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

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

A dental surgical template is a patient-specific product which is produced by the laboratory or dentist via 3D printing or milling. Surgical templates are designed to be fitted onto the soft tissue and/or remaining teeth of the patient in order to guide the placement of dental implants and implant system components. In cases where teeth are partially missing or in cases of a single missing tooth, a surgical template can also be placed onto the remaining teeth of the jaw.

Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves are cylinders which are embedded in a dental surgical template and are used to define the position, direction and height/depth of the implant surgical sites.

- Guided Sleeves and Guided Pilot Drill Sleeves have a long axis which is identical to the planned long axis of the implant. The level of the outer shoulder of the Guided Sleeves and Guided Pilot Drill Sleeve defines the depth of the osteotomy and implant position, since there is a pre-defined relationship between this level and the implant/abutment interface. Guided Sleeves are available in NP, RP, and 6.0/WP platform sizes and are compatible with Nobel Biocare guided drills of the same platform. Guided Pilot Drill Sleeves are available in two diameters (1.5 mm/2.0 mm) for use with different guided pilot and start drills. Refer to Nobel Biocare Instructions for Use (IFU) IFU2011 for information regarding Nobel Biocare guided surgery tooling. This IFU is available for download at ifu.nobelbiocare.com.

- The Guided Anchor Pin Sleeve can optionally be embedded in the surgical template in order to guide the preparation and installation of Guided Anchor Pins. Guided 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. Refer to Nobel Biocare Instructions for Use (IFU) IFU2001 for information regarding the Guided Anchor Pins.

In decentralized/local production of surgical templates, the mounting tools are used to glue the sleeves into the surgical template:

- Mounting tools for Guided Pilot Drill Sleeves consist of the Mounting Tool Pin and Mounting Tool Base. They are used to glue the Guided Pilot Drill Sleeves into the surgical template. The mounting tools 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 required. 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.

- Mounting tools for Guided Sleeves consist of the Guided Cylinder with Pin and the Implant Replica. They are used in a dental laboratory 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 and embedded in the surgical template. An Implant Replica from the Nobel Biocare standard assortment is then screwed onto the pin that goes through the guided cylinder. Because 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 which corresponds 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 Guided Cylinder with Pin is attached together with a Guided Sleeve to the implants installed in the die cast model; as a result, the Guided Sleeves are correctly positioned and are ready to be embedded into the surgical template.

Note The Mounting Tool Pin, Mounting Tool Bases, Guided Cylinders with Pin, and Implant Replicas are intended for laboratory use only.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use/Intended Purpose

Guided Pilot Drill Sleeves and Guided Sleeves

Intended for use as an integral component of a dental implant surgical template to guide instrumentation during preparation of an osteotomy.

Guided Anchor Pin Sleeves

Intended for use as an integral component of a dental implant surgical template to secure the template in the specified location.

Indications

Guided Pilot Drill Sleeves

Guided Pilot Drill Sleeves are indicated for use with a surgical template to guide the use of the first drill (the "pilot drill") in applicable implant platform-specific drill protocol (either 1.5 mm or 2.0 mm), while preparing an osteotomy in the maxilla or mandible.

Guided Sleeves

Guided Drill Sleeves are indicated for use with a surgical template while preparing an osteotomy using guided drills in the maxilla or mandible, following the applicable implant platform-specific drill protocol.

Guided Anchor Pin Sleeve

The Guided Anchor Pin Sleeve is indicated for use as an optional component which is intended to be used as an integral part of a dental surgical template to establish secure fixation and stability of the surgical template to the Guided Anchor Pins, by guiding the preparation and installation of Guided Anchor Pins.

Contraindications

It is contraindicated to use Guided Pilot Drill Sleeves, Guided Sleeves, and the Guided Anchor Pin Sleeve in patients who are allergic or hypersensitive to stainless steel or the surgical template material epoxy-based photopolymer or bonding material.

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

Materials

- Guided Pilot Drill Sleeves and Guided Sleeves: Stainless steel 1.4301/AISI 304 austenitic steel according to ASTM F899.

