Cleaning and sterilization

Guidelines for Nobel Biocare products
including MRI information
**Note:** In order to improve readability, Nobel Biocare does not use ™ or ® in the running text. By doing so, however, Nobel Biocare does not waive any right to the trademark or registered mark and nothing herein shall be construed to the contrary.

**Disclaimer:** Some products may not be regulatory cleared / released for sale in your market. Please contact your local Nobel Biocare office for current product assortment and availability.
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Purpose of this document.

This document gives general guidance on how medical devices supplied by Nobel Biocare that are suitable for cleaning and sterilization may be processed to prepare them for use. It also gives instructions for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

The following devices are suitable for cleaning and sterilization if not otherwise indicated in the instructions for use: multiple-use instruments and drills including surgical kits, temporary and final prosthetic components such as abutments, screws, crowns and bridges.

Note: Do not reprocess implants, single-use devices, NobelGuide surgical templates and Telio® CAD Crowns and Bridges by NobelProcera.

This document is valid in conjunction with the assembly and disassembly instructions for multi-component instruments that need to be disassembled prior to cleaning and sterilization, and the instructions for use that are delivered together with the devices.

Alternative methods of processing may be equally suitable. In the event of conflicting national cleaning and sterilization requirements, these shall prevail over Nobel Biocare recommendations.

The given Nobel Biocare guidelines for cleaning, disinfection and sterilization are based on validated processes. It is recommended to follow these instructions to avoid affecting the performance of the products negatively.

Note: According to ISO 17665, the final responsibility for validation of cleaning, disinfection and sterilization techniques and equipment lies directly with the end user. To ensure optimal processing, all cycles and methods should be validated.

Telio® CAD is a trademark of Ivoclar Vivadent AG.

Nobel Biocare has demonstrated that the processes described in these instructions are effective. Procedures manuals with an earlier publishing date will be superseded by this document with regards to cleaning and sterilization. Wherever the instructions for use for a specific product show other procedure conditions, these will supersede the recommendations given in these general guidelines.

Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing. The healthcare facility should ensure that the combination actually in use results in a medical device that is safe for use.

The information on Nobel Biocare passive implants in MR environment provides the necessary data for radiologists to perform safe diagnostic imaging.
Warnings and precautions.

Devices labeled “Do not reuse” must not be reprocessed for reuse.

When “Do not reuse” devices are supplied non-sterile and require sterilization before use, the appropriate sections in these guidelines may be applied unless other specific instructions are provided in the package.

“Do not resterilize” devices are not designed to perform as intended after the first usage or an additional sterilization process. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and/or resterilization may compromise the integrity of the design and/or material, leading to diminished safety, performance and/or compliance with relevant specifications.

Please refer to the device label to identify single or multiple use.

The devices delivered sterile have a “Sterile” symbol on the label. The “R” in the right rectangle indicates that the device is sterilized by irradiation.

Opened packages of abutments, screws, crowns, bridges and accessories may be cleaned and sterilized / autoclaved again following the procedures stated on the following pages, unless other specific instructions are provided in the package.

Note: Implants are strictly exempted for cleaning and sterilization. Any doubt regarding the sterility of the implant must result in direct disposal of the device or return to the manufacturer for further research.
Symbols used.

Manufacturer
Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

Open the package like this

Do not resterilize
Indicates a medical device that is not to be resterilized.

Do not reuse
Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Note: Synonyms for “Do not reuse” are “Single use” and “Use only once”.

Non-sterile
Indicates a medical device that has not been subjected to a sterilization process.

Sterilized using irradiation
Indicates a medical device that has been sterilized using irradiation.
Use-by date
Indicates the date after which the medical device is not to be used.
Example: June 2015 is expressed as 2015-06.

Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified.

Article number
Indicates the manufacturer's catalog number so that the medical device can be identified.

Consult instructions for use
Indicates the need for the user to consult the instructions for use.

Caution
Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

MR Safe
An item that poses no known hazards in all MR environments (ASTM F 2503-8). For details see the following pages.

MR Conditional
An item that has been demonstrated to pose no known hazards in a specific MR environment with specified conditions of use (ASTM F 2503-8). For details see the following pages.
Magnetic Resonance Imaging (MRI) information.

