Nobel Biocare Guided Surgery Tooling

Instructions for use

Important – 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:

Nobel Biocare guided surgery tooling is designed to be used with a NobelGuide® Surgical Template in order to guide the placement of Nobel Biocare dental implants which are intended for the treatment of edentulous and partially edentulous jaws, including patients missing a single tooth.

Nobel Biocare guided surgery tooling is used for surgical access, guided implant site preparation, guided screw tapping, and guided implant insertion. The tooling enables a predictable and, if indicated, minimally-invasive endosseous implant installation procedure according to case planning performed by the clinician.

A NobelGuide® Surgical Template can be ordered from Nobel Biocare using a design file created by Nobel Biocare's DTX Studio Implant software, or the template can be produced locally using the same design file.

- Refer to Nobel Biocare Instructions for Use (IFU) IFU2001 for information regarding NobelGuide® Surgical Templates. This IFU is available for download at ifu.nobelbiocare.com.
- Refer to the DTX Studio Implant Instructions for Use (available through the software, or on the DTX Studio Go website https://go.dtxstudio.com) for information regarding the DTX Studio Implant Software.

Nobel Biocare guided surgery tooling includes the following components:

- **Guided Drill Guides*** are available in different diameters for use with various guided drills and guided sleeves. They are inserted into the guided sleeves embedded in the surgical template and are used to guide the drill during preparation of the osteotomy.
- The **Handle for Guided Drill Guide*** extends the existing handle on the Guided Drill Guides for easier handling and better accessibility during surgery.
- **Guided Implant Mounts**** are 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. For the NobelActive implant system, the mounts have an outer diameter that matches the dimensions of the implant platform of the NobelActive implant and therefore will be smaller than the guided sleeve with a mandatory guided screw tap step to be used before implant insertion to address the specific needs of the guided NobelActive procedure.
- **Guided Template Abutments*** are used to keep the surgical template in the desired position when preparing osteotomies and placing the remaining implants.
- **Guided Tissue Punches**** can optionally be used during flapless guided surgery, before the drilling protocol, in order to cleanly remove the soft tissue without leaving any soft tissue "tags".
- **Guided Start Drills**** are guided round burs which are used to prepare the entrance point for an osteotomy.
- **Guided Twist Drills and Guided Twist Step Drills**** are guided drills used to prepare the osteotomy prior to implant placement. The Twist Drills and Twist Step Drills are designed in different diameters and lengths and have two cutting diameters, with the smaller diameter at the tip. The implant site is widened step by step to the right diameter and depth according to the drill protocol.
- **Guided Dense Bone Drills Tapered**** are used additionally to the other drills to prepare an osteotomy in dense bone situations, in order to reduce the insertion torque necessary to place an implant.
- **Guided Tapered Drills**** are custom designed per implant length and diameter. The depth reference system should be from the top of the guide sleeve embedded in the surgical template. A cylindrical part at the top of the drill should give guidance through the guide sleeve or a guided drill guide. A hard stop at the drill shaft forces the drill to stop at the correct height.
- **Guided Screw Taps**** are designed to cut threads in an osteotomy in dense bone.

Note: Guided screw tapping is required for guided placement of NobelActive implants.

- **Guided Counterbores**** are designed to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Guided Screw Tap and Guided Implant Mount from colliding with the bone. It can be used if sub-crestal placement is desired or where specific alveolar crest anatomy would prevent full depth insertion of the guided implant mount.

The following components are used in guided surgical procedures but are used for other applications and are therefore described in separate IFU. Refer to the referenced IFU for further information regarding these components.

- The **Unigrip Screwdriver** is used to manually tighten and loosen screws with a Unigrip interface, which are used to fix dental restorations onto Nobel Biocare dental implants. Refer to Nobel Biocare IFU1085 for more information regarding the Unigrip screwdriver.
- **Guided Anchor Pins** are thin rods of stainless steel positioned close to horizontally into the jawbone in order to secure the template in its defined position during surgery. Refer to Nobel Biocare IFU2001 for more information regarding Guided Anchor Pins.
- **Manual Torque Wrench Surgical** is used to insert and tighten Nobel Biocare implants as an alternative to machine tightening. Refer to Nobel Biocare IFU1046 for more information regarding the Manual Torque Wrench Surgical.
- **Manual Torque Wrench Prosthetic** is used to insert and tighten Nobel Biocare abutments and abutment screws as an alternative to machine tightening. Refer to Nobel Biocare IFU1046 for more information regarding the Manual Torque Wrench Prosthetic.
- The **Torque Wrench Prosthetic Adapter** is used to connect the Screwdriver Machine Unigrip and Omnigrip Screwdriver to the Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1046 for more information regarding the Torque Wrench Prosthetic Adapter.
- The **Connection to Handpiece** is used to connect the implant mount/implant assembly to the handpiece. Refer to Nobel Biocare IFU1058 for more information regarding the Connection to Handpiece.
- The **Drill Extension Shaft** is used to increase the length of drill shafts to access areas with limited interdental space and can be used for all Nobel Biocare implant systems. Refer to Nobel Biocare IFU1058 for more information regarding the Drill Extension Shaft.

* Class Ir device; see applicable CE Mark (CE 2797) after the Manufacturer and Distributor Information.

** Class IIa device; see applicable CE Mark (CE 2797) after the Manufacturer and Distributor Information.

Guided surgery tooling is available in PureSet kits for use with the following Nobel Biocare implant platforms:

- NobelParallel™ CC Guided PureSet for the placement of NobelParallel™ CC implants.
- NobelActive® Guided PureSet for the placement of NobelActive® implants.
- NobelReplace® CC Guided PureSet for the placement of NobelReplace® CC implants.

