

NobelGuide® for NobelActive®

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, 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 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. The NobelActive® 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 NobelActive® implants based of the NobelClinician® treatment plan.

The NobelActive® 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 of various diameters.
- Handle for Guided Drill Guide extend the existing handle on the Guided Drill Guides for easier handling and better accessibility in the surgical situation.
- Guided Implant Mounts (NobelActive®) used to facilitate implant placement through the surgical template sleeve. The Guided Implant Mounts have an outer diameter that matches the dimensions of the NobelActive® implant platform, therefore smaller than the sleeves. Precision implant insertion is facilitated through mandatory use of fully guided Guided Screw Tap (soft and medium bone quality) and Guided Dense Bone Screw Tap (dense bone).
- 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.

The kit also contains the following components:

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

Guided Start Drill, Guided Twist/Step Drills, Guided Screw Taps and Guided Dense Bone Screw Tap 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 NobelActive® implants please refer to applicable NobelActive® implant Instructions for Use.

Contraindications:

It is contraindicated to place NobelActive® 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 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 jaw bone, one must avoid damage the 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 NobelActive® 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.

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.

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.

At surgery:

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

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.

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 procedure:

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 any direction from the correct 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.

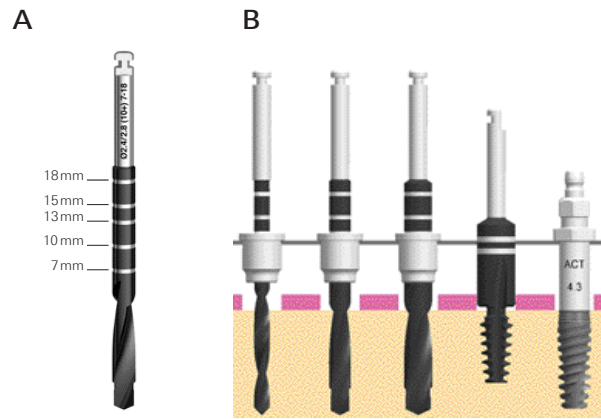
2. During drilling procedures bone quality should be considered. (See Table 1 for recommended drill sequences based on bone quality to ensure optimal primary stability when applying Immediate Function). Use the Guided Start Drill prior to the Guided Twist Drill 2 mm (with the appropriate Guided Drill Guide to 2 mm) to create a start point for the following drill. Then select the appropriate Guided Drill Guide based on the sleeve size and the Guided Twist/Step Drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drilling must proceed at high speed (maximum 800rpm for Guided Twist/Step 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.

Table 1

Recommended drill sequence based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets (-) denote widening of cortex only.

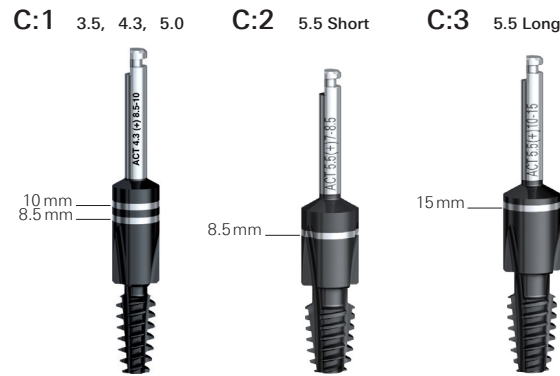
Implant Diameter	Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
3.5	2.0 (2.4/2.8) (Guided Screw Tap 3.5)	2.0 2.4/2.8 (2.8/3.2) Guided Screw Tap 3.5	2.0 2.4/2.8 2.8/3.2 (Guided Dense Bone Screw Tap 3.5)
4.3	2.0 2.4/2.8 (2.8/3.2) (Guided Screw Tap 4.3)	2.0 2.4/2.8 3.2/3.6 Guided Screw Tap 4.3	2.0 2.4/2.8 3.2/3.6 (3.8/4.2) Guided Dense Bone Screw Tap 4.3
5.0	2.0 2.4/2.8 3.2/3.6 (Guided Screw Tap 5.0)	2.0 2.4/2.8 3.2/3.6 3.8/4.2 Guided Screw Tap 5.0	2.0 2.4/2.8 3.2/3.6 3.8/4.2 (4.2/4.6) Guided Dense Bone Screw Tap 5.0
5.5	2.0 2.4/2.8 3.2/3.6 (3.8/4.2) (Guided Screw Tap 5.5)	2.0 2.4/2.8 3.2/3.6 3.8/4.2 4.2/4.6 (4.2/5.0) Guided Screw Tap 5.5	2.0 2.4/2.8 3.2/3.6 3.8/4.2 4.2/5.0 Guided Dense Bone Screw Tap 5.5

