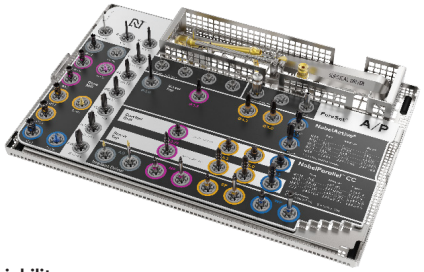
PureSet Tray
Instructions for Use



Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

PureSet Trays are reusable trays to be used in combination with Nobel Biocare surgical/prosthetic instruments and components. The PureSet Trays are used to store and organize the instruments and components during the surgical, restorative and reprocessing procedures. The PureSet Tray consists of three parts: 1) a base with holders to accommodate the different surgical instruments and components, 2) a removable PureSet Plate (spare part) to indicate the surgical workflow (in case of the surgical tray) and the position of the instruments within the tray, and 3) a lid to securely contain the instruments during reprocessing. There are different versions of the PureSet Tray available for the different Nobel Biocare implant systems: Trefoil PureSet Tray (276.1 mm x 176 mm x 78 mm), NobelActive/NobelParallel CC PureSet Tray (276 mm x 176 mm x 63 mm), NobelReplace CC PureSet Tray (276 mm x 176 mm x 51 mm), Nobel Biocare N1™ PureSet (122.1x115x45.6), Prosthetic PureSet Tray (122.1x115x45.6), NobelActive Guided PureSet Tray (276.1 mm x 176 mm x 58.9 mm), Nobel Parallel CC Guided PureSet Tray (276.1mm x 176 mm x 58.9 mm) and NobelReplace CC Guided PureSet Tray (276.1 mm x 176 mm x 58.9 mm).).

Intended Use:

The Nobel Biocare PureSet Trays are intended for use in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterlization wrap. Sterilization validations for the worst case Nobel Biocare PureSet Tray (276.1 mm x 176 mm x 78 mm) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc.

Indications:

TThe Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case PureSet Tray included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1082 grams (NobelActive/NobelParallel CC PureSet Tray), 945 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet Tray), 486 (Prosthetic PureSet Tray), 1117 grams (NobelActive Guided PureSet Tray), 1120 grams (NobelParallel CC Guided PureSet Tray) and 1156 grams (NobelReplace CC Guided PureSet Tray).

Method	Steam Sterilization (Moist Heat Sterilization)	
Cycle	Dynamic-Air-Removal (fractionated vacuum)	Gravity-Displacement
Temperature	132°C (270°F)	132°C (270°F)
Exposure time for a single-use pouched device	4 minutes (full-cycle)	15 minutes (full-cycle)
Minimum drying times	20 minutes	30 minutes

Contraindications:

None identified.

Cautions:

General:

It is strongly recommended that PureSet Trays are used only with dedicated Nobel Biocare surgical instruments and prosthetic components. The storage and organization of non-Nobel Biocare instruments and components can lead to mechanical and/or instrumental failure.

It is strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

To avoid scratching the stainless-steel base, do not apply force, twist, or turn the drill around when evaluating the length of the drill's depth markings on the drill gauge.

Before Surgery:

All components, instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:

Care and maintenance of instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Materials:

- PureSet Tray: stainless steel / polyetheretherketone (PEEK) / silicone.
- PureSet Plate: aluminum anodized with print.

Sterility and Reusability Information:

The PureSet Tray is delivered non-sterile and intended for reuse. Prior to first use and reuse clean, disinfect and/or sterilize using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Cleaning and Sterilization Instructions:

Cleaning and sterilization instructions for devices which are delivered non-sterile by Nobel Biocare, are intended for reuse, and must be sterilized by the user prior to each use, where the devices are mounted in a PureSet Tray, and the tray is sealed in a pouch, container, or wrap.

With these cleaning and sterilization instructions, 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 is actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise, any deviation by the processor from the provided instructions should be properly evaluated for effectiveness and potential adverse consequences.

The PureSet Tray has been designed for both automated and manual cleaning and disinfection (by means of thermodisinfectors) as well as sterilization. The following section describes the reprocessing of the PureSet Tray step by step.

Caution: Do not deviate from the described reprocessing instructions.

