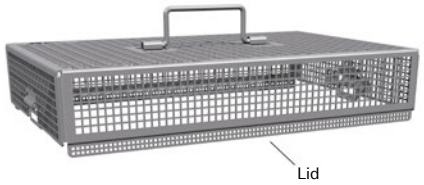
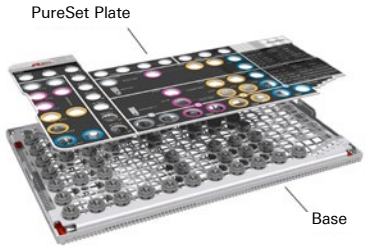
PureSet Tray
Instructions for use





Important: Please read.

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, expressed 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, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

The PureSet Tray is a reusable surgical tray to be used in combination with Nobel Biocare surgical instruments and components. The PureSet Tray is used to store and organize the instruments and components during both the surgical 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 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) and NobelReplace CC PureSet Tray (276 mm x 176 mm x 51 mm), NobelActive Guided PureSet Tray (276.1 mm x 176 mm x 58.9 mm), NobelParallel CC Guided PureSet Tray (276.1 mm 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 Tray is intended for use in healthcare facilities to store and organize Nobel Biocare surgical 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; it is 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:

The Nobel Biocare PureSet Tray is used in healthcare facilities to store and organize Nobel Biocare surgical 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; it is 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) and 945 grams (NobelReplace CC 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:

There are no specific contraindications relevant for the PureSet Tray.

Cautions:

It is strongly recommended that the PureSet Tray is used only with Nobel Biocare surgical instruments and components. The storage and organization of non-Nobel Biocare instruments and components can lead to mechanical, cleaning, sterilization and/or instrumental failures.

It is strongly recommended that clinicians, new as well as experienced implant users, 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.

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

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.

Reprocessing instructions:

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

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

The PureSet Tray has been designed for both manual and automated 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:

118155 Trefoil PureSet Wall Chart

155996 NobelActive PureSet Wall Chart

155997 NobelParallel CC PureSet Wall Chart

155998 NobelReplace CC PureSet Wall Chart

Point of use:
1. Dispose single-use instruments, dull reusable drills and any other worn-out reusable instruments directly after use.
2. 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 running water.
3. During surgery, always put used reusable instruments back into the PureSet Tray using their designated holders (see pictograms and color-coded workflow on the PureSet Plate). The sharp instruments should be handled with a pair of tweezers to avoid injury.

Containment and transportation:
1. 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.
2. Store the PureSet Tray with the instruments in a container to avoid any contamination of the environment.

Automated cleaning, disinfection and drying (incl. pre-cleaning):
1. Remove all multi-piece instruments (e.g. Manual Torque Wrench Surgical) from the PureSet Tray and disassemble the instruments according to their respective Instructions for Use.
2. Remove all instruments with lumens and difficult-to-reach areas (e.g. blind holes, cavities) from the PureSet Tray.
3. Remove the PureSet Plate from the PureSet Tray.
4. Flush thoroughly all lumens and difficult-to-reach areas of the removed instruments with a water pistol.
5. Place all instruments and the disassembled multi-piece instruments back into the designated holders in the PureSet Tray.
6. Place the assembled PureSet Tray in a bath of 0.5% solution of alkaline cleaning agent[A] for 5-10 minutes at 40°C temperature with ultrasonic actions. The manufacturer's instructions for use for the ultrasonic bath and the detergent must be strictly followed.

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

7. Put the PureSet Tray and the PureSet Plate into the washer-disinfector separately.

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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.

8. Carry out automatic cleaning and disinfection under consideration of national requirements in regards to A0-Value (EN ISO 15883). The manufacturer's Instructions for Use for the washer-disinfector must be strictly followed. 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 with a 0.5% solution of alkaline cleaning agent[B].

