Bone Mill with Guide for Brånemark System®
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

Bone Mill Brånemark System® NP 4.5 with outer diameter 4.5 mm and Bone Mill Guide Brånemark System® NP – for use with all Brånemark System® and NobelSpeedy® Groovy NP implants.

Bone Mill Brånemark System® RP 5.1 with outer diameter 5.1 mm and Bone Mill Guide Brånemark System® RP – for use with all Brånemark System® Mk III and NobelSpeedy® Groovy RP implants, 3.75 and 4.0.

Bone Mill Brånemark System® WP 6.5 with outer diameter 6.5 mm and Bone Mill Guide Brånemark System® WP – for use with all Brånemark System® and NobelSpeedy® Groovy WP implants, 5.0.

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 external hex 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.

The use of Bone Mills with RP Mk IV and WP 6.0 implants is not recommended. The top portion of these implants will be scratched if the Bone Mill is seated to full depth onto the Bone Mill Guide. This is due to the fact that flanges on these implants are wider than the implant-abutment interface.

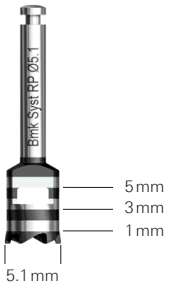
Only use Bone Mill Guides with the corresponding implant dimension, as damage to the implant head and inner threads could occur otherwise.

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.

Bone Mill Brånemark System® RP 5.1



Bone Mill Guide Brånemark System® 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 (60–100 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 (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.

For additional information on surgical procedures please consult the procedures manual for 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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CE 2797

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

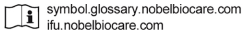

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



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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