Guided (Pilot Drill) Sleeves, Guided Anchor Pin Sleeves, Mounting Tools

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Description

Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves

The Guided (Pilot Drill) Sleeves are highly precise cylinders embedded in dental surgical templates to define the position, direction and height/depth of surgical sites. The surgical template is a plastic device that is to be fitted onto the soft tissue of the patient. In partial and single cases, it also fits onto the remaining teeth of the jaw. The Guided (Pilot Drill) Sleeves have the long axis identical to the planned long axis of the implant. 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.

Also, embedded in the surgical template are Guided Anchor Pin Sleeves. 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 to secure the surgical template in its intended position during implant surgery. Guided Anchor Pin Sleeves are optional.

Mounting Tools for Guided (Pilot Drill) Sleeves

In decentralized/local production of surgical templates, the Mounting Tools for Guided (Pilot Drill) Sleeves can be used to glue the Guided (Pilot Drill) Sleeves into the printed/milled/stereolithography (SLA) produced surgical template by the laboratory or dentist. The Mounting Tools for Guided (Pilot Drill) Sleeves will position the Guided (Pilot Drill) Sleeves accurately flush with the top shoulder of the surgical template's sleeve support material. For fixation of the sleeves a biocompatible glue / cement / adhesive agent is needed.

The Mounting Tool Pins for Guided Pilot Drill Sleeves have either a 1.5 mm or 2.0 mm diameter and the Mounting Tool Base is designed to be used with either diameter. Due to their design, the Mounting Tools for Guided Pilot Drill Sleeves cannot be used in combination of pre-fabrication of master casts.

The Mounting Tools for Guided Sleeves (guided cylinder with pin, implant replica) can be used in a dental lab procedure when making a stone model based on the surgical template. The guided cylinders have an outer diameter that matches the internal dimensions of the Guided Sleeves (NP, RP, and 6.0/WP) and are inserted into the Guided Sleeves, embedded in the surgical template, and an implant replica from the Nobel Biocare standard assortment is screwed onto the pin that goes through the guided cylinder. Since there is a well-defined seating of the guided cylinder in the Guided Sleeve, the head of the implant replica is positioned in the same position in relationship to the surgical template, as the implant will be installed into the bone of the patient. This enables a stone model to be cast using the underside of the surgical template, corresponding to the soft tissue surface of the patient, and the attached implant replicas, corresponding to the pre-defined sites of the implants. The implant connection portion of the guided cylinder should match the available implant connections of tri-channel, external hex and conical connection.

In the analog workflow, the product is attached together with a Guided Sleeve to the implants installed in the die cast model. In doing so, the Guided Sleeves are positioned in a correct position and ready to be molded into a lab-made surgical template.

Intended Use

- The Guided (Pilot Drill) Sleeves are intended to be used in combination with surgical templates to facilitate implant installation by guiding the required instruments in the planned direction.
- The Guided Pilot Drill Sleeves are intended to guide the first drill (either 1.5 mm or 2.0 mm).
- The Mounting Tools are intended to be used in the dental laboratory procedure to enable the correct positioning of the Guided (Pilot Drill) Sleeves in the surgical template.
- The Guided Anchor Pin Sleeves are intended to be used in surgical templates to establish secure fixation and stability of the surgical template, by guiding the preparation and installation of anchor pins.

Indications for Use

The components (Guided (Pilot Drill) Sleeves, Guided Anchor Pin Sleeves and Mounting Tools) are indicated for the assembly within a surgical template for the treatment of edentulous and partially edentulous jaws (including patients missing a single tooth) for placement of dental implants, if indicated in combination with immediate function to restore esthetics and functionality (e.g, masticatory, speech). 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 40 mm) to accommodate guided surgery tooling.
- Exclusion of compromised diseases in conflict with dental implant treatment.
- Adequate compliance.

Contraindications

It is contraindicated to use a surgical template in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitivity to commercially pure titanium grade 4, stainless steel, surgical template material or bonding material.

There are no specific contraindications related to the use of the Guided Cylinder Mounting Tools.

Materials

The Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves are made from stainless steel. The Mounting Tools for the Guided Pilot Drill Sleeves are made of stainless steel. The Mounting Tools for the Guided Sleeves are made of titanium.

