Nobel Biocare™

NobelZygoma™ TiUltra™ system

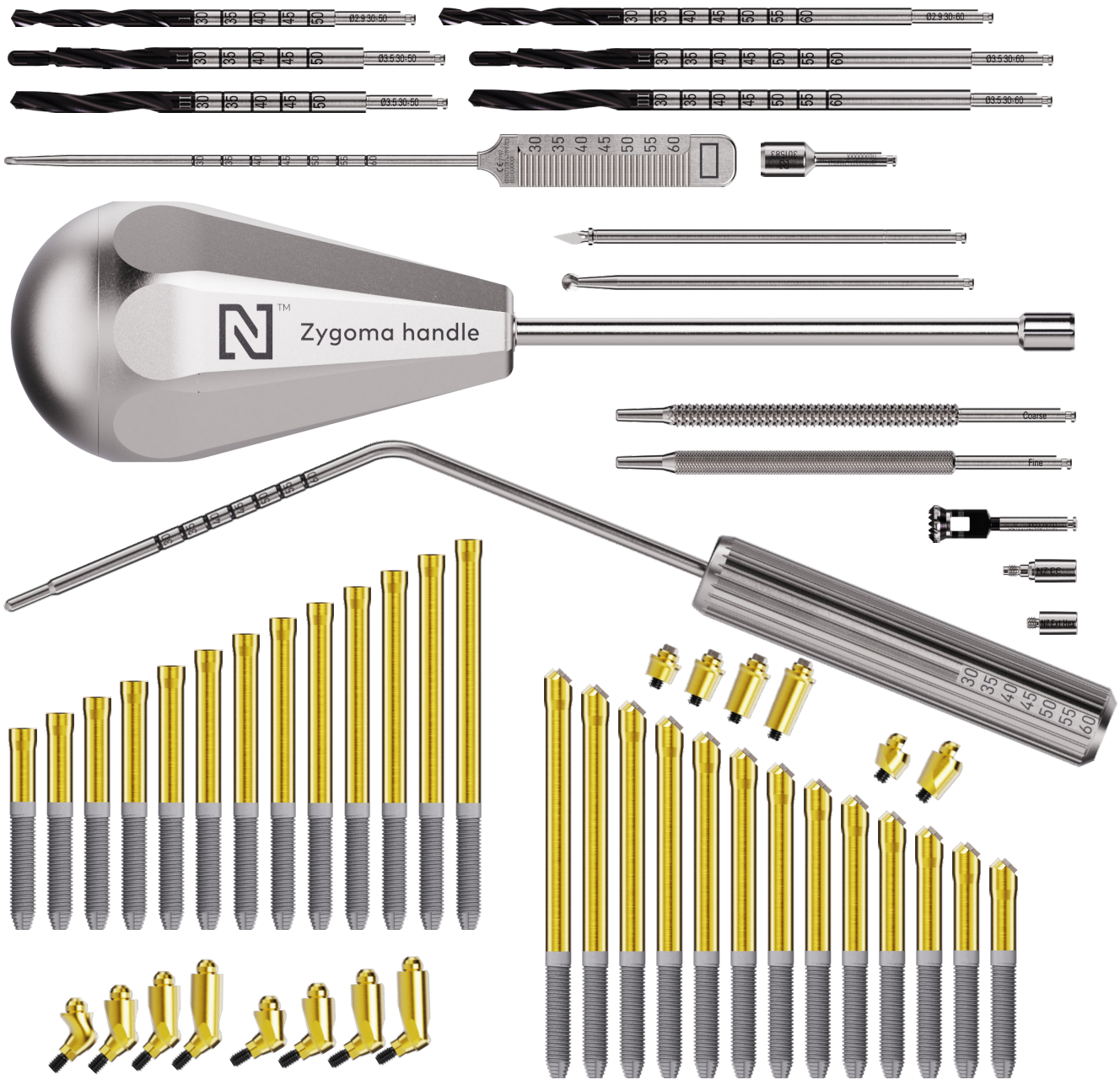


Figure A – NobelZygoma™ TiUltra™ system

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

The scope of devices covered by this Instructions For Use (IFU) is the NobelZygoma™ TiUltra™ system.

The NobelZygoma™ TiUltra™ system comprises four groupings of devices:

- NobelZygoma™ TiUltra™ Implants
- Multi-Unit Abutments Xeal™ Zygoma
- NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws
- NobelZygoma™ Instruments

Implantable components

The NobelZygoma™ TiUltra™ Implants are threaded dental implants, made from biocompatible commercially pure grade 4 titanium, with TiUltra™ anodized surface up to the level of the platform.

The TiUltra™ surface incorporates an additional protective layer comprising of sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

The NobelZygoma™ TiUltra™ Implants are parallel walled devices, incorporating a connection in the collar region to combine with the Multi-Unit Abutments Xeal™ Zygoma. The NobelZygoma™ 0° CC TiUltra™ Implant includes an internal Conical Connection platform (size RP) with an internal hex aligned to the implant axis. The NobelZygoma™ 45° Ext Hex TiUltra™ Implant includes an External Hex platform (size RP) aligned at 45° to the implant axis.

The NobelZygoma™ TiUltra™ Implants are available in lengths of 30-60 mm, in 2.5 mm increments, and feature an 18 mm anodized threaded apex with diameter 3.9 mm, an anodized shaft of diameter 3.9 mm, and an anodized collar of diameter 4.3 mm (Figure B and Figure C). The NobelZygoma™ TiUltra™ Implants are co-packaged with an implant mount made of titanium alloy (Ti-6Al-4V), which is attached via a pre-assembled screw to the platform of the implant (Figure D).

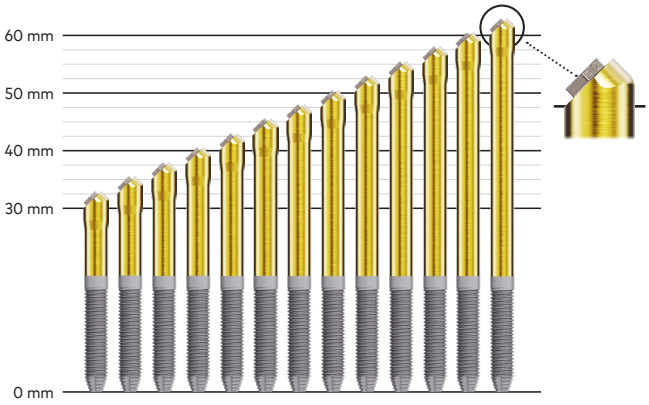


Figure B – Scope of NobelZygoma™ 45° Ext Hex TiUltra™ RP Implants

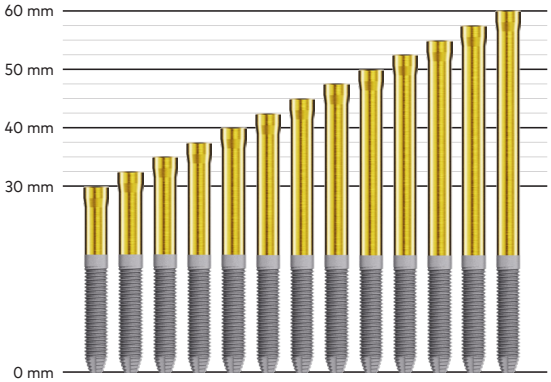


Figure C – Scope of NobelZygoma™ 0° CC TiUltra™ RP Implants

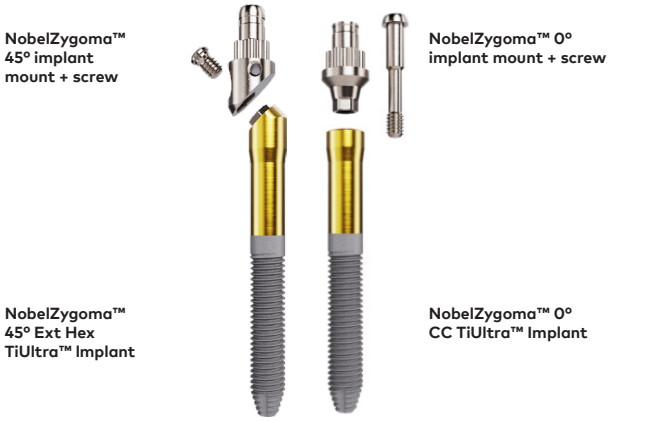


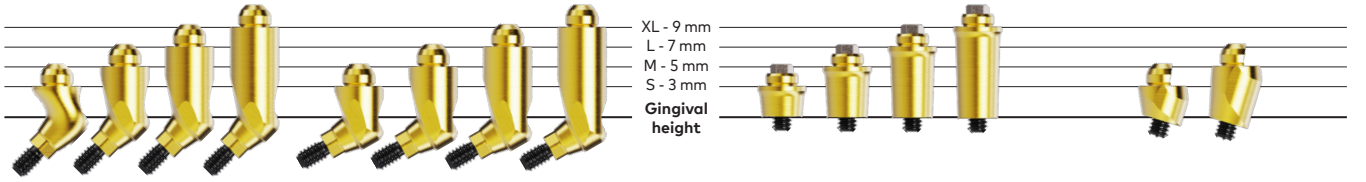
Figure D – NobelZygoma™ 45° Ext Hex TiUltra™ RP Implants and NobelZygoma™ 0° CC TiUltra™ RP Implants, with their respective implant mounts

NobelZygoma™ 0° CC TiUltra™

Conical connection Tightening torque clinical screw = 35 Ncm

NobelZygoma™ 45° Ext Hex TiUltra™ System

External hex Tightening torque clinical screw = 35 Ncm



45° Multi-unit Abutment Xeal™ Zygoma CC | 60° Multi-unit Abutment Xeal™ Zygoma CC | Multi-unit Abutment Xeal™ Zygoma Ext Hex | 17° Multi-unit Abutment Xeal™ Zygoma Ext Hex

Figure E – Scope of Multi-unit Abutments Xeal™ Zygoma

Prosthetic components

Multi-unit Abutments Xeal™ Zygoma

The compatibility between the scope of NobelZygoma™ TiUltra™ Implants (0° CC RP and 45° Ext Hex RP) and the scope of Multi-Unit Abutments Xeal™ Zygoma is outlined in Table 1.

The Multi-Unit Abutment Xeal™ Zygoma Ext Hex and the 17° Multi-Unit Abutment Xeal™ Zygoma Ext Hex (Figure E) feature an external hex connection. The Multi-Unit Abutments Xeal™ Zygoma Ext Hex are available in four heights (S-3 mm, M-5 mm, L-7 mm, XL-9 mm) and the 17° Multi-Unit Abutments Xeal™ Zygoma Ext Hex are available in 2 different heights (S-3 mm, M-5 mm) and can be used with Nobel Biocare's NobelZygoma™ 45° TiUltra™ Implants. The compatible abutment screw and handle for abutment seating are co-packed with the Multi-Unit Abutment Xeal™ Zygoma.

The 45° Multi-Unit Abutment Xeal™ Zygoma CC and the 60° Multi-Unit Abutment Xeal™ Zygoma CC (Figure E) feature an internal conical connection (CC). The 45° and 60° Multi-Unit Abutments Xeal™ Zygoma CC are available in four heights (S-3, M-5, L-7 and XL-9 mm) and can be used with Nobel Biocare's NobelZygoma™ 0° TiUltra™ Implants. The compatible abutment screw and handle for abutment seating are co-packed with the Multi-Unit Abutment Xeal™ Zygoma.

NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws

The NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws (Figure F) are dental implant screws designed to fix dental prostheses or dental implant system components such as multi-unit abutments and implant-level healing abutments to an endosseous dental implant or to another abutment. The abutment screws are co-packed with the compatible Multi-unit Abutment Xeal™ Zygoma, but are also available separately.

Compatibility between the NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws and the Multi-Unit Abutments Xeal™ Zygoma is defined in Table 1.

Figure F – NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws

Table 1 – Compatibility between families of NobelZygoma™ TiUltra™ Implants, Multi-Unit Abutments Xeal™ Zygoma and NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws

NobelZygoma™ TiUltra™ Implants	Multi-Unit Abutment Xeal™ Zygoma	NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma screws
NobelZygoma™ 45° ExtHex TiUltra™ RP Implants Sizes 30-60 mm	Multi-Unit Abutment Xeal™ Zygoma Ext Hex RP Sizes S-XL	Size matched to: NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws Sizes S-XL
	17° Multi-Unit Abutment Xeal™ Zygoma Ext Hex RP Sizes S-M	NobelZygoma™ 17° Multi-Unit Abutment Xeal™ Zygoma Screw
NobelZygoma™ 0° CC TiUltra™ RP Implants Sizes 30-60 mm	45° Multi-Unit Abutment Xeal™ Zygoma CC RP Sizes S-XL	NobelZygoma™ Multi-Unit Abutment Screw 45°/60°
	60° Multi-Unit Abutment Xeal™ Zygoma CC RP Sizes S-XL	

Surgical Instruments

Instruments for osteotomy preparation

NobelZygoma™ Round Burr, Precision Drill, Lateral Burrs ,Twist Drills, and Pilot Drills

The NobelZygoma™ Round Burr, Precision Drill, Lateral Burrs, Twist Drills, and Pilot Drills (see Figure G) support the preparation of the osteotomy for placement of NobelZygoma™ TiUltra™ Implants (0° and 45°), and are for single patient use. The drills are available in different diameters (Ø 2.9 mm and Ø 3.5 mm) and lengths to widen the osteotomy step-by-step to the appropriate diameter and depth. A coarse and a fine lateral burr are available, to create a slot/groove.

