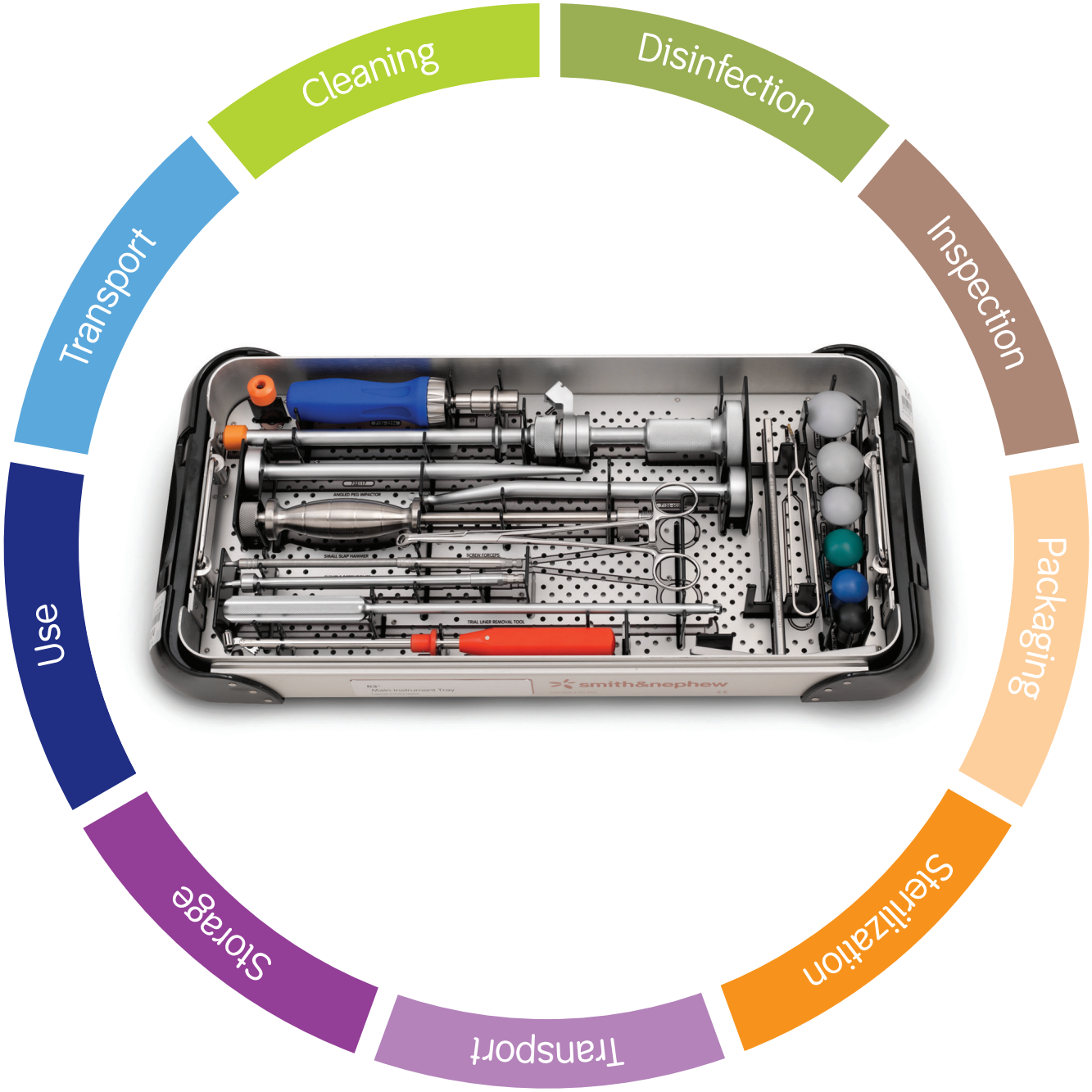
Instructions for Care, Maintenance, Cleaning and Sterilization of Smith & Nephew Orthopaedics Devices

Smith+Nephew



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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.