Recommendation for materials

For surgical template fabrication

The user must use a certified material, intended for printing surgical guides and follow the manufacturer's instructions for use, as well as the recommended parameters and procedures.

The minimum mechanical properties for the surgical template material are provided in Table 1. In addition, the material must be biocompatible.

Table 1 – Minimum mechanical properties of surgical template material

Post-cured Data	Metric	Method
Tensile Strength	≥41 MPa	ASTM D 638
Tensile Modulus	≥2030 MPa	ASTM D 638
Elongation at Break	4 – 7 %	ASTM D 638
Heat Deflection Temperature		ASTM D 638
at 66Psi	46°C	
at 264Psi	41°C	
Flexural Strength	≥50 MPa	ISO 20795-1 / ASTM D 790
Flexural Modulus	≥1500 MPa	ISO 20795-1 / ASTM D 790
Hardness Shore	≥80 D	ASTM D2240

For sleeves bonding into the surgical template

The minimum requirements for the mechanical properties of the glue to be used for bonding the sleeves into the surgical template are provided in Table 2.

Table 2 – Minimum mechanical properties of bonding material

Mechanical Property	Acceptable Range / Level
Compressive Strength	≥ 200 MPa
Flexural Strength	> 2000 MPa
Water Sorption	≤ 200 µg/mm^3

Additional requirements for the bonding material

– The bonding material should be biocompatible and suitable for dental applications.

– The bonding material should be able to bond metals to polymers.

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.

Nobel Biocare Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves must only be used 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 Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves 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.

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.

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 and/or laboratory 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.

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. gauze, dental dam, or 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.

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

1. Check the decentralized/locally produced surgical template.

– Check the sleeve seats for material residues and sharp, protruding edges. Remove or smoothen them if you find any.

– Check that the locally produced surgical template is manufactured from appropriate material: the material should be biocompatible and mechanically fit for purpose. Recommended material properties are listed in table 1.

– Verify optimal fit on stone model if applicable and/or in patient's mouth prior to surgery.

2a. Fixing the Guided Pilot Drill Sleeves into the surgical template.

– Insert the Guided Pilot Drill Sleeve into the sleeve seat of the surgical template.

Note Make sure the flat upper part of the sleeve is on the occlusal surface of the surgical template.

– For the correct fixation of the Guided Pilot Drill Sleeve; use the screw part of the Mounting Tool from below (intaglio/inside of the surgical template) and the thread part from the top (occlusion/outer surface of the surgical template) (see Figure B). Tighten it by hand.

Note The outer diameter of the Guided Pilot Drill Sleeves is the same.

Please confirm that the correct sleeve size is used for each position by comparing the laser marking of the Guided Pilot Drill Sleeves with the planning overview before inserting it into the template (see Figure A).

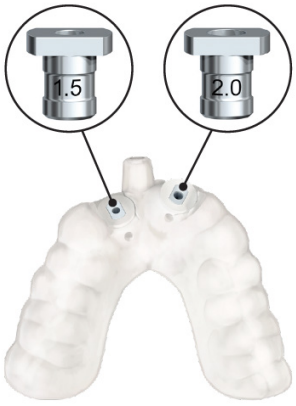


Figure A – Example of a comparison of laser marking on Guided Pilot Drill Sleeves with planning overview

PID	Sleeve name	Article id
1	Guided Pilot Drill Sleeve 1.5 mm	300438
2	Guided Pilot Drill Sleeve 2.0 mm	300440

2b. Fixing the Guided Sleeve into the surgical template.

– Insert the Guided Sleeve into the sleeve seat of the surgical template.

Note As the Guided Sleeve is symmetrical, there is no top or bottom.

– For the correct fixation of the Guided Sleeve; use the upper part of the Guided Cylinder with Pin and its lower part to fix the Guided Sleeve. Tighten the lower part of the Guided Cylinder with Pin to the appropriate Implant Replica (see Figure C). Fix all parts together and tighten them by hand or by using a screwdriver (e.g. Unigrip™).

2c. Fixing the Guided Anchor Pin Sleeve.

– Insert the Guided Anchor Pin Sleeve into the sleeve seat of the surgical template.

Note As the Guided Anchor Pin Sleeve is symmetrical, there is no top or bottom.