Refer to **Table 1** for the associated PureSet Wall Chart, which details the guided surgery tooling which is included in each kit.

Table 1: Guided Surgery Tooling PureSet Wall Charts

Wall Chart Article Number	Wall Chart Description
301165	NobelActive Guided PureSet Wall Chart
301166	NobelParallel CC Guided PureSet Wall Chart
301167	NobelReplace CC Guided PureSet Wall Chart

Guided surgery tooling for use with the following Nobel Biocare implant platforms is available as separate instruments; refer to the respective Surgical Procedure in this IFU for the list of tooling compatible with each implant platform:

- NobelReplace® Tapered.
- Replace Select™ Tapered.
- Brånemark System® (Brånemark System® Mk III Groovy and Brånemark System® Mk III TiUnite® RP).
- NobelSpeedy® Groovy.

Intended Use/Intended Purpose:

Guided Drill Guides, Guided Drill Guides Tapered, and the Handle for Guided Drill Guide:
Intended for use to guide drilling instruments during preparation of an osteotomy.

Guided Implant Mounts:
Intended for use to insert or remove dental implants during dental implant surgery.

Guided Template Abutments:
Intended for use during dental implant surgery to secure a surgical template or guide in its specified position.

Guided Tissue Punches:
Intended for use during guided dental implant surgery to remove a circular area of soft tissue prior to preparation of an osteotomy.

Guided Start Drills/Counterbores, the Guided Pilot Twist Drill, Guided Twist Drills, Guided Twist Step Drills, the Guided Twist Drill Tapered, Guided Drills Tapered, Guided Dense Bone Drills Tapered, Guided Screw Taps, Guided Screw Taps Tapered, Guided Dense Bone Screw Taps, and Guided Counterbores:
Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Indications:

Nobel Biocare Guided Surgery Tooling indicated for use to support guided preparation of an osteotomy, to facilitate placement of endosseous dental implants and implant system components intended to restore chewing function.

The following patient prerequisites must be fulfilled:

- Adequate amount and quality of jaw bone.
- Adequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.

Guided Drill Guides and Guided Drill Guides Tapered:
Guided Drill Guides and Guided Drill Guides Tapered are indicated to be inserted into the Guided Sleeves or Guided Pilot Drill Sleeves embedded in a dental surgical template to facilitate the preparation of an osteotomy in the maxilla or mandible during guided dental implant surgery, according to the position, direction and the height/depth defined according to the surgical plan.

Handle for Guided Drill Guide:
The Handle for Guided Drill Guide is indicated for use to extend the existing handle on Guided Drill Guides to facilitate handling of the drill guides during guided dental implant surgery.

Guided Implant Mounts:
Guided Implant Mounts are indicated for use during guided dental implant surgery to facilitate the insertion of the implant through the Guided Sleeves or Guided Pilot Drill Sleeves embedded in the surgical template and into the osteotomy.

Guided Template Abutments:
Guided Template Abutments are indicated for use during guided dental implant surgery in the maxilla or mandible, in partially edentulous and edentulous situations, as a replacement for the Guided Implant Mount, to fix the surgical template in the correct position when preparing the remaining and placing the remaining implants, and to facilitate removal of the surgical template after surgery.

Guided Tissue Punches:
Guided Tissue Punches are indicated for use during flapless guided dental implant surgery in the maxilla or mandible to cleanly remove soft tissue from the surgical site prior to preparing an osteotomy.

Guided Start Drills:
Guided Start Drills are indicated for use during guided dental implant surgery in the maxilla or mandible, prior to using the 1.5 mm Guided Pilot Twist Drill or the 2 mm Guided Twist Drill to prepare the entrance point for an osteotomy in uneven bone or in pointed bone, including "knife-edge ridge" and fresh extraction alveolas.

Guided Twist Drills, Guided Twist Step Drills, the Guided Twist Drill Tapered, and Guided Drills Tapered:
Guided Twist Drills, Guided Twist Step Drills, Guided Twist Drill Tapered, and Guided Drills Tapered are indicated for use during guided dental implant surgery in the maxilla or mandible to prepare an osteotomy for the placement of an endosseous dental implant.

Guided Dense Bone Drills Tapered:
Guided Dense Bone Drills Tapered are indicated for use during guided dental implant surgery in the maxilla or mandible in to prepare an osteotomy in dense bone for the placement of an endosseous dental implant.

Guided Screw Taps, Guided Screw Taps Tapered, and Guided Dense Bone Screw Taps:
Guided Screw Taps, Guided Screw Taps Tapered, and Guided Dense Bone Screw Taps are indicated for use during guided dental implant surgery in the maxilla or mandible to cut threads in an osteotomy in order to reduce the insertion torque necessary to place an endosseous dental implant in dense bone.

Guided Counterbores:
Guided Counterbores are indicated for use to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Guided Screw Tap and Guided Implant Mount from colliding with the bone.

Guided Start Drills/Counterbores:
Guided Start Drills/Counterbores are indicated for use to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Guided Screw Tap and Guided Implant Mount from colliding with the bone.

