Bone Mill and Cover Screw Mill for Brånemark System®
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

The Bone Mills consist of a working part that cuts the outer periphery of the implant head free from bone and soft tissue. The working part also consists of a small guide peg, which centers the cutting part when placed in the inner canal of the implant.

The Cover Screw Mills consist of a working part that cuts the outer periphery of the cover screw free from bone and soft tissue. The working part also consists of a small guide peg that will centre the cutting part over the cover screw.

Both Bone Mill and Cover Screw Mill are compatible with Nobel Biocare external hex connection implants. Three different versions exist for NP, RP and WP external hex connections, all with corresponding laser marking.

Intended use:

The Bone Mills are used to remove any excessive bone around the implant platform to facilitate placement of prosthetic components.

The Cover Screw Mills are used to remove any bone or tissue overgrowth above the cover screw during a two-stage surgical procedure. This enables removal of the cover screw from the implant head.

Indications:

The Bone Mills are used to remove excess bone from around the coronal aspect of external hex connection implants NP, RP and WP.

The Cover Screw Mills are used for the removal of hard and soft tissue in conjunction with cover screws of external hex connection implants NP, RP and WP.

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 medical grad stainless steel or any of its alloying components.

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.

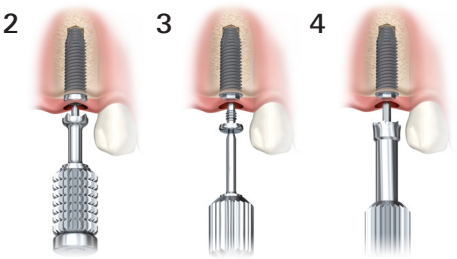
Only use each Bone Mill and Cover Screw Mill with the respective implant dimension mentioned above, as damage to the implant head and inner threads could occur otherwise.

Handling procedure:

Both the Bone Mill and Cover Screw Mill are used during the second-stage surgery as part of the two-stage surgical procedure. The Bone Mill can also be used during single-stage surgery before placing the abutment. Both instruments are designed to be used by hand.

Procedure:

1. Uncover the implant by making an incision to expose cover screw or use the Soft Tissue Punch in case of sufficient amount of attached mucosa.
2. Place the guide peg of the Cover Screw Mill in the central hole of the cover screw head. Bone or connective tissue is removed by gently rotating the instrument.
3. Remove cover screw using Cover Screw Driver Brånemark System® Hexagon.
4. Place the guide peg of the Bone Mill in the inner canal of the implant. Press the Bone Mill slightly towards the implant head and gently rotate the instrument to remove any bone around the implant platform that may hinder an abutment from being fully seated on the implant. Please note that the Bone Mill can also be used independently during surgery without cover screw milling.



5. When the surrounding bone and tissue 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.

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 and Cover Screw Mill: medical grade stainless steel.

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.

MRI 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.

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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

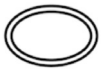
Date


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
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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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