The following definitions of Magnetic Resonance (MR) Safe and MR Conditional have been developed by the American Society for Testing and Materials (ASTM) International.¹

**MR Safe**
Items that pose no known hazards in all MRI environments are labeled MR Safe. This includes all Nobel Biocare products that are non-conducting, non-metallic and non-magnetic. Examples are abutments, crowns and bridges made of ceramic, temporary abutments made of PEEK, and healing caps made of nylon.

Items marked with the MR Safe icon may be taken into, used or placed anywhere within any MRI environment without causing any additional risk to the patient or any other individual.

**MR Conditional**
Items that have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use are labeled MR Conditional. Non-clinical worst-case testing has demonstrated that metallic Nobel Biocare products made of titanium, titanium alloy, gold alloy and cobalt chrome alloy are MR Conditional. Examples are implants, temporary and final abutments, clinical screws, implant bars overdenture, and crowns and bridges.

A patient with such a device may be scanned safely after placement under the following conditions:
- Static magnetic field of 1.5–3.0 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e. per pulse sequence)
- Normal operating mode of the MR system

**MRI-related heating**

In non-clinical worst-case testing, the metallic Nobel Biocare products caused the following maximum temperature rises during 15 minutes of MRI scanning with 1.5 and 3.0 Tesla. These changes do not pose any hazard to the patient.

<table>
<thead>
<tr>
<th></th>
<th>1.5 Tesla</th>
<th>3.0 Tesla</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR system reported, whole body averaged SAR</td>
<td>2.9 W/kg</td>
<td>2.9 W/kg</td>
</tr>
<tr>
<td>Calorimetry measured values, whole body averaged SAR</td>
<td>2.1 W/kg</td>
<td>2.7 W/kg</td>
</tr>
<tr>
<td>Highest temperature change (all tests)</td>
<td>+4.1°C</td>
<td>+2.9°C</td>
</tr>
<tr>
<td>Test system</td>
<td>Magnetom (active-shielded, horizontal field scanner) Software Numaris4, Version Syngo MR 2002B DHHS Siemens Medical Solutions, Malvern, PA, USA</td>
<td>Excite, HDx Software 1.4X.MS General Electric Healthcare, Milwaukee, WI, USA</td>
</tr>
</tbody>
</table>

**Artifact information**

The quality of the MR image may be compromised, if the area of interest is in the same area or relatively close to the position of the MR-conditional device. It may therefore be necessary to optimize the MR imaging parameters to compensate for the presence of the device. The maximum artifact size (as seen on the gradient echo pulse sequence) extends up to approximately 30 mm relative to the size and shape of the device.

<table>
<thead>
<tr>
<th>Pulse sequence</th>
<th>T1-SE*</th>
<th>T1-SE</th>
<th>GRE**</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plane orientation</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
<tr>
<td>Signal void size***</td>
<td>2764 mm²</td>
<td>2229 mm²</td>
<td>4458 mm²</td>
<td>5463 mm²</td>
</tr>
</tbody>
</table>

* T1-SE: Longitudinal relaxation, spin-echo sequence  
** GRE (low flip angle): Gradient-echo MRI sequence  
*** Maximum void size found in all tests

**Notes:**

- Removable restorations may be taken out prior to scanning, as is done with watches, jewelry etc.
- Polymeric (e.g. PEEK, PMMA, PPSU) and ceramic devices are considered to be MR Safe. However, if the restoration consists of multiple parts, it must be classified according to the component with the lowest safety level. For example, a restoration consisting of implant, zirconia abutment and crown made of cobalt chrome alloy is MR Conditional in total, even if the zirconia abutment itself is MR Safe.
Terms and definitions.

To avoid misunderstandings of the most frequently used terms, the meaning of each of these terms inside this document is listed:

**Pre-cleaning**
Wiping or rinsing the device to remove gross soil, blood and tissue before the initial cleaning process starts.

**Cleaning**
Removal of visible soil (e.g. organic and inorganic material) from objects and surfaces. This is normally accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential prior to disinfection and sterilization, as inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

After cleaning no visible contamination is found by inspection with the naked eye under good light conditions. Special attention must be given to edges, lumens, hollows and other soil traps.

**Decontamination**
Removal of pathogenic microorganisms from objects so that the devices are safe to handle, use, or discard.
Disinfection
A process that kills most disease-producing microorganisms, but not necessarily all microbial forms (e.g. bacterial spores).

