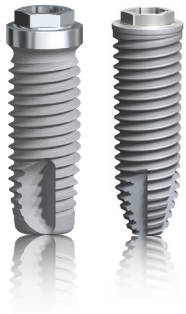
Brånemark System® Mk III TiUnite®, NobelSpeedy®, Twist Drills, Twist Step Drills, Counterbores, Screw Taps



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Description

Brånemark System® Mk III TiU (TiUnite)

Brånemark System® Mk III TiU 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 TiU 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®

NobelSpeedy® dental implants with external hexagon connection are made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. The NobelSpeedy® is a slightly tapered implant, which gives a higher initial stability compared with a parallel implant.

Cover screw is not included.

Tooling

Twist Drills, Twist Step Drills, and Counterbores are required to prepare the osteotomy for placement of Brånemark System® Mk III TiU and NobelSpeedy® implants. Twist Drills and Twist Step Drills are available in different diameters and lengths in order to widen the osteotomy step-by-step to the appropriate diameter and depth. Screw Taps are used to cut threads in the osteotomy in dense bone and are made of stainless steel with DLC (Diamond Like Carbon) coating and should be used in conjunction with Brånemark System® Mk III TiU and NobelSpeedy® implants.

The Twist Drills, Twist Step Drills, Brånemark System® Counterbores, and Screw Taps are compatible with the handpiece connection according to ISO 1797-1. Drills stops are available.

Product Name	Cover Screw	Implant Driver	Screws	Abutments			Impression Coping
				Healing	Temporary	Permanent	
Brånemark System® Mk III TiU NP	Cover Screw Brånemark System NP	Implant Driver NP Brånemark System Implant Driver Wrench Adapter NP	Abutment Screw Multi-unit Angled Prosthetic Screw Multi-unit	Healing Abutment NP	Immediate Temporary Abutment NP Plastic Coping Immediate NP Temporary Abutment NP QuickTemp Abutment Conical NP Plastic Coping QuickTemp Abutment Conical NP Temporary Abutment Engaging NP Temporary Abutment Non-Engaging NP Temporary Abutment Plastic Engaging NP Temporary Abutment Plastic Non-Engaging NP	Procera Esthetic Abutment NP Esthetic Abutment NP 15° Esthetic Abutment NP Snappy™ Abutment NP Universal Base NP GoldAdapt Engaging NP GoldAdapt Non-Engaging NP Multi-Unit Abutment NP 17° Multi-Unit Abutment NP	Impression Coping Closed Tray NP Impression Coping Open Tray NP Impression Coping Open Tray Multi-unit NP Impression Coping Closed Tray Multi-unit NP Impression Coping Bar Closed Tray Multi-unit NP Temporary Coping Multi-unit Titanium NP Temporary Coping Multi-unit Plastic NP
Brånemark System® Mk III TiU RP	Cover Screw Brånemark System RP	Implant Driver RP Brånemark System		Healing Abutment RP	Immediate Temporary Abutment RP Plastic Coping Immediate Temporary Abutment RP QuickTemp Abutment Conical RP Plastic Coping QuickTemp Abutment Conical RP Temporary Abutment Engaging RP Temporary Abutment Non-Engaging RP Temporary Abutment Plastic Engaging RP Temporary Abutment Plastic Non-Engaging RP	Procera Esthetic Abutment RP Esthetic Abutment RP 15° Esthetic Abutment RP Snappy™ Abutment RP Universal Base RP Universal Base Burn-out Coping RP GoldAdapt Engaging RP GoldAdapt Non-Engaging RP Multi-Unit Abutment RP 17° Multi-Unit Abutment RP 30° Multi-Unit Abutment RP 30° Multi-Unit Abutment Non-Engaging RP Locator Abutment RP Ball Abutment Titanium RP	Impression Coping Closed Tray RP Impression Coping Open Tray RP Impression Coping Bar Brånemark System RP Impression Coping Open Tray Multi-unit RP Impression Coping Closed Tray Multi-unit RP Impression Coping Bar Closed Tray Multi-unit RP Temporary Coping Multi-unit Titanium RP Temporary Coping Multi-unit Plastic RP
Brånemark System® Mk III TiU WP	Cover Screw Brånemark System WP	Implant Driver WP Brånemark System Implant Driver Wrench Adapter WP	Prosthetic Screw Multi-unit	Healing Abutment WP	Immediate Temporary Abutment WP Plastic Coping Immediate Temporary Abutment WP QuickTemp Abutment Conical WP Plastic Coping QuickTemp Abutment Conical WP Temporary Abutment Engaging WP Temporary Abutment Non-Engaging WP Temporary Abutment Plastic Engaging WP Temporary Abutment Plastic Non-Engaging WP	Procera Esthetic Abutment WP Esthetic Abutment WP 15° Esthetic Abutment WP Snappy™ Abutment WP Universal Base WP Universal Base Burn-out Coping WP GoldAdapt Engaging WP GoldAdapt Non-Engaging WP Multi-Unit Abutment WP Locator Abutment WP	Impression Coping Closed Tray WP Impression Coping Open Tray WP Impression Coping Open Tray Multi-unit WP Impression Coping Closed Tray Multi-unit WP Impression Coping Bar Closed Tray Multi-unit WP Temporary Coping Multi-unit Titanium WP Temporary Coping Multi-unit Plastic WP

