



Instructions for care, maintenance,
cleaning and sterilization of
Smith & Nephew orthopaedic devices



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Purpose

This document was prepared to provide instructions for the care, maintenance, cleaning and sterilization of the medical devices produced by the Orthopaedics Business of Smith & Nephew, Inc. These methods were developed using standard equipment and practices common to health care facilities. Validation testing to support these instructions was based on recognized guidelines and standards for reusable devices and containment devices from the following organizations:

American National Standards Institute (ANSI)

Association for the Advancement of Medical Instrumentation (AAMI)

Association of Operating Room Nurses (AORN)

German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung

Health Canada

International Standards Organization (ISO)

International Association of Healthcare Central Service Material Management (IAHCSMM)

World Health Organization (WHO)

UK Department of Health

Australian/New Zealand Standard

Scope

These instructions apply to all reusable devices that are sold by Smith & Nephew Orthopaedics and are supplied non-sterile but are intended to be used in a sterile state. These instruction also apply to single use devices that are placed in containment devices prior to sterilization (i.e. plates, nails, screws, pins and wires). This includes single use devices that are packaged sterile but are removed from its sterile packaging and placed in containment devices.

Important information/recommendations for use

Automatic washer/disinfector	<p>Washer-disinfectors are not only used to clean devices, but also to provide intermediate to high level disinfection with a hot water rinse. Cleaning is dependent upon thorough coverage of the devices and the force of the water spray. Therefore, all sections of the device must be accessible for ease of cleaning and penetration of cleaning agents. The automatic washer/disinfector equipment should be operated following the manufacturer's instructions for use.</p>
Definitions	<p>Universal Precautions: Universal precautions are standards of infection control practices designed to reduce the risk of transmission of bloodborne infections.</p> <p>Chemical Indicator (CI): Test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process. CIs assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or sterilizer malfunctions. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile.</p> <p>Biological Indicator (BI): Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.</p> <p>Caddy: A small flip top case that contains multiple small implants (i.e. screws, plates, etc).</p> <p>Containment Device: A reusable rigid sterilization container, instrument case/cassette, caddy or organizing tray and any reusable accessories for use in healthcare facilities for the purpose of containing reusable medical devices for sterilization.</p> <p>Single Use Device (SUD): A device that is intended for one use or on a single patient during a single procedure. For clarity, a single use device that has come into contact with blood, tissue or bodily fluids shall not be reprocessed or reused.</p>
Detergents	<p>Low foaming detergents with a pH range between 6.0 and 8.0 are recommended. Detergents with a pH outside this range can have an adverse effect or be damaging to some instruments and containment devices. Enzymatic detergents aid in the removal of organic soil such as blood.</p> <p>Detergents should be used at the concentration and temperature recommended by the detergent manufacturer.</p> <p>There are some alkaline detergents that have been formulated to be safe for reprocessing medical devices. Refer to the manufacturer's limitations and warnings for information concerning specific materials that are adversely affected by the detergents.</p>
Loaner Instrument Set	<p>It is the hospital's responsibility for cleaning, disinfection, packaging and sterilization of all loaner instruments upon their receipt. In addition, it is also the responsibility of the hospital to clean, disinfect, package and sterilize the instrument sets prior to their return to Smith and Nephew Inc.</p>
Manual cleaning tools	<p>Hospital tools necessary for manual cleaning include: surgical scrub brushes, chenille pipe cleaners, soft low linting cloths, cotton tip applicators, and several size/length brushes.</p> <p>Do not use abrasive cleaning tools (i.e. scouring pads or metal brushes).</p> <p>Cleaning tools must be cleaned and inspected between use. Cloths should be clean and lint free and changed frequently. Brushes should be clean. Discard worn brushes and disposable cleaning tools.</p>
Safety precautions	<p>Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated devices. PPE includes: gown, mask, goggles or face shield and shoe covers.</p> <p>Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated devices. Caution should be exercised when handling devices with sharp points or cutting edges.</p>
Water	<p>The quality of water should be carefully considered for use in cleaning reusable devices. Water hardness is a concern because deposits left on medical devices may result in ineffective cleaning and sterilization. Final rinsing should be carried out using deionized water.</p>

Recommended cleaning instructions

Cleaning is the single most important step in preparing a device for reuse. Effective cleaning must be carried out to achieve proper disinfection/sterilization. Thorough cleaning and rinsing are vital to reprocessing reusable medical devices. Also, thorough rinsing is important for the removal of any residual cleaning agents from the medical devices. The purpose of cleaning and rinsing is to remove all adherent visible debris and to reduce the number of particulates, microorganisms, and pyrogens. The recommended cleaning instructions in this document include both manual and automatic washing/disinfection procedures. While manual cleaning is the most universal method of cleaning, automatic washing is preferred. The cleaning processes presented in this brochure have been validated. Other methods of cleaning may be suitable but must be validated by the user of the device.

