Brånemark System® Zygoma TiUnite®
Instructions for use

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 of doubt, the user has to contact 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:

Implant:
Brånemark System® Zygoma TiUnite® implants are made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. It is a parallel walled implant with a 45° abutment head. The implant has TiUnite® up to the level of the platform. A specific "Brånemark System® Zygoma TiUnite®" restorative assortment is to be used in combination with this implant due to the need for a shorter restorative screw.

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

Tooling:
Nobel Biocare Twist Drills and Pilot 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 Brånemark System® Zygoma TiUnite® 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 aluminium alloy and stainless steel. They should be used in conjunction with Brånemark System® Zygoma TiUnite® implants and are intended for reuse.

Intended use:

Brånemark System® Zygoma TiUnite® implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.

Indication:

Brånemark System® Zygoma TiUnite® implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. These implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.

Contraindications:

Brånemark System® Zygoma TiUnite® implant is contraindicated for patients:

– who are medically unfit for an oral surgical procedure.

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

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

– who are allergic or hypersensitive to commercially pure titanium grade 4 and grade 1, titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), stainless steel or DLC (Diamond Like Carbon) coating.

– who are to be restored with single unit constructions.

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 damaging the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

In general the most notable risks associated with the Brånemark System® Zygoma TiUnite® 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 Brånemark System® Zygoma TiUnite® 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. 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.

Zygoma implants treatments could be performed under local anesthesia, IV-sedation or general anesthesia.

At surgery:
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.

Because of the small size of components, care must be taken that they are not swallowed or aspirated by the patient.

The handpiece used for the zygoma surgical procedure is to be adjustable to a ratio of 20:1.

Brånemark System® Zygoma TiUnite® 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 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:

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.

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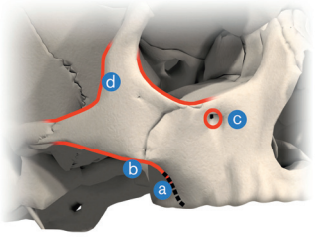
Image (**A**) highlights the following landmarks which may be used in keeping oriented during the anatomic dissection:

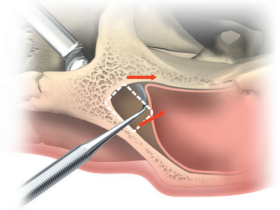
a. Posterior wall of the maxillary sinus
b. Zygomatic-maxillary buttress
c. Infra-orbital foramen
d. Fronto-zygomatic notch

A



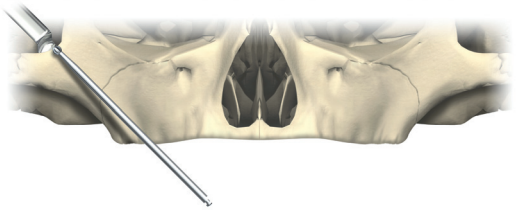
2. For direct visualization of the lateral maxillary wall as well as the fronto-zygomatic notch area, a retractor is placed in the fronto-zygomatic notch with lateral retraction exposing the areas highlighted (**B**).
3. To assist in direct visualization of the drills during the preparation of the osteotomy,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

B



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**).

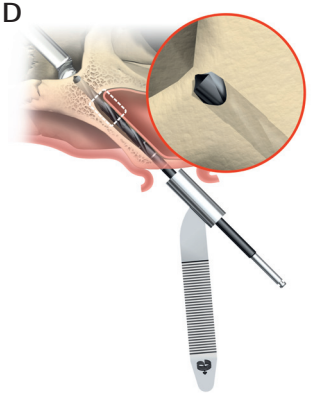
C



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 Guard 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

