Drill Stop Kit
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:

The Drill Stop Kit contains a selection of Drill Stops* which are stored in a Drill Stop Kit Box. A Drill Stop is a hollow cylinder with a retaining screw that can be slid onto the drill and fixed with the set screw thus creating a stop function at a desired drill depth. The Drill Stops come in several diameters for use with different diameter drills.

The Drill Stop Kit is intended for use with Twist Drills and Twist Step Drills for NobelActive®, NobelParallel™ CC, Brånemark System® Mk III Groovy, Brånemark System® Mk III Shorty, Brånemark System® Mk III TiUnite®, Brånemark System® MkIV TiUnite®, NobelSpeedy® Groovy, NobelSpeedy® Replace, NobelSpeedy® Shorty, NobelReplace® Straight, Replace Select™ Straight and Replace Select™ TC.

The Drill Stop Kit is delivered non-sterile and is reusable.

** Class II device; see applicable CE Mark (CE 0086)*

Intended Use:

The Drill Stops are used to create a stop function when drilling holes in the jaw bone during preparation for implant installation to ensure safe and accurate drilling procedure.

The Kit Box for Drill Stops is used to store, autoclave and facilitate the mounting procedure of the Drill Stops.

Indications:

The Drill Stops are used for all Nobel Biocare straight drilling protocols. The Drill Stop Kit is to be used with Drill Stops for Twist Drills and Twist Step Drills with diameter ø2, ø2.8, ø3, ø3.2, ø3.4, ø3.6 and ø4.2 mm.

Contraindications:

In general, contraindications are applicable for implant surgery related procedures in:

– Patients who are medically unfit for an oral surgical procedure.

– Patients who are allergic or hypersensitive to medical grade stainless steel or any of its alloying components, aluminum, polyetheretherketone (PEEK), or polyphenylsulfone (PPSU).

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 from 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 the nerves and vessels by referring to anatomical knowledge and preoperative.

Cautions:

General:

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment 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 procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Surgical Procedure and Handling Procedure:

Handling Procedure:

1. Select Drill Stop according to diameter of Twist Drill or Twist Step Drill (see laser marking).
2. Slide corresponding Drill Stop onto drill. Place drill in mounting hole corresponding to desired drill depth see asterisk (*) in Figure A). The Drill 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.

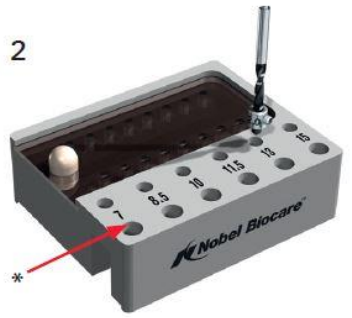

Figure A: Placement of Drill into Mounting Hole in Drill Stop Kit Box

3. Tighten the retaining screw on the Drill Stop using Unigrip™ Screwdriver (refer to the following figure).

Surgical Procedure:

1. Drill until predetermined drill depth is reached and proceed with implant site preparation as described in the respective implant system Instructions for Use.

For additional information on surgical procedures please consult the procedures manual for the respective implant system available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

- Drill Stops: Medical grade stainless steel.
- Drill Stop Kit Box: Aluminium, polyetheretherketone (PEEK) and polyphenylsulfone (PPSU)

Sterility and Reusability Information:

The Drill Stop Kit is delivered non-sterile and intended for reuse. Prior to first use and reuse clean, disinfect and/or sterilize using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Cleaning and Sterilization Instructions:

With these cleaning and sterilization instructions, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise, any deviation by the processor from the provided instructions should be properly evaluated for effectiveness and potential adverse consequences.

Cleaning Guidelines:

Clean the device using automated cleaning, disinfect and dry the device.

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):

The following washer/disinfector was used in the Nobel Biocare process validation: Miele G7836 CD.

Note: The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean, disinfect, and/or dry the device(s) must be strictly followed where applicable.

