Cleaning and sterilization

Guidelines for Nobel Biocare products including MRI information

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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.

Contents

Purpose of this document and general information

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 guidelines for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

General information
The applicability of these guidelines for Nobel Biocare devices is indicated on the respective labels and in the Instructions for Use (IFU), where applicable. For detailed explanations of the symbols, see page 6.

Where required, disassembly and assembly shall be performed in accordance with this document or applicable IFUs.

Nobel Biocare has demonstrated that the processes described in these cleaning, disinfection and sterilization guidelines are effective and that the devices are compatible with the described methods. The guidelines are based on validated processes. It is recommended to follow these instructions to avoid affecting the performance of the products negatively. Procedure manuals with an earlier publishing date will be superseded by this document with regards to cleaning, disinfection and sterilization.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.

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.

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 medical devices that are safe for use.

The information on Nobel Biocare passive implants in MR environments is intended to provide the necessary data for radiologists to perform safe diagnostic imaging.

Note: According to EN ISO 17664 it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Abbreviations

°C	Degree Celsius
°F	Degree Fahrenheit
AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American Nation Standards Institute
ASTM	American Society for Testing and Materials
CFR	Code of Federal Regulations
CFU	Colony Forming Unit
CSA	Canadian Standards Association
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EN	European Norms
EU	Endotoxin Units
FDA	US Food and Drug Administration
IFU	Instructions for Use
ISO	International Standards Organisation
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
PEEK	Polyether Ether Ketone
PMMA	Polymethyl Methacrylate
PPSU	Polyphenylsulfone
RKI	Robert Koch Institute
SAR	Specific Absorption Rate

Explanation of symbols on labels and instruction leaflets

	Batch code
	Legal manufacturer
	Sterilized using irradiation
	Catalog number
	Non-sterile Medical device has not been subjected to a sterilization process
	Caution Consult the Instructions for Use for important cautionary information
	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.
	Consult Instructions for Use
	Open the package like this
	Do not reuse When "Do not reuse" devices are supplied non-sterile and require sterilization prior to usage, the appropriate sections in these guidelines may be applied.
	MR Safe Device poses no known hazards in all MR environments
	Do not use if package is damaged
	MR Conditional Device poses no known hazards in a specified MR environment with specified conditions of use
	Use by Indicates the date after which the medical device is not to be used
	CE-mark and Notified Body number
	Rx only Rx only Federal Law (US) restricts this product to sale by or on the order of a dentist or physician

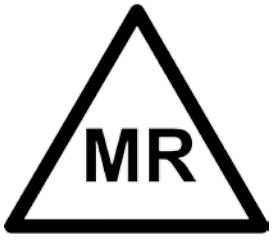
Magnetic Resonance Imaging (MRI) information

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]
This section is intended to provide MR symbol information and is not intended to make any MR claims. It is meant to provide additional information regarding the MR symbol and other MR related information and is not intended to be device specific. Please review the device labeling for specific MRI information.

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.



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 4000 Gauss/cm (40 T/m)
– Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)
– Normal operating mode of the MR system

1 American Society for Testing and Materials (ASTM) International, Designation: F2503. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, West Conshohocken, PA, 2005

MRI-related heating

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

	1.5 Tesla 64 MHz	**3.0 Tesla** 128 MHz
Maximum MR system, whole body averaged SAR	4 W/kg	4 W/kg
Calorimetry measured values, whole body averaged SAR	2.1 W/kg	2.7 W/kg
Highest temperature change (all tests)	+4.1°C	+2.9°C
Maximum spatial gradient magnetic field	4000 W/kg	4000 W/kg
Test system	Magnetom (active-shielded, horizontal field scanner) Software Numaris/4, Version Syngo MR 2002B DHHS Siemens Medical Solutions, Malvern, PA, USA	Excite, HDx Software 14X.M5 General Electric Healthcare, Milwaukee, WI, USA

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.

Pulse sequence	**T1-SE***	**T1-SE**	**GRE****	**GRE**
Plane orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal void size***	2754 mm^2	2229 mm^2	4458 mm^2	5463 mm^2

* 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 should 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.

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). 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 the described processes.

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

Decontamination
Removal of pathogenic microorganisms from objects so that the devices are safe to handle, use or discard.