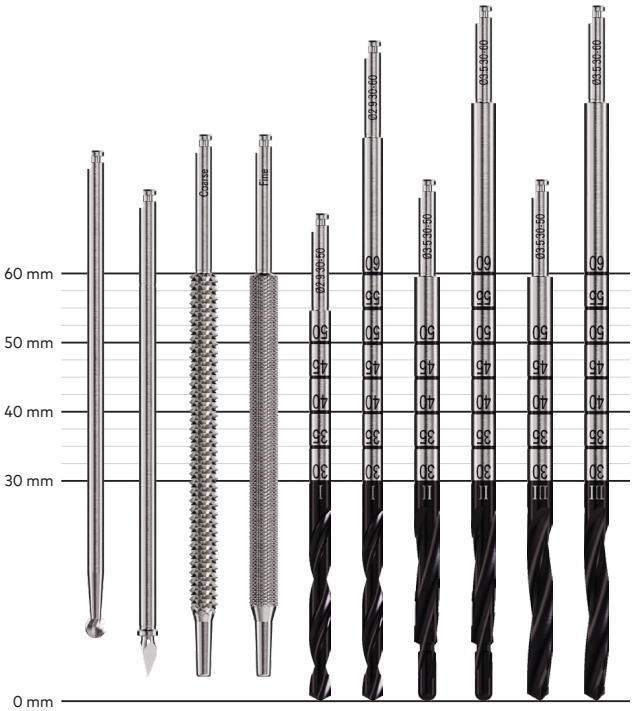


Figure G – NobelZygoma™ Round Burr, Precision Drill, Lateral Burrs, Twist Drills and Pilot Drills

NobelZygoma™ Bone Mill with Guide & Bone Mill Guide

NobelZygoma™ Bone Mills (see Figure H) have a cylindrical cutting surface which is used to remove excess bone which may surround the coronal aspect (the top surface, or platform) of a dental implant immediately after implant placement, or after the implant healing process is complete.

NobelZygoma™ Bone Mill Guide (see Figure H) is temporarily fastened by hand to the implant via the implant connection and are used to guide the bone mill to the correct position and to limit the milling to a predefined depth. Two versions of the Bone mill guide exist, to support the 0° and 45° variants of the NobelZygoma™ TiUltra™ Implants.

The NobelZygoma™ Bone Mills are provided co-packed with the NobelZygoma™ Bone Mill Guides, and the NobelZygoma™ Bone Mill Guides are also available separately.

Figure H – NobelZygoma™ Bone Mill with Guide and Bone Mill Guide (Ext Hex and CC)

Instruments to support implant placement

NobelZygoma™ Handpiece Adapter

The NobelZygoma™ Handpiece Adapter (Figure I) is used to pick up a NobelZygoma™ TiUltra™ Implant when connected to its implant mount, and is connected to a dental handpiece, for insertion and initial placement.

Figure I – NobelZygoma™ Handpiece Adapter

NobelZygoma™ Handle

The NobelZygoma™ Handle (Figure J) connects to the implant mount for final placement of the NobelZygoma™ TiUltra™ Implant into the osteotomy.

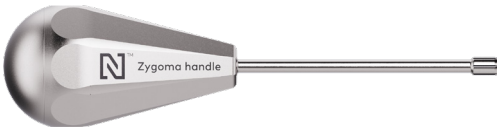


Figure J – NobelZygoma™ Handle

NobelZygoma™ Depth Indicator Straight and Angled

The NobelZygoma™ Depth Indicators Straight and Angled (Figure K) are used to verify the depth of the osteotomy during dental implant surgery. They feature numbered scales on the handle and shaft to verify the depth of the osteotomy and to support selection of the appropriate NobelZygoma™ TiUltra™ Implant length.

Figure K – NobelZygoma™ Depth Indicators Straight/Angled

Compatible devices

Nobel Biocare offers a comprehensive portfolio of dental devices, including other "legacy" zygomatic solutions. The compatibility, or incompatibility, of the devices belonging to this IFU (NobelZygoma™ TiUltra™ Implants, Multi-Unit Abutments Xeal™ Zygoma, NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws and NobelZygoma™ Instruments) to these legacy devices, is outlined in this section.

The NobelZygoma™ Instruments may be used in conjunction with the PureSet™ Zygoma Tray (Figure L). Please refer to the applicable Instructions for Use (IFU1067) for the tray at ifu.nobelbiocare.com. The placement of the devices in the PureSet™ Zygoma Tray is given by the NobelZygoma™ TiUltra™ PureSet™ Wallchart EU.

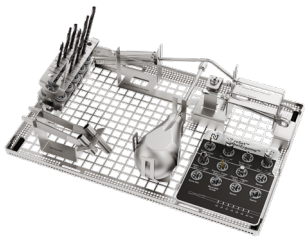


Figure L – PureSet™ Zygoma Tray

The following legacy Nobel Biocare zygomatic instruments are not compatible to the NobelZygoma™ TiUltra™ Implants:

- Zygoma Handle
- Connection to Handpiece
- Zygoma Depth Indicator Straight
- Zygoma Depth Indicator Angled

The Zygoma Drill Guards (Figure M) may be used during preparation of the osteotomy with the NobelZygoma™ Twist Drills and NobelZygoma™ Pilot Drills, acting as a protective shield between the rotating drill shaft and adjacent soft tissues. Please refer to Nobel Biocare Instructions for Use (IFU1095) at ifu.nobelbiocare.com for further information.

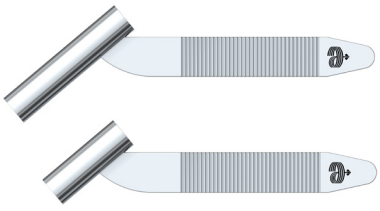


Figure M – Zygoma Drill Guard and Zygoma Drill Guard Short

The osteotomy of the NobelZygoma™ TiUltra™ Implant (device lengths 30-52.5 mm only) may be prepared using the Brånemark System Zygoma Twist Drills, Pilot Drills and Round Burr (see Table 2). Please refer to Nobel Biocare IFU1095 for further information.

Besides of the compatibilities outlined in Table 1, the NobelZygoma™ TiUltra™ Implants are only compatible to the legacy prosthetic devices and instrumentation defined in Table 2.

Caution The NobelZygoma™ TiUltra™ Implants are not compatible to other legacy multi-unit abutments from Nobel Biocare.

Table 2 – Compatibility of NobelZygoma™ TiUltra™ implants to legacy Nobel Biocare devices

Implant	Cover Screw plus Driver	Screwdriver	Healing Abutments	Drills
NobelZygoma™ 0° CC TiUltra™ RP Sizes 30-60 mm	Cover Screw CC RP Unigrip™ Screwdrivers	Screwdrivers Manual Unigrip™ 20, 28, 36 mm Screwdrivers Machine Unigrip™ 20, 25, 30, 35 mm Implant Drivers CC RP 28, 37 mm	Healing Abutments CC RP	Brånemark System® Zygoma Round Burr Brånemark System® Zygoma Twist Drill 2.9 mm Brånemark System® Zygoma Twist Drill 2.9 mm Short 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 Brånemark System® Zygoma Pilot Drill 3.5 mm short
NobelZygoma™ 45° Ext Hex TiUltra™ RP Sizes 30-60 mm	Brånemark System Zygoma Implant Cover Screw	Screwdrivers Manual Unigrip™ 20, 28, 36 mm Screwdrivers Machine Unigrip™ 20, 25, 30, 35 mm	Brånemark Syst Zygoma Healing Abutments	

Besides the compatibilities outlined in Table 1, the Multi-Unit Abutments Xeal™ Zygoma are only compatible to the legacy prosthetic devices, screws, and screwdrivers as defined in Table 3.

Caution The Multi-Unit Abutments Xeal™ Zygoma are not compatible to other legacy implants from Nobel Biocare.

Table 3 – Compatibility of Multi-Unit Abutments Xeal™ Zygoma to legacy Nobel Biocare devices

Multi-Unit Abutment Xeal™	Screw Drivers	Prosthetic Devices & Screws
Multi-Unit Abutment Xeal™ Zygoma Ext Hex RP Sizes S-XL	Screwdriver Manual Multi-Unit 25 mm Screwdriver Machine Multi-Unit 21 mm	Prosthetic Screw Multi-unit Prosthetic Screw Multi-Unit Abutment Omnigrip™ Mini NP/RP Healing Caps Multi-Unit Gold Coping Multi-Unit Temporary Coping Multi-unit Impression Coping Closed Tray Multi-Unit Abutment Plus Impression Coping Open Tray Multi-Unit Abutment Plus Temporary Snap Coping Multi-unit Plus Universal Base Non-Engaging Multi-unit Abutment NP/RP Position Locator Multi-Unit Abutment Intra-oral scanbody for Multi-Unit Abutment Level NP, RP Nobel Biocare Multi-unit PoLo Procera Implant Bar Overdentures Titanium (Multi-Unit Abutment Level only) Procera Implant Bridges Ti (Multi-Unit Abutment Level only) NobelProcera® Zr Implant Bridges (Multi-Unit Abutment Level only)
17° Multi-Unit Abutment Xeal™ Zygoma Ext Hex RP Sizes S-XL	Screwdrivers Manual Unigrip™ 20, 28, 36 mm Screwdrivers Machine Unigrip™ 20, 25, 30, 35 mm	
45° Multi-Unit Abutment Xeal™ Zygoma CC RP Sizes S-XL		
60° Multi-Unit Abutment Xeal™ Zygoma CC RP Sizes S-XL		

Intended Use/Intended Purpose

The NobelZygoma™ TiUltra™ Implants are intended for use as a dental implant in the zygomatic bone for anchoring or supporting dental prostheses to restore chewing function.

The Multi-unit Abutments Xeal™ Zygoma are intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

The NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws are intended for use to fasten dental implant system components to a dental implant or to another component.

The NobelZygoma™ Handle and NobelZygoma™ Handpiece Adapter are intended for use to insert or remove dental implants during dental implant surgery.

The NobelZygoma™ Twist Drills, NobelZygoma™ Pilot Drills, NobelZygoma™ Precision Drill, NobelZygoma™ Round Burr and NobelZygoma™ Lateral Burrs are intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

The NobelZygoma™ Depth Indicator Angled and NobelZygoma™ Depth Indicator Straight are intended for use to verify the depth of an osteotomy during dental implant surgery.

The NobelZygoma™ Bone Mill with Guide and NobelZygoma™ Bone Mill Guide:

The NobelZygoma™ Bone Mills are intended for use to remove bone surrounding a dental implant or connecting surface.

The NobelZygoma™ Bone Mill Guides are intended for use to guide drilling instruments used to remove bone surrounding the connecting surface of a dental implant.

Indications

NobelZygoma™ TiUltra™ Implants

The NobelZygoma™ 0° CC TiUltra™ and NobelZygoma™ 45° Ext Hex TiUltra™ Implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, to restore patient chewing function. Implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.

Multi-unit Abutments Xeal™ Zygoma

The Multi-unit Abutments Xeal™ Zygoma are indicated to support the placement of multiple units, screw-retained prosthetic restorations in the maxilla including full arch dentures.

NobelZygoma™ Multi-unit Abutment Xeal™ Zygoma Screws

The NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

NobelZygoma™ Handle

The NobelZygoma™ Handle is indicated for use to manually pick up and insert a NobelZygoma™ TiUltra™ implant into an osteotomy.

NobelZygoma™ Handpiece Adapter

The NobelZygoma™ Handpiece Adapter is indicated for use to connect an implant mount/implant assembly to a dental handpiece.

NobelZygoma™ Precision Drill

The NobelZygoma™ Precision Drill is indicated for use in the maxilla to prepare the entrance point for an osteotomy prior to implant placement.

NobelZygoma™ Round Burr

The NobelZygoma™ Round Burr is indicated for use to prepare an osteotomy in the zygomatic bone to support the placement of Nobel Biocare zygomatic dental implants.

NobelZygoma™ Lateral Burrs

The NobelZygoma™ Lateral Burrs are indicated for use to prepare an osteotomy in the zygomatic bone to support the placement of Nobel Biocare zygomatic dental implants.

NobelZygoma™ Twist Drills

The NobelZygoma™ Twist Drills are indicated for use to prepare an osteotomy in the zygomatic bone to support the placement of Nobel Biocare zygomatic dental implants.

NobelZygoma™ Pilot Drills

The NobelZygoma™ Pilot Drills are indicated for use to prepare an osteotomy in the zygomatic bone to support the placement of Nobel Biocare zygomatic dental implants.

NobelZygoma™ Depth Indicator Angled and NobelZygoma™ Depth Indicator Straight

The NobelZygoma™ Depth Indicator Straight and Angled are indicated for use to verify the depth of the osteotomy and to support selection of the appropriate zygomatic implant length.

NobelZygoma™ Bone Mill with Guide and NobelZygoma™ Bone Mill Guide

The NobelZygoma™ Bone Mill is indicated for use in conjunction with bone mill guides in the maxilla to remove excess bone from around the coronal aspect of a dental implant, in order to facilitate the subsequent placement of dental prosthetic components.

The NobelZygoma™ Bone Mill Guide is intended for use to guide drilling instruments used to remove bone surrounding the connecting surface of a dental implant.

Contraindications

The NobelZygoma™ TiUltra™ devices are contraindicated in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume for conventional implants and zygoma implant(s).
- 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 to be restored with single unit constructions.
- Patients who are allergic or hypersensitive to commercially pure titanium grade 4, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), Stainless Steel, DLC (Diamond Like Carbon) coating sodium dihydrogen phosphate (NaH_2PO_4), or magnesium chloride ($MgCl_2$).
- Patients who are allergic or hypersensitive to polypropylene (for the Multi-Unit Abutments Xeal™ Zygoma Straight Ext Hex RP only).

The 45° and 60° Multi-Unit Abutments Xeal™ Zygoma with conical connection are contraindicated for all implants other than NobelZygoma™ 0° CC TiUltra™ Implants.

