procedures & products

NobelDirect 3.0®

40 ANNIVERSARY

Nobel Biocare™

First from Nobel Biocare.
NobelPerfect® (NP, RP, WP), NobelDirect® (NP, RP, WP), Brånemark System®, NobelReplace® and NobelSpeedy™ Implants. A complete assortment with ***FDA clearance for immediate function*** *in all single, partial and fully edentulous restorations in the mandible and maxilla.*

Nobel Biocare AB and all production units are certified according to the Environmental Management System ISO 14001.

Some products may not be available in all markets.
Please contact your local Nobel Biocare office for current product assortment and availability.

Nobel Biocare complies with
ISO 13485, ISO 14001 and Council Directive 93/42/EEC
Canadian Medical Devices Regulation.

CE 0086

For USA only: *Federal law restricts this device to sale by or on the order of a licensed dentist or physician.*
All products are subject to change without notice.

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Introduction

NobelDirect® 3.0

The NobelDirect® 3.0 implant encompasses the osseous component and restorative component in one piece. This design is based on the One-Stage Placement concept and offers a number of possible advantages:

- ***New indications:*** NobelDirect® 3.0 is the first FDA-cleared implant on the market with a diameter of 3.0 mm. For the first time the mandibular central and lateral incisors or maxillary lateral incisors can be restored with an excellent esthetic outcome.

- ***Ease-of-use:*** The NobelDirect® 3.0 Implant is a threaded one-piece implant with an integrated abutment designed for one-stage surgical procedures and cemented restorations.

- ***Tissue friendliness:*** The surgery is performed only once, allowing the soft tissue to adapt to the implant/ abutment interface without further manipulation.

- ***Esthetics:*** The abutment can be prepared to an optimized adaptation to the gingival margin.

- The ***TiUnite™ surface*** on NobelDirect® 3.0: Due to a more rapid formation and greater amount of bone to implant contact during healing, Nobel Biocare's Ti-Unite® surfaced implants result in faster and stronger osseointegration and better maintenance of the initial implant stability than machined titanium implants.

Quick Start

Implant Placement

Soft Bone Preparation

Implant Positioning
Drill Guide/
Twist Drill ∅ 1.5 mm

Tissue Punch
Guide/Tissue Punch

Flap Reflection

Soft Bone Drill 3.0

Implant Placement

Manual Torque Wrench

Healing Cap 3.0

Final Prosthetic Procedure after healing

Products You Need:

- *NobelDirect® 3.0 Surgery Kit*
- *Manual Torque Wrench Surgical*
- *NobelDirect® 3.0 Implant*
- *Nobel Biocare Titanium Bur Kit*
- *Healing Cap 3.0*

Quick Start

Implant Placement

Dense Bone Preparation

Implant Positioning
Drill Guide/ Twist Drill ∅ 1.5 mm

Tissue Punch
Guide/Tissue Punch

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Dense Bone Drill 3.0

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Treatment Planning

Indications for Use

The diameter of two-piece implants is limited due to the lesser strength of the hollow implant body and the screwjoint. The one-piece design overcomes this limitation and allows us to offer a special small diameter implant – NobelDirect® 3.0. This implant is intended for use in the tight space challenges in the region of the mandibular central and lateral incisors and maxillary lateral incisors with a delayed loading protocol.

When the implant is placed it should be restored with a **Healing Cap** or temporary crown without occlusal loading during the healing time.

Inclusion/Exclusion Criteria

The following criteria are recommended for the use of NobelDirect® 3.0

- Good gingival/periodontal/periapical status of adjacent teeth
- Favorable and stable occlusal relationship
- No apical disorder/inflammation at the area of the implant site or adjacent teeth
- Good bone volume and density
- No cantilevered restorations
- Angulation requirements of the restoration not exceeding 10°
- High initial implant stability
- Controlled loads

  The treatment plan should identify and reduce potential load factors such as lateral occlusal contacts, unstable dental occlusion and severe bruxism or other pronounced parafunctions.

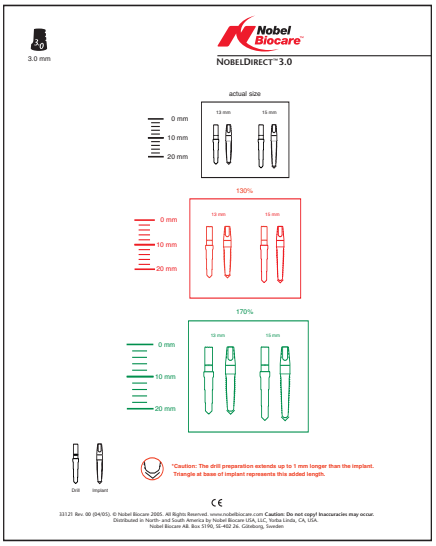
Pretreatment Considerations

- The crestal gingiva must be of adequate width if the tissue punch is to be used. In addition, the facial gingiva must also be of an adequate thickness and width to enable sufficient vestibular depth.
- In the presence of an inadequate quantity of gingiva, shallow vestibular depth, and/or frenula pulling, a free gingival graft must be placed at least 3 months before placing the NobelDirect® 3.0 implants.
- In the presence of a severely resorbed alveolar ridge, bone augmentation may be required.

