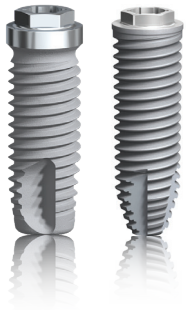
Brånemark System® Mk III TiUnite®, NobelSpeedy®, Twist Drills, Twist Step Drills, Counterbores, Screw Taps



Important – 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

Implant

Brånemark System® dental implants with external hexagon connection are made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. The Cover Screw is made of titanium alloy Ti-6Al-4V.

The Brånemark System® Mk III TiUnite® is a parallel walled implant recommended for all bone qualities. The implants have a machined collar of 0.8 mm for NP 3.3, RP 3.75 and RP 4.0 mm, and a 0.2 mm collar for WP 5.0 mm. Cover screw is co-packed with implant.

NobelSpeedy® Groovy dental implants with external hexagon connection are made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. The NobelSpeedy® Groovy is a slightly tapered implant, which gives a higher initial stability compared with a parallel implant. Cover screw is not included.

Tooling

Nobel Biocare Twist Drills, Twist Step Drills, Counterbores and Screw Taps are made of stainless steel with DLC (Diamond Like Carbon) coating and should be used in conjunction with Brånemark System® and NobelSpeedy® implants.

Intended Use

Brånemark System® implants are intended to be used in the upper or lower jaw bone (osseointegration) and used for anchoring or supporting tooth replacements to restore chewing function.

NobelSpeedy® Groovy endosseous implants are intended to be used in the upper or lower jaw bone (osseointegration) and used for anchoring or supporting tooth replacements to restore chewing function.

Indications

Brånemark System® Mk III TiU and NobelSpeedy® implant restorations range from single tooth to fixed-removable full dental arch overdenture applications to restore chewing function.

This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi-cortical anchorage in cases of reduced bone density to obtain high initial stability.

NobelSpeedy® implants with lengths of 20 mm, 22 mm and 25 mm are indicated to be used in the upper jaw and soft bone only.

Contraindications

It is contraindicated placing Brånemark System® 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 considered.
- in whom adequate sizes, numbers or desirable positions of implants are not reachable to achive safe support of functional or eventually parafunctional loads.
- allergic or hypersensitive to commercially pure titanium grade 4 or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), stainless steel, or DLC (Diamond Like Carbon) coating.

Materials

- NobelSpeedy®, Brånemark System® Mk III TiU implants: commercially pure titanium grade 4.
- Cover Screw: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).
- Twist Drills, Twist Step Drills, Counterbores, and Screw Taps: stainless steel with DLC (Diamond Like Carbon) coating.

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 of asepsis, during drilling in the jaw bone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions

General

One hundred percent implant success cannot be guaranteed. Especially, non-observance 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 Brånemark System® 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.

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 info please visit www.nobelbiocare.com.

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.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).

Special caution is advised in patients who receive bisphosphonate therapy. In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented.

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

At Surgery

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

All instruments and tooling used during procedure 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 components, care must be taken that they are not swallowed or aspirated by the patient.

Brånemark System® and NobelSpeedy® Groovy implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: The tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch.

After the 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 Procedure

During drilling procedures bone quality should be considered (please see tables 1 and 2: recommended drill sequences are based on bone quality to ensure optimal primary stability when applying immediate function).

The recommended drill sequence is based on bone quality. Drill data are stated in mm and the drills within brackets denote widening of cortex only.

Counterbores and Screw Taps are available if deemed necessary.

Platform	Implant diameter Ø	Drill Sequence (according to bone quality)		
		Soft bone	Medium bone	Dense bone
NP	3.3	Ø 2.0 (Ø 2.4/2.8)	Ø 2.0 Ø 2.4/2.8	Ø 2.0 Ø 2.4/2.8
RP	3.75	Ø 2.0 (Ø 2.4/2.8)	Ø 2.0 Ø 2.4/2.8 Ø 3.0	Ø 2.0 Ø 2.4/2.8 Ø 3.2
RP	4.0	Ø 2.0 (Ø 2.4/2.8)	Ø 2.0 Ø 2.4/2.8 Ø 3.2	Ø 2.0 Ø 2.4/2.8 Ø 3.4
WP	5.0	Ø 2.0 Ø 2.4/2.8 (Ø 3.2/3.6)	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6 (Ø 3.8/4.2)	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6 Ø 3.8/4.2

