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: Tissue Punch, Drill Extension, Implant Driver, and Connection to Handpiece.

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, Drill Extension, Connection to Handpiece: 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.

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.

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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CE 2797

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.

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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

Rx Only

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

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

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