

NobelGuide® for NobelReplace® Tapered and Replace Select™ Tapered Instructions for use



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Description:

The NobelGuide® guided surgery system is designed for dental implant treatment of edentulous and partially edentulous jaws including patients missing a single tooth. The system enables a predictable and if indicated minimal invasive endosseous implant installation procedure according to a case planning done by the clinician in NobelClinician® Software. The NobelReplace® Tapered Guided Surgery Kit contains the specific guided surgery tooling which is used in conjunction with the NobelGuide® surgical template to guide the surgical tooling for surgical access, guided implant site preparation, guided screw tapping and guided implant insertion of NobelReplace® Tapered Groovy, Replace Select™ Tapered TiUnite®, Replace Select™ Tapered Partially Machined Collar (PMC), NobelReplace® Conical Connection, NobelReplace® Conical Connection Partially Machined Collar (PMC) and NobelReplace® Platform Shift implants based of the NobelClinician® treatment plan.

The NobelReplace® Tapered Guided Surgery Kit contains the following specific guided surgery tooling:

- Guided Drill Guides used to transfer the direction given by the sleeves embedded in the surgical template to drill to various diameters.
- Handle for Guided Drill Guide extends the existing handle on the Guided Drill Guides for easier handling and better accessibility in the surgical situation.
- Guided Implant Mounts used to facilitate implant placement through the surgical template sleeve. The Guided Implant Mounts have an outer diameter that matches the internal dimensions of the sleeves.
- Guided Template Abutments used in the first 1–2 preparations in order to keep the surgical template in the exact position when preparing and placing the remaining implants.

- Guided Tissue Punch used to remove the soft tissue cleanly, without leaving any soft tissue “tags” for flapless guided surgery.
- Guided Tapered Drills, Guided Dense Bone Drills and Guided Screw Taps used to prepare the implant site.

The kit also contains the following components:

- Unigrip™ Screwdriver
- Guided Anchor Pins
- Torque Wrench Surgical
- Torque Wrench Prosthetic Adaptor
- Connection to Handpiece
- Drill Extension Shaft

Guided Start Drill, Guided Twist Drill and Guided Counterbores NobelReplace® are ordered separately.

Intended use:

The NobelGuide® guided surgery system is intended to transfer a treatment planning done by the clinician into a physical/clinical reality. The system is intended to facilitate implant installation with high predictability and contribute to better restoration of these implants placed in both mandible and maxilla.

Indications:

The guided surgery concept is indicated for the treatment of edentulous and partially edentulous jaws (including patients missing a single tooth) for placement of implant fixtures, if indicated in combination with immediate function to restore esthetics and functionality (e.g. masticatory, speech). The following prerequisites must be fulfilled:

- Adequate amount jawbone.
- The quality of jawbone must be judged as adequate.
- Adequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.
- Exclusion of compromised diseases in conflict with dental implant treatment.
- Adequate compliance.

Note: For Contraindications, Warnings and Cautions for NobelReplace® Tapered and Replace Select™ Tapered implants please refer to applicable implant Instructions for Use.

Contraindications:

It is contraindicated to place NobelReplace® Tapered and Replace Select™ Tapered implants in patients:

- Who are medically unfit for an oral surgical procedure.
- With inadequate bone volume unless an augmentation procedure can be performed.
- In whom adequate sizes, numbers or desirable position of implants are not achieved to provide safe support of functional or eventually parafunctional loads.
- Allergic or hypersensitivity to commercially pure titanium grade 4, stainless steel or DLC (Diamond Like Carbon) coating or surgical template material acrylate-based photopolymer.

Warnings:

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended from lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jawbone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions:

General:

One hundred percent implant success cannot be guaranteed. Especially, nonobservance of the indicated limitations of use and working steps may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

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

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.

It is strongly recommended that NobelReplace® Tapered Groovy, Replace Select™ Tapered TiUnite®, Replace Select™ Tapered Partially Machined Collar (PMC), NobelReplace® Conical Connection, NobelReplace® Conical Connection Partially Machined Collar (PMC) and NobelReplace® Platform Shift implants are used only with Nobel Biocare surgical instruments and prosthetic components, 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.

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.

Before surgery:

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

Before performing guided surgery, the delivered surgical template must be carefully inspected and cleared by the clinician performing the surgery. Optimal fit on stone model and in patient’s mouth needs to be verified. If in doubt, please contact Nobel Biocare technical support.

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.

At surgery:

Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

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

After implant installation, the surgeon’s evaluation of bone quality and initial stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

After surgery:

To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Surgical procedures:

If applicable, anchor the surgical template using an adequate number of anchor pins placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to secure the surgical template is in the correct position in the patient’s mouth and that it does not move in

Continue with implant installation until desired position is achieved using max **45Ncm** installation torque.

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11. In partially edentulous and edentulous situations the Guided Implant Mount can be replaced by the Guided Template Abutment on the first 1–2 implants. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount. Anchor the surgical template using the Guided Template Abutment, tightening manually using the Unigrip™ Screwdriver. Ensure the surgical template maintains its initial correct position for the next implant site preparation.
12. Prepare and install the remaining implant sites.
13. Once all implants are installed, remove Guided Implant Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. Remove anchor pins, if applicable and remove the surgical template.
14. Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical. Do not change depth of implant through torque measurement.
15. Depending on the surgical protocol of choice, place a Cover Screw using the Unigrip™ Screwdriver or an abutment using the Torque Wrench Prosthetic Adapter and suture.

For additional information on surgical procedures please consult the “Procedures & products” treatment guidelines for NobelGuide® available at www.nobelbiocare.com or request the latest printed version from a Nobel Biocare representative.

For additional information on the NobelGuide® surgical templates and related surgical procedures, please refer to the Instructions for Use NobelGuide® Surgical Template.

For additional information on the of NobelReplace® Tapered Groovy, Replace Select™ Tapered TiUnite®, Replace Select™ Tapered Partially Machined Collar (PMC), NobelReplace® Conical Connection, NobelReplace® Conical Connection Partially Machined Collar (PMC) and NobelReplace® Platform Shift implants implant please refer to the implant specific Instructions for Use.

For additional information on the NobelClinician® Software please refer to the NobelClinician® Instructions for Use.

Materials:

All components contained in the NobelReplace® Tapered Guided Surgery Kit, as listed in the “Description” section, are made from stainless steel, except for the Guided Tapered Drills, Guided Dense Bone Drills and Guided Screw Taps which have a DLC (Diamond Like Carbon) coating.

Cleaning and sterilization instructions:

The device is delivered non-sterile and intended for re-use. This device must be cleaned and sterilized prior to use.

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

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

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

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

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

MR safety information:

Note: For Implant MR safety information please refer to applicable Implant IFU.

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

For additional information on Magnetic Resonance Imaging, please consult the “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

After sterilization, place the devices in a dry and dark place such as a closed cupboard or drawer. Follow the instructions of the manufacturer of the sterilization pouch regarding storage conditions and expiration date of sterilized goods.

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.

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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