Cleaning and Sterilization Instructions

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1. Cleaning and Sterilization Instructions (Outside of USA)

1.1 Cleaning and Sterilization Instructions for Single Devices to be processed / re-processed

Devices must be cleaned and sterilized by the end user. The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

– Manual and Automated Cleaning: AAMI TIR 12 /AAMI ST98

– Sterilization: AAMI ST79 and ISO 17665 -1

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The devices have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

The following "Point of Use" and "Containment and Transportation" subsections are applicable only for reusable devices; otherwise go directly to "Automated Cleaning" or "Manual Cleaning "step.

Initial Treatment at Point of Use Prior to Reprocessing

1. Discard single-use instruments and worn reusable instruments immediately after use.

2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe to remove soil and debris from cavities, where applicable.

Caution All dental debris adhering to impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if all dental debris cannot be removed.

3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.

2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Please check "Disassembly Instructions" in Annex 1 to verify if the device needs to be disassembled. Disassemble device prior to cleaning by following the "Disassembly Instructions".

2. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

3. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe until the lumens are free of any visually datable soil.

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute until all visible soil is removed.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.

6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program / Washer disinfector (MMM GmbH) Type: Uniclean PL-II 15-2 EL.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).

2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.

3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold deionized water
   - Draining
   - Minimum of 2 minutes rinsing with cold deionized water
   - Draining

4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.

5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Please check "Disassembly Instructions" in Annex 1 to verify if the device needs to be disassembled. Disassemble device prior to cleaning by following the "Disassembly Instructions".

2. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 1 minute until all visible soil is removed.

4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of 0.5% lukewarm enzymatic cleaning agent (e.g. Cydezyme ASP and / or Neodisher Medizym; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.

6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP and / or Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.

9. Applicable to Manual Torque Wrenches : Flush the inner surfaces, lumina and cavities of Manual Torque Wrenches for a minimum of 15 seconds using a water jet pistol.

10. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.

11. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1CL (pre-vacuum cycle); Amsco Century Sterilizer, Selectomat PL/669-2CL and/or Selectomat PL/666-1CL (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL / Selectomat PL/666-1CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN 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.

Table 1 presents examples of suitable sterilization pouches.

Table 1 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).

3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 2):

Table 2 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes	
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes	
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes	

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical / biological indicators) used for this cycle are validated for these conditions.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization 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 to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed /reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

1.2 Instructions for devices which are sterilized in a PureSet™ Tray

PureSet™ Trays (including the PureSet™ Plate) are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the PureSet™ Tray, Plate, and corresponding surgical/ prosthetic instruments must be cleaned and sterilized by the user.

PureSet™ Trays, Plates, and instruments can be cleaned manually, or can be cleaned in an automatic washer. After cleaning, the fully assembled PureSet™ is sealed in a metal sterilization container, sterilization pouch, or sterilization wrap and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual/Automated Cleaning: AAMI TIR 12
- Sterilization: AAMI ST79 and ISO 17665 -1

According to EN ISO 17664, it is the responsibility of the user/ processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Caution Do not deviate from the following reprocessing instructions.

Assembly: There are different versions of the PureSet™ Tray available for the different Nobel Biocare surgical and prosthetic procedures. The instruments and components which are compatible with the various trays are specified in the respective wall charts. Please contact Nobel Biocare sales office for information regarding the wall charts.

Initial Treatment at Point of Use Prior to Reprocessing

1. During surgery, always return used reusable instruments back into their designated holders in the PureSet™ Tray (refer to the pictograms and color-coded workflow on the plate of the PureSet™ Tray). To avoid potential injury or exposure to contaminated instruments, it is advised to handle the instruments using a pair of tweezers.

2. Discard single-use instruments and worn reusable instruments immediately after use.

3. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe to remove soil and debris from cavities, where applicable.

Caution Excess soil and debris should be removed from reusable devices within 1 hour of use to ensure the efficacy of the reprocessing.

4. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the PureSet™ Tray and instruments in a suitable container to avoid any contamination of personnel or the environment.

2. Transport the PureSet™ Tray and instruments to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the PureSet™ Tray and instruments with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Caution Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Disassembly of Multi-piece Instruments Prior to Cleaning

Note The Manual Torque Wrench Surgical must be disassembled prior to cleaning by removing the adapter and the rod from the wrench body as shown in Figure A.

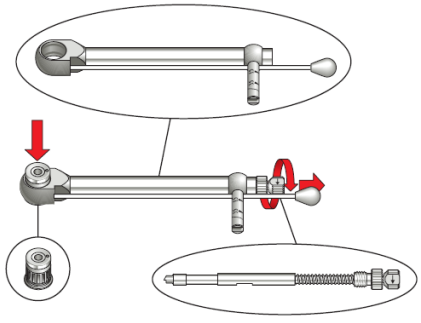


Figure A – Disassembly of the Manual Torque Wrench Surgical

Note Implant Mounts must be disassembled prior to cleaning as follows:

Unscrew the Implant Mount Screw (2) from the Implant Mount Body (1), see Figure B.

