Drill Stop Kits for Guided and Freehand Surgery

Instructions for use

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:

Drill Stops are hollow cylinders with a retaining screw that are attached to Twist Drills/Twist Step Drills and fixed with the set screw. They are designed to create a stop function in order to prevent drilling into an osteotomy beyond the desired depth.

Drill Stops are available in several diameters for use with different diameter drills (Ø 2.0, Ø 2.8, Ø 3, Ø 3.2, Ø 3.4, Ø 3.6 and Ø 4.2 mm); this assortment of Drill Stops can be stored in a Drill Stop Kit Box and together constitute the Drill Stop Kit.

There are two Drill Stop Kits, one Drill Stop Kit for Guided Surgery and the Drill Stop Kit for Freehand Surgery. Both kits can be used with Twist Drills and Twist Step Drills for the following Nobel Biocare implant platforms: NobelActive®, NobelParallel™ CC, Brånemark System® Mk III TiUnite®, NobelSpeedy® Groovy, NobelSpeedy® Shorty, Replace Select™ TC.

The Drill Stop Kit for Guided Surgery is identified by the (10+) designation. This indicates the drills are 10 mm longer than the "freehand" Twist/Step Drills to compensate for the height of the surgical template and the Guided Drill Guide.

Intended Use/Intended Purpose:

Drill Stops and Drill Stop Kits for Guided and Freehand Surgery:
Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Drill Stop Kit Boxes for Guided and Freehand Surgery:
Intended for use to organize and assemble instruments used for dental implant surgical and prosthetic procedures.

Indications:

Drill Stops and Drill Stop Kit for Freehand Surgery:
Drill Stops and the Drill Stop Kit for Freehand Surgery are indicated for use with straight drilling protocols using Twist Drills and Twist Step Drills during dental implant surgery in the maxilla or mandible, in order to prevent drilling into an osteotomy beyond the desired depth.

Drill Stops and Drill Stop Kit for Guided Surgery:
Drill Stops and the Drill Stop Kit for Guided Surgery are indicated for use with straight drilling protocols using Guided Twist Drills and Guided Twist Step Drills during guided dental implant surgery in the maxilla or mandible, in order to prevent drilling into an osteotomy beyond the desired depth.

Drill Stop Kit Boxes for Guided and Freehand Surgery:
The Drill Stop Kit Boxes for Guided and Freehand Surgery are indicated for use to facilitate the attachment of the Drill Stops to their respective Twist Drills and Twist Step Drills and to organize the drills for use during the surgical procedure.

Contraindications:

It is contraindicated to use Drill Stops and the Guided Drill Stop Kit in patients allergic or hypersensitive to stainless steel.

There are no contraindications for the Drill Stop Kit Box for Freehand Surgery or for the Drill Stop Kit Box for Guided Surgery.

Refer to the Nobel Biocare Instructions for Use (IFU) IFU2011 for contraindications and other information specific to the preparation of the dental implant surgical site during guided dental implant surgery. This IFU is available for download at ifu.nobelbiocare.com.

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:
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:
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:
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).

Intended Users and Patient Groups:

- Drill Stops and the Drill Stop Kit (including the Drill Stop Kit Box) is to be used by dental health care professionals.
- Drill Stops and the Drill Stop Kit is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Drill Stops and the Drill Stop Kit:
Drill Stops and the Drill Stop Kit (including the Drill Stop Kit Box) 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 Drill Stops and the Drill Stop Kit:
The use of Drill Stops and the Drill Stop Kit (including the Drill Stop Kit Box) 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
https://www.nobelbiocare.com/complaint-form

Handling Procedure:

1. Select the appropriate Drill Stop according to diameter of the desired Twist Drill or Twist Step Drill (refer to the laser marking on the drill to confirm the compatibility).
2. Slide the Drill Stop onto the drill and place the assembly in the Drill Stop Kit Box, in the mounting hole which corresponds to the desired drill depth (Figure A). The Drill Stop Kit Box contains two different rows: one for the drills with diameter 2 mm to 3.2 mm and one for the drills with diameter 3.4 mm and above (the bottom row marked by the asterisk (*) in the figure is used for the larger diameter drills).