The Straight and 17° Multi-Unit Abutments Xeal™ Zygoma with external hex are contraindicated for all implants other than NobelZygoma™ 45° Ext Hex TiUltra™ Implants.

Materials

NobelZygoma™ TiUltra™ Implants

Implant:
Commercially pure titanium grade 4 per ASTM F67, with sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Implant mount & Screw:
Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Multi-Unit Abutments Xeal™ Zygoma™

Straight Multi-Unit Abutments Xeal™ Zygoma

Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH_2PO_4), magnesium chloride ($MgCl_2$).

Handle:
PP (polypropylene).

Screw:
Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), DLC (Diamond Like Carbon) coating.

17°, 45° and 60° Multi-Unit Abutments Xeal™ Zygoma

Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH_2PO_4), and magnesium chloride ($MgCl_2$).

Handle:
Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium).

Screw:
Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), DLC (Diamond Like Carbon) coating.

NobelZygoma™ Multi-unit Abutment Xeal™ Zygoma Screw

Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating.

NobelZygoma™ Twist Drills & NobelZygoma™ Pilot Drills

Stainless steel 1.4197 according to ASTM F899, with DLC (Diamond Like Carbon) coating.

NobelZygoma™ Precision Drill, Round Burr and Lateral Burrs

Stainless steel 1.4197 according to ASTM F899.

NobelZygoma™ Handle and Handpiece Adapter

Stainless steel 1.4301 according to ASTM F899, and Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) grade 23.

NobelZygoma™ Depth Indicator Angled and Depth Indicator Straight

Stainless steel 1.4301 according to ASTM F899.

NobelZygoma™ Bone Mill with Guide and NobelZygoma™ Bone Mill Guide

Bone Mill:
Stainless steel 1.4197 according to ASTM F899, with DLC (Diamond Like Carbon) coating.

Bone Mill Guide:
Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Warnings

General Warnings

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures (e.g. sinus, Schneiderian membrane).

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, biological 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.

NobelZygoma™ TiUltra™ system devices must only be used with identified 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 the NobelZygoma™ TiUltra™ system 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.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

Devices marked with "CAS: 7440-48-4" contain Cobalt in a concentration more than 0.1% weight by weight. Cobalt is defined as a CMR 1B (carcinogenic, mutagenic and/or reprotoxic) substance. Current scientific evidence supports that the medical devices manufactured from stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

The device has not been evaluated in pediatric/adolescent patients, pregnant or breastfeeding women 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.

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 must 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.

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 and/or laboratory procedure must be maintained in good

condition and care must be taken that instrumentation does not damage implants or other components.

Zygomatic implant treatments could be performed under local anesthesia, IV-sedation, or general anesthesia.

At Surgery

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. gauze, dental dam, or 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 placement, 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, and 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.

If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

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

The NobelZygoma™ TiUltra™ system is to be used by dental health care professionals.

The NobelZygoma™ TiUltra™ system is to be used in edentulous or soon to be edentulous patients.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelZygoma™ TiUltra™ system

The NobelZygoma™ TiUltra™ system is a component 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 NobelZygoma™ TiUltra™ system

The placement of a dental implant constitutes an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. Drilling into the jaw or subsequent placement of the implant may also lead (in rare cases) to bone fracture, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances, depending on the location. During placement of an implant the pharyngeal (gag) reflex may be triggered in patients with a sensitive 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, ulcers, soft tissue hyperplasia, soft and/or hard tissue recession/loss. Some patients may experience discoloration in the mucosal area such as graying.

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

The placement of dental implant abutments and screws is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. During abutment placement or removal, the pharyngeal reflect (gag reflex) may be triggered in patients with a sensitive gag reflex.

Implant abutments are part 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 retained cement, calculus, mucositis, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. 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 NobelZygoma™ TiUltra™ Implants, the Multi-Unit Abutments Xeal™ Zygoma and NobelZygoma™ Multi-Unit Abutment Xeal™ Zygoma Screws. The SSCP can be obtained at the following website:

ec.europa.eu/tools/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
www.nobelbiocare.com/complaint-form

* Website available upon launch of the European Database on Medical Devices (EUDAMED)

Surgical Procedure

Pre-treatment guidelines

Bone resorption patterns and treatment options

It is very important to understand the degree of hard and soft tissue loss, as the degree of atrophy (Figure N) directs the restorative protocol. This means that the remaining alveolar bone directs the surgical protocol (Figure O), which in turn supports the restorative treatment plan.

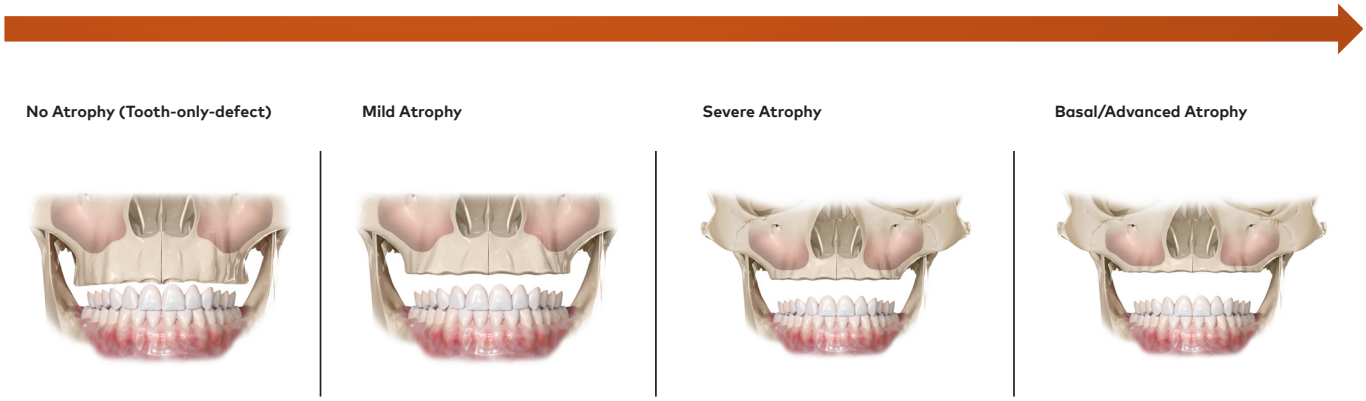


Figure N – Bone Resorption Patterns – Before Rehabilitation

[1] Davo R, Fan S, Wang F, Wu Y. Long-term survival, and complications of Quad Zygoma. Protocol with Anatomy-Guided Approach in severely atrophic maxilla: A retrospective follow-up analysis of up to 17 years. Clin Implant Dent Relat Res. 2023;1-13. doi:10.1111/cid.13296.

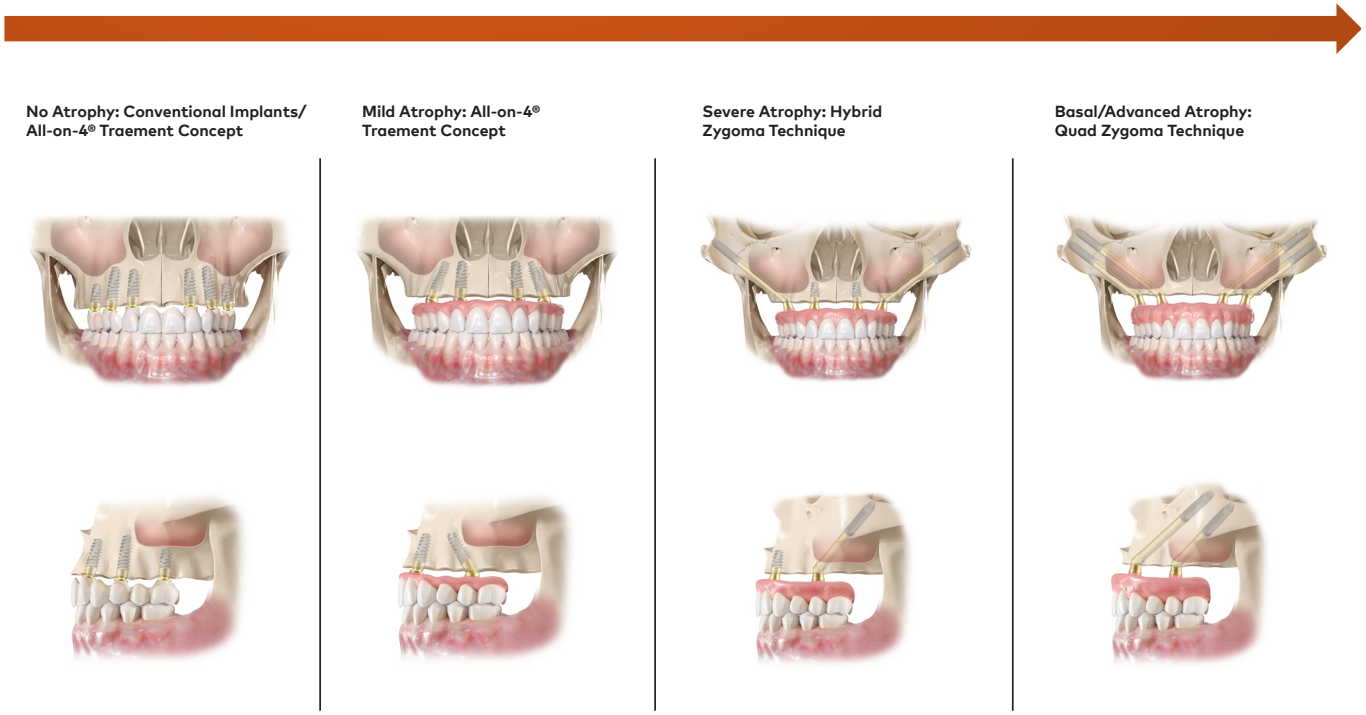


Figure O – Bone Resorption Patterns and Potential Rehabilitation Strategies

Hybrid Zygoma technique

In a treatment following the Hybrid Zygoma Technique (Figure P), two Zygoma implants are positioned posteriorly to emerge in the region of the first or second premolar. In the premaxilla region, a minimum of two dental implants are placed.

Note For a planned hybrid surgery, it is recommended to place anterior implants first, to confirm their stability prior to finalizing the placement of posterior zygoma implants.

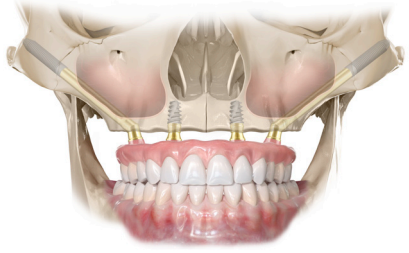


Figure P – Hybrid Zygoma Technique

Quad Zygoma technique

In a Quad Zygoma Technique (Figure Q) using only Zygoma implants, it is recommended to place two implants to emerge in the pre-molar region and two in the canine/lateral incisor region.

Note For a planned quad zygoma surgery, it is recommended to start placing the anterior implants while maintaining a safe distance to the orbital rim to protect the orbital floor. The posterior implant is placed after the anterior one, to avoid collision.

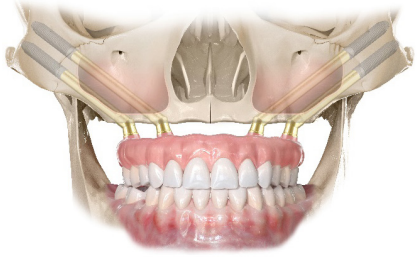


Figure Q – Quad Zygoma Technique

Anatomically guided approach

The objective of the installation is for the threaded part of the zygomatic implant (the apical portion) to be firmly anchored within the zygomatic bone, with the implant platform well positioned to support a prosthesis.

Caution Avoid excessive protrusion of the shaft or platform of the implant beyond the lateral wall of the maxillary sinus or the alveolar crest to minimize sinus-related complications or mucosal recession.

The optimal trajectory of the implant is thus influenced by the anatomical features of the maxillary-zygomatic complex such as the curvature of the maxillary wall and the degree of alveolar atrophy. The three surgical approaches indicated to best achieve this objective can be classified as:

- Intra-sinus
- Sinus slot (along the lateral wall of the maxilla)
- Extra-sinus

Digital planning may help to define the particular approach to be used in advance of surgery, and the use of an anatomically guided approach (see Figure R).

Incision

1. Incise slightly palatal (Figure S) of the crest to secure a sufficient amount of keratinized tissue of the edentulous maxilla with distal vertical releasing incision.
2. Reflect a full thickness mucoperiosteal flap to expose the lateral maxillary wall and the zygoma bone.
3. Design the surgical flap to incorporate thick palatal soft tissue to be repositioned buccal to the implant platform.

Note Whenever feasible, refrain from placing the incision buccally.

