

Nobel Biocare Reusable Instruments

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, 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, 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 Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

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, Ratchet, Ratchet Adapter, Immediate Provisional Implant Insertion Wrench, Immediate Provisional Implant Hand Wrench, Immediate Provisional Implant Retrieval Tool, Immediate Provisional Implant Bending Tool and Immediate Provisional Implant Parallel Pin.

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.

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 contraindicated for treatment with Nobel Biocare implants or restorative components.
- Patients who are allergic or hypersensitive to the materials used.

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

Cautions:

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.

Working the first time with a colleague experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

All 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. 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.

For additional information on surgical and restorative procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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, Ratchet, Ratchet Adapter, Immediate Provisional Implant Insertion Wrench, Immediate Provisional Implant Hand Wrench, Immediate Provisional Implant Retrieval Tool and Immediate Provisional Implant Bending Tool: Stainless steel.

Implant Driver: Stainless steel with or without DLC (Diamond Like Carbon) coating, TiN (Titanium nitride) coating, PEEK (Polyetheretherketone) 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 or titanium alloy 90% Ti, 6% Al, 4% V.

Immediate Provisional Implant Parallel Pin: Titanium alloy 90% Ti, 6% Al, 4% V.

Screw Drivers: Stainless steel with or without TiN (Titanium nitride) coating.

Forceps: Commercially pure titanium.

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 and silicone.

Implant Sleeve Holder: Polyphenylsulfone.

Cleaning and sterilization instructions:

The Nobel Biocare reusable instruments are delivered non-sterile and intended for re-use. Prior to use and re-use clean, disinfect and sterilize the product using the recommended parameters.

For USA: Seal single device in a pouch and steam sterilize at 270°F, max 279°F (132°C, max 137°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C, max 137°C (270°F–275°F, max 279°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C, max 137°C (273°F–275°F, max 279°F) for 3 minutes.

Special instructions for Ratchet: Seal the Ratchet in a pouch and sterilize at 135°C (275°F) for 20 minutes with gravity cycle. Drying time min 5 minutes.

Caution: Ratchet should be cleaned thoroughly after each use. If lubrication is required, use a syringe and needle to apply handpiece lubricating oil in the “gap” in the head.

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.

Full set of recommended parameters are provided in “Cleaning & Sterilization Guidelines including Magnetic Resonance Imaging Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

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:

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

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Canada – License Exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription Device – Rx only

Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.



Rx Only



Non-sterile



Caution



Consult instructions for use



Batch code



Do not use if package is damaged

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