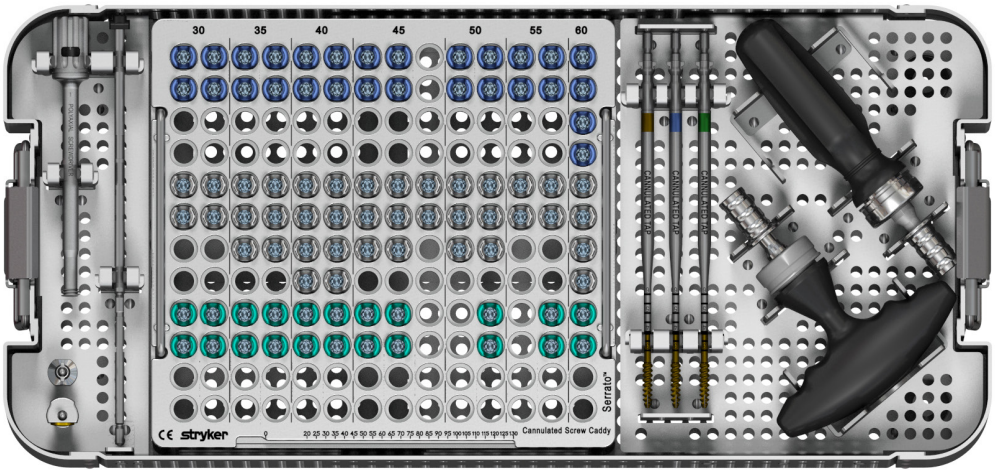
Instructions for:

Cleaning, sterilization, inspection, and maintenance of reusable medical devices

Instructions for Stryker Spine



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1. Introduction

This document is intended to provide detailed instructions for processing reusable devices manufactured by Stryker Spine. All Stryker Spine reusable devices 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 Spine 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 accordance with ISO 17664, two methods of cleaning Stryker Spine 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

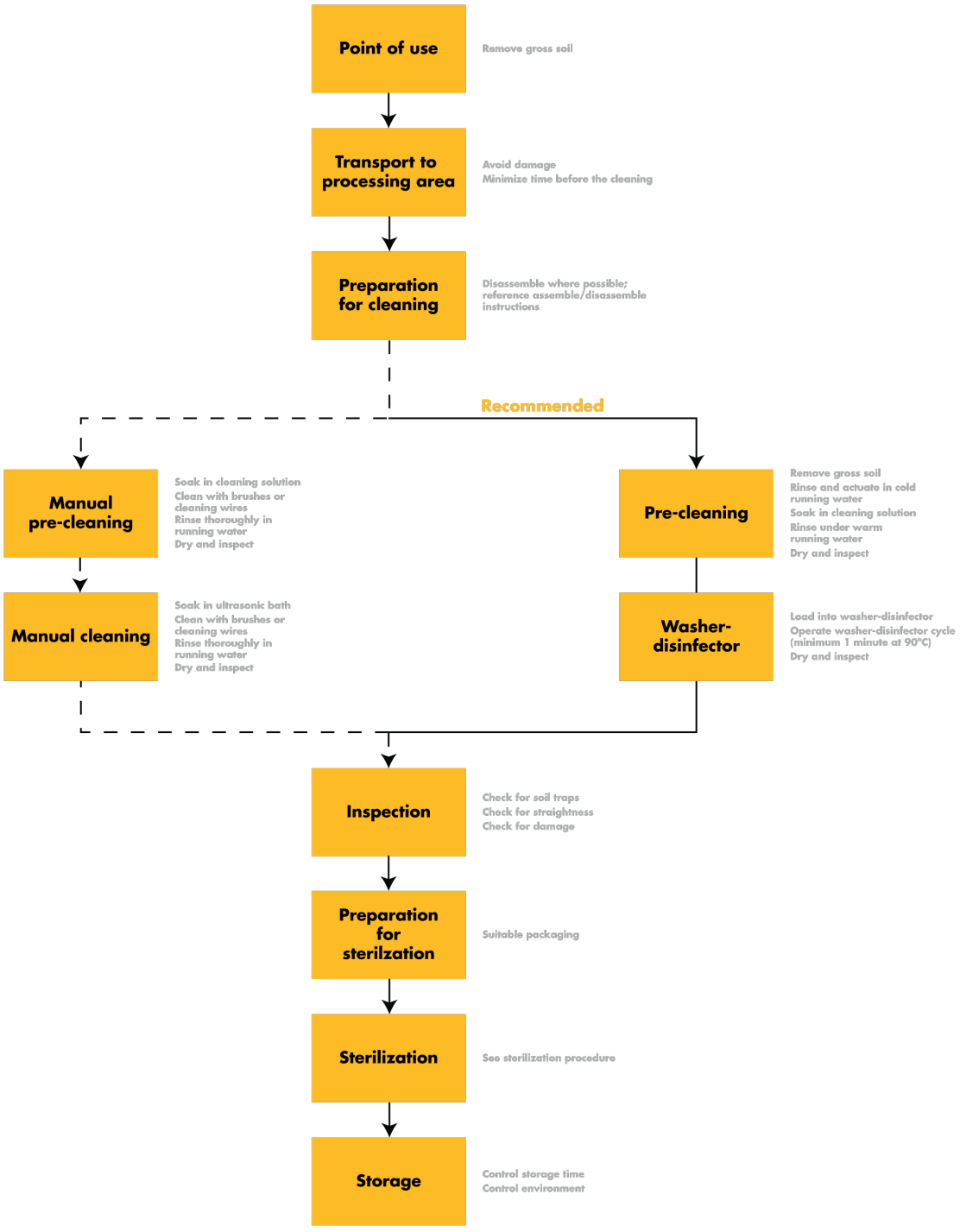
Single use devices must not be reused, as they are not designed to perform as intended after the initial use, unless they are reprocessed by a reprocessor expressly authorized by Stryker Spine. Only then can it be assured that the device is appropriate for reprocessing and that the correct methods of 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 Spine reusable devices 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 device 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 sharp edges, both to avoid personal injury and prevent damage to the reusable devices. Transport the reusable devices 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 prior to cleaning.

