Drill Stop Kits for Guided and Freehand Surgery

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, 3, Ø 3.2, Ø 3.4, Ø 3.6, Ø 3.8, 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.

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.

Table 1 – Devices Compatible with the Drill Stops and Drill Stop Kit Boxes

Product Name	Compatible devices		
	Drill Stop/Drill Stop Kit Box	**Drills**	**Screwdriver**
Drill Stop Ø 2	Guided Drill Stop Kit Box Drill Stop Kit Box	Twist Drill w Tip 2.0 x 18-25 mm Guided Twist Drill 2 x (10+) 7-13 mm Guided Twist Drill 2 x (10+) 7-18 mm Twist Drill w Tip 2 x 7-15 mm Twist Drill 3.2 x 7-10 mm Twist Drill 1.5 x 7-15 mm Twist Drill w Tip 2 x 10-18 mm Twist Drill w Tip 2 x 18-25 mm, LS Guided Drill Guide NP to Ø 2 mm Guided Drill Guide RP to Ø 2 mm Guided Drill Guide 6.0/WP to Ø 2 mm	Screwdriver Manual Unigrip™ Screwdriver Machine Unigrip™
Drill Stop Ø 2.8	Guided Drill Stop Kit Box Drill Stop Kit Box	Guided Twist Drill 2.8 x (10+) 7-13 mm Guided Twist Drill 2.8 x (10+) 7-18 mm Twist Step Drill 2.4/2.8 10-18 mm Twist Step Drill 2.4/2.8 7-15 mm Twist Step Drill 2.4/2.8 7-10 mm Guided Twist Step Drill Ø 2.4/2.8 (10+) 7-13 mm Guided Twist Step Drill Ø 2.4/2.8 (10+) 7-18 mm Twist Step Drill 2.4/2.8 x 18-25 mm, LS Twist Step Drill 2.4/2.8 x 18-25 mm Guided Drill Guide NP to Ø 2.8 mm Guided Drill Guide RP to Ø 2.8 mm Guided Drill Guide 6.0/WP to Ø 2.8 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™
Drill Stop Ø 3	Guided Drill Stop Kit Box Drill Stop Kit Box	Guided Twist Drill 3 x (10+) 7-13 mm Guided Twist Drill 3 x (10+) 7-18 mm Twist Drill 3 x 10-18 mm Twist Drill 3 x 7-15 mm Twist Drill 3 x 7-10 mm Guided Drill Guide NP to Ø 3 mm Guided Drill Guide RP to Ø 3 mm Guided Drill Guide 6.0/WP to Ø 3 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™
Drill Stop Ø 3.2	Guided Drill Stop Kit Box Drill Stop Kit Box	Twist Step Drill 2.8/3.2 7-10 mm Twist Drill 3.2 x 18-25 mm Twist Step Drill 2.8/3.2 10-18 mm Twist Step Drill 2.8/3.2 7-15 mm Guided Twist Drill 3.2 x (10+) 7-13 mm Twist Drill 3.2 x 7-10 mm Guided Twist Drill 3.2 x (10+) 7-18 mm Twist Drill 3.2 x 10-18 mm Guided Twist Step Drill Ø 2.8/3.2 (10+) 7-18 mm Guided Twist Step Drill Ø 2.8/3.2 (10+) 7-13 mm Twist Drill 3.2 x 7-15 mm Guided Drill Guide NP to Ø 3.2 mm Guided Drill Guide RP to Ø 3.2 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™
Drill Stop Ø 3.4	Guided Drill Stop Kit Box Drill Stop Kit Box	Guided Twist Drill 3.4 x (10+) 7-13 mm Guided Twist Drill 3.4 x (10+) 7-18 mm Twist Drill 3.4 x 10-18 mm Twist Drill 3.4 x 7-15 mm Twist Drill 3.4 x 7-10 mm Twist Drill 3.4 x 18-25 mm Guided Drill Guide RP to Ø 3.4 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™
Drill Stop Ø 3.6	Guided Drill Stop Kit Box Drill Stop Kit Box	Twist Step Drill 3.2/3.6 7-15 mm Twist Step Drill 3.2/3.6 7-10 mm Guided Twist Step Drill Ø 3.2/3.6 (10+) 7-18 mm Guided Twist Step Drill Ø 3.2/3.6 (10+) 7-13 mm Twist Step Drill 3.2/3.6 10-18 mm Guided Drill Guide RP to Ø 3.6 mm Guided Drill Guide WP/6.0 to Ø 3.6 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™
Drill Stop Ø 3.8	Guided Drill Stop Kit Box Drill Stop Kit Box	Guided Twist Drill 3.8 x (10+) 7-13 mm Guided Twist Drill 3.8 x (10+) 7-18 mm Guided Drill Guide 6.0/WP to Ø 3.8 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™