Cleaning and sterilization
Validated processes to render a medical device that is designed for multiple use and that has been previously used or contaminated, fit for a subsequent single use on another patient or another treatment.

These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection and/or sterilization.

Sterilization
A validated process used to render a product free from viable microorganisms.

Note: In a sterilization process, the nature of microbial death is described by a mathematical function. Therefore, the presence of microorganisms on any specific device can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.
Workflow.

The preparation for reuse of medical devices or for initial use of new devices requires a sequence of processing steps shown in the workflow. This workflow can be downloaded as PDF document from the Nobel Biocare website: nobelbiocare.com/sterilization

More detailed instructions for each step are given on the following pages. The circled numbers refer to the corresponding section in these guidelines.
Two evaluated methods for cleaning
Nobel Biocare has evaluated two methods for cleaning medical devices, and appropriate instructions are provided in these guidelines:
– Manual method
– Method using an automated thermodisinfector
Whenever possible the automated method should be used. The automated cleaning process is more reproducible and therefore more reliable. In addition, staff is less exposed to contaminated devices and cleaning agents.

Protective clothing and equipment
Whichever method is used, staff should use suitable protective clothing and equipment at all times.
In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

Cleaning agents and disinfectants
For cleaning or disinfecting medical devices only specifically formulated cleaning agents and/or disinfectants (detergents) should be used.

Since not all cleaning agents and disinfectants may be available worldwide, criteria for the selection of appropriate detergents are provided in the appendix (see page 34). A list of cleaning agents and disinfectants that Nobel Biocare used in the validation of these cleaning and sterilization guidelines is also provided in the appendix. Nobel Biocare does not recommend any specific cleaning and/or disinfection agents.

The guidelines for concentrations and times for device immersion in the cleaning solutions and/or disinfectants given by the detergent manufacturers must be observed. If these concentrations and times are significantly exceeded, discolouration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.

Water quality
The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing medical devices should be carefully considered. Application of freshly prepared purified water / highly purified water or sterile water for rinsing purposes (according to the pharmacopeias) with less than 10 cfu/ml and 0.25 EU/ml is highly recommended.

Mineral residues from hard water as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and disinfection.
1 Point of use.

1 Handle devices with tweezers
To avoid contamination of the kit box (mainly the instrument plate) and damage of the sterile gloves by the sharp drills, it is recommended to pick up the devices using a pair of tweezers.

2 Remove gross soil
Directly after use of reusable tools (within a maximum of 1 hour postoperatively), remove gross soil using absorbent paper wipes. Additionally, intensive rinsing of the medical devices with running water is recommended.

3 Dispose devices if needed
Sharp and cutting single-use products, dull multi-use drills, worn out tools etc. must be properly disposed in the surgery room, in containers specially designed for this purpose.
2 Transport.

1 Avoid mechanical damage
Avoid mechanical damage, e.g. do not mix heavy devices with delicate ones. Pay particular attention to cutting edges, both to avoid injury and to avoid damage to the medical devices.

2 Minimize time before cleaning
Get the medical devices to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the medical devices with a damp cloth or store the medical devices in closed boxes to avoid drying of soil and/or debris.

3 Immerse devices in cleaning solution if needed
When longer delays are expected, immerse the devices in a bath of a lukewarm cleaning solution to avoid drying of soil and/or debris.
3 Preparation and disassembly.

1 Disassemble devices
To prepare the devices for cleaning, disassemble if applicable. See information provided in the specific instructions for use.

2 Disassemble kit boxes completely
Kit boxes must be disassembled completely before cleaning and disinfection.
4a Manual cleaning, disinfection and drying.

Cleaning procedure

Required equipment

– Ultrasonic bath large enough to allow complete immersion of the medical devices and instruments; frequency 25–50kHz, temperature according to detergent manufacturer’s instructions.
– Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment, meeting the criteria given on page 34; concentration as specified in detergent manufacturer’s instructions.
– Soft nylon brushes, syringes (20 ml), irrigation needles, absorbent paper etc.
– Freshly prepared purifi ed water / highly purifi ed water or sterile water for rinsing purposes.
– Personal protective equipment as recommended by the cleaning agent supplier (minimum water impermeable protection gown, gloves, face/eye shield).

