Zygoma Implant RP
Instructions for use

Important – 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, they are 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:

This Instructions for Use (IFU) describes the Nobel Biocare Zygoma Implant RP and supporting components, which is comprised of the Zygoma Implants RP (including the co-packaged Implant Mount), the co-packaged Zygoma Implant Cover Screw, and the Zygoma instrumentation which is required during the surgical and handling procedure to prepare the implant site and to place the implant.

Zygoma Implants RP and Zygoma Implant Cover Screw:
Zygoma Implants RP are threaded dental implants intended for use in the zygomatic bone for anchoring or supporting dental prostheses. The implants are available in various lengths and in a single diameter. The implant has the following features:

- The threaded part of the Zygoma Implant RP has a diameter of 4.4 mm in the upper threaded section and 3.9 mm in the lower threaded section.
- The implant macroshape is characterized by an expanding parallel body and a round, non-threaded apex with vent. The angulated 45° head of Zygoma Implants RP have an opening opposite the implant platform (**Figure A**) to use standard Brånemark System prosthetic components.

A

Figure A: Zygoma Implant RP with Opening Opposite the Implant Platform

- The Zygoma Implant RP features an external hex connection in the Regular Platform (RP), which is compatible with Nobel Biocare's Brånemark System Zygoma Multi-unit Abutments 0° and 17°, Zygoma Implant Cover Screw, as well as with standard Brånemark System prosthetic components (RP).
- The Zygoma Implant RP features a machined surface.

The Zygoma Implant RP is co-packaged with an Implant Mount attached to the head of the implant. The Zygoma Handle connects to the Implant Mount and is used to pick up and insert the implant into the osteotomy.

The Zygoma Implant RP is also co-packaged with the Zygoma Implant Cover Screw, which is used to cover the implant and prevent tissue overgrowth during the healing process. The Cover Screw Driver Brånemark System® Hexagon is used to tighten the Zygoma Implant Cover Screw. Refer to Nobel Biocare Instructions for Use (IFU) IFU1026 for further information regarding the Cover Screw Driver Brånemark System® Hexagon. This IFU is available for download at ifu.nobelbiocare.com.

Zygoma Instrumentation:
The following instrumentation is required during the surgical and handling procedures to place Zygoma Implants RP:

- The Brånemark System™ Zygoma Round Bur, Brånemark System™ Zygoma Pilot Drills, and Brånemark System™ Zygoma Twist Drills are required to prepare the osteotomy for placement of Zygoma Implants RP. The drills are available in different diameters and lengths in order to widen the osteotomy step-by-step to the appropriate diameter and depth.
- Zygoma Drill Guards and Drill Guards Short are used during preparation of the osteotomy as a protective shield between the rotating drill shaft and adjacent soft tissues.
- Zygoma Depth Indicators Straight and Angled are used to verify the depth of the osteotomy. They feature numbered length scales on the handle and shaft to verify the depth of the osteotomy and to support selection of the appropriate Zygoma Implant RP length.
- The Zygoma Handle connects to the Implant Mount and is used to pick up and insert the Zygoma Implant RP into the osteotomy.
- Screwdrivers Manual Unigrip are used to tighten and/or loosen the abutment screws or clinical screws used to connect the abutment to the Zygoma Implant RP.
- The Connection to Handpiece connects to a contra-angle handpiece and is used to pick up the Zygoma Implant RP and to place the implant into the osteotomy.

Refer to Nobel Biocare IFU1085 for further information regarding the Screwdrivers Manual Unigrip.

Refer to Nobel Biocare IFU1058 for further information regarding the Connection to Handpiece.

Refer to Nobel Biocare IFU1016 for further information regarding the Cover Screws.

Refer to Nobel Biocare IFU1075 for further information regarding the Multi-unit abutments and compatible prosthetic components.

Table 1 presents an overview of the available Zygoma Implants RP, the compatible cover screws, abutments, abutment screws, and screwdriver.