Contraindications:

It is contraindicated to use Nobel Biocare Guided Surgery Tooling in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be performed.
- Patients with inadequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.
- Patients in whom adequate sizes, numbers or desirable position of implants are not achieved to provide safe support of functional or eventually parafunctional loads.
- Patients allergic or hypersensitive to commercially pure titanium grade 4, stainless steel, diamond-like carbon (DLC) 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 for 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 to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions:

General:
One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) 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 Nobel Biocare Guided Surgery Tooling is used only with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare Guided Surgery Tooling can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

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.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

Before Surgery:
Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The devices have not been evaluated in pediatric/adolescent patients and are not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

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

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components

Before performing guided surgery, the surgical template must be carefully inspected and cleared by the clinician performing the surgery. Optimal fit on stone model or 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.

Care and maintenance of sterile 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 sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

After the implant placement, the surgeon's evaluation of bone quality and primary 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.

If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

After Surgery:
To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Intended Users and Patient Groups:

- Nobel Biocare Guided Surgery Tooling is to be used by dental health care professionals.
- Nobel Biocare Guided Surgery Tooling is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Nobel Biocare Guided Surgery Tooling:
Nobel Biocare guided surgery tooling is a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Nobel Biocare Guided Surgery Tooling:
The use of Nobel Biocare guided surgery tooling is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. Depending on location it may also lead in rare cases to fenestration or fracture of bone, perforation of neighboring structures, sinusitis, or sensory/motor disturbances. During use of these devices, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Notice regarding serious incidents:
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
https://www.nobelbiocare.com/complaint-form

Surgical Procedure: NobelParallel™ CC Guided Surgery Tooling:

1. 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.
2. 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 positioned 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.
3. During drilling procedures bone quality should be considered. (See **Table 2** 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 Ø 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 800 rpm 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 2: Recommended Drill Sequence for NobelParallel™ CC Implants Based on Bone Quality*

Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone (Type I)
Ø 3.75	2.0 | #2 (2.4/2.8) | (#3)	2.0 | #2 2.4/2.8 | #3 Guided Counterbore 3.75 | C (Guided Screw Tap 3.75) | (S)	2.0 | #2 2.4/2.8 | #3 2.8/3.2 | #4 Guided Counterbore 3.75 | C Guided Screw Tap 3.75 | S
Ø 4.3	2.0 | #2 2.4/2.8 | #3 (3.2/3.6) | (#5)	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 Guided Counterbore 4.3 | C (Guided Screw Tap 4.3) | (S)	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 Guided Counterbore 4.3 | C Guided Screw Tap 4.3 | S
Ø 5.0	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 (3.8/4.2) | (#6)	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 3.8/4.2 | #6 Guided Counterbore 5.0 | C (Guided Screw Tap 5.0) | (S)	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 3.8/4.2 | #6 Guided Counterbore 5.0 | C Guided Screw Tap 5.0 | S
Ø 5.5	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 4.2/4.6 | #7 (4.2/5.0) | (#8)	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 4.2/5.0 | #8 Guided Counterbore 5.5 | C (Guided Screw Tap 5.5) | (S)	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 4.2/5.0 | #8 Guided Counterbore 5.5 | C Guided Screw Tap 5.5 | S

* Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

Caution: Guided Twist/Step Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10 mm 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 13 mm implants for 7–13 mm drills and 7, 10, 13, 15 and 18 mm for 7–18 mm drills (**Figure A**). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

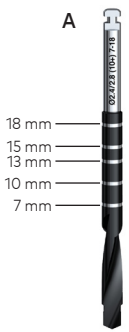
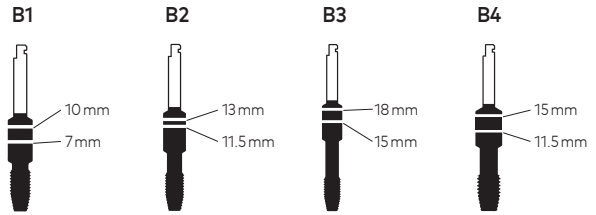


Figure A: Depth Marks on the Guided Twist/Step Drills

4. Prepare implant site.
5. Medium and dense bone protocol: to be used when implant will not be fully seated.
   - Select the Guided Counterbore matching the diameter of the implant. Place the Guided Counterbore directly in the guided sleeve of the surgical template and drill to the built-in drill stop at maximum speed of 800 rpm with copious irrigation.
   - Select the Guided Screw Tap matching the diameter and length of the implant. To select an appropriate Guided Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Screw Tap to feed without pressure to appropriate depth. **Figure B1** shows depth markings which correspond to full depth tapping of 7 mm and 10 mm for Ø 3.75, Ø 4.3, Ø 5.0 and Ø 5.5 implants. **Figure B2** shows depth markings which correspond to full depth tapping of 11.5 mm and 13 mm for Ø 3.75, Ø 4.3, Ø 5.0 and Ø 5.5 implants. **Figure B3** shows depth markings which correspond to full depth tapping of 15 mm and 18 mm for Ø 3.75, Ø 4.3 and Ø 5.0 implants only and **Figure B4** shows depth markings which correspond to full depth tapping of 11.5 mm and 15 mm for Ø 5.5 implants only.
   - Switch the drill device to reverse mode and remove the Guided Screw Tap.



Figures B1 – B4: Depth Marks on Guided Screw Taps

6. Open the implant package. Connect the Guided Implant Mount NobelParallel™ CC to the implant using the Unigrip™ Screwdriver. Insert the Connection to Handpiece in the drilling unit handpiece and pick up the mounted implant. NobelParallel™ CC 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 NobelParallel™ CC includes a vertical stop. Ensure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

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

7. If the implant gets stuck during implant installation or **45 Ncm** is achieved before fully seated, rotate the implant counter clockwise using the drilling device (reverse mode) or the Manual Torque Wrench and remove from the site. Replace the implant in the inner casing before proceeding further (refer to the Medium and 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**.
8. In partially edentulous and edentulous situations it is recommended to use Guided Template Abutments implants instead of Guided Implant Mounts on the first 1 or 2 implant sites. 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.
9. Prepare and install the remaining implant sites.
10. 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.
11. Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical.
12. 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. Refer to the applicable Nobel Biocare IFU for more information regarding abutments and cover screws.

