Instructions for Use: Reprocessing of Reusable Surgical Instrument Sets

Caution: Federal law restricts this device to sale by or on the order of a physician

DESCRIPTION

The sterilization tray is a reusable tray that holds the surgical instruments before, during and after steam sterilization.

The reusable surgical instruments shipped with this sterilization tray are designed for use in orthopedic surgical procedures for implantation of devices manufactured by Paradigm Spine. Prior to use of these instruments, please refer to the implant instructions for use specific to the product line and the surgical procedure to be followed.

MATERIAL

The sterilization tray is a made from stainless steel or Polyphenylsulfone (PPSU) and may include Polypropylene (PP) brackets and/or Silicone.

The surgical instruments are mainly made from medical grade acetal copolymer (POM), stainless steel and may include silicone, aluminium alloy, titanium alloy, Polyamide 6 and/or Polytetrafluoroethylene (PTFE).

INTENDED USE

The sterilization tray is intended to hold instruments during transport, steam sterilization and storage.

The surgical intruments are intended to be used for spinal instrumentation. The actual therapeutic effect is achieved by the implant.

PRECAUTIONS

- Prior to use, thoroughly read these instructions for use.
- Keep the instructions for use accessible to all staff.
- The methods of use of these instruments are to be determined by the user's experience and training.
- Never use or process damaged or defective devices. Contact your local sales representative or Paradigm Spine for repair or replacement.
- The use of a surgical instrument for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- Caution should be used while handling delicate instruments or instruments with sharp tips.
- Use only soft brushes, no metal brushes.
- Do not process the surgical instruments at a temperature at or greater than 140°C/284°F.
- Do not apply excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.
- Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.
- Make sure the product is only used by accordingly qualified or trained staff.
- Follow the general guidelines and aseptic principles when handling items to be sterilized or sterile items.
- The user must thoroughly inspect and clean the instruments prior to steam sterilization. Inadequate cleaning may result in residual contamination that may result in patient injury.
- The personnel entrusted with the processing must have the requisite knowledge and qualifications.
- Please ensure that only appropriate equipment is used for cleaning and sterilization of the reusable surgical devices and that performance requalification, periodic routine tests are carried out on the equipment in accordance with local procedures, guidelines, and standards.

PROCESSING AND REPROCESSING OF REUSABLE SURGICAL DEVICES

FUNDAMENTALS

Paradigm Spine's reusable surgical instruments are delivered unsterile. Therefore, they are to be cleaned and sterilized prior to each application. Effective cleaning is indispensable requirements for an effective sterilization of the instruments.

INSTRUMENT BACKGROUND

Surgical instruments are designed to perform specific functions such as cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures. Surgical instruments are also used to facilitate the insertion of surgical implants. Proper cleaning, sterilization, handling and routine maintenance help to ensure that surgical instruments perform as intended.

HOW SUPPLIED

Paradigm Spine's surgical instruments are supplied non-sterile and must be thoroughly cleaned and sterilized prior to use according to the instructions in this document.

The equipped sterilization tray is supplied individually packed in protective packaging that is labeled according to its contents.

Before processing, inspect the instruments and sterilization tray carefully for damage, wear and/or non-functioning parts. Carefully inspect the inaccessible areas, joints and all moveable parts.

CARE AND HANDLING AT THE POINT OF USE

As soon as possible after use, dismantle where applicable the instruments, rinse, and flush lumened devices. Only disposable wipes and soft brushes (e.g., brushes with nylon bristles) may be used to remove coarse impurities.

TRANSPORTATION

Surgically used instruments are safely transported to the reprocessing site in a closed container.

PRETREATMENT AND CLEANING OVERVIEW

- An automated cleaning procedure (e.g., Washer-Disinfector) should be used for cleaning of the instruments after manual pre-cleaning.
- It is recommended that devices should be processed as soon as reasonably possible after surgical use to facilitate the cleaning process afterwards.
- Instruments must be cleaned separately from instrument trays and cases.
- Do not soak instruments in any solution for more than two hours.
- The cleaning agent should be an enzymatic based detergent suitable for instruments made of metallic or plastic materials for surgical use.
- An alkaline enzymatic detergent with low-foam formulation was utilized for validation testing.

