

Drill Stop Kit

Instructions for use



Important: Please read.

Disclaimer of liability:

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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 Drill Stop Kit Box.

The Drill Stop Kit is valid for 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.

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 Ø 2, Ø 2.8, Ø 3, Ø 3.2, Ø 3.4, Ø 3.6 and Ø 4.2 mm.

Contraindications:

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

- who are medically unfit for an oral surgical procedure.
- 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 the 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.

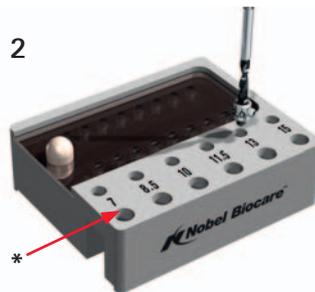
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

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 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. 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*.



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



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. This device must be cleaned and sterilized prior to use. 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 (132°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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Prescription device: Rx only

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



Rx Only



Non-sterile



Caution



Consult instructions
for use



Batch code

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