1 Remove debris in lukewarm water and soak devices in cleaning solution

Remove residual tissue or bone debris by immersing the used instruments in lukewarm water (≤40°C / 104°F). Do not use fixation agents or hot water (≥40°C / 104°F) as this could influence subsequent cleaning results. Instruments should be kept in a wet environment until the next step is initiated.

Soak the instruments in an enzymatic cleaning solution (e.g. enzymatic detergent with a pH level between 7–10) prepared with lukewarm tap water. Soaking time not less than specified in the detergent manufacturer’s instructions (temperature not exceeding 40°C / 104°F).

Cleaning agents are commercially available. For a general description of suitable agents see page 34.
2 Scrub devices with soft bristled nylon brush
Scrub the outer and, if applicable, the inner side of the instruments with a soft bristled nylon brush until all visible soil and/or debris is removed. Pay particular attention to features that may be shielded from the brushing action.

3 Flush reusable drills, abutments and tools with channels / lumen using cleaning solution
Flush the internal channels / lumen with 20 ml cleaning solution using the irrigation needle (provided with the surgical kit or purchased separately) connected to a 20 ml syringe. Check the channels / lumen for residual soil and/or debris.

Note: The irrigation needle must pass the silicone barrier in the middle of the drill.

4 Soak in ultrasonic bath
Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified in the detergent manufacturer’s instructions. Immerse the device completely and activate the bath for at least the time specified in the detergent manufacturer’s instructions.

Note: Avoid direct contact of the instruments with sharp cutting edges during ultrasonic treatment so as not to damage devices or reduce shelf life (e.g. drills).
5 Rinse with purified or sterile water
Rinse for at least 1 minute with freshly prepared purified water / highly purified water or sterile water until all traces of cleaning solution are removed.

6 Flush internal channels / lumen with purified or sterile water
Flush the internal channels / lumen with 20 ml freshly prepared purified water / highly purified water or sterile water using the irrigation needle (provided with the surgical kit or purchased separately) connected to a 20 ml syringe.

Note: The irrigation needle must pass the silicone barrier in the middle of the drill.

7 Repeat cleaning step if needed
If encrusted soil and/or debris remaining on the device have to be removed with a brush after completion of the cleaning step in the ultrasonic bath, the cleaning step must be repeated as described above.
Disinfection and drying procedure

Required equipment

– Bath large enough to allow complete immersion of the medical devices and instruments; temperature according to detergent manufacturer’s instructions.
– Disinfection agent intended for manual disinfection and compatible with the applied cleaning detergent meeting the criteria given on page 34; concentration as specified in detergent manufacturer’s instructions.
– Syringe (20 ml) together with the irrigation needle (provided with the surgical kit or purchased separately).
– Freshly prepared purified water / highly purified water or sterile water for rinsing purposes.
– Filtered medical compressed air (if available) or clean and lint-free single use wipes.
– Personal protective equipment as recommended by the cleaning agent supplier (minimum water impermeable protection gown, gloves, face/eye shield).

Note: The use of an ultrasonic bath is recommended.

8 Soak in disinfection solution

Prepare a bath with a disinfection solution at the concentration and temperature specified in the detergent manufacturer’s instructions.

Immerse the devices completely for at least the time specified in the detergent manufacturer’s instructions.
9 Flush internal channels / lumen with disinfection solution
Flush minimum 3 times the internal channels / lumen with 20 ml disinfection solution using the irrigation needle (provided with the surgical kit or purchased separately) connected to a 20 ml syringe.

Note: The irrigation needle must pass the silicone barrier in the middle of the drill.

10 Rinse with purified or sterile water
Rinse for at least 1 minute with freshly prepared purified water / highly purified water or sterile water until all traces of disinfection solution are removed.

11 Flush internal channels / lumen with purified or sterile water
Flush the internal channels / lumen minimum 3 times with 20 ml freshly prepared purified water / highly purified water or sterile water using the irrigation needle (provided with the surgical kit or purchased separately) connected to a 20 ml syringe.

Note: The irrigation needle must pass the silicone barrier in the middle of the drill.

12 Dry with compressed air or wipes
Dry the medical devices using medical compressed air and clean and lint-free single-use wipes.

13 Repeat complete cleaning and disinfection if needed
Visually inspect and repeat complete manual cleaning and disinfection if necessary.
4b Automated cleaning, disinfection and drying (incl. pre-cleaning).