Table 1 – Compatibility table

Product Name	Cover Screw	Implant Driver	Screws	Abutments			Impression Coping
				Healing	Temporary	Permanent	
NobelSpeedy® Shorty NP NobelSpeedy® Groovy NP	Cover Screw Brånemark System NP	Implant Driver NP Brånemark System Implant Driver Wrench Adapter NP	Abutment Screw Multi-unit Angled Prosthetic Screw Multi-unit	Healing Abutment NP	Immediate Temporary Abutment NP Plastic Coping Immediate NP Temporary Abutment NP QuickTemp Abutment Conical NP Plastic Coping QuickTemp Abutment Conical NP Temporary Abutment Engaging NP Temporary Abutment Non-Engaging NP Temporary Abutment Plastic Engaging NP Temporary Abutment Plastic Non-Engaging NP	Procera Esthetic Abutment NP Esthetic Abutment NP 15° Esthetic Abutment NP Snappy™ Abutment NP Universal Base NP Universal Base Burn-out Coping NP GoldAdapt Engaging NP GoldAdapt Non-Engaging NP Multi-Unit Abutment NP 17° Multi-Unit Abutment NP Locator Abutment NP Gold Coping Bar Multi-unit (Prosthetic screw included) NP	Impression Coping Closed Tray NP Impression Coping Open Tray NP Impression Coping Open Tray Multi-unit NP Impression Coping Closed Tray Multi-unit NP Impression Coping Bar Closed Tray Multi-unit NP Temporary Coping Multi-unit Titanium NP Temporary Coping Multi-unit Plastic NP
NobelSpeedy® Shorty RP NobelSpeedy® Groovy RP	Cover Screw Brånemark System RP	Implant Driver RP Brånemark System Implant Driver Wrench Adapter RP		Healing Abutment RP	Immediate Temporary Abutment RP Plastic Coping Immediate Temporary Abutment RP QuickTemp Abutment Conical RP Plastic Coping QuickTemp Abutment Conical RP Temporary Abutment Engaging RP Temporary Abutment Non-Engaging RP Temporary Abutment Plastic Engaging RP Temporary Abutment Plastic Non-Engaging RP	Procera Esthetic Abutment RP Esthetic Abutment RP 15° Esthetic Abutment RP Snappy™ Abutment RP Universal Base RP Universal Base Burn-out Coping RP GoldAdapt Engaging RP GoldAdapt Non-Engaging RP Multi-Unit Abutment RP 17° Multi-Unit Abutment RP 30° Multi-Unit Abutment RP 30° Multi-Unit Abutment Non-Engaging RP Locator Abutment RP Ball Abutment Titanium RP Gold Abutment Bar Implant Level (Clinical screw included) RP Gold Coping Bar Multi-unit (Prosthetic screw included) RP	Impression Coping Closed Tray RP Impression Coping Open Tray RP Impression Coping Bar Brånemark System RP Impression Coping Open Tray Multi-unit RP Impression Coping Closed Tray Multi-unit RP Impression Coping Bar Closed Tray Multi-unit RP Temporary Coping Multi-unit Titanium RP Temporary Coping Multi-unit Plastic RP
NobelSpeedy® Shorty WP NobelSpeedy® Groovy WP	Cover Screw Brånemark System WP	Implant Driver WP Brånemark System Implant Driver Wrench Adapter WP	Prosthetic Screw Multi-unit	Healing Abutment WP	Immediate Temporary Abutment WP Plastic Coping Immediate Temporary Abutment WP QuickTemp Abutment Conical WP Plastic Coping QuickTemp Abutment Conical WP Temporary Abutment Engaging WP Temporary Abutment Non-Engaging WP Temporary Abutment Plastic Engaging WP Temporary Abutment Plastic Non-Engaging WP	Procera Esthetic Abutment WP Esthetic Abutment WP 15° Esthetic Abutment WP Snappy™ Abutment WP Universal Base WP Universal Base Burn-out Coping WP GoldAdapt Engaging WP GoldAdapt Non-Engaging WP Multi-Unit Abutment WP Locator Abutment WP	Impression Coping Closed Tray WP Impression Coping Open Tray WP Impression Coping Open Tray Multi-unit WP Impression Coping Closed Tray Multi-unit WP Impression Coping Bar Closed Tray Multi-unit WP Temporary Coping Multi-unit Titanium WP Temporary Coping Multi-unit Plastic WP

