NobelGuide® Surgical Templates and Guided Anchor Pins

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Description

NobelGuide® surgical templates are patient-specific products manufactured by Nobel Biocare using 3D printing technology. The templates contain metal sleeves which are intended to guide dedicated instrumentation required for the placement of dental implants implant system components. The templates are based on design files created in Nobel Biocare's treatment planning software DTX Studio Implant, which are supplied by the clinician.

There are two types of NobelGuide® surgical templates: the Pilot Drill NobelGuide® Surgical Template for guided pilot drilling (Figure A) and the Fully-guided NobelGuide® Surgical Template for fully-guided surgery (Figure B).

Figure A – Pilot Drill NobelGuide® Surgical Template

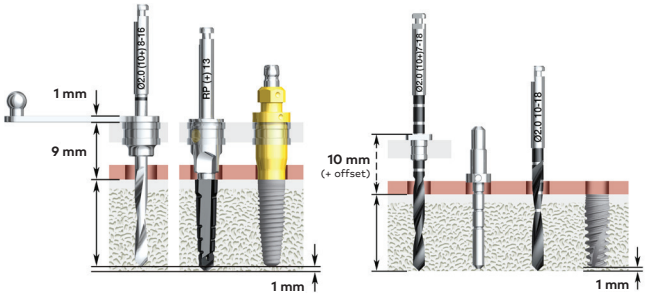
Figure B – Fully-guided NobelGuide® Surgical Template

The templates are made from biocompatible epoxy-based polymer. Embedded into the template are metal cylinders (referred to as "guided pilot drill sleeves" for pilot drilling-only templates, and "guided sleeves" for fully-guided templates) that define the position, direction and height/depth of the implant surgical sites. The sleeves are 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 osteotomy and implant position. There is a pre-defined relationship between this level and the implant/abutment interface (Figures C and D). In case of fully guided protocols, this relationship is also integrated into the design of Nobel Biocare's NobelGuide® surgical tooling and instrumentation: depth marks and stops are calculated with a 9 mm distance from sleeve to implant shoulder (Figure C (=10 mm for parallel drills (9 mm + 1 mm drill guide height))). For pilot drill guides, the sleeve's vertical position can be changed precisely to allow for deeper implant placement. The increased distance is added automatically to the surgical report generated in DTX Studio

Implant software and shipped together with the Nobel Biocare produced surgical templates.

After pilot drilling with Nobel Biocare's original guided pilot drills (1.5 or 2 mm diameter) the Pilot Drill Surgical Template is removed, and a direction indicator (or free-hand drill with identical diameter) is inserted though the pilot drill osteotomy to calibrate the new depth reference against landmarks in patient anatomy (e.g. bone crest, soft tissue height reference). Further free-hand osteotomy to full dimension including implant insertion, are then completed against the new anatomical depth reference (Figure D).



Figures C and D – Relationship Between Level of Outer Shoulder of Guided Pilot Drill Sleeve and Implant/Abutment Interface (Fully Guided in Figure C; Pilot Drilling in Figure D)

Guided anchor pins are thin rods of metal positioned close to horizontally into the jawbone in order to secure the template in its defined position. Guided anchor pin sleeves guide the preparation and installation of guided anchor pins and can be embedded in the template. For fully edentulous templates a minimum of four anchor pins are recommended.

NobelGuide® surgical templates are designed to be used with implant platform-specific tooling. Refer to the Nobel Biocare Instructions for Use (IFU) IFU2011 for detail regarding the tooling and the surgical protocol specific to the implant platform. This IFU is available for download at ifu.nobelbiocare.com.

For additional information on the DTX Studio Implant Software, refer to the DTX Studio Implant Instructions for Use.

Intended Use / Intended Purpose

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

Pilot Drill and Fully-guided Nobel Guide® Surgical Templates

The Pilot Drill NobelGuide® Surgical Template is indicated for use to support guided preparation of an osteotomy in the maxilla or mandible by defining the position of the first drill (the "pilot drill") in the applicable implant platform-specific drill protocol, to guide placement of endosseous dental implants and implant system components intended to restore patient esthetics and chewing function, including immediate function. The Pilot Drill NobelGuide® Surgical Template is indicated for use in edentulous and partially edentulous jaws, including in patients missing a single tooth.

The Fully-guided NobelGuide® Surgical Template is indicated for use to support guided preparation of an osteotomy (including optional guided screw-tapping) in the maxilla or mandible, following the applicable implant platform-specific drill protocol, to guide placement of endosseous dental implants and implant system components intended to restore patient esthetics and chewing function, including immediate function. The Fully-guided NobelGuide® Surgical Template is indicated for use in edentulous and partially edentulous jaws, including in patients missing a single tooth.

