

NobelGuide® Surgical Template

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 surgical template is a patient-specific product made from biocompatible epoxy-based photopolymer. The surgical template is produced based on data from the 3D-planning software, NobelClinician®. Embedded into the surgical template are metal guided sleeves (A:1) or guided pilot drill sleeves (A:2) that define the position, direction and height/depth of the implant surgical sites.

A:1

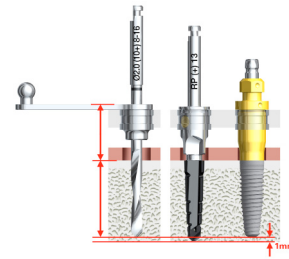


A:2

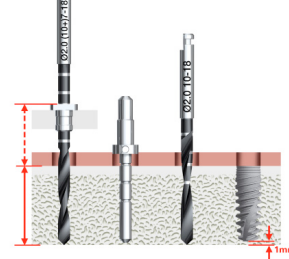


The guided (pilot drill) sleeves are highly precise metal cylinders embedded with the long axis identical to the planned long axis of the planned implant position. The level of the outer shoulder of the guided (pilot drill) sleeve defines the depth of the surgical preparation and implant position since there is a pre-defined relationship between this level and the implant/abutment interface (B:1/B:2). This relationship is also respected in Nobel Biocare's NobelGuide® surgical instrumentation.

B:1 – Fully Guided



B:2 – Pilot Drill



Also embedded in the surgical template are sleeves for anchor pins. These sleeves guide the preparation and installation of anchor pins. The anchor pins are thin rods of metal positioned close to horizontally into the jawbone in order to secure the surgical template in its intended position.

Indications for use:

The surgical template is a device produced through 3D production technology containing precision made cylinder(s), for guided dedicated instrumentation intended to facilitate dental implant placement at a virtually planned position.

Pilot drill and fully guided surgery utilizing surgical templates can be applied in selected cases, identified both clinically by indication for implant treatment; prosthetic needs; mouth opening; parafunction; psychological status and during the virtual planning process by anatomy; bone quality; relationship with adjacent structures.

Guided surgery is indicated for the treatment of a single missing tooth, partially edentulous and edentulous jaws for the preparation of implant sites and the placement of implants to restore the patient's esthetic and chewing function. The following prerequisites must be fulfilled:

- Adequate amount of jawbone volume (height and width).
- Quality of jawbone must be judged as adequate.
- Adequate mouth opening (minimum 40mm) to accommodate guided surgery tooling.
- Exclusion of compromised disease in conflict with dental implant treatment.

The pilot drill surgical template is intended to be used to define the position of the first drill in the selected drill protocol, based on the planned implant system. Following this first drill, the surgical template is removed and the remaining drill sequences and implant placement are carried out "free-hand".

The fully guided surgical template enables guided drilling of the implant site following the appropriate drill protocol and guided placement of the selected planned implant. Optionally, the clinician can also do the screw tapping and implant insertion in a guided way.

Note: For Contraindications, Warnings and Cautions for NobelClinician Software and implants please refer to applicable implant Instructions for Use.

Contraindications:

It is contraindicated to use a surgical template in patients:

- Who are medically unfit for an oral surgical procedure.
- In whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Who are allergic or hypersensitivity to commercially pure titanium grade 4, stainless steel or surgical template material epoxy-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 jawbone, 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, non-observance 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 NobelGuide® surgical templates 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 info 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:

A careful clinical and radiological examination and diagnosis of the patient must 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.

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

At surgery:

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

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

After surgery:

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

Surgical procedure:

Planning details and guided drill depth measurements are obtained in the NobelClinician® treatment plan report of the final approved plan which was the basis for the surgical template ordered. The treatment plan report should be printed and utilized during the surgical procedure.

