NobelParallel™ CC and NobelParallel™ CC TiUltra™ Implants

Instructions for Use

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof.

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

Description:

This Instructions for Use (IFU) describes the Nobel Biocare NobelParallel™ CC and NobelParallel™ TiUltra™ Implants and supporting components, including the instrumentation which is required during the surgical and handling procedure to prepare the implant site and to place the implant.

NobelParallel™ CC / NobelParallel™ TiUltra™ Implants are endosseous threaded implants available in diameters of 3.75, 4.3, 5.0, and 5.5 mm. The implant has the following features:

- The NobelParallel™ CC / NobelParallel™ TiUltra™ Implant: moderately tapered body with a straight collar, double thread, cutting flutes at apex.
- The NobelParallel™ CC / NobelParallel™ TiUltra™ Implants feature an internal conical connection (CC) and are available in platform sizes Narrow Platform (NP), Regular Platform (RP) and Wide Platform (WP). The implants are compatible with Nobel Biocare restorative components featuring the internal conical connection.
- NobelParallel™ CC Implants feature a TiUnite anodized surface.
- NobelParallel™ TiUltra™ Implants feature a TiUltra™ anodized surface.
- The TiUltra™ have the additional protective layer on comprising of sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Table 1: NobelParallel™ CC and NobelParallel™ TiUltra™ Implant Specifications

Platform	Implant diameter	Abutment interface	Lengths	Cover Screw	Color-Coding
NP	∅ 3.75 mm	∅ 3.0 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm	NobelParallel™ CC: co-packed NobelParallel™ TiUltra™: not co-packed	NobelParallel™ CC: Magenta NobelParallel™ TiUltra™: no platform specific color-coding
RP	∅ 4.3 mm	∅ 3.4 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm	NobelParallel™ CC: co-packed NobelParallel™ TiUltra™: not co-packed	NobelParallel™ CC: Yellow NobelParallel™ TiUltra™: no platform specific color-coding
RP	∅ 5.0 mm	∅ 3.4 mm	7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm	NobelParallel™ CC: co-packed NobelParallel™ TiUltra™: not co-packed	NobelParallel™ CC: Yellow NobelParallel™ TiUltra™: no platform specific color-coding
WP	∅ 5.5 mm	∅ 4.4 mm	7.0 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm	NobelParallel™ CC: co-packed NobelParallel™ TiUltra™: not co-packed	NobelParallel™ CC: Blue NobelParallel™ TiUltra™: no platform specific color-coding

Caution: Please note the NobelParallel™ TiUltra™ implant platform color is yellow for all implant sizes and does not reflect Nobel Biocare's platform color-coding.

Caution: The implant drivers, healing abutments, and prosthetic components, as well as the cover screws are color-coded according to Table 1 in order to indicate the compatible implant diameter and platform size (NP, RP, WP).

Instrumentation:
The following instrumentation is required during the surgical and handling procedures to place NobelParallel™ CC and NobelParallel™ CC TiUltra™ Implants:

- The Cortical Drills, Twist Drills, and Twist Step Drills are required to prepare the osteotomy for placement of NobelParallel™ CC and NobelParallel™ CC TiUltra™ Implants. Twist Drills and Twist Step Drills are available in different diameters and lengths in order to widen the osteotomy step-by-step to the appropriate diameter and depth. Refer to Nobel Biocare IFU1001 for information regarding the Twist Drills and Twist Step Drills.
- Screw Taps NobelParallel™ CC NP/RP/WP can be used to cut threads in an osteotomy in dense bone.
- The Depth Probe 7-18 mm Z-shaped is used to verify the depth of the osteotomy. Refer to Nobel Biocare IFU1090 for information regarding the Depth Probe 7-18 mm Z-shaped.

Implant Drivers Conical Connection NP/RP/WP must be used to place NobelParallel™ CC and NobelParallel™ CC TiUltra™ Implants. Refer to Nobel Biocare IFU1090 for information regarding the implant drivers.