Pre-cleaning

Required equipment

– Cleaning bath or vessel large enough to allow complete immersion of the instruments.
– Freshly prepared 0.5% enzymatic cleaning solution (follow the instructions given by the manufacturer) prepared with lukewarm tap water.
– Soft nylon brushes, syringes (20 ml), irrigation needles, absorbent paper etc.
– Personal protective equipment as recommended by the cleaning agent supplier (minimum water impermeable protection gown, gloves, face/eye shield).

Note: In case of highly contaminated medical devices to be subjected to an automatic cleaning process, pre-cleaning in an ultrasonic bath is recommended.

1 Remove debris in lukewarm water and soak devices in cleaning solution

Remove residual tissue or bone debris by immersing the used instruments in lukewarm water (<40°C / 104°F). Do not use fixation agents or hot water (>40°C / 104°F) as this could influence subsequent cleaning results. Instruments should be kept in a wet environment until the next step is initiated.

Soak the instruments in an enzymatic cleaning solution (e.g. enzymatic detergent with a pH level between 7–10) prepared with lukewarm tap water. Soaking time not less than specified in the detergent manufacturer’s instructions (temperature not exceeding 40°C / 104°F).

Cleaning agents are commercially available. For a general description of suitable agents see page 34.
2 Scrub devices with soft bristled nylon brush
Scrub the outer and, if applicable, the inner side of the instruments with a soft bristled nylon brush until all visible soil and/or debris is removed. Pay particular attention to features that may be shielded from the brushing action.

3 Flush reusable drills, abutments and tools with channels / lumen using cleaning solution
Flush the internal channels / lumen with 20 ml cleaning solution using the irrigation needle (provided with the surgical kit or purchased separately) connected to a 20 ml syringe. Check the channels / lumen for residual soil and/or debris.

Note: The irrigation needle must pass the silicone barrier in the middle of the drill.

4 Rinse with tap water
Rinse outer and inner sides of the instruments with tap water to remove all cleaning solution.

Note: The irrigation needle must pass the silicone barrier in the middle of the drill.
Automated cleaning, disinfection and drying

5 Load devices into thermodisinfector
After pre-cleaning, place the instruments in an instrument tray or on an instrument rack and load them into the washer / disinfector.

If the kit box is contaminated, it is recommended to run the cycle twice:
– Run the first cycle with the disassembled kit box alone. Ensure to remove all silicone fittings from the instrument plate.
– After the first cycle, assemble the base plate with the silicone pieces and mount the devices (without devices that are disassembled such as the torque wrench).
– Run a second cycle to clean and disinfect the devices.

6 Run cleaning and disinfection cycle
Start the cycle by applying the following:
– 2 minutes pre-cleaning with cold water and emptying.
– 5 minutes cleaning at 55°C / 131°F with an enzymatic machine cleaner and emptying.
– 3 minutes neutralization with tap water and emptying.
– 2 minutes intermediate rinsing with cold tap water and emptying.

Note: Special instructions provided by the manufacturers of automated washing machines must be followed.

7 Run drying cycle
Dry the outer side of the instruments through drying cycle of washer / disinfector.

8 Dry with compressed air or wipes if needed
If needed, additional manual drying can be performed with clean and lint-free single-use wipes. Insufflate cavities, channels or lumens of the disinfected parts can be dried by using sterile compressed air.
5 Inspection and assembly.

1 Inspect devices visually
Before preparing for sterilization, all medical devices should be inspected. Generally, unmagnified visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:
- Soil “traps” such as mating surfaces, shafts of reamers.
- Recessed features like channels / lumens and threads.
- Features where soil may be pressed into contact with the device, e.g. drill flutes adjacent to the cutting tip.
- Cutting edges should be checked for sharpness and damage.

2 Perform functional check
- Check mating devices for proper assembly.
- Operate medical devices with moving parts to check correct operation.
- Check drills for sharpness (see appendix for examples).

Notes:
- Nobel Biocare does usually not define the maximum number of uses appropriate for reusable medical devices. The useful life of these devices depends on a number of factors including the method and duration of each use, and the handling between uses.
- Careful inspection and functional testing of the device before use is the best method for determining the end of serviceable life for the medical device.
- However, for certain instruments end of life has been defined, verified and specified with either a number of uses (e.g. single-use devices) or an expiration date.
- See appendix “Final inspection” for detailed descriptions.
6a Packaging of single devices.