Radiographic Examinations

Implant templates that are actual size or magnified 130% or 170% are supplied for NobelDirect® 3.0 and used in conjunction with radiographic imaging as a guide to selecting the proper implant to be used. These overlays are to be used as guides only. When more accurate measurements are required, radiographic techniques such as tomograms and computerized tomographic (CT) scans should be utilized.

Additional diagnostic radiographic imaging may be indicated to determine the quality and quantity of alveolar bone or to identify anatomical landmarks.



NobelDirect® 3.0 Radiographic Template

Implant Placement with Flap Reflection

A flap approach is recommended if adequate bone has not been confirmed, if direct vision of anatomic landmarks is necessary or if the facial gingival surface needs connective tissue augmentation.

Implant Placement Immediately after Extraction

The healing capacity of an extraction site is excellent and, as long as the initial stability is reached, implant therapy is well suited to extraction sites. In addition to the above criteria, careful removal of any soft tissue and/or infected tissue is required. If periodontitis is the cause of the extraction, healing before implant treatment is often the procedure of choice.

The following steps are recommended for placement at time of extraction:

- Carry out gentle extraction, where possible keeping the labial bone plate intact
- Carefully remove remnants of any soft tissue from the socket
- Select the length of the implant so its apical end extends beyond the extraction socket
- Using the drills and drill guide, align the preparation as it should ideally be, independent of the direction of the tooth root/extraction socket
- Make optimal use of the interproximal walls for stability
- For immediate placement after an extraction, ensure that the gap between the implant and the bone wall is as small as possible
- Ensure that soft tissue closure around the implant is complete, as this is essential. Vestibular incisons may be required

Flapless Implant Placement

Flapless surgery is indicated in situations where adequate bone and attached gingiva are present, as well as sufficient vestibular depth.

Note: Available bone and significant anatomical landmarks such as blood vessels, nerves and concavities have to be confirmed with conventional diagnostic tools such as radiographic imaging, probing and palpation.

Products & Required Instruments

NobelDirect® 3.0 Surgery Kit

The kit includes all the specific instruments and drills needed for NobelDirect® 3.0 mm implants.

NobelDirect® 3.0 Surgery Kit

Twist Drill 1.5 × 10–16 mm

The twist drill 1.5 is made of surgical stainless steel and used for the pilot hole. This drill is for multiple uses, and should be disposed of when cutting ability is reduced.

NobelDirect® 3.0 Drills

The drills are made from surgical stainless steel and coated with an amorphous diamond coating, which gives them their black color. The drills are used with external irrigation. The drills should be replaced after 20–30 uses or when cutting efficiency declines.

Caution: The drills are approximately 1 mm longer than the implant being placed. Allow for this additional length when drilling near vital anatomical structures.

Implant Driver NobelDirect® 3.0

The implant driver is connected directly to the contra-angle handpiece or to the Manual Torque Wrench Surgical, together with the surgical adapter. The tip of the driver engages the flat portion of the abutment on the implant. The implant driver connection has the capacity both to carry the implant and to transmit the necessary torque for implant placement. Connect the driver to the contra-angle handpiece, pick up the implant and deliver it to the site. Ensure that the driver is in alignment with the implant during installation. Remove the driver with an easy upward motion, pulling the driver away from the implant.

Manual Torque Wrench, Surgical

The Manual Torque Wrench, Surgical is used for the placement and final tightening of the implant.

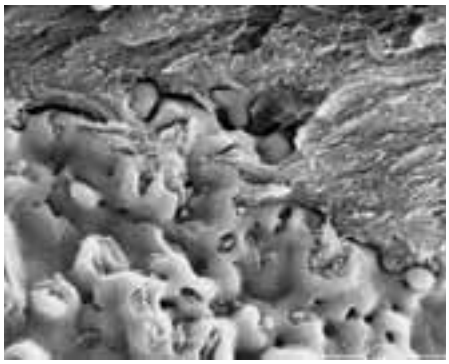
NobelDirect® 3.0 Implant

The design with TiUnite on the entire collar allows placement flexibility of the implant. NobelDirect® 3.0 implants are available in two lengths.

