NuVasive Products
Cleaning and Sterilization Instructions

1. NuVasive Instrument Cleaning and Decontamination Instructions

Manufacturer: NuVasive	Method: Manual and Automated Cleaning
Devices:	All NuVasive Surgical Instruments as supplied with our surgical Implant and Instrument systems.

These instructions are provided in accordance with AAMI TIR12, AAMI TIR30, and ISO 17664 and are intended to supplement a hospital's existing instrument cleaning and disinfecting protocols. Use of these guidelines does not remove or limit the end-user's ultimate responsibility for the cleanliness and sterility of any surgical device used at their facility. This guide applies only to NuVasive Surgical Instruments supplied with our surgical interbody and fixation systems. It does not apply to NVM5 System accessories, single-use sterile accessories and instruments, or NuVasive implants. These instructions must be used prior to sterilizing the devices.

Warnings & Precautions	Neutral pH enzymatic cleaning agents are recommended for use on all NuVasive instruments except as follows: Alkaline agents with a pH equal to or greater than 12 may be used to clean stainless steel and polymer instruments in countries where required by law or local ordinance and/ or where there is a concern relating to prion diseases such as CJD and or any other known transmissible pathogenic agents. Always follow the instructions provided by manufacturer of cleaning solutions and/ or equipment used in cleaning NuVasive surgical instruments. Instruments should always be thoroughly inspected before each use and after a cleaning cycle for broken, worn or damaged instruments. Damaged or non-functional instruments should be returned to your NuVasive representative for replacement. Damaged instruments should be cleaned and sterilized per these guidelines prior to being returned to NuVasive. Any stainless steel or polymer instruments that may have been exposed to transmissible pathogenic agents, such as but not limited to Creutzfeldt-Jakob Disease (CJD) should be processed according to the health care facility's prion decontamination protocol. Contact the Center for Disease Control and/ or the World Health Organization for the most recent information on the transmission and deactivation of CJD or any other known transmissible pathogenic agents. NuVasive instruments sets contain colored titanium instruments, colored aluminum instruments and instruments with colored aluminum handles which should only be cleaned using low foaming neutral pH enzymatic cleaning agents. The MaXcess Retractor and MaXcess Retractor Blades contain aluminum components which also should be cleaned using only low foaming neutral pH enzymatic cleaning agents. Do not use cleaning materials that will scratch instrument surfaces as oxidation may occur. Always wear personal protective equipment (PPE) when cleaning and processing NuVasive Surgical Instruments as defined by the health care facility's policies and procedures. The health care facility is to comply with all laws and ordnances in countries where the reprocessing requirements are more stringent than defined in these guidelines.
Limitations on Reprocessing	Repeated reprocessing as defined in this document and the cleaning and sterilization instructions as defined in the "Instructions For Use" (IFU) supplied with each NuVasive instrument set, should have only minor effects on the reuse and the life of devices listed on this document. End of instrument life is to be determined through the inspection of each instrument after the reprocessing cycle. Damaged or non-functional instruments should be returned to your NuVasive representative for replacement.

Instructions

All instruments must first be thoroughly cleaned using the following validated methods described below before sterilization and introduction into a sterile surgical field.

Point of Use:	Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. Remove excess soil and debris with disposable cloth or paper wipes. NuVasive recommends a combination of a thorough manual and automated surgical instrument cleaning prior to sterilization. Complex instruments (instruments that have more than one piece, small holes, cannulae, moving parts, or threaded holes) require a more thorough cleaning regimen, which are outlined in this cleaning procedure. Pre-soaking is recommended prior to manual cleaning.
Preparation for Decontamination	Instruments should be cleaned as soon as practical to ensure ease of cleaning according to the health care facility's infection control and hazardous waste management procedures. 1. Prior to soaking the instruments in an enzymatic cleaning solution, rinse the instruments under cool running tap water and wipe off any residual soil or debris with a disposable towel. Ensure to flush out any lumens, cracks or crevices while rinsing under running cool tap water. Note: Various instruments are designed to be disassembled for cleaning (designated with a part number beginning with 'D'). For these instruments, please reference the supplemental instructions which illustrate steps required to disassemble and reassemble the instrument. Instruments which are **not** designed for disassembly (e.g., MaXcess Retractor Body) should not be disassembled during cleaning or damage to the device may occur. Please contact your NuVasive representative for additional disassembly information.