Table 1: Zygoma Implants RP and Compatible Screws, Abutments, and Screwdrivers

Implant	Cover Screw	Abutment	Abutment Screw	Screwdriver
Zygoma Implant RP 30 mm	Zygoma Implant Cover Screw	Zygoma Abutment Multi-unit RP Zygoma 17° Abutment Multi-unit RP	Brånemark System Zygoma Abutment Screw Screw Multi-unit Angled Abutment Brånemark System RP	Screwdriver Manual UniGrip
Zygoma Implant RP 35 mm				
Zygoma Implant RP 40 mm				
Zygoma Implant RP 42.5 mm				
Zygoma Implant RP 45 mm				
Zygoma Implant RP 47.5 mm				
Zygoma Implant RP 50 mm				
Zygoma Implant RP 52.5 mm				

Intended Use/Intended Purpose:

Zygoma Implants RP:
Intended for use as a dental implant in the zygomatic bone for anchoring or supporting dental prostheses to restore chewing function.

Brånemark System™ Zygoma Round Bur, Twist Drills, and Pilot Drills:
Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Zygoma Drill Guards and Drill Guards Short:
Intended for use to guide drilling instruments during preparation of an osteotomy.

Zygoma Depth Indicators Straight and Angled:
Intended for use to verify the depth of an osteotomy during dental implant surgery.

Zygoma Handle:
Intended for use to insert or remove dental implants during dental implant surgery.

Zygoma Implant Cover Screw:
Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.

Indications:

Zygoma Implants RP:
Zygoma Implants RP are indicated only for multi-unit constructions, through rigid splinting of a minimum of two Zygoma RP implants. For full-mouth rehabilitation, they are used together with at least two standard endosseous dental implants in the anterior maxilla. Restorations which can be supported by Zygoma RP Implants range from fixed/removable full dental arch applications, to partially-edentulous maxilla with uni- or bilateral loss of premolars and molars.

Zygoma Implants RP and the corresponding surgical technique should only be used in patients with highly reduced amount and poor quality of remaining maxillary bone. Patients with an extensive history of known sinusitis may be considered for treatment with Zygoma RP Implants based on a balanced risk-benefit evaluation.

Brånemark System™ Zygoma Round Bur, Zygoma Twist Drills and Pilot Drills:
Brånemark System™ Zygoma Round Bur, Zygoma Twist Drills and Pilot Drills are indicated for use to prepare an osteotomy in the zygomatic bone to support the placement of Nobel Biocare zygomatic dental implants.

Zygoma Drill Guards and Drill Guards Short:
Zygoma Drill Guards and Drill Guards Short are indicated for use during preparation of an osteotomy in the zygomatic bone as a protective shield between the rotating drill shaft and adjacent soft tissues.

Zygoma Depth Indicators Straight and Angled:
Zygoma Depth Indicators Straight and Angled are indicated for use to verify the depth of the osteotomy and to support selection of the appropriate Zygoma Implant RP length.

Zygoma Handle:
The Zygoma Handle is indicated for use to manually pick up and insert a Zygoma Implant RP into an osteotomy.

Zygoma Implant Cover Screw:
The Zygoma Implant Cover Screw is indicated for use with Zygoma Implants RP.

Contraindications:

It is contraindicated to use Zygoma Implants RP, the Zygoma Implant Cover Screw, and the Zygoma instrumentation in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume for zygomatic and conventional endosseous implants.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

It is contraindicated to use Zygoma Implants RP in patients who are allergic or hypersensitive to commercially pure titanium (grade 4).

It is contraindicated to use the Cover Screw in patients who are allergic or hypersensitive to titanium alloy Ti-6AL-4V.

It is contraindicated to use Zygoma instrumentation in patients who are allergic or hypersensitive to stainless steel, aluminum, or DLC (Diamond Like Carbon) coating.

It is contraindicated to use Zygoma instrumentation with zygoma implants not manufactured by Nobel Biocare.

In case of bruxism or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

Warnings:

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

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

Cautions:

General:
One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) 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 Zygoma Implants RP are used only with compatible Nobel Biocare surgical instruments and prosthetic components. Use of instruments or components that are not intended to be used in combination with Zygoma Implants RP can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery:
Careful psychological and physiological evaluation followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for 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, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile 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 components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:
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.