3.0 × 13 mm
3.0 × 15 mm
The diameter is 3.0 mm.

TiUnite™ Surface

The unique combination of controlled titanium oxide texture and porosity enhances the environment for optimal osseointegration.



The unique combination of controlled titanium oxide texture and porosity makes bone grow directly onto and into the surface. (Courtesy of Dr Peter Schüpbach, Switzerland)

Additional Products & Instruments

Healing Cap 3.0

Can be used for production of a temporary crown to be temporarily cemented on top of the abutment portion of the implant.

Note: Keep the healing temporary crown out of occlusion during the healing phase.

Drill Extension Shaft

The drill extension shaft (#29164) provides additional length to drills. When the drill extension shaft is used, it is important to supplement the external irrigation from the handpiece head with manual irrigation to assure cooling of the entire drill length. The drill extension shaft should only be used together with drills.

Product Reference Line

Soft Bone

For NobelDirect® 3.0 13 mm Implants

NobelDirect® 3.0 recommended instruments:
- Twist Drill ∅ 1.5 mm with Drill Guide 3.0
- NobelDirect® Soft Bone Drill 3.0
- NobelDirect® 3.0 Implant

Note: The product reference line refers only to the relationship between instruments. Specific placement depends on the clinical situation.

∅ 1,5 Soft Bone Drill 13 mm

Product Reference Line

Dense Bone

For NobelDirect® 3.0 13 mm Implants

NobelDirect® 3.0 recommended instruments:
- Twist Drill ∅ 1.5 mm with Drill Guide 3.0
- NobelDirect® Soft Bone Drill 3.0
- NobelDirect® Dense Bone Drill 3.0
- NobelDirect® 3.0 Implant

Note: The product reference line refers only to the relationship between instruments. Specific placement depends on the clinical situation.

∅ 1.5 Soft Bone Drill Dense Bone Drill 13 mm

Step by Step

Implant Placement with Flap Reflection

Depending on the magnitude of the soft tissue and alveolar bone, you may choose either the Immediate Flapless or Flap technique for the surgical procedure.

Flaps are reflected when it is necessary to observe the underlying alveolar bone and/or place connective tissue grafts to enhance the emergence profile for esthetics.

The following drilling procedure represents the installation of NobelDirect® 3.0 13 mm, using flap reflection.

1 Implant Positioning

- Set the motor for drilling speed of 2000 rpm maximum. Drill directly through the gingival tissue and into the alveolar crest with the **Twist Drill ∅ 1.5 mm** using the **Drill Guide 3.0** as guidance for correct positioning.
- Drill to the 16 mm depth line on the drill as measured from the top of the drill guide (for both implant lengths 13 and 15 mm).

Note: Proper positioning of the ∅ 1.5 mm drill is essential to achieve the proper angulation for implant placement.

High speed

2000 rpm

Special precaution:

Often the facial alveolar crest is resorbed, especially on the lower incisor area. The NobelDirect® concept is to place the implant for esthetics and function independently of the location of the hard and soft tissues. The desired axial orientation is through the incisal edge of anterior teeth. Bone anatomy may limit the opportunity to achieve this ideal alignment. Actual implant alignment should be within 10° of this ideal alignment to allow for proper preparation of the abutment.

2 Tissue Punch

- Remove the Drill Guide and insert the **Tissue Punch Guide 3.0** into the pilot hole.
- Insert the **Tissue Punch 3.0** into the contra-angle head and place the punch over the Tissue Punch Guide. Using high speed (800 rpm maximum), cut through the soft tissue down to the crest of the ridge.

Note: If the ridge is narrow do not use the tissue punch as this might destroy the gingival tissue. Instead, reflect a flap just after drilling the ∅ 1.5 mm pilot hole.

High speed

800 rpm

3 Flap Reflection

The incision should be made in the center of the ridge to have an equal amount of gingiva on both the facial and lingual side.

4a Soft Bone Preparation

After determining the implant position and angulation, continue with the **NobelDirect® Soft Bone Drill 3.0**. Drill to the desired depth and appropriate length to enlarge the implant site to its final diameter. In extraction site situations, add the thickness of the tissue to the depth. The tissue thickness can be measured with a probe. In situations where adjacent natural teeth would interfere with the angle head and prevent the drill from reaching the desired depth, a drill extension shaft may be used.

High speed

800 rpm

4b Dense Bone Preparation

Continue with the NobelDirect® Dense Bone Drill 3.0 to the desired depth.

High speed

800 rpm

Be careful and place a reflector between the flap and the submerged drills to protect the soft tissue from damage.

