Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves

Instructions for use

Guided Pilot Drill Sleeves

Guided Sleeves

Guided Anchor Pin Sleeves

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

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.

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 twist drills / twist step 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 or bonding material.

Cautions:

General:
One hundred percent implant success cannot be guaranteed. Especially, non-observance of the indicated limitations of use and working steps may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

It is strongly recommended that Nobel Biocare Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves are used only with Nobel Biocare surgical instruments, implants, prosthetic components, and with surgical templates designed using the 3D-planning software DTX Studio Implant. Use of instruments and/or 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 has to 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 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 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 the implant installation, 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 secure the long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform 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.

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 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.

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

https://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 Bonding 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 (1.5 mm – single pack Article # 300438, 20 pack Article # 300439; 2.0 mm – single pack Article # 300440, 20 pack Article # 300441) 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 (Mounting Tool Pin for Guided Pilot Sleeve 1.5 mm – Article # 300442; Mounting Tool Pin for Guided Pilot Sleeve 2.0 mm – Article # 300443) from below (intaglio/inside of the surgical template) and the thread part ③ (Mounting Tool Base for Guided Pilot Sleeve 1.5/2.0 mm – Article # 300444) from the top (occlusion/outer surface of the surgical template) (see Figure A). Tighten it by hand.

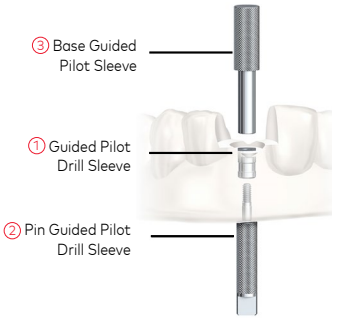
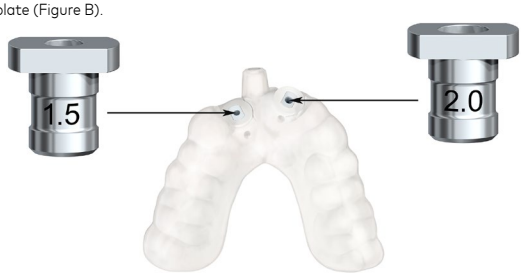


Figure A: Fixation of Guided Pilot Drill Sleeve

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 (NP Article # 32754; RP Article # 32765 or WP Article # 32766) 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 (NP Article # 37172; RP Article # 37173; WP Article # 37950) 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 (NP Article # 36697; RP Article # 36698; WP Article # 37879) (see Figure C). Fix all parts together and tighten them by hand or by using the UnigripTM screwdriver (See Nobel Biocare IFU1085).

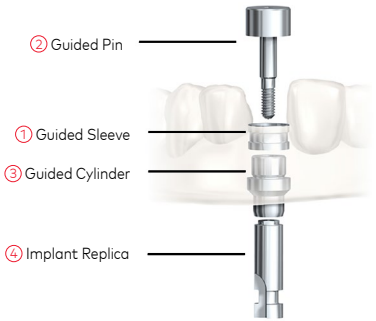


Figure C: Fixation of Guided Sleeve

Fixing the Guided Anchor Pin Sleeve:

1. Insert the Guided Anchor Pin Sleeve (Article # 30908) 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.

Materials:

- Guided Pilot Drill Sleeves and Guided Sleeves: Stainless steel 1.4301 according to ASTM F899.
- Guided Anchor Pin Sleeves: Stainless Steel alloy 303, 1.4305, according to ASTM F899, AISI 303.

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 Disinfection Instructions:

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, Guided Pilot Drill Sleeves, Guided Sleeves, and Guided Anchor Pin Sleeves 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 devices 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:

Manufacturer:
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden.
www.nobelbiocare.com

Distributed in Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 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

Notice Regarding Canadian License Exemption: 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
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

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

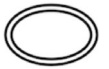
Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

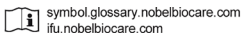

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

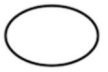
Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier

Use-by date