Table 1 – Brånemark System® Mk III TiUnite®

Platform	Implant diameter Ø	Drill Sequence (according to bone quality)		
		Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
NP	3.3	Ø 2.0	Ø 2.0	Ø2.0 Ø2.4/2.8
RP	4.0	Ø2.0 (Ø2.4/2.8)	Ø 2.0 Ø 2.4/2.8 Ø 3.2	Ø 2.0 Ø 2.4/2.8 Ø 3.4
RP WP	5.0	Ø 2.0 Ø 2.4/2.8 Ø 3.0	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6 Ø 3.8/4.2
WP	6.0	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6 Ø 3.8/4.2	Ø 2.0 Ø 2.4/2.8 Ø 3.2/3.6 Ø 3.8/4.2 Ø 5.0

Table 2 – NobelSpeedy®

Drilling must proceed at high speed (max. 2'000 rpm for Twist Drills and Twist Step Drills) under constant and profuse irrigation by sterile saline at room temperature. In dense bone situation drill with continuous back and forth motion.

Depth measurement system: The parallel drills have a true depth measurement system. All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position.

Caution Twist Drills and Twist Step Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (please see Figures A and B for drill reference lines).

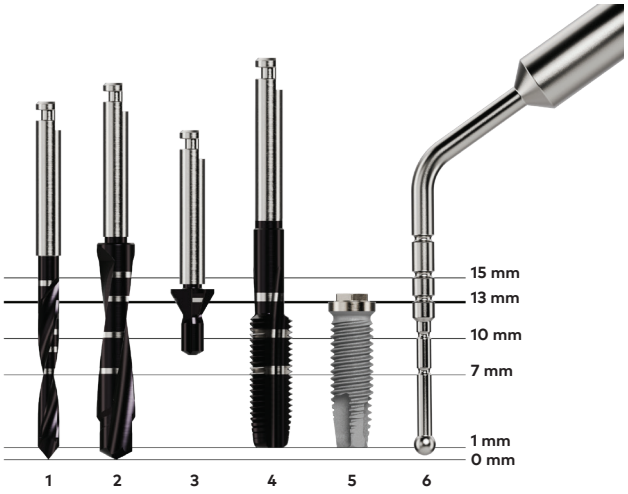


Figure A

Drill reference lines for Twist Drill 7–15 mm (1), Twist Step Drill 7–15 mm (2), Counterbore (3), Screw Tap 7–13 mm (4), Brånemark System® Mk III TiUnite® (5) implants 13 mm and Depth Probe 7–18 mm (6).

Twist Drills and Twist Step Drills are available in three different lengths with depth markings for 7–10 mm, 7–15 mm and 10–18 mm implants.

Screw Taps are available with depth markings for NP 10–15 mm, RP and WP 7–13 mm and 7–18 mm implants.

Note The marks on the Twist Drills and Twist Step Drills indicate actual millimeter lengths and correspond to the implant collar. Final vertical positioning depends on several clinical parameters, including esthetics, tissue thickness and available vertical space.

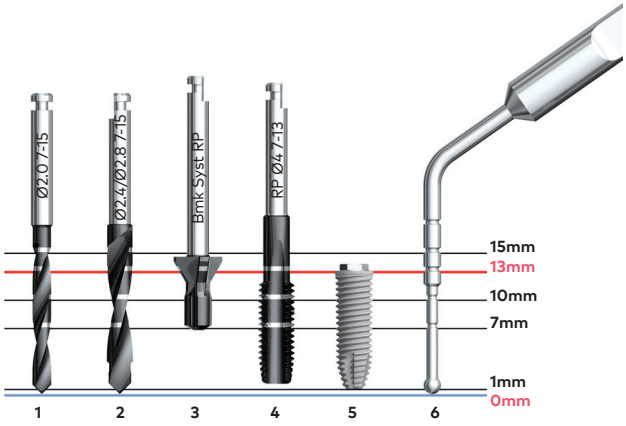


Figure B

Drill reference lines for Twist Drills 7–15 mm (1), Twist Step Drill 7–15 mm (2), Counterbore (3), Screw Tap (4), NobelSpeedy® Groovy implant 13 mm (5) and Depth Probe 7–18 mm (6).

Twist Drills and Twist Step Drills are available in four different lengths with depth markings for 7–10 mm, 7–15 mm, 10–18 mm and 18 – 25 mm implants.

Screw Taps are available with depth markings for NP 7–15 mm, RP and WP 7–13 mm and 7–18 mm implants.

In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, a drill extension shaft may be used.

1. Prepare implant site (Figure C). When using a flapless approach add-on soft tissue height to drill depth.

Figure C

2. Measure the final depth of the implant site for applicable implant length using a Depth Probe with the same measurements as the Twist Drills and Twist Step Drills.