1 Assemble devices and seal them in pouches
Where appropriate, the cleaned, disinfected and checked medical devices should be assembled.

To sterilize abutments, screws, crowns, bridges and instruments place them in sterilization pouches for further processing.

Note: Instruments with sharp or cutting edges like drills must be packed separately in pouches if they are not placed in a kit box.

The packaging for thermal sterilized medical devices should fulfill the following requirements:
– ISO 11607 and/or DIN 58953-7
– Suitable for steam sterilization (temperature resistance up to at least 137 °C / 279 °F; sufficient steam permeability)
– Sufficient protection of the instruments and sterilization packaging from mechanical damage

2 Label pouches
Label the pouches / packages clearly with the following:
– Expiration date
– Name of the person who packed the devices
– Lot (if applicable)
– “Sterile” and the sterilization method (if several methods are available).

Packages without a clear window to identify the devices inside, the following needs to be added to the above mentioned information:
– Product name with article number
– Number of devices
6b Assembly and packaging of kit boxes.

1. Assemble devices and kit box
   Where appropriate, the cleaned, disinfected, and checked medical devices should be assembled.

   Reassemble the surgical and prosthetic kit boxes and mount the instruments in the silicone grommets / brackets.

2. Place kit box into pouch
   Place the kit box in a sterilization pouch.

   The packaging for thermal sterilized medical devices should fulfill the following requirements:
   - ISO 11607 and/or DIN 58953-7
   - Suitable for steam sterilization (temperature resistance up to at least 137 °C / 279 °F, sufficient steam permeability)
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage

3. Label pouch
   The pouches / packages must be labeled clearly and show:
   - Expiration date
   - Name of the person who packed the devices
   - Lot (if applicable)
   - “Sterile” and the sterilization method (if several methods are available)

   Packages without a clear window to identify the devices inside, the following needs to be added to the above mentioned information:
   - Product name with article number
   - Number of devices
Both the pre-vacuum and gravity method have been validated by Nobel Biocare as being capable of achieving sterile medical devices.

However, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should validate the processes that they use, employing the actual equipment and operators that routinely process the devices.

All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance with EN 285/EN 13060, EN ISO 17665, ANSI AAMI ST79 or your national standard.

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle or gravity method (saturated steam) is applicable for most Nobel Biocare medical devices.

For devices made of zirconia, the presence of steam may impair the long-term performance of the device, as it triggers the so-called low temperature degradation or aging of tetragonal zirconia. Therefore the number of sterilization cycles is to be kept as low as necessary.

When loading the autoclave with several blister packages or pouches, place them in an upright position, side by side, with the clear foil surfaces facing each other.

The parameters recommended in this section in general are not applicable to the entire Nobel Biocare portfolio. There are exceptions for which other validated cleaning and sterilization cycles are applicable. These are described in the respective instructions for use and have binding character.

If you are in doubt about the applicable sterilization parameters for a particular product, consult the specific instructions for use or contact your local Nobel Biocare sales office.

Note: According to EN ISO 17665, the final responsibility for validation of sterilization techniques and equipment lies directly with the processor. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.
### Recommended sterilization parameters for single devices sealed in pouches

#### USA

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cycle</strong></td>
<td>Pre-vacuum</td>
</tr>
<tr>
<td>Temperature</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>Temperature max.</td>
<td>279°F (137°C)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 minutes*</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>3 times &lt; 60 mbar</td>
</tr>
<tr>
<td>Drying time</td>
<td>10 minutes (minimum in chamber)</td>
</tr>
<tr>
<td>Cooling time</td>
<td>10 minutes at room temperature</td>
</tr>
</tbody>
</table>

#### Outside USA

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization according to ISO 17665</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cycle</strong></td>
<td>Saturated steam with fractional forced air removal</td>
</tr>
<tr>
<td>Temperature</td>
<td>132–135°C (270–275°F)</td>
</tr>
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<td>Temperature max.</td>
<td>137°C (279°F)</td>
</tr>
<tr>
<td>Exposure time</td>
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<td>Drying time</td>
<td>10 minutes in chamber</td>
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</tbody>
</table>

#### Alternative UK

<table>
<thead>
<tr>
<th>Method</th>
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</thead>
<tbody>
<tr>
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</tbody>
</table>

*Following the recommendations of the Robert Koch Institute (RKI) and other organizations / authorities, the exposure time can be extended up to 20 minutes.*
7b Sterilization of kit boxes.