Warnings

It is the responsibility of the user to ensure that the cleaning process is performed following these procedures to achieve the desired result.

For ultrasonic cleaning, the enzymatic detergent solution should be changed before it becomes heavily soiled so that effective cleaning is not inhibited.

Most electronic devices cannot be submerged during cleaning and could sustain permanent damage as a result of submersion. Check the "Instructions for Use" for information on submersion of electronics.

Do not sonicate powered devices.

All cleaning should be performed in a manner designed to minimize exposure to bloodborne pathogens. Manual cleaning should be done while the instrument is immersed.

Limitations of cleaning instructions

These recommended procedures are intended as a general guide for cleaning of medical devices. Some devices are labeled with more specific instructions.

Limitations of reprocessing

Repeated reprocessing of reusable medical devices has minimal effect on the devices.

End of life is normally determined by wear and damage due to use.

Preparations at the point of use prior to processing

Keep instruments moist after use to prevent soil from drying on them.

Follow Universal Precautions for handling and transporting contaminated instruments to the designated cleaning area. Contaminated instruments should be transported to the area for cleaning in a way that avoids contamination of personnel and hospital.

Prior to cleaning, visible debris should be removed from the surfaces, crevices, mating surfaces, cannulas, joints and all other hard-to-clean design features. Dried on soil is difficult and sometimes impossible to remove with automatic washing.

Instruments should be cleaned as soon as possible after use to prevent blood from drying on the devices. (A four-hour dry time is used for cleaning validations of Smith & Nephew Orthopaedics reusable devices.)

Preparation for cleaning

Disassemble each instrument into its component parts. Containment devices must be cleaned separately from the instrumentation.

Note If you have questions concerning the disassembly of any Smith & Nephew Orthopaedics device, contact your Smith & Nephew sales representative.

Overview of product groups for reusable device cleaning

Cleaning of reusable devices is dependent upon product design features. The cleaning methods for Smith & Nephew reusable devices are based on product groups that have design features that present a similar challenge to cleaning.

Device categories for cleaning:

- Devices WITHOUT challenging design features
- Devices WITH challenging design features
- Flexible reamers
- Powered devices
- Containment devices
- Noncritical devices/equipment

Definition of product groups

Devices WITHOUT challenging design features: Includes all instruments that do not have design features that present a challenge to cleaning by the Smith & Nephew recommended cleaning procedure. These instruments do not have hard to access locations for cleaning such as lumens, interfaces, hinged/mating surfaces, serrations, etc. These are instruments that do not have retractable or moving parts.

Examples: Bone spikes, osteotomes, mallets



Devices WITH challenging design features: Includes all instruments that have design features that present a challenge to cleaning by Smith & Nephew recommended cleaning procedure such as lumens, interfaces, hinged/mating surfaces and serrations etc. These instruments may have retractable and moving features.

Examples: Reamers, T-handles, cable passers, cutting blocks and hinged clamps



Flexible reamers: Includes all instruments that have a laser cut flex reamer design.

Examples: Flexible screw drills and flexible shafts



Powered devices: Those that use pneumatic power or have power cords and require the use of electricity to operate.

Examples: ACCURIS® handpiece and pulse lavage handpiece



Containment devices: Instrument cases, trays, caddies and lids

Non-critical devices/equipment: Those that do not contact the patient or may contact intact skin.

Examples: Power supply boxes and power cable surfaces

Recommended cleaning procedures

Manual cleaning procedures

Devices WITHOUT challenging design features

- 1 Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
- 2 Immerse and soak for a minimum of one (1) minute in enzymatic detergent.
- 3 Use a surgical scrub brush to remove visible debris.
- 4 Rinse for a minimum of one minute using a sufficient volume of deionized water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing. If the components of the instrument are movable or can be retracted, it is necessary to do so during the rinsing process.
- 5 Check for visible debris. Repeat cleaning if debris is visible.

