



**NUVASIVE**

# **NuVasive Supplemental Cleaning and Sterilization Instructions**

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## 1. NuVasive Instrument Cleaning and Decontamination Instructions

Manufacturer: NuVasive                      Method: Manual and Automated Cleaning	
Devices: All non-powered NuVasive Surgical Instruments as supplied with our surgical Implant and Instrument systems.	
<p>These instructions are provided in accordance with AAMI TIR12, AAMI TIR30, ISO 17664 EN ISO 15883-1 and the guidelines of DGKH, DGSV and AKI as well as RKI and are intended to supplement a hospital's existing instrument cleaning and disinfecting protocols.</p> <p>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, powered devices, single-use sterile accessories and instruments, or NuVasive implants. These instructions must be used prior to sterilizing the devices.</p> <p>It remains the responsibility of the processor to ensure that the reprocessing is performed using the recommended equipment, materials, and trained personnel in order to achieve the desired result. This may require validation and routine monitoring of the process at the reprocessing facility.</p> <p><i>Hospitals must ensure that adequate processing has been performed in order to clean, disinfect, package and sterilize of all instruments before use in surgery or return them to NuVasive if there is a concern regarding contamination. Prior to each use, inspect the set upon receipt to verify that all instruments have been adequately cleaned and decontaminated before repeating reprocessing procedures prior to subsequent reuse. NuVasive cannot guarantee that sterility was attained by the previous user and has been maintained during transit.</i></p>	
Warnings and Precautions:	<p>Neutral pH enzymatic cleaning agents are recommended for use on all NuVasive instruments except as follows: Alkaline agents with equal to or greater than 12 pH 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 Creutzfeldt-Jakob Disease (CJD) and or any other known transmissible pathogenic agents.</p> <p>Always follow the instructions provided by manufacturer of cleaning solutions and/ or equipment used in cleaning NuVasive surgical instruments.</p> <p>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.</p> <p>Any stainless steel or polymer instruments that may have been exposed to transmissible pathogenic agents, such as but not limited to 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.</p> <p>NuVasive instruments sets contain colored titanium instruments and implants, colored aluminum instruments and instruments with colored aluminum handles which should only be cleaned using low foaming neutral pH enzymatic cleaning agents that are suitable for use with anodized materials. The MaXcess Retractor and MaXcess Retractor Blades contain aluminum components which also should be cleaned using only low foaming neutral pH enzymatic cleaning agents.</p> <p>Do not use cleaning materials that will scratch instrument surfaces as oxidation may occur.</p> <p>Always wear personal protective equipment (PPE) when cleaning and processing NuVasive Surgical Instruments as defined by the health care facility's policies and procedures.</p> <p>The health care facility is to comply with all local laws and ordinances in countries where the reprocessing requirements are more stringent than defined in these guidelines.</p>
Limitations on Reprocessing:	<p>Repeated reprocessing as defined in this document and the cleaning and sterilization instructions as defined in the "Instructions For Use" (IFU) supplied by NuVasive, 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.</p>
<b>Instructions</b>	
<p>All instruments must first be thoroughly cleaned using the following validated methods described below before sterilization and introduction into a sterile surgical field.</p>	
Point of Use:	<p>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.</p> <p>Pre-soaking is recommended prior to cleaning in order to prevent soil from drying on instruments.</p> <p>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.</p>
Preparation for Decontamination:	<p>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.</p> <p>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 <b>not</b> designed for disassembly (e.g., MaXcess Retractor Body) should not be disassembled during cleaning or damage to the device may occur.</p> <p>Please contact your NuVasive representative for additional disassembly information.</p>

