

Bone Mill with Guide for NobelReplace®

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

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

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 internal tri-channel 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 titanium alloy grade 5 (Ti 6Al-4V), stainless steel or diamond-like carbon (DLC) coating.

Warnings:

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.

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

Handling procedure:

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 in regards to collar height.

Markings start 1 mm from implant platform. 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.

For additional information on surgical procedures please consult the procedures manual of the respective implant system available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

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

Cleaning and sterilization instructions:

The device is delivered non-sterile and intended for re-use. This device 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 for Nobel Biocare products including MRI information" 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 re-sterilize



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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