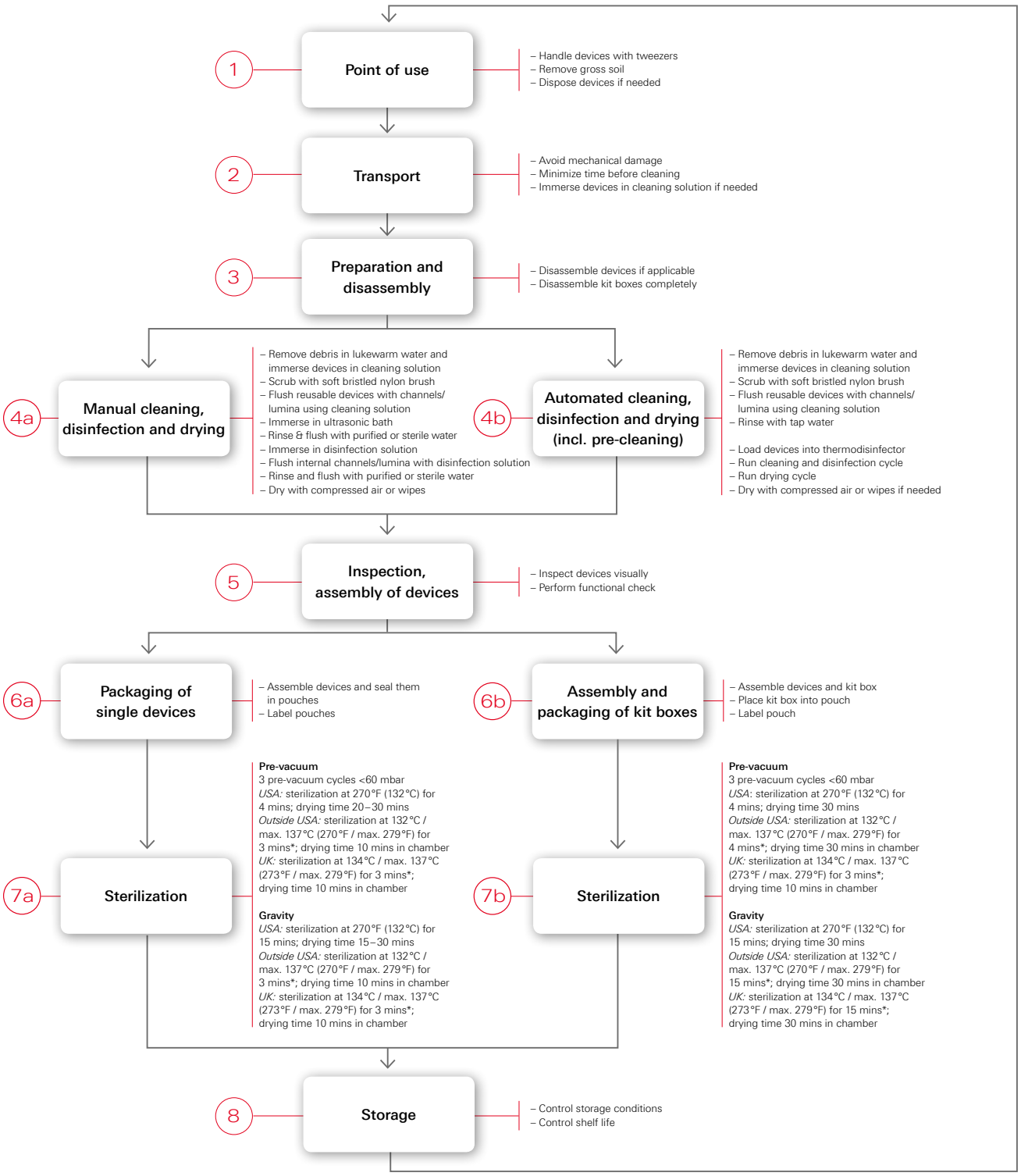
Disinfection
A process that kills most disease-producing microorganisms, but not necessarily all microbial forms (e.g., bacterial spores).

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 this workflow. More detailed instructions for each step are given on the following pages. The circled numbers refer to the corresponding section in these guidelines.



* Following the recommendations of the Robert Koch Institute (RKI), the exposure time can be extended up to 20 minutes.

The preparation for reuse of medical devices or for initial use of new devices requires a sequence of processing steps shown in this workflow. 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. A list of cleaning agents and disinfectants that Nobel Biocare used in the validation of these cleaning and sterilization guidelines is also provided (see page 37). 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, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.

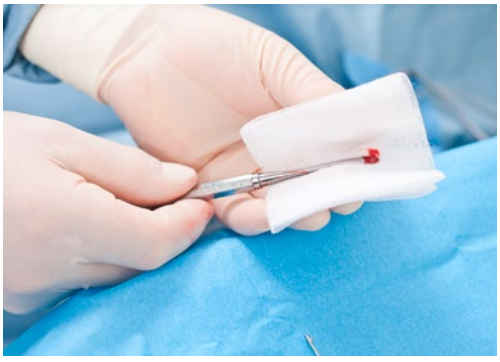
Water quality
The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing medical devices should be carefully considered. Application of freshly prepared purified water / highly purified water or sterile water for rinsing purposes (according to the pharmacopeias) with 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 reuseable 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 of in the surgery room, in containers specially designed for this purpose.

2 Transport

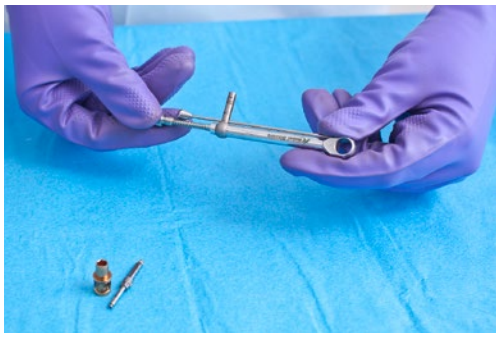
1 Avoid mechanical damage
Avoid mechanical damage, e.g., do not mix heavy devices with delicate ones. Pay particular attention to cutting edges, both to avoid injury and to avoid damage to the medical devices.

