Bone Mill with Guide for Conical Connection Implants

Instructions for Use

Important – Disclaimer of Liability:

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Description:

The Bone Mills are used in combination with Bone Mill Guides to remove excess bone from around an implant platform to facilitate the placement of prosthetic components. The Bone Mill Guide is temporarily screwed into the implant to guide the Bone Mill to the right position. The Bone Mill then removes the excess bone.

Bone Mills are co-packed with the corresponding Bone Mill Guide; Bone Mill Guides are also available separately.

The Bone Mills and Bone Mill Guides are available in the following dimensions:

Bone Mill CC 3.0 ø 4.0* with outer diameter 4.0 mm and Bone Mill Guide CC 3.0 – for use with NobelActive® 3.0 implants.

Bone Mill CC NP ø 4.4* / Bone Mill CC NP ø 5.2* with outer diameter 4.4 mm / 5.2 mm and **Bone Mill Guide CC NP** – for use with NobelActive® implants, ø 3.5, NobelReplace® Conical Connection implants, ø 3.5 and NobelParallel™ CC implants, ø 3.75.

Bone Mill CC RP ø 5.2* / Bone Mill CC RP ø 6.2* with outer diameter 5.2 mm / 6.2 mm and **Bone Mill Guide CC RP** – for use with NobelActive® implants, ø 4.3 and ø 5.0, NobelReplace® Conical Connection implants, ø 4.3 and ø 5.0 and NobelParallel™ CC implants, ø 4.3 and ø 5.0.

Bone Mill CC WP ø 6.7* with outer diameter 6.7 mm and **Bone Mill Guide CC WP** – for use with NobelActive® implants, ø 5.5 and NobelParallel™ CC implants, ø 5.5.

The Bone Mills and Bone Mill Guides are delivered non-sterile and are reusable.

** Class II device; see applicable CE Mark (CE 0086)*

Intended Use:

The Bone Mills in conjunction with Bone Mill Guides are used by dental professionals around implants to remove excessive bone.

Indications:

The Bone Mills in conjunction with Bone Mill Guides are used to remove excess bone from around the coronal aspect of Conical Connection implants to facilitate placement of prosthetic components.

Contraindications:

In general, contraindications are applicable for implant surgery related procedures in patients:

- who are medically unfit for an oral surgical procedure.
- who are allergic or hypersensitive to commercially pure titanium grade 4, titanium alloy grade 5 (Ti 6Al-4V), stainless chromium steel or diamond-like carbon (DLC) coating.

For specific contraindications, please refer to the respective Instructions for Use for the implant or restorative component.

Cautions:

General:

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

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Only use Bone Mill Guides with the corresponding implant dimension, as damage to the implant head and inner threads could occur otherwise.

Before Surgery:

All components, instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:

Care and maintenance of 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 size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Surgical Procedure and Handling Procedure:

To facilitate the removal of hard and soft tissue around the implant head, the Bone Mill with Guide may be used. The Bone Mill and Guide can be handled either manually (Handle for Machine Instruments) or by the drilling machine.

Surgical Procedure:

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 the Unigrip™ Screwdriver.
3. Attach Handle for Machine Instruments for manual usage of the Bone Mill or connect the Bone Mill to the contra-angle handpiece. Before starting the machine, place the Bone Mill onto the Bone Mill Guide and start to run, only using low speed (60–100 rpm). Copious irrigation is recommended.

   Caution: Make sure that no bending forces are used during use of the Bone Mill.
4. When the surrounding bone close to the implant platform has been sufficiently reduced, it is ready for abutment connection. Ensure that the implant platform is clean from bone remnants. The height markings (in 1 mm steps) on the Bone Mill can be used to guide abutment selection with regard to collar height.

   Markings start 1 mm from implant platform (see **Figure A**). Use markings as reference height of soft tissue. The window in the upper part of the Bone Mill makes it easy to inspect visually when the instrument is fully seated on the guide.

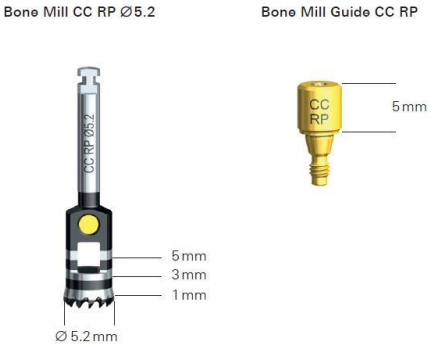

Figure A: **Bone Mill CC RP ø 5.2 and Bone Mill Guide CC RP**

Materials:

- Bone Mill: stainless chromium steel and diamond-like carbon (DLC) coating.
- Bone Mill Guide: titanium alloy grade 5 (Ti 6Al-4V).

Sterility and Reusability Information:

The Bone Mill with Guide is delivered non-sterile and is intended for reuse. Prior to first use and reuse clean, disinfect and/or sterilize using the recommended parameters.

