

Recommendations for Care,  
Maintenance, Cleaning and  
Sterilization of Smith & Nephew Inc.  
Endoscopy Surgical Instruments  
and Instrument Trays

Smith+Nephew





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This guide is for informational and educational purposes only. It is the responsibility of the healthcare organization to determine and utilize the appropriate products and techniques for the cleaning and sterilization of products. For more information on the instructions for the care, maintenance, cleaning, and sterilization of medical devices produced by the Endoscopy Business of Smith & Nephew, please refer to the product's label and the inserts packaged with the product.

### Purpose and Scope

This document was prepared to provide recommendations for the care, maintenance, cleaning, and sterilization of the surgical instruments and instrument trays produced by the Endoscopy Business of Smith & Nephew, Inc. These methods were developed using standard equipment and practices common to health care facilities. Validation testing to support these instructions was based on recognized guidelines and standards for reusable medical devices. Using the guidance given in AAMI TIR 12 (Designing, Testing, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers), ISO 17664 (Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices) and Health Technical Memorandum (HTM) 2030.

### Definitions

**Critical Devices:** Medical devices that are introduced into or have contact with the bloodstream or normally sterile areas of the body.

**Semi-critical Devices:** Medical Devices that contact intact mucous membranes or nonintact skin but do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

**Non-critical Devices:** Medical Devices that contact only intact patient skin.

**Critical Water:** Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material 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.

**Lumen:** Cavity or channel within a tube.

**Cleaning:** Removal of contamination from an item to the extent necessary for further processing or for the intended use.

**Disinfection:** Process that kills pathogenic and other microorganisms by physical or chemical means.

**Sterilization:** Validated process used to render a product free from viable microorganisms.

**Prions:** Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle and Creutzfeldt-Jakob disease in humans.

### 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. In addition, 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 and Recommendations for Use

#### *Automatic washer/disinfector*

Washer-disinfectors are not only used to clean devices, but also to provide intermediate to high-level disinfection with a hot water rinse. Cleaning is dependent upon thorough coverage of the devices and the force of the water spray. Therefore, all sections of the device must be accessible for ease of cleaning and penetration of cleaning agents. The automatic washer/disinfector equipment should be operated following the manufacturer's instructions for use. The automatic washer/disinfector must be of proven efficacy complying with the ISO 15883 series standard.

#### *Detergents*

Enzymatic detergents with a neutral 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 such as Prolystica 2 or equivalent should be used at the concentration and temperature recommended by the detergent manufacturer. 1 to 4 mL/L of Prolystica 2X Concentrate Enzymatic Presoak and cleaner (neutral pH enzymatic detergents manufactured by STERIS Corporation) was used in the validation of the cleaning processes for Smith & Nephew Endoscopy devices.

#### *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.

## **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.
- When cleaning instrument sets, the case and instruments should be treated as separate items. For automatic washing, devices must be cleaned separate from the instrument case/tray.
- 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.
- These procedures do not apply to single-use devices. Smith & Nephew Endoscopy does not support the reuse of single-use devices.
- The surgical instruments and instrument trays are shipped non-sterile. Upon receipt the devices must be cleaned to remove contaminants from handling and then get sterilized. They must be cleaned before the first use and every subsequent use.
- After each use the instrument trays and accessories must be cleaned with a neutral pH enzymatic detergent. Scrub the pin mat and other accessories with a brush to reach hard-to-clean areas such as between the pins on the mat, and inside the holes of the silicone instrument holders. Rinse thoroughly.
- The instrument trays and accessories should be inspected following cleaning to verify that there is no damage to the instrument trays, insert trays, or detachable lids, and that the closure system functions properly.
- Discard the instrument trays if there is visible damage or if handles, latches, or instrument brackets become loose.

## **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.
- 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.

## **Limitations on Processing**

### ***Limitations of cleaning instructions***

These recommended procedures are intended as a general guide for cleaning of medical devices. Products requiring more specific cleaning details are supplied with inserts describing recommended cleaning methods. Users should check package inserts to determine if more specific cleaning instructions are recommended for individual devices than those found herein. Where the package insert only describes an alternate cleaning method, it may be used interchangeably with the methods described herein.

### ***Limitations of processing***

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

## **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 (i.e. utility water, etc.) 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 Endoscopy devices, contact your Smith & Nephew sales representative or Customer Service Department (see Contact Information).