Devices WITH challenging design features

- 1 Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
- 2 Immerse and soak for a minimum of five (5) minutes in enzymatic detergent.
- 3 Remove additional soil from challenging design features (i.e. holes, lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common hospital cleaning tools.
 - a Move and/or retract all moveable parts and remove visible debris using a brush.
 - b Scrub lumens or holes with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. Small diameter lumens may be irrigated with the cleaning solution using a syringe.
 - c Open hinged devices and scrub hinged area with a brush.
 - d Scrub crevices with a brush.
- 4 Sonicate instrument in enzymatic detergent in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
- 5 Rinse for a minimum of one minute using a sufficient volume of deionized water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing. If the components of the instrument are movable or can be retracted, it is necessary to do so during the rinsing process.
- 6 Check instruments for visible debris (see “Verifying Cleaning”). Repeat cleaning if debris is visible.

Flexible reamer devices

- 1 Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
- 2 Immerse and soak for a minimum of ten (10) minutes in enzymatic detergent.
- 3 Scrub lumen with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. (The bristles should be stiff enough to remove bone and tissue.)
- 4 Scrub the surface with a surgical scrub brush to remove all visible debris from the surface and crevices.
- 5 Bend the reamer in a U-shape and scrub the surface with a scrub brush.
Note Bend at several locations along the length to access all crevices.
- 6 Rinse thoroughly with warm water making sure to irrigate the lumen and crevices.
Note Use a clean brush during the rinse cycle and move back and forth several times through the lumen during rinsing.
- 7 Sonicate in enzymatic detergent for a minimum of 15 minutes in an ultrasonic cleaner containing enzymatic detergent.
- 8 Rinse for a minimum of one minute using a sufficient volume of deionized water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing.
- 9 Check instrument for visible debris (see “Verifying Cleaning”). If debris is visible, repeat cleaning steps 2 – 8.

Powered instruments

Note Leave the instrument that directly connects to the motorized device (i.e. the hose that connects to a powered handpiece) in place during cleaning to prevent an excessive amount of water from entering the motor.

Note Do not sonicate powered instruments.

Clean the motorized device as follows:

- 1 Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
- 2 Immerse the motorized device, with the connecting instrument still in place, in enzymatic detergent and soak for three minutes.
- 3 Scrub the device in enzymatic detergent using cleaning brushes.
- 4 Rinse for a minimum of one minute using a sufficient volume of deionized water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing.

Note Final rinsing should be carried out using deionized water.

- 5 Remove the motorized device from the water before disassembly of the connecting instrument.

Note Clean the connecting instrument separately following the cleaning instructions for “Devices WITH challenging design features.”

Containment devices

- 1 Inspect containment device for visible debris.
- 2 If dried visible debris is observed, follow the manual instructions for “Devices WITH challenging design features.”
- 3 If dried visible debris is not observed, clean following the manual instructions for “Devices WITHOUT challenging design features.”

Non-critical devices/equipment

Sterile hospital grade covers can be used whenever possible to prevent contamination of non-critical devices or equipment.

Note Porous items like foam that are contaminated must be discarded.

Clean surfaces by wiping with a cloth and using enzymatic detergent and water.

Verifying cleaning

- 1 After cleaning, visually inspect devices under normal lighting for the removal of visible debris.
- 2 For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.

Note Rinse the instruments thoroughly with deionized water following hydrogen peroxide testing.

- 3 Repeat cleaning if not visibly clean and reinspect.

Devices WITHOUT challenging design features

- 1 Manual precleaning:
 - IS NOT REQUIRED if the device does not have dried-on visible debris. Place the device directly into the automatic washer for cleaning.
 - IS REQUIRED if the device does have dried on visible debris. Follow the manual cleaning steps below prior to placing the device in the automatic washer for cleaning.
 - a Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
 - b Immerse and soak for a minimum of one (1) minute in enzymatic detergent.
 - c Use a surgical scrub brush to remove visible debris.
 - d Rinse for a minimum of one minute using a sufficient volume of water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing
- 2 Place the device in the automatic washer and run the recommended automatic washer steps (see Section “Automatic Washing Cycle Steps and Parameters.”)

Note Final rinsing should be carried out using deionized water.