Figure B – Disassembly of the Implant Mount

Note Template abutments must be disassembled prior to cleaning as follows:

Unscrew the Template Abutment Screw (2) from the Template Abutment Body (1), see Figure C.

Figure C – Disassembly of the Guided Template Abutment

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Remove all instruments from the PureSet™ Tray.
2. Remove the plate from the PureSet™ Tray.
3. Disassemble the multi-piece instruments as described above, where applicable.
4. Thoroughly rinse all instruments, including any lumina and/or difficult-to-reach areas with lukewarm tap water using a water pistol.
5. Place all instruments back into the designated holders in the PureSet™ Tray. Use the PureSet™ Plate as a reference to ensure the instruments are placed in the correct position. Keep the multi-piece instruments disassembled.
6. Place the PureSet™ Tray with instruments in an ultrasonic bath (e.g. Bandelin Sonorex 35 kHz, 300 W_{eff}) containing 0.5% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) and treat for minimum of 10 minutes at minimum 40°C (104°F).

Caution Do not place the PureSet™ Plate into the ultrasonic bath as this can damage the plate and impact the legibility of the text and pictograms.

Automated Cleaning and Drying

The following washers were used in the Nobel Biocare validations: Steelco DS 500 and Miele G7836 CD.

1. Place the PureSet™ Tray containing the instruments and the plate into the washer separately. Ensure the PureSet™ Tray and plate are oriented in a vertical position.

Caution Remove the PureSet™ Plate from the PureSet™ Tray prior to automatic cleaning to ensure the tray and instruments are adequately cleaned.

2. Perform automatic cleaning. The following parameters were used in the Nobel Biocare validation:
   - Minimum of 2 minutes pre-washing with cold tap water at a minimum 14°C (57°F)
   - Minimum of 5 minutes washing with tap water with a 0.5% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) at 55°C (131°F)
   - Minimum of 3 minutes rinsing with cold demineralized water at minimum 18°C (64°F)

Caution The use of a cleaning solution with acidic pH (pH < 7) could potentially damage the PureSet™ Plate.

3. Dry the PureSet™ Tray containing the instruments and the PureSet™ Plate at minimum 70°C (158°F) for a minimum of 10 minutes.

Manual Cleaning and Drying

PureSet™ Tray and Plate

1. Remove all the instruments from the PureSet™ Tray.
2. Remove the plate from the PureSet™ Tray.
3. Scrub the PureSet™ Tray under running tap water with a soft bristled nylon brush for a minimum of 3 minutes until all visible soil is removed.
4. Immerse a soft bristled nylon brush in a 0.5% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) at minimum 40°C (104°F). Scrub the PureSet™ Plate with the soft bristled nylon brush for a minimum of 1 minute until all visible soil is removed. Ensure the entire surface of the plate is thoroughly scrubbed.

Caution The use of a cleaning solution with acidic pH (pH < 7) could potentially damage the PureSet™ Plate.

5. Thoroughly rinse the PureSet™ Plate for a minimum of 1 minute under running tap water to remove all detergent.
6. Flush the grommets (instrument holders) with tap water using a water pistol for a minimum of 30 seconds.
7. Place the PureSet™ Tray (without the plate) into an ultrasonic bath (e.g. frequency 37 kHz effective ultrasonic power 400 W) for a minimum of 10 minutes with a 0.6% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) at minimum 40°C (104°F).
8. Rinse the PureSet™ Tray for a minimum of 1 minute under cold running tap water to remove all cleaning solution.
9. Dry the PureSet™ Tray and the plate with suitable equipment (compressed air).

PureSet™ Instrumentation

1. Disassemble the multi-piece instruments prior to cleaning as described above.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; Neodisher Medizym) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing 0.5% lukewarm enzymatic cleaning agent (e.g. Cidezyme ASP; Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20ml lukewarm tap water using an irrigation needle connected to a 20ml syringe.
9. Flush the inner surfaces, lumina and cavities of Manual Torque Wrenches for a minimum of 1 minute using a water jet pistol.
10. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.
11. Dry with compressed air or clean with lint-free single use wipes.

Reassembly of the PureSet™ Tray, Plate, and Instrumentation

Reassemble the PureSet™ Tray and plate and replace the instruments (including multi-piece instruments) in their designated holders in the PureSet™ Tray (refer to the pictograms and color-coded workflow on the plate of the PureSet™ Tray). To

avoid potential injury, it is advised to handle the instruments using a pair of tweezers.

Caution Ensure that the plate is properly seated on the PureSet™ Tray to prevent damage to the plate or to instruments during subsequent handling.

Caution Keep dissimilar metals separated to prevent corrosion during sterilization. Refer to the Materials section in the Nobel Biocare IFU for the respective surgical/prosthetic tooling for information regarding the metals contained in the device.