For additional information on the NobelParallel™ CC implant refer to Nobel Biocare IFU1002.

Surgical Procedure: NobelActive® Guided Surgery Tooling:

1. 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.
2. 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 positioned, 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.
3. During drilling procedures bone quality should be considered. (See **Table 3** 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 Ø 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 800 rpm 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.

   Note: Screw tapping is a mandatory step for guided implant insertion.

Table 3: Recommended Drill Sequence for NobelActive® Implants Based on Bone Quality*

Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone (Type I)
Ø 3.75	2.0 | #2 (2.4/2.8) | (#3) Guided Screw Tap 3.5 | S	2.0 | #2 2.4/2.8 | #3 (2.8/3.2) | (#4) Guided Screw Tap 3.5 | S	2.0 | #2 2.4/2.8 | #3 2.8/3.2 | #4 Guided Dense Bone Screw Tap 3.5 | S
Ø 4.3	2.0 | #2 2.4/2.8 | #3 (3.2/3.6) | (#4) Guided Screw Tap 4.3 | S	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 Guided Screw Tap 4.3 | S	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 (3.8/4.2) | (#6) Guided Dense Bone Screw Tap 4.3 | S
Ø 5.0	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 Guided Screw Tap 5.0 | S	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 3.8/4.2 | #6 Guided Screw Tap 5.0 | S	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 3.8/4.2 | #6 (4.2/4.6) | (#7) Guided Dense Bone Screw Tap 5.0 | S
Ø 5.5	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 (3.8/4.2) | (#6) Guided Screw Tap 5.5 | S	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 3.8/4.2 | #6 4.2/4.6 | #7 (4.2/5.0) | (#8) Guided Screw Tap 5.5 | S	2.0 | #2 2.4/2.8 | #3 3.2/3.6 | #5 3.8/4.2 | #6 4.2/5.0 | #8 Guided Dense Bone Screw Tap 5.5 | S

* Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

Caution: Guided Twist/Step Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10 mm 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 13 mm implants for 7-13 mm drills and 7, 10, 13, 15, and 18 mm for 7-18 mm drills (**Figure C**). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated (**Figure D**). Allow for this additional length when drilling near vital anatomical structures.

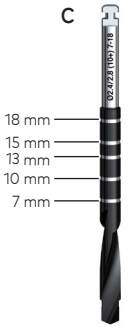


Figure C: Depth marks on drills

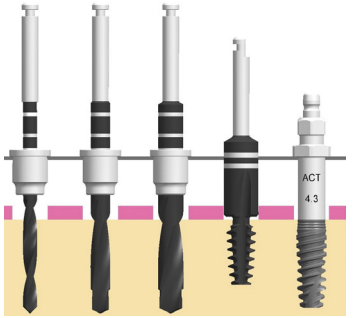
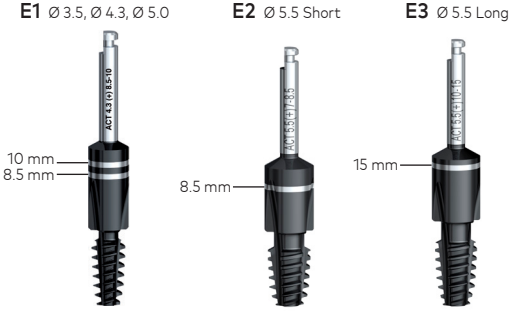


Figure D: Drill extension

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

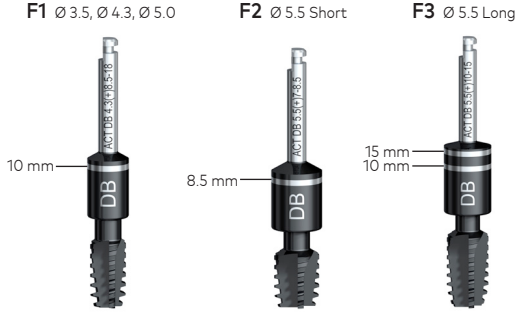
Soft and medium bone -use the Guided Screw Tap (see **Table 3** for recommended screw taps). Select the Guided Screw Tap NobelActive® matching the diameter of the implant. To select an appropriate Guided Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Screw Tap to feed without pressure to appropriate depth. **Figure E1** shows Guided Screw Tap depth markings which correspond to full depth tapping of 8.5 mm and 10 mm for Ø 3.5, Ø 4.3 and Ø 5.0 implants. **Figure E2** shows Guided Screw Tap depth markings which correspond to full depth tapping of 8.5 mm for Ø 5.5 implants. **Figure E3** shows Guided Screw Tap depth markings which correspond to full depth tapping of 15 mm for Ø 5.5 implants.



Figures E1 – E3: Depth Markings of Guided Screw Taps

Dense bone – use the Guided Dense Bone Screw Tap (see **Table 3** 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. To select an appropriate Guided Dense Bone Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Dense Bone Screw Tap to feed without pressure to appropriate depth. **Figure F1** shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 10 mm for Ø 3.5, Ø 4.3, and Ø 5.0 implants. **Figure F2** shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 8.5 mm for Ø 5.5 implants. **Figure F3** shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 10 mm and 15 mm for Ø 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.