Care and maintenance of sterile 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 sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

The 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.

After Surgery:
To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Intended Users and Patient Groups:

Zygoma Implants RP, Zygoma Implant Cover Screw, and Zygoma instrumentation are to be used by dental health care professionals.

Zygoma Implants RP, Zygoma Implant Cover Screw, and Zygoma instrumentation are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Zygoma Implants RP, Zygoma Implant Cover Screw, and Zygoma Instrumentation:
Zygoma Implants RP, Cover Screw, and Zygoma Tooling are components of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Zygoma Implants RP, Zygoma Implant Cover Screw, and Zygoma Instrumentation:
The placement of dental implants constitutes an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. Depending on the location, placement of the implant may also lead (in rare cases) to bone fracture, perforation of neighboring structures, sinusitis, or sensory/motor disturbances. During placement of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

During placement of the cover screw, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex. During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

During use of the Zygoma instrumentation, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Dental implants are the substructure of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as mucositis, calculus, peri-implantitis, fistulas, ulcera, soft tissue hyperplasia, soft and/or hard tissue recession/loss. Some patients may experience discoloration in the mucosal area, such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the [Implantable Device Type(s)]. The SSCP can be obtained at the following website:

https://ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED).

Notice regarding serious incidents:
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB

https://www.nobelbiocare.com/complaint-form

Surgical Procedure:

Implant Position:
The Zygoma Implants RP typically pierces the oral mucosa in the premolar region (**Figure B1**) and passes through the sinus along the lateral wall of the maxilla. Depending on the contour of the lateral maxillary wall, the mid-portion of the implant may also pass lateral to the lateral wall. The implant tip enters the base of the body of the zygoma (the superior-lateral corner of the maxillary sinus), travels through the zygoma and pierces through its lateral cortex. The implant trajectory is usually parallel to the zygomatic buttress (**Figure B2**).

B1

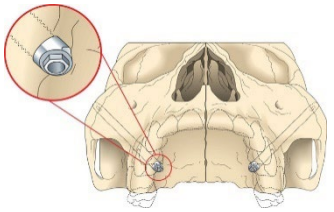

Figure B1: Premolar implant position

B2

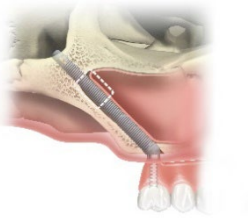

Figure B2: Implant position

Note: It is recommended to have at least two Zygoma implants of every length available. Identifying the required implant length is a clinical process during the preparation of the osteotomy.

To maintain continuity by using the same prosthetic components NobelSpeedy implants with external hex connection are generally used for the pre-maxillary implant position.

Anatomical Landmarks:

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.

   Figure C 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.

C

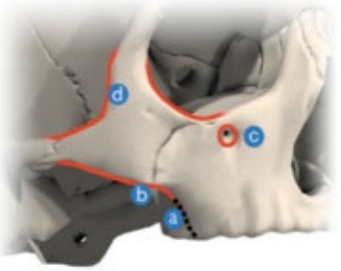

Figure C: Landmarks which may be used in keeping oriented during the anatomic dissection

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 (**Figure D**).
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 (**Figure D**).

D

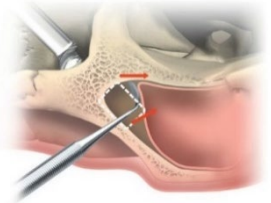

Figure D: Direct visualization of anatomical structures

The recommended drill sequences for Zygoma RP (Figure E):

a. Brånemark System™ Zygoma Round Bur.
b. Brånemark System™ Zygoma Twist Drill 2.9 mm.
c. Widening of the osteotomy with Brånemark System™ Zygoma Pilot Drill 3.5 mm.
d. Brånemark System™ Zygoma Twist Drill 3.5 mm.