## Cleaning Product Groups

### *Overview of product groups for reusable device cleaning*

Cleaning of medical devices is dependent upon the extent of soiling and product design features. Some Smith & Nephew Endoscopy devices do not have design features that are a challenge to validated cleaning methods, while others do. Therefore, the following cleaning procedures are divided into groups based on these criteria:

- Devices **without** challenging design features
- Devices **with** challenging design features
- Instrument Trays

### **Devices *without* challenging design features:**

Includes all devices that do not have design features that present a challenge to cleaning by the Smith & Nephew Endoscopy 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: Rasps, Osteotomes, Knives, Sizing tubes, Pins & wires, Obturators, Trocars

### **Devices *with* challenging design features:**

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

Examples: Cannulations (Lumens) or Holes (Reusable Cannulas, Cannulated Drill, Rotatable Cannulas); Interfaces (T-Handles, Rotary Handles); Hinged Instruments with Mating Surfaces (ACUFEX<sup>®</sup> Hand Instruments such as graspers, scissors, forceps, Suction Punches, Laparoscopic Hand Instruments, Sterilization Trays); Instrument Trays with Crevices (Cutting Blocks/Strips, ENDOBUTTON<sup>®</sup> Holder Block, GRAFTMASTER<sup>®</sup> Boards/Bases etc.)

### **Notes:**

- Pay careful attention to cleaning devices with challenging design features. Challenging design features can include, but not limited to, suction levers, stopcocks, interfaces, cannulations, holes, blind holes, crevices, hinges, mating surfaces, etc.
- Blind holes should be repeatedly filled and emptied.

- Low-sudsing, neutral 6.0–8.0 pH, enzymatic detergents are recommended.
- Do not use detergents above 11.0 pH.
- Use deionized water for washing and rinsing.

## Warnings

- **Cannula** – The flush valve on the outflow tubing of cannula may be opened momentarily (2 seconds maximum) to flush the joint. During normal use, the flush valve should remain completely closed to ensure accurate pressure control. Failure to completely close the flush valve may result in under-pressurization of the joint. Do not connect a suction source to the outflow barb of the inflow cannula.
- **Inflow Cannula and Irrigation Extenders** – When using inflow cannula and irrigation extenders with a fluid management system, refer to the instructions for use provided with the fluid management system for the recommended configuration.
- **Cannulas with Silicone Seals** – Prior to use, inspect the silicone seal for any sign of deterioration and if necessary replace seal with replacement part 72200027.

## Instrument Trays

The Smith & Nephew Instrument Trays are designed to contain and protect reusable surgical instruments during transport, sterilization, and storage and to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

The instrument trays are perforated Radel™ Stainless Steel or Aluminum cases with latchable lids and handles. Dedicated trays may be fitted with silicone instrument holders, protective mats, or be preformed to organize specific Smith & Nephew instrument sets. Multipurpose trays contain silicone protective mats and are not marked to designate instrument placement.

## Manual Cleaning

### **Devices *Without* challenging design features**

1. Rinse in cold water <43° C (109.4° F) to remove visible debris and to prevent coagulation of blood.
2. If applicable, disassemble the instrument into its component parts. Ensure that suction levers or stopcocks are in the full open position or disassembled.
3. Immerse and soak for a minimum of ten (10) minutes in enzymatic detergent and deionized water.
4. With the device completely immersed in the cleaning solution, use a surgical scrub brush to remove visible debris from the surfaces of the device.
5. Rinse for a minimum of one minute using a sufficient volume of warm water that will completely immerse the device. Water should be changed a minimum of two times to ensure thorough rinsing.
6. Check for visible debris. Repeat cleaning if debris is visible.