5 Implant pick-up

Remove the implant from the sterile package. Connect the **Implant Driver One-Piece 3.0** to the handpiece. Align the flat portion of the NobelDirect® 3.0 Implant Driver with the flat surface on the abutment portion of the implant. Pick up the implant and deliver it into the site.

6 Implant Placement

- Install the implant into the osteotomy, using low speed (25 rpm) and a chosen torque between 35–45 Ncm. Do not exceed 45 Ncm. Place the flat surface of the abutment portion buccally.
- Remove the implant driver with an easy upward motion, pulling the driver away from the implant.

Low speed

max 45 Ncm

7 Manual Torque Wrench, Surgical

- Perform the final tightening or evaluation of implant tightness manually, using the Manual Torque Wrench, Surgical together with the Implant Driver One-Piece 3.0.

Do not exceed 45 Ncm torque on the Manual Torque Wrench, Surgical.

Note: When the coronal alveolar is compromised, implant threads may be exposed, especially on the facial side. Once primary stability is established (35–45 Ncm), the flap can be replaced to cover facial threads.

8 Closure

Use a 6-0 suture to secure the flap. Position the flap at the coronal level of the TiUnite surface.

9a Alteration of the Abutment Portion

Alteration of the implant is sometimes required to establish the appropriate length, shape and margin for a temporary crown. If an alteration is carried out on the day of surgery, the soft tissue on the surgical site needs to be protected.

- Place a rubber dam using a lower anterior-size rubber dam clasp.
- Use special carbide burs or diamond burs with high-speed and copious irrigation. There is a special Nobel Biocare Titanium Bur Kit available for this procedure.
- Place a chairside adjusted temporary acrylic restoration onto the implant. Care should be taken not to contaminate the wound with cement. Post-operative radiographs can be taken to check for excess cement that may have been trapped in the gingival incision.

Note: Place the temporary margin 0.5 mm above the gingival sulcus 360 degrees around the soft tissue. Keep the temporary crown/implant out of occlusion during the healing phase.

or

9b Healing Cap 3.0

If a temporary crown is not required, cement a Healing Cap onto the 3.0 mm implant with temporary cement. Care should be taken not to contaminate the wound with the cement. Adjust the contour of the Healing Cap if necessary to avoid any occlusal contact.

Note: Keep the Healing Cap/implant out of occlusion during the healing phase.

Flapless Implant Placement

When adequate attached gingival tissue and bone is present, flapless surgery may be performed.

1. Use the Twist Drill ∅ 1.5 mm with the Drill Guide 3.0 to verify proper angulation and position of the implant.

2. Use the same Tissue Punch Guide and Tissue Punch procedure as described in the Flap Reflection protocol.

3. Measure the thickness of the tissue with a probe. Drill using the **NobelDirect® Soft Bone Drill 3.0** and **NobelDirect® Dense Bone Drill 3.0**, depending on the bone quality, to the appropriate depth (the thickness of the tissue included).

Final Restoration

1 Final Preparation

The final preparation and the final restoration can be made after sufficient osseous bone healing and soft tissue maturation. Retraction cord is first placed into the gingival sulcus around the implant to protect the tissue.

- Remove temporization or Healing Cap
- Place retraction cord
- Make the final preparation as for a normal tooth

Note: At this stage, soft tissue protection with a rubber dam is not necessary for the preparation.

2 Impression

- Take a conventional crown and bridge impression
- Send the impression to the dental laboratory for making a Procera or conventional crown
- Replace temporization or Healing Cap

Note: Multiple adjacent 3.0 mm implants must be splinted together.

3 Final Restoration

- Remove the temporization
- Cement the final restoration

Appendix

Electronic Drilling Unit & Manual Torque Wrench

OsseoSet™ 100

The OsseoSet™ 100 unit is a surgical and prosthetic delivery system. Also, OsseoSet has a pump to supply coolant to the drills and implants during procedures. For restorative applications, all abutment screws and prosthetic gold screws can be tightened electronically to proper specifications.

OsseoSet™ 100

Manual Torque Wrench, Surgical

Intended for tightening or adjusting the position of implants.

1. Insert the implant driver.

2. For the correct handling and tightening torque, *see the Instruction for use.* The maximum tightening torque, 45 Ncm, is indicated by the line on the scale.

3. If necessary, the implant can be backed out using the wrench with the direction indicator arrow pointing counter-clockwise.

Cleaning and Sterilization Recommendation

Instruments and Reusable Drills

The devices must be cleaned and sterilized before intraoral use in accordance with established routines at the hospital/clinic.