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

Cleaning and Sterilization Instructions:

Cleaning and sterilization instructions for devices which are delivered non-sterile by Nobel Biocare, are intended for reuse, and must be sterilized by the user prior to each use, where the devices are individually sealed in pouches during sterilization.

With these cleaning and sterilization instructions, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise, any deviation by the processor from the provided instructions should be properly evaluated for effectiveness and potential adverse consequences.

Cleaning Guidelines:

Clean the device using automated or manual cleaning, disinfect and dry the device.

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):

The following washer/disinfector was used in the Nobel Biocare validation: Miele G7836 CD.

Note: The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean, disinfect, and/or dry the device(s) must be strictly followed where applicable.

1. Disassemble the devices, where applicable.
2. Immerse in cold enzymatic cleaning agent 0.5% (e.g. Neodisher Medizym) for 5 minutes.
3. Fill lumina (where applicable) with cleaning solution 0.5% (e.g. Neodisher Medizym) with a syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) until all visible residues are removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with bottle brushes (e.g. OD = 1.2mm / 2.0mm / 5.0mm) until all visible residues are removed.
6. Rinse with cold running tap water.
7. Rinse lumina (where applicable) with a syringe with 20ml tap water.
8. Load devices into washer / disinfector.
9. Perform automatic cleaning and disinfection under consideration of national requirements with regard to the A0-Value (EN ISO 15883). The following parameters are based on the Vario TD program on the Miele G7836 CD Washer-disinfector:
    - 2 min pre-cleaning with cold water
    - Draining
    - 5 minutes cleaning with 55°C tap water and 0.5% alkaline cleaning agent (e.g. Neodisher Mediclean)
    - Draining
    - 3 minutes neutralization with cold desalinated water
    - Draining
    - 2 minutes rinsing with cold desalinated water
    - Draining
10. Run drying cycle.
11. Dry with compressed air or wipes if needed.

Manual Cleaning, Disinfection and Drying:

Note: The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean, disinfect, and/or dry the device(s) must be strictly followed where applicable.

1. Immerse devices for a minimum of 5 minutes in sterile NaCl solution.
2. Scrub the outer side of the devices with soft bristled nylon brush until all visible soil is removed.
3. Flush channels / lumina (where applicable) with 20ml cleaning solution (e.g. Cidezyme ASP) with an irrigation needle connected to a 20ml syringe.
4. Brush lumina (where applicable) with a bottle brush (e.g. OD = 1.2mm / 2.0mm / 5.0mm).
5. Rinse the outer side and lumina of the devices with cold running tap water to remove all cleaning solutions.
6. Immerse in ultrasonic bath with 0.5% enzymatic Detergent Solution (e.g. Cidezyme ASP) and treat for 5 min at 40°C (104°F).
7. Flush inner lumina (where applicable) with 20ml cold running tap water with an irrigation needle connected to a 20ml syringe.
8. Rinse the outer side of the devices with purified or sterile water to remove all cleaning solutions.
9. Repeat cleaning steps if needed.
10. Immerse in 100% disinfection solution (e.g. Cidex OPA) for 5 minutes.
11. Flush internal channels / lumina (where applicable) with disinfection solution.
12. Rinse and flush lumina and outer side of devices with cold running tap water.
13. Flush internal channels / lumina (where applicable) with purified or sterile water.
14. Dry with compressed air or wipes.
15. Repeat complete cleaning and disinfection if needed.

Visual Inspection:

After cleaning, disinfection, 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:

Assemble (where applicable), inspect and seal the single device in a suitable sterilization pouch and steam sterilize. Both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

- Gravity Cycle Method: Steam sterilization at 132°C (270°F) for 10 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method: Steam sterilization at 132°C (270°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (for UK): Steam sterilization at 134°C (273°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (recommended to ensure inactivation of prions): Steam sterilization at 134°C (273°F) for 18 minutes, followed by drying for a minimum of 20 minutes in chamber.

Magnetic Resonance (MR) Safety Information:

The Bone Mill with Guide has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Bone Mill with Guide in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

If there is no MR Safety symbol on the product label, the device has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

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
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 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 I Devices

CE 0086 Mark for Class II Devices

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Symbols Glossary:

The following table describes symbols which may be present on the device labeling. Refer to the device labeling for the symbols which are applicable to the device.

Batch code

Catalogue number


Caution


Consult instructions for use

Contains or presence of phthalate


Date of manufacture

Do not re-sterilize

Do not re-use

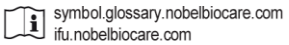

Do not use if package is damaged

For prescription use only

Patient Identifier


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal


Manufacturer

Medical device

Magnetic resonance conditional

Non-sterile

Patient number

Serial number

Sterilized using irradiation


Use-by date