Manual Cleaning:	<p><i>Recommended Equipment: Medical grade ultrasonic cleaner (such as Bandelin SONOREX SUPER RK1028/H or equivalent)</i></p> <ol style="list-style-type: none"> <li>1. Immerse the instruments for 5 minutes in approximately 40°C (104°F), 0.5% neodisher MediClean forte (or equivalent) for 5 minutes. Actuate all knobs and moving elements (if applicable) under the cleaning solution 5 times and leave immersed for another 5 minutes.</li> <li>2. Brush the outer surfaces of the instruments with a soft nylon brush (such as Medisafe Med 100.33) under running cold tap water until no residues were visible.</li> <li>3. Brush the inner surfaces of the instruments under running cold tap water with a soft bottle brush (such as OD=1mm to OD=10mm) until no residues are visible.</li> <li>4. Submerge the instruments in fresh cold tap water 22°C – 25°C (72°F – 77°F) and rinse with the aid of a water jet gun (3-4 bar) for at least 3 seconds per critical spot (approximately 1 minute per instrument).</li> <li>5. Place the instruments into an ultrasonic cleaner in cleaning solution approximately 40°C (104°F), 0.5% neodisher MediClean forte (or equivalent) for 5 minutes. Note: the MaXcess 4 Driver Body must be sonicated in the open position.</li> <li>6. After sonication, immerse all instruments (including MaXcess 4 Driver Body) in fresh cold tap water 22°C – 25°C (72°F – 77°F) and rinse with the aid of a water jet gun (3-4 bar) for at least 3 seconds per critical spot (approximately 1 minute per instrument).</li> </ol> <p><b>*MaXcess Only:</b> Repeat steps 5 and 6 above with the MaXcess 4 Driver Body in the closed position.</p>																									
Automated Cleaning and Disinfection:	<p><i>Recommended Equipment: Medical grade washer/disinfector (such as Miele G7836 CD or equivalent)</i></p> <p>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.</p> <ol style="list-style-type: none"> <li>7. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Connect instruments with lumens to rinsing ports if available. Below is the validated and recommended automated washing cycle:</li> </ol> <table border="1" data-bbox="386 674 1425 947"> <thead> <tr> <th>Step</th> <th>Phase</th> <th>Recirculation Time</th> <th>Solution</th> <th>Detergent Type &amp; Concentration (If applicable)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Pre-Cleaning</td> <td>2 Minutes</td> <td>Cold Tap Water</td> <td>N/A</td> </tr> <tr> <td>2</td> <td>Cleaning</td> <td>5 Minutes</td> <td>Desalinated Water at 55°C (131°F)</td> <td>0.5% Cleaning Agent</td> </tr> <tr> <td>3</td> <td>Rinsing and Neutralization</td> <td>3 Minutes</td> <td>Desalinated Water</td> <td>N/A</td> </tr> <tr> <td>4</td> <td>Final Rinse</td> <td>2 Minutes</td> <td>Desalinated Water</td> <td>N/A</td> </tr> </tbody> </table> <p><b>*Ensure to drain washer/disinfector after each step.</b></p> <ol style="list-style-type: none"> <li>8. Dry and thermally disinfect instruments. Thermal disinfection should be conducted in line with applicable national laws, recommended in country practices, or standard hospital processes. A minimum A0 value of 900 is recommended and all NuVasive reusable instruments are capable of being disinfected up to an A0 value of 6000.</li> <li>9. Once devices are removed from the washer-disinfector, dry the instruments using a clean non-linting cloth to remove residual liquid.</li> </ol>	Step	Phase	Recirculation Time	Solution	Detergent Type & Concentration (If applicable)	1	Pre-Cleaning	2 Minutes	Cold Tap Water	N/A	2	Cleaning	5 Minutes	Desalinated Water at 55°C (131°F)	0.5% Cleaning Agent	3	Rinsing and Neutralization	3 Minutes	Desalinated Water	N/A	4	Final Rinse	2 Minutes	Desalinated Water	N/A
Step	Phase	Recirculation Time	Solution	Detergent Type & Concentration (If applicable)																						
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3	Rinsing and Neutralization	3 Minutes	Desalinated Water	N/A																						
4	Final Rinse	2 Minutes	Desalinated Water	N/A																						
Maintenance and Inspection:	<p>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.</p> <p>All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.</p> <p>Note: Certain cleaning solutions such as those containing bleach or formalin may damage some instruments and must not be used.</p> <p>Contact your NuVasive representative for any additional information related to cleaning and sterilization of NuVasive surgical instruments.</p>																									
Packaging:	<p>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.</p>																									
Sterilization:	<p>Sterilization parameters are provided in the system IFU supplied with the instruments.</p> <p>NuVasive instrument sets are 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.</p>																									
Storage:	<p>Packaged and sterilized instruments are only to be stored in areas that provide protection from dust, moisture, insects and extremes of temperature and humidity.</p>																									

## 2. NuVasive Implant and Instrument Sterilization Instructions

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

Some NuVasive 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 non-sterile 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 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:





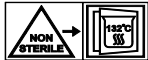


Method: Steam	Method: Steam
Cycle: Pre-vacuum	Cycle: Pre-vacuum
Temperature: 132°C (270°F)	Temperature: 134°C (273°F)
Exposure Time: 4 minutes	Exposure Time: 3 minutes
Minimum Dry Time: 30 minutes	Minimum Dry Time: 30 minutes
Minimum Cool Down Time: 40 minutes	Minimum Cool Down Time: 40 minutes

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 <a href="http://www.nuvasive.com">www.nuvasive.com</a>
	Catalogue Number
	Batch Code
	Quantity
	Non-Sterile, Sterilize by Steam before Use
	Manufacturer
	European Community Representative



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