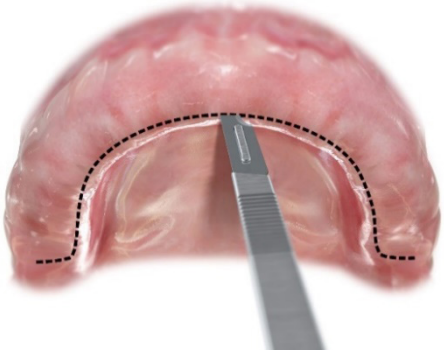


Figure S – Crestal Incision

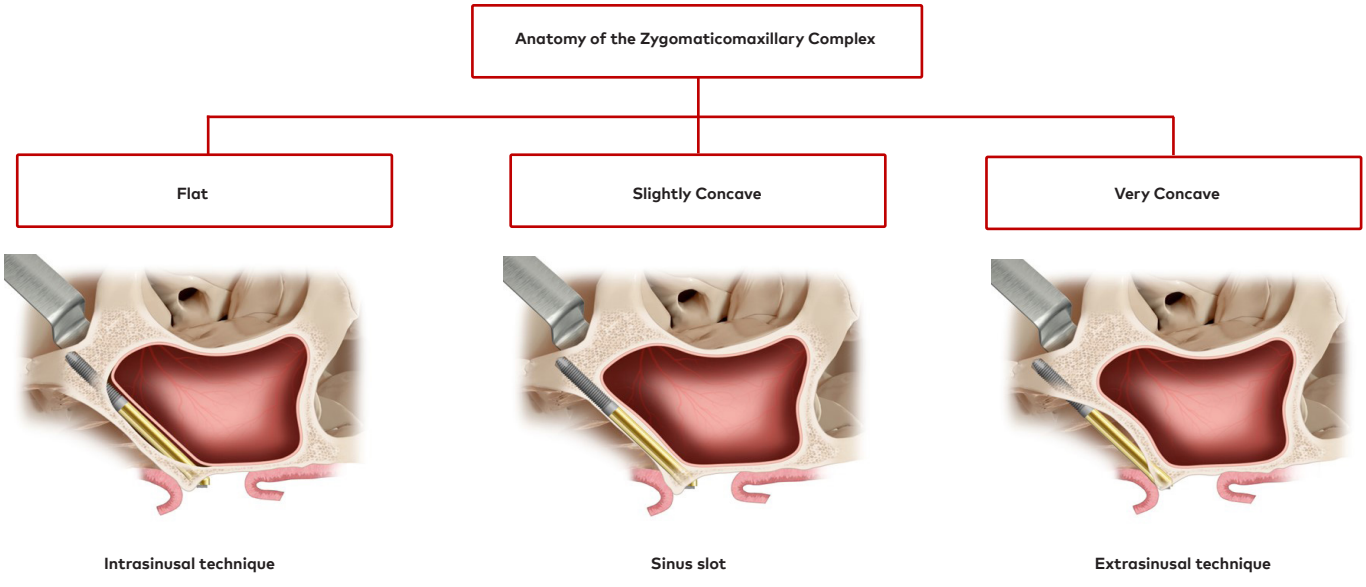


Figure R – Anatomically Guided Surgical Approach

Anatomical landmarks

Warning When performing exposure of the surgical site, it is imperative to be aware of vital structures including nerves, veins and arteries. Injuries to vital anatomic structures can lead to complications including injury to the eye as well as extensive bleeding and nerve-related dysfunction.

A comprehensive understanding of various anatomical reference points is crucial to prevent undesired surgical complications. Some key landmarks, as shown in Figure T, include:

1. Infraorbital foramen
2. Orbital floor angle
3. Frontozygomatic notch
4. Zygomaticomaxillary suture
5. Inferolateral border of the zygomatic bone – masseter muscular insertion
6. Posterior and lateral wall of the maxillary sinus
7. Infratemporal fossa
8. Nose angle

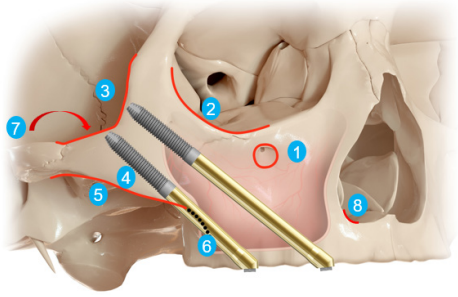


Figure T – Anatomical Landmarks

Initial orientation

Identification of the maxillary bone and infraorbital region

1. The visualization of the maxillary bone is generally performed from mesial to lateral and posteriorly.
2. Starting with the identification of the bony structure of the nasal cavity, nasal floor, and nasal angle, arriving apically to the infraorbital foramen (Figure U), find the position of the infraorbital rim and take precautions to safeguard it throughout the entire procedure.

Warning To avoid nerve damage it is crucial to identify and safeguard the infraorbital nerve.

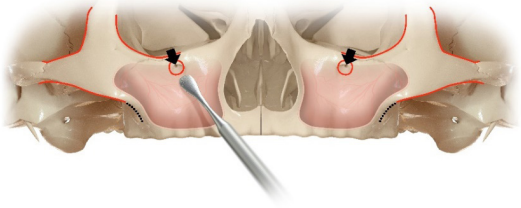


Figure U – Landmarks Identification – Maxillary Bone and Infraorbital Region

Laterally expose the body of the zygomatic bone

3. Dissect laterally over the buccal aspect of the zygomatic bone, finding the zygomaticomaxillary suture, extending up to the frontozygomatic notch (Figure V).
4. Caudally isolate and eventually detach (in rare cases) any fibers of the masseter muscle which impede access from the zygomatic bone.
5. Expose the inferolateral border of the maxillary bone until the body of the zygomatic bone.

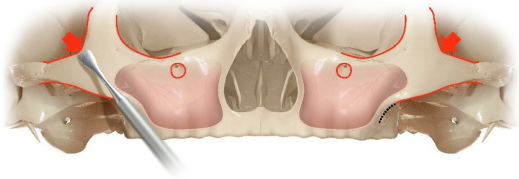


Figure V – Landmarks Identification – Body of the Zygomatic Bone

Identify surgical outcome of entry point and path of the implants

With reference to the virtual (digital) plan, identify the trajectory of the implant(s) along the lateral wall of the maxilla towards the frontozygomatic notch, preserving the integrity of noble structures (Figure W).

Caution While the trajectory of the Zygoma implants can be towards any point on the zygomatic bone, take into account potential collisions between two zygoma implants in case of a quad zygoma procedure, or in case of a hybrid zygoma procedure, the potential need for available space for implantation when converting to quad configuration in the future.

It is not necessary for the threaded tip of the implant to arrive up to the frontozygomatic notch.

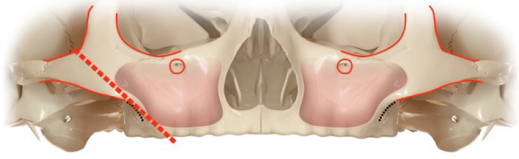


Figure W – Identification of Implant Trajectory

Osteotomy preparation

Guidelines for an effective drilling technique, applicable to all the three surgical approaches

1. Place a retractor to visualize the apical region of the zygomatic bone (corresponding to the emergence of the zygomatic implant).
2. Additionally, position the retractor in the frontozygomatic notch to enhance the visualization of the intended apical emergence points of the implant.
3. Once the dissection is complete, the following landmarks will be visible: angle of the nose, infraorbital foramen, maxilla-zygoma suture, masseter muscle insertion, and body of the zygomatic bone.
4. Find the correct entry point of the drill, to obtain the intrasinus osteotomy (when applicable), just palatal to the alveolar crest.

5. Utilize an in-and-out motion, drilling into the bone for 1 to 2 seconds at a time.

6. Employ the drill without stopping the handpiece motor. This ensures continuous irrigation to flush away debris.

Caution All drilling and bone preparation should be performed under copious irrigation and at a maximum speed of 2000 rpm.

7. Maintain copious irrigation with saline throughout the drilling process, upon completion of the sequence, and before removing the retractor (Figure X).

Drill Guard

Drill guards can help prevent injury to the tongue or lip from the drill shaft.

The surgeon and assistant should ensure the protection of these tissues throughout the procedure.

Note Drill guards are available in two lengths, as shown in Figure M.

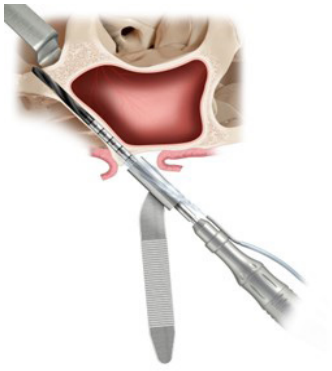


Figure X – Osteotomy Preparation with the NobelZygoma™ Drill

Caution Avoid applying lateral pressure on twist drills, as this may lead to device fracture and/or injury to the patient.

Warning Verify that all interconnecting instruments are securely locked before use. A loose drill may pose a risk of accidental harm to the patient or members of the surgical team and prevent accidental swallowing or aspiration of the device.

Warning Take care to avoid damaging critical/vital anatomical structures when drilling, either due to wrong trajectory or excessive depth, as this may incur permanent patient injury.

Depth verification system

All Drills (I-III) are available in a short and a long version, and can be used equally for the NobelZygoma™ 0° CC and NobelZygoma™ 45° Ext Hex TiUltra™ Implants.

All NobelZygoma™ Twist Drills are marked to facilitate the preparation of the site to the correct depth position (see Figure Y).

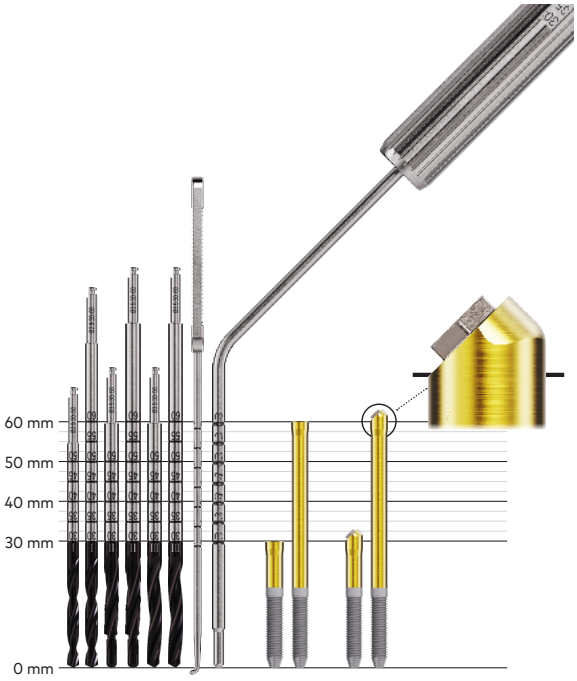


Figure Y – Depth Verification System

Brånemark intrasinusal technique

Goal: The intention of this approach is that the threaded portion of the implant is anchored in the zygomatic bone whilst the shaft of implant is housed within the sinus cavity.

Surgical access for intrasinus window

Optionally, creating an inspection window through the anterior wall of the maxillary sinus enables the location and gentle manipulation of the sinus mucosa, while providing a direct visual assessment of the inner aspect of the zygomatic bone.

In the case of the hybrid zygoma technique, a 10 x 5 mm window is created along the inferolateral border of the maxilla (Figure Z). For the quad zygoma technique, the window may be larger, extending further toward the direction of the inferior orbital border (Figure AA).

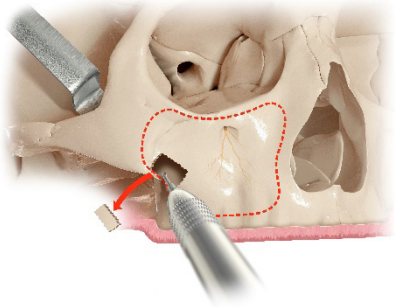


Figure Z – Intrasinus Window for Hybrid Zygoma

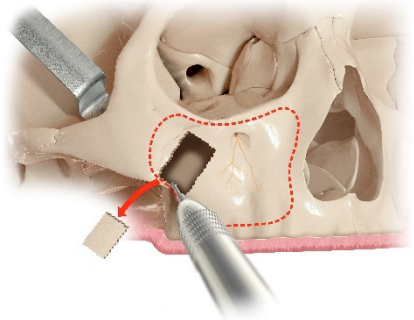


Figure AA – Intrasinus Window for Quad Zygoma

With careful dissection, the sinus mucosa can be identified, mobilized, and shifted away from the planned trajectory of the implants (Figure AB).

Caution Endeavor to preserve the integrity of the sinus/ Schneiderian membrane throughout this process.

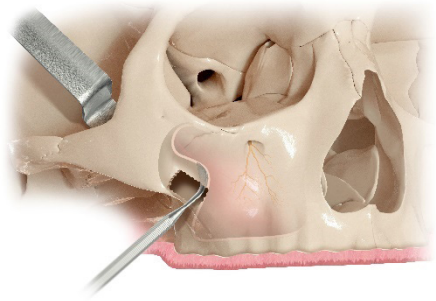


Figure AB – Identification of the sinus membrane

Osteotomy preparation

Management of the alveolar bone, entry point

It is recommended to start drilling in a safe area from the centre of the crest to 4 to 6 mm mesial to the crest in the palatal area.

Drilling Sequence

Drill using NobelZygoma™ Twist Drill 2.9 mm (Drill I)

To support ease of osteotomy creation (and avoid drill slipping/ skipping over the bone surface), an initial entry point for the drills may be created using either the NobelZygoma™ Round Burr or NobelZygoma™ Precision Drill.

Advance with NobelZygoma™ Twist Drill 2.9 mm along the identified trajectory until it penetrates the outer cortical layer of the zygomatic bone (Figure AC).

Ensure direct visualization of the body of the zygomatic bone or feel the tip of the drill with the tip of your finger.

Caution All drilling and bone preparation should be performed under copious irrigation and at a maximum speed of 2000 rpm.

Caution Be attentive to the drill markings to prevent excessive drilling.

Caution In cases where part of the drill may pass through the sinus, consider the use of the small window to avoid damage the integrity of the membrane.

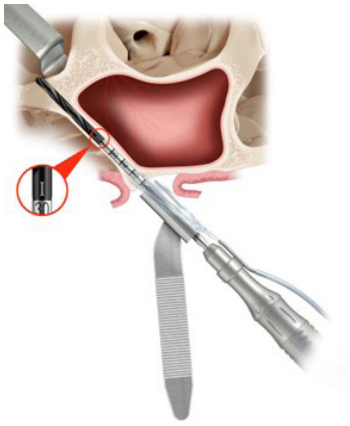


Figure AC – Drill using NobelZygoma™ Twist Drill 2.9 mm (Drill I)

Evaluate osteotomy length to avoid protrusion beyond the zygomatic bone

Insert the NobelZygoma™ Depth Indicator Straight into the osteotomy path until the angled tip securely hooks onto the outer surface of the zygomatic bone (Figure AD).