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 critical, semi-critical, and non-critical medical devices as defined in ISO 17664-1 and 2.

Critical and semi-critical medical devices present a high degree of risk of transmission of infection if contaminated since these are devices that are introduced directly into the human body either in contact with the bloodstream or into other normally sterile areas of the body. These devices must be cleaned and sterilized.

Non-critical medical devices are those that are intended to come into contact with intact skin only or a medical device not intended for direct patient contact. Non-critical devices do not present a high risk of transmission of infection and must be provided cleaned but not sterile at the time of use.

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 and Semi-critical Medical Device: A device that enters normally sterile parts of the human body or a medical device that comes into contact with mucous membranes or non-intact skin.

Critical Water: Water that meets specific water quality measurement values[6]. To achieve these values, the water generally requires extensive treatment by a multi-step process that can include a pretreatment, does include primary treatment (e.g. Reverse Osmosis (RO) and/or Deionization (DI)), storage distribution, and can include final treatment to provide a level of assurance that microorganisms and inorganic material are removed from the water. This water is mainly used for the final rinse after high-level disinfection, for the final rinse for critical devices prior to sterilization and feedwater for process steam production.

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

Immediate Use Steam Sterilization (IUSS): 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.

Lumen: Cavity or channel within a tube.

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.

Non-Critical Medical Device: A device that is not intended to be sterilized; a medical device that is intended to come into contact with intact skin only or a medical device not intended for direct patient contact.

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 specific water quality measurement values[6]. This water is mainly used for flushing, washing, and intermediate rinsing (e.g., rinsing between cleaning and disinfection).

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

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

Important Information/ Recommendations for Use

The instructions provided in this manual have been validated by Smith & Nephew and are capable of preparing orthopaedic devices for use. It is the responsibility of the hospital to ensure that processing of medical devices is performed using the appropriate equipment and materials, and that personnel in the processing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be verified and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences. All critical and semi-critical instruments must be cleaned and sterilized before each use, but particularly before the first use after delivery, since all instruments are supplied non-sterile. Remove the protective transport packaging before cleaning the instruments.

Limitations of cleaning and sterilization instructions

These recommended procedures are intended as a general guide for care, maintenance, cleaning and sterilization of medical devices. Some devices are labeled with more specific instructions. Refer to the Instruction for Use for that device.

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.

Automatic washer/disinfector

Washer-disinfectors are not only used to clean devices, but also to provide intermediate to high level thermal 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. The automatic washer/disinfector must be of proven efficacy complying with the ISO 15883 series standard.

Hospital Responsibilities for Smith & Nephew Loaner Sets

Orthopaedic surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to Smith & Nephew. Notify your Smith & Nephew representative of any instrument problems.

Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization described in this instruction document before being returned to Smith & Nephew.

Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to your Smith & Nephew representative to ensure that the instrument sets remain in good working order. Contact information is provided at the end of this instruction document.

Warnings

Cleaning and Sterilization

- **Instruments should never be soaked in saline or sodium hypochlorite (bleach) solution. The chloride ions in both solutions are highly corrosive, causing the breakdown of the finish on instruments, as well as the metal.**
- **Single-use devices must not be reused. Reuse may damage or compromise the performance of the device, resulting in product malfunction, failure, or patient injury and may also expose the patient to the risk of transmitting infectious diseases. Refer to the device label to identify single-use devices.**
- **It is the responsibility of the user to ensure that the cleaning process is performed following these procedures to achieve the desired result.**
- **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.**
- **Rinse aids can leave residues and is not recommended for use unless validated by the processor and is of proven biocompatibility.**
- **Always observe the cleaning agent concentrations, temperatures, and final rinse instructions specified by the manufacturer.**
- **For ultrasonic cleaning, the enzymatic detergent solution should be changed when it becomes visibly 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.**
- **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.**
- **Steam sterilization is the only method that has been validated for processing by Smith & Nephew. Sterrad or hydrogen peroxide based gas systems have not been validated.**
- **Smith & Nephew recommends consulting the Immediate-Use Steam Sterilization (IUSS) statement in AAMI ST 79 for guidance on IUSS.**
- **Package inserts are provided with external fixators to provide directions for processing.**
- **It is the responsibility of the user to verify that their sterilization equipment is able to achieve the recommended sterilization parameters. Steam sterilizers should be validated to local standards, guidance and ISO 17665.**

Limitations on Processing

Repeated processing of reusable medical devices following the instructions in this instruction document 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. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. pitting), deep scratches, gouges, flaking, cracks, and surface damage that impairs the function of the device. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, color changes that prevent the appropriate surgical use of plastic parts, damaged and excessively worn devices should not be used.

