

Guided Drill Stop Kit

Instructions for use



Important: Please read.

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, it is 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 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 Stop comes in several diameters for different diameter drills which are stored in a Guided Drill Stop Kit Box.

The Guided Drill Stop Kit is valid for Guided Twist Drills and Guided Twist Step Drills for NobelActive®, NobelParallel™ CC, Brånemark System® Mk III Groovy, Brånemark System® Mk III Shorty and Brånemark System® Mk III TiUnite®, NobelSpeedy® Groovy, NobelSpeedy® Replace, NobelSpeedy® Shorty, NobelReplace® Straight and Replace Select™ Straight

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 Guided Drill Stop Kit is to be used with Drill Stops for Guided Twist Drills and Guided Twist Step Drills with diameter 2, 2.8, 3, 3.2, 3.4, 3.6 and 4.2 mm.

Contraindications:

It is contraindicated to perform implant related surgeries 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.

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

Cautions:

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.

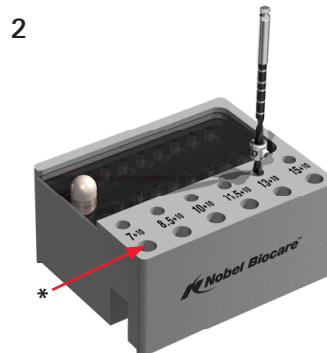
Working the first time with a colleague, experienced with a new device / treatment method, will provide further insight and understanding. Nobel Biocare has a global network of mentors available for this purpose.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Handling procedure:

Procedure:

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



3. Tighten the retaining screw on the Drill Stop using Unigrip™ Screwdriver.

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4. 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.

Cleaning and sterilization instructions:

The device is delivered non-sterile and intended for re-use. Prior to use and re-use clean, disinfect and sterilize the product using the recommended parameters. After use, disassemble Drill Stop and retaining screw for manual or automated cleaning and disinfection. After visual inspection of the parts, reassemble the kit box and continue with sterilization according to cleaning and sterilization guidelines.

For USA: Seal kit box in a pouch and steam sterilize at 270°F, max 279°F (132°C, max 137°C) for at least 4 minutes, depending on the sterilization cycle.

For outside USA: Seal kit box in a pouch and steam sterilize at 132°C–135°C (270°F–275°F) for at least 4 minutes, depending on the sterilization cycle.

Alternative UK: Seal kit box in a pouch and steam sterilize at 134°C–135°C (273°F–275°F) for at least 4 minutes, depending on the sterilization cycle.

Full set of recommended parameters are provided in "Cleaning and Sterilization Guidelines for Nobel Biocare products including MRI information" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

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

MRI safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.



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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only

Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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

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



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

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