Figures F1 – F3: Depth Markings of Guided Dense Bone Screw Taps

Warning: Avoid early bone contact (**Figure G**). 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.

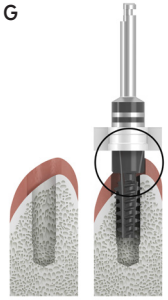
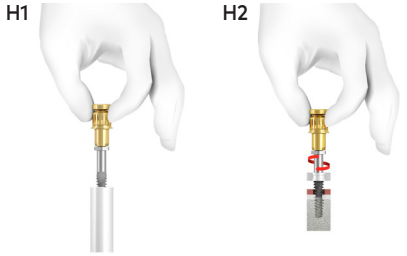


Figure G: Avoid Early Bone Contact with Screw Tap

6. 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 Adapter form the Manual Torque Wrench Surgical (**Figure H1**). 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 (**Figure H2**).

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



Figures H1 and H2: Using Surgical Adapter and Manual Torque Wrench Surgical to Start Placing Implant

7. Remove the surgical adapter and continue with implant insertion using the Connection to Handpiece and drilling unit. NobelActive® implants must be installed with low speed, maximum 25 rpm using the drilling unit. For final implant insertion, use the Manual Torque Wrench to avoid implant over-tightening. The maximum insertion torque for the implant is **70 Ncm** for NobelActive® Ø 3.5, Ø 4.3, Ø 5.0, and Ø 5.5 implants 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 **70 Ncm** for NobelActive® Ø 3.5, Ø 4.3, Ø 5.0, and Ø 5.5 implants. 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 4** and **Figure I**). 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 4: Diameter References for NobelActive® CC Guided Components

Component	NP	RP 4.3	RP 5.0	WP 5.5
Guided Sleeve (A)	Ø 4.11	Ø 5.02	Ø 6.22	Ø 6.22
Implant Mount (B)	Ø 3.52	Ø 3.9	Ø 3.9	Ø 5.08
Diameter Difference	0.59	1.12	2.32	1.14

Diameters and Diameter Differences presented in mm.

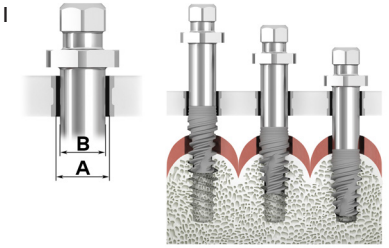


Figure I: Implant Mount is Smaller than Guided Sleeve

8. If the implant gets stuck during implant installation or **70 Ncm** for NobelActive® Ø 3.5, Ø 4.3, Ø 5.0, and Ø 5.5 implants 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 **35-70 Ncm**.
9. In partially edentulous and fully 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.
10. Prepare and install the remaining implant sites.
11. 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.
12. Depending on the loading 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 the NobelActive® implant please refer to the NobelActive® Instructions for use (IFU1001).

Surgical Procedure: Brånemark System® Mk III Groovy, Brånemark System® Mk III TiUnite® (RP only) and NobelSpeedy® Groovy Guided Surgery Tooling:

Table 5 presents a summary of the Nobel Biocare guided surgery tooling which is compatible with the Brånemark System®:

Table 5: Guided Surgery Tooling for Brånemark System

Article Number	Description
29081	Connection to Handpiece
29149	Screwdriver Manual Unigrip 28 mm
29151	Screwdriver Machine Unigrip 20 mm
29164	Drill Extension Shaft
29167	Manual Torque Wrench Adapter Prosthetic
30909	Guided Anchor Pin Ø 1.5 mm
32110	Brånemark System Manual Torque Wrench Surgical
32797	Guided Drill Guide Kit Box
32802	Guided Template Abutment w. Screw Brånemark System NP
32804	Guided Template Abutment with Screw Brånemark System RP
32807	Guided Template Abutment w. Screw Brånemark System WP
32813	Handle for Guided Drill Guide
32814	Guided Drill Guide NP to Ø 2 mm
32815	Guided Drill Guide RP to Ø 2 mm
32816	Guided Drill Guide 6.0/WP to Ø 2 mm
32817	Guided Drill Guide NP to Ø 2.8 mm
32818	Guided Drill Guide RP to Ø 2.8 mm
32819	Guided Drill Guide NP to Ø 3 mm
32820	Guided Drill Guide RP to Ø 3 mm
32821	Guided Drill Guide 6.0/WP to Ø 3 mm
32822	Guided Drill Guide RP to Ø 3.2 mm
32823	Guided Drill Guide RP to Ø 3.4 mm
32824	Guided Drill Guide 6.0/WP to Ø 3.8 mm
32825	Guided Drill Guide 6.0/WP to Ø 4.2 mm
32863	Guided Implant Mount Brånemark System NP
32865	Guided Implant Mount Brånemark System RP
32868	Guided Implant Mount Brånemark System WP

Table 6 presents a summary of the Nobel Biocare guided surgery tooling which is compatible with the NobelSpeedy® Groovy implant platform:

