NobelZygoma™ 0° Implant and 45°, 60° Multi-unit Abutment

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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description

NobelZygoma™ 0°

Implant

NobelZygoma™ 0° implants are endosseous implants made from biocompatible commercially pure grade 4 titanium with TiUnite® surface. It is a parallel walled implant with a 0° abutment head. The implant has TiUnite® up to the level of the platform.

The "Brånemark System®" restorative assortment is to be used in combination with this implant. Furthermore, dedicated 45°/60° Multi-unit Abutments are also available.

Tooling

Nobel Biocare Twist Drills are made of stainless steel with a DLC (Diamond Like Carbon) coating. Round Burs are made of stainless steel with no DLC (Diamond Like Carbon) coating. They should be used in conjunction with NobelZygoma™ 0° implants and are for single use only.

Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Zygoma Depth Indicator Angled are made of stainless steel. Zygoma Handle is made of aluminum alloy and stainless steel. They should be used in conjunction with NobelZygoma™ 0° implants and are intended for reuse.

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

45° and 60° Multi-Unit Abutment

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

The 45° and 60° Multi-unit Abutments are made of pure titanium and/or titanium alloy.

Note The 45° and 60° Multi-Unit Abutments do not have a holder.

Multi-unit Abutment angled 45° & 60°.

External hex connection for: NobelZygoma™ 0°.

Intended Use

NobelZygoma™ 0°

NobelZygoma™ 0° endosseous implants are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.

45° and 60° Multi-unit Abutment

Multi-unit Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Indications for Use

NobelZygoma™ 0° implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma™ Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Contraindications

It is contraindicated to use NobelZygoma™ 0° implant and Multi-unit Abutment in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable position of implants are not achievable for safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially pure titanium grade 4 or grade 1, stainless steel, DLC (Diamond Like Carbon) coating, polypropylene or PBT (Polybuthylene terephtalate) and Titianium alloy Ti-6Al-4V.

NobelZygoma™ 0° implant is contraindicated in:

- Patients who are to be restored with single unit constructions.
- Patients with inadequate bone volume for conventional implants and zygoma implant(s).

The 45° and 60° Multi-unit Abutment external hex connection are contraindicated for all other implants other than NobelZygoma™ 0°.

Materials

NobelZygoma™ 0° implant:
Commercially pure titanium grade 4.

Cover Screw:
Commercially pure titanium grade 1.

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

Round Bur:
Stainless Steel.

Zygoma Handle:
Aluminum alloy and stainless steel.

Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Zygoma Depth Indicator Angled:
Stainless steel.

45° and 60° Multi-unit Abutment and Abutment/Prosthetic screws:
Titanium alloy 90% Ti, 6% Al, 4%V.

Warnings

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

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.

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

Cautions

General

One hundred percent implant success cannot be guaranteed. Especially, non-observance of the indicated limitations of use and working steps may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

NobelZygoma™ 0° implants must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with NobelZygoma™ 0° implants can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

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

Never exceed the recommended maximum prosthetic tightening torque for the abutment screw (see Table 1). Overtightening of abutment may lead to a screw fracture.

Before surgery

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

It is highly recommended to perform a medical CT scan or a CBCT (cone beam CT) analysis prior to the final treatment decision. The patient must have clinically symptom-free sinuses, no pathology in associated bone and soft tissue and completed all necessary dental treatment.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulation.

All instruments and tooling used during 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.

Zygoma implant treatments may be performed under local anesthesia, IV-sedation or general anesthesia.

During surgery

Care and maintenance of instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small size of components, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

NobelZygoma™ 0° implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: the tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch.

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

Bending moments: forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant- supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

After surgery

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow-up after implant treatment and to inform about appropriate oral hygiene.

Surgical Procedure

1. To begin exposure of the lateral maxillary wall, a full thickness mucoperiosteal flap is reflected following a crestal incision with bilateral distal vertical releasing incisions over the tuberosity areas.

Warning It is imperative to be aware of vital structures including nerves, veins and arteries during the surgical exposure of the lateral maxillary wall. Injuries to vital anatomic structures can lead to complications including injury to the eye as well as extensive bleeding and nerve-related dysfunction.