Subsequently, the implant length appropriate for the osteotomy can be determined from the markings on the indicator.

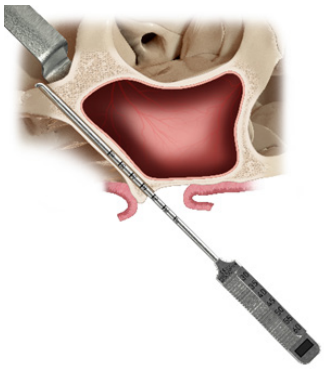


Figure AD – Evaluation of the osteotomy length using NobelZygoma™ Straight Depth Indicator

Widen and finalize the osteotomy with NobelZygoma™ Pilot Drill 3.5 mm and Twist Drill 3.5mm

Utilize NobelZygoma™ Pilot Drill 3.5 mm (Drill II) to engage the original osteotomy created by NobelZygoma™ Twist Drill Ø2.9 mm (Drill I), (Figure AE). The NobelZygoma™ Pilot Drill 3.5 mm will perform a partial 3.5 mm osteotomy through the zygoma body.

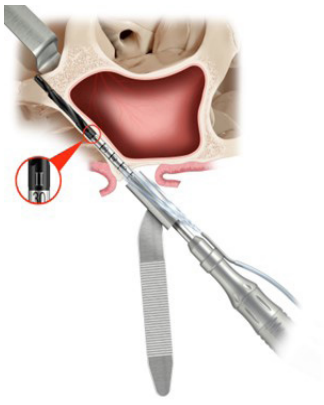


Figure AE – Widen the osteotomy with NobelZygoma™ Pilot Drill 3.5 mm (Drill II)

Use NobelZygoma™ Twist Drill 3.5 mm (Drill III) to finalise the osteotomy preparation (see Figure AF).

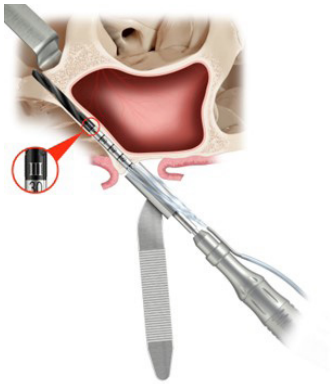


Figure AF – Finish the osteotomy with NobelZygoma™ Twist Drill 3.5 mm (Drill III)

Caution Ensure correct angulation and avoid drill wobble, as this can inadvertently widen the preparation site. Before placing the implant, irrigate to clear debris from the field.

Caution Incomplete preparation of the osteotomy may result in excessive insertion torque for the implant and may result in fracture of the zygomatic bone and/or pressure necrosis.

Verify implant length

Verify the required implant length with either the NobelZygoma™ Depth Indicator Angled (see Figure AG) or NobelZygoma™ Depth Indicator Straight (see Figure AD).

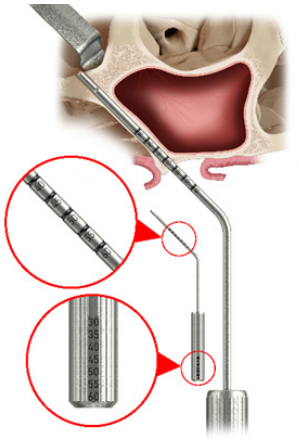


Figure AG – Verification of the required implant length using NobelZygoma™ Depth Indicator Angled

Note It is possible to gauge the depth of the tip of NobelZygoma™ Depth Indicator Angled by palpating the skin over the zygomatic bone, or by direct visualization of the bone.

An appropriate crestal emergence of the zygomatic implant must be achieved to align with prosthetic objectives.

Final rinsing after completing the osteotomy drilling trajectories for Intrasinusal implant placement

When the osteotomy is completed, thoroughly rinse the intrasinusal cavity, the inner aspect of the zygomatic bone, and the outer aspect of the zygomatic bone with a saline solution, to prevent infection related to the accumulation of debris following drilling procedures (see Figure AH).

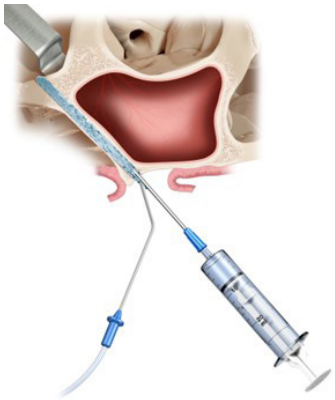


Figure AH – Final Rinsing

Sinus Slot Technique

Goal: The intention is that the threaded portion of the implant is anchored in the zygomatic bone whilst the shaft of implant is housed within a groove or 'slot' extending from the base of the zygoma and running along the lateral wall of the maxillary sinus towards the alveolar crest.

Management of the alveolar bone, entry point and design of the groove (slot)

1. The design of the groove is established with the virtual plan.

2. To create the groove, the lateral wall of the maxilla is penetrated below the zygomatic buttress with either the NobelZygoma™ Round Burr or Precision Drill. A second hole is made along this line, approximately 5 mm above the crest of the alveolar ridge (Figure AI).

Note The precision drill can be employed to create a notch in the zygomatic bone.

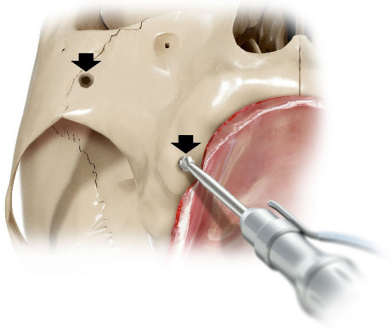


Figure AI – Sinus Slot Technique: Entry Point Preparation with the Round Burr

Caution All drilling and bone preparation should be performed under copious irrigation and at a maximum speed of 2000 rpm.

Prepare groove for implant placement (Optional)

1. The two prepared holes are then connected with a slot/groove, which continues through to the alveolar crest to receive the coronal part of the implant, by using the NobelZygoma™ Lateral Burr Coarse then NobelZygoma™ Lateral Burr Fine. Using the blunt tip of the NobelZygoma™ Lateral Burr in the notch, perform a side-cutting milling operation to prepare an unimpeded path for seating of the Zygoma implant (Figure AJ).

Note The side-cutting lateral burrs are designed to create a channel for the implant.

Note It is desirable to conserve bone at the crest of the ridge where possible. Therefore, the use of the lateral burrs may not be appropriate in all cases.

Caution The NobelZygoma™ Lateral Burrs Coarse and Fine should be used sequentially (Coarse followed by Fine) to prevent over-reaming of the bone and avoid exposure/damage to the sinus membranes.

2. The groove should be sized to neatly fit the implant to avoid protrusion of the coronal part of the implant beyond the crest, avoiding pressure on the mucosa.

3. Consider using a small window to lift away the sinus mucosa. Take care to protect and conserve the sinus membrane – although the implant can still be placed if the integrity of the membrane is compromised.

Caution Use copious irrigation when preparing the osteotomy with the Lateral Burrs to prevent overheating of the device tip. Overheating may lead to localised tissue damage and reduce the potential for osseointegration of the zygoma implants.

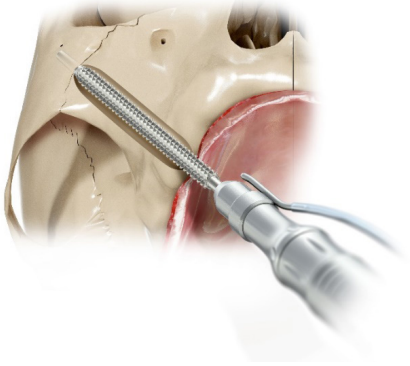


Figure AJ – Sinus Slot Technique - Creation of the Slot with Lateral Burrs

Osteotomy Preparation

Drill using NobelZygoma™ Drill I (Twist Drill 2.9 mm)

To support ease of osteotomy creation (and avoid drill slipping/skipping over the bone surface), an initial entry point for the drills may be created using either the NobelZygoma™ Round Burr or NobelZygoma™ Precision Drill.

The tip of the drill is guided along the slot and advanced superiorly toward the zygomatic bone to prepare the implant osteotomy (Figure AK).

Caution Place the reference point to locate the osteotomy within the bulk of the zygoma to avoid fracture of the lateral bone plate.

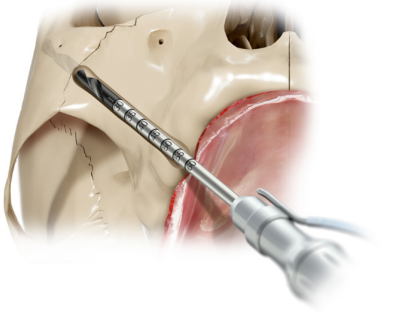


Figure AK – Drill using NobelZygoma™ Twist Drill 2.9 mm (Drill I)

Widen the osteotomy with NobelZygoma™ Drill II (Pilot Drill 3.5 mm) per Figure AL

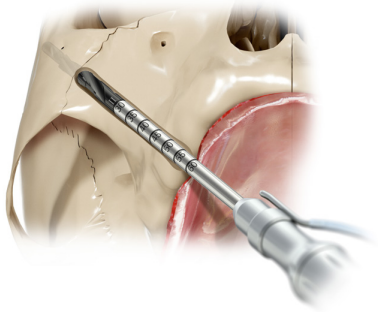


Figure AL – Widen the osteotomy with NobelZygoma™ Pilot Drill 3.5 mm (Drill II)

Finish the osteotomy preparation with NobelZygoma™ Drill III (Twist Drill 3.5 mm)

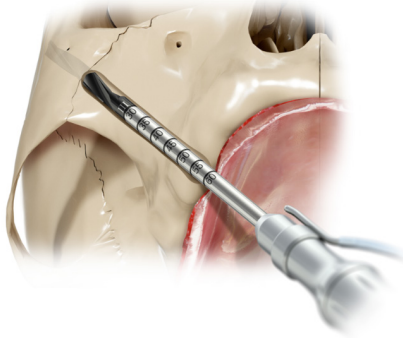


Figure AM – Finish the osteotomy preparation with NobelZygoma™ Twist Drill 3.5 mm (Drill III)

Verify the required implant length with either the NobelZygoma™ Depth Indicator Angled (see example in Figure AG) or NobelZygoma™ Depth Indicator Straight (see example in Figure AD).

Note It is possible to gauge the depth of the tip of NobelZygoma™ Depth Indicator Angled by palpating the skin over the zygomatic bone, or by direct visualization of the bone (see Figure AG).

An appropriate crestal emergence of the zygomatic implant must be achieved to align with prosthetic objectives (see example in Figure AN).

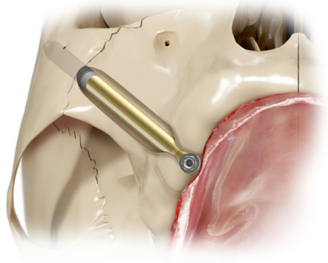


Figure AN – Implant Positioning with Sinus Slot Technique

Final rinsing after completing the osteotomy drilling trajectories for Sinus Slot implant placement

When the osteotomy is completed, thoroughly rinse the intrasinusal cavity, the inner aspect of the zygomatic bone, and the outer aspect of the zygomatic bone with a saline solution, to prevent infection related to the accumulation of debris following drilling procedures (see example in Figure AH).

Extrasinus technique

Goal: By employing this method, zygomatic implants are primarily positioned externally to the sinus cavity, with the coronal portion nestled within a groove in the maxilla, while a segment of the body extends outward along the lateral wall of the maxilla.

Management of the alveolar bone, entry point

The zygoma implant finds anchorage in the zygomatic bone and within a groove traversing the residual alveolar process and the lower aspect of the maxilla's lateral wall.

The amount of allocation of the implant within the inferior maxilla may vary based on the curvature of the maxilla, resulting in a considerable portion of the implant located beyond the sinus and lateral wall of the maxilla.

Caution All drilling and bone preparation should be performed under copious irrigation and at a maximum speed of 2000 rpm.

1. The initial perforation is performed using the NobelZygoma™ Round Burr at the level of the alveolar crest to create a groove to house the coronal part of the implant (Figure AO).

2. Subsequently, the tip of the round burr (or the precision drill) is guided towards the zygomatic bone (a window can facilitate the procedure), and utilizing the device's tip, a reference point is marked at the desired insertion site within the inner aspect of the zygomatic bone.

Caution Place the reference point far enough from the outer edge of the zygomatic bone to avoid fracturing the bone plate.

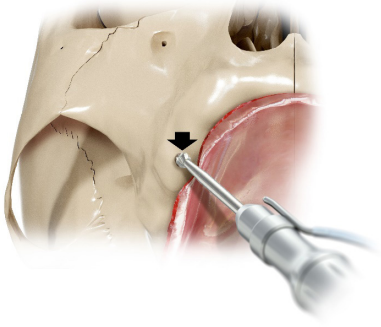


Figure AO – Extrasinus Technique: Initial Perforation with Round Burr

Prepare groove for implant placement (Optional)

1. The NobelZygoma™ Lateral Burrs Coarse and Fine are used to prepare the slot/groove in the inferior lateral wall of the maxilla. Using the blunt tip of the NobelZygoma™ Lateral Burr in the notch, perform a side-cutting milling operation to prepare an unimpeded path for seating of the Zygoma implant.

Note The side-cutting lateral burrs are designed to create a channel for the implant.

Note It is desirable to conserve bone at the crest of the ridge where possible. Therefore, the use of the lateral burrs may not be appropriate in all cases.

Caution The NobelZygoma™ Lateral Burrs Coarse and Fine should be used sequentially (Coarse followed by Fine) to prevent over-reaming of the bone and avoid exposure/damage to the sinus membranes (Figure AP).

2. The groove should be sized to neatly fit the implant to avoid protrusion of the coronal part of the implant beyond the crest, avoiding pressure on the mucosa.

