# Zygoma RP

## Important – Disclaimer of Liability

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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

Zygoma RP implants are endosseous implants made from biocompatible commercially pure grade 4 titanium. They are parallel walled implants with a 45° abutment head.

The implants have a machined surface up to the level of the platform. On the back side of the implant head there is a hole for the restorative component screw to protrude. Due to the design of the open screw hole specific "Zygoma" named restorative components or Brånemark System®, regular platform, restorative assortment are to be used in combination with this implant.

The implant comes with a co-packed Cover Screw made of titanium alloy Ti-6Al-4V.

### 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 without DLC (Diamond Like Carbon) coating. They should be used in conjunction with Zygoma RP implants and are for single use only.

## Intended Use

Zygoma RP endosseous implants are intended to be used in the upper jaw arch (osseointegration) for anchoring or supporting prosthetic devices such as tooth replacements to restore chewing function.

## Indications for Use

Zygoma RP implants are to be integrated in the zygomatic bone, (osseointegration).

These implants are only indicated for multi-unit constructions, through rigid splinting of a minimum of two implants. For full-mouth rehabilitation, they are used together with at least two standard implants in the anterior maxilla for anchoring or supporting tooth replacement. Restorations range from a fixed/removable full dental arch application to partially edentulous maxilla with uni or bilateral loss of premolars and molars to restore chewing function.

These implants 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 such surgical treatments based on a balanced risk benefit evaluation.

## Contraindications

It is contraindicated to use dental implants in:

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

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

# Materials

Zygoma RP implant:
Commercially pure titanium grade 4.

Cover Screw:
Titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

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

Round Bur:
Stainless Steel.

# 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 Zygoma RP implants are sinusitis and fistula formations.

# Cautions

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.

Zygoma RP implants must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Zygoma RP implants 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 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.

All instruments and tooling used during the clinical and/or laboratory must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

### At surgery

Because of the small size of components, 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. gauze, dental dam, or throat shield).

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

Zygoma RP 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 unfa-vorable, 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 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.

# 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.

Image (Figure 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

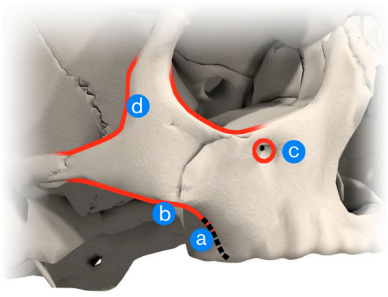


**Figure A**

5. 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 B).

6. 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 B).

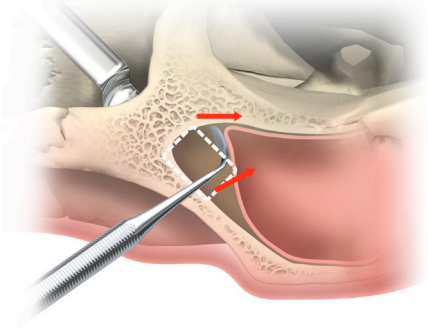

**Figure B**

7. 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 (Figure C).

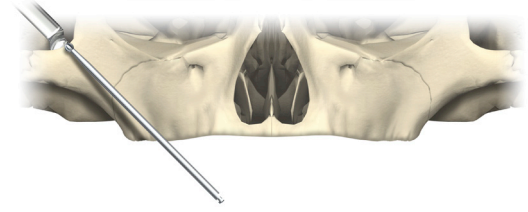

**Figure C**

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

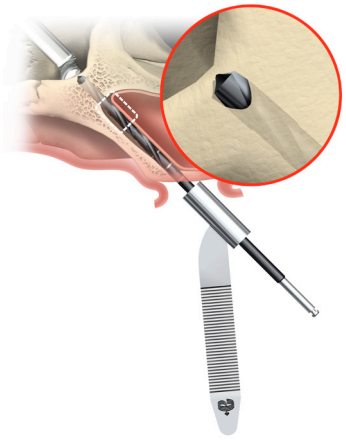

**Figure D**

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 Figure E for drill reference lines).