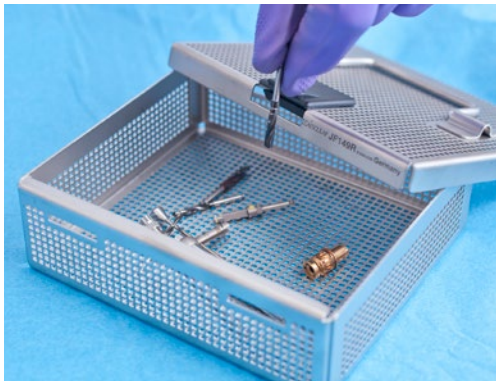
2 Minimize time before cleaning
Get the medical devices to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the medical devices with a damp cloth or store the medical devices in closed boxes to avoid drying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

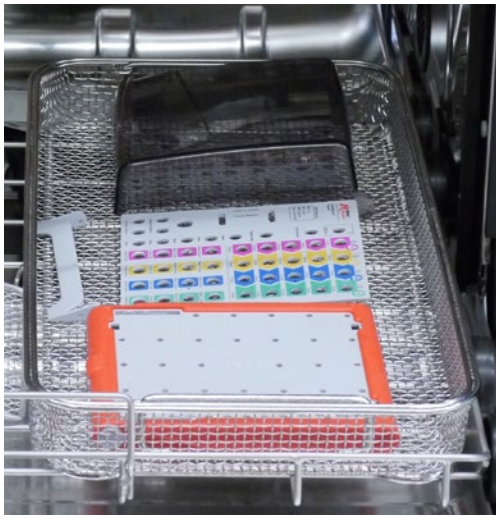
1 Disassemble devices
Demountable devices must be disassembled prior to cleaning:
– Abutment Retrieval Instrument Zirconia
(see IFU for instructions)
– Manual Torque Wrench Surgical and Prosthetic
(see IFU for instructions)
– Impression Coping Open Tray
– Impression Coping Closed Tray
– Handle for Guided Drill Guide
– Guided Template Abutment
– Guided Implant Mount
– Drill Stop





2 Disassemble kit boxes completely
Kit boxes must be disassembled completely before cleaning and disinfection.

Note: It is recommended that the grommets are disassembled.



4a Manual cleaning, disinfection and drying

Cleaning procedure

Required equipment
– Ultrasonic bath large enough to allow complete immersion of the devices; frequency 25–50 kHz, temperature according to detergent manufacturer's instructions.
– Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment, meeting the criteria given on page 37; concentration as specified in detergent manufacturer's instructions.
– Soft nylon brushes, syringes (20 ml), irrigation needles, absorbent paper, etc.
– Freshly prepared purified water / highly purified 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 immerse 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.

Immerse the instruments in an enzymatic cleaning solution (e.g., enzymatic detergent with a pH level between 7–10) prepared with lukewarm tap water. Follow the detergent manufacturer's instructions.

Cleaning agents are commercially available. For a general description of suitable agents see page 37.

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 under cold tap water until all visible soil and debris is removed. Pay particular attention to features that may be shielded from the brushing action.

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

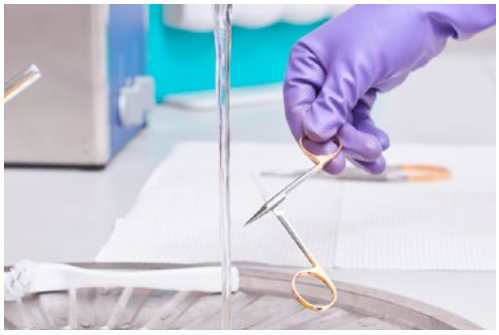
Note: The irrigation needle must pass the silicone barrier in the middle of the drills with irrigation holes.

4 Immerse 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.

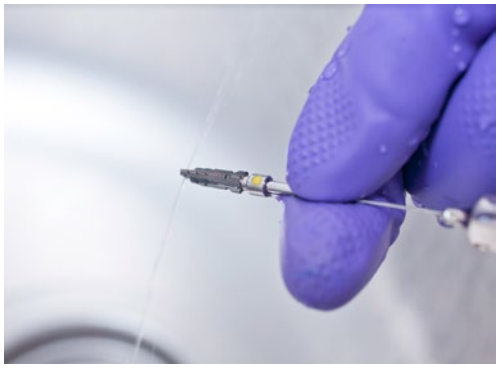
Notes:
– Avoid direct contact of the instruments with sharp cutting edges during ultrasonic treatment so as not to damage devices or reduce shelf life (e.g., drills).
– Detergent used in Nobel Biocare validation see page 37.

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/lumina with purified or sterile water
Flush the internal channels/lumina 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.

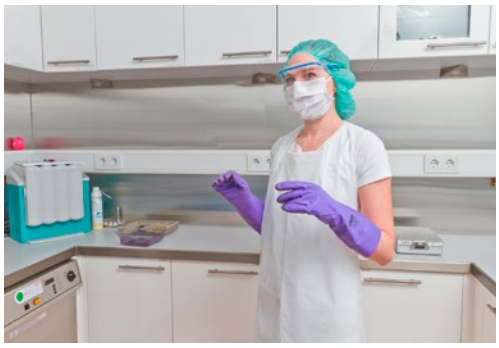
Note: The irrigation needle must pass the silicone barrier in the middle of the drills with irrigation holes.



7 Repeat cleaning steps if needed
If encrusted soil and/or debris remain on the device after cleaning, repeat all cleaning steps from 1 to 6.