Assembly:

The type and number of surgical instruments and components used in combination with the PureSet Tray is specified in the wall charts of the respective products:

Table 1: Information on wall charts

Wall Chart Article Number	Wall Chart Description
300211	Wall Chart Trefoil PureSet
300565	NobelActive® PureSet Wall Chart
300566	NobelParallel™ CC PureSet Wall Chart
300567	NobelReplace® CC PureSet Wall Chart
300781	NobelActive®/NobelParallel™ CC PureSet Tray Wall Chart
301232	Wall Chart Prosthetic PureSet Basic

Point of Use:

Dispose of single-use instruments, dull reusable drills and any other worn-out reusable instruments directly after use.

Remove excess soil from reusable instruments directly after use (within a maximum of 1 hour postoperatively), using absorbent paper wipes. Additionally, rinse the medical devices with cold running tap water.

During surgery, always put used reusable instruments back into their designated holders of the PureSet Tray (see pictograms and color-coded workflow on the PureSet Plate). To avoid potential injury or exposure to contaminated instruments, it is advised to pick up the instruments using a pair of tweezers.

Containment and Transportation:

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

Store the PureSet Tray with the instruments in a container to avoid any contamination of the environment.

Cleaning Guidelines:

Clean the device using automated or manual cleaning, disinfect and dry the device.

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**.

A

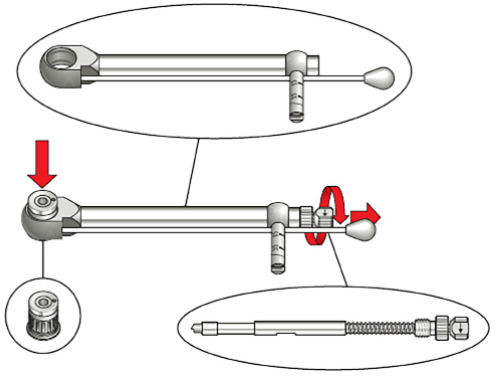


Figure A: Disassembly of the Manual Torque Wrench Surgical

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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**.

B

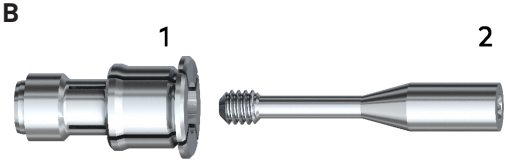

Figure B: Implant Mount

Template abutment must be disassembled prior to cleaning as follows:

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

C

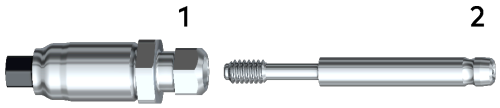

Figure C: Implant Mount

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):
The following washer/disinfector was used in the Nobel Biocare validation: Steelco DS 500.

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

1. Remove all multi-piece instruments from the PureSet Tray.
2. Disassemble all multi-piece instruments, where applicable.
3. Remove all instruments with lumina (where applicable) and difficult-to-reach areas (e.g. blind holes, cavities) from the PureSet Tray.
4. Remove the PureSet Plate from the PureSet Tray.
5. Flush thoroughly all lumens (where applicable) and difficult-to-reach areas of the removed instruments with a with a syringe with 20ml tap water.
6. Place all instruments and the disassembled multi-piece instruments back into the designated holders in the PureSet Tray.
7. Place the assembled PureSet Tray in a bath of 0.5% solution of alkaline cleaning agent (e.g. Neodisher Mediclean) for 5-10 minutes at 40°C (104°F) with ultrasonic actions.

Caution: Do not place the PureSet Plate into the ultrasonic bath.

8. Put the PureSet Tray and the PureSet Plate into the washer-disinfector separately. Place the PureSet Plate beside the PureSet Tray in a vertical position.

Caution: Please ensure that the PureSet Plate is removed from the PureSet Tray before the automatic cleaning and disinfection is carried out.

9. Carry out automatic cleaning and disinfection under consideration of national requirements with regard to the A0-Value (EN ISO 15883). The following parameters were used in the Nobel Biocare validation:
   - 2 minutes pre-washing with cold demineralized water
   - 5 minutes washing with tap water at 55°C (131°F) with a 0.5% solution of alkaline cleaning agent (e.g. Neodisher Mediclean)

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

   - 3 minutes rinsing with cold demineralized water
   - 5 minutes thermal disinfection with demineralized water at 93°C (200°F)

10. Dry the PureSet Tray and the PureSet Plate according to the cleaner/disinfector manufacturer's instructions for use.

Manual Cleaning, Disinfection and Drying:
Caution: The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean, disinfect, and/or dry the device(s) must be strictly followed where applicable.