E

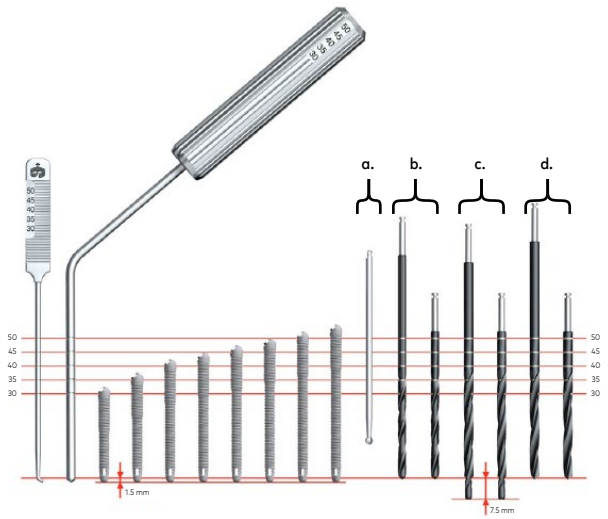

Figure E: Drill sequence a.-d. (long drills and short drills available)

Note: 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 **Figure E** for drill reference lines).

Caution: The Pilot Drills extend up to 7.5 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (please see **Figure E**).

Caution: The ratio of the contra-angle handpiece used is 20:1 at a speed of maximum 2000 rpm. Drill under constant and profuse irrigation with in and out motion using a sterile saline at room temperature.

Caution: Due to the length of the drills avoid lateral pressure on drills during implant-site preparation. Lateral pressure may cause drill fracture.

Caution: Verify that drills lock in the contra-angle 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.

Use of Drill Guard:

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 (**Figure F**). Injury to the tongue, corner of the lips and or other soft tissues may occur if the drill shaft is unprotected.

F

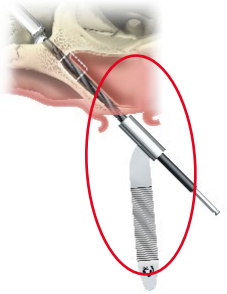

Figure F: Use of a Drill Guard

Identify implant trajectory and starting point for drilling:

4. Identify the trajectory of the implant by placing the round bur over the lateral wall of the maxilla. 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 front o-zygomatic notch (**Figure G**).

G

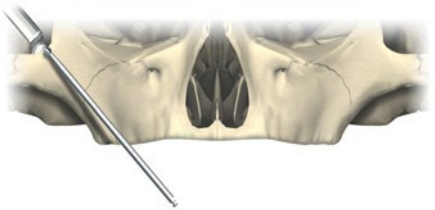

Figure G: Identification of the trajectory of the Zygoma implant

Make entrance mark with round bur (Figure H):

5. Make the palatal/crestal mark for the implant entrance with the round bur.
6. Penetrate and pass the round bur through the sinus while checking the direction of the bur through the sinus window.
7. Make an entrance mark in the posterior-superior roof of the sinus to allow seating of the 2.9 mm drill without chatter.

H

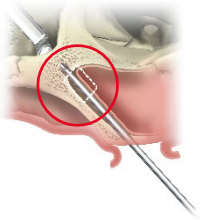

Figure H: Preparation of entrance mark

Use of Drill with Brånemark System™ Twist Drill 2.9 mm:

8. Continue with the Brånemark System™ Twist Drill 2.9 mm until it penetrates the outer cortical layer of the zygomatic bone at the incisura (**Figure I**).

I

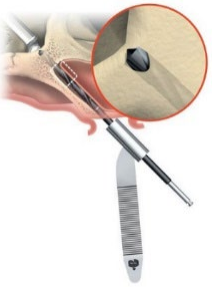

Figure I: Drill with Brånemark System™ Twist Drill 2.9 mm

Caution: It is imperative to protect the soft tissue at the zygomatic bone penetration site by using the drill guard; and to have full control of the area where the drill penetrates at the level of the zygoma.

Determine implant length:

9. Use the Zygoma Depth Indicator Straight to determine the required implant length (**Figure J**).

J

Figure J: Determination of implant length

Widen osteotomy with Pilot Drill 3.5 mm:

10. Use the Pilot Drill 3.5 mm (Ø 2.9/3.5 mm) to find the penetration of the sinus roof previously made by the Brånemark System™ Twist Drill 2.9 mm. It makes a partial 3.5 mm osteotomy through the zygoma body (**Figure K**).