## ***Devices With challenging design features***

1. Rinse in cold tap/utility water <43° C (109.4° F) to remove visible debris and to prevent coagulation of blood for a minimum of 2 minutes.
2. If applicable, disassemble the instrument into its component parts.
3. Ensure that suction levers or stopcocks are in the full open position or disassembled.
4. Immerse and soak for a minimum of ten (10) minutes in enzymatic detergent and deionized water.
5. With the device completely immersed in the cleaning solution,
  - a. use a surgical scrub brush to remove visible debris from the surfaces of the device.  
**Note:** to access the surfaces of flexile devices, gently bend the instrument by pushing it against the side of the cleaning tub with one hand, making sure not to damage the device. Bend at several locations along the length of the device to access all crevices.
  - b. Scrub interfaces, cannulations, holes and all crevices of the flexible portion(s) of the instrument with tight-fitting cleaning brushes/pipe cleaners, using a twisting motion to remove additional soil.
  - c. Scrub crevices and around hinged/mating surfaces with a brush.
6. Rinse thoroughly with warm tap water >40° C (104° F) for a minimum of 2 minutes. While rinsing, use a clean brush to irrigate the cannulations, holes, and all crevices. To do so, move the brush back and forth through the cannulations, holes, and all crevices several times.
7. Sonicate for a minimum of 15 minutes in an ultrasonic cleaner containing enzymatic detergent and deionized water.
8. Rinse thoroughly with warm deionized water for a minimum of 2 minutes, making sure to irrigate any lumens and/or crevices.
9. Examine the device for visible debris.  
**Note:** Magnification may be used to determine the cleanliness of the instruments.
10. Check the lumen and crevices of the device for blood.  
**Note:** The most effective method for testing is to immerse the instrument in 3% hydrogen peroxide. Bubbling indicates the presence of blood. If hydrogen peroxide is used for testing, rinse the instrument thoroughly with warm water.
11. If visible debris or blood remains on the device, repeat steps 3–9.
12. If all visible debris has been removed, the device may be processed in an automatic washer cycle followed by a thermal disinfection cycle and then sterilized.
13. Inspect the device for any wear or damage. Discard the device if any wear or damage is observed.

## **Automatic Cleaning**

1. Complete step 1-6 (device without challenging design feature) or step 1–13 (device with challenging design features) detailed in the “Manual Cleaning” section.
2. Using the following minimum parameters, put the devices through an automatic washing cycle. Follow the instructions included with the automatic washer for instrument load and configuration.
 

**Minimum Parameters:**

  - a. Use deionized water
  - b. 5 minute cold prewash
  - c. 5 minute enzymatic wash at 109° F (43° C)
  - d. 5 minute detergent wash at 131° F (55° C)
  - e. 1 minute rinse at 113° F (45° C)
3. Inspect the device for any wear or damage. Discard the device if any wear or damage is observed.

## **Thermal Disinfection**

1. Perform thermal disinfection achieving an A0 ≥ 600 by maintaining a temperature of 196° F (91° C) for 1 minute.
2. Inspect the device for any wear or damage. Discard the device if any wear or damage is observed.

## **Instrument Trays Cleaning**

### ***Stainless Steel and Radel Trays***

1. Separate the lid from the tray and remove shelves or instrument modules that are not attached to the main tray. Remove any pin mats from the tray. All removable parts should be cleaned separately from the tray itself.
2. Soak the removable components in a bath containing an enzymatic neutral pH cleaner for a minimum of 5 minutes at <55° C. Scrub the components including the pin mat with a nylon-bristled brush, being careful to access any holes, openings or mating parts. Use a brush to scrub the “pins” on the pin mat.
3. Rinse the main tray body and lid under running DI water for >30 seconds, changing the position of the tray and the lid under the water to allow access to all areas of the tray and the lid.
4. With the tray in a bath containing enzymatic neutral pH cleaner use a nylon-bristled brush to brush the area around the holes and the internal “instrument holders” for a minimum of one minute.
5. Use the brush to scrub the printed areas on the tray lid and base.
6. Rinse all removable components and the main tray and lid thoroughly with running deionized water for a minimum of one minute

# Recommended Cleaning Instructions

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## Aluminum Trays

1. Rinse in cold utility water <math><45^{\circ}\text{C}</math> (113°F) for a minimum of 2 minutes to remove visible debris and to prevent coagulation of blood.
2. Immerse and soak for a minimum of five (5) minutes in a neutral pH enzymatic detergent.
3. With the device/tray completely immersed in the cleaning solution, remove additional soil from the surfaces and challenging design features. (I.e. crevices) using common hospital cleaning tools. Move all moveable parts and remove visible debris using a brush. Remove additional soil from the surfaces and from the challenging design features (i.e. holes, lumens, hinged/mated surfaces, interfaces, crevices, and serrations using common hospital cleaning tools.
4. Move and/or retract all moveable parts and remove visible debris using a brush.
5. 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.
6. Open hinged devices and scrub hinged area with a brush.
7. Scrub crevices with a brush.
8. Scrub the surfaces of the device with a toothbrush styled brush.
9. Sonicate the device in enzymatic detergent in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner.
10. 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.

