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	5555-5103
	General - Triathlon Precision (Upper Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	5555-5102

Appendix 3: US Parameters RigidContainer Compatibility for Legacy InstrumentSets

Knee Instruments

	Non-Nav Triathlon Precision (Upper Tray) The Distal Ankle Clamp (Part Number 6541-2-610) must be removed and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	5555-5151
	MIS 3-6 Femoral Tibial Prep (Upper Tray) The MIS Femoral Trial Extractor (Part Number 6541-7-809) must be removed and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6541-8-030
	MIS 3-6 Femoral Tibial Prep (LowerTray) The Tibial Alignment Distal Assembly (Part Number 6541-2-610) must be removed from the tray and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6541-8-130
Triathlon TS Revision	1, 2, 7, 8 TS+ Insert Trials (Single Tray)	6543-8-011
	7, 8 TS+ Insert Trials (Single Tray)	6543-8-013
	3-6 TS+ Insert Trials (SingleTray)	6543-8-007
	1,2,7,8 Femoral/Tibial (Lower Tray)	6543-8-109
	1,2,7,8 Femoral/Tibial (Upper Tray)	6543-8-009
	3-6 Revision Femoral Prep & Trialing (Lower Tray)	6543-8-103
	3-6 Revision Femoral Prep & Trialing (Upper Tray)	6543-8-003
	3-6 Revision Tibial Prep & Trialing (Lower Tray)	6543-8-102
	3-6 Revision Tibial Prep & Trialing (Upper Tray)	6543-8-002
	1, 2, 7, 8 Trial Cutting Guides (Lower Tray)	6543-8-115
	1, 2, 7, 8 Trial Cutting Guides (Upper Tray)	6543-8-015
	3-6 Trial Cutting Guides (Lower Tray)	6543-8-114
	3-6 Trial Cutting Guides (Upper Tray)	6543-8-014
	1-8 TCG Max Thickness Insert Trials (Single Tray)	6543-8-016
	9mm-21mm IM Reamers (Upper Tray)	6543-8-001
	9mm-21mm IM Reamers (Lower Tray)	6543-8-101
	19mm-22mm Stem Trials (Upper Tray)	6543-8-005
	19mm-21mmStem Trial (Lower Tray)	6543-8-105
	22 - 25mm Reamers & StemTrials	6543-8-108
	Misc. Revision Instruments (Upper Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	6543-8-004
	Misc. Revision Instruments (Lower Tray) The Slap Hammer (Part Number 6541-4-803) must be removed from the tray and sterilized separately. The remaining instruments must be removed from the tray and placed loosely in a basket inside the rigid container.	6543-8-104

Appendix 3: US Parameters Rigid Container Compatibility for Legacy Instrument Sets

KneeInstruments

	Triathlon Femoral Cone Prep 1 Tray (Single Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	6543-8-118
	Triathlon Femoral Cone Prep 2 Tray (Single Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	6543-8-018
	Triathlon Tibial Cone Upper Tray (Single Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	6543-8-017
	Triathlon Tibial Cone Lower Tray (Single Tray) Instruments must be removed from tray and placed loosely in a basket inside the rigid container.	6543-8-117

Appendix 4: OUS Parameters Blue Sterilization Wrap Compatibility for Legacy Instruments Sets

Stryker Orthopaedics has conducted validation testing for compatibility of Hips and Knees Instrument Sets for OUS Parameters (134-137°C for minimum 3minutes).

Below are instructions for Hip and Knee instrument sets which contain Slap Hammer, Non Threaded Impactor and Head Impactor.

Knee Instrument	Triathlon Misc. Revision Instruments (Lower Tray) 6543-8-104 Triathlon Primary Miscellaneous Instruments (Lower Tray) 6541-8-104 The Slap Hammer (Part Number 6541-4-803) must be removed from the tray and sterilized separately using Double Blue Sterilization Wrap or Double Sterilization Pouch.

Hip Instrument	Cutting Edge Acetabular Reamer Tray 2402-0007 OMNIFIT Acetabular Instrument Tray Trident Acetabular Instrument Tray Non Threaded Impactor (Part Number 2101-0130) must be removed from the tray, disassembled and sterilized separately using Double Blue Sterilization Wrap or Double Sterilization Pouch.
	ABG II Femoral InstrumentTray 4849-6-300 Exeter Femoral V40 FET ray Head Impactor (Part Number 4842-2000) must be removed from the tray, disassembled and sterilized separately using Double Blue Sterilization Wrap or Double Sterilization Pouch.