Caution:
Stryker Spine 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 device 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 and/or firm bristle brushes, clean the re-usable instrument thoroughly, paying particular attention to rough surfaces, threaded areas and features where soil may be impacted or shielded from the cleaning process.

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.

4. Manual cleaning

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, threaded areas 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 re-usable instruments, only specifically formulated cleaning agents should be used.

As not all cleaning agents may be available around the globe, Stryker Spine does not recommend any specific cleaning agent. The end user should verify the selected cleaning agent is appropriate for use on reusable surgical devices.

5. Automated cleaning and disinfection

Equipment required:

- 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 rinse/disinfection program (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 device 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:
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 devices 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, threaded areas, and flexible shafts.
- Recessed features (holes, cannulations and textured surfaces).
- Features where soil may be impacted into the device, such as taps, drills, rongeurs
- 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).

“Flexible” instruments should be checked for damage to the spiral element.

Note:
The useful life of reusable devices depends on many factors, including the method and duration of each use and the handling between uses.

Devices should be examined for wear and damage prior to surgery. The examination shall include a visual and functional inspection of the working surfaces, articulation points and springs.

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 Spine case/tray configurations should be double wrapped according to AAMI/CSR technique.

The packaging for terminally sterilized reusable devices 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:

- AAMI ST79
- ISO 11607
- CE mark
- FDA 510(k) clearance for specified sterilization parameters

For rigid containers:

Stryker Spine has validated steam sterilization of complete reusable device trays with Aesculap SterilContainer System.

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

For all sterilization packaging configurations, Stryker Spine 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 Spine 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 ISO 17665 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/AAMI ST79, and EN ISO 17665 and recommended for sterilization. Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) or a gravity displacement 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 Spine has validated the recommended sterilization cycle for complete reusable device cases/ trays.

Compatibility with rigid container systems is provided in Appendix 2. Rigid Container Steam Sterilization Instructions for outside USA are provided in Appendix 4.

Caution:
These parameters may differ in the instructions for use for some of Stryker Spine systems. However, both parameters have been validated.

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 (minimum, in chamber)

Method	Moist heat sterilization according to ANSI/AAMI ST79
Cycle	Gravity displacement
Temperature	132°C (270°F)
Exposure time[1]	15 minutes
Drying time[2]	30 minutes (minimum, in chamber)

Outside USA

Method	Moist heat sterilization according to ISO 17665
Cycle	Pre-vacuum (dynamic air removal)
Temperature	134°C (273°F)
Exposure time[1]	3 minutes (minimum)
Drying time[2]	30 minutes (minimum, in chamber)

Caution:
Stryker Spine 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. Therefore, dry time may be repeated if moisture is present on the wrap and/or instruments.

9. **Storage** before use

After sterilization, reusable devices 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 devices should be defined by each health care facility based on the recommendations of the wrap or container manufacturer.

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

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

5. EN 285: Sterilization — Steam sterilizers — large sterilizers

6. EN 13060: Small steam sterilizers

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

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

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

10. 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

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

Appendix 1:

Instructions for disassembly for cleaning

Part number	Instrument name	Surgical system	Steps	Instructions
48805090	Quick Turn Screwdriver	Anterior Cervical Plate System (ACP)	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the "unlock" button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.
			4	Release the quick connect handle from the quick connect mechanism.