Caution: Guided Twist/Step Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10mm longer than the “freehand” Twist/Step Drills to compensate for the height of the surgical template and the Guided Drill Guide. The depth marks on the Guided Twist/Step Drills correspond to 7, 10, and 13mm implants for 7–13mm drills and 7, 10, 13, 15 and 18mm for 7–18mm drills (A). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated (B). Allow for this additional length when drilling near vital anatomical structures.



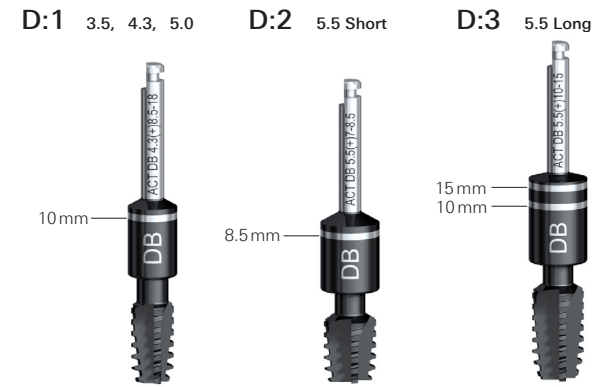
3. Prepare implant site.
4. Following preparation of the osteotomy using the Guided Twist/Step Drills, it is mandatory to use the Guided Screw Tap.

Soft and medium bone – use the Guided Screw Tap (see Table 1 for recommended screw taps). Select the Guided Screw Tap NobelActive® matching the diameter of the implant. Place the Screw Tap directly in the guided sleeve of the surgical template and prepare the site to the desired depth using the lowest speed (20–45 rpm) with copious irrigation. **C:1** shows Guided Screw Tap depth markings which correspond to full depth tapping of 8.5mm and 10mm for 3.5, 4.3 and 5.0 implants. **C:2** shows Guided Screw Tap depth markings which correspond to full depth tapping of 8.5mm for 5.5 implants and **C:3** shows Guided Screw Tap depth markings which correspond to full depth tapping of 15mm for 5.5 implants.

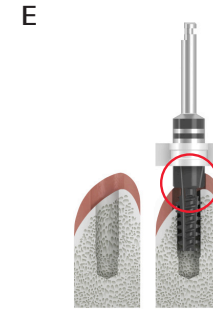


Dense bone – use the Guided Dense Bone Screw Tap (see Table 1 for recommended screw taps), which are labeled with “DB” on the guiding cylinder. Select the Guided Dense Bone Screw Tap NobelActive® matching the diameter of the implant. Place the Guided Dense Bone Screw Tap directly in the guided sleeve of the surgical template and prepare the site to the desired depth using the lowest speed (20–45 rpm) with copious irrigation. **D:1** shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 10mm for 3.5, 4.3 and 5.0 implants. **D:2** shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 8.5mm for 5.5 implants. **D:3** shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 10mm and 15mm for 5.5 implants.

Note: Depth of tapping using the Guided Screw Tap or Guided Dense Bone Screw Tap will depend on the bone quality. Tapping of just two to three threads (height of cortical bone) may be sufficient. Always consider tapping to full depth may not be possible due to anatomical constraints.