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

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

Caution It is essential to identify and protect the infraorbital nerve.

2. For direct visualization of the lateral maxillary wall as well as the fronto-zygomatic notch area, a retractor is placed in the fronto-zygomatic notch with lateral retraction exposing the areas highlighted (Figure B).

3. To assist in direct visualization of the drills during the preparation of the osteotomy, a "window" is made through the lateral maxillary wall as shown. Attempt to keep the Schneiderian membrane intact, if possible (Figure B).

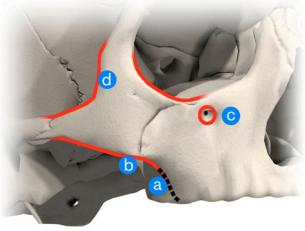

Figure A – Anatomical Landmarks Established

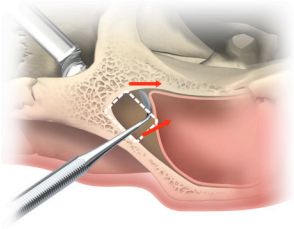

Figure B – Sinus "window" with retractor in the fronto-zygomatic notch (Schneiderian membrane remains intact)

4. Begin the trajectory of the implant at the first-second bicuspid area on the maxillarycrest, follow the posterior maxillary wall and end at the lateral cortex of the zygomatic bone slightly inferior to the fronto-zygomatic notch (Figure C).

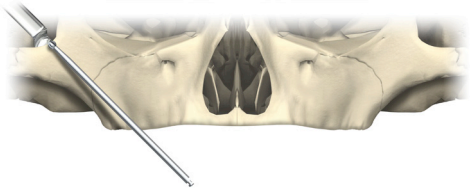

Figure C – Position trajectory of the implant

5. Drilling procedure: The ratio of the handpiece used is 20:1 at a speed of max. 2000 rpm. Drill under constant and profuse irrigation by sterile saline at room temperature.

Caution The Drill guide may be used during the preparation of the osteotomy to avoid contact of the rotating drill with the adjacent soft tissues (Figure D). Injury to the tongue, corner of the lips and or other soft tissues may occur if the drill shaft is unprotected.

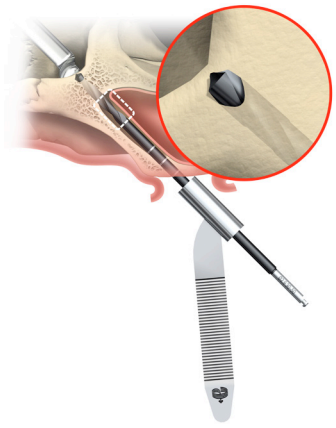

Figure D – Drill guard used

Depth measurement system: The parallel drills have a true depth measurement system. All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position. Please see Figure E for drill reference lines.

Caution Avoid lateral pressure on drills during implant-site preparation. Lateral pressure may cause drill fracture.

Caution Verify that drills lock in the handpiece before starting any drilling. A loose drill may accidentally harm the patient or members of the surgical team.

Caution Verify that all interconnecting instruments lock properly before intraoral use to prevent accidental swallowing or aspiration.

6. Drilling Sequence: (Figure E shows relation between drills and implants). The initial osteotomy is made using the Brånemark System® Zygoma Round Bur and the NobelZygoma™ 0° Twist Drill 2.9 mm, followed by the NobelZygoma™ 0° Twist Drill 3.5 mm and NobelZygoma™ 0° Twist Drill 4.0 mm. Finally, the NobelZygoma™ 0° Twist Drill 4.4 mm is used.

Caution Ensure correct angulation and avoid drill wobble, as this can inadvertently widen the preparation site.

Caution If the sinus membrane cannot be kept intact during osteotomy preparation, carefully irrigate away debris when inserting the implant. Any mucosal remnants in the bone site may prevent osseointegration of the implant.