Table 6: Guided Surgery Tooling for NobelSpeedy® Groovy Implant Platform

Article Number	Description
29081	Connection to Handpiece
29149	Screwdriver Manual Unigrip 28 mm
29151	Screwdriver Machine Unigrip 20 mm
29164	Drill Extension Shaft
29167	Manual Torque Wrench Adapter Prosthetic
30909	Guided Anchor Pin Ø 1.5 mm
32110	Brånemark System Manual Torque Wrench Surgical
32797	Guided Drill Guide Kit Box
32802	Guided Template Abutment w. Screw Brånemark System NP
32804	Guided Template Abutment with Screw Brånemark System RP
32807	Guided Template Abutment w. Screw Brånemark System WP
32813	Handle for Guided Drill Guide
32814	Guided Drill Guide NP to Ø 2 mm
32815	Guided Drill Guide RP to Ø 2 mm
32816	Guided Drill Guide 6.0/WP to Ø 2 mm
32817	Guided Drill Guide NP to Ø 2.8 mm
32818	Guided Drill Guide RP to Ø 2.8 mm
32819	Guided Drill Guide NP to Ø 3 mm
32820	Guided Drill Guide RP to Ø 3 mm
32821	Guided Drill Guide 6.0/WP to Ø 3 mm
32822	Guided Drill Guide RP to Ø 3.2 mm
32823	Guided Drill Guide RP to Ø 3.4 mm
32824	Guided Drill Guide 6.0/WP to Ø 3.8 mm
32825	Guided Drill Guide 6.0/WP to Ø 4.2 mm
32863	Guided Implant Mount Brånemark System NP
32865	Guided Implant Mount Brånemark System RP
32868	Guided Implant Mount Brånemark System WP
32816	Guided Drill Guide 6.0/WP to Ø 2 mm
32821	Guided Drill Guide 6.0/WP to Ø 3 mm
32824	Guided Drill Guide 6.0/WP to Ø 3.8 mm
32825	Guided Drill Guide 6.0/WP to Ø 4.2 mm
32826	Guided Drill Guide 6.0/WP to Ø 6 to Ø 5 mm
32868	Guided Implant Mount Brånemark System WP
32807	Guided Template Abutment w. Screw Brånemark System WP

1. 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.
2. 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.
3. During drilling procedures bone quality should be considered. (See **Table 7** 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 Ø 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 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 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.

Table 7: Recommended Drill Sequence for Brånemark System® Implants Based on Bone Quality*

Platform	Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone** (Type I)
NP	Ø 3.3	2.0	2.0	2.0 2.8
RP***	Ø 3.75	2.0 (2.8)	2.0 3.0	2.0 3.2
RP***	Ø 4.0	2.0 (2.8)	2.0 3.2	2.0 2.8 3.4
WP	Ø 5.0	2.0 3.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2

* Drill data are stated in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

** Screw taps are available and recommended for use if insertion torque exceeds 45 Ncm.

*** For Brånemark System® Mk III TiUnite® RP implants use Guided Start Drill Counterbore former Mk III RP (Art. No. 33113).

Table 8: Recommended Drill Sequence for NobelSpeedy® Groovy Implants Based on Bone Quality*

Platform	Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone** (Type I)
NP	Ø 3.3	2.0	2.0	2.0 2.8
RP	Ø 4.0	2.0 (2.8)	2.0 3.2	2.0 2.8 3.4
WP	Ø 5.0	2.0 3.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2
6.0	Ø 6.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2	2.0 3.0 3.8 4.2 5.0

* Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

** Screw taps are available and are recommended for use if the insertion torque exceeds 45 Ncm.

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

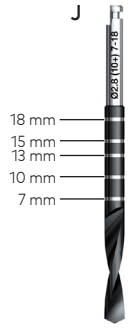
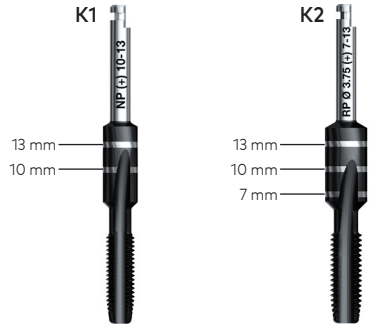


Figure J: Depth Marks on Guided Twist Drills

4. Prepare implant site.
5. Dense bone protocol: to be used if insertion torque exceeds **45 Ncm** and the implant will not be fully seated.
   - Select the Guided Screw Tap matching the diameter and length of the implant. To select an appropriate Guided Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Screw Tap to feed without pressure to appropriate depth. **Figure K1** shows depth markings which correspond to full depth tapping of 10 mm and 13 mm for Ø 3.3 mm implants. **Figure K2** shows depth markings which correspond to full depth tapping of 7 mm, 10 mm and 13 mm for Ø 3.75, Ø 4.0, Ø 5.0 and Ø 6.0 implants.
   - Switch the drill device to reverse mode and remove the Guided Screw Tap.



Figures K1 and K2: Depth Marks on Guided Screw Taps

6. If the implant shoulder was planned below the bone crest, use the Guided Start Drill/Counterbore to generate adequate access for the Guided Implant Mount. Select the Guided Start Drill/Counterbore matching the diameter of the implant.

Note: A specific Guided Start Drill/Counterbore is available for Brånemark System® Mk III TiUnite® RP.

7. Drill to the built-in stop at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution.
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 unit handpiece and pick up the mounted implant. Brånemark System® NobelSpeedy® Groovy 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. Secure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

Caution: Never exceed insertion torque of **45 Ncm** for Brånemark System® and NobelSpeedy® Groovy Implants. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

9. If the implant gets stuck during implant installation or **45 Ncm** is achieved before fully seated, rotate the implant counter clockwise using the drilling device (reverse mode) or the Manual Torque Wrench and remove from the 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. 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.
11. Prepare the remaining implant sites and install the implants.
12. 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.
13. Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical.
14. 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 regarding Brånemark System® please refer to the Nobel Biocare Instructions for Use (IFU) for the implant (IFU1015).

For additional information regarding NobelSpeedy® Groovy implants please refer to the Nobel Biocare Instructions for Use (IFU) for the implant (IFU1007).