Both the pre-vacuum and gravity method have been validated by Nobel Biocare as being capable of achieving sterile medical devices.

However, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices.

All autoclaves / sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance with, EN 285/EN 13060, EN ISO 17665, ANSI AAMI ST79 or your national standard.

Complete kit boxes with tools and assembled instruments must be sterilized in their “ready for use” state. There is no need to disassemble these instruments for sterilization. The process parameters shown are validated and recommended by Nobel Biocare for sterilization.

The parameters recommended in this section in general are applicable for all Nobel Biocare devices, if not stated otherwise in the instructions for use. There are exceptions for which other validated cleaning and sterilization cycles are applicable. These are described in the instructions for use and have binding character.

If you are in doubt about the applicable sterilization parameters for a particular product, consult the specific instructions for use or contact your local Nobel Biocare sales office.

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle or gravity method (saturated steam) is applicable for all Nobel Biocare devices, if not otherwise stated in the instructions for use.

Note: According EN ISO 17665, the final responsibility for validation of sterilization techniques and equipment lies directly with the processor. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.
Recommended sterilization parameters for devices mounted in kit boxes and sealed in pouches

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</tr>
<tr>
<td>Pre-vacuum</td>
<td>3 times &lt; 60 mbar</td>
</tr>
<tr>
<td>Drying time</td>
<td>30 minutes in chamber</td>
</tr>
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<td>Cooling time</td>
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</table>

*Following the recommendations of the Robert Koch Institute (RKI) and other organizations / authorities, the exposure time can be extended up to 20 minutes.*
8 Storage.

After sterilization, place the devices in a dry and dark place such as a closed cupboard or drawer.

Follow the instructions of the manufacturer of the pouches regarding storage conditions and expiration date of sterilized goods.
References.

21 CFR58 (1978) Good Laboratory Practice for Non-clinical Studies

AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR39:2009 Guidance on selecting a microbial challenge and inoculation sites sterilization validation of health care products

ANSI/AAMI ST8:2008 Hospital Steam Sterilizers


ANSI/AAMI ST81:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices


ASTM E 1837-96 (2007) Standard Test Method to Determine Efficiency of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)


Bundesgesundheitsblatt 2006: Infektionsprävention in der Zahnheilkunde – Anforderungen an die Hygiene

Bundesgesundheitsblatt 2012: Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten (Recommendations of the Robert Koch Institute, RKI)

CSA Standard Z314.8-08, 2008 Decontamination of reusable medical devices

CSA Standard Z314.3-09, 2009 Effective Sterilization in Health Care Facilities by the Steam Process

DIN 58953-7:2010-05 Anwendungs-technik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen

FDA Guidance Document UCM253010 (2011) Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling


ISO 14161:2009 Sterilization of Health Care Products – Biological Indicators – Guidance for the selection, use and interpretation of results

ISO 14937:2009 Sterilization of Health Care Products – General Requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

ISO 17664:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices

## Cleaning agents and disinfectants.

<table>
<thead>
<tr>
<th>Cleaning and sterilization step</th>
<th>Detergents used in Nobel Biocare validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>If cleaning is delayed, place the devices in a bath of a cleaning and disinfection solution to avoid drying of soil and/or debris, blood and other contaminations.</td>
<td>Commercially available mild pre-cleaning solution with a pH value 7–10 and approx. 35°C / 95°F</td>
</tr>
<tr>
<td><strong>Manual cleaning</strong></td>
<td><strong>Manual disinfection</strong></td>
</tr>
<tr>
<td>A mild agent is recommended to remove all visible soil and/or debris, blood and other contaminations from the devices.</td>
<td>The solution was prepared according to the manual of the detergent manufacturer and the devices were soaked in the bath.</td>
</tr>
</tbody>
</table>
| Cidecyme / Enzol 0,5% solution in an ultrasonic bath for 5 minutes at 40°C / 104°F | Cidex Opa  
Minimum effective concentration 0.3%  
Minimum temperature 20°C / 68°F (according to manufacturer’s instruction for use) |
| **Automated cleaning, disinfection and drying** | Machine: Miele G7735 CD  
Detergent: neodisher Mediclean  
Cleaning Program Vario TD  
– 2 minutes pre-washing with cold water  
– Emptying  
– 5 minutes washing at 55°C / 131°F with 0.5% cleaner neodisher MediClean  
– Emptying  
– 3 minutes neutralizing with cold tap water  
– Emptying  
– 2 minutes intermediate rinsing with cold tap water  
– Emptying |
| If the used detergents are not commercially available in your market, use an equivalent one and follow the instructions of the manufacturer. |