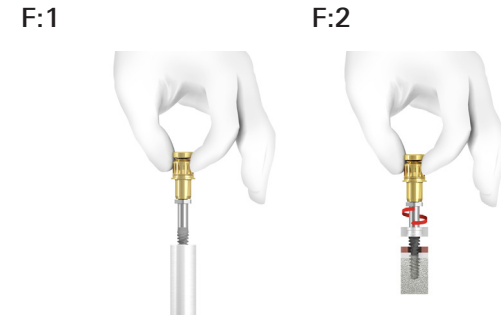


Warning: Avoid early bone contact (E). Before using the screw tap, the shape of the crest should be checked to avoid early collision between the upper half of the screw tap (with the largest diameter) and the bone. This might block the screw tap and jeopardize site preparation. Remove the bone to allow insertion of the screw tap.



5. Open the implant package. Connect the Guided Implant Mount NobelActive® to the implant using the Unigrip™ Screwdriver. Pick up the mounted implant using the surgical adaptor from the Manual Torque Wrench Surgical (F:1). Perform the first turns of the insertion by hand. Start with a gentle left turn until you can feel the implant falling into the pre-tapped thread. Then turn right into the pre-tapped path. This technique makes it easier to find the correct pre-tapped path and optimize the accuracy of the implant placement (F:2).

Secure visually that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.



- Remove the surgical adaptor and continue with implant insertion using the Connection to Handpiece and drilling unit. NobelActive® implants are ideally installed with low speed, maximum 25rpm using the drilling unit. Final implant insertion can be done manually using the Manual Torque Wrench Surgical. The maximum insertion torque for the implant is **70Ncm** for NobelActive® 3.5, 4.3, 5.0 and 5.5 implants (for all others **45Ncm**) and may be measured with the NobelActive® Manual Torque Wrench Surgical. Stop tightening the implant when the Guided Implant Mount touches the surgical template.

Caution: Never exceed insertion torque of **70Ncm** for NobelActive® 3.5, 4.3, 5.0 and 5.5 implants (for all others **45Ncm**). Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

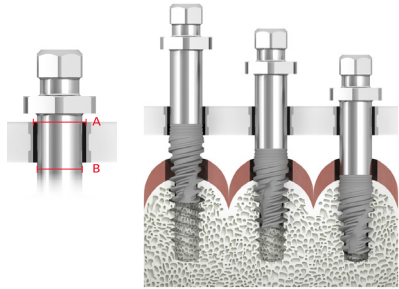
Note: The Guided Implant Mount NobelActive® includes a vertical stop. The implant mount body has the same outer diameter as the implant platform and therefore is smaller than that of the guided sleeve in the template sleeve see Table 2 and (G). This makes it possible to plan and place the implants sub-crestally without the removal of additional bone on the neighboring crest only to allow for the implant mount diameter to pass. Additionally this allows for measuring real clinical torque values between implant and bone.

Table 2: Diameter and diameter references

	NP	RP 4.3	RP 5.0	WP 5.5
Guided sleeve (A)	4.11	5.02	6.22	6.22
Implant mount (B)	3.52	3.90	3.90	5.08
Diameter difference	0.59	1.12	2.32	1.14

Diameter and diameter difference in mm

G



- If the implant gets stuck during implant installation or **70Ncm** for NobelActive® 3.5, 4.3, 5.0 and 5.5 implants (for all others **45Ncm**) is achieved before fully seated, rotate the implant counter clockwise approximately ½ turn enabling use of self-tapping capacity of implant or back out implant, replace in inner casing before proceeding further and widening the site. 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 **35–70Ncm**.
- 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.
- Prepare and install the remaining implant sites.
- 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.
- Depending on the surgical protocol of choice, place a cover screw or abutment 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 NobelActive® implant please refer to the NobelActive® Instructions for Use.

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

Materials:

All components contained in the NobelActive® Guided Surgery Kits, as listed in the “Description” section, are made from stainless steel.

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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