K

Figure K: Widen Osteotomy with Brånemark System™ Twist Drill 2.9 mm

Final osteotomy with Brånemark System™ Twist Drill 3.5 mm:

11. Complete the osteotomy with the Brånemark System™ Twist Drill 3.5 mm (**Figure L**).

L

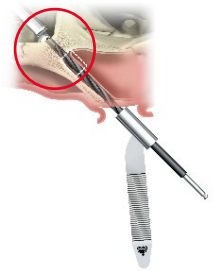

Figure L: Final osteotomy with Brånemark System™ Twist Drill 3.5 mm

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.

Verification of the drill depth:

12. Verify the drill depth of the prepared osteotomy with the Zygoma Depth Indicator Angled to ensure that the selected implant length will fully be seated without apical bone interference (**Figure M**).

M

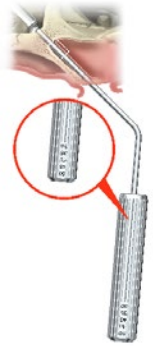

Figure M: Verification of the drill depth

Implant pick-up and insertion:

13. Engage the implant mount (already pre-mounted on the implant) with the Connection to Handpiece, and pick up the implant (**Figure N1**).

N1

Figure N1: Implant pick-up

14. Implant placement: The implant may be inserted using the drilling unit with 20 Ncm insertion torque (**Figure N2**) or using the Zygoma handle for manual insertion (**Figure N3**).

N2

Figure N2: Implant insertion (handpiece)

N3

Figure N3: Implant insertion (manual)

Increasing the insertion torque up to maximum 50 Ncm may be used for the complete seating of the implant (**Figure N2**).

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.

The Zygoma handle (**Figure N3**) may be used to tighten the implant manually to the correct final position. Engage the connecting part directly to the implant mount.

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.

15. 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.
16. Verifying the correct position of the implant platform: Place the Screwdriver Manual Unigrip into the implant mount screw (**Figure O**). The shaft of the Unigrip driver should be perpendicular to the crest of the maxilla to ensure the proper position of the Zygoma Implant RP platform. Remove the implant mount.

O

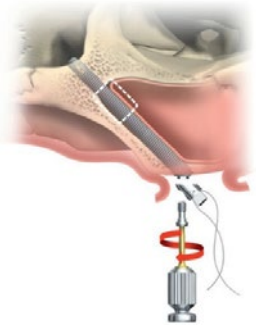

Figure O: Verifying the correct position of the implant platform

17. The premaxillary implants are placed following the conventional protocol for placement of implants.
18. 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.

Caution: Tighten the Cover screw only finger-tight to avoid excessive loads.

19. For two-stage protocol relieve the denture over the implants (**Figure P**).

P

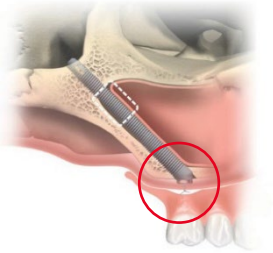

Figure P: Relieving the denture to create space above the implant

Materials:

- Zygoma Implants RP: Commercially pure titanium grade 4 per ASTM F67.
- Zygoma Implant Cover Screw: Titanium alloy Ti-6AL-4V (90% titanium, 6% aluminum, 4% vanadium) per ASTM F136 and ISO 5832-3.
- Brånemark System™ Zygoma Pilot Drill: Stainless steel 1.4197 according to ASTM F899.
- Brånemark System™ Zygoma Twist Drills: Stainless steel, DLC (Diamond Like Carbon) coating per 1.4197 Type 420F Mod according to ASTM A895 and ISO 5832-1.
- Brånemark System™ Zygoma Round Bur: Stainless steel 1.4197 according to ASTM F899.
- Zygoma Drill Guards and Drill Guards Short, Zygoma Depth Indicators Straight and Angled, and the Connection to Handpiece: Stainless steel 1.4301 according to ASTM F899.
- Zygoma Handle: Stainless steel and aluminum: Adapter and Pin: Stainless Steel Type 304, Cap and Body: Aluminum Alloy 6082 according to ISO AlSi1MgMn.

