

Bone Mills and Bone Mill Guides



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

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.

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.

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	
Bone Mill with Guide Conical Connection NP Ø 5.2		NobelReplace® CC NP NobelParallel™ CC NP	
Bone Mill with Guide Conical Connection RP Ø 5.2	Bone Mill Guide Conical Connection RP	NobelActive® RP	
Bone Mill with Guide Conical Connection RP Ø 6.2		NobelReplace® CC RP NobelParallel™ CC RP	
Bone Mill with Guide Conical Connection WP Ø 6.7	Bone Mill Guide Conical Connection WP	NobelActive® WP NobelParallel™ CC WP	
Bone Mill with Guide Brånemark System® NP Ø 4.5	Bone Mill Guide Brånemark System® NP	NobelSpeedy® Groovy NP Brånemark System® NP	Unigrip™
Bone Mill with Guide Brånemark System® RP Ø 5.1	Bone Mill Guide Brånemark System® RP	NobelSpeedy® Groovy RP Brånemark System® RP NobelZygoma™	
Bone Mill with Guide Brånemark System® WP Ø 6.5	Bone Mill Guide Brånemark System® WP	NobelSpeedy® Groovy WP Brånemark System® 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	Omnigrip™ Mini
Bone Mill with Guide NobelReplace™ NP Ø 4.6	Bone Mill Guide NobelReplace® NP Ø 4.6	Replace Select™ TC NP Replace Select™ Tapered Replace Select™ Tapered PMC	
Bone Mill with Guide NOBELREPLACE® 6.0 Ø 7	Bone Mill Guide NOBELREPLACE® 6.0 Ø 7	Replace Select™ Tapered Replace Select™ Tapered PMC	Unigrip™
Bone Mill with Guide NobelReplace™ RP Ø 5.3	Bone Mill Guide NobelReplace® RP Ø 5.3	Replace Select™ TC RP Replace Select™ Tapered Replace Select™ Tapered PMC	
Bone Mill with Guide NobelReplace™ WP Ø 6.5	Bone Mill Guide NobelReplace® WP Ø 6.5	Replace Select™ Tapered Replace Select™ Tapered PMC	

* 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.

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.

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.

For contraindications specific to the implant systems, refer to the Nobel Biocare Instructions for Use for the component.

Materials

- Bone Mill Nobel Biocare N1™: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Bone Mill Guide Nobel Biocare N1™: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.

- Bone Mill Guide Brånemark System®: Stainless steel 1.4305/AISI 303 austenitic steel according to ASTM F899 and EN 10088-3.
- Bone Mill Guide Conical Connection: Stainless steel 1.4197/AISI420F Mod according to ASTM F899.
- Bone Mill with Guide Brånemark System®
 - Bone Mill: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
 - Bone Mill Guide: Stainless steel 1.4305/AISI 303 austenitic steel according to ASTM F899 and EN 10088-3.
- Bone Mill with Guide Conical Connection
 - Bone Mill: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
 - 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.
 - Bone Mill Guide: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

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.

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. 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.

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

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 Mills and Bone Mill Guides have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

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.

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. Disassemble the N1™ bone mill guide and screw prior to cleaning by unscrewing the screw of the bone mill guide.
2. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g., Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g., Neodisher Medizym) using a 20 ml syringe.
4. 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.
5. 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.
6. 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.
7. 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 and/or 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.

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. Disassemble the N1™ bone mill guide and screw prior to cleaning by unscrewing the screw of the bone mill guide.
2. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g., Cydezyme ASP and/or Neodisher Medizym; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. 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 10 seconds until all visible soil is removed.
6. 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.
7. 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 and/or Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F)/maximum 45°C (113°F).
8. 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.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. 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 and/or Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer and/or 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/666-1 CL, it is recommended to perform sterilization with a maximum load of 1 container with 8.6 kg of metal and 2 packages of linen.

1. Reassemble any multi-piece devices and 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 2 presents examples of suitable sterilization pouches.

Table 2 – 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 (Table 3):

Table 3 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time	Minimum Pressure
Gravity Cycle ¹	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar ⁴
Pre-Vacuum Cycle ¹	132°C (270°F)	4 minutes	20 minutes	≥2868.2 mbar ⁴
Pre-Vacuum Cycle ²	134°C (273°F)	3 minutes	20 minutes	≥3042 mbar ⁵
Pre-Vacuum Cycle ³	134°C (273°F)	18 minutes	20 minutes	≥3042 mbar ⁵

¹ Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10⁻⁶ in accordance to EN ISO 17665-1.
² Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.
³ Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.
⁴ Saturated steam pressure at 132°C as per required by EN ISO 17665-2.
⁵ Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

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.

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 	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
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class Ir/Ila Devices	
UKCA Mark for Class I Devices	
UKCA Mark for Class Ila Devices	

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
Bone Mill Guide Conical Connection	73327470000001567A
Bone Mill Guide Brånemark System®	
Bone Mill Guide Nobel Biocare N1™ TCC	
Bone Mill with Guide Conical Connection	733274700000014779
Bone Mill with Guide Brånemark System®	
Bone Mill Nobel Biocare N1™ TCC	
Bone Mill with Guide NobelReplace®	


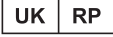















































Legal Statements

EN All rights reserved.

Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images in this folder are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product.

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		
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
							
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	