Devices WITH challenging design features

- 1 Manual precleaning is required for all devices in this product group. Follow the manual cleaning steps below prior to placing the device in the automatic washer for cleaning.
 - a Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
 - b Immerse and soak for a minimum of five (5) minutes in enzymatic detergent.
 - c Remove additional visible debris from challenging design features (i.e. holes, lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common hospital cleaning tools.
 - Move and/or retract all moveable parts and remove visible debris using a brush.
 - Scrub lumens or holes with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. Small diameter lumens may be irrigated with the cleaning solution using a syringe.
 - Open hinged devices and scrub hinged area with a brush.
 - Scrub crevices with a brush.
 - d Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing enzymatic detergent.
 - e Rinse for a minimum of one minute using a sufficient volume of deionized water that will completely immerse the instrument. If the the components of the instrument are movable or can be retracted, it is necessary to do so during the rinsing process. Water should be changed a minimum of two times to ensure thorough rinsing.
- 2 Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and lumens and holes positioned to drain).
- 3 Run the recommended automatic washer steps (see Section “Automatic Washing Cycle Steps and Parameters.”)

Note Final rinsing should be carried out using deionized water.
- 4 Check instruments for visible debris (see “Verifying cleaning”). Repeat cleaning if debris is visible and reinspect.

Flex reamer devices

- 1 Manual precleaning is required for all devices in this product group. Follow the manual cleaning steps below prior to placing the device in the automatic washer for cleaning.
 - a Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
 - b Immerse and soak for a minimum of ten (10) minutes in enzymatic detergent.
 - c Scrub lumen with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. (The bristles should be stiff enough to remove bone and tissue.)
 - d Scrub the surface with a surgical scrub brush to remove all visible debris from the surface and crevices.
 - e Bend the reamer in a U-shape and scrub the surface with a scrub brush.
Note Bend at several locations along the length to access all crevices.
 - f Rinse for a minimum of one minute using a sufficient volume of water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing. Make sure to irrigate the lumen and crevices.
 - g Sonicate for a minimum of 15 minutes in an ultrasonic cleaner containing enzymatic detergent.
- 2 Place the device in the automatic washer and run the recommended automatic washer steps (see Section “Automatic Washing Cycle Steps and Parameters”).
Note Final rinsing should be carried out using deionized water.

Powered instruments

Note Leave the instrument that directly connects to the motorized device (i.e. the hose that connects to a powered handpiece) in place during cleaning to prevent an excessive amount of water from entering the motor.

Note Do not sonicate powered instruments.

Clean the motorized device as follows:

- 1 Rinse in cold water (<43°C) to remove visible debris and to prevent coagulation of blood.
- 2 Use a surgical scrub brush to remove visible soil.
- 3 Rinse for a minimum of one minute using a sufficient volume of water that will completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing.
- 4 Place the device with the connecting device attached in the automatic washer and run the recommended automatic washing steps (see Section “Automatic Washing Cycle Steps and Parameters”).
Note Final rinsing should be carried out using deionized water.
Note Clean the connecting instrument separately following the cleaning instructions for “Devices WITH challenging design features.”

Containment devices

- 1 Inspect containment device for visible debris.
- 2 If dried visible debris is observed:
 - a Immerse/soak in enzymatic detergent for five (5) minutes.
 - b Scrub surfaces including brackets and hinges with cleaning brush.
 - c Rinse for a minimum of one minute using a sufficient volume of water that will completely immerse the containment device. Water should be changed a minimum of two times to ensure thorough rinsing.
 - d Place the containment device in the automatic washer and run the recommended automatic washer steps (see Section “Automatic Washing Cycle Steps and Parameters”).
Note Final rinsing should be carried out using deionized water.
- 3 If dried debris is not observed, place the containment device in the automatic washer and run the automatic washer steps given below (see Section “Automatic Washing Cycle Steps and Parameters”).
Note Final rinsing should be carried out using deionized water.

Automatic washing and thermal disinfecting procedures (continued)

Automatic washing cycle steps and parameters

Minimum cycle parameters:

- Five (5) minute cold prewash (<43°C)
- Five (5) minute enzyme wash
- Five (5) minute detergent wash
- One (1) minute rinse

Note Final rinsing should be carried out using deionized water.

Thermal disinfection parameters

Minimum cycle parameters:

- One (1) minute at 91° C

Verifying cleaning

- 1 After cleaning, visually inspect devices under normal lighting for the removal of visible debris.
- 2 For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.

Note Rinse the instruments thoroughly with deionized water following hydrogen peroxide testing.