Product Name	Compatible devices		
	Drill Stop/Drill Stop Kit Box	**Drills**	**Screwdriver**
Drill Stop Ø 4.2	Guided Drill Stop Kit Box Drill Stop Kit Box	Guided Twist Step Drill 3.8/4.2 (10+) 7-18 Twist Step Drill 3.8/4.2 10-18 mm Twist Step Drill 3.8/4.2 7-15 mm Twist Step Drill 3.8/4.2 7-10 mm Guided Twist Drill 4.2 x (10+) 7-13 mm Guided Twist Drill 4.2 x (10+) 7-18 mm Guided Twist Step Drill 3.8/4.2 (10+) 7-13 Guided Drill Guide RP to Ø 4.2 mm Guided Drill Guide 6.0/WP to Ø 4.2 mm	Screwdriver Machine Unigrip™ Screwdriver Manual Unigrip™
Drill Stop Kit Box	Drill Stop Ø 2 Drill Stop Ø 2.8 Drill Stop Ø 3 Drill Stop Ø 3.2 Drill Stop Ø 3.4 Drill Stop Ø 3.6 Drill Stop Ø 3.8 Drill Stop Ø 4.2	Twist Drill w Tip 2.0 x 18-25 mm Twist Drill w Tip 2 x 7-15 mm Twist Drill 3.2 x 7-10 mm Twist Drill 1.5 x 7-15 mm Twist Drill w Tip 2 x 10-18 mm Twist Drill w Tip 2 x 18-25 mm, LS Twist Step Drill 2.4/2.8 10-18 mm Twist Step Drill 2.4/2.8 7-15 mm Twist Step Drill 2.4/2.8 7-10 mm Twist Step Drill 2.4/2.8 x 18-25 mm, LS Twist Step Drill 2.4/2.8 x 18-25 mm Twist Step Drill 2.4/2.8 x 18-25 mm Twist Drill 3 x 10-18 mm Twist Drill 3 x 7-15 mm Twist Drill 3 x 7-10 mm Twist Step Drill 2.8/3.2 7-10 mm Twist Drill 3.2 x 18-25 mm Twist Step Drill 2.8/3.2 10-18 mm Twist Step Drill 2.8/3.2 7-15 mm Twist Drill 3.2 x 7-10 mm Twist Drill 3.2 x 10-18 mm Twist Drill 3.2 x 7-15 mm Twist Drill 3.4 x 10-18 mm Twist Drill 3.4 x 7-15 mm Twist Drill 3.4 x 7-10 mm Twist Drill 3.4 x 18-25 mm Twist Step Drill 3.2/3.6 7-15 mm Twist Step Drill 3.2/3.6 7-10 mm Twist Step Drill 3.2/3.6 10-18 mm Twist Step Drill 3.8/4.2 10-18 mm Twist Step Drill 3.8/4.2 7-15 mm Twist Step Drill 3.8/4.2 7-10 mm	N/A
Guided Drill Stop Kit Box	Drill Stop Ø 2 Drill Stop Ø 2.8 Drill Stop Ø 3 Drill Stop Ø 3.2 Drill Stop Ø 3.4 Drill Stop Ø 3.6 Drill Stop Ø 3.8 Drill Stop Ø 4.2	Guided Twist Drill 2 x (10+) 7-13 mm Guided Twist Drill 2 x (10+) 7-18 mm Guided Twist Drill 2.8 x (10+) 7-13 mm Guided Twist Drill 2.8 x (10+) 7-18 mm Guided Twist Step Drill Ø 2.4/2.8 (10+) 7-13 mm Guided Twist Step Drill Ø 2.4/2.8 (10+) 7-18 mm Guided Drill Guide NP to Ø 2.8 mm Guided Drill Guide RP to Ø 2.8 mm Guided Drill Guide 6.0/WP to Ø 2.8 mm Guided Twist Drill 3 x (10+) 7-13 mm Guided Twist Drill 3 x (10+) 7-18 mm Guided Twist Drill 3.2 x (10+) 7-13 mm Guided Twist Drill 3.2 x (10+) 7-18 mm Guided Twist Step Drill Ø 2.8/3.2 (10+) 7-18 mm Guided Twist Step Drill Ø 2.8/3.2 (10+) 7-13 mm Guided Twist Drill 3.4 x (10+) 7-13 mm Guided Twist Drill 3.4 x (10+) 7-18 mm Guided Twist Step Drill Ø 3.2/3.6 (10+) 7-18 mm Guided Twist Step Drill Ø 3.2/3.6 (10+) 7-13 mm Guided Twist Drill 3.8 x (10+) 7-13 mm Guided Twist Drill 3.8 x (10+) 7-18 mm Guided Twist Step Drill 3.8/4.2 (10+) 7-18 Guided Twist Drill 4.2 x (10+) 7-13 mm Guided Twist Drill 4.2 x (10+) 7-18 mm Guided Twist Step Drill 3.8/4.2 (10+) 7-13	N/A

Intended Use/Intended Purpose

Drill Stops 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 for Freehand Surgery

Drill Stops 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 for Guided Surgery

Drill Stops 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.

