

Instructions for Care, Maintenance, Cleaning and Sterilization of Smith & Nephew Orthopaedics Devices

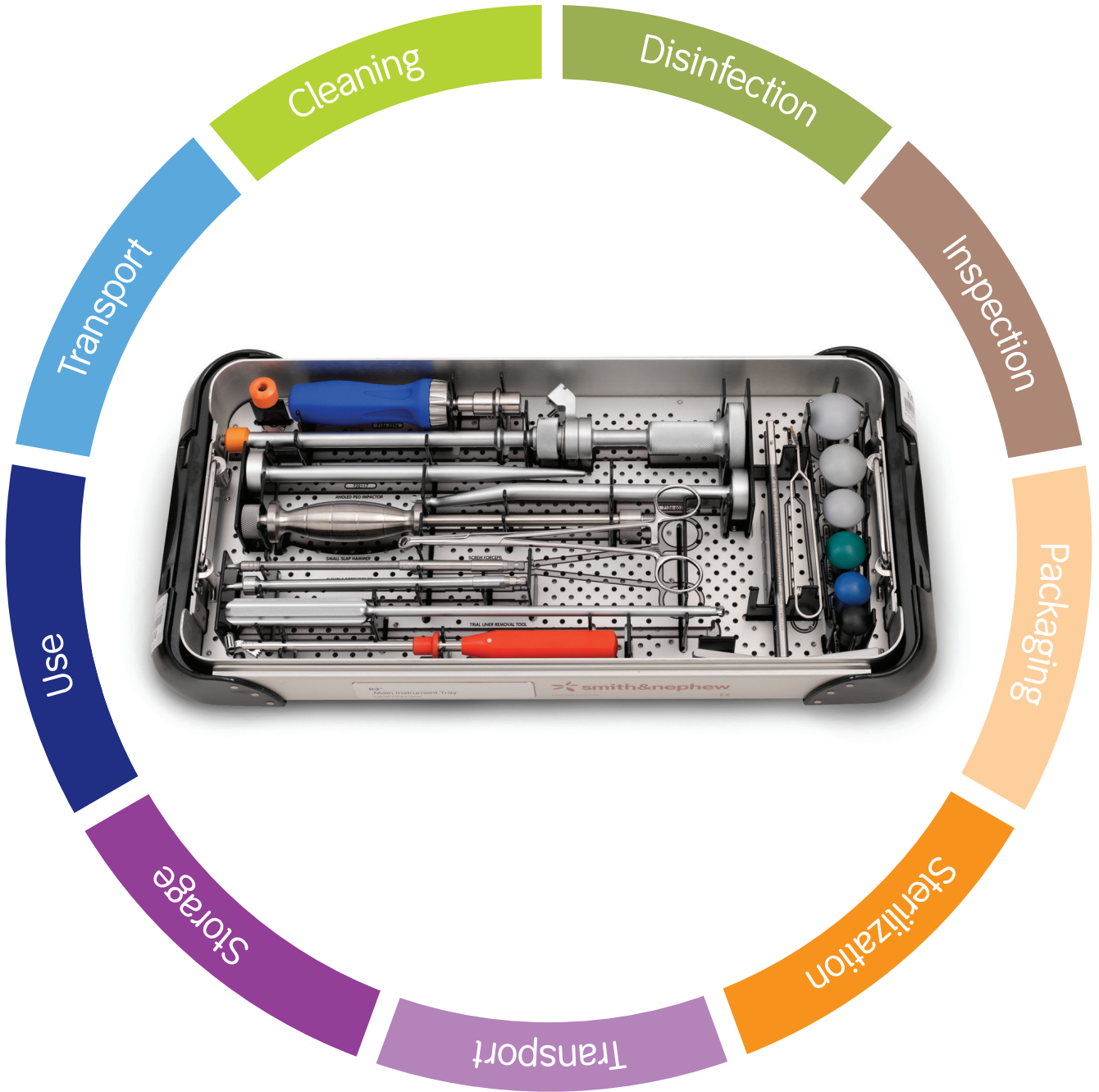


Table of Contents

Purpose	4	Containment devices	10
Scope	4	Automatic washing cycle steps and parameters	10
Definitions	4	Disinfection	10
Recommended Cleaning Instructions	5	Verifying cleaning	10
Important Information/Recommendations for Use	5	Inspection and function testing	10
Warnings	6	Maintenance and Care	11
Limitations on Processing	6	Storage Between Cleaning and Sterilization	11
Limitations of cleaning instructions	6	Recommended Sterilization Instructions	11
Limitations of processing	6	Warnings	11
Cleaning Product Groups	6	Limitations of Processing	11
Overview of product groups for reusable device cleaning	6	Implants	11
Definition of product groups	6	Containment Devices	11
Initial Treatment at the Point of Use	7	Preparation for Sterilization	12
Transportation	7	Reusable Medical Devices	12
Preparation Before Cleaning	7	Single Use Medical Devices	12
Water Quality for Cleaning	7	Sterilization Wrap/Reusable Rigid Containers	12
Cleaning: Manual	7	Water Quality	12
Devices Without challenging design features	7	Recommended Sterilization Parameters	13
Devices With challenging design features	7	Dynamic Air Removal (Prevacuum) Steam	13
Flexible reamer devices	8	Gravity Displacement Steam	13
Powered Devices	8	For Non-US Customers - UK Steam Cycle Prevacuum cycle	13
Containment Devices	8	World Health Organization (WHO) Steam Cycle	13
Non-critical Devices	8	Storage After Cleaning and Sterilization	13
Verifying Cleaning	9	Cleaning and Sterilization Validation Information	14
Drying	9	References	14
Cleaning: Automated	9	Contact Information	14
Devices Without challenging design features	9	Glossary of Symbols	16
Devices With challenging design features	9		
Flexible reamer devices	9		
Powered devices	10		

Purpose/Scope/Definitions

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.

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
- Centers for Disease Control (CDC)
- U.S. Food and Drug Administration (FDA)

Scope

These instructions apply to all reusable medical devices that are sold by Smith & Nephew Orthopaedics that are initially supplied nonsterile or sterile and require the user to process them after initial/subsequent use. These instructions also apply to single use medical devices that are supplied sterile and nonsterile and require processing. Both sterile and nonsterile single use medical devices i.e. plates, nails, screws, pins and wires are commonly placed in containment devices for use and therefore require processing prior to use.

These instructions apply to Smith & Nephew Orthopaedic devices that fall under Spaulding's classification scheme for medical devices as "Critical Devices" and "Noncritical Devices". "Critical Devices" are introduced directly into the human body either into or in contact with the bloodstream or into other normally sterile areas of the body. "Critical Devices" present a high degree of risk of transmission of infection if contaminated and therefore must be sterile at the time of use. "Noncritical Devices" contact only the intact skin of the patient.

