Bone Mills and Bone Mill Guides

Important – Disclaimer of Liability

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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

Bone mills* have a cylindrical cutting surface which is used to remove excess bone which may surround the coronal aspect (the top surface, or platform) of a dental implant immediately after implant placement, or after the implant healing process is complete. This sometimes is necessary to facilitate the subsequent placement of prosthetic components.

Bone mills are used together with a compatible bone mill guide**, which is temporarily fastened to the implant via the implant connection and is used to guide the bone mill to the correct position and to limit the milling to a predefined depth.

Bone mills and bone mill guides are available in several different diameters which are compatible with different Nobel Biocare implant systems. Additionally, certain bone mills are co-packed with the corresponding bone mill guide, but in all cases the bone mill guides are available separately.

The Bone Mill Guide Nobel Biocare N1 TCC consists of two parts, the main body and the screw. The two parts are delivered co-packed but are disassembled and must be assembled prior to use.

* Class IIa device; see applicable CE Mark (CE 2797) after the Manufacturer and Distributor Information.

** Class Ir device; see applicable CE Mark (CE 2797) after the Manufacturer and Distributor Information.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use/Intended Purpose

Bone Mills

Intended for use to remove bone surrounding a dental implant or connecting surface.

Bone Mill Guides

Intended for use to guide drilling instruments used to remove bone surrounding the connecting surface of a dental implant.

Indications

Bone Mills

Bone mills are indicated for use in conjunction with bone mill guides in the maxilla or mandible to remove excess bone from around the coronal aspect of a dental implant, in order to facilitate the subsequent placement of dental prosthetic components.

Bone Mill Guides

Same as Intended Use/Intended Purpose.

Contraindications

It is contraindicated to use Bone Mills and Bone Mill Guides in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients allergic or hypersensitive to titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), stainless steel, or DLC (Diamond Like Carbon) coating.

Materials

Bone Mill Nobel Biocare N1™, Bone Mill Guide Nobel Biocare N1™

- Bone Mill: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating. The average composition of the coating (DLC) of 1 to 4 µm thick is around: 73 wt.% tungsten (W), 23 wt.% carbon (C), and 4 wt.% nickel (Ni).
- Bone Mill Guide: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating on screw. The average composition of the coating (DLC) of 1 to 4 µm thick is around: 73 wt.% tungsten (W), 23 wt.% carbon (C), and 4 wt.% nickel (Ni).

Bone Mill with Guide Conical Connection

- Bone Mill: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating. The average composition of the coating (DLC) of 1 to 4 µm thick is around: 73 wt.% tungsten (W), 23 wt.% carbon (C), and 4 wt.% nickel (Ni)./Insert: Silicone
- Bone Mill Guide: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Bone Mill with Guide NobRpl

- Bone Mill: Stainless steel 1.4197/AISI420F Mod according to ASTM F899, DLC (Diamond Like Carbon) coating. The average composition of the coating (DLC) of 1 to 4 µm thick is around: 73 wt.% tungsten (W), 23 wt.% carbon (C), and 4 wt.% nickel (Ni)./Insert: Silicone
- Bone Mill Guide: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Bone Mill with Guide Brånemark System®

- Bone Mill: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating. The average composition of the coating (DLC) of 1 to 4 µm thick is around: 73 wt.% tungsten (W), 23 wt.% carbon (C), and 4 wt.% nickel (Ni).
- Bone Mill Guide: Stainless steel 1.4305/AISI 303 austenitic steel according to ASTM F899.

Warnings

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

Bone mills and bone mill guides 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 Bone mills and bone mill guides 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.

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

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 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

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

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 a 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.

Intended Users and Patient Groups

Bone mills and bone mill guides are to be used by dental health care professionals.

Bone mills and bone mill guides are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Bone Mills and Bone Mill Guides

Bone mills and bone mills guides a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Bone Mills and Bone Mill Guides

The use of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. Depending on location it may also lead in rare cases to fenestration or fracture of bone, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During use of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Bone Mills and Bone Mill Guides. The SSCP can be obtained at the following website:
ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Surgical Procedure

To facilitate the removal of hard tissue around the coronal aspect of the implant, a bone mill with a bone mill guide can be used. Bone mills can be handled either manually (using a Handle for Machine Instruments) or connected to the contra-angle handpiece.

1. Remove the cover screw or healing abutment, if applicable.

2. Secure the bone mill guide onto the implant and tighten it finger-tight by using a compatible screwdriver. If a Bone Mill Guide N1 TCC is used, assemble the screw into the main body and then secure it onto the implant.

Caution Tighten the bone mill guide screw finger-tight. Overtightening the screw can damage or fracture the inner threads of the implant.

Note When using Nobel Biocare N1 TCC NP components, start by using the bone mill guide Nobel Biocare N1™ TCC NP Ø 4.0. If the prosthetic components still do not fit, proceed to bone mill guide Nobel Biocare N1™ TCC NP Ø 5.2.

3. For manual use of the bone mill, engage it to the Handle for Machine Instruments and press the bone mill slightly towards the implant platform and gently rotate the instrument to remove any tissue that may hinder an abutment from being fully seated on the implant.

4. For machine use of the bone mill, connect the bone mill to the contra angle. Before starting the machine, place the bone mill onto the bone mill guide.

Note All bone mills include a window in the upper part of the bone mill to facilitate visual inspection to determine when the bone mill is fully seated on the bone mill guide.

5. Begin milling at low speed (do not exceed 60-100 rpm). Copious irrigation is recommended.

Caution Ensure that no bending forces are applied during use of the bone mill to prevent the bone mill from colliding with the bone mill guide.

6. After the excess bone surrounding the implant platform has been removed, the prosthetic component (abutment) can be connected. Ensure that no bone remnants remain on the implant platform. The height markings (in 1 mm increments) on the bone mill can be used to guide the abutment selection with regard to the collar height.

Sterility and Reusability Information

Bone Mills and Bone Mill Guides 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.

Before each use, inspect the devices for signs of degradation that may limit the useful life of the device such as the following:

- Visible corrosion
- Dull cutting edges
- The laser marking on the device is illegible

The devices shall be discarded if any of the above listed signs of degradation are apparent.

Warning Do not use device if the packaging has been damaged.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, bone mills and bone mill guides must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with bone mills and bone mill guides, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
CE Mark for Class Ir/IIa Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA Mark for Class IIa Devices	UK CA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Bone Mill Guide Conical Connection Bone Mill Guide Brånemark System® Bone Mill Guide Nobel Biocare N1™ TCC	7332747000000156 7A
Bone Mill with Guide Conical Connection Bone Mill with Guide Brånemark System® Bone Mill Nobel Biocare N1™ TCC Bone Mill with Guide NobelReplace®	733274700000014779

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.