Disinfection and drying procedure

Required equipment
- Bath large enough to allow complete immersion of the devices; 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 37; 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 Immerse in disinfection solution

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

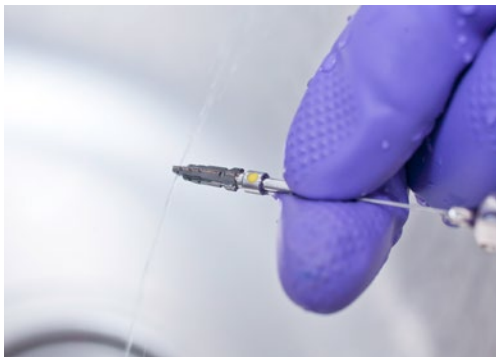
Ensure all lumina are filled with the disinfection solution and all surfaces are wetted with it.

Immerse the devices for at least the time specified in the detergent manufacturer's instructions.

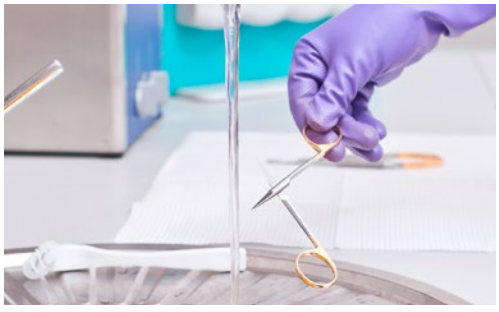
Note: Detergent used in Nobel Biocare validation see page 37.

9 Flush internal channels/lumina with disinfection solution
Flush the internal channels/lumina a minimum of three times 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 drills with irrigation holes.

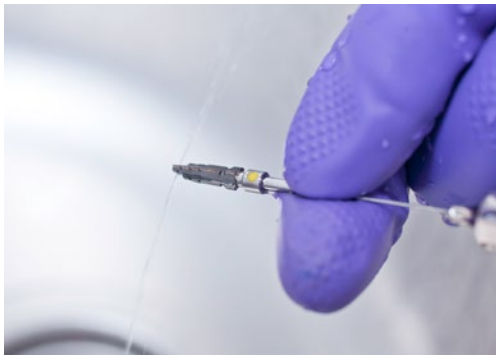


10 Rinse with purified or sterile water
Thoroughly rinse the device for a minimum of 1 minute with freshly prepared purified water / highly purified water or sterile water. Remove the device and discard the rinse water. Repeat this stage another two times, for a total of three rinses. Do not reuse the water. Always use fresh volumes of water for each rinse.



11 Flush internal channels/lumina with purified or sterile water
Flush the internal channels/lumina a minimum of three 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 drills with irrigation holes.



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
– Ultrasonic bath large enough to allow complete immersion of the devices; frequency 25–50 kHz, temperature according to detergent manufacturer's instructions.
– Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment, meeting the criteria given on page 37; concentration as specified in detergent manufacturer's instructions.
– 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).

1 Remove debris in lukewarm water and immerse 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.

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

Immerse the instruments in an enzymatic cleaning solution (e.g., enzymatic detergent with a pH level between 7–10) prepared with lukewarm tap water. Immersion 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 37.

Note: Detergent used in Nobel Biocare validation see page 37.

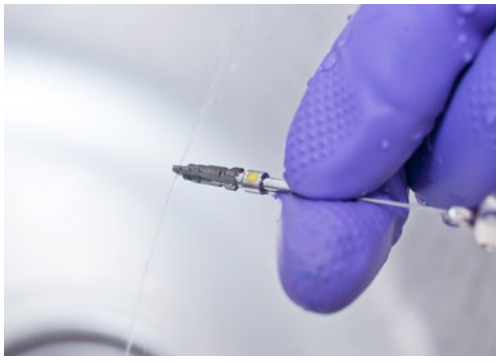
2 Scrub devices with soft bristled nylon brush
Scrub the outer and, if applicable, the inner side of the instruments with a soft bristled nylon brush until all visible soil and debris is removed. Pay particular attention to features that may be shielded from the brushing action.

3 Flush reusable devices with channels/lumina using cleaning solution
Flush the internal channels/lumina 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/lumina for residual soil and/or debris.

Note: The irrigation needle must pass the silicone barrier in the middle of the drills with irrigation holes.

4 Rinse with tap water
To remove all cleaning solution:
– Rinse the outer surface with cold tap water.
– Flush the lumina with cold tap water using a 20 ml syringe connected to an irrigation needle.

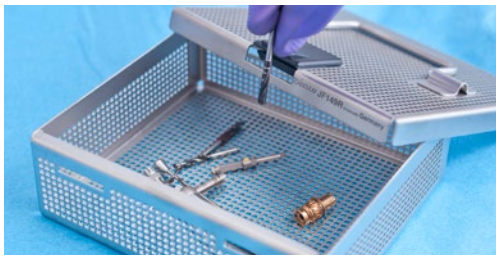
Note: The irrigation needle must pass the silicone barrier in the middle of the drills with irrigation holes.



Automated cleaning, disinfection and drying

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

Note: Kit boxes must be disassembled completely before cleaning and disinfection. It is recommended that the grommets are disassembled.