1. Remove all the instruments from the PureSet Tray.
2. Disassemble all multi-piece instruments, where applicable.
3. Remove the PureSet Plate from the PureSet Tray.
4. Manually clean all the instruments according to the information provided in the respective Nobel Biocare Instructions for Use for the implant, restorative component or instrument (please refer to the corresponding IFUs).
5. Scrub the PureSet Tray under cold running tap water with a soft bristled nylon brush until all visible soil is removed.
6. Take the soft bristled nylon brush and immerse it into a 0.5% solution of alkaline cleaning agent (e.g. Neodisher Mediclean) at 40°C (104°F). Scrub the PureSet Plate with the soft bristled nylon brush until all visible soil are removed.

Caution: The use of a cleaning solution with acidic pH (pH < 7) could potentially damage the PureSet Plate. Make sure the complete surface area is scrubbed. If needed, repeat several times.

7. Rinse the PureSet Plate to remove all cleaning solution under cold running tap water.
8. Flush the grommets (instrument holders) with water pistol until all visible soil is removed.
9. Place the PureSet Tray (without the PureSet Plate) into an ultrasonic bath for 5-10 minutes with a 0.5% solution of alkaline cleaning agent (e.g. Neodisher Mediclean) at 40°C (104°F).
10. Rinse the PureSet Tray under cold running tap water to remove all cleaning solution.
11. Dry the PureSet Tray and the PureSet Plate with suitable equipment (compressed air).
12. Immerse the PureSet Tray into a 100% disinfection solution (e.g. Cidex OPA) at ambient temperature (10°-30°C (50°-86°F)) for 12 minutes.

Caution: Do not place the PureSet Plate into the disinfection solution.

13. Disinfect the PureSet Plate using wipe disinfection (e.g. Meliseptol HBV) for 1 minute ± 10 seconds.
14. Rinse the PureSet Tray and the PureSet Plate with demineralized water 3 times for 1 minute ± 10 seconds to remove all disinfection solution.
15. Dry the PureSet Tray and the PureSet Plate with suitable equipment (compressed air).
16. Assemble PureSet Tray with PureSet Plate and reusable instruments (including multi-piece instruments).

Caution: Ensure that the PureSet Plate is carefully placed on the PureSet Tray.

Visual Inspection:
After cleaning, disinfection and drying, visually inspect the PureSet Tray (including PureSet Plate and reusable instruments) for cleanliness, function and readability of text. Check all parts for visual soil, corrosion and damage. All devices with signs of corrosion and/or damage must be disposed and replaced. The PureSet Plate is available as a spare part and should be replaced as soon as discoloration is compromising visibility of the pictograms or readability of the text.

Note: The PureSet Tray (excluding PureSet Plate) has been validated to withstand at least 500 reprocessing cycles.

Packaging and Labeling:

1. Pack the assembled PureSet Tray in a metal sterilization container, sterilization pouch or single wrap. The metal sterilization container, sterilization pouch or sterilization single wrap 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.
   - FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

   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.

Sterilization:
Note: The manufacturer's instructions for use for the sterilization equipment and any accessories must be strictly followed where applicable.

Place the sealed PureSet Tray into the autoclave/sterilizer. The PureSet Tray must be sterilized in its "ready for use" state.

Both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

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

- Gravity Cycle Method: Steam sterilization at 132°C (270°F) for 15 minutes, followed by drying for a minimum of 30 minutes in chamber.
- Pre-Vacuum Method: Steam sterilization at 132°C (270°F) for 4 minutes, followed by drying for a minimum of 20 minutes in chamber

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, SN EN 13060, EN 285, EN ISO 17665-1, AAMI ST79 or your national standard. The manufacturer's instructions for use for the autoclave / sterilizer 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 and sterilization wraps regarding the storage conditions and expiration date of sterilized goods.

Caution: Keep dissimilar metals separated during sterilization to prevent corrosion.

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.

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden.
www.nobelbiocare.com

Distributed in USA by:
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887 USA

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Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate


Date


Date of manufacture


Do not resterilize


Do not re-use


Do not use if package is damaged


Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry

Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation


Temperature limit


Tooth number


Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier


Use-by date