Visual Inspection

After cleaning, drying, and reassembly of the PureSet™ Tray, plate, and instrumentation, inspect all components to confirm the functional integrity, to confirm the legibility of any text (where applicable) and to ensure there is no residual soil, corrosion or damage. Any devices with signs of corrosion or damage must be discarded and replaced. The PureSet™ Plate is available as a spare part and should be replaced if the plate is discolored or if the legibility of the pictograms or the text is compromised.

Sterilization

1. Pack the assembled PureSet™ Tray (with instruments and plate) in a metal sterilization container, sterilization pouch or sterilization single wrap. The metal sterilization container, sterilization pouch or sterilization single wrap should fulfill the following requirements:
   - EN ISO 11607, ST 77 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

Table 3 presents examples of suitable sterilization containers, pouches, and wraps.

Table 3 – Recommended Sterilization Containers, Pouches, and Wraps for PureSet™

Container/Pouch/Wrap	Description
Sterilization Container	Aesculap® Sterilization Container (Part # JK289)
Sterilization Pouch	Cardinal Health 18"x22" Pouch (Part # 91822)
Sterilization Wrap	Cardinal Health Convertor Brand Bioshield Regular Sterilization Wrap (Part # 4040)

Note The PureSet™ Tray is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated sterilization container, sterilization pouch or sterilization wrap in order to maintain sterility of the enclosed medical instruments until used.

2. Label the metal sterilization container, sterilization pouch or sterilization wrap with necessary information such as expiration date, lot (if applicable), sterility information, product name with article number.

3. Ensure the PureSet™ Tray is sealed in the sterilization container/ pouch/wrap and place into the autoclave/sterilizer. The PureSet™ Tray must be sterilized in its "ready for use" state.

4. Sterilize the devices. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters Table 4:

Table 4 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes	
Gravity Cycle[1]	134°C (273°F)	10 minutes	
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes	
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes	

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1 at saturated steam pressure.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical / biological indicators) used for this cycle are validated for these conditions.

Caution Do not use gravity sterilization if the PureSet™ Tray is sealed in a metal sterilization container.

After sterilization of the PureSet™ Tray, inspect the sterilization container, pouch, or wrap to confirm its integrity.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization 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 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the sealed PureSet™ Tray in a dry and dark place such as a closed cupboard or drawer. Follow the instructions provided by the manufacturer of the sterilization containers, sterilization pouches, or sterilization wraps regarding the storage conditions and expiration date of the sterilized goods.

Note At the Point of Use, carefully remove the PureSet™ Tray from the sterilization container, pouch or wrap. If using a metal sterilization container, avoid hitting the PureSet™ Tray against the inside of container to avoid unintended opening of the lid.

Caution Keep dissimilar metals separated during sterilization to prevent corrosion.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

1.3 Instructions for Surgical Templates

Surgical templates must be cleaned and disinfected prior to intraoral use. During processing in the dental laboratory, templates can be cleaned as necessary without disinfection.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment used to clean and disinfect the device(s) must be strictly followed where applicable.

Cleaning the Surgical Template

1. Place the template in an ultrasonic cleaner with water and mild detergents.
2. Perform ultrasonic cleaning according to the template material manufacturer's instructions for use.
3. Remove the template from the ultrasonic cleaner and rinse thoroughly with water.
4. Allow the template to air-dry thoroughly.
5. Place the template in a suitable protective container pending disinfection or further processing.

Disinfecting the Surgical Template

1. Immerse the surgical template in a high-level disinfectant, according to the template material manufacturer's instructions for use.
2. Remove the template from the disinfectant and rinse the template thoroughly with sterile water.
3. Allow the template to air-dry thoroughly, but for no longer than 40 minutes.
4. Place the template in a suitable protective container pending the surgical procedure.

Caution Do not use heat on the surgical template.

Caution Do not autoclave the surgical template.

1.4 Instructions for NobelProcera® Supra-constructions (custom - made solutions)

Cleaning and sterilization instructions for NobelProcera® supra-constructions that include non-metallic materials, which require cleaning and disinfection and/or sterilization prior to patient contact.

Clean, disinfect, and/ or sterilize the device (incl. final abutment or framework) according to the glaze, stain, and/or veneering material manufacturer's instructions prior to use.

2. Cleaning and Sterilization Instructions (USA)

2.1 Cleaning and Sterilization Instructions for Single Devices to be processed / re-processed

Devices must be cleaned and sterilized by the end user. The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12 /AAMI ST98
- Sterilization: AAMI ST79 and ISO 17665 -1

According to EN ISO 17664, it is the responsibility of the user/ processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The devices have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

The following "Point of Use" and "Containment and Transportation" subsections are applicable only for reusable devices; otherwise go directly to "Automated Cleaning" or "Manual Cleaning "step.

Initial Treatment at Point of Use Prior to Reprocessing

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe to remove soil and debris from cavities, where applicable.