<table>
<tr><td>Cleaning: Manual</td><td>Recommended Equipment: Small, medium and large nylon brushes, appropriately sized "K" wire as supplied with NuVasive surgical instrument sets, lint free disposable cloth or sponge, and Low foaming - Neutral pH - Phosphate-Free cleaning solution (such as MetriWash or equivalent such as Prolystica Ultra Concentrate Neutral Detergent).
2. Prepare an enzymatic cleaning solution, such as MetriZyme, per manufacturer’s recommendations using warm tap water. Place the instruments into a fresh batch of an enzymatic cleaning solution in the open position (as appropriate) and allow to soak for a minimum of 50 seconds. While soaking, actuate the instruments through a full range of motion (as appropriate for the specific instrument) to allow complete penetration of the cleaning solution. Instruments that are designed to be disassembled should be disassembled prior to cleaning. Instruments that do not disassemble may require additional soaking.
3. After the 50 seconds soak time, remove the instruments and wipe any soil or debris using a disposable towel. Then, place the instruments into a fresh batch of an enzymatic cleaning solution using warm tap water. Brush the entire surface of the instrument with a soft bristled brush. Actuate the instruments through a full range of motion while brushing and ensure to brush all hard to reach areas. Use a sterile syringe and lumen brush to clean hard to reach areas and flush each end of the instruments with a minimum of 60 mL.
4. Remove the instruments from the detergent and rinse by agitating and actuating in RO/DI water for a minimum of 30 seconds. Flush all hard to reach areas with a sterile syringe at each end of the instrument with a minimum of 60 mL.</td></tr>
<tr><td>Automated Cleaning and Disinfection</td><td>Recommended Equipment: Medical grade ultrasonic cleaner (Such as Steris Caviwave Ultrasonic Cleaning System or equivalent), Enzymatic Cleaner that is compatible with stainless steel, plastics and soft metals including aluminum (Such as MetriZyme Enzymatic Cleaner or equivalent such as Prolystica Ultra Concentrate Enzymatic Cleaner), Medical grade washer / disinfector capable of sustained wash and or rinse temperatures of 203°F / 95°C, adjustable cycle times, adjustable temperature controls, adjustable pressure controls for varying soil conditions, water filtering to adjust for water quality and automatic detergent injection to control solution concentrations (such as Steris AMSCO Reliance 444 single chamber washer disinfector or equivalent), Low foaming - Neutral pH - Phosphate-Free cleaning solution (such as MetriWash or equivalent such as Prolystica Ultra Concentrate Neutral Detergent).
Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.
All instruments must be manually cleaned as prescribed above prior to any automated cleaning process to ensure best possible cleanliness and removal of debris, blood and tissue prior to sterilization.
5. Use a low foaming, neutral pH, phosphate-free cleaning solution and prepare per manufacturer’s recommendations using warm tap water in a sonication unit. Allow the instruments to sonicate for 10 minutes. Instruments should be properly placed to maximize cleaning and to avoid damage or dislodgement of instruments and components.
6. Remove the instruments from the detergent and rinse by agitating and actuating in ambient RO/DI water for a minimum of 30 seconds. Actuate the instruments through a full range of motion while rinsing and flush all hard to reach areas with a sterile syringe at each end of the instruments with a minimum of 60 mL.
7. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Below is the validated and recommended cycle:
<table>
<tr><th>Phase</th><th>Recirculation Time</th><th>Water Temperature</th><th>Detergent Type & Concentration (If applicable)</th></tr>
<tr><td>Pre-wash</td><td>2 minutes</td><td>Cold Tap Water</td><td>N/A</td></tr>
<tr><td>Enzyme Wash</td><td>2 minutes</td><td>Hot Tap Water</td><td>MetriZyme, (1 oz/gallon) or Equivalent (per manufacturer’s instructions)</td></tr>
<tr><td>Wash</td><td>2 minutes</td><td>65.5°C (set point)</td><td>MetriWash, (1 oz/gallon) or Equivalent (per manufacturer’s instructions)</td></tr>
<tr><td>PURW Rinse</td><td>1 minute</td><td>43°C</td><td>N/A</td></tr>
<tr><td>Drying</td><td>15 minutes</td><td>90°C</td><td>N/A</td></tr>
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8. Dry the instruments using a clean non-linting cloth.</td></tr>
<tr><td>Maintenance & Inspection</td><td>Visually inspect the instruments following performance of the cleaning instructions prescribed above. Ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps above. Otherwise, contact your NuVasive representative – contaminated instruments should not be used, and should be returned to NuVasive.
All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.
Note: Certain cleaning solutions such as those containing bleach or formalin may damage some instruments and must not be used.
Contact your NuVasive representative for any additional information related to cleaning and sterilization of NuVasive surgical instruments.</td></tr>
<tr><td>Packaging:</td><td>Instruments should be placed in the appropriate sterilization case in the designated location for each instrument. Single damaged or non-functional instruments should be returned to your NuVasive representative for replacement. Sterilization cases should be placed in the appropriate shipping container supplied by NuVasive for shipment or pick up.</td></tr>
<tr><td>Sterilization:</td><td>Sterilization parameters are provided in the system IFU supplied with the instruments. Some NuVasive sets will require cycle times that may extend beyond those typically recommended in sterilizer manufacturer instructions.
NuVasive instrument sets are specially designed to maximize instrument surface contact during the sterilization process. Ensure that all instruments are placed in their proper location and orientation prior to sterilization.</td></tr>
<tr><td>Storage:</td><td>Packaged and sterilized instruments are only to be stored in areas that provide protection from dust, moisture, insects and extremes of temperature and humidity.</td></tr>
<tr><td colspan="2">It remains the responsibility of the processor to ensure that the reprocessing as actually performed using the equipment, materials and trained personnel in the reprocessing facility achieves the desired result. This normally requires validation and routine monitoring of the process at the reprocessing facility.</td></tr>
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2. NuVasive Implant and Instrument Sterilization Instructions