Definitions

Biological Indicator (BI): Test system that contains viable microorganisms that provide a defined resistance to a specified sterilization process.

Caddy: A small flip top containment device that contains multiple small implants (i.e. screws, plates, etc.).

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.

Cleaning: The removal of contaminants to the extent necessary for further processing or for intended use.

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.

Critical Water: Water that has been extensively treated (usually by a multi-step treatment process that could include a carbon bed, softening, Deionized (DI), and Reverse Osmosis (RO) or distillation) to ensure that the microorganisms and the inorganic and organic materials are removed from the water. A final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or steam generation.

Disinfection: A process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose.

Immediate Use: The shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use or held from one case to another.

Manual Cleaning: The removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process. Ultrasonic cleaning is considered a manual cleaning step for the purposes of this document.

Manufacturer: The natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf of another person(s).

Medical Device: Instrument, apparatus, implant, reagent for in-vitro use, software, material or other similar or related article intended by the manufacturer to be used alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining of life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Processing: Preparation of medical devices or activity to prepare a new or used healthcare products for its intended use. In this document processing includes cleaning, disinfection and sterilization.

Reusable Medical Device: A medical device designated or intended by the manufacturer as suitable for processing and reuse.

Single Use Medical Device (SUD): A medical device that is designated or intended by the manufacturer for one-time use only. For clarity, a single use device that has come into contact with blood, tissue, or bodily fluids is not intended to be further processed and used again.

Sterile: Free from viable microorganisms.

Sterility Assurance Level (SAL): The probability of a single viable microorganism occurring on an item after sterilization, expressed as the negative exponent to the base 10.

Sterilization: The process used to render product free from viable microorganisms.

Utility Water: Water as it comes from the tap that might require further treatment to achieve the specifications. This water is mainly used for flushing, washing, and rinsing.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Washer-Disinfectant: Equipment that is designed to clean and disinfect product.