Metal reusable devices are susceptible to discoloration from steam impurities and detergent residues which may form multi-colored surface layers of oxide deposits. The oxide deposits may darken following repeated sterilization processing. This discoloration poses no harm to the patient and does not affect the normal function of the instrument.

Plastic medical devices are susceptible to color fading following repeated processing. Color changes do not affect the mechanical function of plastic devices.

Safe Disposal

Single use devices should be disposed of or returned to Smith & Nephew after use. Reusable devices that have been inspected and have reached the end of their lifetime should be sterilized, if possible and disposed according to institutional procedures. Devices that are unable to be sterilized before disposal should be disposed properly as a potential biohazard. All devices associated with submitted complaints should be returned to Smith & Nephew for analysis.

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. Either method may be chosen for sufficient and effective cleaning of the devices. 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.

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.

Refer to the manufacturer's limitations and warnings for information concerning specific materials that are adversely affected by the detergents.

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 between uses. Brushes should be clean. Discard worn brushes and disposable cleaning tools.

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

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
- Non-critical devices that do not have direct patient contact

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 that do not have direct patient contact: Includes all devices that do not have direct patient contact and are not sterilized after cleaning.

Examples: Computer Control Units, power supply boxes and power cable surfaces.

Pre-treatment at the Point of Use

The cleaning of instruments should begin during the surgical procedure and should continue at the point of use post-procedure to prevent drying of blood, soil and debris on the surface and within lumens.

Gross contaminants should be removed from the instruments directly after use. Gross contaminants and blood can be removed from the surface of devices using sterile water. Instruments with lumens should be flushed with a sterile, water-filled syringe to remove blood and debris.

It is recommended that soaking soiled instruments begin in the OR at the completion of the procedure (within a maximum of 2 hours). The instruments can be placed in a basin of sterile water.

Instruments should never be soaked in saline or sodium hypochlorite (bleach) solution. The chloride ions in both solutions are highly corrosive, causing the breakdown of the finish on instruments, as well as the metal.

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.

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. Scrub the devices using a brush until visible debris is removed.
   a. Move and/or retract all movable 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. 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. Lumens should be flushed 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 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.) Scrub until visible debris is removed. Lumens should be flushed 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 utility water >45° C (113° F) making sure to irrigate the lumens and crevices. Lumens should be flushed 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. Lumens should be flushed 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 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. Scrub the device until visible debris is removed.
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."

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.

Non-critical Devices that do not have direct patient contact

Sterile hospital grade covers can be used whenever possible to prevent contamination of non-critical devices that do not have direct patient contact. Porous items like foam that are contaminated must be discarded. Clean the noncritical device as follows:

1. Wipe the surface with a clean lint free cloth using a neutral pH detergent until visible debris is removed.
2. Using a new clean lint free cloth, wipe the surface with critical water.
3. Dry the surface with a new clean lint free cloth.

Verify cleaning under normal lighting for any visible debris.

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 movable 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. Scrub until visible debris is removed. Lumens should be flushed 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. Lumens should be flushed 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.) Scrub until visible debris is removed.
   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. Scrub until visible debris is removed. **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

Devices should be loaded into the washer such that all design features of the device are accessible to cleaning and rinsing and such that design features that might retain liquid can drain. Lumens should be positioned for adequate rinsing and draining.

