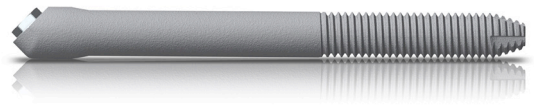
NobelZygoma™ 45°



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

Implant

NobelZygoma™ 45° are threaded dental implants intended for use in the zygomatic bone for anchoring or supporting dental prostheses.

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

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

Instrumentation

The following instrumentation is required during the surgical and handling procedures to place NobelZygoma™ 45° implants:

- The Brånemark System® Twist Drills and The Brånemark System® Pilot Drills are required to prepare the osteotomy for placement of Zygoma implants and are for single use only. The drills are available in different diameters and lengths in order to widen the osteotomy step-by-step to the appropriate diameter and depth. They should be used in conjunction with NobelZygoma™ 45° implants and are for single use only.

- Zygoma Drill Guard, Zygoma Drill Guard Short are used during preparation of the osteotomy as a protective shield between the rotating drill shaft and adjacent soft tissues.

- Zygoma Depth Indicator Straight and Angled are used to verify the depth of the osteotomy. They feature numbered length scales on the handle and shaft to verify the depth of the osteotomy and to support selection of the appropriate Zygoma implants length.

- Zygoma Handle connects to the Implant Mount and is used to pick up and insert the Zygoma implants into the osteotomy.

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

Refer to Nobel Biocare IFU1090 for further information regarding the Connection to Handpiece.

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

Refer to Nobel Biocare IFU1095 for further information regarding Zygoma Drills and Instrumentation.

Zygoma Drill Guard, Zygoma Drill Guard Short, Zygoma Depth Indicator Straight and Angled, Zygoma Handle: They should be used in conjunction with NobelZygoma™ 45° implants and are intended for reuse.

Intended Use/Intended Purpose

NobelZygoma™ 45° implants

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

Indications

NobelZygoma™ 45° implants are endosseous dental implants indicated to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. These implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.

Contraindications

It is contraindicated to use NobelZygoma™ 45° implant in:

- Who are medically unfit for an oral surgical procedure.
- With inadequate bone volume for conventional implants and zygoma implant(s).
- In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Who are allergic or hypersensitive to commercially pure titanium grade 4 and titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).
- Who are to be restored with single unit constructions.

Materials

NobelZygoma™ 45° implant:
Commercially pure titanium grade 4.

Cover Screw:
Titanium alloy Ti-6Al-4V.

Brånemark System® Zygoma Pilot Drill:
Stainless steel 1.4197 according to ASTM F899.

Brånemark System® Zygoma Twist Drills:
Stainless steel, DLC (Diamond Like Carbon) coating per 1.4197 Type 420F Mod according to ASTM A895 and ISO 5832-1.

Brånemark System® Zygoma Round Bur:
Stainless steel 1.4197 according to ASTM F899.

Zygoma Drill Guards and Drill Guards Short, Zygoma Depth Indicators Straight and Angled, and the Connection to Handpiece:
Stainless steel 1.4301 according to ASTM F899.

Zygoma Handle:
Stainless steel and aluminum: Adapter and Pin: Stainless Steel Type 304, Cap and Body: Aluminum Alloy 6082 according to ISO AlSi1MgMn.

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.

Cautions

General

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

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

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

NobelZygoma™ 45° implants must only be used with compatible Nobel Biocare instruments and components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with instruments or components 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.

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.

The device has not been evaluated in paediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jawbone growth phase has been properly documented.

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

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

At Surgery

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, 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.

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

NobelZygoma™ 45° Implants are to be used by dental health care professionals.

NobelZygoma™ 45° Implants are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelZygoma™ 45° Implants

NobelZygoma™ 45° Implants are 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™ 45° Implants

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. Depending on the location, placement of the implant may also lead (in rare cases) to bone fracture, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During placement of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

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

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Zygoma™ 45° Implants. The SSCP can be obtained at the following website: ec.europa.eu/tools/eudamed[1]

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

Notice regarding serious incidents

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

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Surgical Procedure

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 (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 (B).

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

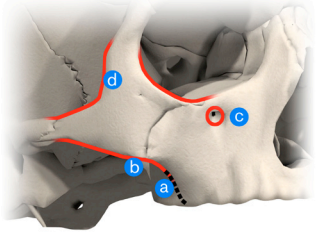


Figure A – Anatomical Landmarks Established

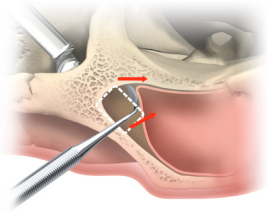


Figure B – Sinus "window" with retractor in the fronto-zygomatic notch (Schneiderian membrane remains intact)

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

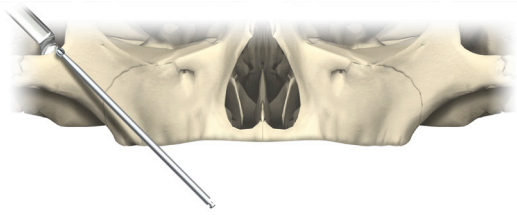


Figure C – Position trajectory of the implant

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 Guard may be used during the preparation of the osteotomy to avoid contact of the rotating drill with the adjacent soft tissues (d). Injury to the tongue, corner of the lips and or the other soft tissue may occur if the drill shaft is unprotected.

