

# Bone Mills and Bone Mill Guides

## Instructions for use



### Important – Disclaimer of Liability:

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### 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-packaged 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.

Table 1 presents an overview of the available bone mills and bone mill guides, their respective diameters, and the compatible Nobel Biocare implant systems. The required screwdriver is also identified; refer to the Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the screwdrivers. This IFU is available for download at [ifu.nobelbiocare.com](http://ifu.nobelbiocare.com).

**Table 1: Bone Mills and Compatible Bone Mill Guides, Implant Systems and Screwdrivers**

Bone Mill	Bone Mill Guide	Compatible Implant System	Screwdriver
Bone Mill with Guide Conical Connection 3.0	Bone Mill Guide Conical Connection 3.0	NobelActive 3.0	Unigrip
Bone Mill with Guide Conical Connection NP Ø 4.4	Bone Mill Guide Conical Connection NP	NobelActive NP NobelReplace CC NP NobelParallel CC NP	
Bone Mill with Guide Conical Connection NP Ø 5.2			
Bone Mill with Guide Conical Connection RP Ø 5.2	Bone Mill Guide Conical Connection RP	NobelActive RP NobelReplace CC RP NobelParallel CC RP	OmniGrip Mini
Bone Mill with Guide Conical Connection RP Ø 6.2			
Bone Mill with Guide Conical Connection Ø 6.7 WP	Bone Mill Guide Conical Connection WP	NobelActive WP NobelParallel CC WP	
Bone Mill Nobel Biocare N1™ TCC Ø 4.0	Bone Mill Guide Nobel Biocare N1™ TCC NP Ø 4.0	Nobel Biocare N1™ TiUltra TCC NP	
Bone Mill Nobel Biocare N1™ TCC Ø 5.2	Bone Mill Guide Nobel Biocare N1™ TCC NP Ø 5.2		
Bone Mill Nobel Biocare N1™ TCC Ø 5.2	Bone Mill Guide Nobel Biocare N1™ TCC RP Ø 5.2	Nobel Biocare N1™ TiUltra TCC RP	

### Intended Use:

#### 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 for use:

#### 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 commercially pure titanium grade 4, titanium alloy grade 5 (Ti 6Al-4V), stainless steel or diamond-like carbon (DLC) coating.

For contraindications specific to the dental implant, refer to the Nobel Biocare Instructions for Use (IFU) for the respective implant. These IFU are available for download at [ifu.nobelbiocare.com](http://ifu.nobelbiocare.com).

### 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 Mills Guide must only be used with compatible Nobel Biocare instruments and components. Use of instruments and components that are not intended to be used in combination with Bone Mills and Bone Mills Guide 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 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:

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. Refer to Table 1 for the appropriate screwdriver.

**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.

**Materials:**

- Bone mills: stainless steel, diamond-like carbon (DLC) coating (ASTM A899 and ISO 15608, ASTM A895).
- Bone mill guides: titanium alloy grade 5 (90% Ti, 6% Al, 4% V) (ASTM F136 and ISO 5832-3).

**Sterility and Reusability Information:**

Bone mills and bone mill guides are delivered non-sterile and 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.

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

Bone mills and bone mill guides are reusable devices which must be inspected before each reuse to ensure that the integrity and performance continues to be maintained. 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 these signs of degradation are apparent.

**Note:** Bone mills and bone mill guides 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](http://ifu.nobelbiocare.com).

**Cleaning and Sterilization Instructions:**

**Bone mills and bone mill guides are 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 bone mill and bone mill guides have been validated to withstand these cleaning and sterilization procedures.

**Initial Treatment at Point of Use Prior to Reprocessing:**

1. Discard single-use instruments and worn reusable instruments immediately after use.
  2. Disassemble the screw from the bone mill guide where applicable.
- Caution:** Screws and their compatible guides may be misidentified for reassembly if not tracked carefully during the cleaning and sterilization process. A stock of replacement clinical screws (article number 300968 for NP bone mill guide and article number 300969 for RP bone mill guide) is recommended.
3. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
  4. 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 20 seconds 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 20 seconds 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 10 seconds 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.

**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 2 minutes pre-cleaning with cold tap water.
  - Draining.
  - Minimum 5 minutes cleaning with minimum 55°C tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
  - Draining.
  - Minimum 3 minutes neutralization with cold desalinated water.
  - Draining.
  - Minimum 2 minutes rinsing with cold desalinated water.
  - Draining.
4. Run drying cycle at minimum 50°C (122.0 °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 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 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 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 appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds 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 10 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water 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 of 10 seconds 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 dispose any devices that fail the inspection.

**Sterilization:**

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

**Note:** It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization. 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 2 presents examples of suitable sterilization pouches.

Table 2: Recommended Sterilization Pouches	
Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

2. Label the sterilization pouch with information necessary to identify the device (for example, 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 15-30 minutes in chamber.
  - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying 20-30 minutes in chamber.

**Note:** FDA-cleared sterilization equipment and 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 SN 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 (introfacility transportation or shipping to an external site) into account.

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

## 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.



Batch code



Catalogue number



Date



Date of manufacture



Manufacturer



Serial number



Unique Device Identifier



Health care centre or doctor



Patient identification



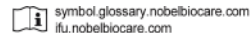
Patient number



Tooth number



Consult instructions for use



Link to Online Symbols Glossary and IFU Portal



Patient information website



Caution



Do not resterilize



Do not re-use



Do not use if package is damaged and consult instructions for use



Use-by date



Temperature limit



Upper limit of temperature



Keep away from sunlight



Keep dry



Contains biological material of animal origin



Contains hazardous substances



Contains or presence of DEHP phthalate



Contains or presence of natural rubber latex



Contains or presence of phthalate



Non-pyrogenic



Magnetic resonance conditional



Magnetic resonance safe



Non-sterile



Sterilized using Ethylene Oxide



Sterilized using irradiation



Sterilized using steam or dry heat



Single sterile barrier system



Single sterile barrier system with protective packaging inside



Single sterile barrier system with protective packaging outside



Double sterile barrier system



Authorised Representative in Switzerland



Authorized representative in the European Community / European Union



UK Responsible Person



CE mark



CE mark with Notified Body number



EU Importer



Swiss Importer



UKCA mark



UKCA mark with Approved Body number



Medical device

Rx only

For prescription use only

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