Please ensure the following checklist for Surgical Templates is completed:

Checklist:

Before performing guided surgery, the delivered surgical template must be carefully inspected and cleared by the clinician performing the surgery:

- Confirm the surgical template corresponds with the virtual treatment plan in the NobelClinician® Software.
- Verify optimal fit on stone model if applicable and/or in patient's mouth. If in doubt, please contact Nobel Biocare technical support. If adjustment is required, carefully modify the surgical template accordingly using a Lab bur.
- If adjusted, strengthen/reinforce surgical template with compatible resin when needed by reinforcing the outer surface with a compatible resin material (e.g. Triad, Dentsply International Inc., USA).
- Confirm that there is no excess support material or guided sleeve extending through to the fitting surface of the surgical template. If adjustment is required, carefully modify the surgical template accordingly using a Lab bur.
- Check thoroughly and carefully for excess material within the internal portion of the guided sleeves and confirm the fit of the guided drill guides and/or the guided (twist)drills.
- In order to confirm correct seating of the surgical template in partially edentulous situations, create inspection windows by grinding small windows over a cusp or corner of a tooth so the underlying dentition protrudes through. Create 3–4 windows, evenly distributed over the entire arch.
- Ensure mechanical strength of the surgical template is maintained by confirming the template covers the entire arch of the jaw being treated and fulfills the recommended minimum thickness of 2.5 mm.

Note: The surgical template must be disinfected using a high level disinfectant immediately prior to the surgical procedure. Please follow Cleaning and sterilization instructions for Laboratory and Clinical cleaning.

Anchoring of the surgical template:

An adequate number of anchor pins, using the Guided Twist Drill 1.5 mm, should be placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to ensure that the surgical template does not move in any direction from the correct position when being manipulated with instruments (e.g. lateral shift through inadequate handling of (pilot-) 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 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.

A. Guided Pilot Drilling procedure using the pilot drill Surgical Template (C):

C



Note: It is recommended that guided pilot drilling is done prior to raising a (mini-) flap to ensure the correct position of the surgical template is maintained.

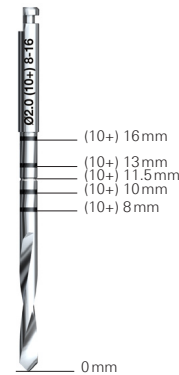
1. Depending on the pilot sleeve size of the surgical template (1.5 mm or 2.0 mm) select either the Guided Pilot Twist Drill 1.5 mm or the Guided Twist Drill 2.0 mm and drill at high speed (maximum 800 rpm) under constant and copious irrigation to the depth as defined in the NobelClinician® treatment plan report. An in-and-out motion over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Caution: Guided Pilot/Twist Drills are identified by the (10+) designation on the shaft, which indicates the drills are 10 mm longer to compensate for the height of the surgical template. All measurements are taken from the tip of the guided twist drill to the bottom edge of the depth marking (D:1/D:2).

D:1 – Guided Twist Drill



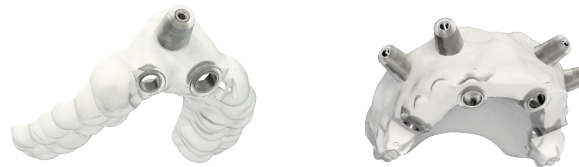
D:2 – Guided Twist Drill Tapered



2. After guided drilling using the Guided Pilot/Twist Drill, the anchor pins (if applicable) are removed and the surgical template is removed.
3. The orientation and depth of the osteotomy will act as a reference for the free-hand surgical tooling. Explore and learn orientation, depth and identified vertical reference for free-hand surgical instrumentation with the patient's anatomy by using a position indicator with depth markings or use the freehand drill (not rotating) in the respective final pilot drill diameter.
4. Continue with freehand surgery and carefully apply all common clinical rules and procedures attached to this.

B. Guided drilling procedures using the fully guided surgical template (E):

E



For information on the surgical access techniques and implant specific guided drilling protocols, please refer to the implant specific NobelGuide® Instructions for Use.

