NobelGuide® Surgical Templates and Guided Anchor Pins

Important – Disclaimer of Liability

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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.

Figure A:1 – Pilot Drill NobelGuide® Surgical Template

Figure A:2 – Fully-guided NobelGuide® Surgical Template

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.

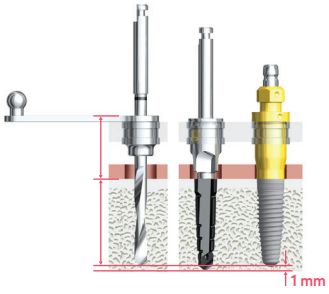

Figure B:1 – Fully Guided

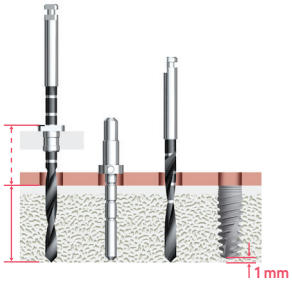

Figure B:2 – Pilot Drill

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.

Intended Use

Pilot Drill and Fully-guided Nobel Guide® Surgical Templates

Intended for use during guided dental implant surgery to prepare an osteotomy according to a specified location, orientation, and/or depth.

Guided Anchor Pins

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

Indications

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 perquisites must be fulfilled:

- Adequate amount of jawbone volume (height and width).
- Quality of jawbone must be judged as adequate.
- Adequate mouth opening (minimum 40 mm) 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.

Materials

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

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 NobelGuide® surgical templates and guided anchor pins are used only with compatible Nobel Biocare instruments and/or components. Use of instruments and/or components that are not intended to be used in combination with the NobelGuide® Surgical Templates and Guided Anchor Pins 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.

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.

The device has not been evaluated in pediatric/adolescent patients and is 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 and/or in patient's mouth needs to be verified.

At Surgery

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 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.

Handling 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):

Figure C – Pilot Drill Surgical Template

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).

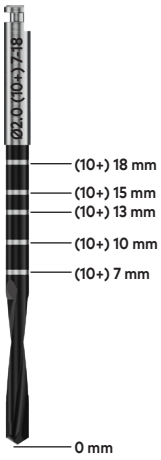

Figure D:1 – Guided Twist Drill

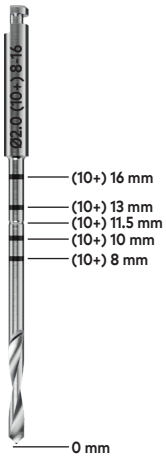

Figure D:2 – Guided Twist Drill Tapered

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):

Figure E – Fully Guided Surgical Templates

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 or the opposite nail 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 sleeve of the surgical template (F).

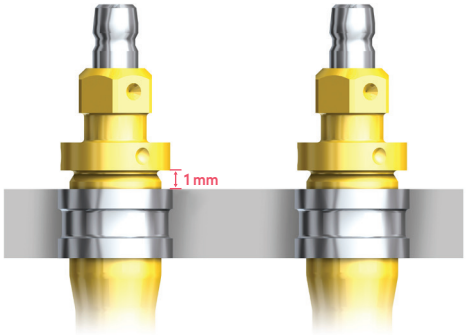

Figure F – Position of Guided Implant Mount in Sleeve of Surgical Template

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.

Cleaning and Sterilization Instructions

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.

Magnetic Resonance (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, Handling and Transportation

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.

Manufacturer and Distributor Information

Manufacturer

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Phone: +46 31 81 88 00. Fax: +46 31 16 31 52.

Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

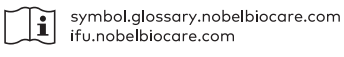
Prescription device: Rx only

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

Legal Statements

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 / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
							
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	