

Bone Mill with Guide for Brånemark System®

Instructions for use



Important: Please read.

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 Mill Brånemark System® NP Ø 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 Ø 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, Ø 3.75 and Ø 4.0.

Bone Mill Brånemark System® WP Ø 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, Ø 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 Ø 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.

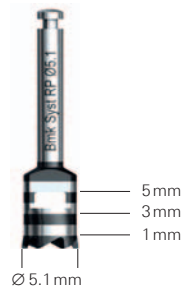
Only use Bone Mill Guides with the corresponding implant dimension, as damage to the implant head and inner threads could occur otherwise.

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 Ø5.1 **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.



Manufacturer: Nobel Biocare AB, Box 5190, 402 26
Västra Hamngatan 1, 411 17 Göteborg, Sweden.
Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

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.



Rx Only



Non-sterile



Caution



Consult instructions
for use



Batch code

US 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.