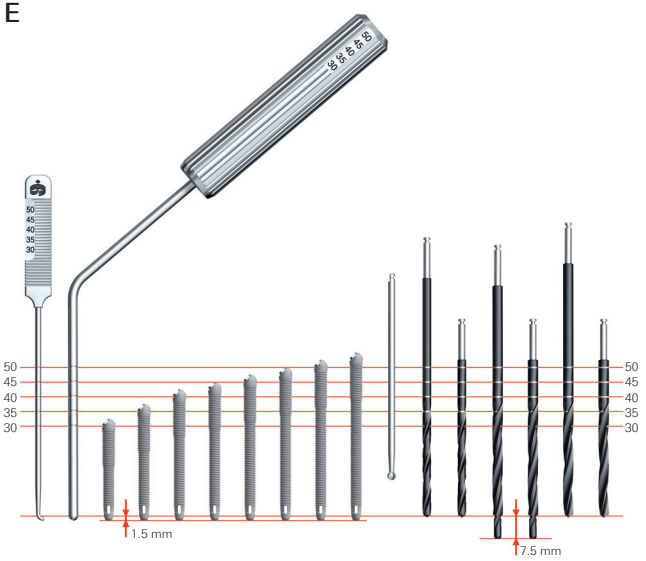


Depth measurement system: The parallel drills have a true depth measurement system. All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position.

Caution: Twist Drills 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 **E** for drill reference lines).

6. Drilling Sequence: (Image **E** shows relation between drills and implants). The initial osteotomy is made using the Brånemark System® Zygoma Round Bur, followed by the Brånemark System® Zygoma Twist Drill 2.9 mm. Widening of the osteotomy is made by the Brånemark System® Zygoma Pilot Drill 3.5 mm and finally the Brånemark System® Zygoma Twist Drill 3.5 mm.

E



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. Implant placement: The implant may be inserted using the drilling unit using **20 Ncm** insertion torque.

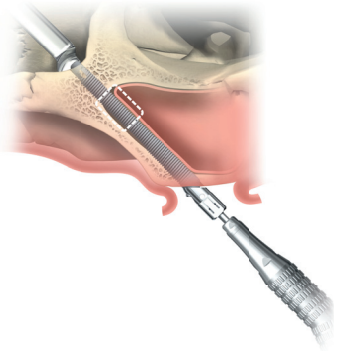
Increasing the insertion torque up to maximum **50 Ncm** may be used for the complete seating of the implant (**F**).

Caution: Exceeding **50 Ncm** of insertion torque may lead to damage to the implant, the implant mount or lead to necrosis of the zygomatic bone.

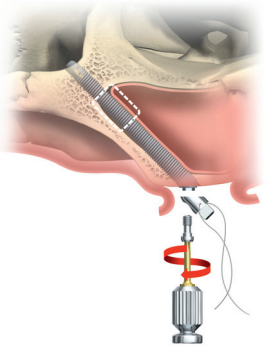
Note: Through the "window" of the lateral maxillary wall, visualize the apex of the implant as it travels through the maxillary sinus to ensure its engaging into the zygomatic bone.

9. Verifying the correct position of the implant platform: Place the Screwdriver Manual Unigrip™ into the implant mount screw (**G**). The shaft of the Unigrip™ driver should be perpendicular to the crest of the maxilla to ensure the proper position of the Brånemark System® Zygoma implant platform. Remove the implant mount.

F

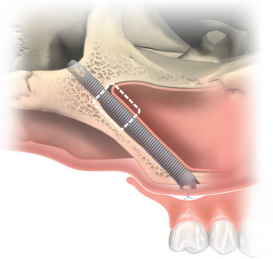


G



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 implant should be able to withstand a final torque between **35-45 Ncm**. For two-stage protocol relieve the denture over the implants (**H**).

H



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

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Materials:

Brånemark System® Zygoma TiUnite® implant: Commercially pure titanium grade 4.
Cover Screw: Commercially pure titanium grade 1.
Twist Drills, Pilot Drill: Stainless Steel with a DLC (Diamond Like Carbon) coating.
Round Bur: Stainless Steel.
Zygoma Handle: Aluminium alloy and stainless steel.
Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Zygoma Depth Indicator Angled: Stainless steel.

Cleaning and sterilization instructions:

Brånemark System® Zygoma TiUnite® implant and Cover Screw are delivered sterile and for single use only prior to the labeled expiration date.

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

Caution: Brånemark System® Zygoma TiUnite® implant, Twist Drill, Pilot Drill, Round Bur and Cover Screw are single use products not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination.

Twist Drills, Pilot Drills and 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 products 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, max 279°F (132°C, max 137°C) for 3 minutes.

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.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Magnetic Resonance (MR) safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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 law restricts this device to sale by or on the order of a licensed physician or dentist.

CE 0086 **Rx Only**

STERILE R
Sterilized using irradiation

Consult instructions for use

Use-by date

Do not re-use

LOT
Batch code

Do not use if package is damaged

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