Multi-unit Aligning Instrument
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

The Multi-unit Aligning Instrument is a reusable instrument to be attached to Nobel Biocare implant drivers. It has an angulation indicator to help the user to identify the angulation of the most suitable Multi-unit Abutment as well as the implant rotational position, that defines the abutment screw access hole.

Intended use:

The Multi-unit Aligning Instrument is a reusable instrument and it is intended to be used to identify the angulation of the best suitable Multi-unit Abutment as well as the implant rotational position, that defines the abutment screw access hole.

Indications:

The Multi-unit Aligning Instrument is indicated to be used as a reusable instrument during dental implant treatments with Nobel Biocare implants and restorative components.

Contraindications:

It is contraindicated using the Multi-unit Aligning Instrument 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 stainless steel.

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 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 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.

Care and maintenance of instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

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

Handling procedure:

Multi-unit Aligning Instrument handling procedure:

Please place the appropriate implant following corresponding Instructions For Use. Once the implant has been inserted and seated, proceed as follows:

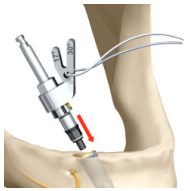
1. Secure the Multi-unit Aligning Instrument with dental floss as shown on **Figure 1a**.
2. Assemble the Multi-unit Aligning Instrument on the implant driver see **Figure 1a**. If a Tri-Channel implant driver is used, then the laser marking on the implant driver (red arrow) has to be aligned with the Multi-unit Aligning Instrument as shown in **Figure 1b**.

Figure 1a

Figure 1b

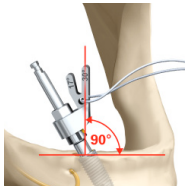
3. Insert the implant driver Multi-unit Aligning Instrument assembly into the implant see **Figure 2**.

Figure 2



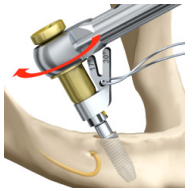
4. The angulation indicator of the Multi-unit Aligning Instrument indicates the position of the prosthetic screw hole when selecting a 17° or 30° Multi-unit Abutment. Position the Multi-unit Aligning Instrument so that the angulation indicator is perpendicular to the bone. The arm of the Multi-unit Aligning Instrument perpendicular to the bone, indicates the recommended Multi-unit Abutment to use. The red line in **Figure 3** illustrates the 30° option.

Figure 3



5. Adjust the rotational position of the implant if necessary with the Manual Torque Wrench see **Figure 4**.

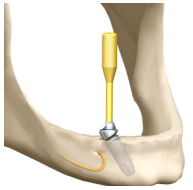
Figure 4



Caution: Never exceed insertion torque detailed in the respective implant Instructions For Use. Overtightening of implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid over tightening.

6. Remove the implant driver and Multi-unit Aligning Instrument assembly and insert the appropriate Multi-unit Abutment.
Figure 5 illustrates a 30° Multi-unit Abutment including the insertion handle.

Figure 5



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.

Material:

The Multi-unit Aligning Instrument is made of stainless steel.

Cleaning and sterilization instructions:

The Multi-unit Aligning Instrument is delivered non-sterile and intended for re-use. Prior to use and re-use clean, disinfect and sterilize the product using the recommended parameters.

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

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

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Multi-unit Aligning Instrument must be disassembled from the implant driver prior to cleaning.

Clean the device using manual or automated cleaning, disinfect and dry the device following instructions in Cleaning and Sterilization Guidelines available at http://www.nobelbiocare.com/sterilization.

Inspect and seal the single device in a pouch and steam sterilize, both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following 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.

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.

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.

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

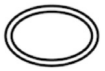
Date


Date of manufacture


Do not resterilize


Do not re-use


Do not use if package is damaged


Double sterile barrier system

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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