NobelGuide® for Brånemark System® Mk III Groovy and NobelSpeedy® Groovy
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:

The NobelGuide® guided surgery system is designed for dental implant treatment of edentulous and partially edentulous jaws including patients missing a single tooth. The system enables a predictable and if indicated minimal invasive endosseous implant installation procedure according to a case planning done by the clinician in NobelClinician® Software. The Brånemark System® Guided Surgery Kit contains the specific guided surgery tooling which is used in conjunction with the NobelGuide® surgical template to guide the surgical tooling for surgical access, guided implant site preparation, guided screw tapping and guided implant insertion of Brånemark System® Mk III Groovy and NobelSpeedy® Groovy implants based of the NobelClinician® treatment plan.

Note: Guided surgery is only available for Brånemark System® Mk III TiUnite® in RP.

The Brånemark System® Guided Surgery Kit contains the following specific guided surgery tooling:

– Guided Drill Guides used to transfer the direction given by the sleeves embedded in the surgical template to drill to various diameters.

– Handle for Guided Drill Guide extends the existing handle on the Guided Drill Guides for easier handling and better accessibility in the surgical situation.

– Guided Implant Mounts used to facilitate implant placement through the surgical template sleeve. The Guided Implant Mounts have an outer diameter that matches the internal dimensions of the sleeves.

– Guided Template Abutments used in the first 1–2 preparations in order to keep the surgical template in the exact position when preparing and placing the remaining implants.

The kit also contains the following components:

– Unigrip™ Screwdriver

– Guided Anchor Pins

– Torque Wrench Surgical

– Torque Wrench Prosthetic Adapter

– Connection to Handpiece

– Drill Extension Shaft

Guided Tissues Punches, Guided Start Drill, Guided Twist Drills, Guided Screw Taps and Guided Start Drill/Counterbores are ordered separately.

Intended use:

The NobelGuide® guided surgery system is intended to transfer a treatment planning done by the clinician into a physical/clinical reality. The system is intended to facilitate implant installation with high predictability and contribute to better restoration of these implants placed in both mandible and maxilla.

Indications:

The guided surgery concept is indicated for the treatment of edentulous and partially edentulous jaws (including patients missing a single tooth) for placement of implant fixtures, if indicated in combination with immediate function to restore esthetics and functionality (e.g. masticatory, speech). The following prerequisites must be fulfilled:

– Adequate amount jawbone.

– The quality of jawbone must be judged as adequate.

– Adequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.

– Exclusion of compromised diseases in conflict with dental implant treatment.

– Adequate compliance.

Note: For Contraindications, Warnings and Cautions for Brånemark System® Mk III Groovy and NobelSpeedy® Groovy implants please refer to the applicable implant Instructions for Use.

Contraindications:

It is contraindicated to place Brånemark System® Mk III Groovy and NobelSpeedy® Groovy implants in patients:

– Who are medically unfit for an oral surgical procedure.

– With inadequate bone volume unless an augmentation procedure can be performed.

– In whom adequate sizes, numbers or desirable position of implants are not achieved to provide safe support of functional or eventually parafunctional loads.

– Allergic or hypersensitivity to commercially pure titanium (grade 4), stainless steel or surgical template material acrylate-based photopolymer.

Warnings:

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended from lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

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

Cautions:

General:
One hundred percent implant success cannot be guaranteed. Especially, nonobservance of the indicated limitations of use and working steps may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

It is strongly recommended 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.

It is strongly recommended that Brånemark System® Mk III Groovy and NobelSpeedy® Groovy implants are used only with Nobel Biocare surgical instruments and prosthetic components, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Before surgery:
Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

Before performing guided surgery, the delivered surgical template must be carefully inspected and cleared by the clinician performing the surgery. Optimal fit on stone model and in patient's mouth needs to be verified. If in doubt, please contact Nobel Biocare technical support.

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.

At surgery:
Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

After implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

After surgery:
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Surgical procedures:

If applicable, anchor the surgical template using an adequate number of anchor pins placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to secure the surgical template is in the correct position in the patient's mouth and that is does not move in any direction from the correction position when being manipulated with instruments (e.g. lateral shift through inadequate handling of twist drills in "knife-edge ridge" situations or shift/deformation of surgical template due to excessive vertical force application during implant installation). In situations where two or more neighboring implants are placed, regardless if it is a free-end situation or a situation with one or more distal teeth for support of the surgical template, it is recommended to use at least one anchor pin in this area. If necessary, place implants in a staggered approach.

1. If a flapless procedure is chosen, it is recommended to use the Guided Soft Tissue Punch before any other instruments are used to generate a clean cut. The surgical template can be temporarily detached after punching to carefully remove the punched soft tissue. The surgical template is carefully repositioned and the anchor pins replaced into the existing anchorage holes in the bone.

   If a (mini) flap procedure is chosen, it is recommended that the surgical template is first repositioned and the anchor pins placed prior to any manipulations of the soft tissue.

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Remove the anchor pins and surgical template, perform the incision, respecting the position of the implants and elevate the flap. If required, carefully modify the surgical template by relieving as much material as required to accommodate the flap, rinsing with sterile saline solution prior to carefully repositioning.

2. During drilling procedures bone quality should be considered. (See Tables **1** & **2** for recommended drill sequences based on bone quality to ensure optimal primary stability when applying Immediate Function). Use the Guided Start Drill prior to the Guided Twist Drill 2 mm (with the appropriate Guided Drill Guide to 2 mm) to create a start point for the following drill. Then select the appropriate Guided Drill Guide based on the sleeve size and the Guided Twist Drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution. An in-and-out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

1 Brånemark System® Mk III Groovy

Recommended drill sequence based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets (–) denote widening of cortex only.

* Screw taps are available and advised for use if insertion torque exceeds **45 Ncm**.