3. Open the implant package and pick up the implant from its inner casing with the implant driver (Figure D). The implants are ideally installed with low speed, max. 25 rpm using a drill device (Figure D) or Manual Torque Wrench Surgical (Figure E).

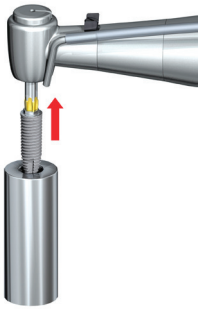


Figure D

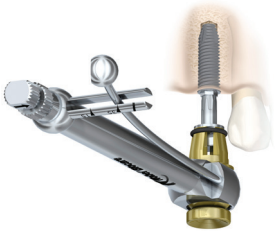


Figure E

4. Place and tighten the implant using max. 45 Ncm insertion torque.

Caution Never exceed insertion torque of 45 Ncm for the implants. Overtightening an implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid over tightening.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counter clockwise using a drill device (reverse mode) or the Manual Torque Wrench Surgical and remove the implant from the site. Replace the implant back into its inner casing before proceeding further.

5. Dense bone protocol to be used when the implant cannot be fully seated.

   a. In cases of a thick cortical layer or dense bone a Counterbore and/or a Screw Tap is recommended to be able to get the implant fully seated and to release pressure around the implant neck.

   b. Select the Screw Tap matching the diameter of the implant.

   c. Place the Screw Tap into the prepared implant site using low speed 25 rpm and drill to appropriate depth. Switch the drill device with handpiece or Manual Torque Wrench Surgical to reverse mode and remove the Screw Tap.

Continue with implant installation until the desired position is achieved using max. 45 Ncm installation torque.

6. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm.

7. Depending on the surgical protocol of choice, place a Cover Screw or Abutment and suture (Figure F).

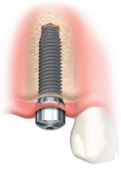


Figure F

See tables for implant specifications for Brånemark System® Mk III TiUnite® (Table 3), NobelSpeedy® Groovy (Table 4).

Platform	Platform diameter	Implant diameter	Lengths
NP	Ø 3.5 mm	Ø 3.3 mm	10 mm, 11.5 mm, 13 mm, 15 mm
RP	Ø 4.1 mm	Ø 3.75 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm
RP	Ø 4.1 mm	Ø 4.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm
WP	Ø 5.1 mm	Ø 5.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm

Table 3 – Brånemark System® Mk III Groovy & Brånemark System® Mk III TiUnite®

Platform	Platform diameter	Implant diameter	Lengths
NP	Ø 3.5 mm	Ø 3.3 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm
RP	Ø 4.1 mm	Ø 4.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm, 20 mm, 22 mm, 25 mm
		Ø 5.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm
WP	Ø 5.1 mm	Ø 5.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm
		Ø 6.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm

Table 4 – NobelSpeedy® Groovy

For additional information on surgical procedures please consult the Brånemark System® Mk III TiUnite®, NobelSpeedy® Groovy "Procedures & products" treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Cleaning and Sterilization Instructions

Brånemark System® Mk III Groovy, Brånemark System® Mk III TiUnite® and Brånemark System® Mk IV TiUnite® implants, Cover Screws, Twist Drills, Twist Step Drills, Counterbores and Screw Taps are delivered sterile and for single use only prior to the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened.

Caution Implants, Cover Screws, Twist Drills, Twist Step Drills, Counterbores and Screw Taps are single use products not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

NobelSpeedy® Groovy implants, Twist Drill, Twist Step Drills, Counterbores and Screw Taps are delivered sterile and for single use only prior to the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened.

Caution Implants, Twist Drills, Twist Step Drills, Counterbores and Screw Taps are single use products not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

Magnetic Resonance (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.

For additional information on Magnetic Resonance Imaging, please consult the"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.

Non-clinical testing has demonstrated that the NobelSpeedy® Groovy implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the NobelSpeedy® Groovy implant is expected to produce a maximum temperature rise of 4.1ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the NobelSpeedy® Groovy implant when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Storage, Handling and Transportation

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 and Distributor Information

Manufacturer

Nobel Biocare AB
PO Box 5190, 402 26
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Göteborg
411 17
Sweden
www.nobelbiocare.com

CE Mark for Class IIa/IIb Devices

CE 2797

Note Refer to the product label to determine the applicable conformity marking for each device.

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.

Legal Statements

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 / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
					Rx only		symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	