Intended Use / Intended Purpose:

NobelParallel™ CC / NobelParallel™ CC TiUltra™ implants:
Intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function.

Screw Tap NobelParallel™ / NobelParallel™ CC Cortical Drill:
Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Indications:

NobelParallel™ CC implants:
NobelParallel™ CC implant restorations range from single tooth to fixed-removable full dental arch overdenture applications to restore chewing function. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi-cortical anchorage in cases of reduced bone density to obtain high initial stability.

NobelParallel™ CC TiUltra™ implants:
NobelParallel™ CC TiUltra™ implant restorations range from single tooth to fixed-removable full dental arch overdenture applications to restore chewing function.

This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

Implants allow also for bi-cortical anchorage in cases of reduced bone density to obtain high initial stability.

Screw Taps NobelParallel™:
Screw Taps NobelParallel™ are indicated for use in the maxilla or mandible to prepare an osteotomy in dense bone for placement of NobelParallel™ CC Implants. and NobelParallel™ TiUltra™.

Cortical Drill NobelParallel™:
Cortical Drill NobelParallel™ are indicated for use in the maxilla or mandible to prepare an osteotomy for the placement of a dental implant.

Contraindications:

It is contraindicated placing NobelParallel™ CC / NobelParallel™ CC TiUltra™ implants in patients:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be considered.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially pure titanium (grade 4) titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium), stainless steel, DLC (Diamond Like Carbon) coating, sodium dihydrogen phosphate (NaH_2PO_4), or magnesium chloride ($MgCl_2$).

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.

NobelParallel™ CC and NobelParallel™ CC TiUltra™ 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 NobelParallel™ CC and NobelParallel™ CC TiUltra™ 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 pediatric/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 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:
Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

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:

NobelParallel™ Conical Connection (CC) TiUltra™ / NobelParallel™ Conical Connection (CC) Implants are to be used by dental health care professionals.

NobelParallel™ Conical Connection (CC) TiUltra™ / NobelParallel™ Conical Connection (CC) Implants are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with NobelParallel™ CC TiUltra / NobelParallel™ CC Implants and instrumentation:
NobelParallel™ CC TiUltra / NobelParallel™ CC, Screw Taps, and Cortical Drills 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 NobelParallel™ CC TiUltra / NobelParallel™ CC Implants and instrumentation:
The placement of a dental implant and cover screws 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 and cover screw 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. During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

The use of screw taps and cortical drills constitute an invasive treatment which may be associated with typical side effects such as bone necrosis, inflammation, infection, bleeding, hematoma, pain, swelling. Depending on its location of use it may, in rare cases, lead to fenestration or fracture of bone, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During use of these devices the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

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

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

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

Notice regarding serious incidents:

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

Nobel Biocare AB

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

Surgical Procedure:

Surgical procedure:

1. During drilling procedures bone quality should be considered (please see table A recommended drill sequences are based on bone quality to ensure optimal primary stability when applying immediate function).

A NobelParallel™ CC / NobelParallel™ CC TiUltra™
Recommended drill sequence based on bone quality. Drill data are stated in mm and the drills within brackets denote as optional.

Table A: Drill sequence according to bone quality

Platform	Implant diameter	Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
NP	∅ 3.75	2.0 (2.4/2.8)	2.0 2.4/2.8 Cortical Drill 3.75 (Screw Tap 3.75)	2.0 2.4/2.8 2.8/3.2 Cortical Drill 3.75 Screw Tap 3.75
RP	∅ 4.3	2.0 2.4/2.8 (3.2/3.6)	2.0 2.4/2.8 3.2/3.6 Cortical Drill 4.3 (Screw Tap 4.3)	2.0 2.4/2.8 3.2/3.6 (3.8/4.2) Cortical Drill 4.3 Screw Tap 4.3
RP	∅ 5.0	2.0 2.4/2.8 3.2/3.6 (3.8/4.2)	2.0 2.4/2.8 3.2/3.6 3.8/4.2 Cortical Drill 5.0 (Screw Tap 5.0)	2.0 2.4/2.8 3.2/3.6 3.8/4.2 Cortical Drill 5.0 Screw Tap 5.0
WP	∅ 5.5	2.0 2.4/2.8 3.2/3.6 4.2/4.6 (4.2/5.0)	2.0 2.4/2.8 3.2/3.6 4.2/5.0 (4.2/5.0) Cortical Drill 5.5 (Screw Tap 5.5)	2.0 2.4/2.8 3.2/3.6 4.2/5.0 Cortical Drill 5.5 Screw Tap 5.5

