Nobel Biocare Reusable Instruments
Instructions for Use

Important – Disclaimer of Liability:

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Description:

Nobel Biocare reusable instruments and components are divided into the following categories based on their use.

Instruments for implant site preparation and implant placement:

Tissue Punch*, Tissue Punch Guide, Drill Guide, All-on-4 Guide*, Drill Extension*, Irrigation Needle, Depth Probe, Direction Indicator, Implant Driver*, Implant Driver Wrench Adapter, Surgical Driver, Connection to Handpiece*, Zygoma Drill Guard, Zygoma Depth Indicator, Zygoma Handle.

Instruments for restorative procedures:

Try in Abutments, Impression Copings, Screw Drivers, Cover Screw Driver Brånemark, Screwdriver/Activator and Handle for Machine Instruments*.

Auxiliary instruments:

Forceps, Kit Box and Implant Sleeve Holder.

* Class II device; see applicable CE Mark (CE 0086)

Intended Use:

Nobel Biocare reusable instruments are intended to be used as a part of dental implant treatments with Nobel Biocare implants and restorative components. For specific intended use, please refer to the respective Instructions For Use for the implant or restorative component.

Indications:

Nobel Biocare reusable instruments are used as a part of dental implant treatments with Nobel Biocare implants and restorative components. For specific indications, please refer to the respective Instructions For Use for the implant or restorative component.

Contraindications:

It is contraindicated using Nobel Biocare reusable instruments in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to commercially pure titanium (grade 4), stainless steel, aluminum, titanium nitride, polyetheretherketone (PEEK), silicone, nylon, or polyphenylsulfone.

For specific contraindications, please refer to the respective Instructions for Use for the implant or restorative component.

Cautions:

General:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

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 info please visit www.nobelbiocare.com.

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

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:

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Handling Procedure:

For specific information on the instruments and their use please refer to the respective Instructions For Use for the implant or restorative component.

Materials:

- Tissue Punch, All-on-4 Guide, Drill Extension, Irrigation Needle, Depth Probe, Implant Driver Wrench Adapter, Surgical Driver, Connection to Handpiece, Cover Screw Driver Brånemark, Screwdriver/Activator, Handle for Machine Instruments, Zygoma Drill Guard and Zygoma Depth Indicator: Stainless steel.
- Implant Driver: Stainless steel with or without DLC (Diamond Like Carbon) coating, Titanium nitride (TiN) coating, Polyetheretherketone (PEEK) retention ring or silicone color coding plug.
- Zygoma Handle: Stainless steel and aluminum.
- Tissue Punch Guide, Drill Guide, Direction Indicator, Impression Copings: Stainless Steel, commercially pure titanium (grade 4) or titanium alloy 90% Ti, 6% Al, 4% V.
- Screw Drivers: Stainless steel with or without Titanium nitride (TiN) coating.
- Forceps: Commercially pure titanium (grade 4).
- Try-in Abutments for external hex and internal tri-channel implants: Nylon.
- Try-in Abutments for internal conical connection implants: Titanium alloy 90% Ti, 6% Al, 4% V.
- Kit Box: Polyphenylsulfone (PPSU) and silicone.
- Implant Sleeve Holder: Polyphenylsulfone (PPSU).

Sterility and Reusability Information:

The Nobel Biocare Reusable Instruments are delivered non-sterile and are 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 individually sealed in pouches during sterilization.

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.

Cleaning Guidelines:

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

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):

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

Note: 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. Disassemble the devices, where applicable.
2. Immerse in cold enzymatic cleaning agent 0.5% (e.g. Neodisher Medizym) for 5 minutes.
3. Fill lumina (where applicable) with cleaning solution 0.5% (e.g. Neodisher Medizym) with a syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) until all visible residues are removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with bottle brushes (e.g. OD = 1.2mm / 2.0mm / 5.0mm) until all visible residues are removed.
6. Rinse with cold running tap water.
7. Rinse lumina (where applicable) with a syringe with 20ml tap water.
8. Load devices into washer / disinfector.
9. Perform automatic cleaning and disinfection under consideration of national requirements with regard to the A0-Value (EN ISO 15883). The following parameters are based on the Vario TD program on the Miele G7836 CD Washer-disinfector:
    - 2 min pre-cleaning with cold water
    - Draining
    - 5 minutes cleaning with 55°C tap water and 0.5% alkaline cleaning agent (e.g. Neodisher Mediclean)
    - Draining
    - 3 minutes neutralization with cold desalinated water
    - Draining
    - 2 minutes rinsing with cold desalinated water
    - Draining
10. Run drying cycle.
11. Dry with compressed air or wipes if needed.

Manual Cleaning, Disinfection and Drying:

Note: 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. Immerse devices for a minimum of 5 minutes in sterile NaCl solution.
2. Scrub the outer side of the devices with soft bristled nylon brush until all visible soil is removed.
3. Flush channels / lumina (where applicable) with 20ml cleaning solution (e.g. Cidezyme ASP) with an irrigation needle connected to a 20ml syringe.
4. Brush lumina (where applicable) with a bottle brush (e.g. OD = 1.2mm / 2.0mm / 5.0mm).
5. Rinse the outer side and lumina of the devices with cold running tap water to remove all cleaning solutions.
6. Immerse in ultrasonic bath with 0.5% enzymatic Detergent Solution (e.g. Cidezyme ASP) and treat for 5 min at 40°C (104°F).
7. Flush inner lumina (where applicable) with 20ml cold running tap water with an

irrigation needle connected to a 20ml syringe.

8. Rinse the outer side of the devices with purified or sterile water to remove all cleaning solutions.
9. Repeat cleaning steps if needed.
10. Immerse in 100% disinfection solution (e.g. Cidex OPA) for 5 minutes.
11. Flush internal channels / lumina (where applicable) with disinfection solution.
12. Rinse and flush lumina and outer side of devices with cold running tap water.
13. Flush internal channels / lumina (where applicable) with purified or sterile water.
14. Dry with compressed air or wipes.
15. Repeat complete cleaning and disinfection if needed.

Visual Inspection:

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

Sterilization:

Assemble (where applicable), inspect and seal the single device in a suitable sterilization pouch and steam sterilize. Both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

- Gravity Cycle Method: Steam sterilization at 132°C (270°F) for 10 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method: Steam sterilization at 132°C (270°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (for UK): Steam sterilization at 134°C (273°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (recommended to ensure inactivation of prions): Steam sterilization at 134°C (273°F) for 18 minutes, followed by drying for a minimum of 20 minutes in chamber.

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 Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 Australia
Phone: +61 1800 804 597

Distributed in New Zealand by:
Nobel Biocare New Zealand Ltd
33 Spartan Road
Takanini, Auckland, 2105 New Zealand
Phone: +64 0800 441 657

CE Mark for Class I Devices

CE 0086 CE Mark for Class II Devices

Canada – License Exemption: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

Symbols Glossary:

The following table describes symbols which may be present on the device labeling. Refer to the device labeling for the symbols which are applicable to the device.

LOT Batch code	REF Catalogue number	Caution	Consult instructions for use
PHT DEHP Contains or presence of phthalate	Date of manufacture	2 STERILIZE Do not re-sterilize	2 Do not re-use
Do not use if package is damaged	Rx Only For prescription use only	ID Patient Identifier	Keep away from sunlight
Keep dry	symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com Link to Online Symbols Glossary and IFU Portal	Manufacturer	
MD Medical device	MR Magnetic resonance conditional	NON STERILE Non-sterile	# Patient number
SN Serial number	STERILE R Sterilized using irradiation	Use-by date	