- Guided Anchor Pin Sleeves: Stainless Steel, 1.4305/AISO 303 austenitic steel according to ASTM F899 and EN 10088-3.

- Guided Cylinder w Pin: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.

- Mounting Tool Pin Guided Pilot Sleeve: Wrought austenitic Stainless 1.4305/AISI 303 according to ASTM F899.

- Mounting Tool Base Guided Pilot Sleeve: Wrought austenitic Stainless 1.4305/AISI 303 according to ASTM F899.

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, and with surgical templates designed using the 3D-planning software DTX Studio Implant. 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

Small diameter implants and angled abutments are not recommended for the posterior region.

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.

Intended Users and Patient Groups

- Guided Pilot Drill Sleeves, Guided Sleeves, and the Guided Anchor Pin Sleeve are to be used by laboratory professionals.
- Guided Pilot Drill Sleeves, Guided Sleeves, and the Guided Anchor Pin Sleeve are to be used in patients subject to dental implant treatment.
- Mounting Tools are to be used by laboratory professionals.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Guided Pilot Drill Sleeves, Guided Sleeves, and the Guided Anchor Pin Sleeve

Guided Pilot Drill Sleeves, Guided Sleeves, and the Guided Anchor Pin Sleeve are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Clinical Benefits Associated with Mounting Tools and Guided Cylinder with Pin

Mounting Tools and Guided Cylinder with Pin are used to produce dental surgical templates which 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 Guided Pilot Drill Sleeves, Guided Sleeves, and the Guided Anchor Pin Sleeve

During use of these devices the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Undesirable Side Effects Associated with Mounting Tools and Guided Cylinder with Pin

None known.

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

Handling Procedure

Recommended Materials for the Surgical Template

Materials Used for Fabricating the Surgical Template

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	46°C (at 66 psi) 41°C (at 264 psi)	ASTM D 638
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

Materials Used for Bonding the Sleeves 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 Surgical Template Material

Mechanical Property	Acceptable Range/Level
Compressive Strength	≥ 200 MPa
Flexural Strength	> 2000 MPa
Water Sorption	≤ 200 µg/mm³

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.

Inspecting the Surgical Template

1. Check the sleeve seats for material residues and sharp, protruding edges. Remove or smoothen them if you find any.
2. 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.
3. Verify optimal fit on stone model if applicable and/or in patient's mouth prior to surgery.

Fixing the Guided Pilot Drill Sleeves into the Surgical Template

1. Insert the Guided Pilot Drill Sleeve ① 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.

2. For the correct fixation of the Guided Pilot Drill Sleeve; use the screw part of the Mounting Tool ② from below (intaglio/inside of the surgical template) and the thread part ③ from the top (occlusion/outer surface of the surgical template) (see Figure A). Tighten it by hand.

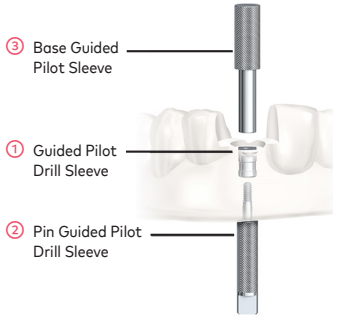
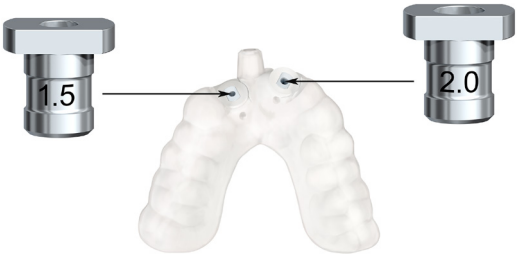


Figure A – Fixation of Guided Pilot Drill Sleeve

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

3. 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 (Figure B).



