

Tapered Drills and Screw Taps – Reusable

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

Reusable Tapered Drills, Dense Bone Drills and Screw Taps are made of stainless steel with DLC (Diamond Like Carbon) coating and should be replaced after 20–30 uses, or when cutting efficiency declines. Tapered Drills are internally-irrigated and require a specific technique to prevent irrigation holes becoming plugged with bone. Tapered drills are unique for each implant length.

Intended use:

Tapered Drills, Dense Bone Drills and Screw Taps are to be used in the upper or lower jaw to prepare osteotomy prior to implant placement.

Indications:

Tapered Drills, Dense Bone Drills and Screw Taps are to be used to in combination with NobelReplace® Tapered Groovy®, Replace Select™ Tapered TiUnite®, Replace Select™ Tapered Partially Machined Collar (PMC), NobelReplace® Conical Connection (CC), NobelReplace® Conical Connection Partially Machined Collar (CC PMC), NobelDirect® Oval, and NobelDirect® Posterior implants.

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 stainless steel or diamond-like carbon (DLC) coating.
- in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

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 radiographs.

Cautions:

General:

It is strongly recommended that surgical instruments are used only with Nobel Biocare implants as detailed, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

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 info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Before surgery:

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulation.

At surgery:

All 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.

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

After surgery:

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Surgical procedures:

Drilling must proceed at high speed for Tapered Drills (maximum 800rpm) under constant and profuse irrigation by sterile saline at room temperature. Tapered Drills are internally-irrigated and require a specific technique to prevent irrigation holes becoming plugged with bone debris. During drilling use an in-and-out motion and drill in bone for 1–2 seconds. Move the drill up without stopping handpiece motor which allows the irrigation to flush away bone debris.

Caution: Tapered Drills extend up to 1 mm longer than the implant when seated.

Allow for this additional length when drilling near vital anatomical structures.

Dense bone protocol (optional) – as indicated:

Dense Bone Drill is only needed for 13mm and 16mm implants. If shorter implants are used, go directly to step (b).

- Select the Dense Bone Drill matching the diameter and length (13 or 16mm) of final Tapered Drill. Drill one pass into the prepared site with high speed (800rpm) using Bone Drill.
- Select the Screw Tap matching the diameter of final Tapered Drill. Place into prepared implant site using low speed (25rpm).

c. Apply firm pressure and begin rotating the Screw Tap slowly. When the threads engage, allow Screw Tap to feed without pressure to appropriate depth.

d. Switch the handpiece to reverse mode and back the Screw Tap out.

For additional information on surgical procedures please consult the NobelReplace® Tapered Groovy®, Replace Select™ Tapered TiUnite®, Replace Select™ Tapered Partially Machined Collar (PMC), NobelReplace® Conical Connection (CC), NobelReplace® Conical Connection Partially Machined Collar (CC PMC), NobelDirect® Groovy®, NobelDirect® Oval, and NobelDirect® Posterior “Procedures & products” treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

Tapered Drills, Dense Bone Drills and Screw Taps: stainless steel, DLC (Diamond Like Carbon) coating.

Cleaning and sterilization:

Tapered Drills, Dense Bone Drills and Screw Taps are delivered non-sterile and must be cleaned and sterilized prior to use.

For USA: Seal single device in a pouch and steam sterilize at 270° F (132° C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132° C–135° C (270° F–275° F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134° C–135° C (273° F–275° F) for 3 minutes.

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

Full set of recommended parameters are provided in “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

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.

For additional information on Magnetic Resonance Imaging, please consult the “Cleaning & 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.

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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