Caution All dental debris adhering to impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if all dental debris cannot be removed.

3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Please check "Disassembly Instructions" in Annex 1 to verify if the device needs to be disassembled. Disassemble device prior to cleaning by following the "Disassembly Instructions".
2. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe until the lumens are free of any visually datable soil.

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute until all visible soil is removed.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.

6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program / Washer disinfector (MMM GmbH) Type: Uniclean PL-II 15-2 EL.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).

2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.

3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer / Washer disinfector (MMM GmbH) Type: Uniclean PL-II 15-2 EL:
   - Minimum of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold deionized water
   - Draining
   - Minimum of 2 minutes rinsing with cold deionized water
   - Draining

4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.

5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Note FDA-cleared washer- disinfectors are to be used for the recommended cleaning parameters.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Please check "Disassembly Instructions" in Annex 1 to verify if the device needs to be disassembled. Disassemble device prior to cleaning by following the "Disassembly Instructions".

2. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 1 minute until all visible soil is removed.

4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of 0.5% lukewarm enzymatic cleaning agent (e.g. Cydezyme ASP and / or Neodisher Medizym; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.

6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP and / or Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.

9. Applicable to Manual Torque Wrenches: Flush the inner surfaces, lumina and cavities of Manual Torque Wrenches for a minimum of 15 seconds using a water jet pistol.

10. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.

11. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1CL (pre-vacuum cycle); Amsco Century Sterilizer, Selectomat PL/669-2CL and/or Selectomat PL/666-1CL (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL / Selectomat PL/666-1CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN 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.
   - Table 5 presents examples of suitable sterilization pouches.

Table 5 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).

3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 6):

Table 6 – Recommended Sterilization Cycles

Cycle Type	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle	132°C (270°F)	15 minutes	30 minutes
Pre-Vacuum Cycle	132°C (270°F)	4 minutes	20 minutes

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization 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 to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed /reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

2.2 Instructions for devices which are sterilized in a PureSet™ Tray

PureSet™ Trays (including the PureSet™ Plate) are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the PureSet™ Tray, Plate, and corresponding surgical/ prosthetic instruments must be cleaned and sterilized by the user.

PureSet™ Trays, Plates, and instruments can be cleaned manually, or can be cleaned in an automatic washer. After cleaning, the fully assembled PureSet™ is sealed in a metal sterilization container, sterilization pouch, or sterilization wrap and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual/Automated Cleaning: AAMI TIR 12
- Sterilization: AAMI ST79 and ISO 17665 -1

According to EN ISO 17664, it is the responsibility of the user/ processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Caution Do not deviate from the following reprocessing instructions.

Assembly: There are different versions of the PureSet™ Tray available for the different Nobel Biocare surgical and prosthetic procedures. The instruments and components which are compatible with the various trays are specified in the respective wall charts. Please contact Nobel Biocare sales office for information regarding the wall charts.

Initial Treatment at Point of Use Prior to Reprocessing

1. During surgery, always return used reusable instruments back into their designated holders in the PureSet™ Tray (refer to the pictograms and color-coded workflow on the plate of the PureSet™ Tray). To avoid potential injury or exposure to contaminated instruments, it is advised to handle the instruments using a pair of tweezers.

2. Discard single-use instruments and worn reusable instruments immediately after use.

3. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe to remove soil and debris from cavities, where applicable.

Caution Excess soil and debris should be removed from reusable devices within 1 hour of use to ensure the efficacy of the reprocessing.

4. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the PureSet™ Tray and instruments in a suitable container to avoid any contamination of personnel or the environment.

2. Transport the PureSet™ Tray and instruments to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the PureSet™ Tray and instruments with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Caution Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Disassembly of Multi-piece Instruments Prior to Cleaning

Note The Manual Torque Wrench Surgical must be disassembled prior to cleaning by removing the adapter and the rod from the wrench body as shown in Figure D.

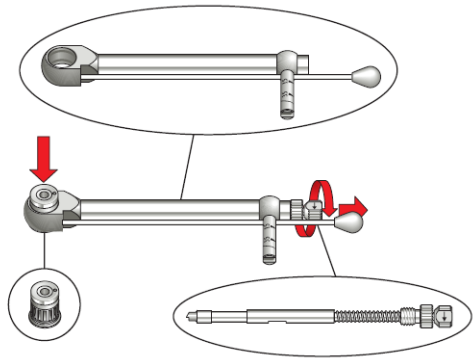


Figure D – Disassembly of the Manual Torque Wrench Surgical

Note Implant Mounts must be disassembled prior to cleaning as follows:

Unscrew the Implant Mount Screw (2) from the Implant Mount Body (1), see Figure E.

Figure E – Disassembly of the Implant Mount

Note Template abutments must be disassembled prior to cleaning as follows:

Unscrew the Template Abutment Screw (2) from the Template Abutment Body (1), see Figure F.