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. Cleaning begins at the point of use to prevent soil and contaminants from drying on the medical devices after use. Thorough cleaning and rinsing are vital to processing 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.

Important Information/Recommendations for Use

Automatic washer/disinfectant

Washer-disinfectants 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/disinfectant equipment should be operated following the manufacturer's instructions for use.

Detergents

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 medical devices and containment devices. Enzymatic detergents aid in the removal of organic soil such as blood.

Detergents should be used at the concentration and temperature recommended by the detergent manufacturer.

Some alkaline detergents have been formulated to be safe for processing medical devices. Refer to the manufacturer's limitations and warnings for information concerning specific materials that are adversely affected by the detergents.

Loaner Instrument Set

It is the hospital's responsibility to clean, disinfect, package and sterilize all loaner devices upon 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 & Nephew.

Manual cleaning tools

Hospital tools necessary for manual cleaning include: surgical scrub brushes, chenille pipe cleaners, soft low linting cloths, cotton tip applicators, and several various sizes and lengths of brushes.

Do not use abrasive cleaning tools (i.e. scouring pads or metal brushes).

Cleaning tools must be cleaned and inspected after use. Cloths should be clean and lint free and changed frequently. Brushes should be clean. Discard worn brushes and disposable cleaning tools.

Safety precautions

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.

Universal precautions are standards of infection control practices designed to reduce the risk of transmission of bloodborne infections. Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated devices. Exercise caution when handling devices with sharp points or cutting edges.

Water

The quality of water should be carefully considered for use in cleaning reusable devices. The water quality can affect the life of the device. 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 critical water.

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 on Processing

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. Refer to the Instruction for Use for that device.

Limitations of processing

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

The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the medical device. Do not use devices that show evidence of damage and wear. 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 used.

Cleaning Product Groups

Overview of product groups for reusable device cleaning

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

Cleaning Product Groups:

- Devices **without** challenging design features
- Devices **with** challenging design features
- Flexible reamers
- Powered devices
- Containment devices
- Noncritical devices

Definition of product groups

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

Examples: Bone spikes, osteotomes, mallets.



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

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



Flexible reamers: Includes all devices that have a laser cut flexible 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: Those that do not contact the patient or may contact intact skin.

Examples: Power supply boxes and power cable surfaces.

Initial Treatment at the Point of Use

Cleaning begins at the point of use to prevent soil and contaminants from drying on the devices. Keep the devices moistened after use and before cleaning.

Transportation

Used devices must be transported to the processing location (i.e. Sterile Processing) in closed or covered containers to prevent contamination risks.

Preparation Before Cleaning

Disassemble each device into its component parts. Containment devices must be cleaned separately from the medical devices. If you have questions concerning the disassembly of any Smith & Nephew Orthopaedics device, contact your Smith & Nephew sales representative.

Water Quality for Cleaning

Use utility water for flushing, washing and rinsing during cleaning except for the final rinse. For the cleaning final rinse use critical water.

Cleaning: Manual

Devices *Without* challenging design features

1. Rinse in cold water <45° C (113° F) 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. With the device completely immersed in the cleaning solution, use a surgical scrub brush to remove visible debris from the surfaces of the device.
4. Rinse for a minimum of one minute using a sufficient volume of critical water that will completely immerse the device. Water should be changed a minimum of two times to ensure thorough rinsing.
5. Check for visible debris. Repeat cleaning if debris is visible.

Devices *With* challenging design features

1. Rinse in cold water <45° C (113° F) 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. With the device completely immersed in the cleaning solution, remove additional soil from the surfaces and from the 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.

Recommended Cleaning Instructions *continued*

- 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. Thoroughly flush lumens with enzymatic detergent using a syringe.
 - c. Open hinged devices and scrub hinged area with a brush.
 - d. Scrub crevices with a brush.
 - e. Scrub the surfaces of the device with a toothbrush styled brush.
4. Sonicate the device in enzymatic detergent in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner.
 5. Rinse for a minimum of one minute using a sufficient volume of critical water that will completely immerse the device. Water should be changed a minimum of two times to ensure thorough rinsing. If the components of the device are movable or can be retracted, it is necessary to do so during the rinsing process. Thoroughly flush lumens with critical water using a syringe.
 6. Check devices for visible debris (see “Verifying Cleaning”). Repeat cleaning if debris is visible.