9. 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.

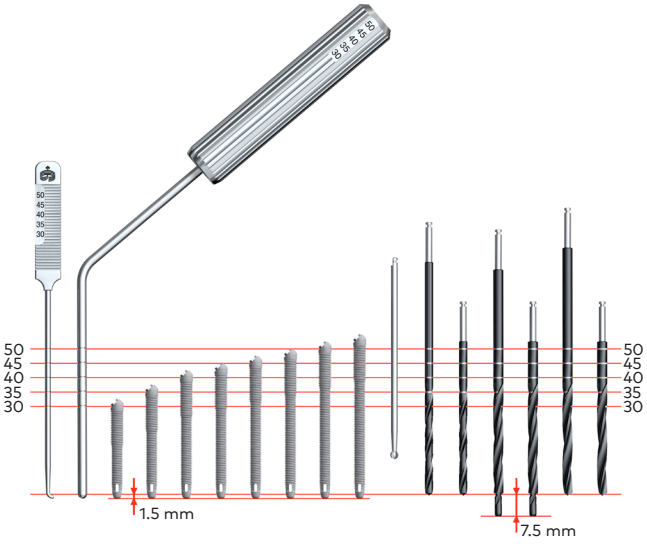


**Figure E**


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10. 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.

11. 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 (Figure 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.

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

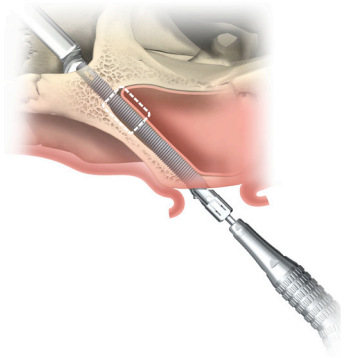

**Figure F**

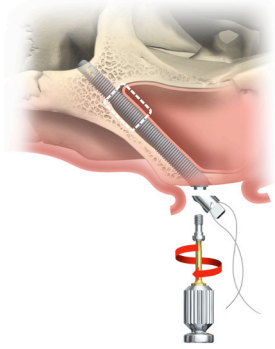

**Figure G**

13. 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 frontozygomatic notch.

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

15. 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 (Figure 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.

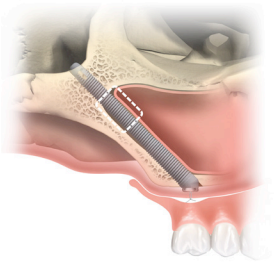

Figure H

## Sterility and Reusability Information

Zygoma RP implants have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Prior to reuse clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

**Warning** Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

**Caution** Zygoma RP implants are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

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

Pilot Drills are delivered non-sterile and are intended for single use only. Prior to use clean and sterilize the product 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** Pilot Drills are a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Depth Indicators are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

The instrument shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The instrument shall be discarded if any wear, abrasion, deformations, or corrosion is visible.

**Warning** Do not use device if the packaging has been damaged.

# Cleaning and Sterilization Instructions

Pilot Drills are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the device must be cleaned and sterilized by the user.

Depth Indicators are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the device 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 Pilot Drills and Depth Indicators have been validated to withstand these cleaning and sterilization procedures.

**Caution** Do not deviate from the following reprocessing instructions.

## 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. Use a dental probe to remove soil and debris from cavities, where applicable.

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 washers were used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program/Washer disinfector (MMM GmbH) Type: Uniclean PL-II 15-2 EL.

**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 of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining

4. Run drying cycle at a minimum of 50°C (122°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.

**Note** FDA-cleared washer- disinfectors are to be used for the recommended cleaning parameters.

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 the 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 of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP and/or Neodisher Medizym; maximum of 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 an 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 $W_{eff}$) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP and/or Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F)/maximum 45°C (113°F).

7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml 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 discard any devices that fail the inspection.

## Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 (pre-vacuum cycle) and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1CL; Amsco Century Sterilizer, Selectomat PL/669-2CL and/or Selectomat PL/666-1CL (gravity cycle).

**Note** When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL/Selectomat PL/666-1CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Seal each device in a suitable sterilization pouch. 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 1 presents examples of suitable sterilization pouches.

**Table 1 – Recommended Sterilization Pouches**

| Method | Recommended Sterilization Pouch |
|---|---|
| Gravity Cycle | SPSmedical Self-Seal sterilization pouch |
| | Steriking pouch (Wipak) |
| Pre-vacuum Cycle | SteriCLIN® pouch |
| | Steriking pouch (Wipak) |

2. Label the sterilization pouch with the information necessary to identify the device (e.g. 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 1):
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying for a minimum of 30 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying for a minimum of 20 minutes in chamber.

**Note** FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

**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 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 processed /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

## MR Safety Information

| MRI Safety Information |  | |
|---|---|---|
| Non-clinical testing has demonstrated the Zygoma RP Implant and Cover Screw is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient. | | |
| Nominal value(s) of Static Magnetic Field [T] | 1.5-Tesla (1.5 T) | 3-Tesla (3 T) |
| Maximum Spatial Field Gradient [T/m and gauss/cm] | Maximum spatial field gradient of 44.4 T/m (4,440 G/cm). | |
| RF Excitation | Circularly Polarized (CP) | |
| RF Transmit Coil Type | Whole body transmit coil | |
| Maximum Whole-Body SAR [W/kg] | Inferior to the shoulders: 2.0 W/kg<br>Superior to the shoulders: 0.2 W/kg | Inferior to the navel: 2.0 W/kg<br>Superior to the navel: 0.1 W/kg |
| Limits on Scan Duration | Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0°C after 15 minutes of continuous scanning. | |
| MR Image Artifact | In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3 T MRI system. | |
| Caution | Configurations with more than 2 Zygoma implants 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 configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury. | |

# 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**  | Nobel Biocare AB<br>PO Box 5190, 402 26<br>Västra Hamngatan 1<br>Göteborg<br>411 17<br>Sweden<br>www.nobelbiocare.com |
| **Distributed in USA by** | Nobel Biocare USA, LLC<br>22715 Savi Ranch Parkway<br>Yorba Linda, CA, 92887 USA |

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

# Legal Statements

# 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 / European Union | UK Responsible Person | Authorised Representative in Switzerland | Sterilized using Ethylene Oxide | Sterilized using irradiation | Sterilized using steam or dry heat | |
|  |  |  |  |  |  | |
| Batch code | Catalogue number | Unique Device Identifier | Serial number | Medical device | Magnetic resonance safe | |
|  |  |  |  |  |  |  |  |
| Caution | Magnetic resonance conditional | Non-sterile | Contains hazardous substances | Contains or presence of DEHP phthalate | Contains or presence of natural rubber latex | Contains or presence of phthalate | Contains biological material of animal origin |
|  |  |  |  |  | Rx only |  symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com | |
| CE mark | CE mark with Notified Body number | UKCA mark | UKCA mark with Approved Body number | Consult instructions for use | For prescription use only | Link to Online Symbols Glossary and IFU Portal | |
|  |  |  |  |  |  |  |  |
| Date of manufacture | Manufacturer | Use-by date | Upper limit of temperature | Temperature limit | Do not resterilize | Do not re-use | Non-pyrogenic |
|  |  |  |  |  |  |  |  |
| Date | Tooth number | Patient number | Patient identification | Health care centre or doctor | Patient information website | EU Importer | Swiss Importer |
|  |  |  |  |  |  |  | |
| Double sterile barrier system | Single sterile barrier system | Single sterile barrier system with protective packaging inside | Single sterile barrier system with protective packaging outside | Do not use if package is damaged and consult instructions for use | Keep away from sunlight | Keep dry | |