Appendix 4: OUS Parameters Blue Sterilization Wrap Compatibility for Legacy Instruments Sets

Thermoform Hip and Knee Instrument/Tray configurations which are not in the scope for OUS sterilization using Blue Sterilization Wrap can only be sterilized for use in a Blue Sterilization Wrap using US Parameters (132°C for 4 Minutes).

Below are lists of Thermoform Hip and Knee Trays which are not in the scope for OUS Sterilization using Blue Sterilization Wrap (134-137 °C, minimum 3 minutes).

Hip System – Thermoform Trays

Description	Tray #
Modular Starter Instrument Tray Insert Assembly	6278-9-900*
Cone Body – Trial Body Tray # 2 27mm – 31mm Restoration Modular Instrument System	6278-9-941*
Conical Reamer Tray #1 13mm – 20mm Restoration Modular Instrument System	6278-9-910*
Conical Reamer Tray # 2 21mm – 28mm Restoration Modular Instrument System	6278-9-911*
Broach Tip Tray - 167mm Straight Restoration Modular Instrument System	6278-9-933*
127mm & 167mm Broach Tip Tray 23mm –26mm Restoration Modular Instrument System	6278-9-934*
Broached Body Tray Restoration Modular Instrument System	6278-9-930*
Broach Tip Tray - 127mm Straight Restoration Modular Instrument System	6278-9-932*
Calcar Body Trial Tray # 1 19mm – 25mm Restoration Modular Instrument System	6278-9-960*
Calcar Body Trial Tray # 2 27mm – 31mm Restoration Modular Instrument System	6278-9-961*
Proximal Cone Reamer Tray 19mm – 31mm Restoration Modular Instrument System	6278-9-942*
Milled body Instrument Tray Restoration Modular Instrument System	6278-9-952*
Calcar Body Instrument Tray Restoration Modular Instrument System	6278-9-962*
Modular Starter Instrument Tray Insert Assembly	6278-9-900*
Cylindrical Distal Stem Trial Tray – 127mm Straight Restoration Modular Instrument System	6278-9-920*
Cylindrical Distal Stem Trial Tray – 167mm Straight Restoration Modular Instrument System	6278-9-921*

* Product is not CE Marked.

Appendix 4: OUS Parameters Blue Sterilization Wrap Compatibility for Legacy Instruments Sets

Hip System – Thermoform Trays

Description	Tray #
127mm & 167mm Cylindrical Distal Trial Tray 23mm – 26mm Restoration Modular Instrument System	6278-9-922*
Cylindrical Reamer Tray #1 10mm – 14.5mm Restoration Modular Instrument System	6278-9-912*
Cylindrical Reamer Case #2 15mm – 18.5mm Restoration Modular Instrument System	6278-9-913*
Cylindrical Reamer Tray #3 19.0mm – 22.5mm Restoration Modular Instrument System	6278-9-914*
Cylindrical Reamer Tray #4 23.0mm – 26.0mm Restoration Modular Instrument System	6278-9-915*
Restoration Modular Finishing Instrument Tray	6278-9-970*
Finishing Instrument Tray #2 Restoration Modular Instrument System	6278-9-971*
Trident Sterilization Top Tray	2402-0040*
Trident Sterilization Middle Tray	2402-0060*
Trident Instrument Bottom Tray	2402-0020*
Cutting Edge Acetabular Reamer / Trial Tray (small sizes)	2402-0009
Trident Instrument Bottom Tray	2402-0080*
Tritanium Window Trials Top Tray	2402-4040*
Tritanium Window Trials Bottom Tray	2402-4060*
217 mm Bowed Distal Stem Trial Tray 10-22mm Straight Restoration Modular Instrument System	6278-9-924*
167 mm and 217 mm Bowed Distal Stem Trial Tray 23-26mm Straight Restoration Modular Instrument System	6278-9-925*

* Product is not CE Marked.