Flexible reamer devices

1. Gently bend the flexible reamer in a U-shape and rinse in cold water <45° C (113° F) 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. With the device completely immersed in the cleaning solution, 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.) Thoroughly flush lumens with enzymatic detergent using a syringe.
4. With the device completely immersed in the cleaning solution, scrub the surface with a surgical scrub brush to remove all visible debris from the surface and crevices.
5. With the device completely immersed in the cleaning solution, gently bend the reamer in a U-shape and scrub the surface with a scrub brush.
Note: Gently bend at several locations along the length to access all crevices.
6. Gently bend the reamer in a U-shape and rinse thoroughly with warm water making sure to irrigate the lumens and crevices. Thoroughly flush lumens with water using a syringe.
Note: Use a clean brush during the rinse cycle and move it back and forth through the lumen several times during rinsing.
7. Sonicate in enzymatic detergent for a minimum of 15 minutes in an ultrasonic cleaner.

8. Rinse for a minimum of one minute using a sufficient volume of critical water to completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing. Thoroughly flush lumens with critical water using a syringe.
9. Check the devices for visible debris (see “Verifying Cleaning”). If debris is visible, repeat cleaning steps 2 – 8.

Powered Devices

Leave the device 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.

Do not sonicate powered devices.

Clean the Motorized Device as Follows:

1. Rinse in cold water <45° C (113° F) to remove visible debris and to prevent coagulation of blood.
2. With the connecting device still in place, immerse the motorized device, with the connecting instrument still in place, in enzymatic detergent and soak for three minutes.
3. With the device completely immersed in the cleaning solution, scrub the surfaces of the device in the enzymatic detergent using cleaning brushes.
4. Rinse for a minimum of one minute using a sufficient volume of critical water to completely immerse the instrument. Water should be changed a minimum of two times to ensure thorough rinsing.
5. Remove the motorized device from the water before disassembly of the connecting device.
Clean the connecting device separately following the cleaning instructions for the correct Cleaning Product Group.

Containment Devices

1. Remove medical devices from the containment device prior to cleaning. Inspect the 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

Sterile hospital grade covers can be used whenever possible to prevent contamination of non-critical devices. Porous items like foam that are contaminated must be discarded. Clean surfaces by wiping with a cloth and using detergent and water.

Verifying Cleaning

1. After cleaning, visually inspect devices under normal lighting for any remaining visible debris.
2. For difficult to view design features, apply 3% hydrogen peroxide. Bubbling indicates the presence of blood. Rinse the devices thoroughly with critical water following hydrogen peroxide testing.
3. If not visibly clean, repeat cleaning and reinspect the device.

Drying

Use clean filtered compressed air or a clean lint free towel to remove moisture from the devices.

Cleaning: Automated

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 <45° C (113° F) 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. With the device completely immersed in the cleaning solution, use a surgical scrub brush to remove visible debris.
 - d. Rinse for a minimum of one minute using a sufficient volume of water to completely immerse the device. 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.”)

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 <45° C (113° F) 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. With the device completely immersed in the cleaning solution, remove additional visible debris from the device surfaces and from the 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 use a brush to remove visible debris.
 - Scrub lumens and 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. Thoroughly flush lumens with enzymatic detergent using a syringe.
 - Open hinged devices and scrub hinged area with a brush.
 - Scrub crevices with a brush.
 - d. Sonicate the device 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 water to completely immerse the device. If the components of the instrument are movable or can be retracted, do so during the rinsing process. Change the water a minimum of two times to ensure thorough rinsing. Thoroughly flush lumens with water using a syringe.
2. Load the devices into 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.”)
 4. Check devices for visible debris (see “Verifying cleaning”). Repeat cleaning if debris is visible and reinspect.

Flexible 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. Gently bend the flexible reamer in a U-shape and rinse in cold water <45° C (113° F) 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. With the device completely immersed in the cleaning solution, scrub the 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. With the device completely immersed in the cleaning solution, scrub the surface with a surgical scrub brush to remove all visible debris from the surface and crevices. Thoroughly flush lumens with enzymatic detergent using a syringe.

- e. With the device completely immersed, gently 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. Gently bend the reamer in a U-shape and rinse for a minimum of one minute using a sufficient volume of water to completely immerse the device. Change the water a minimum of two times to ensure thorough rinsing. Make sure to irrigate the lumen and crevices. Thoroughly flush lumens with enzymatic detergent using a syringe.
 - 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 the section “Automatic Washing Cycle Steps and Parameters”).