- 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.
   a. Following hydrogen peroxide testing, manual rinse the devices for a minimum of one minute using a sufficient volume of critical water to completed immerse the devices, or by using an automated washer using the recommended automatic washing steps (see Automatic washing cycle steps and parameters).
3. Repeat cleaning if not visibly clean and reinspect the device.

Inspection and function testing

Upon receipt in the hospital, instrument sets should be inspected for completeness. Inspect for thumb, wing, set, or other types of screws; screw-in or other detachable handles; and auxiliary exchangeable parts such as blades, right/left attachments or heads. Many organizing cases have shadow graphs, outlines, catalog numbers, and instrument names or sizes silk-screened or otherwise marked on the case or tray.

Orthopaedic surgical procedures follow a precise order in which the instruments are used. Also, many instruments have dimensional features which govern bone resections, determine implant sizes, and measure intramedullary canal sizes, depth of drill holes, angles of tube/plate, acetabular cup placements, etc. Therefore, it is very important that all requested sizes of a specific instrument series are available (specific instruments are routinely omitted from instrument sets due to infrequent use unless requested by the user). Contact your Smith & Nephew representative if requested instruments have been omitted but are required for surgery.

Markings on instruments used for measuring anatomical dimensions must be legible. These may include gauge markings, angles, inner or outer diameters, length or depth calibrations, and right/left indications. Notify your Smith & Nephew representative if scales and other markings are not legible.

Additional details regarding inspection and function testing specific to device type or features are provided below.

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. Only use lubricant, without anti-corrosion additives, that is approved for steam sterilization (taking account of the maximum sterilization temperature used) and is of proven biocompatibility. 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 should be thoroughly dried following cleaning (including after manual cleaning and automatic washer cleaning) to remove any moisture from the surfaces and lumens of the devices prior to steam sterilization. Filtered compressed air can be used to ensure adequate drying of lumens.

After cleaning, reusable devices should be prepared and packaged for sterilization. Approved instrument wraps, containment devices, and pouches may be used for packaging. See Reusable Devices in the Preparation for Sterilization Section for more details.

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.

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. Use of a device is defined as contact of the device with blood, tissue, or bodily fluids (including contact with soiled gloves or aerosolized contaminants) from a patient.

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 kg) or less. Please be aware that there are some older models that cannot be separated to achieve a weight below 25 pounds (11.34 kg). 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 External Fixation Devices

External fixation devices are considered to be single use medical devices.

External fixation implants (i.e. pins, wires) should not be processed or reused if they have come into contact with blood, tissue, or bodily fluids.

Non-invasive external fixation devices (eg. rings, bolts, clamps) 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. While non-invasive external fixation devices do not enter the patient's body through orifice or surgical wound, the devices may become contaminated through contact with blood during surgery, including contact with soiled gloves. Contaminated devices should be manually cleaned before being returned to the tray (see Cleaning: Manual) in preparation for sterilization.

Non-invasive external fixation devices are considered to have completed the single use once they have been incorporated in the final frame construct on the patient. After this use, the device should not subsequently be reprocessed for re-use.

Single Use Medical Devices (other than External Fixation Devices)

Trauma plates, nails, screws, pins, and wires are implants and are 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 (including contact with soiled gloves or aerosolized contaminants). Prior to sterilization of the device, remove all original packaging and labeling inserts. Place the device in its designated location in the containment device. Do not resterilize Single Use Medical Devices with internal plastic bushings/sleeves because they can become damaged during resterilization. The labels on these products will be noted with the symbol "Do not resterilize".

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.

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

- Review ANSI/AAMI ST77 for guidance regarding rigid containers to be used with Immediate Use Steam Sterilization (IUSS) cycles.
- Contact Aesculap and Case Medical for further information and guidance.

Water Quality

Use critical water for steam generation.

Recommended Sterilization Parameters

Smith & Nephew devices have been validated to appropriate sterility assurance levels (SAL) for the sterilization cycle parameters below. It is the responsibility of the user to confirm their sterilization equipment can achieve the recommended parameters. Steam sterilizers should be validated to local standards, guidance, and ISO 17665.