3. Consider using a small window to lift away the sinus mucosa. Take care to protect and conserve the sinus membrane – although the implant can still be placed if the integrity of the membrane is compromised.

Caution In cases where part of the implant may pass through the sinus, consider using a small window to lift away the sinus mucosa, helping to preserve its integrity.

Caution Use copious irrigation when preparing the osteotomy with the Lateral Burrs to prevent overheating of the device tip. Overheating may lead to localised tissue damage and reduce the potential for osseointegration of the zygoma implants.

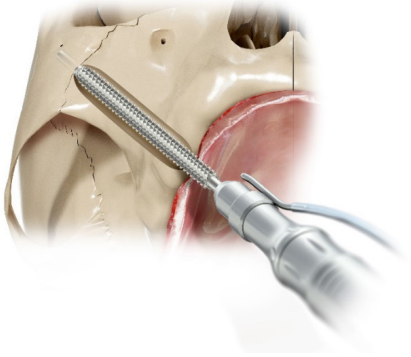


Figure AP – Extrasinus technique: Groove preparation with the NobelZygoma™ Lateral Burr Coarse

Osteotomy preparation

Drilling sequence

To support ease of osteotomy creation (and avoid drill slipping/skipping over the bone surface), an initial entry point for the drills may be created using either the NobelZygoma™ Round Burr or NobelZygoma™ Precision Drill.

The drill assortment is used to prepare the slot/groove in the inferior lateral wall of the maxilla and the osteotomy at the zygoma.

Note The groove in the maxilla goes through the remnant alveolar bone in order to receive the coronal part of the implant and it should be sufficiently deep and wide to house it.

Caution The coronal part of the implant should not protrude beyond the crest to avoid pressure on the mucosa. Design the surgical flap to incorporate thick palatal soft tissue to be repositioned buccal to the implant platform. Consider using a small window to lift away the sinus mucosa.

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.

Drill using NobelZygoma™ Twist Drill 2.9 mm (Drill I) per Figure AQ

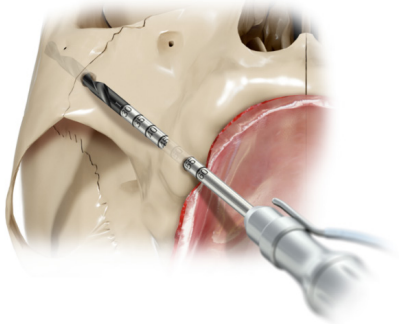


Figure AQ – Drill using NobelZygoma™ Twist Drill 2.9mm (Drill I)

Widen the osteotomy with NobelZygoma™ Pilot Drill 3.5 mm (Drill II) per Figure AR

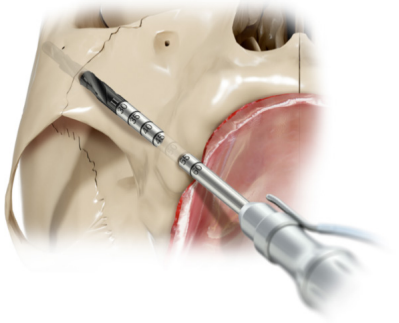


Figure AR – Widen the osteotomy with NobelZygoma™ Pilot Drill 3.5 mm (Drill II)

Finish the osteotomy preparation with NobelZygoma™ Twist Drill 3.5 mm (Drill III) per Figure AS

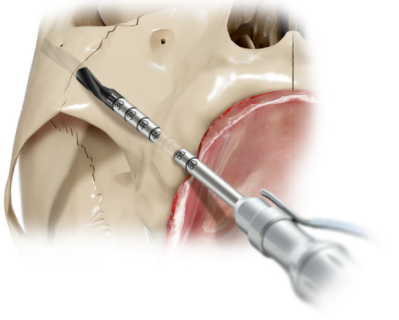


Figure AS – Finish the osteotomy preparation with NobelZygoma™ Twist Drill 3.5 mm (Drill III)

Verify the required implant length with either the NobelZygoma™ Depth Indicator Angled (see example in Figure AG) or NobelZygoma™ Depth Indicator Straight (see example in Figure AD).

Note It is possible to gauge the depth of the tip of NobelZygoma™ Depth Indicator Angled by palpating the skin over the zygomatic bone, or by direct visualization of the bone.

An appropriate crestal emergence of the zygomatic implant must be achieved to align with prosthetic objectives (see example in Figure AT).

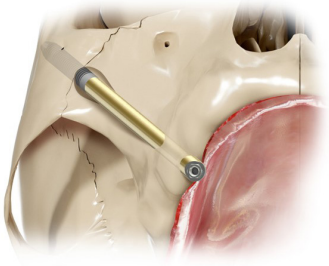


Figure AT – Extrasinus Technique: Implant Positioning

Final rinsing after completing the osteotomy drilling trajectories for Extrasinus implant placement

When the osteotomy is completed, thoroughly rinse the intrasinusal cavity, the inner aspect of the zygomatic bone, and the outer aspect of the zygomatic bone with a saline solution, to prevent infection related to the accumulation of debris following drilling procedures (see example in Figure AH).

Zygomatic Implant insertion

Prepare handpiece and pick up Zygoma Implant

Attach the NobelZygoma™ Handpiece Adapter to the Handpiece (Figure AU).

Warning Ensure that devices are securely locked in the handpiece before initiating use. A loose device may pose a risk of accidental harm to the patient or members of the surgical team. Verify that all interconnecting instruments are securely locked before use to prevent accidental swallowing or aspiration.

Figure AU – Preparation of the Handpiece

Unpack and pick-up the implant

Engage the implant mount with the Handpiece adapter and pick up the implant (Figure AV).

Figure AV – Pick-up of the NobelZygoma™ TiUltra™ Implants from the packaging sleeve

Insertion of NobelZygoma™ 45° Ext Hex TiUltra™ Implant

Implant insertion with drilling unit

Note Confirm that the screw connection between the zygoma implant and implant mount is secure prior to installation. If the connection is deemed loose, hand tighten using the Unigrip™ Screwdriver.

Caution Take care to ensure that the screw does not drop into the patient's mouth during removal, as it may lead to it being swallowed or aspirated.

Caution During insertion of Zygoma implant, apply controlled axial force to engage the zygomatic bone. Under applied axial force, the implant may experience an uncontrolled and sudden jump forward as the threaded section of the implant disengages from the maxillary crest.

1. Confirm the correct insertion angle of the implant while progressing past the sinus until the implant apex engages in the zygomatic bone.

2. Insert the implant using the handpiece adapter into the prepared bone site with a maximum speed of 25 RPM and a maximum torque setting of 40 Ncm (Figure AW).

Note For immediate function, the implants should be able to withstand a final torque of at least 35 Ncm.

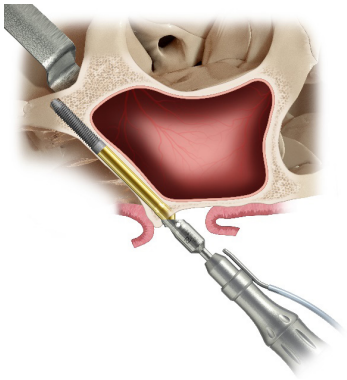


Figure AW – Insertion of the NobelZygoma™ 45° Implant with drilling unit and NobelZygoma™ Handpiece Adapter

Tighten 45° Implant Manually

1. The NobelZygoma™ Handle may be used to manually tighten the implant to the proper insertion depth and orientation of the platform.

2. Disengage the Connection to Handpiece from the implant mount and connect the NobelZygoma™ Handle to the implant mount (Figure AX).

3. Rotate the NobelZygoma™ Handle clockwise until the desired depth and orientation of the platform are achieved. The 45° implant platform can be accurately positioned by observing the black lines on the NobelZygoma™ Handle, and the emergence direction of the implant mount screw. They indicate the planes of the projection of the multi-unit abutment angulations. (Figure AX).

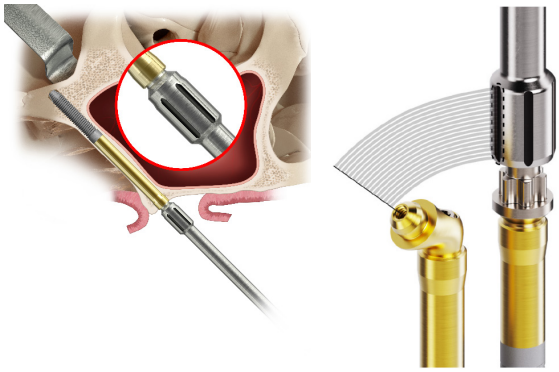


Figure AX – Tightening of the NobelZygoma™ 45° TiUltra™ Implant manually, and alignment of NobelZygoma™ Handle markings with plane of projection of the multi-unit abutments

Caution When using the NobelZygoma™ Handle and Handpiece Adapter, applying excessive torque, or bending loads can distort the implant head or fracture the implant mount and/or the implant mount screw. To prevent possible damage of the head or of the implant mount, it is advisable to perform controlled in and out axial movements; the backward action of the implant allows the elastic response of the bone, enabling the forward movement.

The 45° implant platform can be accurately positioned by observing the screw that locks the implant mount to the implant.

The implant mount screw position marks the future position of the abutment screw. Ideally, its position needs to be perpendicular to the occlusal plane, verifying the correct position of the implant platform by placing Screwdriver Manual Unigrip™ into the screw head of the implant mount (Figure AY).

Note Compatible multi-unit abutments can make corrections of 17° compared to the emergence angle of the 45° Implants.

Note Align the shaft of the screwdriver to be perpendicular to the crest of the ridge.

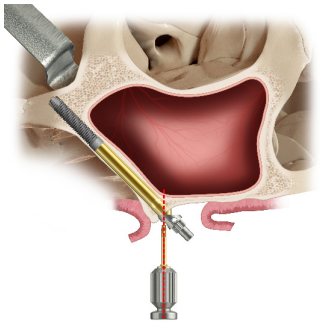


Figure AY – Verification of Implant Orientation

Remove NobelZygoma™ 45° implant mount

1. Secure the implant mount with a surgical suture through the tool's hole (Figure AZ).

2. Unscrew the screw of the implant mount with machine Unigrip™ Screwdriver using the contra-angle or torque wrench.

3. If necessary, gently ease the implant mount from side to side to ensure that it does not bind on the implant head.

4. Carefully remove the screw from the implant mount and then remove the implant mount.

Caution Take care to ensure that the screw does not drop into the patient's mouth during removal, as it may lead to it being swallowed or aspirated.

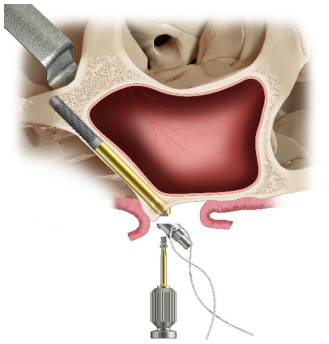


Figure AZ – Removal of the NobelZygoma™ 45° Implant Mount

Utilization of NobelZygoma™ 45° Implant Bone Mill with Guide and Bone Mill Guide

For the cases in which immediate loading is performed, following implant placement, the use of a bone mill with a bone mill guide is recommended to facilitate the removal of bone impinging upon the implant platform.

When performing delayed loading for the NobelZygoma™ TiUltra™ Implant, without placement of the multi-unit abutment, protect the platform connection by placing a compatible cover screw or healing abutment.

1. If applicable, remove the cover screw.

Caution Take care to ensure that the cover screw does not drop into the patient's mouth during removal, as it may lead to it being swallowed or aspirated.

2. Attach the bone mill guide dedicated to the NobelZygoma™ 45° TiUltra™ Implant and hand-tighten using the Screwdriver Manual UniGrip™ (Figure BA).

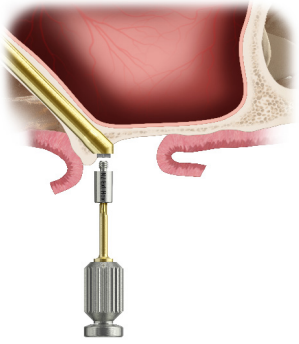


Figure BA – Place NobelZygoma™ 45° Implant Bone Mill with Guide

Caution Overtightening the screw may cause damage or fracture to the inner threads of the implant, causing implant damage or preventing disassembly.

3. Connect the bone mill to the handpiece. Before starting the machine, position the bone mill over the bone mill guide (Figure BB).

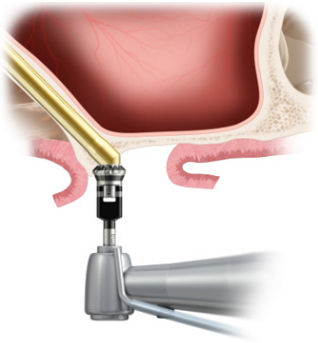


Figure BB – Utilization of NobelZygoma™ 45° Implant Bone Mill with Guide and Bone Mill Guide

Note The bone mill features an upper window for visual inspection, aiding in determining when the bone mill is fully seated on the bone mill guide.

4. Start milling at a low speed (not exceeding 100 rpm) and ensure generous irrigation.

Caution Avoid applying bending forces during bone milling procedure to prevent collisions with the bone mill guide.

5. The height markings on the bone mill are in 1 mm increments.

One-stage, Immediate Function

Provisionalize the implant for Immediate Function at the abutment level by fabricating a provisional bridge using Nobel Biocare multi-unit abutments in combination with Temporary Copings Multi-Unit (Figure BC).

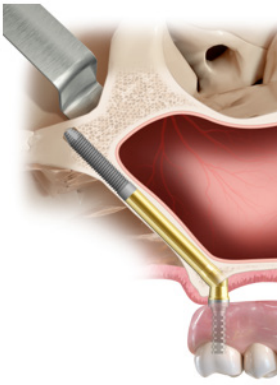


Figure BC – One-stage Immediate Function

Two-stage, Early/Delayed Function

Use the Cover Screwdriver Brånemark System Hexagon to connect the cover screw to the NobelZygoma™ 45° Implant.