## Storage Between Cleaning and Sterilization

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

## 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.
- Discard blunt, worn or damaged devices.
- Discard devices that do not function properly. Please follow these cleaning and sterilization instructions prior to disposal.

## Precautions

- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device. As with any surgical instrument, careful attention should be exercised to ensure that excessive force is not placed on the instrument. Excessive force can result in instrument failure.
- Do not use these instruments as levers for manipulating hard tissue or bone.
- Excessive force should not be applied to the instrument when manipulating soft tissue bone or hard objects. Misuse of these instruments may result in bent distal tips or jaws; and dull or uneven cutting edges.
- Careful attention must be paid to asepsis and avoidance of anatomical hazards.
- Surgical instruments must be thoroughly cleaned and rinsed according to the manufacturer's instructions prior to placement into the instrument trays.
- Do not use instrument trays with high pH detergents or other caustic chemicals.
- The use of nonabsorbent tray liners such as silicone mats can cause condensate to pool. Adequate drying time for the sterilization cycle should eliminate residual moisture.
- Carefully inspect the wrapped instrument trays following steam sterilization. Reprocess if moisture is apparent on the outside of the pack.
- Small baskets, trays, or other types of accessories, especially with covers or lids, should be used with the instrument trays only if the trays have been specifically designed and tested for this purpose.
- Only use accessories such as silicone mats, instrument holders, or slotted brackets that come with the instrument trays. These have been designed and validated specifically for use with Smith & Nephew Instrument Trays.
- Use Central Supply Room (CSR) wrap intended for sterilization. All wraps may not be approved for all cycle types. Check with the manufacturer of the wrap for the recommended use. Wrap should provide a sterile barrier, allow for the passage of steam and be free from loose particles, while guaranteeing sterility under the proper storage conditions.  
Note to US Customers: Sterilizers and wraps used in your sterilization process must be cleared by the FDA.
- Since sterilizers vary in design and performance characteristics, it is recommended that the user verify the cycle parameters for the specific sterilizer and types of instruments being sterilized.
- Complex and lumened instruments should be cleaned and sterilized according to the instrument manufacturer's instructions.
- Certain devices are made of stainless steel which may contain trace amounts of Cobalt. Cobalt is defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Use of these devices may expose patients to Cobalt in levels above 0.1% weight/weight.
- This product contains Nickel (Ni) which may cause allergic reactions.

## Recommended Sterilization Instructions

Recommended sterilization methods have been validated to sterility assurance level (SAL 10<sup>-6</sup>) 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 Endoscopy 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.
- Steam is the only method that has been validated for processing by Smith & Nephew.
- 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 Endoscopy Division of Smith & Nephew, Inc. Some devices are labeled with instructions that are more specific.
- Most reusable devices are sold non-sterile. It is critical to properly clean all reusable devices prior to sterilization.
- It is important that proper cleaning of instrument cases/ trays be performed prior to sterilization. Reference the recommended cleaning procedures.

### Specific to all trays:

- It is the responsibility of the user to be familiar with the appropriate sterilization technique(s) and the manufacturer's recommended method(s) prior to use of this device.
- It is the responsibility of the user to perform infection control techniques correctly.
- Instrument trays are not intended to maintain a sterile barrier. Instrument trays must be encased in validated sterilization wrap during sterilization and storage.
- Inspect the sterilization wrap for breaches prior to use of the instruments. Do not use instruments contained in a tray with punctured or torn sterilization wrap.
- Do not stack or overload the trays. The effectivity of the sterilization process may be compromised.

### Specific to multi-purpose trays:

- Not validated for use with porous loads, flexible endoscopes, or for devices with lumens longer than 101.6 mm (4") and less than 3 mm ID (.118").
- Balance contents uniformly within the container and arrange to allow steam to come in contact with all objects in the container. Failure to do so may cause inadequate sterilization.
- Silicone mat accessories should be placed in alignment with perforations in trays so that sterilant pathways are not obstructed.

## 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.

### Instrument Trays

The Smith & Nephew Instrument Trays are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization, and transport between usages. The instrument trays are suitable for use in a prevacuum steam sterilization method.