These sterilization instructions do not apply to implants and instruments provided sterile.

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components are sterilizable by steam autoclave using standard hospital practices.

The implants and instruments can be sterilized using the provided standard open cases or Case Medical SteriTite closed cases, Aesculap closed cases (standard or PrimeLine lid), and One Tray closed cases. Small baskets, trays, and other types of accessories, especially with covers or lids, not provided by NuVasive for a specific system should not be used. Only NuVasive standard open cases, Case Medical SteriTite closed cases, Aesculap closed cases (standard or PrimeLine lid), and One Tray closed cases are validated for use with NuVasive products.

For standard open cases, devices are to be packaged in a FDA-cleared sterilization wrap prior to placement in an autoclave.

For information regarding closed cases, please refer to appropriate Instructions for Use provided by the closed case manufacturer.

In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the following parameters:

Method: Steam	Method: Steam
Cycle: Pre-vacuum	Cycle: Pre-vacuum
Temperature: 270°F (132°C)	Temperature: 273°F (134°C)
Exposure Time: 4 minutes	Exposure Time: 3 minutes
Minimum Dry Time*: 30 minutes	Minimum Dry Time*: 30 minutes
Minimum Dry Time for EXMICROINS: 70 minutes	Minimum Dry Time for EXMICROINS: 70 minutes
Minimum Cool Down Time: 40 minutes	Minimum Cool Down Time: 40 minutes

* Drying time is the period which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. Drying time may vary due to load configuration, wrapping method, and material. Therefore, dry time may be repeated if moisture is present on the wrap and/or other instruments.

Always sterilize the implants in the fully collapsed position (where applicable). Avoid sudden cooling of the device components. Ensure that all functions are unimpaired before use.

In addition, periodically inspect the instruments for wear and tear, such as corrosion or discoloration. For instruments that are no longer functional, or exhibit excessive wear and tear, please return instruments to NuVasive.

Before proceeding with surgery, verify that all devices are correctly assembled and that all instruments and implants are undamaged.

Rx Only

GRAPHICAL SYMBOLS	
	Consult Instructions Before Use. Available on the NuVasive website at www.nuvasive.com
REF	Catalogue Number
LOT	Batch Code
QTY	Quantity
	Non-Sterile, Sterilize by Steam before Use
	Manufacturer
EC REP	European Community Representative

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