   Caution: The use of a cleaning solution with acidic pH (pH below 7) could potentially damage the PureSet Plate.
   – 3 minutes rinsing with cold demineralized water.
   – 5 minutes thermal disinfection with demineralized water at 93°C.
9. Dry the PureSet Tray and the PureSet Plate by following the instructions provided by the manufacturers of the washer-disinfector.

Manual cleaning, disinfection and drying:

1. Remove all the instruments from the PureSet Tray.
2. Disassemble the multi-piece instruments (e.g. Manual Torque Wrench Surgical) according to their respective Instructions for Use.
3. Remove PureSet Plate from PureSet Tray.
4. Manually clean all the instruments according to the information provided in the respective Instructions for Use for the implant, restorative component or instrument.
5. Scrub the PureSet Tray under running water (water quality: drinking water) with a soft bristled nylon brush until all visible soil are removed.
6. Take the soft bristled nylon brush and immerse it into a 0.5% solution of alkaline cleaning agent[A] at 40°C. 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 below 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 (follow the instructions provided by the manufacturer of the cleaning solution) under running water (water quality: drinking water).
8. Flush the grommets (instrument holders) with a water pistol until all visible soil are 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[A] at 40°C. The manufacturer's Instructions for Use for the ultrasonic bath and detergent must be strictly followed.
10. Rinse the PureSet Tray to remove all cleaning solution (follow the instructions provided by the manufacturer of the cleaning solution) under running water (water quality: drinking water).
11. Dry the PureSet Tray and the PureSet Plate with suitable equipment (compressed air).
12. Immerse the PureSet Tray into a 100% disinfection solution[C] at ambient temperature (20° ± 10°C) for 12 minutes.

    Caution: Do not place the PureSet Plate into the disinfection solution.
13. Disinfect the PureSet Plate using wipe disinfection[D] for 1 minute ± 10 seconds or follow the instructions provided by the manufacturer.
14. Rinse the PureSet Tray and the PureSet Plate with demineralized water 3 times for 1 minute ± 10 seconds to remove all disinfection solution (follow the instructions provided by the manufacturer of the 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 (incl. multi-piece instruments).

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

[A, B, C, D] See section "Reprocessing validation study information" for more details about the cleaning agents and disinfectants used during Nobel Biocare validation.

Maintenance and packaging:

1. 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.
2. Pack the assembled PureSet Tray in a sterilization pouch or single wrap. The 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, FDA-cleared sterilization pouch or sterilization wrap in order to maintain sterility of the enclosed medical instruments until used.
3. Label sterilization pouch or sterilization wrap with necessary information such as expiration date, lot (if applicable), sterility information, product name with article number.

Sterilization:

1. Place the sealed PureSet Tray into the autoclave/sterilizer. The PureSet Tray must be sterilized in its "ready for use" state.
2. Run the autoclave/sterilizer with the following recommended parameters:
   – Temperature 270°F (132°C) for 4 minutes when using pre-vacuum method (sterilization pouch and sterilization wrap) and 15 minutes when using the gravity method (sterilization pouch and sterilization wrap). Dry for 30 minutes.

Note: Autoclave 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.

3. 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 pouches and sterilization wraps regarding storage conditions and expiration date of sterilized goods.

Precautions: Keep dissimilar metals separated during sterilization to resist corrosion.

Nobel Biocare reprocessing validation study information:

[A] Alkaline cleaning agent - ultrasonic bath: Neodisher® MediClean

[B] Alkaline cleaning agent - automated cleaning: Neodisher® MediClean

[C] Manual disinfection solution: CIDEX® OPA

[D] Wipe disinfection: Meliseptol® HBV tissues

Washer/disinfector: Steelco DS 500

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 as 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.

Warning: The use of non-sterile components may lead to infection of tissues or infectious diseases.

Warning: Do not use device if the packaging has been damaged or previously opened.

Materials:

PureSet Tray: stainless steel / polyetheretherketone (PEEK) / silicone.

PureSet Plate: aluminium anodized with print.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels 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.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

For Prescription Use Only.
Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

Catalogue number

Batch code


Caution

Non-sterile


Consult instructions for use


Do not use if package is damaged

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