Table 1 – Compatibility table (continued)

Intended Use / Intended Purpose

Brånemark System® Mk III TiU, NobelSpeedy® implants

Intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function.

Twist Drills, Twist Step Drills, Screw Taps, Counterbores

Intended to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Indications

Brånemark System® Mk III TiU and NobelSpeedy® implants are indicated for 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.

Twist Drills and Twist Step Drills are indicated for use in the maxilla or mandible to prepare an osteotomy for the placement of a dental implant.

Screw Taps are indicated for use in the maxilla or mandible to prepare an osteotomy in dense bone for placement of a dental implant.

Counterbores are indicated for use to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Screw Tap and Implant Mount from colliding with the bone.

Contraindications

It is contraindicated to use NobelSpeedy® and Brånemark System® Mk III TiU implants in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be considered.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially pure titanium (grade 4), titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), stainless steel, and/or DLC (Diamond Like Carbon) coating.

For contraindications specific to the Cover Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016).

For contraindications specific to the Manual Torque Wrenches Surgical and Prosthetic, refer to the Nobel Biocare Instructions for Use for the component (IFU1098).

For contraindications specific to the Screwdrivers, refer to the Nobel Biocare Instructions for Use for the component (IFU1085).

For contraindications specific to the Nobel Biocare Reusable Instruments and Components, refer to the Nobel Biocare Instructions for Use for the component (IFU1090).

For contraindications specific to the PureSet™ Trays, refer to the Nobel Biocare Instructions for Use for the component (IFU1067).

Materials

- NobelSpeedy®, Brånemark System® Mk III TiU implants: unalloyed titanium grade 4 according to ASTM F67 and ISO 5832-2.
- Cover screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
- Twist Drills, Twist Step Drills, Screw Taps, Counterbores: Stainless steel 1.4197/AISI420F Mod according to ASTM F899 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. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) 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.

NobelSpeedy® Groovy and Brånemark System® Mk III TiU implants must only be used with compatible Nobel Biocare instruments and components and prosthetic components. Use of instruments or components or prosthetic components that are not intended to be used in combination with NobelSpeedy® Groovy and Brånemark System® Mk III TiU implants can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

It is strongly recommended that new and experienced users of Nobel Biocare products 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.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

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, other parafunctional habits or unfavorable jaw relationships reappraisal of the treatment option may be considered.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile 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 angulations.

All components, instruments and tooling used during the clinical and/or laboratory procedure 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.

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. dental dam, gauze, or throat shield).