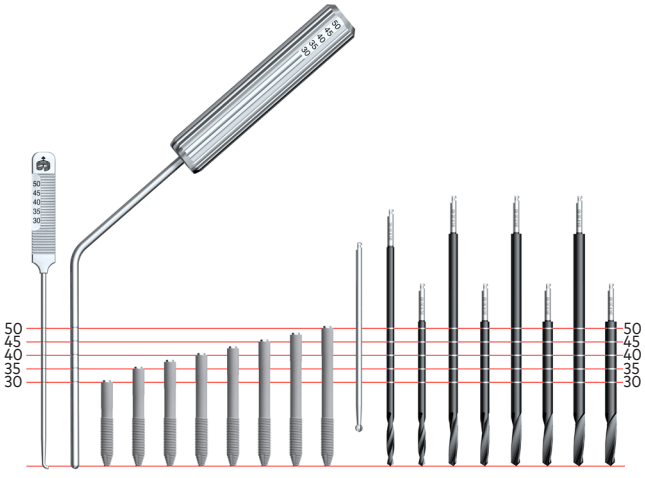

Figure E – From left to right: Z Depth Indicator Straight, Z Depth Indicator Angled

7. Use the Z depth indicators to determine the length of the Zygoma implant to be placed. Copious irrigation of the sinus is recommended prior to implant placement.

8. Plan to insert the implant as posteriorly as possible, with the implant head as close to the alveolar crest as possible (typically in the 2nd premolar region.) Anchorage of the implant will be achieved by entering the base of the zygoma bone (the posterior- lateral portion of the maxillary sinus roof), engaging through the lateral cortex of the zygoma below the fronto-zygomatic notch. Depending on the anatomy of the patient, the implant body may be positioned inside or outside the maxillary sinus.

Note Adjustment to this implant placement may be considered due to anatomical variations in the maxilla as well as the maxillary sinus.

9. Implant placement.

Insert implant with drilling unit

The implant may be inserted using an implant driver and the drilling unit at 20 Ncm insertion torque. Increasing the insertion torque up to maximum 50 Ncm may be used for the complete seating of the implant (Figure F). Once an insertion torque of 40 to 50 Ncm is reached, the Z Handle may be used. Disengage the implant driver with Handpiece.

Now connect the Z Handle to the Implant Driver Wrench Adapter and insert into the implant (Figure G). Rotate the Z Handle clockwise until the desired depth and head position are achieved.

Confirm through the "window" of the lateral maxillary wall the correct insertion angle of the implant while continuing through the sinus until the implant apex engages in the zygomatic bone.

Tighten manually

Disengage the implant driver with Handpiece. Now connect the Z Handle to the Implant Driver Wrench Adapter and insert into the implant (Figure G). Rotate the Z Handle clockwise until the desired depth and head position are achieved.

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

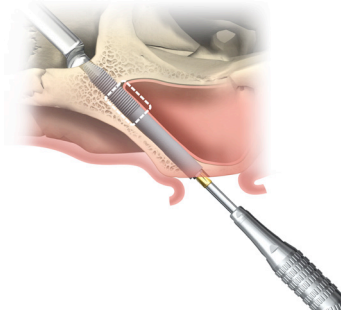

Figure F – Seating the NobelZygoma™ 0° with handpiece (Sinus "window" shown)

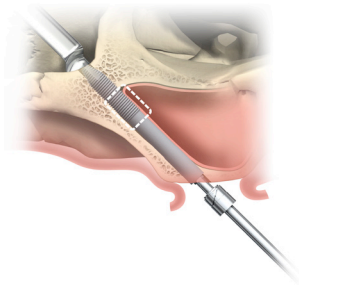

Figure G – Seating the NobelZygoma™ 0° with Z Handle (Sinus "window" shown)

10. Perform copious irrigation of the apical portion of the implant (the subperiosteal portion of the zygomatic bone) prior to the removal of the retractor from the fronto-zygomatic notch.

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

12. Depending on surgical protocol of choice, place a cover screw or abutment and suture. For Immediate Function, the implants should be able to withstand a final torque between 35–45 Ncm. For two-stage protocol relieve the denture over the implants (Figure H).

Caution Use only Brånemark System® cover screws. There are dedicated Multi-unit Abutments 45°/60° available for this implant.