PROCEDURE: PRETREATMENT (Manual Pre-Cleaning Method)

- Multi-part or complex instruments may require disassembly for effective cleaning. Refer additional disassembly instructions included in this IFU.
- Rinse the instruments a minimum 1 minute under running water (temperature < 35 °C/95 °F). If applicable actuate movable parts a minimum 3 times. Thoroughly flush all lumens or cavities of the instruments at the beginning of the soaking time. Use a syringe or a jet pistol to flush until no more soil is visible or to apply a rinsing volume of a minimum 150ml.
- Soak the disassembled instruments for the recommended soaking time (Reference the instructions from the detergent manufacturer regarding concentration and soaking time) in the pre-cleaning solution so that the instruments are sufficiently covered. Pay attention not to overlap the instruments.
- Assist cleaning by carefully brushing of all inner and outer surfaces with an appropriate soft brush. Brush size should be approximately the same diameter and a minimum the same length as the lumen to be cleaned. Using a brush that is either too large or mall in diameter or too short in length may result in ineffective cleaning of the lumen/cannulation.
- Rinse the instruments a minimum 1 minute under running water (temperature < 35 °C/95 °F). If applicable actuate movable parts a minimum 3 times during pre-rinsing. Thoroughly flush all lumens or cavities of the instruments at the end of the soaking time. Use a syringe or a jet pistol to flush until no more soil is visible or to apply a rinsing volume of a minimum 150ml.
- Activate ultrasound for an additional soaking time (but not less than 5 min).
- Then, remove the instruments from the pre-cleaning solution, final rinse them intensively a minimum 1 minute under running water (temperature < 35 °C/95 °F). If applicable actuate movable parts a minimum 3 times during post-rinsing. Thoroughly flush all lumens or cavities of the instruments at the end of the soaking time. Use a syringe or a jet pistol to flush until no more soil is visible or to apply a rinsing volume of a minimum 150ml.
- Dry instruments with a soft, clean, absorbent non-shedding lint-free cloth. Blow clean with compressed filtered air through areas difficult to access and all lumens.

Prepare the cleaning solution/bath according to the recommendations of the detergent manufacturer regarding concentration, water quality, temperature, and soaking time as well as post-rinsing and suitability for ultrasonic bath. Please use only freshly prepared solutions, only sterile or reverse osmosis deionized water (RODI).

PROCEDURE: AUTOMATED CLEANING-DISINFECTION METHOD

- Use a Washer-Disinfector (WD) with fundamentally approved efficiency (CE mark or FDA clearance/approval according to EN ISO 15883) with regular maintenance and testing.
- Load the disassembled, pre-treated instruments (refer additional disassembly instructions) in the WD making sure that the lumens/cannulations can drain freely by choosing a suitable orientation and fixating them.
  If applicable connect the instruments to the rinsing ports of the WD.
  Caution shall be taken not to overlap the instruments.

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- Process instruments using a validated standard WD instrument cycle in accordance with the WD manufacturer's instruction taking into account following minimal setting:

Cycle	Cycle time	Process temperature	Medium
Pre-rinsing	1 min	< 40 °C (104 °F)	Tap water
Cleaning	5 min	55 °C ± 4 (131 °F)	Alkaline enzymatic detergent
Rinsing	1 min	> 40 °C (104 °F)	RODI water
Thermal disinfection	5 min	90 °C ±3 (194 °F)	AD
Drying	25 min	100 °C (212 °F)	Filtered Air

- Disconnect and remove the instruments from the WD after end of the program.
- Check and pack the instruments immediately (see section "Inspection, Maintenance and Functional check") if necessary, after post-drying at a clean place).

Note:
Thermal disinfection cycle should be performed to achieve a value A0 ≥ 3000 (e.g., 90°C/194°F for at least 5 minutes according to ISO 15883-1).

Use purified water (distilled water or RODI water) for post-rinsing and thermal disinfection.

Only use of filtered air for drying.

