Tapered Drills, Dense Bone Drills, Screw Taps

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

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.

Single use Tapered Drills, Dense Bone Drills, and Screw Taps are made of stainless steel and are delivered sterile. The single use drills are for one patient and for one surgical treatment only. 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.

The Tapered Drills, Dense Bone Drills, and Screw Taps, reusable and single use, are compatible with the handpiece according to ISO 1797 type 1.

The compatibility for the Drill kit 7-15 mm is shown in Table 1.

Table 1 – Compatibility for the Drill kit 7-15 mm

Drill kit 7-15 mm	Included components in the kit	Compatibility
	Guide Drill	Handpiece ISO 1797 type 1
	Twist Drill w Tip 2x7-15 mm	Drill Stop 2 mm Handpiece ISO 1797 type 1
	Twist Step Drill 2.4/2.8 7-15 mm	Drill Stop 2.8 mm Handpiece ISO 1797 type 1

Intended Use/Intended Purpose

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

Indications

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

Contraindications

It is contraindicated to use Tapered Drills, Dense Bone Drills, and Screw Taps in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to stainless steel, diamond-like carbon (DLC) coating, or silicone.

For contraindications specific to the Implant System, refer to the Nobel Biocare Instructions for Use for the component.

Materials

Table 2 – Material Information

Product Family	Materials Information
Drill Tapered 2 mm	Stainless steel 1.4197/AISI420F Mod according to ASTM F899.
Drill Tapered	Stainless steel 1.4542/AISI 630 according to ASTM F899, DLC (Diamond Like Carbon) coating, and silicone rubber compound according to ASTM D297, ASTM D412, ASTM D624, and ASTM D2240.
Drill Tapered Single-patient Use	Stainless steel 1.4542/AISI 630 according to ASTM F899 and silicone rubber compound according to ASTM D297, ASTM D412, ASTM D624, and ASTM D2240.
Dense Bone Drill Tapered	Stainless steel 1.4542/AISI 630 according to ASTM F899, DLC (Diamond Like Carbon) coating, and silicone rubber compound according to ASTM D297, ASTM D412, ASTM D624, and ASTM D2240.
Dense Bone Drill Tapered Single-patient Use	Stainless steel 1.4542/AISI 630 according to ASTM F899 and silicone rubber compound according to ASTM D297, ASTM D412, ASTM D624, and ASTM D2240.
Screw Tap Tapered	Stainless steel 1.4543 GG according to ASTM F899, DLC (Diamond Like Carbon) coating, and silicone rubber compound according to ASTM D297, ASTM D412, ASTM D624, and ASTM D2240.
Screw Tap Tapered Single-patient Use	Stainless steel according to UNS S45500 ASTM A564 and silicone rubber compound according to ASTM D297, ASTM D412, ASTM D624, and ASTM D2240.
Drill Kit 7-15 mm	Guide Drill: stainless steel 1.4197/AISI420F Mod according to ASTM F899. Twist Drill w Tip 2x7-15 mm: stainless steel 1.4197/AISI420F Mod according to ASTM F899. Twist Step Drill 2.4/2.8 7-15 mm: stainless steel 1.4197/AISI420F Mod according to ASTM F899Twist Drill w Tip 2x7-15 mm: stainless steel 1.4197/AISI420F Mod according to ASTM F899. Twist Step Drill 2.4/2.8 7-15 mm: stainless steel 1.4197/AISI420F Mod according to ASTM F899.

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

Tapered Drills, Dense Bone Drills, and Screw Taps must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Tapered Drills, Dense Bone Drills and Screw Taps can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

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

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

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

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

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 throat shield).

After Surgery

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Surgical Procedure

Drilling must proceed at high speed for Tapered Drills (maximum 800 rpm) 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 13 mm and 16 mm implants. If shorter implants are used, go directly to step (2).

1. Select the Dense Bone Drill matching the diameter and length (13 or 16 mm) of final Tapered Drill. Drill one pass into the prepared site with high speed (800 rpm) using Bone Drill.

2. Select the Screw Tap matching the diameter of final Tapered Drill. Place into prepared implant site using low speed (25 rpm).

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

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

Sterility and Reusability Information

Tapered Drills, Dense Bone Drills, Screw Taps - Single-Patient Use and Drill Kit have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Caution Tapered Drills, Dense Bone Drills, Screw Taps – Single-Patient Use and Drill Kit are single use product(s) and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Tapered Drills, Dense Bone Drills, and Screw Taps -Reusable 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.

Tapered drills, Dense bone drills and Screw taps - Reusable are reusable components which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained.

Note Tapered Drills, Dense Bone Drills, and Screw Taps 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

Tapered Drills, Dense Bone Drills, and Screw Taps – Reusable 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 Tapered Drills, Dense Bone Drills, and Screw Taps – Reusable are validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

Caution Replace worn-out and damaged drills.

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. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

2. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.

3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute until all visible soil is removed.

4. 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 1 minute until all visible soil is removed.

5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program/Washer disinfector (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.

Note FDA-cleared washer- disinfectors are to be used for the recommended cleaning parameters.

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. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 1 minute until all visible soil is removed.

3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP/Neodisher Medizym; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.

4. 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 1 minute until all visible soil is removed.

5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

6. 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/Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F)/maximum 45°C (113°F).

7. 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.

8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum off 1 minute to remove all cleaning agent.

9. 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/Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer/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/666-1CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. 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 3 presents examples of suitable sterilization pouches.

Table 3 – 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:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying for a minimum of 30 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying for a minimum of 20 minutes in chamber.

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

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.

Magnetic Resonance (MR) 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, 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
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

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

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
					Rx only		symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com
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	