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

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, they are 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:

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 is does not move in

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any direction from the correction position when being manipulated with instruments (e.g. lateral shift through inadequate handling of twist drills in "knife-edge ridge" situations or shift/deformation of surgical template due to excessive vertical force application during implant installation). In situations where two or more neighboring implants are placed, regardless if it is a free-end situation or a situation with one or more distal teeth for support of the surgical template, it is recommended to use at least one anchor pin in this area. If necessary, place implants in a staggered approach.

1. If a flapless procedure is chosen, it is recommended to use the Guided Soft Tissue Punch before any other instruments are used to generate a clean cut. The surgical template can be temporarily detached after punching to carefully remove the punched soft tissue. The surgical template is carefully repositioned and the anchor pins replaced into the existing anchorage holes in the bone.

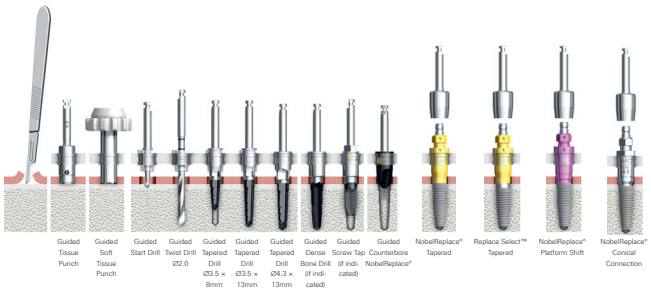
   If a (mini) flap procedure is chosen, it is recommended that the surgical template is first repositioned and the anchor pins placed prior to any manipulations of the soft tissue. Remove the anchor pins and surgical template, perform the incision, respecting the position of the implants and elevate the flap. If required, carefully modify the surgical template by relieving as much material as required to accommodate the flap, rinsing with sterile saline solution prior to carefully repositioning.

2. Drilling must proceed at high speed (maximum 800 rpm) under constant and profuse irrigation by sterile saline at room temperature. Guided Tapered Drills are internally and externally irrigated and require a specific technique to prevent irrigation holes becoming plugged with bone debris. An in-and-out motion, over the complete extent of the osteotomy, is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Caution: Guided Tapered Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (the yellow safety zone in the NobelClinician® Software includes the extended drill lengths).

Image (**A**) shows the drilling sequence for the Ø4.3 RP 13 mm implant.

A



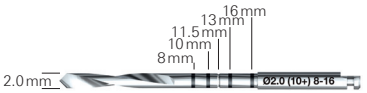
Note: For Replace Select™ Tapered PMC use the as drill protocol as for Replace Select™ Tapered and for NobelReplace® Conical Connection PMC use the same drill protocol as for NobelReplace® Conical Connection.

3. Prepare implant site. Start with the Guided Start Drill with the appropriate Guided Drill Guide Ø2 mm to create a start point for the following drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drill to the full depth as defined by the in-built drill stop at high speed (maximum 800 rpm) under constant and profuse irrigation. The Guided Start Drill (round bur) allows for the exact preparation of the entry point of the Guided Twist Drill Tapered Ø2 mm.

4. Drill using the Guided Twist Drill Tapered Ø2 mm using the same Guided Drill Guide to the intended depth based on the implant to be placed. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution. An in-and-out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Caution: The Guided Twist Drill Tapered Ø2 mm is identified by the (10+) designation on the shaft. This indicates the drill is 10 mm longer to compensate for the height of the surgical template and Guided Drill Guide (**B**). The level should be measured with the Guided Drill Guide 2 mm in place.

B

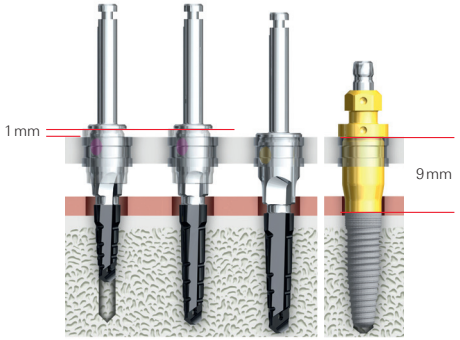


5. Following the 2 mm Guided Twist Drill, the Guided Tapered Drill NP 8 mm must be used for all implants. Drilling must proceed at high speed (maximum 800 rpm) under constant and profuse irrigation by sterile saline at room temperature. An in-and-out motion, over the complete extent of the osteotomy, is needed when preparing the site to avoid overheating. This drill is guided by the template sleeve before engaging the bone and provides guidance for the longer NP Guided Drills (if an implant longer or wider than NP 8 mm is placed).