Surgical Procedure: NobelReplace® Tapered and Replace Select™ Tapered Guided Surgery Tooling:

1. 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.
2. 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.
3. During drilling procedures bone quality should be considered. (See **Figure L** 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 Ø 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 800 rpm 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.

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 DTX Studio Implant Software includes the extended drill lengths).

L

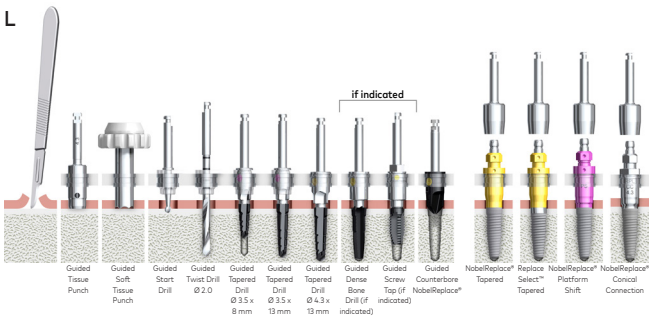


Figure L: Example Complete Drilling Sequence for the Ø 4.3 RP 13 mm Implant

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.

4. Prepare implant site. Start with the Guided Start Drill with the appropriate Guided Drill Guide Ø 2 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 Ø 2 mm.
5. Drill using the Guided Twist Drill Tapered Ø 2 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 Ø 2 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 (**Figure M**). The level should be measured with the Guided Drill Guide 2 mm in place.

M

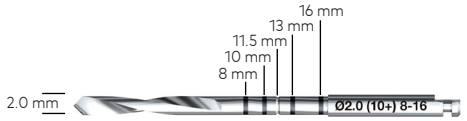


Figure M: Guided Twist Drill Tapered

6. 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 (**Figure N**). Drills extend up to 1 mm longer than the implant when seated.

N

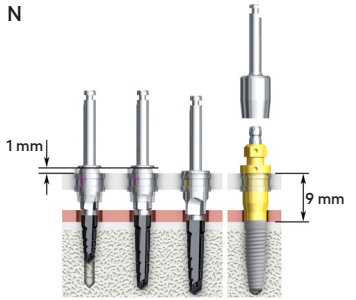


Figure N: Depth marks on Guided Tapered Drills

7. 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.
8. 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.
9. 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.
10. 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 (**Figure O**).

O

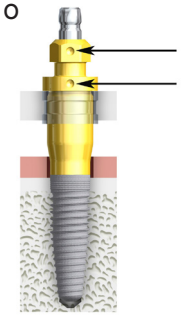


Figure O: Indication marks on the Guided Implant Mount

11. 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 (**Figure P**).

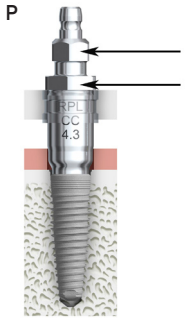


Figure P: The flat surfaces of the hexagon of the inbuilt drill stop on the Guided Implant Mount indicate the position of the internal hexagon

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.

12. 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**.
13. 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. The 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 Tapered 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 Tapered 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 (**Figure Q**). 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.
14. Continue with implant installation until desired position is achieved using max **45 Ncm** installation torque.

Figure Q: Product reference line Guided Screw Tap versus implant length

15. In partially edentulous and fully 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.
16. Prepare and install the remaining implant sites.
17. 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.
18. 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.
19. 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 regarding the NobelReplace® Tapered and Replace Select™ Tapered implants, refer to the Nobel Biocare Instructions for Use (IFU) for the implants (IFU1008 and IFU1010 respectively).

Materials:

- Guided Drill Guides: Titanium alloy Ti6Al4V ELI according to ASTM F136 and ISO 5832-3.
- Handle for Guided Drill Guide: Stainless Steel 1.4301 according to ASTM F899.
- Connection to Handpiece: Stainless Steel Sandvik Bioline 1RK91 according to ASTM F899.
- Connection to Handpiece O-Ring: Fluorelastomer Compound #9844Guided Implant Mounts Body NobelReplace: Titanium alloy according to ASTM F136.
- Guided Implant Mounts Body NobelActive and NobelParallel: Stainless Steel 1.4197 according to ASTM F899.
- Guided Implant Mounts Screw: Titanium alloy Ti6Al4V according to ASTM F136.
- Guided Template Abutments Body: Stainless steel 1.4441 according to ASTM F138.
- Guided Template Abutments Screw: Stainless steel Sandvik 1RK91 according to ASTM F899.
- Guided Tissue Punch: Stainless Steel 1.4542/UNS S17400 according to ASTM A564M.
- Guided Anchor Pin: Stainless Steel alloy 303, 1.4305, according to ASTM A582, AISI 303.
- Drill Extension Shaft: Stainless Steel UNS S45500 according to ASTM A564, Stainless Steel 303 and Teflon.
- Drill Extension Shaft.
- Guided Start Drill: Stainless Steel 630 according to ASTM A564M/ASTM F899 with diamond-like carbon (DLC) coating.
- Guided Twist Drills and Guided Twist Step Drills: Stainless Steel 420F Mod according to ASTM A895/ASTM F899 with diamond-like carbon (DLC) coating.
- Guided Screw Tap: Stainless Steel 420F Mod according to ASTM A895/ASTM F899 with diamond-like carbon (DLC) coating.
- Guided Counterbore: Stainless Steel 630 according to ASTM A564M/ASTM F899 with diamond-like carbon (DLC) coating.
- Guided Dense Bone Drills Tapered: Stainless Steel 630 according to ASTM A564M/ASTM F899 with diamond-like carbon (DLC) coating.
- Guided Drill Tapered: Stainless Steel 630 according to ASTM A564M/ASTM F899 with diamond-like carbon (DLC) coating.
- Guided Twist Drill Ø 1.5 × 20 mm: Stainless Steel 420F Mod according to ASTM A895/ASTM F899.
- Guided Twist Drill Tapered 2 × (10+) 8-16 mm: Stainless Steel 420F Mod according to ASTM A895/ASTM F899.