1. Remove all Drills and Drill Stops from the Drill Stop Kit Box.
2. Disassemble the Drills from the Drill Stops by removing the retaining screw. Clean and sterilize the Drills according to the applicable Nobel Biocare Instructions for Use.
3. Disassemble the Drill Stop Kit Box completely.
4. Immerse the Drill Stops, retaining screws, and Drill Stop Kit Box into 0.5% cold enzymatic cleaning solution (e.g. Neodisher Medizym) at 35°C (95°F) for 5 minutes.
5. Brush all surfaces with soft bristled nylon brush (e.g. Medisafe MED-100.33) until all visible residues are removed.
6. Rinse the Drill Stops, retaining screws, and Drill Stop Kit Box under cold running tap water. Rinse lumens (where applicable) with a 20ml syringe.
7. Load the Drill Stops, retaining screws, and Drill Stop Kit Box into washer/disinfector.
8. Carry out automatic cleaning and disinfection under consideration of national requirements with regard to the A0-Value (EN ISO 15883). The following parameters were used in the Nobel Biocare validation:
   - 2 minutes pre-cleaning with cold tap water
   - Draining
   - 5 minutes cleaning with tap water at 55°C (131°F) with a 0.5% solution of alkaline cleaning agent (e.g. Neodisher Mediclean)

   Caution: The use of a cleaning solution with acidic pH (pH < 7) could potentially damage the Drill Stop Kit Box.

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- Draining
- 3 minutes neutralizing with cold desalinated water
- Draining
- 2 minutes rinsing with cold desalinated water
- Draining
- 5 minutes thermal disinfection with demineralized water at 93°C (200°F)

9. Dry the Drill Stops, retaining screws, and Drill Stop Kit Box using compressed air. If needed, additional drying can be performed with clean and lint-free single use wipes.

Visual Inspection:

1. After cleaning, disinfection and drying, visually inspect the Drill Stops, retaining screws, and Drill Stop Kit Box for cleanliness, function and readability of text. Check all parts for visual soil, corrosion and damage. All devices with signs of corrosion and/or damage must be disposed and replaced.
2. Reassemble the Drill Stops and retraining screws.
3. Reassemble the Drill Stop Kit Box and mount the Drill Stops.

Packaging and Labeling:

1. Pack the assembled Drill Stop Kit Box in a sterilization pouch. The sterilization pouch or sterilization single wrap 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.

Note: The kit box is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated sterilization pouch (e.g Steriking sterilization pouch) in order to maintain sterility of the enclosed medical instruments until used.

2. Label the sterilization pouch with necessary information such as expiration date, lot (if applicable), sterility information, product name with article number.

Sterilization:

1. Place the sealed Drill Stop Kit Box into the autoclave/sterilizer. The Drill Stop Kit Box must be sterilized in its "ready for use" state.
2. Both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

- Gravity Cycle Method: Steam sterilization at 132°C (270°F) for 15 minutes, followed by drying for a minimum of 15 minutes in chamber.
- Pre-Vacuum Method: Steam sterilization at 132°C (270°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (for UK): Steam sterilization at 134°C (273°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (recommended to ensure inactivation of prions): Steam sterilization at 134°C (273°F) for 18 minutes, followed by drying for a minimum of 20 minutes in chamber.

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 with, EN 13060, EN 285, EN ISO 17665-1, AAMI ST79 or your national standard. The manufacturer's instructions for use for the autoclave / sterilizer must be strictly followed.

Storage and Maintenance:

After sterilization, place the sealed Drill Stop Kit Box in a dry and dark place such as a closed cupboard or drawer. Follow the instructions provided by the manufacturer of the sterilization pouches and sterilization wraps regarding storage conditions and expiration date of sterilized goods.

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:

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CE Mark for Class I Devices

CE 0086 Mark for Class II Devices

Canada – License Exemption: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

Symbols Glossary:

The following table describes symbols which may be present on the device labeling. Refer to the device labeling for the symbols which are applicable to the device.

LOT Batch code	REF Catalogue number	Caution	Consult instructions for use
PHT DEHP Contains or presence of phthalate	Date of manufacture	2 STERILIZE Do not re-sterilize	2 Do not re-use
Do not use if package is damaged	Rx Only For prescription use only	ID Patient Identifier	Keep away from sunlight
Keep dry	symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com Link to Online Symbols Glossary and IFU Portal		Manufacturer
MD Medical device	MR Magnetic resonance conditional	NON STERILE Non-sterile	# Patient number
SN Serial number	STERILE R Sterilized using irradiation	Use-by date	