Appendix 4: OUS Parameters Blue Sterilization Wrap Compatibility for Legacy Instruments Sets

Knee System – Thermoform Trays

Description	Tray #
X-Celerate P2S Scorpio Patellar Resection Instrument Tray	8000-2017*
X-Celerate F4 Scorpio CR Femoral Trial Tray	8000-2003*
X-Celerate T3 Scorpio CR Tibial Insert Trial Tray	8000-2024*
X-Celerate F1 AR Femoral Alignment Tray	8000-2007*
X-Celerate F2 Scorpio AR Femoral Preparation Tray	8000-2008*
X-Celerate F3 Scorpio Femoral Recess /Notch Preparation Tray	8000-2009*
X-Celerate Miscellaneous Instruments Tray	6676-1-104
X-Celerate Kinemax Femoral Trial Tray	6676-1-107*
Tibial Insert Tray	6676-1-116
X-Celerate Scorpio Miscellaneous Instruments Tray	8000-2011*
X-Celerate T1 Tibial Alignment Tray	8000-2020*
X-Celerate T2 Scorpio Tibial Preparation Tray	8000-2021*
X-Celerate F4 Scorpio PS Femoral Trial Tray	8000-2005*
X-Celerate T3 Scorpio PS Tibial Insert Trial Tray	8000-2025*
SR1 – IM Reamer Tray 1 Scorpio IM Revision System	8200-0150*
SR1 Scorpio TS IM Reamer Tray 17-23mm	8200-0151*
SR2 Extension Gap Prep Tray 1 Scorpio IM Revision System	8200-0152*
SR2 Extension Gap Prep Tray 2 Scorpio IM Revision System	8200-0153*
SR2 Extension Gap Prep Tray 1 Scorpio IM Revision System	8200-0154*
SR3 Scorpio TS Tibial Preparation Tray # 2	8200-0155*
SR4 Femoral Preparation Tray # 1 Scorpio IM Revision System	8200-0156*
SR4 Femoral Preparation Tray # 2 Scorpio IM Revision System	8200-0157*
SR5 Stem Trial Tray Scorpio IM Revision System	8200-0158*
SR6 – Femoral Trial Tray Scorpio IM Revision System	8200-0160*
SR6 – Tibial Augment Trial Tray Scorpio IM Revision System	8200-0161*

* Product is not CE Marked.

Appendix 4: OUS Parameters Blue Sterilization Wrap Compatibility for Legacy Instruments Sets

Knee System – Thermoform Trays

Description	Tray #
SR6 – Femoral & Tibial Augment Trial Tray Scorpio IM Revision System	8200-0162*
SR7 Tibial Trial Tray # 1 Scorpio IM Revision System	8200-0163*
SR7 Tibial Trial Tray # 2 Scorpio IM Revision System	8200-0164*
SR8 – Miscellaneous Tray 1 Scorpio IM Revision System	8200-0165*
SR8 – Miscellaneous Tray 2 Scorpio IM Revision System	8200-0166*

* Product is not CE Marked.

Appendix 5: OUS Parameter Rigid Container Compatibility for Complete Instruments Sets

Stryker Orthopaedics has validated steam sterilization of complete, fully loaded reusable instrument trays for OUS Parameters with Aesculap's SterilContainer System. All trays are screen printed with the words RIGID CONTAINER COMPATIBLE. Other rigid container systems may be suitable for use, but must be evaluated by the end-user.

Stryker Orthopaedics has conducted validation testing for compatibility of Instrument Sets for OUS Parameters (134-137°C for minimum 3 minutes).

Refer to Aesculap Instructions for Use for Care & Handling of Aesculap SterilContainer Systems (JN442).

HipInstruments	Exeter Broach Tray	Tray: 0585-9-900 Lid: 6147-0-100	Aesculap Configuration Base: JN442 Lid: JK48x
	Exeter Plug Trial Tray	Tray: 0585-9-901 Lid: 6147-0-100	
	Exeter Retractor Tray	Tray: 0585-9-902 Lid: 6147-0-100	
	Exeter Extension Broach Tray	Tray: 0585-9-903 Lid: 6147-0-100	
	ETS Instrument Tray	Tray: 0585-9-904 Lid: 6147-0-100	
	General Femoral Tray	Tray: 0585-9-905 Lid:6147-0-100	
	Trident II Core Reamers (38-66) mm Tray*	Tray: 7000-0100	
	Trident II General Instruments Tray*	Tray: 7000-0101	
	Trident II Core Trials Tray*	Tray: 7000-0102	
	Trident II Auxiliary Trials Tray *	Tray: 7000-0103	

* The compatible Trident II Implant system is not CE Marked and is not available outside of the USA.

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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.
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