

Kit Boxes

Instructions for use



Important: Please read.

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Description:

Kit Boxes are made from autoclavable material and have two main parts: A base and a plate (see Figure 1). The plastic base is over molded with a silicon rubber and carries the top plate that can be exchanged. The plate has holes or indentations for surgical instruments and tools. These holes hold the silicon grommet used for securing the instruments and tools. The grommets are designed to allow sterilization of the instruments. A lid made from transparent or semitransparent autoclavable plastic covers the base and the plate.

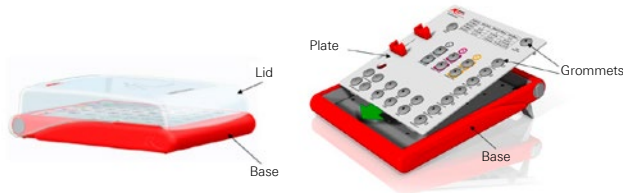


Figure 1: Pictorial representation of the Kit Box and its components.

The Kit Boxes are available in two sizes: The larger size Kit Boxes 170 mm x 145 mm x 57 mm and the smaller size Kit Boxes 170 mm x 70 mm x 57 mm. The Kit Boxes are available for a variety of Nobel Biocare implants, prosthetics and retrieval instruments.

Assortment of large size Kit Boxes:

Branemark System Surgery Kit Box, NobelReplace Straight Surgery Kit Box, Branemark System Guided Surgery Kit Box, NobelReplace Straight Guided Surgery Kit Box, NobelReplace Tapered Guided Surgery Kit Box, Guided Drill Guide Tapered Kit Box, NobelActive Guided Surgery Kit Box, Guided Drill Guide NobelActive Kit Box, NobelReplace Tapered Surgery Kit Box, NobelReplace Tapered Guided Surgical Access Kit Box, NobelReplace Tapered Guided Drilling Kit Box, NobelReplace Conical Connection Surgery Kit Box, Abutment Screw Retrieval Kit Box, NobelSpeedy Groovy Surgery Kit Box, NobelActive Surgery Kit Box, NobelActive Guided Surgical Access Kit Box, NobelActive Guided Drilling Kit Box, NobelParallel CC Surgery Kit Box, NobelParallel CC Guided Surgical Access Kit Box, NobelParallel CC Guided Drilling Kit Box.

Assortment of small size Kit Boxes:

Spare Kit Box, Branemark System Second Stage Surgery Kit Box, Nobel Biocare Flapless Surgery Kit Box, Immediate Provisional Implant Kit Box, Guided Drill Guide Kit Box,

Implant Driver Kit Box Conical Connection, NobelReplace Guided Implant Insertion Kit Box, NobelReplace PS Guided Implant Insertion Kit Box, NobelReplace CC Guided Implant Insertion Kit Box, Prosthetic Kit Box, Implant Retrieval Kit Box, Abutment Retrieval Kit Box, Bone Mill Kit Box Conical Connection, NobelActive Guided Implant Insertion Kit Box, NobelParallel CC Implant Insertion Kit Box.

Intended use:

The Nobel Biocare Kit Boxes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses.

Indications:

The Nobel Biocare Kit Boxes are used in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses.

Contraindications:

There are no specific contraindications relevant for the Kit Boxes.

Cautions:

It is strongly recommended that the Kit Boxes are used only with Nobel Biocare surgical instruments and 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 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.

Materials:

The Kit Boxes are composed of autoclavable Silicon and Polymer.

Sterility and reusability information:

The Kit Boxes are delivered non-sterile and are intended for re-use. Prior to first use and re-use clean, disinfect and sterilize the Kit Boxes using the recommended parameters.

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

Cleaning and sterilization instructions:

The Kit Boxes have been designed for automated cleaning and disinfection (by means of thermo-disinfectors) as well as sterilization. The following section describes the reprocessing of the Kit Boxes step by step.

Caution: Do not deviate from the described reprocessing instructions.

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 Kit Boxes using their designated holders (see pictograms and color-coded workflow on the plate of the Kit Boxes). The sharp instruments should be handled with a pair of tweezers to avoid injury.

Containment and transportation:

1. Transport the Kit Boxes 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 Kit Boxes with a damp cloth or store them in a closed container to avoid drying of soil and/or debris.
2. Store the Kit Boxes with the instruments in a container to avoid any contamination of the environment.

Automated cleaning, disinfection and drying (incl. pre-cleaning):

1. Remove all instruments from the Kit Box. To avoid contamination of the Kit Box, it is advised to pick up the instruments using a pair of tweezers. Disassemble and clean the instruments according to their respective Instructions for Use.
2. Disassemble the Kit Box completely (incl. removal of grommets).
3. Immerse the Kit Box components into cold cleaning solution (e.g. Neodisher Medizym) for 5 minutes.
4. Brush all surfaces with soft bristle brush (e.g. Medisafe MED-100.33) until all visible residues are removed.
5. Rinse the Kit Box components under running cold tap water.
6. Load the Kit Box components into washer/disinfector (Figure 2).



Figure 2: Disassembled kit box loaded into washer/disinfector.

7. 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-cleaning with cold tap water.
 - Draining.
 - 5 minutes cleaning with tap water at 55°C with a 0.5% solution of alkaline cleaning agent (e.g. Neodisher Mediclean).
 - **Caution:** The use of a cleaning solution with acidic pH (pH below 7) could potentially damage the Kit Boxes.
 - Draining.
 - 3 minutes neutralizing with cold desalinated water.
 - Draining.
 - 2 minutes rinsing with cold desalinated water.
 - Draining.
 - 5 minutes thermal disinfection with demineralized water at 93°C.
8. Dry the Kit Boxes Using compressed air. If needed, additional drying can be performed with clean and lint-free single use wipes.

The following washer/disinfector was used in the Nobel Biocare validation: Miele G7836 CD.

Maintenance and packaging:

1. After cleaning, disinfection and drying, visually inspect the Kit Boxes 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 plate of the Kit Box 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.
2. Reassemble the Kit Box and mount the instruments in the silicon grommets/brackets (Figure 3).



Figure 3: Reassembled Kit Box with mounted instruments.

3. Pack the assembled Kit Boxes in a sterilization pouch or single wrap (Figure 4). 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 Kit Boxes 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 in order to maintain sterility of the enclosed medical instruments until used.



Figure 4: Assembled Kit Box packed in sterilization pouch.

4. 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 Kit Box into the autoclave/sterilizer. The Kit Box must be sterilized in its "ready for use" state.
2. Run the autoclave/sterilizer with the following recommended parameters:
 - For USA: Steam sterilization 270°F (132°C) for 4 minutes when using pre-vacuum method and 15 minutes when using the gravity method. Dry for 20 to 30 minutes when using pre-vacuum method and 15 to 30 minutes when using the gravity method.
 - For USA: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.
 - For outside USA: Temperature 132°C (270°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.
 - Alternative UK: Temperature 134°C (273°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

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 Kit Box 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.

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

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: 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.

Storage, handling and transportation:

The Kit Boxes 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:

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

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For Prescription Use Only. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed dentist.



Caution



Batch code



Catalogue number



Non-sterile



Consult instructions for use

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