- 3 Repeat cleaning if not visibly clean and reinspect.

Inspection and function testing

All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive “play.”
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect “chuck” end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.
Powered devices	Verify that power is supplied when the device is turned on and ceases when the device is turned off.

Maintenance and care

For devices with hinged/mating surfaces, surgical-grade lubricant should be added to the hinged area while in the open position.

Discard blunt or damaged instruments.

Storage

Reusable devices that will be stored between cleaning and sterilization should be dried with a low-linting, non abrasive soft cloth to prevent microbial contamination that could result from wet instruments. Containment devices can be stacked for storage.

Recommended sterilization instructions

Recommended sterilization methods have been validated to sterility assurance levels (SAL) in compliance with federal and international standards. Other sterilization cycles may also be suitable, but the individuals or hospitals are advised to validate other methods for use with Smith & Nephew orthopaedic products.

Warnings	<p>It is the responsibility of the user to ensure that the sterilization process is actually performed using qualified equipment, materials and personnel such that the recommended parameters are achieved.</p>
	<p>Smith and Nephew recommends consulting the Immediate-Use Sterilization statement in AAMI ST 79 for guidance on IUSS.</p>
	<p>Steam is the only method that has been validated for reprocessing by Smith & Nephew. Sterrad or hydrogen peroxide based gas systems have not been validated.</p>
	<p>Package inserts are provided with external fixators to provide directions for resterilization.</p>
	<p>These recommended procedures are intended as a general guide for sterilization of reusable medical devices sold by the Orthopaedics Division of Smith & Nephew, Inc. Some devices are labeled with more specific instructions.</p>
	<p>It is the responsibility of the user to validate their sterilization equipment to ensure that the recommended parameters are achieved.</p>
	<p>Note The “Express” prevacuum steam sterilization cycle is not approved for Smith & Nephew containment devices.</p>
Limitations of reprocessing	<p>Repeated reprocessing has minimal effect on the devices. End of life is normally determined by wear and damage due to use.</p>
Updates for sterilization	<p>For sterilization updates go to http://global.smith-nephew.com/us/DECONTAMINATION.htm</p>
Implants	<p>All implants are sold as single-use devices.</p>
	<p>The method of initial sterilization for implants that are supplied sterile is noted on the package label.</p>
Reusable devices	<p>Most reusable devices are sold non-sterile. It is critical to properly clean all reusable devices prior to sterilization.</p>
	<p>Instruments are sterilized assembled unless otherwise instructed.</p>

Containment devices

Smith & Nephew Orthopaedics containment devices are categorized into families based on the design, density and material of the inner and outer containment devices. Each family has been validated to a 10^{-6} Sterility Assurance Level (SAL).

Smith & Nephew designs the proper placement of instruments and other devices into each containment device layout. The layout has predetermined brackets and artwork descriptions. If instruments are added, the user is responsible for validation of the new layout.

When applicable, adhesive labels shipped with the containment device should be applied to the outer containment device. Large labels typically have a designated outlined box with the instructions "PLACE LABEL HERE." Small labels are placed on the end caps under the labels.

CI and BI placement: Some Smith & Nephew containment device designs have multiple layers of instrument caddies or trays.

Testing has shown that the following CI and BI placement locations should be used for qualification testing by the hospital or healthcare facility:

- **For containment devices that do not contain internal instrument case caddies:** At the center and at each corner of the bottom internal containment device or tray.
- **For containment devices that contain internal instrument case caddies:** At each corner of the caddy on the bottom level of the case.

Containment device weight: Smith & Nephew containment devices are designed to achieve a total case weight (outer case, device, plus inner trays/caddies) of 25 pounds (11.34 kgs) or less. Please be aware that there are some older models that cannot be separated to achieve a weight below 25 pounds (11.34kgs). These older models have been validated to achieve a 10^{-6} SAL.

Only hospital trained personnel should be utilized for inspection and maintenance of containment devices.

Modifications to the containment devices should only be made by Smith & Nephew unless the materials and instructions for modifications are supplied by Smith & Nephew (see "Contact Information").

The sterilization of containment devices is validated with the instruments placed and positioned in the predetermined placement locations of the containment device.

A single absorbent towel (i.e. a huck towel) can be placed under the containment device to aid in drying.

Smith & Nephew is the only authorized service/repair company for Smith & Nephew, Inc. containment devices. Containment devices in need of repair/replacement must be returned to Smith & Nephew.

