Instructions for use

External hex connection for: NobelZygoma™ 0°.

Multi-unit Abutment angled 45° & 60°.

The 45° and 60° Multi-unit Abutments are made of pure titanium and/or titanium alloy. NobelZygoma™ 0° implants and are intended for reuse. They should be used in conjunction with NobelZygoma™ 0° implants and are for single use only. Coating. They should be used in conjunction with NobelZygoma™ 0° implant. Furthermore, dedicated 45°/60° Multi-unit Abutments are also available.

Description:
NobelZygoma™ 0°:

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 “Bränemark 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 (Polybutylene terephthalate).

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 splatted, 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.
3. To assist in direct visualization of the drills during the preparation of the osteotomy, bleeding and nerve-related dysfunction. Structures can lead to complications including injury to the eye as well as extensive 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.

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). 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).

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

4. Begin the trajectory of the implant at the first-second bicuspud 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). 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 head position is 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.

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 other soft tissues may occur if the drill shaft is unprotected.

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.


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.
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.

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).

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.

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.
Sterilized using irradiation
Non-sterile
Caution
Consult instructions for use

Use-by date
Do not re-use
LOT
Do not use if package is damaged

USA

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization</th>
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<tbody>
<tr>
<td>Cycle</td>
<td>Pre-vacuum, Gravity</td>
</tr>
<tr>
<td>Temperature</td>
<td>270°F (127°C)</td>
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<tr>
<td>Exposure time</td>
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<tr>
<td>Pre-vacuum</td>
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<tr>
<td>Drying time</td>
<td>20-30 minutes, 15-30 minutes</td>
</tr>
<tr>
<td>Cooling time</td>
<td>10 minutes at room temperature</td>
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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.

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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 (United States) law restricts this device to sale by or on the order of a licensed dentist.