Powered devices

Leave the device 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.

Do not sonicate powered device.

Clean the motorized device as follows:

1. Rinse in cold water <45° C (113° F) to remove visible debris and to prevent coagulation of blood.
2. With the device completely immersed in the cleaning solution, use a surgical scrub brush to remove visible soil from the surfaces of the device and connecting device.
3. Rinse for a minimum of one minute using a sufficient volume of water to completely immerse the device. Change the water a minimum of two times to ensure thorough rinsing.
4. Place the motorized device with the connecting device attached to it in the automatic washer and run the recommended automatic washing steps (see the section “Automatic Washing Cycle Steps and Parameters”).

Clean the connecting device separately following the cleaning instructions for the correct Cleaning Product Group.

Containment devices

1. Remove all medical devices from the containment device and inspect it for visible debris.
2. If dried visible debris is observed follow the manual cleaning instructions for “Devices with challenging design features”.
 - a. Then place the containment device in the automatic washer and run the recommended automatic washer steps (see the section “Automatic Washing Cycle Steps and Parameters”).
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”).

Automatic washing cycle steps and parameters

Load the devices into the automatic washer-disinfector.

- Connect any device lumen(s) to the rinsing ports of the washer-disinfector. If no direct connection is possible, place the lumen(s) on injector jets or in injector sleeves of the injector basket.
- Place blind holes at a downwards incline for drainage.
- Place all instruments in the open position whenever possible (i.e. hinged/mating features, articulating surfaces).

Minimum cycle parameters:

- Five (5) minute cold prewash <45° C (113° F)
- Five (5) minute neutral enzymatic detergent wash
- Five (5) minute neutral detergent wash
- One (1) minute rinse with critical water.

Disinfection

All Smith & Nephew orthopaedics reusable devices can be thermally disinfected using the parameters below.

- minimum 91° C for 1 minute
- 25 minute minimum dry time

Use clean filtered compressed air or a clean lint free towel to remove remaining moisture from the devices.

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 indicates the presence of blood. Rinse the devices thoroughly with critical water following hydrogen peroxide testing.
3. Repeat cleaning if not visibly clean and reinspect the device.

Inspection and function testing

All reusable devices: Visually inspect for damage or wear, including components in their disassembled state prior to re-assembly. Ensure components are re-assembled securely.

Hinged devices: Check for smooth movement of the hinge without excessive “play.”

Locking mechanisms: Check for action.

Cutting features: Check edges for distortion and/or 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. Ensure components are re-assembled securely.

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 devices: 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.

Measuring devices (i.e. gauges, calipers): Check for legible measuring markings.

Maintenance and Care

Prior to sterilization, individual reusable devices that have moving parts (i.e. hinges and sliding parts) may be lubricated using a water soluble lubricant. The use of lubricants is not recommended for implants.

Discard blunt, worn or damaged devices.

Discard devices that do not function properly.

Storage Between Cleaning and Sterilization

Reusable devices that will be stored between cleaning and sterilization should be dry to prevent microbial contamination that could result from wet devices. Containment devices can be stacked for storage. Store in a dry dust-free place.

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 orthopaedics products.

Warnings

- **It is the responsibility of the user to ensure that the sterilization process is performed using qualified equipment, materials and personnel such that the recommended parameters are achieved.**
- **Smith & Nephew recommends consulting the Immediate-Use Sterilization statement in AAMI ST 79 for guidance on IUSS.**
- **Steam is the only method that has been validated for processing by Smith & Nephew. Sterrad or hydrogen peroxide based gas systems have not been validated.**
- **Package inserts are provided with external fixators to provide directions for resterilization.**
- **These recommended procedures are intended as a general guide for sterilization of reusable medical devices sold by the Orthopaedics Division of Smith & Nephew. Some devices are labeled with more specific instructions.**

- **It is the responsibility of the user to validate their sterilization equipment to ensure that the recommended parameters are achieved.**

Limitations of Processing

Repeated processing has minimal effect on the devices. Reference the useful life statement from the Recommended Cleaning Instructions on page 6 “Limitations of Reprocessing”.

Implants

Implants are sold as single-use devices. The method of initial sterilization for implants that are supplied sterile is noted on the package label. Do not reuse as this may result in product malfunction, failure, or patient injury and may also expose the patient to the risk of infectious diseases.