6 Run cleaning and disinfection cycle
Follow the instructions provided by the manufacturers of the washing machines.

The following parameters were used in Nobel Biocare validation (Miele G7735 CD / Miele G7836 CD; cleaning Program Vario TD):
– 2 minutes pre-cleaning with cold tap water
– Draining
– 5 minutes cleaning at 55°C/131°F tap water with a 0.5% solution of alkaline cleaning agent (e.g., neodisher® MediClean)
– Draining
– 3 minutes neutralization with tap water
– Draining
– 2 minutes intermediate rinsing with cold tap water
– Draining

Note: Detergents used in Nobel Biocare validation see page 37.

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 lumina of the disinfected parts can be dried by using sterile compressed air.

5 Inspection

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.

Following questions need to be answered (if applicable):
– Is the device visibly clean?
– 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?

Check that the device has not reached the end of its shelf life. Please find examples in the appendix on pages 38–51.

Particular attention should be paid to:
– Soil "traps" such as mating surfaces and shafts of reamers.
– Recessed features like channels/lumina and threads.
– Features where soil may be pressed into contact with the device, e.g., drill flutes adjacent to the cutting tip.

2 Perform functional check
– Check mating devices for proper assembly.
– Perform a functional check with devices with moving parts to ensure proper function (e.g., manual torque wrench).
– Check drills for sharpness and damages (for examples see pages 42-44).

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.
– Single-use devices that must be cleaned, disinfected and sterilized prior to use are not intended to be reused.

6a Assembly and 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.
– For USA: Use FDA-cleared sterilization accessories.

2 Label pouches
It is common practice to label the pouches 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).

For packages without a clear window for identifying the devices inside, it is recommended that the following 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.

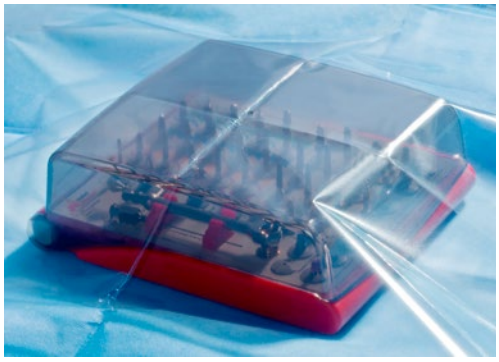
Reassemble the surgical and prosthetic kit boxes and mount the instruments in the silicone grommets / brackets.

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.
– For USA: Use FDA-cleared sterilization accessories.

3 Label pouch
It is common practice to label the pouches/packages 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)

For packages without a clear window for identifying the devices inside, it is recommended that the following be added to the above-mentioned information:
– Product name with article number
– Number of devices



7a Sterilization of single devices

Most heat sterilization methods have been validated by Nobel Biocare including pre-vacuum, gravity, saturated steam and saturated steam with fractional forced air removal.

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 SN EN 13060, EN 285, EN ISO 17665-1, AAMI ST79 or your national standard.

For USA: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

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 applicable to the Nobel Biocare portfolio. Always consult the Instructions for Use in case of exceptions.

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: With these cleaning and sterilization guidelines, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Recommended sterilization parameters for single devices sealed in pouches

USA

Method	Moist heat sterilization	
Cycle	Pre-vacuum	Gravity
Temperature	270°F (132°C)	
Exposure time	4 minutes	15 minutes
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	20–30 minutes	15–30 minutes
Cooling time	10 minutes at room temperature	

Outside USA

Method	Moist heat sterilization according to ISO 17665	
Cycle	Saturated steam with fractional forced air removal	Saturated steam
Temperature	132°C (270°F)	
Temperature max.	137°C (279°F)	
Exposure time	3 minutes*	
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	10 minutes in chamber	

Alternative UK

Method	Moist heat sterilization according to ISO 17665	
Cycle	Saturated steam with fractional forced air removal	Saturated steam
Temperature	134°C (273°F)	
Temperature max.	137°C (279°F)	
Exposure time	3 minutes*	
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	10 minutes in chamber	

Special instructions for Ratchet
Seal the Ratchet (art.no. 2080) in a pouch and sterilize at 135°C (275°F) for 20 minutes with gravity cycle.
Drying time minimum 5 minutes.

*Following the recommendations of the Robert Koch Institute (RKI), the exposure time can be extended up to 20 minutes.

7b Sterilization of kit boxes

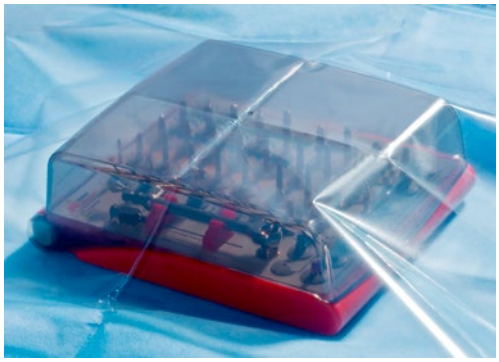
Most heat sterilization methods have been validated by Nobel Biocare including pre-vacuum, gravity, saturated steam and saturated steam with fractional forced air removal.

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, SN EN 13060, EN 285, EN ISO 17665-1, AAMI ST79 or your national standard.

For USA: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

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 to the Nobel Biocare portfolio. Always consult the Instructions for Use in case of exceptions.

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.