Figure F – Disassembly of the Guided Template Abutment

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Remove all instruments from the PureSet™ Tray.
2. Remove the plate from the PureSet™ Tray.
3. Disassemble the multi-piece instruments as described above, where applicable.
4. Thoroughly rinse all instruments, including any lumina and/or difficult-to-reach areas with lukewarm tap water using a water pistol.
5. Place all instruments back into the designated holders in the PureSet™ Tray. Use the PureSet™ Plate as a reference to ensure the instruments are placed in the correct position. Keep the multi-piece instruments disassembled.
6. Place the PureSet™ Tray with instruments in an ultrasonic bath (e.g. Bandelin Sonorex 35 kHz, 300 W_{eff}) containing 0.5% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) and treat for minimum of 10 minutes at minimum 40°C (104°F).

Caution Do not place the PureSet™ Plate into the ultrasonic bath as this can damage the plate and impact the legibility of the text and pictograms.

Automated Cleaning and Drying

The following washers were used in the Nobel Biocare validations: Steelco DS 500 and Miele G7836 CD.

1. Place the PureSet™ Tray containing the instruments and the plate into the washer separately. Ensure the PureSet™ Tray and plate are oriented in a vertical position.

Caution Remove the PureSet™ Plate from the PureSet™ Tray prior to automatic cleaning to ensure the tray and instruments are adequately cleaned.

2. Perform automatic cleaning. The following parameters were used in the Nobel Biocare validation:
   - Minimum of 2 minutes pre-washing with cold tap water at a minimum 14°C (57°F)
   - Minimum of 5 minutes washing with tap water with a 0.5% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) at 55°C (131°F)
   - Minimum of 3 minutes rinsing with cold demineralized water at minimum 18°C (64°F)

Caution The use of a cleaning solution with acidic pH (pH < 7) could potentially damage the PureSet™ Plate.

3. Dry the PureSet™ Tray containing the instruments and the PureSet™ Plate at minimum 70°C (158°F) for a minimum of 10 minutes.

Manual Cleaning and Drying

PureSet™ Tray and Plate

1. Remove all the instruments from the PureSet™ Tray.
2. Remove the plate from the PureSet™ Tray.
3. Scrub the PureSet™ Tray under running tap water with a soft bristled nylon brush for a minimum of 3 minutes until all visible soil is removed.
4. Immerse a soft bristled nylon brush in a 0.5% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) at minimum 40°C (104°F). Scrub the PureSet™ Plate with the soft bristled nylon brush for a minimum of 1 minute until all visible soil is removed. Ensure the entire surface of the plate is thoroughly scrubbed.

Caution The use of a cleaning solution with acidic pH (pH < 7) could potentially damage the PureSet™ Plate.

5. Thoroughly rinse the PureSet™ Plate for a minimum of 1 minute under running tap water to remove all detergent.
6. Flush the grommets (instrument holders) with tap water using a water pistol for a minimum of 30 seconds.
7. Place the PureSet™ Tray (without the plate) into an ultrasonic bath (e.g. frequency 37 kHz effective ultrasonic power 400 W) for a minimum of 10 minutes with a 0.6% solution of mildly alkaline detergent (e.g. Neodisher Mediclean) at minimum 40°C (104°F).
8. Rinse the PureSet™ Tray for a minimum of 1 minute under cold running tap water to remove all cleaning solution.
9. Dry the PureSet™ Tray and the plate with suitable equipment (compressed air).

PureSet™ Instrumentation

1. Disassemble the multi-piece instruments prior to cleaning as described above.

2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

3. Scrub the outer surfaces of the device with soft-bristled nylon brush until all visible soil is removed.

4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; Neodisher Medizym) using an irrigation needle connected to a 20 ml syringe.

5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.

6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. Immerse the device in an ultrasonic bath (e.g. Bandelin frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing 0.5% lukewarm enzymatic cleaning agent (e.g. Cidezyme ASP; Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F).

8. Flush the inner surfaces, lumina and cavities (where applicable) with 20ml lukewarm tap water using an irrigation needle connected to a 20ml syringe.

9. Flush the inner surfaces, lumina and cavities of Manual Torque Wrenches for a minimum of 1 minute using a water jet pistol.

10. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.

11. Dry with compressed air or clean with lint-free single use wipes.

Reassembly of the PureSet™ Tray, Plate, and Instrumentation

Reassemble the PureSet™ Tray and plate and replace the instruments (including multi-piece instruments) in their designated holders in the PureSet™ Tray (refer to the pictograms and color-coded workflow on the plate of the PureSet™ Tray). To avoid potential injury, it is advised to handle the instruments using a pair of tweezers.

Caution Ensure that the plate is properly seated on the PureSet™ Tray to prevent damage to the plate or to instruments during subsequent handling.

Caution Keep dissimilar metals separated to prevent corrosion during sterilization. Refer to the Materials section in the Nobel Biocare IFU for the respective surgical/prosthetic tooling for information regarding the metals contained in the device.