- The instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.
- Dedicated trays are indicated for use only with specific Smith & Nephew instrument systems. Multipurpose trays are indicated for use only with non-porous loads, non-flexible endoscopes, or for devices with lumens shorter than 101.6 mm (4") and greater than 3 mm ID (.118").
- The Multi-purpose sterilization tray (Ref. 72202428) was validated with a variety of common nonporous surgical instruments such as drills, drivers, chisels, graspers, pliers, and taps, including devices with lumens with dimensions 8.5" (215.9 mm) in length by .093" (2.4 mm ID) in diameter and lumens with dimensions 2.0" (50.8 mm) in length by .050" (1.27 mm) in diameter with an overall length of 10.5" (266.7 mm).
- Smith & Nephew Multi-Purpose Sterilization Tray (Ref. 72202428) have not been validated for use with air-powered instruments, flexible endoscopes, or devices with lumens or working channels longer than 10.5" (266.7 mm) or less than .050" (1.27 mm ID). Always refer to the instrument manufacturer's instructions.
- The Smith & Nephew Instrument Trays dedicated for specific instrument sets are for exclusive use with the validated instrument systems listed in Table 1.
- The Smith & Nephew Instrument Trays for multipurpose use are validated only for maximum load weights listed in Table 1.
- Load wrapped instrument trays into the sterilizer or onto the cart or shelf in the upright position with the lid facing up. Do not orient instrument trays on sides or upside down with the lid facing down.
- The ACUFEX GRAFTMASTER III System Trays are for exclusive use with the validated ACUFEX GRAFTMASTER III System.
- The Hip Arthroscopy Repair Instrument Tray is for exclusive use with the validated hip arthroscopy repair system.
- Surgical instruments must be thoroughly cleaned and rinsed according to the manufacturer's instructions prior to placement into the instrument trays.

## Recommended Sterilization Instructions

- a. Follow the pre-marked configuration on the trays to load clean instruments into clean instrument trays. When loading trays designed with non-dedicated storage compartments, ensure adequate room between instruments for sterilant penetration.
  - b. Cover the instrument tray with the lid and secure the lid by completely closing the latches.
  - c. Prior to sterilization, double wrap the loaded tray. Refer to Table 1 and hospital procedures.
  - d. Sterilize the loaded tray using the validated sterilization cycle listed in Table 2.
- Note:** Standard sterility assurance practices for routine monitoring and product testing include placement of chemical indicators and biological indicators in the most challenging areas of the sterilization load.
- Note:** Trays have a validated weight for sterilization the symbol for this is:  If there is no symbol located on the tray refer to Table 1, for Maximum Load Weights. If the weight is still not found, please notify customer service or your authorized representative.

**Table 1.** Maximum load weights

Multipurpose Trays			
REF	Tray Description	Max. Weight	Material
7207369	Medium, multipurpose	3 lbs (1.4 kg)	Radel
011703	Small, multipurpose	3 lbs (1.4 kg)	Radel
7207357	Large, multipurpose	9 lbs (4.1 kg)	Radel
7205683	X-Large, multipurpose	11 lbs (5.0 kg)	Radel
7208209	3" x 19" multipurpose	4 lbs (1.8 kg)	Radel
72202428	MULTI-PURPOSE STERILIZATION Tray	13.0 lbs (5.8 kg)	Stainless Steel*
Dedicated Trays			
REF	Tray Description	Max. Weight	Material
011702	Meniscal Sticher Set	1.8 lbs (.8kg)	Radel
7207032	Guhl Ankle Distractor	6.7 lbs (3 kg)	Radel
7207934	Hip Arthroscopy System	10.4 lbs (4.7 kg)	Radel
7207182	GRAFTMASTER <sup>®</sup> II System	7.1 lbs (3.2 kg)	Radel
7207019	Small Joint Arthroplasty System	4.5 lbs (2 kg)	Radel
72200808	ELITE <sup>®</sup> Instrument Tray	9.1 lbs (4.1 kg)	Radel
7207935	Micro Instrument Set	4.5 lbs (2 kg)	Radel
7204737	4 mm Arthroscope	2.1 lbs (.9 kg)	Radel
7209182	ARTHRO-PIERCE <sup>®</sup> Instrument Tray	5.4 lbs (2.4 kg)	Radel
011673	Linear Punch and Grasper	5.6 lbs (2.5 kg)	Stainless steel*
011804	Fixation Post Instrument System	1.5 lbs (.7 kg)	Radel
014870	ACL REDUX <sup>®</sup> Instrumentation System	5.7 lbs (2.6 kg)	Radel
7205507	MOSAICPLASTY <sup>®</sup> Complete System	6.4 lbs (2.9 kg)	Radel
7207169	RCI Screw System	3 lbs (1.4 kg)	Radel
7207637	Cruciate Dilator System	7.3 lbs (3.3 kg)	Radel
72201731	Tray ACUFEX DIRECTOR ELITE	16.5 lbs (7.4 kg)	Stainless Steel*
72201847	Tray CROSSTRAC <sup>®</sup>	6.5 lbs (2.9 kg)	Stainless Steel*
72201938	Tray BIOSURE TAPS	6.9 lbs (3.1 kg)	Stainless Steel*
72201939	Tray BIOSURE EASY TAPS	6.1 lbs (2.7 kg)	Stainless Steel*
72202042	Tray ELITE <sup>®</sup> PREMIUM II Shoulder ARTHRO System	16.5 lbs (7.4 kg)	Stainless Steel*
72202044	Tray ELITE <sup>®</sup> PREMIUM Instability System	12.1 lbs (5.4 kg)	Stainless Steel*