The 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 primary 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.

Bending moments: Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

After Surgery

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Intended Users and Patient Groups

NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps are to be used by dental health care professionals.

NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps

NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps

The placement of a dental implant constitutes an invasive treatment which may be associated with typical side effects such as bone necrosis, inflammation, infection, bleeding, hematoma, pain, and swelling. Drilling into the jaw or subsequent placement of the implant may also lead (in rare cases) to fenestration or bone fracture, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances, depending on the location. During placement of an implant the pharyngeal (gag) reflex may be triggered in patients with a sensitive reflex.

Dental implants are the substructure of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as mucositis, calculus, peri-implantitis, fistulas, ulcers, soft tissue hyperplasia, soft and/or hard tissue recession/loss. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the NobelSpeedy® and Brånemark System® Mk III TiU implants. The SSCP can be obtained at the following website:

ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Surgical Procedure

During drilling procedures bone quality should be considered, please refer to Table 2 for NobelSpeedy® and to Table 3 for Brånemark System® Mk III TiUnite®. Recommended drill sequences are based on bone quality to ensure optimal primary stability when applying immediate function.

Platform	Implant diameter	Drill Sequence (according to bone quality) [mm]		
		Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
NP	Ø 3.3 mm	Ø2.0	Ø2.0	Ø2.0 Ø2.4/2.8
RP	Ø 4.0 mm	Ø2.0 (Ø2.4/2.8)	Ø2.0 Ø2.4/2.8 Ø3.2	Ø2.0 Ø2.4/2.8 Ø3.4
RP WP	Ø 5.0 mm	Ø2.0 Ø2.4/2.8 Ø3.0	Ø2.0 Ø2.4/2.8 Ø3.2/3.6	Ø2.0 Ø2.4/2.8 Ø3.2/3.6 Ø3.8/4.2
WP	Ø 6.0 mm	Ø2.0 Ø2.4/2.8 Ø3.2/3.6	Ø2.0 Ø2.4/2.8 Ø3.2/3.6 Ø3.8/4.2	Ø2.0 Ø2.4/2.8 Ø3.2/3.6 Ø3.8/4.2 Ø5.0

Table 2 – Recommended drill sequence based on bone quality for NobelSpeedy® implants. Drills listed within brackets denote widening of cortex only. Counterbores and Screw Taps are available if deemed necessary. No Screw Taps are available for NobelSpeedy® RP 20 mm, 22 mm and 25 mm implants.

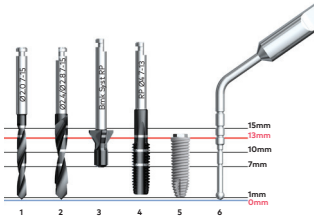
Platform	Implant diameter	Drill Sequence (according to bone quality) [mm]		
		Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
NP	Ø 3.3 mm	Ø2.0 (Ø2.4/2.8)	Ø2.0 Ø2.4/2.8	Ø2.0 Ø2.4/2.8
RP	Ø 3.75 mm	Ø2.0 (Ø2.4/2.8)	Ø2.0 Ø2.4/2.8 Ø3.0	Ø2.0 Ø2.4/2.8 Ø3.2
RP	Ø 4.0 mm	Ø2.0 (Ø2.4/2.8)	Ø2.0 Ø2.4/2.8 Ø3.2	Ø2.0 Ø2.4/2.8 Ø3.4
WP	Ø 5.0 mm	Ø2.0 Ø2.4/2.8 (Ø3.2/3.6)	Ø2.0 Ø2.4/2.8 Ø3.2/3.6 (Ø3.8/4.2)	Ø2.0 Ø2.4/2.8 Ø3.2/3.6 Ø3.8/4.2

Table 3 – Recommended drill sequence based on bone quality for Brånemark System® Mk III TiU implants. Drills listed within brackets denote widening of cortex only. Counterbores and Screw Taps are available if deemed necessary.