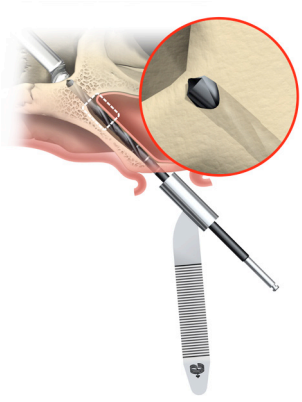


Figure D – Drill guard used

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

Caution Pilot Drills extend up to 7.5 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (please see image 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: (Image E shows relation between drills and implants). The initial osteotomy is made using the Brånemark System® Zygoma Round Bur, followed by the Brånemark System® Zygoma Twist Drill 2.9 mm. Widening of the osteotomy is made by the Brånemark System® Zygoma Pilot Drill 3.5 mm and finally the Brånemark System® Zygoma Twist Drill 3.5 mm.

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.

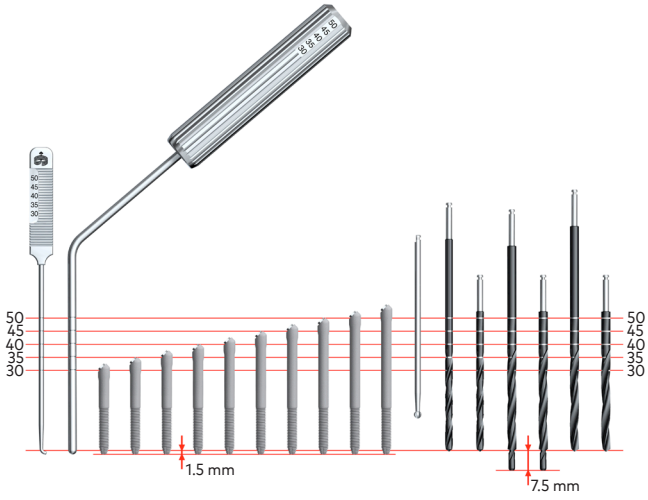


Figure E – From left to right: Zygoma Depth Indicator Straight, Z Depth Indicator Angled, NobelZygoma 45° Implants, Round Bur, Twist Drills

7. Use the Zygoma 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 frontozygomatic 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 the drilling unit using 20 Ncm insertion torque. Increasing the insertion torque up to maximum 50 Ncm may be used for the complete seating of the implant (F).

Once an insertion torque of 40 to 50 Ncm is reached, the Z Handle may be used to tighten the implant manually to the proper insertion depth. 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 Connection to Handpiece from the implant mount and connect the Zygoma Handle to the implant mount. Rotate the Z Handle clockwise until the desired depth and head position are achieved.

Caution When using the Zygoma Handle, applying excessive torque can distort the implant head or fracture the implant mount and/or the implant mount screw.

10. Verifying the correct position of the implant platform: Place the Screwdriver Manual Unigrip™ into the implant mount screw (G). The shaft of the Unigrip™ driver should be perpendicular to the crest of the maxilla to ensure the proper position of the NobelZygoma™ 45° implant platform.

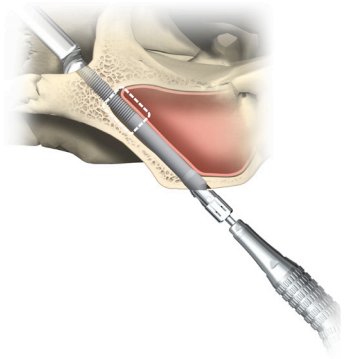


Figure F

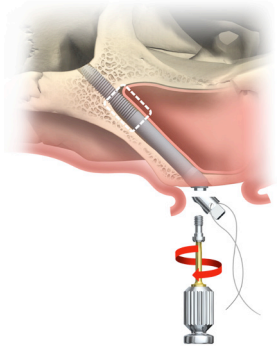


Figure G

11. 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.

12. Remove Implant mount.

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

14. 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 (H).

Caution There are dedicated cover screws.

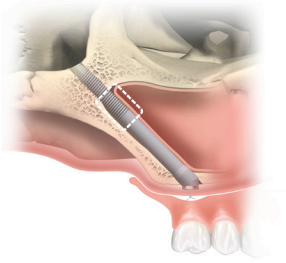


Figure H

Sterility and Reusability Information

NobelZygoma™ 45° implants 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™ 45° implants are single use product(s) 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

MRI Safety Information		
Non-clinical testing has demonstrated the NobelZygoma™ 45° Implants are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg	Inferior to the navel: 2.0 W/kg
	Superior to the shoulders: 0.2 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 3T 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.	

Performance Requirements and Limitations

To achieve the desired performance, NobelZygoma™ 45° Implants 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 NobelZygoma 45° Implants, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

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

Storage, Handling and Transportation

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

Disposal

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

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

Manufacturer and Distributor Information

Manufacturer	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 IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

Note Regarding Canadian Device Licensure, not all products described in the IFU may have a device licence according to Canadian Law.

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™ 45° implant	73327470000000016C

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	