With these cleaning and sterilization guidelines, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Recommended sterilization parameters for devices mounted in kit boxes and sealed in pouches

USA

Method	Moist heat sterilization	
Cycle	Pre-vacuum	Gravity
Temperature	270°F (132°C)	
Exposure time	4 minutes	15 minutes
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	30 minutes	
Cooling time	10 minutes at room temperature	

Outside USA

Method	Moist heat sterilization according to ISO 17665	
Cycle	Saturated steam with fractional forced air removal	Saturated steam
Temperature	132°C (270°F)	
Temperature max.	137°C (279°F)	
Exposure time	4 minutes*	15 minutes*
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	30 minutes in chamber	

Alternative UK

Method	Moist heat sterilization according to ISO 17665	
Cycle	Saturated steam with fractional forced air removal	Saturated steam
Temperature	134°C (273°F)	
Temperature max.	137°C (279°F)	
Exposure time	3 minutes*	15 minutes*
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	10 minutes in chamber	30 minutes in chamber

*Following the recommendations of the Robert Koch Institute (RKI), 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.

Handpiece Zygoma 20:1 – specific cleaning and sterilization guidelines

1 Pre-cleaning

Required equipment
– Piece of cloth.
– Soft bristled brush.
– Ultrasonic bath.
– Cleaning agent suitable for ultrasonic treatment, meeting the criteria given on page 37; concentrations as specified in detergent manufacturer's instructions.
– Personal protective equipment as recommended by the cleaning agent supplier (minimum water impermeable protection gown, gloves, face/eye shield).

1 Wipe with a cloth
Remove gross contamination by wiping the Handpiece Zygoma with a wetted piece of cloth.

2 Brush under lukewarm water
Brush the Handpiece Zygoma under running lukewarm tap water with a soft bristled brush until all visible contamination (blood, residual tissue or bone debris) is removed.

3 Immerse in cleaning solution
Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified in the detergent manufacturer’s instructions. Place the device so that three quarters of the Handpiece Zygoma are immersed in the cleaning solution.

Activate the bath for at least the time specified in the detergent manufacturer’s instructions.

Notes:
– Place the Handpiece Zygoma vertically into the solution. Do not place it horizontally to avoid contact of fluid with the inner components.
– Detergent used in Nobel Biocare validation see page 37.

2a – Manual cleaning

Required equipment
– Water jet gun.
– Adapter, e.g., piece of a flexible plastic tube (see picture).
– Compressed air supply.

1 Rinse outer surface with water jet gun
Rinse the outer surface of the Handpiece Zygoma with a water jet gun. Pay special attention to the gaps near the locking mechanism. Repeat this step three times for 5 seconds each (static pressure 3–4 bar).

2 Flush lumen
Connect the lumen of the Handpiece Zygoma via an adapter from behind to a water jet gun and flush three times for 5 seconds (static pressure 3–4 bar).

3 Dry handpiece
Dry the outer surface and the lumen of the Zygoma Handpiece with compressed air.

2b – Automated cleaning

Required equipment
– Washer/disinfector

1 Place handpiece in washer/disinfector
Place the Handpiece Zygoma on an ophthalmologic rack in the washer/disinfector (e.g., Miele G 7836 CD).

Make sure that the Handpiece Zygoma is connected via adapters to the flushing ports of the rack.

Note: Detergent used in Nobel Biocare validation see page 37.

2 Run cleaning program
Use a general purpose cleaning program (e.g., Vario TD).

Nobel Biocare validation was performed with the following steps:
– 2 minutes pre-washing with cold water
– Draining
– 5 minutes washing at 55°C/131°F with a 0.5% solution of alkaline cleaning agent (e.g., neodisher® MediClean)
– Draining
– 3 minutes neutralizing with cold water
– Draining
– 2 minutes rinsing with cold water
– Draining

3 Disinfection

Required equipment
– Washer/disinfector
– Cleaning agent

1 Disinfect in washer/disinfector
Disinfect the Handpiece Zygoma by means of washer/disinfector. Follow the detergent manufacturer's instructions.

Nobel Biocare recommends thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g., Miele G 7836 CD – validation was carried out with program “Vario TD” using cleaning agent neodisher® MediClean).

Note: Do not place the Handpiece Zygoma in disinfectant baths, as this may result in malfunction. Only disinfect in the thermodisinfector.

4 Sterilization

1 Ensure that the handpiece is dry
In order to prevent negative effects on the Handpiece Zygoma, make sure that interior and exterior are dry after completion of the cleaning.

2 Lubricate with suitable spray
Lubricate the Handpiece Zygoma before autoclaving by using a suitable lubricant spray that meets the local regulatory requirements.

Insert the Handpiece Zygoma in the nozzle and spray for about one second. Hold the handpiece firmly against the nozzle during spraying.

3 Pack handpiece
Single pack the Handpiece Zygoma in a sterilization pouch. Depending on the clinical procedure, use either a single or double pouch.

Sterilize the Handpiece Zygoma in a pre-vacuum steam sterilization process with the following parameters:
– 3 pre-vacuum phases
– Sterilization temperature: 132°C
– Holding time: 3 minutes (full cycle)
– Drying time: 1 minute

Note: Remove the Handpiece Zygoma from the autoclave immediately after each cycle to prevent the risk of contact corrosion.

5 Storage

Store the Handpiece Zygoma in a dry place at room temperature away from direct sunlight.