Smith & Nephew does not recommend stacking of containment devices during sterilization.

Preparation for sterilization

Reusable devices

It is important that adequate cleaning be carried out prior to sterilization.

Reusable devices should be placed in suitable packaging for the sterilization process (i.e. central supply wrap [CSR], paper/plastic pouches, rigid containers, etc.) and sterilized prior to surgical use.

**Preparation for sterilization
(continued)**

Trauma plates, nails, screws, pins and wires

Trauma plates, nails, screws, pins and wires are implants and are considered single use devices. These devices are sold both nonsterile and sterile and are often removed by the user from their original packaging and placed in a containment device (i.e. instrument case) for processing. These devices should be cleaned prior to sterilization (see cleaning instructions for Devices without challenging design features). These instructions do not apply to reprocessing or reuse of single use devices that have come in contact with blood, tissue or bodily fluids.

Prior to sterilization of the device, remove all original packaging and labeling inserts. Place the device in its designated location in the containment device.

It is important that adequate cleaning be carried out prior to sterilization.

Sterilization wrap/reusable rigid containers

Containment devices can be wrapped with an approved CSR wrap or placed in an approved reusable rigid container for sterilization.

All sterilization wraps may not be approved for all cycle types. Check with the manufacturer for approvals.

Aesculap SterilContainer™ and Case Medical SteriTite® rigid containers with perforated bottoms have been approved for use with Smith & Nephew Orthopaedics instrument sets. These rigid containers are not approved for Immediate Use Steam Sterilization (IUSS) or (Flash Sterilization).

Note to US customers Sterilizers and wraps used in your sterilization process must be FDA cleared.

**Recommended sterilization
parameters**

Dynamic air removal (prevacuum) steam

Exposure temperature: 132°C (270°F)
Exposure time: 4 minutes

OR

Exposure temperature: 135°C (275°F)
Exposure time: 3 minutes

Minimum drying time: Devices not in a containment device – 15 minutes;
Devices in a containment device – 30 minutes*

Gravity displacement steam

Exposure temperature: 132°C (270°F)

Exposure time:

- 15 minutes for devices not in a containment device
- 30 minutes for devices in a containment device*

Minimum vacuum drying: 30 minutes

Immediate Use Steam Sterilization (IUSS) or Flash Steam

Dynamic air removal (prevacuum) steam

- Exposure temperature: 132°C (270°F)
- Exposure time: 4 minutes

*This sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Recommended sterilization parameters (continued)

For non-US customers

UK steam cycle

Prevacuum cycle

Exposure temperature: 134°C (273°F)

Exposure time: 3 minutes

Vacuum drying: 30 minutes

Note The procedure outlined in HTM 2010 should be followed.

World Health Organization (WHO) steam cycle

Exposure temperature: 134°C (273°F)

Exposure time: 18 minutes

Vacuum drying: 30 minutes

Recommended sterilization methods for device types

Device type

Plates, nails, screws, pins and wires	Gravity displacement steam
	Dynamic air removal (prevacuum) steam
External fixation devices	Dynamic air removal (prevacuum) steam
	UK steam cycle
	WHO steam cycle
Reusable devices (instruments, containment devices, powered devices)	IUSS or Flash steam
	Gravity displacement steam
	Dynamic air removal (prevacuum) steam
	UK steam cycle
	WHO steam cycle

Storage

Sterile packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature and humidity extremes. Storage is event related and not time related. Sterile packaged devices can be stored as long as sterile packaging is not breached. Smith & Nephew does not recommend stacking of wrapped containment devices or rigid containers.

Cleaning and Sterilization Validation Information

The detergents and equipment used to support the validation of cleaning and sterilization were as follows:

Detergents:
 Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner, Steris Corporation
 Klenzyme® Enzymatic Presoak and Cleaner, Steris Corporation
 Note 1: The manufacturer’s instructions were followed for use of the detergents.
 Note 2: Suitability of alternative agents should be checked by the reference to the manufacturer’s information and/or physical testing

Steam Sterilizer:
 AMSCO Model SV-120

Washer-Disinfectant:
 Steris Reliance 444 Single Chamber Washer/Disinfectant

References

AAMI TIR 12:2010, “Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: a Guide for Device Manufacturers,” 2nd edition.

AAMI TIR 30: 2003, “A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.”

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