Visual Inspection

After cleaning, drying, and reassembly of the PureSet™ Tray, plate, and instrumentation, inspect all components to confirm the functional integrity, to confirm the legibility of any text (where applicable) and to ensure there is no residual soil, corrosion or damage. Any devices with signs of corrosion or damage must be discarded and replaced. The PureSet™ Plate is available as a spare part and should be replaced if the plate is discolored or if the legibility of the pictograms or the text is compromised.

Sterilization

1. Pack the assembled PureSet™ Tray (with instruments and plate) in a metal sterilization container, sterilization pouch or sterilization single wrap. The metal sterilization container, sterilization pouch or sterilization single wrap should fulfill the following requirements:
   - EN ISO 11607, ST 77 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

Table 7 presents examples of suitable sterilization containers, pouches, and wraps.

Table 7 – Recommended Sterilization Containers, Pouches, and Wraps for PureSet™

Container/Pouch/Wrap	Description
Sterilization Container	Aesculap® Sterilization Container (Part # JK289)
Sterilization Pouch	Cardinal Health 18"x22" Pouch (Part # 91822)
Sterilization Wrap	Cardinal Health Convertor Brand Bioshield Regular Sterilization Wrap (Part # 4040)

Note The PureSet™ Tray is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated sterilization container, sterilization pouch or sterilization wrap in order to maintain sterility of the enclosed medical instruments until used.

2. Label the metal sterilization container, sterilization pouch or sterilization wrap with necessary information such as expiration date, lot (if applicable), sterility information, product name with article number.

3. Ensure the PureSet™ Tray is sealed in the sterilization container/ pouch/wrap and place into the autoclave/sterilizer. The PureSet™ Tray must be sterilized in its "ready for use" state.

4. Sterilize the devices. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters Table 8:

Table 8 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle[1] at saturated steam pressure	132°C (270°F)	15 minutes	30 minutes
Pre-Vacuum Cycle[1] at saturated steam pressure	132°C (270°F)	4 minutes	20 minutes

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

Caution Do not use gravity sterilization if the PureSet™ Tray is sealed in a metal sterilization container.

After sterilization of the PureSet™ Tray, inspect the sterilization container, pouch, or wrap to confirm its integrity.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization 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 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the sealed PureSet™ Tray in a dry and dark place such as a closed cupboard or drawer. Follow the instructions provided by the manufacturer of the sterilization

containers, sterilization pouches, or sterilization wraps regarding the storage conditions and expiration date of the sterilized goods.

Note At the Point of Use, carefully remove the PureSet™ Tray from the sterilization container, pouch or wrap. If using a metal sterilization container, avoid hitting the PureSet™ Tray against the inside of container to avoid unintended opening of the lid.

Caution Keep dissimilar metals separated during sterilization to prevent corrosion.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

2.3 Instructions for Surgical Templates

Surgical templates must be cleaned and disinfected prior to intraoral use. During processing in the dental laboratory, templates can be cleaned as necessary without disinfection.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment used to clean and disinfect the device(s) must be strictly followed where applicable.

Cleaning the Surgical Template

1. Place the template in an ultrasonic cleaner with water and mild detergents.
2. Perform ultrasonic cleaning according to the template material manufacturer's instructions for use.
3. Remove the template from the ultrasonic cleaner and rinse thoroughly with water.
4. Allow the template to air-dry thoroughly.
5. Place the template in a suitable protective container pending disinfection or further processing.

Disinfecting the Surgical Template

1. Immerse the surgical template in a high-level disinfectant, according to the template material manufacturer's instructions for use.
2. Remove the template from the disinfectant and rinse the template thoroughly with sterile water.
3. Allow the template to air-dry thoroughly, but for no longer than 40 minutes.
4. Place the template in a suitable protective container pending the surgical procedure.

Caution Do not use heat on the surgical template.

Caution Do not autoclave the surgical template.

2.4 Instructions for NobelProcera® without restoration - NobelProcera® devices / Titanium Abutment Blank Nobel Biocare N1™ TCC)

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe. Repeat this step until the lumens are free of any visually datable soil.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washers were used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program / MMM GmbH Type: Uniclean PL-II 15-2 EL.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum of 2 minutes pre-cleaning with cold tap water
   - Draining
   - For all NobelProcera® devices expect Titanium Abutment Blank Nobel Biocare N1™ TCC: Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean). For Titanium Abutment Blank Nobel Biocare N1™ TCC use instead: Minimum of 10 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % high alkaline detergent (e.g. Neodisher Mediclean Forte).
   - Draining
   - For all NobelProcera® devices expect Titanium Abutment Blank Nobel Biocare N1™ TCC: Minimum of 3 minutes neutralization with deionized water. For Titanium Abutment Blank Nobel Biocare N1™ TCC use instead: Minimum 3 minutes with 0.1% neodisher Z in cold deionized water.
   - Draining
   - Minimum of 2 minutes rinsing with cold deionized water
   - Draining

4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.