References

21CFR58 Good Laboratory Practice for Non-clinical Studies

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

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

ANSI/AAMI ST8 Hospital Steam Sterilizers

ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

ANSI/AAMI ST81 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

ASTM E 1054-02 Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents

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

ASTM E 2314-03 Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)

ASTM F 2503-08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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 Decontamination of reusable medical devices

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

DIN 58953-7 Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen

FDA Guidance Document 1748 Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

ISO 11607 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

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

ISO 14937 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 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

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

ISO 17665-1 Sterilization of health care products Part 1: Development, validation and routine control of a sterilization process for medical devices

Cleaning agents and disinfectants

Cleaning and sterilization step	Detergents used in Nobel Biocare validation
If cleaning is delayed, place the devices in a bath of lukewarm cleaning solution to avoid the drying of soil and debris.	Commercially available mild pre-cleaning solution with a pH value of 7–10 and a temperature of approx. 35°C/95°F
Ultrasonic bath A mild agent is recommended for removing all visible soil and/or debris, blood and other contaminations from the devices.	Cidecyme / Enzol General devices: 0.5% cleaning solution in an ultrasonic bath for 5 minutes at 40°C/104°F Handpiece Zygoma: 0.5% cleaning solution in an ultrasonic bath for 10 minutes at 40°C/104°F
Manual disinfection The solution was prepared according to the detergent manufacturer's Instructions for Use. Devices were immersed in the bath.	Cidex Opa Minimum effective concentration 0.3% Minimum temperature 20°C/68°F Immersion time at least 12 minutes (do not exceed 14 days) (specifications according to manufacturer's Instructions for Use)
Automated cleaning, disinfection and drying For this step, a washer/thermodisinfector was used.	0.5% solution of neodisher® MediClean

If the used detergents are not commercially available in your market, use an equivalent one and follow the instructions of the manufacturer.

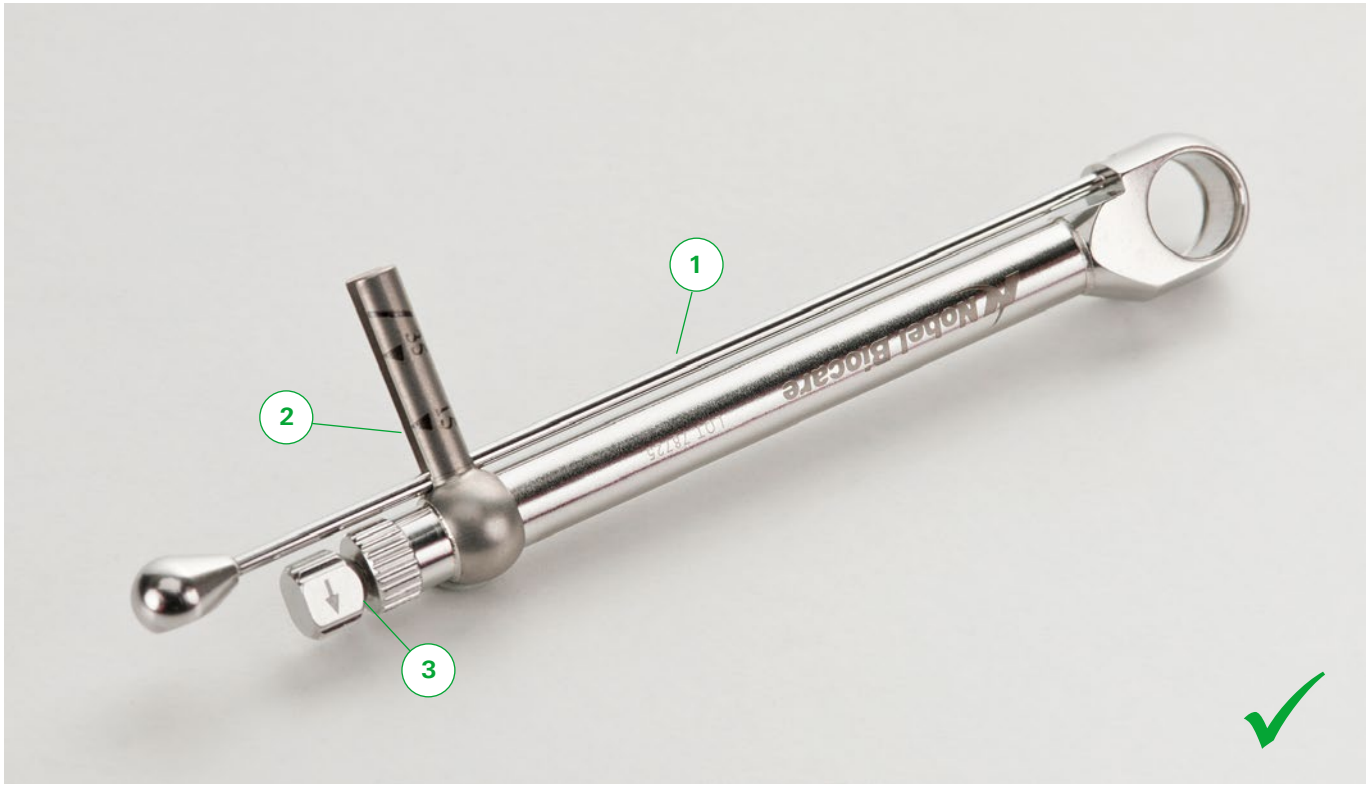
Notes:
- Nobel Biocare does not recommend these detergents in preference to others that are available. Other detergents may perform equally well or better in conjunction with the equipment being used.
- The detergent manufacturer's Instructions for Use should be followed.
- Suitability of alternative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

Examples for end of shelf life

The following pages show examples that help determine whether a device has reached the end of its shelf life or not.