– Make sure that the upper part of the sleeve is set flush into the seat socket of the surgical template (see Figure D)

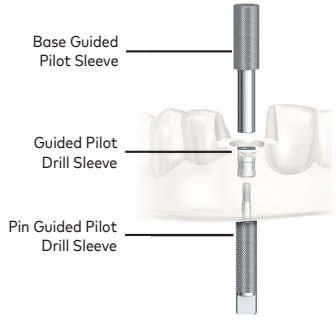


Figure B – Fixation of Guided Pilot Drill Sleeve

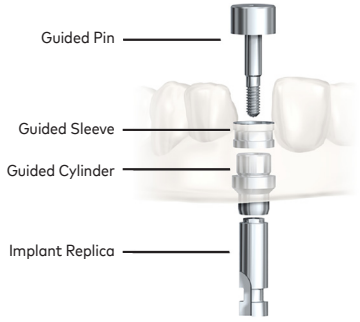


Figure C – Fixation of Guided Sleeve

Figure D – Insertion of Anchor Pin Sleeve

3. Bonding process for the Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves.

– Visually verify that the sleeves are flush with the top surrounding surface of the surgical template. If they are not flush, remove material as required.

For permanent fixation of the sleeves a biocompatible glue / cement / adhesive agent is needed. The user must use a biocompatible material and follow the manufacturer's instructions for use. Recommended material properties are listed in Table 2.

Note Once all the Guided (Pilot Drill) Sleeve(s) and Guided Anchor Pin Sleeve(s) are in place, glue them into the surgical template.

– Place the tip of the mixing cannula inside the glue hole located in the surgical template.

– Slowly squeeze the bonding material into the glue hole until it completely goes all the way around the Guided (Pilot Drill) Sleeve(s) or Guided Anchor Pin Sleeve(s).

– Repeat the application of bonding material to each Guided (Pilot Drill) Sleeve(s) and Guided Anchor Pin Sleeve(s).

– Once the bonding material has hardened, unscrew the Mounting Tools.

– Visually verify that there is no bonding material present on the top or bottom of the Guided (Pilot Drill) Sleeve(s) or Guided Anchor Pin Sleeve(s).

Dual curing is advised to control the timing of the curing process and ensure material is fully cured.

Caution Introduce only as much bonding material to cover the outer diameter of the Guided (Pilot Drill) Sleeve(s) or Guided Anchor Pin Sleeve(s) in the glue channel. While introducing the bonding material, you should be able to see the progression of it. Avoid to introduce too much bonding material. Leaked bonding material should be removed immediately using a suitable instrument.

Warning Do not introduce bonding material into the internal diameter of the Guided (Pilot Drill) Sleeve(s) or Guided Anchor Pin Sleeve(s). This could have a negative effect on the guided surgery.

For additional information on surgical procedures please consult the NobelGuide Concept Manual available at www.nobelbiocare.com or request the latest printed version from a Nobel Biocare representative.

Sterility and Reusability Information

Delivered non-sterile for single use

Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves are delivered non-sterile for single use only and do not need to be sterilized prior to use.

Caution Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.

Cleaning and Sterilization Instructions

Surgical Template construct cleaning

Following fixation of the Guided (Pilot Drill) Sleeves and (optionally) Guided Anchor Pin Sleeves into the surgical template, the surgical template construct should be cleaned and disinfected, as applicable per the guide material manufacturer's instructions, before intraoral use. The cleaning protocol selected should be appropriate for the surgical guide material, according to the material manufacturer's instructions. Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves are resistant to mild pH enzymatic detergents (e.g Cidezyme/ Enzol), high-level disinfectants (e.g., Cidex OPA), 0.5% of alkaline cleaning agents (e.g. neodisher Mediclean), and temperatures up to and including 90°C. For further information please contact a Nobel Biocare representative.

Cleaning of mounting tools

Delivered non-sterile for multiple use to be used extra orally only.

Mounting Tools are used only in the dental laboratory (no intraoral use) and have no cleaning and sterilization requirements.

Magnetic Resonance (MR) Safety Information

The Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Guided (Pilot Drill) Sleeves and Guided Anchor Pin Sleeves in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

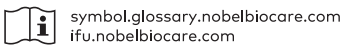
Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

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	