Dedicated Trays			
REF	Tray Description	Max. Weight	Material
72202202	Tray ELITE° PREMIUM BICEPS TENODESIS System	10.2 lbs (4.6 kg)	Stainless Steel*
72202437	Tray ACUFEX ELITE Anatomic ACL Guide System	7.1 lbs (3.2 kg)	Stainless Steel*
72203085	Tray CLANCY FLEXIBLE System	15.8 lbs (7.1 kg)	Stainless Steel*
72203448	Tray PINPOINT AACL Guide System	14.2 lbs (6.4 kg)	Stainless Steel*
72203451	Tray PINPOINT AACL SGL BNDL Guide	7.5 lbs (3.4 kg)	Stainless Steel*
72203782	Tray INSTRUMENT FOOT & ANKLE	16.5 lbs (7.4 kg)	Stainless Steel*
72204363	MANUAL INSTRUMENT Tray	10.8 lbs (4.8 kg)	Stainless Steel*
72205139	ACUFEX EXTRA ARTICULAR RECON System Tray	9.0 lbs (4.0 kg)	Stainless Steel*
72205564	QUADTRAC° Quadriceps Tendon Harvest Guide System	6.7 lbs (3.0 kg)	Stainless Steel*
72202441	GRAFTMASTER III System Tray	17.0 lbs (7.7 kg)	Stainless Steel*
72202732	INSTRUMENT TRAY, HIP ARTHROSCOPY	17.8 lbs (8.0 kg)	Stainless Steel*
4450	HAND HOLDER/STER TRAY,ECTRA II	Total weight of loaded tray: ≤ 25.0 lbs (11.3 kg)	Radel
71935618	ARTHROSCOPIC LATARJET/BONE BLOCK Tray	Max. Weight Load: 4.6 lbs (2.1 kg)	Aluminum
71935619	ARTHROSCOPIC LATARJET/BONE BLOCK LID	Total weight of loaded tray: ≤ 25.0 lbs (11.3 kg)	
71935449	MINI-OPEN ARTHRO ASSIST LATARJET BB Tray	Max. Weight Load: 4.0 lbs (1.8 kg)	Aluminum
71935450	MINI-OPEN ARTHRO ASSIST LATARJET BB LID	Total weight of loaded tray: ≤ 25.0 lbs (11.3 kg)	

\* Stainless Steel Trays contain the trace element of Nickel (Ni).