Caution: For reasons of drilling precision the step using the Guided Tapered Drill NP 8 mm is mandatory and must not be omitted.

Caution: The Guided Tapered Drills are identified by the (+) designation on the shaft. The inbuilt depth stops on the Guided Tapered Drills correspond to the 8, 10, 11.5, 13 and 16 mm implants. This indicates the tapered drills are 9 mm longer than the non-guided instruments to compensate for the height of the surgical template's inbuilt guided sleeve (**C**). Drills extend up to 1 mm longer than the implant when seated.

C



6. Continue with the respective Guided Tapered Drills depending on the implant to be installed, length and platform. For example in the event that a 16 mm implant is planned, first use the Guided Tapered Drill NP 8 mm, followed by the Guided Tapered Drill NP 13 mm and then Guided Tapered Drill NP 16 mm.

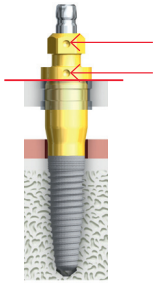
7. Following the last Guided Tapered Drill the Guided Counterbore NobelReplace® must be used at max. 800 rpm to allow adequate access for the Guided Implant Mount when placing the implant. Drill to the inbuilt drill stop using profuse and constant irrigation.

8. Open the implant package. Connect the Guided Implant Mount to the implant using the Unigrip™ Screwdriver. Insert the Connection to Handpiece in the drilling device and pick up the mounted implant. 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 ideally installed with low speed, maximum 25 rpm, using the drilling device. Place and tighten the implant using maximum **45 Ncm** installation torque.

   Stop tightening the implant when the Guided Implant Mount touches the surgical template. The Guided Implant Mount includes a vertical stop. Avoid further tightening of the implant as this may affect the correct position of the surgical template. Secure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

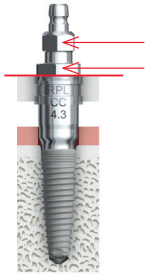
To ensure ideal prosthetic abutment orientation for internal tri-channel implants, position one of the tri-channel lobes in the buccal/facial position. The dots on the Guided Implant Mount indicate the position of the tri-channel lobes (**D**).

D



To ensure ideal prosthetic abutment orientation for internal conical connection implants, position one of the internal hexagon flat surfaces in the implant towards buccal/facial. The flat surfaces of the hexagon of the inbuilt drill stop on the Guided Implant Mount indicate the position of the internal hexagon (**E**).

E



Caution: Never exceed insertion torque of **45 Ncm**. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

Caution: Guided Implant Mount Conical Connection is developed for NobelReplace® Tapered Conical Connection implants only and must not be used for NobelActive® implants.

9. If the implant gets stuck during implant installation or **45 Ncm** is achieved before fully seated the "dense bone protocol" may be required. Rotate the implant counter clockwise using the drilling device (reverse mode) or Manual Torque Wrench and remove implant from site. Replace the implant in the inner casing before proceeding further (refer to the Dense bone protocol section). Without removing the surgical template, continue with implant installation until desired position is achieved. For Immediate Function, the implant should be able to withstand a final torque of **35–45 Ncm**.

10. Dense bone protocol: The Dense Bone Drill in conjunction with the Guided Screw Tap should be used in hard bone situations when the implant cannot be fully seated.

    a. Guided Dense Bone Drill Tapered is only needed for 13 mm and 16 mm implants. If shorter implants are used, go directly to step c. Select the Guided Dense Bone Drill matching the diameter and length (13 or 16 mm) of the final Guided Tapered Drill used.

    b. Drill one pass into the prepared site with high speed (800 rpm) using the Guided Dense Bone Drill under constant and profuse external irrigation with sterile saline solution to the inbuilt drill stop.

    c. Select the Screw Tap matching the diameter of the implant. For product reference line Guided Screw Tap versus implant length see (**F**). Place the Screw Tap into the prepared site using low speed (25 rpm).

    d. Apply firm, axial pressure and begin rotating the Guided Screw Tap slowly and keep centered while inserting through the guided sleeve. When the threads engage, allow Guided Screw Tap to feed without pressure to the appropriate depth.

    e. Switch the handpiece into reverse mode and back the Screw Tap out.

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

F

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.

CE 0086 **Rx Only**

Non-sterile


Consult instructions for use


Use-by date

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