NobelSpeedy® Groovy
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

Implant:
NobelSpeedy® Groovy dental implants with external hexagon connection are made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. NobelSpeedy® Groovy implants with lengths of 20, 22 and 25 mm are recommended for use in soft bone such as mainly found in the upper jaw.

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 NobelSpeedy® Groovy implants.

Indications for use:

NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. 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.

NobelSpeedy® Groovy 20, 22 and 25 mm implants when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

Contraindications:

It is contraindicated placing NobelSpeedy® Groovy 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 position 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), stainless steel or 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 for 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 jaw bone, 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, 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 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.

The NobelSpeedy® Groovy 20, 22 and 25 mm implants are intended to be used only in situations that allow anatomically for such a length. When using the NobelSpeedy® Groovy 20, 22 and 25 mm implants, special attention needs to be paid to available bone volume and critical structures such as nerves, vessels and sinuses.

Special attention has to be given to patients who have localized 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.

Implant placement in soft bone is a demanding and technique-sensitive procedure. There are several ways to improve the situation when placing implants, especially when aiming for an Immediate Function protocol. Possibilities include, but are not limited to:

– Splinting in a multi-unit restoration

– Bi-cortical anchorage, and

– Long implants (as long as possible) to increase the bone to implant contact area.

The NobelSpeedy® Groovy 20, 22 and 25 mm implants are designed to allow surgeons to take advantage of the option “long implants”, which may be combined with the bi-cortical anchorage and also other options listed above.

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 angulations.

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.

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

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.

Tilting of implants is a technique to accomplish the following:

– Extend the Anterior- Posterior spread (to reduce cantilever lengths)

– Allow for placement of a longer implant

– Avoid critical structures such as the maxillary sinus or the mandibular nerve

A common concept that utilizes this tilting in both jaws is the All-on-4® treatment concept.

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.

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 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 table **A**: 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.

No Screw Taps are available for NobelSpeedy RP 20 mm, 22 mm and 25 mm implants.

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A

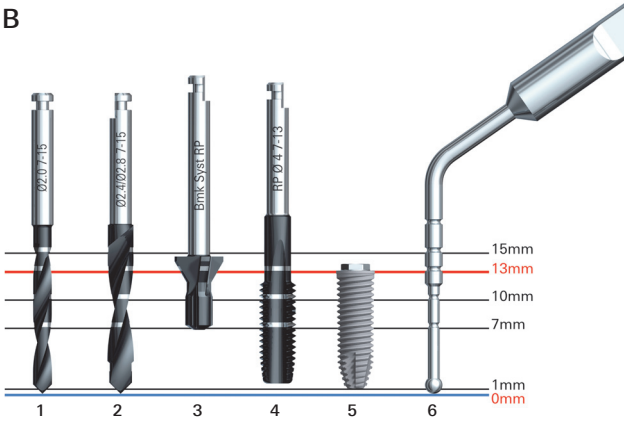
Platform	Implant diameter	Drill Sequence (according to bone quality) Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
NP	3.3	Ø2.0	Ø2.0	Ø2.0 Ø2.4/2.8
RP	4.0	Ø2.0 (Ø2.4/2.8)	Ø2.0 Ø2.4/2.8 Ø3.2	Ø2.0 Ø2.4/2.8 Ø3.4
RP WP	5.0	Ø2.0 Ø2.4/2.8 Ø3.0	Ø2.0 Ø2.4/2.8 Ø3.2/3.6	Ø2.0 Ø2.4/2.8 Ø3.2/3.6 Ø3.8/4.2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

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 image **B** for drill reference lines).

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.

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.

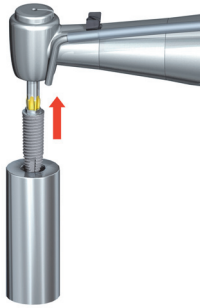
In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, a drill extension shaft may be used.

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

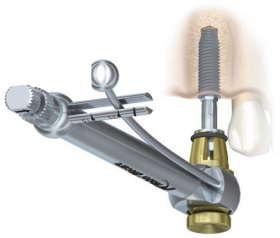
C

2. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist Drills and Twist Step Drills.
3. Open the implant package and pick up the implant from inner casing with implant driver (please see **D**). The implants are ideally installed with low speed, max. 25 rpm using a drill device (**D**) or Manual Torque Wrench Surgical (**E**).

D



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

5. Dense bone protocol to be used when implant will not 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 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 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 surgical protocol of choice, place a Cover Screw or Abutment and suture (**F**).

F

See table for implant specifications for NobelSpeedy® Groovy (**G**).

G

NobelSpeedy® Groovy

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, 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

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

Materials:

NobelSpeedy® Groovy implant: commercially pure titanium grade 4.

Twist Drills, Twist Step Drills, Counterbores and Screw Taps: stainless steel with DLC (Diamond Like Carbon) coating.

Cleaning and sterilization instructions:

NobelSpeedy® Groovy implants, Twist Drill, Twist Step Drills, Counterbores and Screw Taps are delivered sterile 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.

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

MR safety information:

MR Conditional:

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 4.1°C 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.

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Storage and handling:

The product 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:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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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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Rx Only

Sterilized using irradiation


Consult instructions for use


Use-by date


Do not re-use

Batch code


Do not use if package is damaged

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