INSPECTION, MAINTENANCE AND FUNCTIONAL CHECK

INSPECTION

The cleaned instruments should be visually inspected for soil or detergent residues, damage, and moisture. Worn-out, corroded, deformed, or otherwise damaged instruments are not to be further reprocessed. Instruments that are still contaminated at this stage should be sorted out and subjected once more to the cleaning process. In case of damages, the cleaned instruments are sterilized and made available for repair.

Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

If moisture is detected, manual drying should be performed.

MAINTENANCE

No maintenance is carried out by the processing facility.

FUNCTIONAL CHECK AND LUBRICATION

A functional check should be performed where possible. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used. The disassembled instruments should be reassembled for the functional check.

Use only instrument lubricant (white oil) compatible with steam sterilization considering the maximum possible sterilization temperature and with proven biocompatibility. Apply only a small amount and only to the joints.

PACKAGING

Place the cleaned, inspected and dry devices on the specified holders within the sterilization cases provided.

Use of an FDA cleared wrap is recommended used in compliance with the manufacturer's instructions for packaging terminally sterilized devices to ensure product sterility.

Place the sterilization trays in a sterilization container, which fulfills following requirements:

- EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilization (temperature resistance up to a minimum of 140 °C /284 °F, sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings against mechanical damage
- regular maintenance of the sterilization container according to the instructions of the manufacturer

The total weight of the instrument case should not exceed 10.8kg or 24 lbs (for metallic tray) and 6.2 kg or 13.6 lbs (for plastic sterilization trays).

STERILIZATION

The use of a fractionated vacuum steam sterilization process is recommended with following validated parameters:

Cycle type	Pulses	Exposure temperature	Recommended exposure time	Recommended drying time
Dynamic air removal	3	132 °C (270 °F)	4 min	30

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer Selectomat PL 669 (MMM Sterilisatoren AG) and the fractionated vacuum/dynamic air removal procedure and the instrument oil Sterilit i (JG600), Aesculap. *Serilization containers with paper filter and double pouches according to EN ISO 11607 (for individually packed instruments) were used.*

Drying time for instruments processed in containers and wrapped trays can vary depending upon the type of packaging, type of instruments, type of sterilizer and total load. A minimum drying time of 30 minutes is recommended but might be extended if necessary.

Use a steam sterilizer with demonstrated efficiency in accordance with EN 13060/EN 285 or ANSI AAMI ST79, which is validated according to EN ISO 17665, properly maintained and calibrated. It is the responsibility of the medical facility to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained.

Do not use flash sterilization procedure, dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

MATERIAL RESISTANCE

The following substances must not be ingredients of the cleaning detergent:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum pH-value 11 or more, weak alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

It is not recommended to add corrosion inhibitors, neutralizing agents, and/or rinse aids to the detergents; they may potentially cause critical remnants on the instruments.

Do not expose any instruments or sterilization trays to temperatures at or greater than 140°C/284°F.

LIMITATIONS ON REPROCESSING

Repeated processing cycles in compliance with these instructions for use have minimal effects on device life cycle and function. Instruments do not have an indefinite life cycle. Their end of life is determined by wear and damage due to surgical use and handling.

Evidence of damage and wear on a device may include but is not limited to corrosion (i.e., rust, pitting), discoloration, excessive scratches, flaking, wear, and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be further used.

A maximum of 100 reprocessing cycles is recommended.

STORAGE

After sterilization, the reusable instruments should be stored in dry and dust-free hospital environmental conditions.

WARRANTY

All warranty rights are lost if repairs or modifications are carried out by an unauthorized service center. The manufacturer does not take responsibility for any effects on safety, reliability, or performance of the product if the product is not used in conformity with the instructions for use. Technical alterations reserved.

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FOR FURTHER INFORMATION

Please contact Xtant Medical if further information on this product is needed.

US Contact	Manufacturer
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SYMBOLS

	Manufacturer
	Country and date of manufacture Note: CC is the letter country code as defined in ISO 3166-1
	Batch code
	Catalog number
	Content of usable units(s)
	Keep dry
	Consult instructions for use at this website.
	Caution
	Medical device
	Unique device identifier
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician