NobelZygoma™ 0°, 45° and 60° Multi-unit Abutment
Instructions for use

NobelZygoma™ 0°, 45° and 60° Multi-unit Abutments

Important: Please read.

Disclaimer of liability:
This product is part of an overall concept and may only be used in conjunction with the associated original products (according to the instructions and recommendation of Nobel Biocare). Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases where clarifications are needed, the user should contact a representative of Nobel Biocare. Since the utilization of this product is under the control of the user, it is 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:

NobelZygoma™ 0°:

Implant:
NobelZygoma™ 0° implants are endosseous implants made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. It is a parallel walled implant with a 0° abutment head. The implant has TiUnite® up to the level of the platform.

The "Brånemark System®" restorative assortment is to be used in combination with this implant. Furthermore, dedicated 45°/60° Multi-unit Abutments are also available.

Tooling:
Nobel Biocare Twist Drills are made of stainless steel with a DLC (Diamond Like Carbon) coating. Round Burs are made of stainless steel with no DLC (Diamond Like Carbon) coating. They should be used in conjunction with NobelZygoma™ 0° implants and are for single use only.

Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Zygoma Depth Indicator Angled are made of stainless steel. Zygoma Handle is made of aluminum alloy and stainless steel. They should be used in conjunction with NobelZygoma™ 0° implants and are intended for reuse.

The implant comes with a co-packed Cover Screw made of commercially pure grade 1 titanium.

45°and 60° Multi-Unit Abutment:

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

The 45° and 60° Multi-unit Abutments are made of pure titanium and/or titanium alloy.

Note: The 45° and 60° Multi-Unit Abutments do not have a holder.

Multi-unit Abutment angled 45° & 60°.

External hex connection for: NobelZygoma™ 0°.

Intended use:

NobelZygoma™ 0°:
NobelZygoma™ 0° endosseous implants are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.

45° and 60° Multi-unit Abutment:
Multi-unit Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Indications:

NobelZygoma™ 0° implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma™ Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Contraindications:

NobelZygoma™ 0° implant and Multi-unit Abutment are contraindicated for patients:

– who are medically unfit for an oral surgical procedure.

– in whom adequate sizes, numbers or desirable position of implants are not achievable for safe support of functional or eventually parafunctional loads.

– who are allergic or hypersensitive to commercially pure titanium grade 4 or grade 1, stainless steel, DLC (Diamond Like Carbon) coating, polypropylene or PBT (Polybuthylene terephtalate).

NobelZygoma™ 0° implant is contraindicated for patients:

– who are to be restored with single unit constructions.

– with inadequate bone volume for conventional implants and zygoma implant(s).

The 45° and 60° Multi-unit Abutment external hex connection are contraindicated for all other implants other than NobelZygoma™ 0°.

Warnings:

Failure to recognize actual lengths and direction of drills relative to radiographic measurements and surrounding anatomical structures can result in permanent injury to nerves or other surrounding vital structures.

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

In general the most notable risks associated with the Zygoma implants are sinusitis and fistula formations.

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 NobelZygoma™ 0° 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 information please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, should be considered and is recommended. Nobel Biocare has a global network of mentors available for this purpose.

Never exceed the recommended maximum prosthetic tightening torque for the abutment screw (see table 1). Overtightening of abutment may lead to a screw fracture.

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. It is highly recommended to perform a medical CT scan or a CBCT (cone beam CT) analysis prior to the final treatment decision. The patient must have clinically symptom-free sinuses, no pathology in associated bone and soft tissue and completed all necessary dental 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 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.

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.

Zygoma implant treatments may be performed under local anesthesia, IV-sedation or general anesthesia.

During surgery:
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 the small size of components, care must be taken that they are not swallowed or aspirated by the patient. It is recommended to use a rubber dam in order to prevent inhalation of loose parts.

NobelZygoma™ 0° 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.

IFU1051 016 01

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:

1. To begin exposure of the lateral maxillary wall, a full thickness mucoperiosteal flap is reflected following a crestal incision with bilateral distal vertical releasing incisions over the tuberosity areas.

Warning: It is imperative to be aware of vital structures including nerves, veins and arteries during the surgical exposure of the lateral maxillary wall. Injuries to vital anatomic structures can lead to complications including injury to the eye as well as extensive bleeding and nerve-related dysfunction.

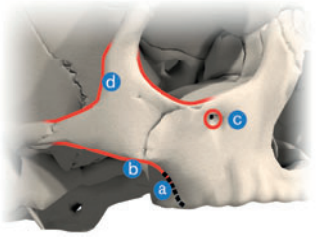
Image (**A**) highlights the following landmarks which may be used in keeping oriented during the anatomic dissection:

a. Posterior wall of the maxillary sinus
b. Zygomatic-maxillary buttress
c. Infra-orbital foramen
d. Fronto-zygomatic notch

Caution: It is essential to identify and protect the infraorbital nerve.

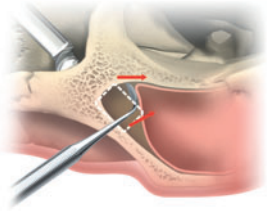
2. For direct visualization of the lateral maxillary wall as well as the fronto-zygomatic notch area, a retractor is placed in the fronto-zygomatic notch with lateral retraction exposing the areas highlighted (**B**).
3. To assist in direct visualization of the drills during the preparation of the osteotomy, a "window" is made through the lateral maxillary wall as shown. Attempt to keep the Schneiderian membrane intact, if possible (**B**).

A



Anatomical Landmarks Established

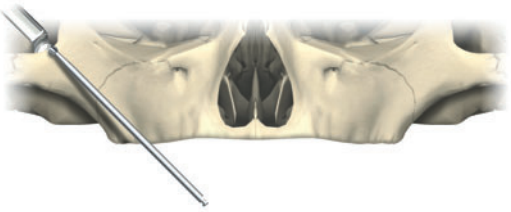
B



Sinus "window" with retractor in the fronto-zygomatic notch (Schneiderian membrane remains intact)

4. Begin the trajectory of the implant at the first-second bicuspid area on the maxillary crest, follow the posterior maxillary wall and end at the lateral cortex of the zygomatic bone slightly inferior to the fronto-zygomatic notch (**C**).

C

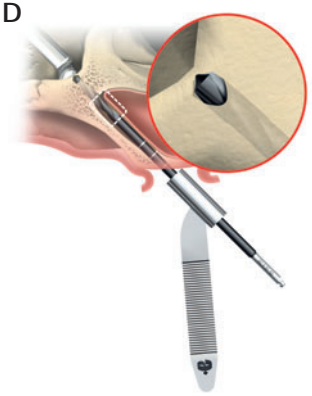


Position trajectory of the implant

5. Drilling procedure: The ratio of the handpiece used is 20:1 at a speed of max. 2000 rpm. Drill under constant and profuse irrigation by sterile saline at room temperature.

Caution: The Drill guide may be used during the preparation of the osteotomy to avoid contact of the rotating drill with the adjacent soft tissues (**D**). Injury to the tongue, corner of the lips and or other soft tissues may occur if the drill shaft is unprotected.

D



Drill guard used

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. Please see image **E** for drill reference lines.

Caution: Avoid lateral pressure on drills during implant-site preparation. Lateral pressure may cause drill fracture.

Caution: Verify that drills lock in the handpiece before starting any drilling. A loose drill may accidentally harm the patient or members of the surgical team.

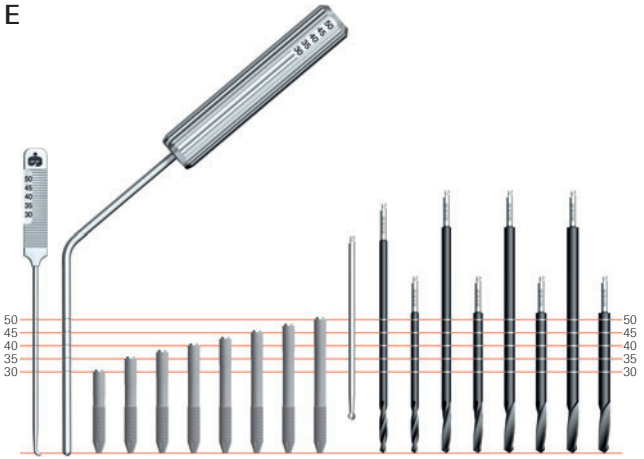
Caution: Verify that all interconnecting instruments lock properly before intraoral use to prevent accidental swallowing or aspiration.

6. Drilling Sequence: (Image **E** shows relation between drills and implants). The initial osteotomy is made using the Brånemark System® Zygoma Round Bur and the NobelZygoma 0° Twist Drill 2.9 mm, followed by the NobelZygoma 0° Twist Drill 3.5 mm and NobelZygoma 0° Twist Drill 4.0 mm. Finally the NobelZygoma 0° Twist Drill 4.4 mm is used.

Caution: Ensure correct angulation and avoid drill wobble, as this can inadvertently widen the preparation site.

Caution: If the sinus membrane cannot be kept intact during osteotomy preparation, carefully irrigate away debris when inserting the implant. Any mucosal remnants in the bone site may prevent osseointegration of the implant.

E



From left to right: Z Depth Indicator Straight, Z Depth Indicator Angled, NobelZygoma 0° Implants, Round Bur, Twist Drills

7. Use the Z depth indicators to determine the length of the Zygoma implant to be placed. Copious irrigation of the sinus is recommended prior to implant placement.
8. Plan to insert the implant as posteriorly as possible, with the implant head as close to the alveolar crest as possible (typically in the 2nd premolar region.) Anchorage of the implant will be achieved by entering the base of the zygoma bone (the posterior- lateral portion of the maxillary sinus roof), engaging through the lateral cortex of the zygoma below the fronto-zygomatic notch. Depending on the anatomy of the patient, the implant body may be positioned inside or outside the maxillary sinus.

Note: Adjustment to this implant placement may be considered due to anatomical variations in the maxilla as well as the maxillary sinus.

9. Implant placement.

Insert implant with drilling unit:

The implant may be inserted using an implant driver and the drilling unit at **20 Ncm** insertion torque. Increasing the insertion torque up to maximum **50 Ncm** may be used for the complete seating of the implant (**F**). Once an insertion torque of **40** to **50 Ncm** is reached, the Z Handle may be used. Disengage the implant driver with Handpiece. Now connect the Z Handle to the Implant Driver Wrench Adapter and insert into the implant (**G**). Rotate the Z Handle clockwise until the desired depth and head position are achieved.

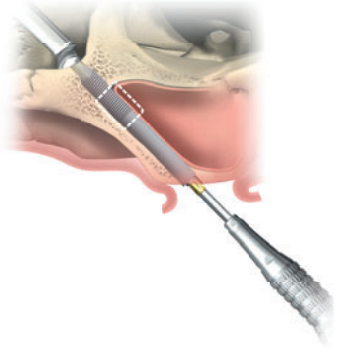
Confirm through the "window" of the lateral maxillary wall the correct insertion angle of the implant while continuing through the sinus until the implant apex engages in the zygomatic bone.

Tighten manually:

Disengage the implant driver with Handpiece. Now connect the Z Handle to the Implant Driver Wrench Adapter and insert into the implant (**G**). Rotate the Z Handle clockwise until the desired depth and head position are achieved.

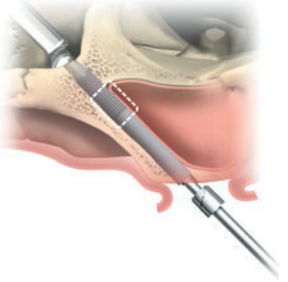
Caution: When using the Z Handle, applying excessive torque can distort or fracture the implant head.

F



Seating the NobelZygoma™ 0° with handpiece (Sinus "window" shown)

G



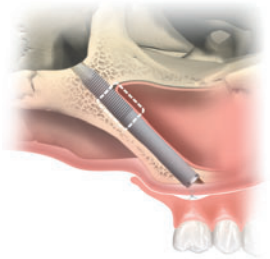
Seating the NobelZygoma™ 0° with Z Handle (Sinus "window" shown)

10. Perform copious irrigation of the apical portion of the implant (the subperiosteal portion of the zygomatic bone) prior to the removal of the retractor from the fronto-zygomatic notch.
11. The premaxillary implants are placed following the conventional protocol for placement of implants.
12. Depending on surgical protocol of choice, place a cover screw or abutment and suture. For Immediate Function, the implants should be able to withstand a final torque between **35–45 Ncm**. For two-stage protocol relieve the denture over the implants (**H**).

Caution: Use only Brånemark® System cover screws. There are dedicated Multi-unit Abutments 45°/60° available for this implant.

IFU1051 016 01

H



Seating the NobelZygoma™ 0° with Z Handle (Sinus "window" shown)

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

45° - 60° Multi-unit Abutment Handling instructions:

Clinical procedure:

1. Place appropriate angulated abutment (**A**). It is recommended to verify the final abutment seating using radiographic imaging.

A

Note: The 45° and 60° Multi-Unit Abutments do not have a holder.
Caution: The screw is not locked by a holder. Ensure that the screw is engaged to the Unigrip™ Screwdriver when placing the abutment.

2. Tighten the abutment to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic.

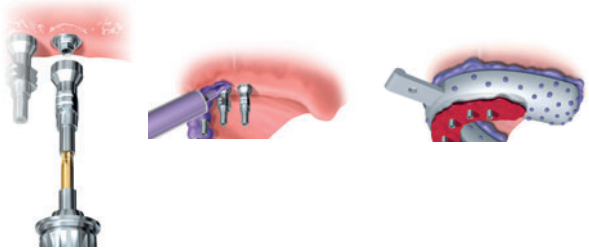
Caution: Never exceed recommended maximum **35 Ncm** tightening torque for the abutments screw. Overtightening of abutment may lead to screw fracture.