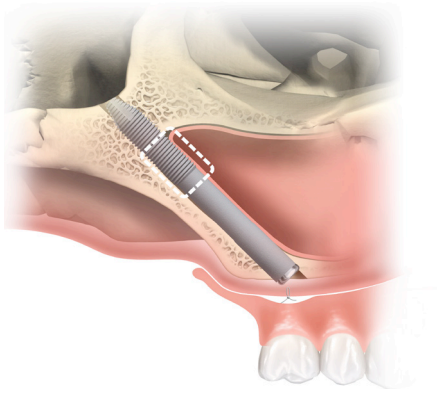

Figure H – Seating the NobelZygoma™ 0° with Z Handle (Sinus "window" shown)

For additional information on surgical procedures please consult the NobelZygoma™ "Procedures & products" treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

45° - 60° Multi-unit Abutment Handling instructions

Clinical procedure

1. Place appropriate angulated abutment (Figure I). It is recommended to verify the final abutment seating using radiographic imaging.

Figure I

Note The 45° and 60° Multi-Unit Abutments do not have a holder.

Caution The screw is not locked by a holder. Ensure that the screw is engaged to the Unigrip™ Screwdriver when placing the abutment.

2. Tighten the abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic.

Caution Never exceed recommended maximum 35 Ncm tightening torque for the abutments screw. Overtightening of abutment may lead to screw fracture.

3. Take impression of abutments using open or closed impression tray technique (Figure J).

Note Hand tighten only and close impression coping recess prior to impression taking.

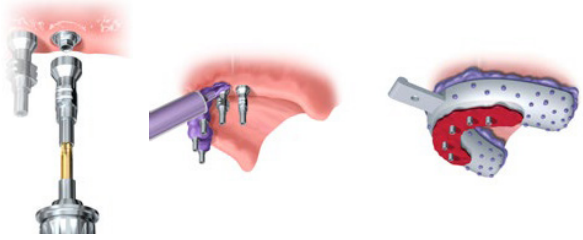

Figure J – Open tray

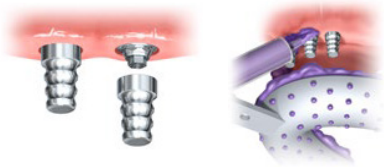

Figure K – Closed tray

4. Provisionalize or attach healing caps.

Laboratory procedure

5. Attach abutment replicas to impression copings.

6. Fabricate a working model with removable gingival material (Figure L).

Figure L

7. NobelProcera® Implant Bridge Wax-up:
   a. Create implant bridge framework using non-engaging temporary cylinders as a foundation and add pattern resin to fabricate desired framework design.
   b. Scan the acrylic framework using the NobelProcera® Scanner according to the tutorial found within the software.
   c. Once precision milled framework is delivered back to lab, veneering material is added for completion.

Clinical procedure

8. Remove temporary restoration if applicable.

9. Use the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to verify tightening of the 45° and 60° Multi-Unit Abutment to 35 Ncm.

10. Insert fixed prosthesis and tighten the prosthetic screws by alternating left and right side (Figure M). Finally tighten the prosthetic screws according to table 1 using Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (Figure N).

Table 1

Abutment (clinical) Screw Tightening Torque	Angulated 45° - 60°
Nobel Biocare implant systems	35 Ncm

Figure M

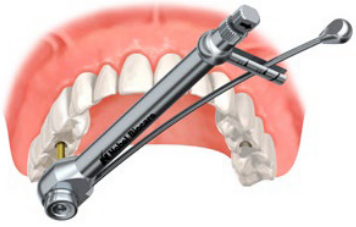

Figure N

11. Close screw access channel.

For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Sterility and Reusability Information

NobelZygoma™ 0° implant, NobelZygoma™ 0° Twist Drills, and Cover Screw have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

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

Caution NobelZygoma™ 0° implant, NobelZygoma™ 0° Twist Drills, and Cover Screw 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.

Magnetic Resonance (MR) Safety Information

MR Safety Information

MRI Safety Information	MR	
Non-clinical testing has demonstrated the NobelZygoma™ 0° implant and 45° and 60° Multi-unit Abutment is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg	Inferior to the navel: 2.0 W/kg Superior to the navel: 0.1 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0°C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3 T MRI system.	
Caution	Configurations with more than 2 Zygoma implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.	

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

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

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

Manufacturer and Distributor Information

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

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

Legal Statements

Symbols Glossary

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

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