Part number	Instrument name	Surgical system	Steps	Instructions
48921011 **48921013** **48921015** **48921017** **48921019** **48921100**	Guide Assembly (11mm, 13mm, 15mm, 17mm, 19mm) Inserter Guide Inner Shaft	Aero-AL	1	Unthread the inserter guide inner shaft from the main body of the inserter guide.
48921005	Revision Guide		1	Unthread the revision guide inner shaft from the main body of the inserter guide.

Appendix 1:

Instructions for disassembly for cleaning

Part number	Instrument name	Surgical system	Steps	Instructions
49177225	Blocker Driver	Anterior Lumbar Plating	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the "unlock" button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.
			4	Release the quick connect handle from the quick connect mechanism.
49177240	Rescue Screwdriver		1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the "unlock" button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.
			4	Release the quick connect handle from the quick connect mechanism.

Part number	Instrument name	Surgical system	Steps	Instructions
48280178 **48280179** **48280180** **48280181** **48280182** **48280183**	Ratchet Knob Adjustable Arm Distraction Shaft 2 Level Rack 4 Level Rack Fixed Arm	ES2	1	Put the latch on the compression/ distraction mechanism in the unlock position.
			2	Slide the Adjustable Arm off of the rack.
			3	Remove the Ratchet Knob from the compression/distraction mechanism by firmly pulling on the knob straight back and away from the instrument.
			4	Press the lever on the Fixed Arm into the "unlock: position and slide the Fixed arm off of the rack. Note: The outer sleeve of the arms should be in the locked, neutral position for cleaning.

Appendix 1:

Instructions for disassembly for cleaning

Part number	Instrument name	Surgical system	Steps	Instructions: Polyaxial Screwdriver
48280310	Polyaxial Screwdriver	ES2	1	Release the quick connect handle from the Screwdriver shaft Adapter.
			2	Remove the Screwdriver Adapter by pressing the "unlock" button on the Locking Nut.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.

Part number	Instrument name	Surgical system	Steps	Instructions: Recovery System
48280095 **48280096** **48280097**	Inner Shaft Outer Sleeve T-Hex Handle	ES2	1	Fully loosen the instrument components by rotating the hex on top of the Recovery Outer Sleeve in a Counter Clockwise direction. This will disengage the threads.
			2	While squeezing the tips of the inner shaft and expanding the arms of the outer sleeve with your other hand, rotate the outer sleeve 90 degrees in the other directions.
			3	Pull inner shaft and outer sleeve apart as shown.
			4	Final tightening should be done with the Recovery System in place and Counter torque Tube on adjacent screw.

Part number	Instrument name	Surgical system	Steps	Instructions
48562018	Polyaxial Screwdriver	Oasys	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the "unlock" button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.
			4	Release the quick connect handle from the quick connect mechanism.

Appendix 1:

Instructions for disassembly for cleaning

Part number	Instrument name	Surgical system	Steps	Instructions
48583016	Polyaxial Screwdriver	Oasys Square Drive	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the "unlock" button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.
			4	Release the quick connect handle from the quick connect mechanism.

Part number	Instrument name	Surgical system	Steps	Instructions
482397004	Low Profile Screwdriver	Xia Elegance	1	Release the quick connect handle from the Screwdriver shaft Adapter.
			2	Remove the Screwdriver Adapter by pressing the "unlock" button on the Locking Nut.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.

Part number	Instrument name	Surgical system	Steps	Instructions
48261330 48261330S	Polyaxial Screwdriver, Polyaxial Screwdriver, Short	Xia 3 - Serrato	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the "unlock" button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.
			4	Release the quick connect handle from the quick connect mechanism.

Appendix 1:

Instructions for disassembly for cleaning

Part number	Instrument name	Surgical system	Steps	Instructions
48235001	Lateral Persuader	Xia 3	1	Release the quick connect handle from the Screwdriver shaft Adapter.

Part number	Instrument name	Surgical system	Steps	Instructions
48231330 **482391330S** **482391330L** **48231320** **482391320S** **482391320L**	Polyaxial Screwdriver Polyaxial Short Screwdriver Polyaxial Long Screwdriver Monoaxial Standard Screwdriver Monoaxial Short Screwdriver Monoaxial Long Screwdriver	Xia (3 and Elegance)	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the “unlock” button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.

Part number	Instrument name	Surgical system	Steps	Instructions
482331330	Uniplanar Screwdriver Reduction	Xia 3	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the “unlock” button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.