3. Take impression of abutments using open or closed impression tray technique (**B**).

Note: Hand tighten only and close impression coping recess prior to impression taking

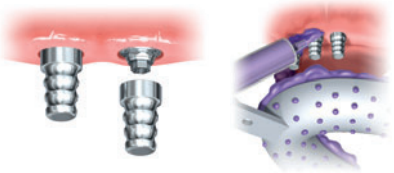
Open tray

B:1



Closed tray

B:2

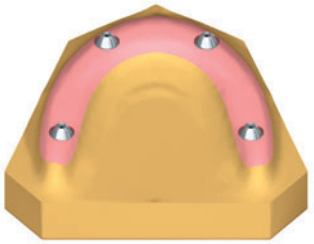


4. Provisionalize or attach healing caps.

Laboratory procedure:

5. Attach abutment replicas to impression copings.
6. Fabricate a working model with removable gingival material (**C**).

C



6A. NobelProcera® Implant Bridge Wax-up:

1. Create implant bridge framework using non-engaging temporary cylinders as a foundation and add pattern resin to fabricate desired framework design.
2. Scan the acrylic framework using the NobelProcera® Scanner according to the tutorial found within the software.
3. Once precision milled framework is delivered back to lab, veneering material is added for completion.

Clinical procedure:

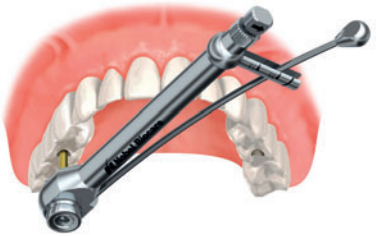
7. Remove temporary restoration if applicable.
8. Use the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to verify tightening of the 45° and 60° Multi-Unit Abutment to **35 Ncm**.
9. Insert fixed prosthesis and tighten the prosthetic screws by alternating left and right side (D). Finally tighten the prosthetic screws according to table 1 using Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (**E**).

Table 1

Abutment (clinical) Screw Tightening Torque	Angulated 45° - 60°
Nobel Biocare implant systems	35 Ncm

D

E



10. Close screw access channel.

For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

NobelZygoma™ 0° implant: Commercially pure titanium grade 4.

Cover Screw: Commercially pure titanium grade 1.

Twist Drills: Stainless Steel with a DLC (Diamond Like Carbon) coating.

Round Bur: Stainless Steel.

Zygoma Handle: Aluminum alloy and stainless steel.

Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Zygoma Depth Indicator Angled: Stainless steel.

45° and 60° Multi-unit Abutment and Abutment/Prosthetic screws: Titanium alloy 90% Ti, 6% Al, 4%V.

Cleaning and sterilization instructions:

NobelZygoma™ 0° implant, NobelZygoma 0° Twist Drills and Cover Screw are delivered sterile and for single use only prior to the labeled expiration date.

45° and 60° Multi-unit Abutments are delivered sterile for single use only prior to the labelled expiration date.

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

Caution: NobelZygoma™ 0° implant, Twist Drills, Round Bur and Cover Screw are single use products and must not be reprocessed.

45° and 60° Multi-unit Abutments are single use products and may not be reprocessed.

Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

Round Burs are delivered non-sterile for single use. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Zygoma Handle, Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Zygoma Depth Indicator Angled are delivered non-sterile and are intended for re-use. Prior to use and re-use clean, disinfect and sterilize the product using the recommended parameters.

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

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 4 minutes when using the pre-vacuum method and 15 minutes when using the gravity method.

IFU1051 016 01

USA

Method	Moist heat sterilization	
Cycle	Pre-vacuum	Gravity
Temperature	270°F (132°C)	
Exposure time	4 minutes	15 minutes
Pre-vacuum	3 times	N/A
Drying time	20-30 minutes	15-30 minutes
Cooling time	10 minutes at room temperature	

Only use FDA cleared sterilization packaging for the devices delivered non-sterile and requiring end user sterilization.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C - 135°C, max 137°C (270°F -275°F, max 279°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C - 135°C, max 137°C (273°F -275°F, max 279°F) for 3 minutes.

Magnetic Resonance (MR) safety information:

NobelZygoma 0™ implant, 45° and 60° Multi-unit Abutments have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of NobelZygoma 0™ implants, 45° and 60° Multi-unit Abutments in the MR environment is unknown. Scanning a patient who has this devices may result in patient injury.

Storage and handling:

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

Disposal:

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

Manufacturer: Nobel Biocare AB, Box 5190, 402 26
Västra Hamngatan 1, 411 17 Göteborg, Sweden.
Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only:
Caution: Federal (United States) law restricts this device to sale by or on the order of a licensed dentist.

CE 0086

Rx Only

Sterilized using irradiation

Non-sterile


Caution


Consult instructions for use


Use-by date


Do not re-use

Batch code


Do not use if package is damaged

IFU1051 016 01