Guided dental implant surgery using NobelGuide® surgical templates can be applied in selected cases, depending on the clinical status of the patient and on the specific treatment plan. 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 Anchor Pins

Guided anchor pins are indicated for use in the maxilla or mandible to secure Pilot Drill and Fully-Guided NobelGuide® Surgical Templates in its specified position.

Contraindications

It is contraindicated to NobelGuide® surgical templates and guided anchor pins 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 or surgical template material epoxy-based polymer.

Materials

- NobelGuide® Surgical Templates: Accura Clear Vue, Glue for Surgical Template.
- Guided sleeves, guided pilot drill sleeves (embedded in surgical template): Stainless Steel 1.4301 according to ASTM F899.
- Guided anchor pin sleeves (embedded in surgical template): Stainless Steel alloy 303, 1.4305, according to ASTM F899, AISI 303.
- Guided anchor pins: Stainless Steel alloy 303, 1.4305, according to ASTM F899, AISI 303.

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.

Intended Users and Patient Groups

– NobelGuide® surgical templates and guided anchor pins are to be used by dental health care professionals.

– NobelGuide® surgical templates and guided anchor pins are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelGuide® Surgical Templates and Guided Anchor Pins

NobelGuide® surgical templates and guided anchor pins are components 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 NobelGuide® Surgical Templates and Guided Anchor Pins

The use of the NobelGuide® surgical templates and guided anchor pins 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
www.nobelbiocare.com/complaint-form

Surgical Procedure

The detailed surgical plan, including the depth measurements for guided drilling, is obtained from the DTX Studio Implant final treatment plan report (the same report as that used to order the NobelGuide® Surgical Template from Nobel Biocare). The treatment plan report should be printed and utilized during the surgical procedure.

Note that this IFU describes only the pre-surgery preparation and anchoring of the template. Refer to the Nobel Biocare Instructions for Use (IFU) for the applicable guided surgery tooling for information regarding the surgical protocol for implant placement.

Warning Only use NobelGuide® surgical templates with compatible Nobel Biocare surgical instruments and/or components.

Warning Drill under constant and profuse irrigation using an in-and-out motion when preparing the site to avoid overheating.

Caution NobelGuide® surgical templates must be disinfected using a high-level disinfectant prior to placement in the patient's mouth. Refer to the Cleaning and Disinfection Instructions for Surgical Templates in the section below.

A. Pre-surgery Checklist

- The NobelGuide® surgical template must be carefully inspected upon delivery and approved for use by the clinician prior to surgery by completing the following steps (contact Nobel Biocare technical support for guidance, if needed).
- Confirm the Nobel Guide® surgical template corresponds with the treatment plan in the DTX Studio Implant Software.
- Verify the correct seating of the template using a model (if applicable) and/or in patient's mouth. For partially edentulous cases, verify the correct seating of the template by creating inspection windows (grind small windows over a cusp or corner of a tooth so the underlying dentition becomes visible). Create 3–4 windows as needed, evenly distributed over the entire arch.
- If adjustment is required, carefully modify the template accordingly using a bur.
- Strengthen/reinforce the template where needed by reinforcing the outer surface with a compatible photocuring resin material.
- Thoroughly inspect the template to confirm that the guided sleeve(s) and/or any (excess) resin does not extend through to the fitting surface of the template. If adjustment is required, carefully modify the surgical template and/or sleeve accordingly using a bur.
- Thoroughly inspect the template to confirm there is no excess resin within the lumen of the guided sleeve(s) and confirm the fit of the desired surgical tooling (e.g. guided drill guides and/or the guided (twist) drills) as applicable in each sleeve.
- Confirm that the minimum thickness is 2.5 mm across the entire surface of the template to ensure the structural integrity of the template is maintained.

B. Anchoring the NobelGuide® Surgical Template

- An adequate number of guided anchor pins should be placed, with strategic positioning and orientation, to secure the template in the correct position. The osteotomy for the placement of the Guided Anchor Pins is prepared using the Guided Twist Drill Ø 1.5 x 20 mm.
- 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.

C. Guided Pilot Drilling Procedure using the Pilot Drill Surgical Template (Figure E)

Figure E – 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 Ø 1.5 mm or the Guided Twist Drill Ø 2.0 mm and drill at high speed (maximum 800 rpm) under constant and copious irrigation to the depth as defined in the DTX Studio Implant treatment plan report. An in-and-out motion over the complete extent of the osteotomy is needed when preparing the site to avoid overheating.

Caution Guided pilot and 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 (see Figures F and G).