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

Figure B – Comparison of Laser Marking on Guided Pilot Drill Sleeves with Planning Overview

Fixing the Guided Sleeve into the Surgical Template

1. Insert the Guided Sleeve ① into the sleeve seat of the surgical template.

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

2. For the correct fixation of the Guided Sleeve; use the upper part of the Guided Cylinder with Pin ② and its lower part to fix the Guided Sleeve. Tighten the lower part of the Guided Cylinder with Pin ③ to the appropriate Implant Replica ④ (see Figure C). Fix all parts together and tighten them by hand or by using the Unigrip™ screwdriver (See Nobel Biocare IFU1085).

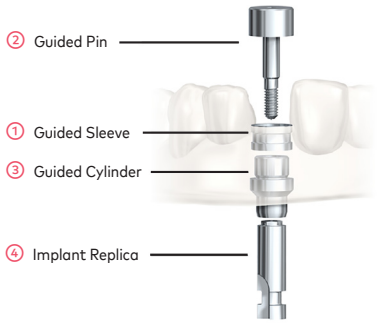


Figure C – Fixation of Guided Sleeve

Fixing the Guided Anchor Pin Sleeve

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

Note The Guided Anchor Pin Sleeve is symmetrical and has no top or bottom.

2. Ensure that the upper part of the sleeve is set flush into the seat socket of the surgical template (see Figure D).

Figure D – Insertion of Anchor Pin Sleeve

Bonding Process for the Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves

1. 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 Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves are in place, glue them into the surgical template.

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

3. Slowly squeeze the bonding material into the glue hole until it completely goes all the way around the Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves.

4. Repeat the application of bonding material to each Guided Pilot Drill Sleeve, Guided Sleeve, and Guided Anchor Pin Sleeve.

5. Once the bonding material has hardened, unscrew the mounting tools.

6. Visually verify that there is no bonding material present on the top or bottom of the Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves.

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 as needed to cover the outer diameter of the Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves in the glue channel. Observe the glue channel while introducing the bonding material in order to avoid introducing excessive material. Immediately remove any excess bonding material using a suitable instrument.

Cleaning and Disinfecting the Surgical Template

Following fixation and bonding of the Guided Pilot Drill Sleeves, Guided Sleeves and Guided Anchor Pin Sleeves into the surgical template, the surgical template construct must be cleaned and disinfected prior to intraoral use. Refer to the Cleaning and Disinfection Instructions for greater detail.

Sterility and Reusability Information

Guided Pilot Drill Sleeves, Guided Sleeves and Guided Anchor Pin Sleeves are delivered non-sterile and are intended for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Caution Guided Pilot Drill Sleeves, Guided 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. Reuse could cause local or systemic infection.

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

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

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 the 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.

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
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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
CE Mark for Class I Devices	CE
UKCA Mark for Class I Devices	UK CA

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Guided Pilot Drill Sleeves 1.5 mm/2.0 mm	733274700000013572
Guided Sleeves NP/RP/6.0/WP	733274700000013572
Guided Anchor Pin Sleeve 1.5 mm	73327470000001957L
Guided Cylinder w Pin Unigrip BmkSyst NP	733274700000020874
Guided Cylinder w Pin Unigrip BmkSyst RP	733274700000020874
Guided Cylinder w Pin Unigrip BmkSyst WP	733274700000020874
Guided Cylinder w Pin Unigrip NobRpl NP	733274700000020874
Guided Cylinder w Pin Unigrip NobRpl RP	733274700000020874
Guided Cylinder w Pin Unigrip NobRpl WP	733274700000020874
Guided Cylinder w Pin Unigrip NobRpl 6.0	733274700000020874
Guided Cylinder w Pin Conical Connection NP	733274700000020874
Guided Cylinder w Pin Conical Connection NP 3.5	733274700000020874
Guided Cylinder w Pin Conical Connection RP 4.3	733274700000020874
Guided Cylinder w Pin Conical Connection RP 5.0	733274700000020874
Guided Cylinder with Pin CC WP 5.5	733274700000020874
Mounting Tool Pin Guided Pilot Sleeve 1.5 mm	733274700000020874
Mounting Tool Pin Guided Pilot Sleeve 2.0 mm	733274700000020874
Mounting Tool Base Guided Pilot Sleeve 1.5/2.0 mm	733274700000020874

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.