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 devices into each containment device layout. The layout has predetermined brackets and artwork descriptions. If devices 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 (11.34 kgs). 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 be made only 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 devices 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 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 Medical Devices

It is important that adequate cleaning be carried out prior to sterilization. Reusable medical 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 each surgical use. Devices are sterilized assembled unless otherwise instructed. If devices were disassembled, ensure components are re-assembled securely with no complications.

Single Use Medical Devices

Trauma plates, nails, screws, pins, and wires are implants and are considered to be single use medical devices. External fixation devices are also considered to be single use medical 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 the cleaning instructions for Devices **without** challenging design features). These instructions do not apply to processing 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 cleared by the FDA.

Water Quality

Use critical water for steam generation.

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:	30 minutes

Gravity Displacement Steam

Exposure temperature:	132° C (270° F)
Exposure time:	
Devices not in a containment device	15 minutes
Devices in a containment device	30 minutes*
Minimum vacuum drying:	30 minutes

Immediate Use Steam Sterilization (IUSS)

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).

For Non-US Customers - UK Steam Cycle Prevacuum cycle

Exposure temperature:	134° C (273° F)
Exposure time:	3 minutes
Vacuum drying:	30 minutes

World Health Organization (WHO) Steam Cycle

Exposure temperature:	134° C (273° F)
Exposure time:	18 minutes
Vacuum drying:	30 minutes

Storage After Cleaning and Sterilization

Sterile packaged devices 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, or until expiration date. Smith & Nephew does not recommend stacking of wrapped containment devices or rigid containers. Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.

Cleaning and Sterilization Validation Information

Cleaning and Sterilization Validation Information

The detergents, accessories 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: The manufacturer's instructions were followed for use of the detergents.	
Note: 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, AMSCO Lab LV250
Sterilization Accessories:	KC 600 One Step Sterilization Wrap Aesculap SterilContainer™ System Containers JN 440 and JN442 with lid JK489 and Case Medical SteriTite™ SC06FG
Washer-Disinfector:	Steris Reliance 444 Single Chamber Washer/Disinfector Drying Parameters: 116° C minimum for 25 minutes
Ultrasonic Cleaner:	Branson 8510, 40 kHz
Brushes:	Key surgical sterile processing products and O.R. supplier

References

- AAMI TIR 12, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: a Guide for Device Manufacturers,"
- AAMI TIR 30, "A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices."
- AAMI TIR 34, "Water for reprocessing of medical devices."
- ANSI/AAMI ST79, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."
- AAMI/ANSI ST81, Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- AORN, Perioperative Standards and Recommended Practices.
- Centers for Disease Control, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
- Health Canada June 2011, "Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations."
- ISO 17664, Sterilization of medical devices —Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- German Redbook, Proper Maintenance of Instruments, Instrumenten-Aufbereitung [Instrument Preparation Working Group].
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff, March 17, 2015.
- UK Department of Health, Health Technical Memorandum 01-01: Decontamination of reusable medical devices. Parts A and B.
- ANSI/AAMI ST77 "Containment devices for reusable medical device sterilization".
- SO 15883-1, Washers-disinfectors- Part : Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-1 Sterilization of healthcare products, most heat- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Contact Information






US Customer Service phone: +1 800 238 7538





International Customer Service phone: +1 901 396 2121

US/International Customer Service Fax: +1 901 332 7289

UK Customer Service phone: +44 (0) 845 056 8333

Glossary of Symbols

	Medical Device
	Contains hazardous substances
	Sterilized using vaporized hydrogen peroxide
	Single patient – multiple use
 ifu.smith-nephew.com	Electronic instructions of use

Manufacturer	CE Mark	Contact Information
 Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 USA		+1 901 396 2121 Telephone +1 800 821 5700 Information +1 800 238 7538 Orders/Inquiries
 Smith & Nephew Orthopaedics Ltd Harrison Way Leamington Spa Warwickshire UK CV31 3HL		+44 (0) 845 056 8333 Customer Service



European Representative
 Smith & Nephew Orthopaedics GmbH
 Alemannenstrasse 14
 78532 Tuttlingen, Germany
 T +1 07462/208-0
 F +1 07462/208-135

www.smith-nephew.com

°Trademark of Smith & Nephew. All Trademarks acknowledged.

©2015, 2019 Smith & Nephew, Inc.
 All rights reserved.
 05/2019 81103630 Rev. A / 01004 V3
 Catalog Number 71381340