5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Manual Cleaning and Drying

1. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.

3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Neodisher Medizym; maximum of 45°C (113°F) using an irrigation needle connected to a 20 ml syringe.

4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 1 minute until all visible soil is removed.

5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.

8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.

9. Dry with compressed air or clean and lint-free single use wipes.

Sterilization

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN 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
   - Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).

2. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

3. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters.

Table 9 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle[1] at saturated steam pressure	132°C (270°F)	15 minutes	15 minutes
Pre-Vacuum Cycle[1] at saturated steam pressure	132°C (270°F)	4 minutes	20 minutes

2.5 Instructions NobelProcera® devices with restoration

2.5.1 Universal Abutment Nobel Biocare N1™ Base Tri; Universal Abutment Nobel Biocare N1™ Base Tri Bridge

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Disassemble the Universal Abutment prior to cleaning by removing the screw from the device.

2. Immerse the devices in lukewarm water for a minimum of 5 minutes until the next step is initiated.

3. Immerse the devices in an 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 20 minutes.

4. Scrub the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.

5. Flush lumina (where applicable) with tap water using a 20 ml syringe until all visible soil is removed. Use a single-use wipe to catch dripping fluid from flushing. If the discoloration of the wipe is indicating soil, then repeat steps 2-5.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).

2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.

3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum of 4 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum temperature of 55°C (131°F) tap water and an 0.5% alkaline detergent (e.g. Neodisher Mediclean Forte)
   - Draining
   - Minimum of 6 minutes rinsing with 0.1% neodisher Z
   - Draining
   - Minimum of 3 minutes rinsing with cold deionized water
   - Draining

4. Dry with compressed air or lint-free single-use wipes.

Manual Cleaning and Drying

1. Disassemble the Universal abutment prior to cleaning by removing the screw from the device.

2. Immerse devices in lukewarm water until the next step is initiated for a minimum of 5 minutes.

3. Immerse the devices in an 0.5% enzymatic cleaning solution (e.g. Neodisher Medizym) prepared with lukewarm tap water for a minimum of 20 minutes.

4. Scrub the outer surfaces of the devices with a soft-bristled nylon brush under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.

5. Flush lumina and cavities (where applicable) with cold tap water using a 20 ml syringe. Use a single-use wipe to catch dripping fluid from flushing. If the discoloration of the wipe is indicating soil, then repeat steps 1-4.

6. Prepare an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing the 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym). Degas the solution by running the ultrasonic bath for a minimum of 30 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

7. Immerse the device in the ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing the 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

8. Rinse the device with deionized water for a minimum of 1 minute until all residues of cleaning solution are removed.

9. Dry with compressed air or lint-free single-use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, or if dental debris remains on the device. Properly dispose of any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Selectomat PL/666-1CL (pre-vacuum cycle); Selectomat PL/666-1CL (gravity cycle).

Note When using Selectomat PL/666-1CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - FDA cleared sterilization accessories are to be used for the recommended sterilization parameters for wrapping the devices supplied non-sterile before user sterilization.
   - EN ISO 11607 compliant
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F) and sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging from mechanical damage.

Table 10 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).

3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters:

Table 11 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle at saturated steam pressure	132°C (270°F)	15 minutes	15 minutes
Pre-Vacuum Cycle at saturated steam pressure	132°C (270°F)	4 minutes	20 minutes

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization 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 to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

2.5.2 Universal Base Conical Connection and Brånemark System®; Universal Abutment Nobel Biocare N1™ TCC

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Disassemble the Universal Abutment prior to cleaning by removing the screw from the device.

2. Immerse the devices in lukewarm water for a minimum of 5 minutes until the next step is initiated.

3. Immerse the devices in an 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 20 minutes.

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.

5. Flush lumina (where applicable) with tap water using a 20 ml syringe until all visible soil is removed. Use a single-use wipe to catch dripping fluid from flushing. If the discoloration of the wipe is indicating soil, then repeat steps 1-4.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).

2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.

3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum of 4 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 10 minutes cleaning with a minimum temperature of 55°C (131°F) tap water and an 0.5% alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes rinsing with cold deionized water
   - Draining

4. Dry with compressed air or lint-free single-use wipes.

Manual Cleaning and Drying

1. Disassemble the Universal abutment prior to cleaning by removing the screw from the device.

2. Immerse devices in lukewarm water until the next step is initiated for a minimum of 5 minutes.

3. Immerse the devices in an 0.5% enzymatic cleaning solution (e.g. Neodisher Medizym) prepared with lukewarm tap water for a minimum of 20 minutes.

4. Scrub the outer surfaces of the devices with a soft-bristled nylon brush under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.