Note: All data is stated in mm.

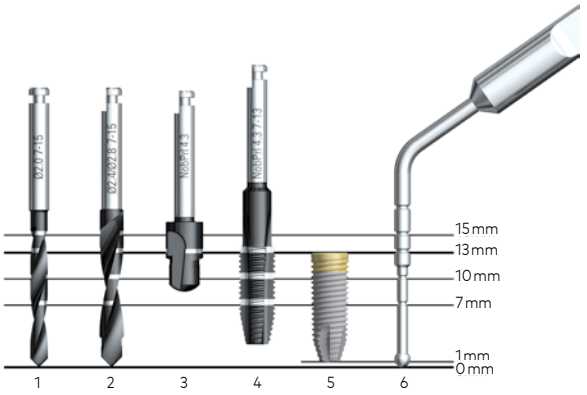
Drilling must proceed at high speed (max. 2'000 rpm/min. for step/twist drills) under constant and profuse irrigation by sterile saline at room temperature. In dense bone situation drill with continuous back and forth motion.

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

Caution: Twist/Step Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (please see image B for drill reference lines).

Note: It is not recommended to use a cortical drill for sinus lift procedures. This is in order to maximize the potential for primary stability.

B



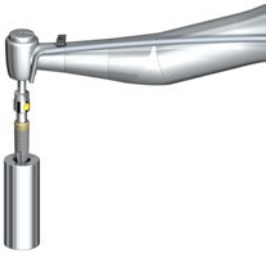
Note: The marks on the Twist/Step Drills indicate actual millimeter lengths and correspond to the implant collar. Final vertical positioning depends on several clinical parameter, including esthetics, tissue thickness and available vertical space.

Note: When the depth marking of the screw tap is aligned with the implant length the apical portion is not pre-tapped to allow direct engagement in the apical portion.

In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, a drill extension shaft may be used.

2. Prepare implant site. When using a flapless approach add-on soft tissue height to drill depth.
3. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist/Step Drills.
4. Open the implant package and pick up the implant from inner casing with implant driver (please see C). The implants are ideally installed with low speed, max. 25 rpm, using a drilling device.

C



Pick up of implant from inner casing with implant driver.

5. Place and tighten the implant using max. 45 Ncm insertion torque.

Caution: Never exceed insertion torque of 45 Ncm for the implants. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid over tightening.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counterclockwise using drilling device (reverse mode) or manual torque wrench and remove implant from site. Replace the implant back into inner casing before proceeding further.

6. Medium and dense bone protocol:

a. In cases of a thick cortical layer or dense bone a Cortical Drill and/or a Screw Tap is mandatory to be able to get the implant fully seated and to release pressure around the implant neck.

b. Select the Cortical Drill and/or use Screw Tap matching the diameter of the implant.
   - If Cortical Drill is used: proceed with drilling at high-speed max. 2'000 rpm/min and drill to appropriate depth (see image B).
   - If Screw Tap is used: place the screw tap into prepared implant site using low speed 25 rpm, applying firm pressure. When the threads engage, allow Screw Tap to feed without pressure to appropriate depth (see image B). Switch the drill device with handpiece to reverse mode and remove the Screw Tap.

c. Continue with implant installation until desired position is achieved using max.45 Ncm of insertion torque.