Sterility and Reusability Information:

Zygoma Implants RP and Zygoma Implant Cover Screw have been sterilized using irradiation and are intended 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.

Brånemark System™ Zygoma Round Bur, Pilot Drills, and Twist Drills are delivered non-sterile for single use only. Prior to use clean and sterilize the products following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution: Zygoma Implants RP and Brånemark System™ Zygoma Round Bur, Pilot Drills, and Twist Drills are for single use and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Zygoma Drill Guards and Drill Guards Short, Zygoma Depth Indicators Straight and Angled, and the Zygoma Handle are delivered non-sterile and intended for reuse. Prior to first use and re-use clean and sterilize the products following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Zygoma Drill Guards and Drill Guards Short are reusable instruments which must be inspected before each reuse to ensure that the integrity and performance of the instruments are maintained. If there is any visible evidence of deformation or surface corrosion, or if the readability of the markings is compromised, the instruments must not be reprocessed and shall be discarded.

Zygoma Depth Indicators Straight and Angled are reusable instruments which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The Depth Probe shall be discarded if any wear, deformations or corrosion is visible on the instrument, or if the readability of the markings is compromised.

The Zygoma Handle is a reusable instrument which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The Implant Driver shall be discarded if any wear, deformations or corrosion is visible on the instrument, or if the readability of the markings is compromised.

Cleaning and Sterilization Instructions:

The Brånemark System™ Zygoma Round Bur, Pilot Drills, and Twist Drills are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

The Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight, Zygoma Depth Indicator Angled and Zygoma Handle are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: The devices been validated to withstand these cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122.0 °F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX -320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 2 presents examples of suitable sterilization containers, pouches, and wraps.

Table 2: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (**Table 3**):

Table 3: Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information:

Zygoma Implants RP contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that Zygoma Implants RP are unlikely to interfere with patient safety under the following MRI 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 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, this device is expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that Zygoma Implants RP are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for these devices.

Performance Requirements and Limitations:

To achieve the desired performance, Zygoma Implants RP, Zygoma Implant Cover Screw, and Zygoma instrumentation must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product.

To confirm the compatibility of products which are intended to be used in conjunction with Zygoma Implants RP, Zygoma Implant Cover Screw, and Zygoma instrumentation, check the color coding, dimensions, lengths, connection type and/or any direct marking on the products or product labeling.

Facilities and Training:

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation:

The device 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:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
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CE 2797
CE Mark for Class Ir/IIa/IIb Devices

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
Zygoma Implants RP	73327470000000016C
Zygoma Implant Cover Screw	73327470000001326U
Brånemark System® Zygoma Twist Drill 2.9 mm Brånemark System® Zygoma Twist Drill 2.9 mm short Brånemark System® Zygoma Pilot Drill 3.5 mm Brånemark System® Zygoma Twist Drill 3.5 mm Brånemark System® Zygoma Twist Drill 3.5 mm short Brånemark System® Zygoma Pilot Drill 3.5 mm short Brånemark System® Zygoma Round Bur	73327470000001206M
Zygoma Drill Guard Zygoma Drill Guard Short	73327470000015272
Zygoma Handle	73327470000001587E
Zygoma Depth Indicator Straight Zygoma Depth Indicator Angled	73327470000001606Z

Implant Card:

The Zygoma Implant RP is accompanied by an Implant Card which contains important information for patients regarding the device.

Complete the Implant Card by filling it out with the patient- and device-specific information as indicated and provide the completed Implant Card to the patient.

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

Date


Date of manufacture


Do not resterilize


Do not re-use


Do not use if package is damaged

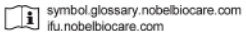

Double sterile barrier system

Rx Only
For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation


Temperature limit


Tooth number


Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier


Use-by date