5. Flush lumina and cavities (where applicable) with cold tap water using a 20 ml syringe. Use a single-use wipe to catch dripping fluid from flushing. If the discoloration of the wipe is indicating soil, then repeat steps 2-5.

6. Prepare an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing the 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym). Degas the solution by running the ultrasonic bath for a minimum of 30 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

7. Immerse the device in the ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing the 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

8. Rinse the device with deionized water for a minimum of 1 minute until all residues of cleaning solution are removed.

9. Dry with compressed air or lint-free single-use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, or if dental debris remains on the device. Properly dispose of any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Selectomat PL/666-1CL (pre-vacuum cycle); Selectomat PL/666-1CL (gravity cycle).

Note When using Selectomat PL/666-1CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - FDA cleared sterilization accessories are to be used for the recommended sterilization parameters for wrapping the devices supplied non-sterile before user sterilization.
   - EN ISO 11607 compliant
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F) and sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging from mechanical damage.

Table 12 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	Steriking pouch (Wipak)
Pre-vacuum Cycle	Steriking pouch (Wipak)

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).

3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters:

Table 13 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)
Gravity Cycle at saturated steam pressure	132°C (270°F)	15 minutes	15 minutes
Pre-Vacuum Cycle at saturated steam pressure	132°C (270°F)	4 minutes	20 minutes

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization 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 to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/

sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

2.5.3 On1™ Concept

Cleaning

1. Remove debris in lukewarm water and immerse device in cleaning solution.
2. Scrub device with soft bristled nylon brush and flush lumen.
3. Manual cleaning: Prepare an ultrasonic bath using an enzymatic cleaning solution and immerse device in ultrasonic bath for at least 5 minutes.
4. Automated cleaning: Load device into washer and run the cleaning and disinfection cycle.
5. Rinse and dry device.

Sterilization

The user should consult the crown/restoration material manufacturer's recommendations regarding sterilization.

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 4 minutes when using the pre-vacuum method and 15 minutes when using the gravity method.

Table 14

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	

Only use FDA cleared sterilization packaging and sterilizers for the abutments delivered non- sterile and requiring end user sterilization.

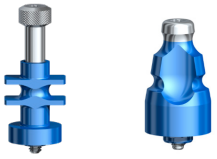
3. Annex 1: Disassembly Instructions

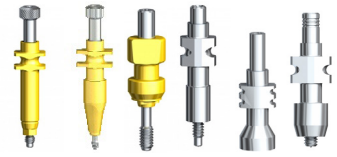
3.1 Esthetic Abutments

Disassemble Esthetic Abutment prior to Manual and/or Automated Cleaning by removing the screw.

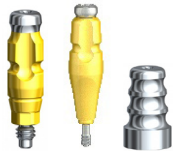
3.2 Impression Copings

(incl. On1™ Impression Copings)





Impression Copings Open Tray



Impression Copings Closed Tray

Disassemble Impression Copings prior to Manual and/or Automated cleaning by removing the screw or guide pin from the coping.

3.3 Nobel Biocare N1™ Base Concept

Disassemble the devices prior to Manual and/or Automated cleaning by removing the screw from the device with exception of the Position Locator.

Position Locators Nobel Biocare N1™ Base do not require the disassembly of the screw prior to cleaning and sterilization.

3.4 Bone Mill and Bone Mill Guide

Disassemble the N1™ bone mill guide and screw prior to Manual and/or Automated cleaning by unscrewing the screw of the bone mill guide.

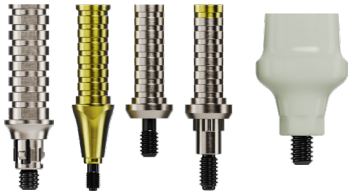
3.5 Position Locators

Disassemble the position locator from the Link if applicable and screw prior to cleaning and sterilization.

3.6 Drill Stops

Disassemble the Drill Stops by removing the screw prior to Manual and/or Automated cleaning.

3.7 Temporary Abutments and Copings



Disassemble the screw from the abutment prior to Manual and/or Automated cleaning.

3.8 Abutment Retrieval Instrumentation

Disassemble Abutment Retrieval Instrument Zirconia CC prior to Manual and/or Automated cleaning by removing the hollow cylinder from the activating pin prior to Manual and/or Automated cleaning.

3.9 Trefoil™

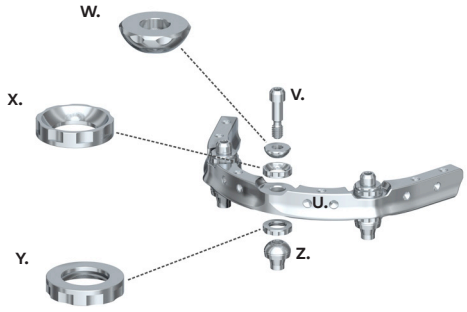


Figure G – Disassembly of Trefoil™ Bar

Disassemble Trefoil™ Bar prior to Manual and/or Automated cleaning following the Instructions in Figure G.