

Bone Mill with Guide for Conical Connection Implants

Instructions for use

Important: Please read.

Disclaimer of liability:

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Description:

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

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

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

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

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

Intended use:

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

Indication:

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.



Warning:

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions:

It is strongly recommend 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 information please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with a new device / treatment method, will provide further insight and understanding. Nobel Biocare has a global network of mentors available for this purpose.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

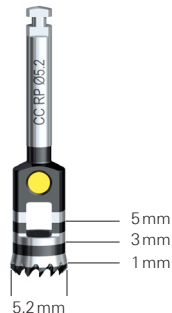
Handling procedure:

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.

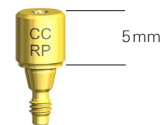
Procedure:

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.

Bone Mill CC RP 5.2



Bone Mill Guide CC RP



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 (60–100rpm). 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 in regards to collar height.

Markings start 1 mm from implant platform (see picture). 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.

Materials:

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

Cleaning and sterilization instructions:

This device is delivered non-sterile and must be cleaned and sterilized prior to use.

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C (270°F–275°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C (273°F–275°F) for 3 minutes.

Full set of recommended parameters are provided in “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

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

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.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only

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

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



Batch code



Catalogue number



Caution



CE marking



Consult instructions for use



Contains hazardous substances



Contains or presence of phthalate



Date



Date of manufacture



Do not resterilize



Do not re-use



Do not use if package is damaged



Double sterile barrier system

Rx Only

For prescription use only



Health care centre or doctor



Keep away from sunlight



Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

Link to Online Symbols Glossary and IFU Portal



Magnetic resonance conditional



Manufacturer



Medical device



Non-pyrogenic



Non-sterile



Patient identification



Patient information website



Patient number



Serial number



Single sterile barrier system



Single sterile barrier system with protective packaging inside



Single sterile barrier system with protective packaging outside



Sterilized using ethylene oxide



Sterilized using irradiation



Temperature limit



Tooth number



Upper limit of temperature



Sterilized using steam or dry heat



Unique Device Identifier



Use-by date

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