Sterility and Reusability Information:

Guided Start Drills, Guided Twist/Step Drills, Guided Screw Taps and Guided Counterbores have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

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

Caution: Guided Start Drills, Guided Twist/Step Drills, Guided Screw Taps and Guided Counterbores are single use devices and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Guided Drill Guides, Handle for the Guided Drill Guide, Guided Implant Mounts, Guided Template Abutments, Guided Tissue Punches, Guided Anchor Pins, Drill Extension Shaft, Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered are delivered non-sterile and intended for reuse. Prior to first use and reuse clean, disinfect and/or sterilize following the manual or automated procedure in the Cleaning, Disinfection, and Sterilization Instructions.

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

The Guided Drill Guides, Handle for the Guided Drill Guide, Guided Implant Mounts, Guided Template Abutments, Guided Tissue Punches, Guided Anchor Pins, Drill Extension Shaft, Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered are reusable components which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The devices shall be discarded if any wear, abrasion of the anodization, deformations or corrosion is visible on the component.

The Guided Implant Mounts must specifically be inspected before each use, to ensure that the coated hex of the implant mount body has no visible deformation; if any deformation is visible the implant mounts shall be discarded.

The Guided Drill Guides must specifically be inspected before each use, to ensure that no deep scratches, dents, flakes, chippings are visible on the guiding surface or any surface corrosion is visible; if any deep scratches, dents, flakes, chippings on the guiding surface or any surface corrosion is visible, the Guided Drill Guide shall be disposed.

The Guided Template Abutments must specifically be inspected before each use, to check if any plastic deformation and/or corrosion is visible. In particular, the Guided Template Abutment shall slide inside the sleeve without applying any force. If plastic deformation and/or corrosion is visible or force needs to be applied, the Guided Template Abutments shall be disposed.

Nobel Biocare recommends that the Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered are replaced after 20 uses, or when cutting efficiency declines.

Caution: Worn-out and damaged drills need to be discarded and replaced with new sharp drills. The over-extended use may cause bone overheating and lead to implant failure.

Note: Guided Drill Guides, Handle for the Guided Drill Guide, Guided Implant Mounts, Guided Template Abutments, Guided Tissue Punches, Guided Anchor Pins Drill Extension Shaft, Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered can be processed as individual devices as described in the Cleaning, Disinfection, and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Note: The Unigrip Screwdriver, Manual Torque Wrenches Surgical and Prosthetic, Torque Wrench Prosthetic Adapter, and Connection to Handpiece are reusable instruments which are delivered non-sterile and must be cleaned, disinfected, and sterilized prior to use and reuse. Prior to reuse, the instruments should also be inspected to ensure that the integrity and performance continues to be maintained. Refer to the following Nobel Biocare IFU for information regarding the cleaning, disinfection, and sterilization procedures and reusability criteria for these instruments (**Table 9**):

Table 9: Instruments with Cleaning/Sterilization and Reusability Information in Other IFU

Component	IFU Number
Unigrip Screwdriver	IFU1085
Manual Torque Wrenches Surgical and Prosthetic Torque Wrench Prosthetic Adapter	IFU1046
Connection to Handpiece	IFU1058

Note: Nobel Biocare guided surgery tooling can be processed as individual devices as described in the Cleaning, Disinfection, and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Cleaning and Sterilization Instructions:

The Guided Drill Guides, Handle for the Guided Drill Guide, Guided Implant Mounts, Guided Template Abutments, Guided Tissue Punches, Guided Anchor Pins, Drill Extension Shaft, Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: Nobel Biocare guided surgery tooling has been validated to withstand these cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Caution: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122.0 °F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vaccum cycle); Amsco Century Sterilizer (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Seal each device in a suitable sterilization. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 10 presents examples of suitable sterilization containers, pouches, and wraps.

Table 10: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (**Table 11**):

Table 11: Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Performance Requirements and Limitations:

To achieve the desired performance, Nobel Biocare Guided Surgery Tooling must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with Nobel Biocare Guided Surgery Tooling, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training:

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

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:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
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Distributed in New Zealand by:
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CE Mark for Class I Devices

CE 2797 Mark for Class Ir Devices

Note: Refer to the product label to determine the applicable CE mark for each device.

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
Guided Drill Guides, Guided Drill Guides Tapered, and Handle for Guided Drill Guide	733274700000015578
Guided Implant Mounts	7332747000000157 7C
Guided Template Abutments	7332747000000134 6Y
Guided Tissue Punches	7332747000000187 7M
Guided Start Drills/Counterbores, Guided Pilot Twist Drill, Guided Twist Drills, Guided Twist Step Drills, Guided Twist Drill Tapered, Guided Screw Taps, Guided Dense Bone Screw Taps, and Guided Counterbores	733274700000014473
Guided Dense Bone Drills Tapered, Guided Drills Tapered, Guided Screw Taps Tapered	733274700000014677

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

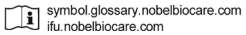
Rx Only

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



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