**CAUTION:** This product contains Nickel (Ni) which may cause allergic reactions.

## Storage After Cleaning and Sterilization

**Table 2.** Validated sterilization cycle for Instrument Trays

Tray Type	Pre-vacuum Steam Cycle
<b>Metal Trays</b>	Minimum Temperature: 132° C (270° F) Minimum Exposure time: 4 minutes Minimum Drying time: 30 minutes
<b>Metal Tray Ref. 72202732</b>	Minimum Temperature: 132° C (270° F) Minimum Exposure time: 4 minutes Minimum Drying time: 45 minutes
<b>Radel Trays</b>	Minimum Temperature: 132° C (270° F) Minimum Exposure time: 4 minutes Minimum Drying time: 45 minutes
<b>Graftmaster III Tray QUADTRAC® Quadriceps Tendon Harvest Guide System</b>	Minimum Temperature: 132° C (270° F) Minimum Exposure time: 4 minutes Minimum Drying time: 60 minutes
<b>Aluminum Trays: 71935449 (Base) &amp; 71935450 (Lid)</b>	Minimum Temperature: 132° C (270° F) Minimum Exposure time: 4 minutes or Minimum Temperature: 135° C (275° F) Minimum Exposure time: 3 minutes Minimum Drying time: Wrapped devices – 15 minutes; containerized devices – 30 minutes
	<b>Gravity - Displacement Steam Cycle</b>
	Minimum Temperature: 132° C (270° F) Minimum Exposure Time: – 15 minutes for wrapped devices – 30 minutes for containerized devices Minimum vacuum drying time: 30 minutes
Tray Type	WHO Steam Cycle*
<b>Metal Trays</b>	Minimum Temperature: 134° C (273.2° F) Minimum Exposure time: 18 minutes Minimum Drying time: 30 minutes
<b>Metal Tray Ref. 72202732</b>	Minimum Temperature: 134° C (273.2° F) Minimum Exposure time: 18 minutes Minimum Drying time: 45 minutes
<b>Radel Trays</b>	Minimum Temperature: 134° C (273.2° F) Minimum Exposure time: 18 minutes Minimum Drying time: 45 minutes
<b>Graftmaster III Tray QUADTRAC® Quadriceps Tendon Harvest Guide System</b>	Minimum Temperature: 134° C (273.2° F) Minimum Exposure time: 18 minutes Minimum Drying time: 60 minutes
<b>Aluminum Trays: 71935449 (Base) &amp; 71935450 (Lid)</b>	Minimum Temperature: 134° C (273° F) Minimum Exposure time: 18 minutes Minimum Vacuum Drying time: 30 minutes

\*For use only by facilities outside of the United States. This sterilization cycle has not been validated for prion inactivation.

**Note:** Endoscopic instruments may be sterilized by steam. Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material. Please review the sterilizer manufacturer's sterilization instructions, or hospital procedures, prior to sterilization.

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

### Steam Sterilization for Surgical Instruments

The minimum recommended parameters for steam sterilization are as follows:

#### Prevacuum Steam cycle

<b>Minimum Temperature:</b>	270° F (132° C)
<b>Minimum Exposure time:</b>	4 minutes
<b>Minimum Drying time:</b>	30 minutes

#### World Health Organization (WHO) Steam Cycle\*

<b>Minimum Temperature:</b>	273° F (134° C)
<b>Minimum Exposure time:</b>	18 minutes
<b>Minimum Drying time:</b>	30 minutes

\*For use only by facilities outside of the United States. This sterilization cycle has not been validated for prion inactivation.

#### UK Steam Cycle

<b>Minimum Temperature:</b>	273° F (134° C)
<b>Minimum Exposure time:</b>	3 minutes
<b>Minimum Drying time:</b>	30 minutes

**Note:** The UK cycle is not an FDA cleared sterilization cycle and therefore only for use outside the US.

## 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. Sterile packaged devices can be stored as long as sterile packaging is not breached. Smith & Nephew does not recommend stacking of wrapped containment devices or rigid containers. Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.

## Safe Disposal

After use, reprocess the devices according to the cleaning and sterilization procedures prior to disposal.

## For Further Information

If further information on products is needed, please contact Smith & Nephew Customer Service at +1 800 343 5717 in the US, or your authorized representative.

## References

- AAMI ST77, "Containment devices for reusable medical device sterilization."
- 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."
- BS EN 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"
- BS 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"
- BS EN ISO 15883-2, "Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc."
- ISO-TS 15883-5, "Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy."
- BS EN ISO 11138-3, "Sterilization of health care products. Biological indicators. Biological indicators for moist heat sterilization processes."
- BS EN ISO 17665-1, "Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices."

## Glossary of Symbols

	Medical Device
	CE Mark
	Caution
	Consult electronic instructions for use

°Trademark of Smith & Nephew. All Trademarks acknowledged