Part number	Instrument name	Surgical system	Steps	Instructions
48856006 **48138012** **48138013**	Cannulated Screwdriver Shaft Screwdriver Outer Sleeve Screwdriver Locking Nut	Xia 4.5 Xia CT	1	Release the quick connect handle from the quick connect mechanism.
			2	Remove the quick connect mechanism by pressing the “unlock” button. Remove the quick connect mechanism from the inner shaft.
			3	Remove the inner sleeve by sliding it through the bottom of the outer shaft.

Appendix 2:

Rigid container compatiblilty for complete instruments sets

Stryker Spine has validated steam sterilization of complete, fully loaded reusable device trays with Aesculap's SterilContainer System. 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 & Handling of Aesculap SterilContainer Systems.

Brand name		
	Aero-AL	Instrument Tray 1: 4892200 Instrument Tray 2: 4822001
	Aero-C	Instrument Container: 48890000
	Aero-LL	Instrument Container: 48940000
	ES2 Augmentable	Alignment Guide: 48491301 Hex Handle: 48491302 Monoaxial ScrewDriver Inner Shaft: 48491304
	IBD PEEK C	Instrument Container: 48808200A
	LITe	LLIF Implant Container: 49179000 ALIF Implant Container: 49179100 Buttress Plate Container: 49179102 Plating Instrument Container: 49179200
	Tritanium C	Instrument Container: 48980001
	UniVise	Instrument Container: 48590000
	Anterior Cervical Plate System (ACP)	Instrument Container: 48805200

Appendix 3:

Rigid container steam sterilization instructions

In order to ensure proper sterilization of Stryker Spine devices when using the Aesculap SterilContainer (JN series) reusable, rigid sterilization containers, the information below must be following:

1. Only the following Aesculap reusable rigid container configuration, FDA-cleared, shall be used in a pre-vacuum steam sterilization cycle for use in the USA:

Name	Part Number	Description
Container base	JN442	Full size, 6-inch height, perforated bottom
Lid	JK489	Full size, 2000 lid, aluminum
Filter	US994	7½ inches round, single use

2. Only the following Aesculap reusable rigid container configuration shall be used in a pre-vacuum steam sterilization cycle for use outside the USA:

Name	Part Number	Description
Container base	JN442	Full size, 6-inch height, perforated bottom
Lid	JK489	Full size, 2000 lid, aluminum
Filter	JK095	Round filter paper with process indicator, CE marked

3. Aesculap SterilContainer instructions for use must be followed. If questions arise regarding the use of the Aesculap SterilContainer reusable, rigid sterilization container, Stryker Spine recommends contacting Aesculap directly for guidance.

Appendix 3:

Rigid container steam sterilization instructions

4. Sterilization instructions:

a. No more than two (2) individual Stryker Spine Tray inserts can be placed directly into the Aescula SterilContainer (JN Series) reusable, rigid sterilization container (perforated bottom).

b. Stryker Spine devices must be placed in their designated locations within the tray inserts.

Stryker Spine's single devices or modules/caddies/racks may be placed into an Aesculap basket (JC223R or similar) which can be loaded into the Aesculap SterilContainer reusable, rigid sterilization containers.

Note: Devices must be placed such that individual devices are not stacked and remain in an open position to allow uniform exposure to steam.

c. Stryker Spine Container lids must be removed prior to use with the Aesculap reusable, rigid sterilization container.

d. Stryker Spine devices were validated under the following USA sterilization parameters for a pre-vacuum, three pulse steam cycle:

- **Temperature:** 132°C (270°F)
- **Exposure time:** 4 minutes
- **Cycle dry time:** 30 minutes

e. Stryker Spine devices were validated under the following outside the USA sterilization parameters for pre-vacuum, three pulse steam cycle:

- **Temperature:** 134°C (270°F)
- **Exposure time:** 3 minutes
- **Cycle dry time:** 30 minutes

f. Reusable rigid sterilization containers must not be stacked within the autoclave as doing so may negatively impact ventilation and sterilization.

Appendix 4:

OUS Parameters blue sterilization wrap combatibility for Xia 3 sets

Stryker Spine has conducted validation testing for compatiblity of the Xia 3 sets noted below for OUS Parameter (134°C for a minimum 3 minutes).

Below are instructions for Xia 3 sets which contain the French Bender.

Name	Description
Xia 3 Degenerative Instrument Tray	48230012B (Base tray) The French Bender (Part Number 48237010) must be removed from the tray and sterilized separately using a double blue sterilization wrap.

Name	Description
Xia 3 Rods and Cross Connectors Box	48230006 (Base tray) The French Bender (Part number 48237010) must be removed from the tray and sterilized separately using a double blue sterilization wrap.

stryker

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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 MedicalDeviceDirective93/42/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.

NSRDEV-RG-1_17768