### Notes:
- Nobel Biocare does not recommend these detergents in preference to others that are available. Other detergents may perform equally well or better in conjunction with the equipment being used.
- The instructions provided by the supplier of the detergents should be followed.
- Suitability of alternative detergents should be checked by referencing the supplier’s information and/or physical testing.
- Personal protection for operators should be provided in accordance with the supplier’s instructions and safety data sheets.
Final inspection.

If there are devices that do not function properly during the intervention, these instruments need to be discarded immediately at the point of use according to your local regulations for biohazard substances.

All instruments need to be checked properly after disinfection:
- Are they visibly clean?
- Do they function properly (perform a function check, e.g. torque wrench)?
- Are the cutting edges dull or worn out?
- Are the fittings deformed?
- Are any parts broken?
- Have any parts fallen apart?
- Is there any rust or corrosion?

The following pages show examples that help determine whether a product has reached the end of its shelf life or not. The following examples are shown:
- Torque wrench (without adapter)
- Torque wrench adapter
- Screwdriver
- Tapered multiple-use drill
- Implant driver
- Bone mill
- Latch
- Drill extension
- Guided implant mount
- Depth probe
- Rust
New torque wrench:
1. The torque spring is parallel to the tube.
2. The torque spring is properly guided and the laser marking is clear.
3. The direction indicator moves properly back into the tube after changing the working direction.
Direction indicator does not move back completely into tube

Direction indicator broken

Spring no longer fixed

Head of tool broken

Spring out of guidance pillar

Spring bent due to overload
Torque wrench adapter

New adapter

Adapter structure worn out

New adapter

O-ring broken
Screwdriver

New screwdriver

Deformed tip

Deformed and worn-out tip
Tapered multiple-use dense bone drill

New dense bone drill with sharp blades
Blades with lost sharpness

- Edge starts to lose sharpness
- Worn coating

Dull blades

- Edge is round
- Coating is gone on the blade and the steel shines silver
Tapered multiple-use drill

New drill with sharp cutting edges

Cutting edges are dull / worn out

Starting corrosion
Implant driver

New implant driver

Worn-out implant driver

Missing sliding ring
Worn-out edges
Corrosion

New implant driver
Worn-out edges
Bone mill

New bone mill with sharp cutting edge

Bone mill with round cutting edge
Broken bone mill
Latch

Intact connection to the handpiece

Broken connection

Incomplete connection
Drill extension

New drill extension

Drill extension fallen apart
Guided implant mount

Broken guided implant mount
Depth probe

New depth probe

Bent depth probe

Broken depth probe
Rust

Instruments with rusty surface need to be discarded
How do you reprocess implants made of titanium?  

Implants must not be cleaned and sterilized. Any doubt regarding the sterility of the implant must result in direct disposal of the device or send it back to the manufacturer for further investigation.

Can we use other sterilization parameters?  

Conditions other than those recommended by Nobel Biocare can be used and may also lead to safe and sterile medical devices. It is the responsibility of the processor to validate and maintain their processes and equipment according to the applicable standards.

Are these cleaning and sterilization guidelines legally binding?  

Yes, as these guidelines are part of the instructions for use.

Are guidance documents from legal authorities (FDA, RKI etc) legally binding?  

No, these are only recommendations. However, they are sophisticated information and represent the thinking of legal authorities.

How often can a multiple-use drill be used?  

A direct value for re-usable instruments cannot be given. The shelf life of an instrument depends on a number of factors during use as well as cleaning and sterilization. Chapter 6 on inspection and assembly gives recommendations and advice for your decision.

Is it possible to rework drills for further use?  

Drills are not designed for rework or re-sharpening due to their special coating, which provides a smooth surface for better transport of tissue and bone fragments.

For questions that are not answered in these cleaning and sterilization guidelines, contact sterilization@nobelbiocare.com
Customer service worldwide.

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