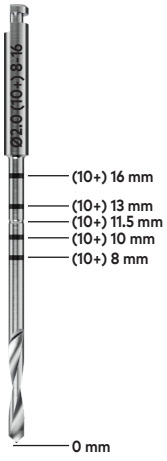


Figure F – Guided Twist Drill

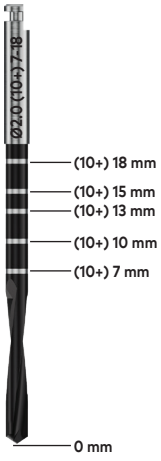


Figure G – Guided Twist Drill Tapered

2. After guided drilling using the guided pilot or twist drills, 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.

D. Guided Drilling Procedures using the Fully-guided Surgical Template (Figure H)

Figure H – Fully Guided Surgical Templates

For information on the surgical access techniques and implant specific guided drilling protocols, please refer to the implant specific Guided Surgery Tooling Instructions for Use (IFU2011).

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. Refer to Nobel Biocare IFU1085 for information regarding the Unigrip™ Screwdriver.

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 the 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.

Guided Implant Insertion – 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 (see Figure I). Leave the guided implant mount in position.

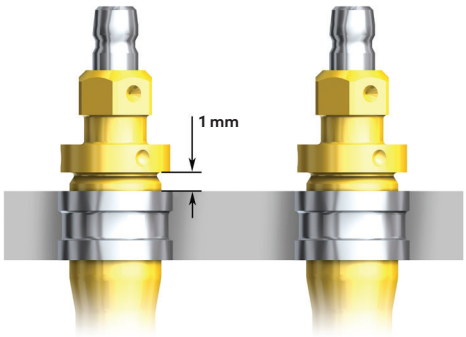


Figure I – Position of Guided Implant Mount in Sleeve of Surgical Template

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 surgical template sleeve.

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. Refer to Nobel Biocare IFU1085 for information regarding the Unigrip™ Screwdriver.

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 the 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 Nobel Biocare implants please refer to the implant specific Instructions for Use.

Refer to the Nobel Biocare Instructions for Use (IFU2011) for the applicable guided surgery tooling for additional information regarding the Guided Twist Drill Ø 1.5 x 20 mm.

Sterility and Reusability Information

Guided anchor pins are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Guided anchor pins are reusable components which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Guided anchor pins shall be discarded if any wear, abrasion of the anodization, deformations or corrosion is visible on the component.

NobelGuide® surgical templates must be cleaned and disinfected prior to intraoral use following the procedures in the Cleaning and Disinfection Instructions for Surgical Templates. During processing in the dental laboratory, templates can be cleaned as necessary without disinfection.

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

Caution NobelGuide® surgical templates are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Cleaning and Sterilization Instructions

Guided anchor pins 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 The guided anchor pins have 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.

Note 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 (131°F) 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°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; maximum 45°C (113°F)) 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-vacuum 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 pouch. 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 1 presents examples of suitable sterilization containers, pouches, and wraps.

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

Table 1 – Recommended Sterilization Pouches

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 2):

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		

Table 2 – Recommended Sterilization Cycles

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.

Cleaning and Disinfection Instructions for Surgical Templates

Surgical templates must be cleaned and disinfected prior to intraoral use. During processing in the dental laboratory, templates can be cleaned as necessary without disinfection.

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

Cleaning the Surgical Template

1. Place the template in an ultrasonic cleaner with water and mild detergents.

2. Perform ultrasonic cleaning according to the template material manufacturer's instructions for use.

3. Remove the template from the ultrasonic cleaner and rinse thoroughly with water.

4. Allow the template to air-dry thoroughly.

5. Place the template in a suitable protective container pending disinfection or further processing.

Disinfecting the Surgical Template

1. Immerse the surgical template in a high-level disinfectant (e.g. 1 mg/ml Fresenius Kabi AB Chlorhexidine solution), according to the template material manufacturer's instructions for use.

2. Remove the template from the disinfectant and rinse the template thoroughly with sterile water.

3. Allow the template to air-dry thoroughly, but for no longer than 40 minutes.

4. Place the template in a suitable protective container pending the surgical procedure.

Caution Do not use heat on the surgical template.

Caution Do not autoclave the surgical template.

Performance Requirements and Limitations

To achieve the desired performance, the NobelGuide® Surgical Template and Guided Anchor Pins 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 these devices, 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. For more information 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.

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

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	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class I Devices	CE
CE Mark for Class Ir Devices	CE 2797
UKCA Mark for Class I Devices	UK CA

Note Refer to the product label to determine the applicable conformity marking 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
Pilot Drill NobelGuide® Surgical Templates Fully-guided NobelGuide® Surgical Templates	73327470000001857H
Guided Anchor Pins Ø 1.5 mm/Ø 1.5 mm Short Shaft	73327470000001346Y

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
					Rx only	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
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	