Principal Cleaning and Sterilization Procedure

1. Clean and disinfect instruments and drills in a dishwasher. Alternative: Disinfect, clean by hand and put in an ultrasonic cleaner.
2. Dry the instruments. Place in sterilization packets.
3. Sterilize the instrument using a steam autoclave (according to the recommendations of the manufacturer of the autoclave).

Note: Worn-out or damaged drills should be discarded and replaced with new, sharp drills.

Cleaning the Contra-angle

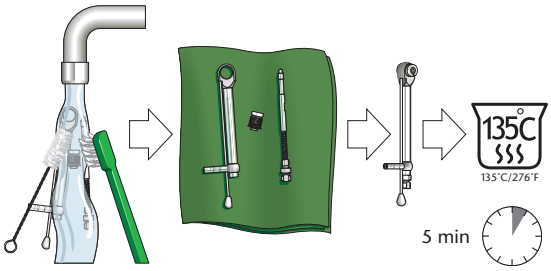
The contra-angle must be cleaned carefully immediately after an operation. It should first be cleaned in a washer or under running water. The head should be separated from the shank and both parts carefully lubricated. Another alternative is to clean and lubricate the contra-angle in an automatic unit (for contra-angles). Place the contra-angle while still disassembled in a double peel-open bag or in a tray and sterilize it in the autoclave.

Restoration

Restorations from the dental laboratory are cleaned and sterilized (if indicated) according to commonly accepted routines for dental laboratory work.

Manual Torgue Wrench

Clean the parts thoroughly. Allow them to dry completely. Sterilize the instrument using a steam autoclave at 135°C for minimum hold time of 5 minutes or according to recommendations from the manufacturer of the autoclave.



Product Catalog

Article #/Description

Products illustrations are not to scale.

31465 NobelDirect® 3.0 × 13 mm

31466 NobelDirect® 3.0 × 15 mm

31417 Healing Cap 3.0

Healing Cap 3.0

NobelDirect® 3.0 × 13 mm
NobelDirect® 3.0 × 15 mm

32792 NobelDirect® 3.0 Surgery Kit

Tissue Punch 3.0 Tissue Punch Guide 3.0

The Surgery Kit includes the following components:

- 32793 NobelDirect® 3.0 Surgery Kit Box
- 28910 Tissue Punch 3.0
- 29144 Tissue Punch Guide 3.0
- 29145 Drill Guide 3.0
- 30941 Implant Driver NobelDirect® 3.0

Drill Guide 3.0

- 28965 Twist Drill 1.5 × 10–16 mm
- 32168 NobelDirect® Soft Bone Drill 3.0 3 × 13 mm
- 32169 NobelDirect® Soft Bone Drill 3.0 3 × 15 mm
- 32170 NobelDirect® Dense Bone Drill 3.0 3 × 13 mm
- 32171 NobelDirect® Dense Bone Drill 3.0 3 × 15 mm
- 33121 NobelDirect® 3.0 Radiographic Template

Implant Driver NobelDirect® 3.0

28839 Manual Torque Wrench Surgical

Manual Torque Wrench Surgical

28945 Nobel Biocare Titanium Bur Kit

our qualifications are

your security

Achievements

- Inheritors and developers of the work of Professor Brånemark – founder of modern implantology. World-leaders in the field
- Providers of the most comprehensive and flexible crown, bridge and implant solutions in the world
- Creators of unique biocompatible material TiUnite® for optimal osseointegration, Immediate Function™ and Soft Tissue Integration™
- Creators of CAD/CAM dentistry
- Creators of unique Procera® System – one seamless procedure from 3D planning to fully guided surgery right through to customized ceramic restoration
- FDA cleared for Immediate Function™ (except 3.0 and Zygoma)
- FDA cleared for Teeth-In-An-Hour™ in 2004

Quality

- Zero non-conformities in 2004 FDA inspection of Nobel Biocare production units in Göteborg, Karlskoga and Stockholm

Research

- Formal collaboration with over 50 academic institutions and 600 independent scientists around the world
- More clinical studies on immediate or early loading than all other competitors combined (Medline Feb 2005)
- More prospective clinical studies with at least 5-year follow-up than all other competitors combined (Berglund et al 2002)

Support

- 165,000 customers trained by 1,985 dental professionals in 37 countries and in 19 languages, during 2004
- Own sales organisations with local Nobel Biocare staff in 29 countries
- Leading business website in 8 languages, with complete online service supplying all products and at least 500 courses available at all times

SOS-CHILDREN'S VILLAGES

Nobel Biocare cares about the enviroment and all production units are certified according to the Environmental Management System ISO 14001.

www.nobelbiocare.com

ANNIVERSARY
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