Using Hand-tightening only, ensure the screw is fully seated to avoid bone ingrowth.

Caution Tighten the cover screw only finger-tight to avoid excessive loads that might damage the cover screw parts or the implant connection.

Caution Take care to ensure that the cover screw does not drop into the patient's mouth during installation, as it may lead to it being swallowed or aspirated.

Two-stage flap closure, reline denture and healing

1. Close and suture the tissue flap around the implant (see Figure BD).

2. Adjust and soft reline the patient's full upper denture (see Figure BE).

Wait for sufficient healing

3. Allow for the implants to osseointegrate before the second-stage surgery (exposure of implants).

Note Ensure to relieve the denture intaglio (tissue) surface to avoid contact between the implant and denture. Confirm that the flange of the denture does not impinge on the shaft of the implant.

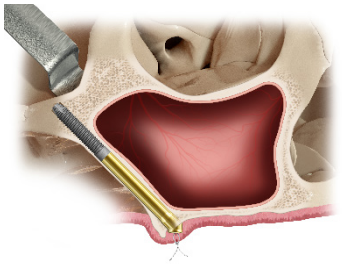


Figure BD – Two-stage flap closure and healing for the NobelZygoma™ 45° Implant

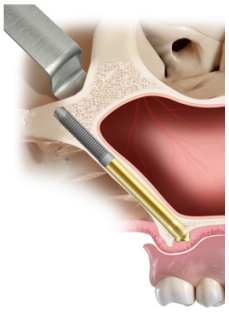


Figure BE – Two-stage Delayed Function

Insertion of NobelZygoma™ 0° CC TiUltra™ Implant

Implant insertion with drilling unit

Note Confirm that the screw connection between the Zygoma implant and implant mount is secure prior to installation. If the connection is deemed loose, hand tighten using the Unigrip™ Screwdriver.

Caution During insertion of Zygoma implant, apply controlled axial force to engage the zygomatic bone. Under applied axial force, the implant may experience an uncontrolled and sudden jump forward as the threaded section of the implant disengages from the maxillary crest.

1. Confirm the correct insertion angle of the implant while progressing past the sinus until the implant apex engages in the zygomatic bone.

2. Insert the implant into the prepared bone site with a maximum speed of 25 RPM and a maximum torque setting of 40 Ncm (Figure BF).

Note For immediate function, the implants should be able to withstand a final torque of at least 35 Ncm.

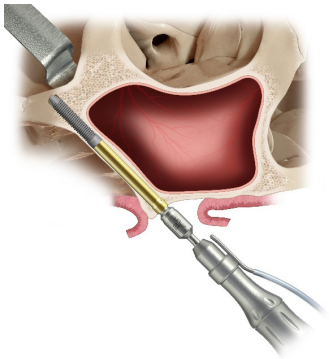


Figure BF – Insertion of the NobelZygoma™ 0° Implant with Drilling Unit

Tighten 0° Implant Manually

1. The NobelZygoma™ Handle may be used to manually tighten the implant to the proper insertion depth and orientation of the platform.

2. Disengage the Connection to Handpiece from the implant mount and connect the NobelZygoma™ Handle to the implant mount.

3. Rotate the NobelZygoma™ Handle clockwise until the desired depth and orientation of the platform are achieved (Figure BG). The 0° implant platform can be accurately positioned by observing the black lines on the NobelZygoma™ Handle, which indicate the planes of projection of the multi-unit abutment angulations.

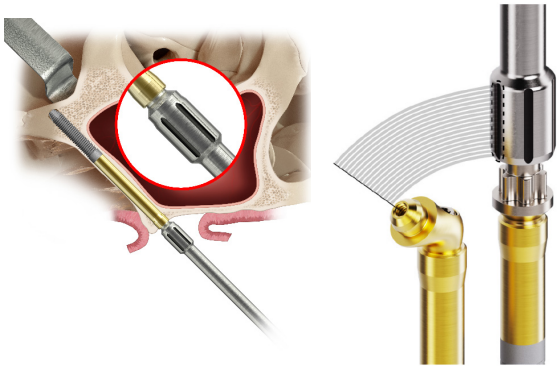


Figure BG – Tightening of the NobelZygoma™ 0° CC TiUltra™ Implant manually, and alignment of NobelZygoma™ Handle markings with plane of projection of the multi-unit abutments

Caution When using the NobelZygoma™ Handle and Handpiece Adapter, applying excessive torque, or bending loads can distort the implant head or fracture the implant mount and/or the implant mount screw. To prevent possible damage of the head or of the implant mount, it is advisable to perform controlled in and out axial movements; the backward action of the implant allows the elastic response of the bone, enabling the forward movement.

Remove NobelZygoma™ 0° CC TiUltra™ implant mount

1. Unscrew the screw of the implant mount with Screwdriver Manual Unigrip™ (Figure BH) or Screwdriver Machine Unigrip™ Screwdriver using the contra-angle or torque wrench.

2. If necessary, gently ease the implant mount from side to side to ensure that it does not bind on the implant head.

3. Carefully remove the screw from the implant mount and then remove the implant mount.

Caution Take care to ensure that the screw does not drop into the patient's mouth during removal, as it may lead to it being swallowed or aspirated.

Caution If the implant insertion torque is low, then to prevent rotation of the implant consider stabilizing the implant mount with a clamp during the removal.

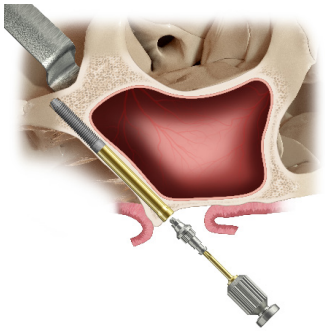


Figure BH – Removal of the NobelZygoma™ 0° CC TiUltra™ Implant Mount

Utilization of NobelZygoma™ 0° CC TiUltra™ Bone Mill with Guide and Bone Mill Guide

For the cases in which immediate loading* is performed, following implant placement, the use of a bone mill with a bone mill guide is recommended to facilitate the removal of bone impinging upon the implant platform.

When performing delayed loading for the NobelZygoma™ TiUltra™ Implant, without placement of the multi-unit abutment, protect the platform connection by placing a compatible cover screw or healing abutment.

1. If applicable, remove the cover screw.

Caution Take care to ensure that the cover screw does not drop into the patient's mouth during removal, as it may lead to it being swallowed or aspirated.

2. Attach the bone mill guide dedicated to the NobelZygoma™ 0° CC TiUltra™ Implant to the implant and tighten it finger-tight using a Screwdriver Manual UniGrip™ (Figure BI).

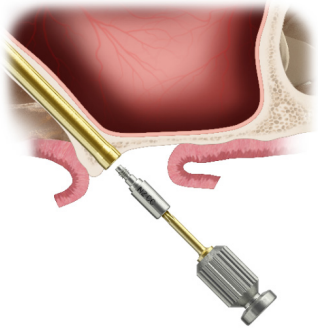


Figure BI – Installation of NobelZygoma™ 0° CC TiUltra™ Bone Mill with Guide

Caution Overtightening the screw may cause damage or fracture to the inner threads of the implant, causing implant damage or preventing disassembly.

3. Connect the bone mill to the handpiece. Before starting the machine, position the bone mill over the bone mill guide (Figure BJ).

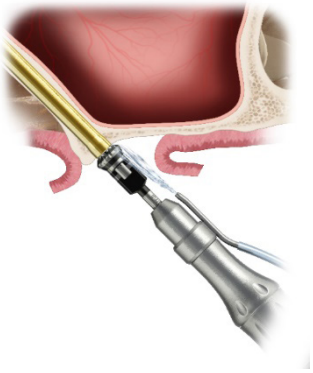


Figure BJ – Utilization of NobelZygoma™ 0° CC TiUltra™ Bone Mill with Guide and Bone Mill Guide

Note The bone mill features an upper window for visual inspection, aiding in determining when the bone mill is fully seated on the bone mill guide.

4. Start milling at a low speed (not exceeding 100 rpm) and ensure generous irrigation.

Caution Avoid applying bending forces during bone milling procedure to prevent collisions with the bone mill guide.

5. The height markings on the bone mill are in 1 mm increments.

One-stage Immediate Function

Provisionalize the implant for immediate function at the abutment level by fabricating a provisional bridge using Nobel Biocare multi-unit abutments in combination with Temporary Copings Multi-unit (Figure BK).

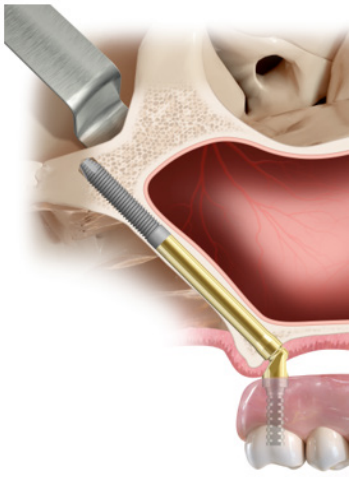


Figure BK – One-stage Immediate Function

Two-stage Delayed Function

1. Use the Unigrip™ Screwdriver to connect the cover screw.

Caution Take care to ensure that the cover screw does not drop into the patient's mouth during installation, as it may lead to it being swallowed or aspirated.

2. Ensure the screw is fully seated to avoid bone ingrowth (hand-tightening only).

Caution Tighten the cover screw only finger-tight to avoid excessive loads that might damage the cover screw parts or the implant connection.

Two-stage flap closure, reline denture and healing

3. Close and suture the tissue flap around the implant (see Figure BL).

4. Adjust and soft reline the patient's full upper denture (see Figure BM).

Wait for sufficient healing

5. Allow for the implants to osseointegrate before the second-stage surgery (exposure of implants).

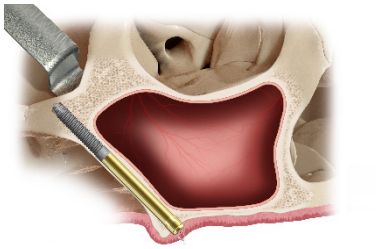


Figure BL – Two-stage Flap Closure and Healing for the NobelZygoma™ 0° Implant

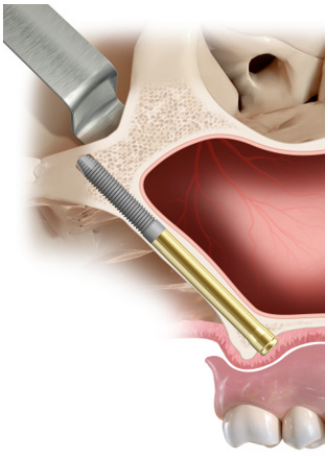


Figure BM – Two-stage Delayed Function

Note Ensure to relieve the denture intaglio (tissue) surface to avoid contact between the implant and denture. Confirm that the flange of the denture does not impinge on the shaft of the implant.

Prosthetic Procedure

Multi-Unit Abutment placement for NobelZygoma™ 45° Ext Hex TiUltra™ Implants

Ensure adequate implant stability before initiating the prosthetic procedure.

1. Select the appropriate multi-unit abutment height (based on the gingival thickness) and angulation (based upon the implant orientation).

2. Place the abutment, using the holder to facilitate insertion.

3. Hand-tighten the abutment screw using the compatible screwdriver (see Table 3).

Note For the Multi-unit Abutment Xeal™ Zygoma, first remove the plastic holder by bending the handle away from the multi-unit abutment, prior to hand-tightening of the abutment screw with the Screwdriver Manual Multi-Unit.

Note For the 17° Multi-unit Abutment Xeal™ Zygoma, hand-tighten the abutment screw using Screwdriver Manual UniGrip™.

4. Tighten the abutment screw to the required torque (see Table 4) and with the compatible Screwdriver Machine Using the Manual Torque Wrench Prosthetic (see Figure BN for the Multi-Unit Abutment Xeal™ Zygoma and Figure BO for the 17° Multi-Unit Abutment Xeal™ Zygoma).

Refer to Nobel Biocare IFU1085 for information regarding the screwdrivers, and IFU1098 for information regarding the Manual Torque Wrench Prosthetic.