Guided implant insertion:

Partially edentulous:

1. Insert the implant until the flange of the Guided Implant Mount touches the outer surface of the guided sleeve in the surgical template. Avoid further tightening of the implant as this may affect the correct position of the surgical template.
2. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount.

Note: if the implant mount is difficult to remove, use an open-end wrench or forceps to gently wiggle it free.

3. 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.
4. Prepare and install the remaining implant sites following the implant specific guided drilling procedure.

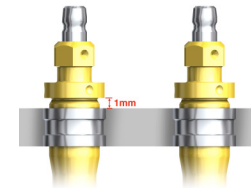
Note: if only two implants are placed, there is no need for a Guided Template Abutment on the second implant.

5. Once all implants are installed remove Guided Implant Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. If the Guided Implant Mount is difficult to remove, use an open-end wrench or forceps to gently wiggle it free. Remove the anchor pins and the surgical template.
6. Depending on the surgical protocol of choice, place a cover screw or abutment and suture.

Edentulous:

1. Insert the first implant (for example in the canine position) until the flange of the Guided Implant Mount is 1 mm short of the outer surface of the surgical template sleeve. Leave the Guided Implant Mount in position.
2. Choose the implant site strategically placed in the middle of the opposite half of the arch to obtain proper distribution. Prepare and insert the second implant until the flange of the Guided Implant Mount is 1 mm short of the outer surface of the sleeve of the surgical template. (F)

F



3. Using the Manual Torque Wrench Surgical, carefully seat implants 1 and 2 alternately until the flange of the Guided Implant Mounts slightly touch the surgical template.

Note: follow the described protocol to minimize risk of over-torquing and to minimize movement of the surgical template.

4. Release the Guided Implant Mounts using the Unigrip™ Screwdriver and remove the Guided Implant Mounts.

Note: if the implant mount is difficult to remove, use an open-end wrench or forceps to gently wiggle it free.

5. Anchor the surgical template using the Guided Template Abutment on implants 1 and 2, manually tightening alternately using the Unigrip™ Screwdriver. Ensure the surgical template maintains its initial correct position for the next implant site preparation.
6. Prepare and install the remaining implant sites following the implant specific guided drilling procedure. Leave the Guided Implant Mounts in position until all implants are placed.
7. Once all implants are installed remove Guided Implant Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. If the Guided Implant Mount is difficult to remove, use an open-end wrench or forceps to gently wiggle it free. Remove the anchor pins and the surgical template.

8. 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 latest printed version from a Nobel Biocare representative.

For additional information on Nobel Biocare implants please refer to the implant specific Instructions for Use.

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

Materials:

Surgical templates are made from a epoxy-based photopolymer material.

Cleaning and sterilization:

Due to the fact that pre-processing in the dental laboratory is needed to optionally prefabricate master casts containing implant replicas at the planned implant locations for preparing provisional's prior to surgery, the surgical template is delivered non-sterile. Use disinfecting agents described below.

In the laboratory:

Use ultrasonic cleaning with water and mild detergents. Rinse thoroughly with water, dry thoroughly and return to the protection bag in which it was delivered.

In the clinic:

Immediately prior to surgery, disinfect the surgical template in a high level disinfectant, according to the manufacturer's instructions (e.g. Chlorhexidine solution). Rinse thoroughly with sterile water and dry thoroughly but not longer than 40 minutes.

Caution: Do not use heat on the surgical template.

Caution: Do not autoclave the surgical template.

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

MR safety information:

Note: For Implant MR safely information please refer to applicable Implant Instructions for Use.

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 surgical template must be stored in the original bag in which it was delivered.

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.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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CE Mark for Class I Devices

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



Sterilized using ethylene oxide



Sterilized using irradiation



Temperature limit



Tooth number



CE marking



Consult instructions for use



Contains hazardous substances



Contains or presence of phthalate



Upper limit of temperature



Sterilized using steam or dry heat



Unique Device Identifier



Use-by date



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

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