Standard Sterilization Cycles

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*

For Non-US Customers - UK Steam Cycle Prevacuum cycle	
Exposure temperature:	134° C (273° F)
Exposure time:	3 minutes
Vacuum drying:	30 minutes*

For Non-US Customers - World Health Organization (WHO) Steam Cycle	
Exposure temperature:	134° C (273° F)
Exposure time:	18 minutes
Vacuum drying:	30 minutes*

*Sterilizer loads that contain individually wrapped heavy instruments (>3lbs) require a minimum of 45 minutes of drying.

Gravity Displacement

Gravity Displacement Steam cycle parameters are provided for global markets, but may not be standard in all markets. These cycles should only be used if in alignment with the state-of-the art for the region.

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*

**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).

Immediate Use Steam Sterilization (IUSS) - Prevacuum

Per ANSI/AAMI ST79, Immediate Use Steam Sterilization (IUSS) should be kept to a minimum and should be used only in urgent clinical situations (ie. intra-operative contamination). IUSS should not be used for purposes of convenience of as a substitute for sufficient instrumentation. HCPs should ensure instrument inventories are sufficient to meet anticipated surgical volume and to ensure that there is enough time to complete all critical elements of reprocessing (decontamination, disinfection, inspection, and sterilization). Instrumentation should be placed in a rigid container approved for use in IUSS cycles and sterilized according to the following parameters. HCPs should follow guidance available in the “Immediate-use steam sterilization” section of ANSI/AAMI ST79.

Immediate Use Steam Sterilization (IUSS)*	
Exposure temperature:	132° C (270° F)
Exposure time:	4 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.

Note to US customers: Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.

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

1. AAMI TIR 12. *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*.
2. AAMI TIR 30. *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.*
3. AAMI TIR 34. *Water for reprocessing of medical devices.*
4. ANSI/AAMI ST79. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
5. AAMI/ANSI ST81. *Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices*.
6. ANSI/AAMI ST108. Water for the processing of medical devices.
7. AORN. *Perioperative Standards and Recommended Practices*.
8. Centers for Disease Control. *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008.
9. Health Canada June 2011. *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations.*
10. ISO 17664-1. *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices.*
11. ISO 17664-2. *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 2: Non-critical medical devices.*
12. German Redbook. *Proper Maintenance of Instruments,* Instrumenten-Aufbereitung [Instrument Preparation Working Group].
13. *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff,* March 17, 2015.
14. UK Department of Health. *Health Technical Memorandum 01-01: Decontamination of reusable medical devices. Parts A and B*.
15. ANSI/AAMI ST77. *Containment devices for reusable medical device sterilization.*
16. ISO 15883-1. *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*.
17. ISO 17665-1. *Sterilization of healthcare products, moist heat- Parts 1, 2, and 3: Requirements for the development, validation and routine control of a sterilization process for medical devices.*

Adverse Event Reporting

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

complaints@smith-nephew.com

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

MD	Medical Device
	Contains hazardous substances*
	Non-sterile
	Single sterile barrier system
	Double sterile barrier system
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
UDI	Unique device identification
	Single patient – multiple use
	Consult instruction for use

Manufacturer	CE Mark	Contact Information
Smith & Nephew Asia Pacific Pte. Limited 29 Media Circle #06-05 Alice @ Mediapolis Singapore 138565		+65 6270 0552 Telephone +65 6708 7197 Fax
Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 USA	CE CE 2797	+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	CE CE 0344	+44 (0) 845 056 8333 Customer Service
Blue Belt Technologies, Inc. 2905 Northwest Blvd., Suite 40 Plymouth, MN 55441 USA	CE CE 0123	+1 763 452 4910 Telephone +1 763 452 4980 Fax

**Note:* The outer package labeling of invasive components containing substances that may be carcinogenic, mutagenic, toxic to reproduction or endocrine-disrupting (hazardous substances) in quantities greater than 0.1% weight/weight indicates the presence of the hazardous substance using the hazardous substance symbol. The symbol is accompanied by a Chemical Abstracts Service (CAS) number, identifying the substance.*

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