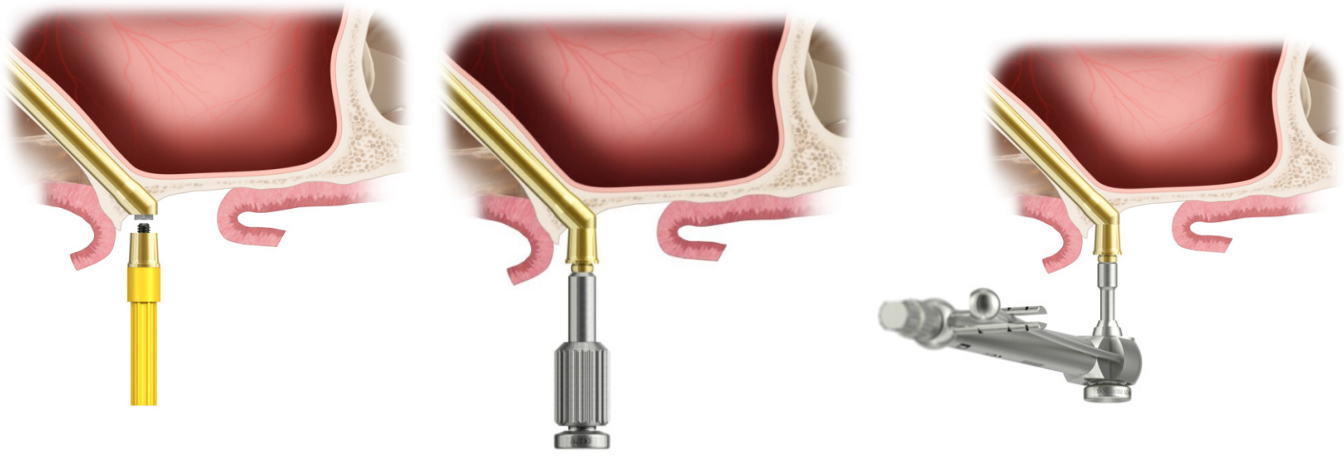


Figure BN – Steps for installation of the Multi-Unit Abutment Xeal™ Zygoma to the NobelZygoma™ 45° ExtHex TiUltra™ Implant

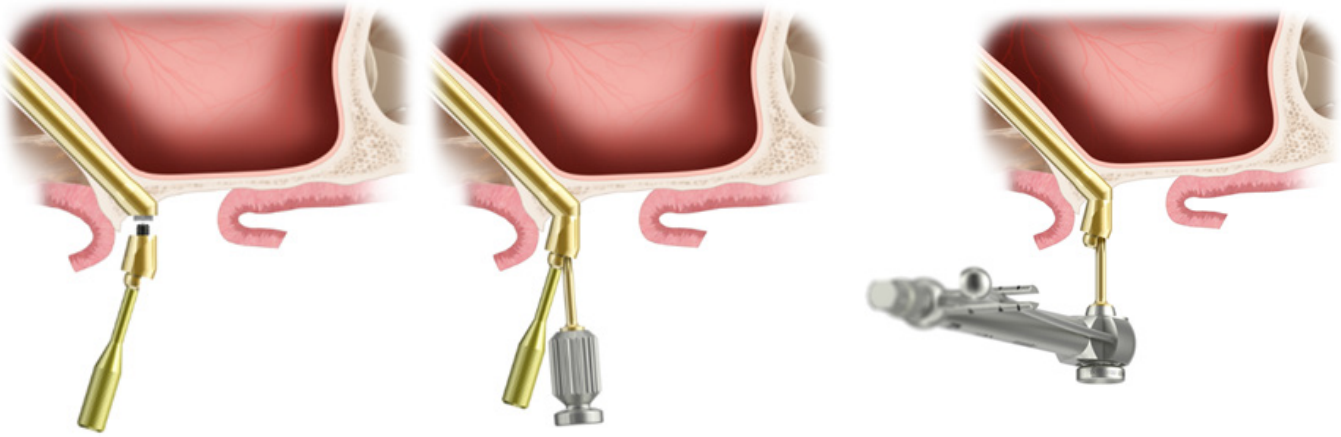


Figure BO – Steps for installation of the 17° Multi-Unit Abutment Xeal™ Zygoma to the NobelZygoma™ 45° ExtHex TiUltra™ Implant

Table 4 – Specifications for installation of multi-unit abutments compatible to the NobelZygoma™ 45° Ext Hex TiUltra™ Implants

Multi-unit Abutment	Tightening Torque	Screwdriver
Multi-Unit Abutment Xeal™ Zygoma	35 Ncm	Screwdriver Manual/ Machine Multi-Unit
17° Multi-Unit Abutment Xeal™ Zygoma	35 Ncm	Screwdriver Manual/ Machine UniGrip™

Caution Not applying recommended tightening torques may lead to component fracture or system performance issues.

Caution Ensure all surfaces are clean prior to assembly of the multi-unit abutment to the implant, to ensure effective mechanical locking and to prevent infection due to trapped biological materials.

Healing cap for multi-unit abutment placement

1. Select the appropriate healing cap (see Table 3).
2. Hand-tighten using Screwdriver Manual UniGrip™ (see example in Figure BP).

Caution Ensure all surfaces are clean prior to assembly of the healing cap to the implant, to ensure effective mechanical locking and to prevent infection due to trapped biological materials.

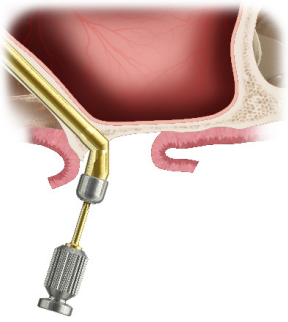


Figure BP – Placement of a healing cap on the multi-unit abutment

Multi-Unit Abutment placement for NobelZygoma™ 0° CC TiUltra™ Implants

Ensure sufficient implant stability before starting the prosthetic procedure.

1. Select the appropriate abutment height (based on the gingival thickness) and angulation (based upon the implant orientation).
2. Pre-assemble the screw and the selected abutment via the retention thread within the multi-unit abutment.

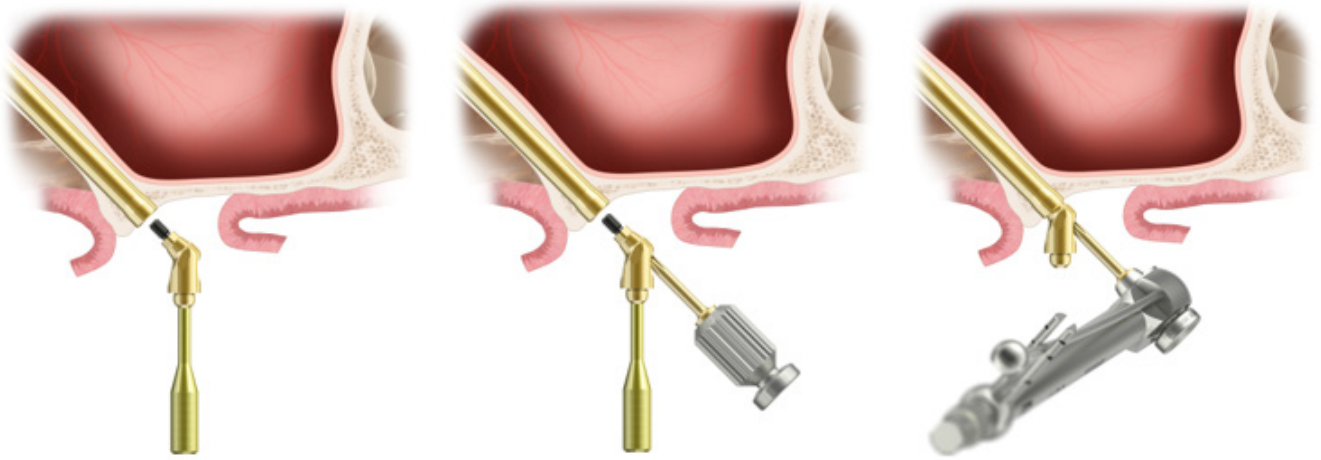


Figure BQ – Steps for installation of a multi-unit abutment to the NobelZygoma™ 0° CC TiUltra™ Implant

3. Place the abutment, using the handle to facilitate proper positioning (see example in Figure BQ).

4. Hand-tighten the abutment screw using the Screwdriver Manual UniGrip™.

5. Unscrew the handle.

6. Tighten the abutment screw to the required torque of 35 Ncm using the Screwdriver Machine UniGrip™ and Manual Torque Wrench Prosthetic (Figure BQ).

Caution Not applying recommended tightening torques may lead to component fracture or system performance issues.

Caution Ensure all surfaces are clean prior to assembly of the multi-unit abutment to the implant, to ensure effective mechanical locking and to prevent infection due to trapped biological materials.

Healing cap for muti-unit abutment placement

1. Select the appropriate healing cap (see Table 2).

2. Hand-tighten using Screwdriver Manual UniGrip™ (see example in Figure BR).

Caution Ensure all surfaces are clean prior to assembly of the healing cap to the implant, to ensure effective mechanical locking and to prevent infection due to trapped biological materials.

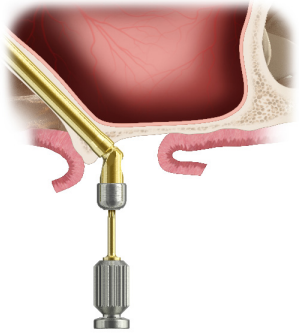


Figure BR – Placement of a Healing cap on the multi-unit abutment

Sterility and Reusability Information

NobelZygoma™ TiUltra™ Implants, Multi-unit Abutments Xeal™ Zygoma, Multi-unit Abutments Xeal™ Zygoma Abutment screws, NobelZygoma™ Precision Drill, NobelZygoma™ Round Burr, NobelZygoma™ Lateral Burrs and NobelZygoma™ Twist Drills, have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

NobelZygoma™ Handle, NobelZygoma™ Handpiece Adapter, NobelZygoma™ Depth Indicator Angled and Depth Indicator Straight, Bone Mills and Bone Mill Guides 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.

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 NobelZygoma™ TiUltra™ Implants, Multi-unit Abutments Xeal™ Zygoma, Multi-unit Abutments Xeal™ Zygoma Abutment screws, NobelZygoma™ Precision Drill, NobelZygoma™ Round Burr, NobelZygoma™ Lateral Burrs and NobelZygoma™ Twist Drills, 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 non-sterile devices may lead to infection of tissues or infectious diseases.

Before each use, inspect the devices for signs of degradation that may limit the useful life of the device such as the following:

– Visible corrosion

– Dull cutting edges

– Illegible laser marking

The NobelZygoma™ Handle, NobelZygoma™ Handpiece Adapter, NobelZygoma™ Depth Indicator Angled, NobelZygoma™ Depth Indicator Straight, NobelZygoma™ Bone Mill and Guide and NobelZygoma™ Bone Mill Guide shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The instruments shall be discarded if any wear, abrasion, deformations, or corrosion is visible.

Note The NobelZygoma™ Handle, NobelZygoma™ Handpiece Adapter, NobelZygoma™ Depth Indicator Angled, NobelZygoma™ Depth Indicator Straight, NobelZygoma™ Bone Mill and Guide and NobelZygoma™ Bone Mill Guide can be processed as individual devices as described in the Cleaning and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Cleaning and Sterilization Instructions

The NobelZygoma™ Handle, NobelZygoma™ Handpiece Adapter, NobelZygoma™ Depth Indicator Angled, NobelZygoma™ Depth Indicator Straight, NobelZygoma™ Bone Mill and Guide, and NobelZygoma™ Bone Mill Guides 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 ST98; 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 NobelZygoma™ Handle, NobelZygoma™ Handpiece Adapter, NobelZygoma™ Depth Indicator Angled, NobelZygoma™ Depth Indicator Straight, NobelZygoma™ Bone Mill and Guide, and NobelZygoma™ Bone Mill Guides 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 storing 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. For NobelZygoma™ Handle and NobelZygoma™ Handpiece Adapter, flush inner lumen with a water jet pistol filled with cold deionized water for 1 minute (at approximately 40 psi).

3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute until all visible soil is removed.

5. 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 1 minute until all visible soil is removed.

6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

8. For NobelZygoma™ Handle and NobelZygoma™ Handpiece Adapter, flush inner lumen with a water jet pistol filled with cold deionized water for 1 minute (at approximately 40 psi).

Automated Cleaning and Drying

The following washers were used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program; 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 of 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 the 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.

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 1 minute 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. For NobelZygoma™ Handle and NobelZygoma™ Handpiece Adapter, flush inner lumen with a water jet pistol filled with cold deionized water for 1 minute (at approximately 40 psi).

5. 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 1 minute until all visible soil is removed.

6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

7. 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).

8. 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.

9. For NobelZygoma™ Handle and NobelZygoma™ Handpiece Adapter, flush inner lumen with a water jet pistol filled with cold deionized water for 1 minute (at approximately 40 psi).

10. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.

11. 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, Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer, Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL (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 and/or Selectomat PL/666-1 CL, it is recommended to perform sterilization with a maximum load of 1 container with 8.6 kg of 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 5 presents examples of suitable sterilization pouches.

Table 5 – 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 6):

Table 6 – 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 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.

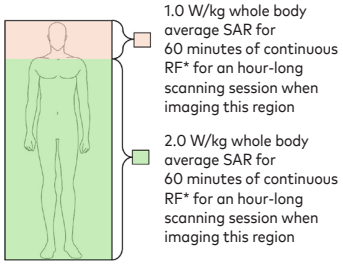
Containment and Transportation/ Shipping to Point of Use

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

MRI Safety Information	

A patient with a Nobel Biocare Device multiple tooth configuration may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Nobel Biocare Device – Multiple Tooth Configuration
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	See details below
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
1.5 T Limits on SAR and Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF*
3 T Limits on SAR and Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF* for scanning inferior to the neck 1.0 W/kg whole body average SAR for 60 minutes of continuous RF* for scanning superior to the neck 
MR Image Artifact	The presence of this implant may produce an image artifact of 35 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

* A sequence or back-to-back series/scan without breaks.

Performance Requirements and Limitations

To achieve the desired performance, the NobelZygoma™ TiUltra™ system 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 the NobelZygoma™ TiUltra™ system, check the compatibility matrix.

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 such 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 PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK responsible person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105, New Zealand Phone: +64 0800 441 657
CE Mark for Class Ir/IIa/IIb Devices	CE 2797
UKCA Mark for Class I Devices	UKCA
UKCA Mark for Class IIa/IIb Devices	UKCA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelZygoma™ TiUltra™ Implants	73327470000000016C
Multi-unit Abutments Xeal™ Zygoma	73327470000001687H
NobelZygoma™ Multi-unit Abutment Xeal™ Zygoma Screws	73327470000001827B
NobelZygoma™ Handle	73327470000001587E
NobelZygoma™ Handpiece Adapter	73327470000001597G
NobelZygoma™ Twist Drills NobelZygoma™ Precision Drills NobelZygoma™ Pilot Drills NobelZygoma™ Round Burr NobelZygoma™ Lateral Burrs	73327470000001206M
NobelZygoma™ Depth Indicators	73327470000001606Z
NobelZygoma™ Bone Mill with Guide	733274700000014779
NobelZygoma™ Bone Mill Guide	73327470000001567A

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	