7. For Immediate Function, the implant should be able to withstand a final torque between 35–45 Ncm.

8. Depending on surgical protocol of choice, place a cover screw or an abutment and suture. See table D for implant specifications.

Table D: Implant Specifications

Platform	Platform diameter	Implant diameter	Lengths
NP	∅ 3.5	∅ 3.75	7, 8.5, 10, 11.5, 13, 15, 18
RP	∅ 3.9	∅ 4.3 ∅ 5.0	7, 8.5, 10, 11.5, 13, 15, 18 7, 8.5, 10, 11.5, 13, 15, 18
WP	∅ 5.1	∅ 5.5	7, 8.5, 10, 11.5, 13, 15

Note: All data is stated in mm.

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

Materials:

- NobelParallel™ CC implant: Commercially pure titanium grade 4 according to ASTM F67.
- NobelParallel™ CC TiUltra™ implant: Commercially pure titanium grade 4 according to ASTM F67. Implants feature a TiUltra™ anodized surface. The TiUltra™ have the additional protective layer on comprising of sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).
- Cover Screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) per ASTM F136 and ISO 5832-3.
- Twist Drills, Twist Step Drills, Screw Taps, Cortical Drills, and Implant Drivers: Stainless steel, DLC (Diamond Like Carbon) coating per 1.4197 Type 420F Mod according to ASTM A895 and ISO 5832-1.
- Depth Probe: Stainless steel according to ASTM F899.

Sterility and Reusability Information:

NobelParallel™ CC / NobelParallel™ CC TiUltra™ implants, Cortical Drills and Screw Taps 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.

Caution: NobelParallel™ CC / NobelParallel™ CC TiUltra™ implants, Cortical Drills and Screw Taps are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

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

Magnetic Resonance (MR) Safety Information:

Note: Only the NobelParallel™ CC / NobelParallel™ CC TiUltra™ Implants has been assessed as MR Conditional. The other Twist/Step Drills, Cortical Drills and Screw Taps has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

If there is no MR Safety symbol on the product label, the device has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

Performance Requirements and Limitations:

To achieve the desired performance, NobelParallel™ CC TiUltra™ / NobelParallel™ CC Implants and instrumentation must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with NobelParallel™ CC TiUltra™ / NobelParallel™ CC, and instrumentation, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labelling.

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
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in Australia by:
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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 2797
CE Mark for Class IIa/IIb Devices

Note: Refer to the product label to determine the applicable CE mark for each device.

Basic UDI-DI Information:

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

Product	Basic UDI-DI Number
NobelParallel™ CC / NobelParallel™ CC TiUltra™	733274700000012773
Screw Tap NobelParallel™	7332747000001226R
NobelParallel™ CC Cortical Drill	7332747000001206M

Implant Card:

NobelParallel™ CC / NobelParallel™ CC TiUltra™ accompanied by an Implant Card which contains important information for patients regarding the device.

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

Symbols Glossary:

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

Batch code

Catalogue number

Date


Date of manufacture


Manufacturer

Serial number

Unique Device Identifier

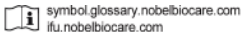

Health care centre or doctor


Patient identification


Patient number


Tooth number


Consult instructions for use



Link to Online Symbols Glossary and IFU Portal


Patient information website


Caution

Do not resterilize


Do not re-use


Do not use if package is damaged and consult instructions for use


Use-by date


Temperature limit


Upper limit of temperature


Keep away from sunlight


Keep dry

Contains biological material of animal origin


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate


Non-pyrogenic

Magnetic resonance conditional

Magnetic resonance safe

Non-sterile

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat

Single sterile barrier system

Single sterile barrier system with protective packaging inside

Single sterile barrier system with protective packaging outside

Double sterile barrier system

Authorised Representative in Switzerland

Authorized representative in the European Community / European Union

UK Responsible Person

CE mark

CE mark with Notified Body number

EU Importer

Swiss Importer

UKCA mark

UKCA mark with Approved Body number

Medical device

Rx only

For prescription use only