** For Brånemark System® Mk III TiUnite® RP implants use Guided Start Drill Counterbore former Mk III RP (Art. No. 33113).

Platform	Implant diameter	Soft Bone Type IV	Medium Bone Type II–III	Dense Bone* Type I
NP	3.3	2.0	2.0	2.0 2.8
RP**	3.75	2.0 (2.8)	2.0 3.0	2.0 3.2
RP**	4.0	2.0 (2.8)	2.0 3.2	2.0 2.8 3.4
WP	5.0	2.0 3.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2

2 NobelSpeedy® Groovy

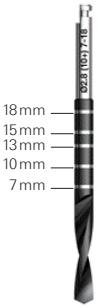
Recommended drill sequence based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets (–) denote widening of cortex only.

* Screw taps are available and advised for use if insertion torque exceeds **45 Ncm**.

Platform	Implant diameter	Soft Bone Type IV	Medium Bone Type II–III	Dense Bone* Type I
NP	3.3	2.0	2.0	2.0 2.8
RP	4.0	2.0 (2.8)	2.0 3.2	2.0 2.8 3.4
WP	5.0	2.0 3.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2
6.0	6.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2	2.0 3.0 3.8 4.2 5.0

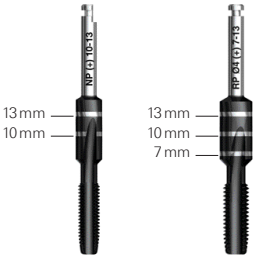
Caution: Guided Twist Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10 mm longer than the "freehand" Twist Drills to compensate for the height of the surgical template and the Guided Drill Guide. The depth marks on the Guided Twist Drills correspond to 7, 10, and 13 mm implants for 7–13 mm drills and 7, 10, 13, 15 and 18 mm for 7–18 mm drills (**A**). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

A



3. Prepare implant site.
4. Dense bone protocol: to be used if insertion torque exceeds **45 Ncm** and the implant will not be fully seated.
   – Select the Guided Screw Tap matching the diameter and length of the implant. Place the Guided Screw Tap directly into the guided sleeve of the surgical template and prepare the site to the appropriate depth the using low speed (20–45 rpm) with copious irrigation. **B:1** shows depth markings which correspond to full depth tapping of 10 mm and 13 mm for 3.3 mm implants. **B:2** shows depth markings which correspond to full depth tapping of 7 mm, 10 mm and 13 mm for 3.75, 4.0, 5.0 and 6.0 implants.
   – Switch the drill device to reverse mode and remove the Guided Screw Tap.

B:1 B:2



5. If the implant shoulder was planned below the bone crest, use the Guided Start Drill/Counterbore to generate adequate access for the Guided Implant Mount. Select the Guided Start Drill/Counterbore matching the diameter of the implant.

Note: A specific Guided Start Drill/Counterbore is available for Brånemark System® Mk III TiUnite® RP.

Drill to the built-in stop at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution.

6. Open the implant package. Connect the Guided Implant Mount to the implant using the Unigrip™ Screwdriver. Insert the Connection to Handpiece in the drilling unit handpiece and pick up the mounted implant. Brånemark System® Mk III Groovy and NobelSpeedy® Groovy implants are ideally installed with low speed, maximum 25 rpm, using the drilling device. Place and tighten the implant using maximum **45 Ncm** installation torque. Stop tightening the implant when the Guided Implant Mount touches the surgical template. The Guided Implant Mount includes a vertical stop. Secure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

Caution: Never exceed insertion torque of **45 Ncm**. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

7. If the implant gets stuck during implant installation or **45 Ncm** is achieved before fully seated, rotate the implant counter clockwise using the drilling device (reverse mode) or the Manual Torque Wrench and remove from the site. Replace the implant in the inner casing before proceeding further (refer to the Dense bone protocol section). Without removing the surgical template, continue with implant installation until desired position is achieved. For Immediate Function, the implant should be able to withstand a final torque of **35–45 Ncm**.
8. In partially edentulous and edentulous situations the Guided Implant Mount can be replaced by the Guided Template Abutment on the first 1–2 implants. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount. Anchor the surgical template using the Guided Template Abutment, tightening manually using the Unigrip™ Screwdriver. Ensure the surgical template maintains its initial correct position for the next implant site preparation.
9. Prepare and install the remaining implant sites.
10. Once all implants are installed, remove Guided Implants Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. Remove anchor pins, if applicable and remove the surgical template.
11. Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical.
12. Depending on the surgical protocol of choice, place a cover screw using the Unigrip™ Screwdriver or an abutment using the Torque Wrench Prosthetic Adapter and suture.

For additional information on surgical procedures please consult the "Procedures & products" treatment guidelines for NobelGuide® available at www.nobelbiocare.com or request the latest printed version from a Nobel Biocare representative.

For additional information on the NobelGuide® surgical templates and related surgical procedures, please refer to the Instructions for Use NobelGuide® Surgical Template.

For additional information on the Brånemark System® Mk III Groovy and NobelSpeedy® Groovy implants please refer to the respective Instructions for Use.

For additional information on the NobelClinician® Software please refer to the NobelClinician® Instructions for Use.

Materials:

All components contained in Brånemark System® Guided Surgery Kits, as listed in the "Description" section, are made from 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.

Caution: Use of non-sterile device may lead to infection of tissues or infectious diseases.

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.

MR safety information:

Note: For Implant MR safety information please refer to applicable Implant IFU.

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.

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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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.

After sterilization, place the devices in a dry and dark place such as a closed cupboard or drawer. Follow the instructions of the manufacturer of the sterilization pouch regarding storage conditions and expiration date of sterilized goods.

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

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

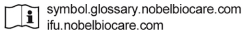

Double sterile barrier system

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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