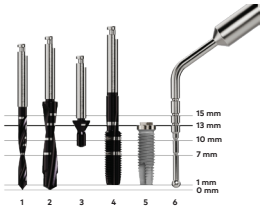
Drilling must proceed at high speed (max. 2'000 rpm for Twist Drills and Twist Step Drills) under constant and profuse irrigation by sterile saline at room temperature. In dense bone situation drill with continuous back and forth motion.

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 Figure A for drill reference lines).



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).



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 TiU (5) implants 13 mm and Depth Probe 7–18 mm (6).

Figure A

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 7-15mm for Ø3.3 mm implants, and 7-13mm and 7-18mm for Ø3.75, Ø4, Ø5 and Ø6 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. 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 the implant site (Figure B). When using a flapless approach add-on soft tissue height to drill depth.

Figure B – Preparation of implant site

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 C). The implants are ideally installed with low speed, max. 25 rpm using a drill device (Figure C) or Manual Torque Wrench Surgical (Figure D).

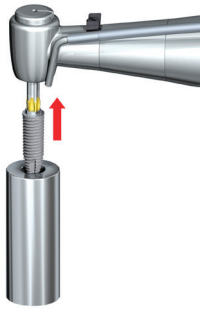


Figure C – Implant driver picking up implant

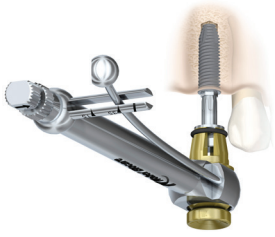


Figure D – Manual Torque Wrench Surgical

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 E).

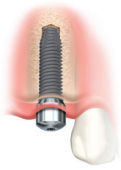


Figure E – Implant with Cover Screw

Refer to Table 4 for NobelSpeedy® implant specifications and to Table 5 for Brånemark System® Mk III TiU implant specifications.

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 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	

Table 4 – Implant specifications for NobelSpeedy®

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
		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 5 – Implant specifications for Brånemark System® Mk III TiU

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

Sterility and Reusability Information

NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Caution NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Twist Drill long shaft and Twist Step Drill long shaft are delivered non-sterile and are intended for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution Twist Drill long shaft and Twist Step Drill long shaft are a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Cleaning and Sterilization Instructions

Twist Drill long shaft and Twist Step Drill long shaft are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

– Manual and Automated Cleaning: AAMI TIR 12

– Sterilization: AAMI ST79 and ISO 17665 -1

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The Twist Drill long shaft and Twist Step Drill long shaft have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following processing instructions.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 20 seconds until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2mm / 2.0mm / 5.0mm diameter) for a minimum of 20 seconds until all visible soil is removed.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining
4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 6 presents examples of suitable sterilization pouches.

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

Table 6 – Recommended Sterilization Pouches

2. Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 7):

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

Table 7 – Recommended Sterilization Cycles

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical / biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information

MR Safety Information for Single Tooth Configurations

MRI Safety Information		
Non-clinical testing has demonstrated the Brånemark System® TiU and NobelSpeedy® are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T).
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3T MRI system.	

MR Safety Information for Multiple Teeth Configurations

MRI Safety Information		
Non-clinical testing has demonstrated the Brånemark System® TiU and NobelSpeedy® are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T).
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg	Inferior to the navel: 2.0 W/kg Superior to the navel: 0.1 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 2.7 cm from the devices or device assemblies when imaged in a 3T MRI system.	

Performance Requirements and Limitations

To achieve the desired performance, NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with NobelSpeedy® and Brånemark System® Mk III TiU implants, Twist Drills, Twist Step Drills, Counterbores, and Screw Taps, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK responsible person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class IIa/IIb Devices	CE 2797
UKCA Mark for Class IIa/IIb Devices	UK CA 0086

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelSpeedy®	73327470000012773
Brånemark System® Mk III TiU	7332747000001266Z
Twist Drills	7332747000001206M
Twist Step Drills	
Counterbores	
Screw Taps	

Implant Card

NobelSpeedy® and Brånemark System® Mk III TiU implants are accompanied by an Implant Card which contains important information for patients regarding the device.

Complete the Implant Card by filling it out with the patient- and device-specific information as indicated and provide the completed Implant Card to the patient.

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	