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).

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 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

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 a throat shield).

Intended Users and Patient Groups

Drill Stops and the Drill Stop Kit Box (including the Drill Stop Kit Box) are to be used by dental health care professionals.

Drill Stops and the Drill Stop Kit Box are 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 Box

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 Box

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

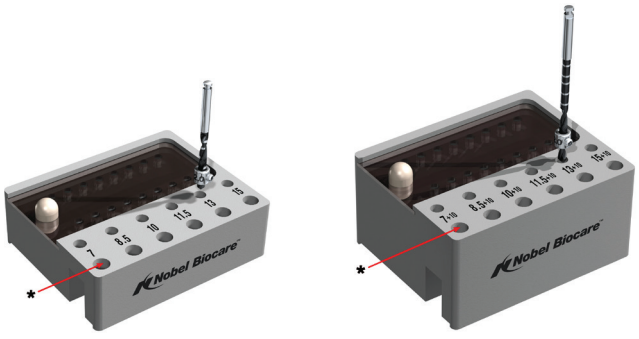
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
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).



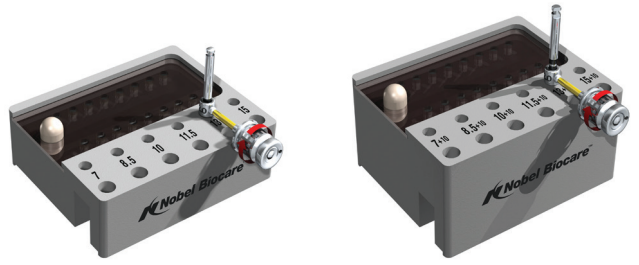
Drill Stop Kit Box for Freehand Surgery **Drill Stop Kit Box for Guided Surgery**

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 IFU1058 for information regarding the Unigrip™ Screwdriver.

Warning Ensure the retaining screw on the drill stop is sufficiently tightened to ensure the drill stop does not fall off the drill and is possibly swallowed or aspirated by the patient.



Drill Stop Kit Box for Freehand Surgery **Drill Stop Kit Box for Guided Surgery**

Figure B – Tightening the Retaining Screw on the Drill Stop

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

Sterility and Reusability Information

Drill Stops, Drill Stop Kit Box, and Guided Drill Stop Kit Box 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.

The Drill Stop Kit Box is a reusable component which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The Drill Stop Kit Box shall be discarded if any wear, abrasion, deformations or corrosion is visible on the component.

The Guided Drill Stop Kit Box is a reusable component which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The Guided Drill Stop Kit Box shall be discarded if any wear, abrasion, deformations or corrosion is visible on the component.

The Drill Stop is a reusable component which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The Drill Stop shall be discarded if any wear, abrasion, deformations or corrosion is visible on the component.

Note Drill Stops can be processed as individual devices as described in the Cleaning and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Cleaning and Sterilization Instructions

Drill Stops, Drill Stop Kit Box, and Guided Drill Stop Kit Box 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, Drill Stop Kit Box, and Guided Drill Stop Kit Box have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

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. Use a dental probe to remove soil and debris from cavities, where applicable.
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 Stop Kit Box and Guided Drill Stop Kit Box prior to cleaning by removing the cover.
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 washers were used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program/MMM GmbH Type: Uniclean PL-II 15-2 EL.

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 of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining
4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Disassemble Drill Stop Kit Box and Guided Drill Stop Kit Box prior to cleaning by removing the cover.
2. Immerse the 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 of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP and/or Neodisher Medizym; maximum of 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 an 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_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP and/or Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F)/maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml 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 discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL/Selectomat PL/666-1 CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Reassemble any multi-piece devices (where applicable) and 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 2 presents examples of suitable sterilization pouches.

Table 2 – Recommended Sterilization Pouches

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

2. Label the sterilization pouch with the information necessary to identify the device e.g. 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 3):

Table 3 – 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 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 Drill Stop Kit Boxes 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 Drill Stop Kit Boxes, 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
UK Responsible Person 	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class I Devices	CE
CE Mark for Class IIa Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA Mark for Class IIa Devices	UK CA 0086

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

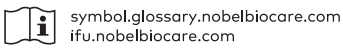
Basic UDI-DI Information

Product	Basic UDI-DI Number
Drill Stop Kit Box Guided Drill Stop Kit Box	73327470000001426X
Drill Stops (Ø 2/Ø 2.8/Ø 3/Ø 3.2/Ø 3.4/Ø 3.6/Ø 3.8/Ø 4.2)	73327470000001226R

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	