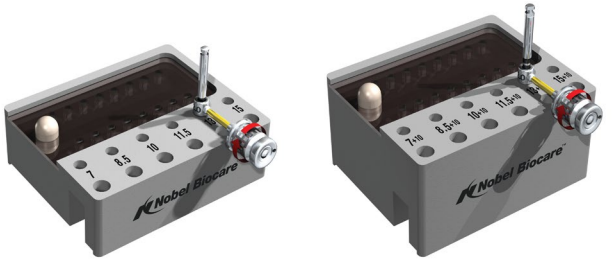
Drill Stop Kit for Freehand Surgery | Drill Stop Kit for Guided Surgery

Figure A: Placing the Drill/Drill Stop Assembly in Guided Drill Stop Kit Box

Note: The drills for Guided Surgery are 10 mm longer than the "freehand" Twist Drills and Twist Step Drills to compensate for the height of the surgical template and the Guided Drill Guide. This is indicated by the (10+) marking printed on the Guided Drill Stop Kit Box (see Figure A).

3. Tighten the retaining screw on the Drill Stop using the Unigrip™ Screwdriver (Figure B). Refer to Nobel Biocare IFU1085 for information regarding the Unigrip™ Screwdriver.

Warning: Ensure the retaining screw on the drill stop is sufficiently tightened to ensure the drill stop does fall off the drill and is possibly swallowed or aspirated by the patient.



Drill Stop Kit for Freehand Surgery | Drill Stop Kit for Guided Surgery

Figure B: Tightening the Retaining Screw on the Drill Stop

4. For information specific to the preparation of the dental implant surgical site during guided dental implant surgery, refer to the Nobel Biocare IFU2011.

Materials:

- Drill Stops: medical grade stainless steel per ASTM F899 Type 303, ISO 7153-1 Type N and UNS S30300.
- Drill Stop Kit Box: Box (Aluminium per EN-AW-6082/SS-EN-573-3); Cover (polyphenylsulfone (PPSU); Radel R 5000/5500 Grade 99055); Cover Stop Top (polyetheretherketone (PEEK) 4506).

Sterility and Reusability Information:

Drill Stops and the Drill Stop Kit Boxes 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.

Drill Stops and the Drill Stop Kit Boxes are reusable devices which must be inspected prior to each use to ensure the integrity of the device is maintained. The device must be discarded if there are any signs of corrosion or other damage, or the legibility of the text is compromised.

Cleaning and Sterilization Instructions:

Drill Stops and the Drill Stop Kit Boxes 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 Drill Stops and the Drill Stop Kit Boxes 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. Disassemble Drill Stops prior to cleaning by removing the Drill Stops from the drills.
2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. 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.
5. 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.
6. 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.
7. 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 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 (122.0°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. Disassemble the Drill Stops prior to cleaning by removing the Drill Stops from the drills.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. 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.
5. 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.
6. 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.
7. 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).
8. 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.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. 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.

Table 1: Recommended Sterilization Pouches

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

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):

Table 2: Recommended Sterilization Cycles

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		

[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.

Performance Requirements and Limitations:

To achieve the desired performance, Drill Stops and the Drill Stop Kits 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 Drill Stops and the Drill Stop Kits, 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
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

CE 2797 CE Mark for Class IIa Devices

Note: Refer to the product label to determine the applicable CE mark 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
Drill Stop Kit Box Guided Drill Stop Kit Box	7332747000000142 6X
Drill Stops (Ø 2/Ø 2.8/Ø 3/Ø 3.2/Ø 3.4/Ø 3.6/Ø 3.8/Ø 4.2)	7332747000000122 6R

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.

EC REP — Authorized representative in the European Community

LOT — Batch code

REF — Catalogue number

Caution

CE marking

Consult instructions for use

Contains hazardous substances

PHT DEHP — 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

Rx Only — For prescription use only

Health care centre or doctor

Keep away from sunlight

Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com
Link to Online Symbols Glossary and IFU Portal

MR — Magnetic resonance conditional

Manufacturer

MD — Medical device

Non-pyrogenic

NON STERILE — Non-sterile

Patient identification

Patient information website

Patient number

SN — Serial number

Single sterile barrier system

Single sterile barrier system with protective packaging inside

Single sterile barrier system with protective packaging outside

STERILE EO — Sterilized using ethylene oxide

STERILE R — Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

STERILE — Sterilized using steam or dry heat

UDI — Unique Device Identifier

Use-by date