Examples are shown for specific devices, features and corrosion:
– Torque wrench (without adapter)
– Torque wrench adapter
– Screwdriver
– Tapered multiple-use drill
– Implant driver
– Bone mill
– Latch of various instruments
– Drill extension
– Guided implant mount
– Depth probe
– Rust/corrosion

Torque wrench (without adapter)



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

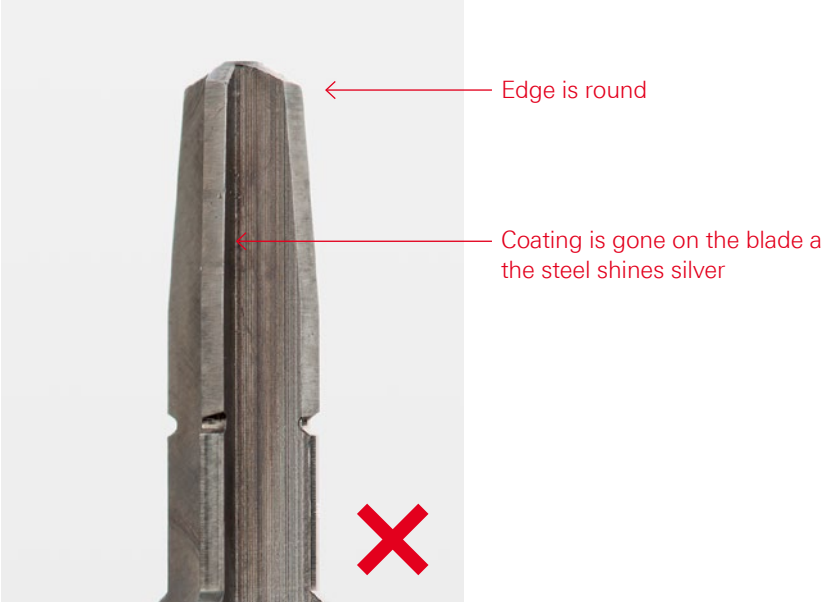
Deformed tip

Deformed and worn-out tip

Tapered multiple-use dense bone drill

New dense bone drill with sharp blades

Blades with lost sharpness



Dull blades

Tapered multiple-use drill

New drill with sharp cutting edges

Cutting edges are dull / worn out

Starting corrosion

Implant driver

New implant driver

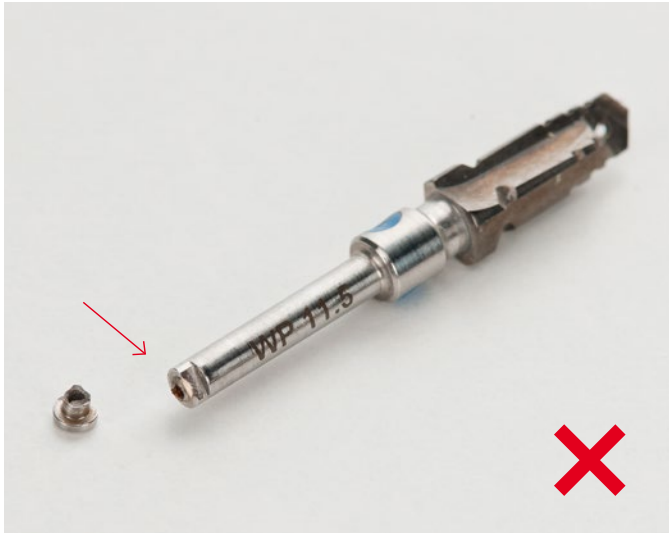
Worn-out implant driver

New implant driver

Worn-out edges

Latch

Intact connection to the handpiece



Broken connection

Incomplete connection

Bone mill

New bone mill with sharp cutting edge

Bone mill with round cutting edge

Broken bone mill

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/corrosion

Instruments with rusty surface need to be discarded. Pictures are examples only and do not show acceptance limits. Already slightly corroded instruments can be non-biocompatible.

Frequently asked questions

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.
Can I deviate from these cleaning and sterilization guidelines?	With these cleaning and sterilization guidelines, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664 it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.
Are guidance documents from health authorities (FDA, RKI, etc.) legally binding?	No, these are only recommendations. However, they are sophisticated information and represent the thinking of health authorities.
How often can a multiple-use drill be used?	A direct value for reusable 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 5 gives recommendations and advice for your decision.
Is it possible to rework drills for further use?	Drills are not designed for rework or resharpening due to their special coating, which provides a smooth surface for better transport of tissue and bone fragments.
What are the specific requirements for thermal disinfection according to the A_0 concept?	The required final A_0 value for thermal disinfection according to the A_0 concept (ISO 15883-1) is country-specific. However, it can be stated that any required final A_0 value will be reached safely if the temperature in and on the instrument follows the water temperature in the washer / disinfector (in compliance with ISO 15883) without delay.
Can I produce pure water applying the reverse osmosis technology?	Yes. Reverse osmosis is one of the accepted and widely used methods to produce pure water for the final flushing (by applying high pressure, the salts are being removed). An alternative method would be distillation, for example.

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

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