Replace Select™ TC

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

Replace Select™ TC (Tissue Collar) dental implants are made from commercially pure titanium (grade 4).

- Implant macroshape: straight with moderately tapered apex, cutting flutes
- Implant connection: tri-channel
- Implant surface: TiUnite® anodized implant surface and 3 mm machined collar

Replace Select™ TC includes a co-packed Cover Screw made of titanium alloy Ti-6Al-4V. For information specific to the Cover Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016).

Table 1 describes the compatibility of the products with each other.

Intended Use / Intended Purpose

Replace Select™ TC implants:

Intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function.

Indications

Replace Select™ TC implant restorations range single tooth to fixed-removable full dental arch overdenture applications to restore chewing function. This can be achieved with 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.

Contraindications

It is contraindicated to use Replace Select™ TC implants in:

- 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) or titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium).

For contraindications specific to the Cover Screws and Healing Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016 and IFU1094).

For contraindications specific to the Manual Torque Wrenches Surgical and Prosthetic, refer to the Nobel Biocare Instructions for Use for the component (IFU1098).

Table 1 – Compatibility with Accessories or Other Devices

Product Name	Cover Screw	Implant Driver	Clinical Screws	Abutments			Impression Coping	Other
				Healing	Temporary	Permanent		
Replace Select™ TC NP	Healing Screw RplSel TC NP Cover Screw NobRpl NP	Implant Driver NobRpl NP	Screw Multi-unit Angled Abutm NobRpl NP Screw Ceramic Abutment NobRpl NP Abutment Screw NobRpl NP	Healing Abutment NobRpl NP	Temporary Abutment Engaging NobRpl NP Temporary Abutment Non-Eng NobRpl NP Temporary Abutment Plastic Eng NobRpl NP Temp Abutm Plastic Non-Eng NobRpl NP Immediate Temporary Abutment NobRpl NP	Snappy™ Abutments NobRpl NP Esthetic Abutment NobRpl NP 15° Esthetic Abutment NobRpl NP Universal Base Tri-Channel NP GoldAdapt Engaging NobRpl NP GoldAdapt Non-Engaging NobRpl NP Multi-unit Abutment NobRpl NP 17° Multi-unit Abutment NobRpl NP Ball Abutment Titanium NobRpl NP NobelProcera Ab Ti NobelReplace NP w-u NobelProcera Ab Ti NobelReplace NP Procera® Abutm Zr NobRpl NP	Impr Coping Open Tray NobRpl NP Ø4.5 mm Impr Coping Closed Tray NobRpl NP Impr Cop Cl Tray Low Prof NRpl NP Impr Coping Open Tray NobRpl NP	PIB IBO Impl Retr Instr Hex & Tri-Ch NP/RP 22 mm Bone Mill with Guide NobRpl NP Ø4.6 Implant Rescue Collar Tri-Channel Ø3.5
Replace Select™ TC RP	Healing Screw RplSel TC RP Cover Screw NobRpl RP	Implant Driver NobRpl RP	Screw Multi-unit Angled Abutm NobRpl RP Screw Ceramic Abutment NobRpl RP/ WP/6.0 Abutment Screw NobRpl RP/ WP/6.0	Healing Abutment NobRpl RP	Temporary Abutment Engaging NobRpl RP Temporary Abutment Non-Eng NobRpl RP Temporary Abutment Plastic Eng NobRpl RP Temp Abutm Plastic Non-Eng NobRpl RP Immediate Temporary Abutment NobRpl RP	Snappy™ Abutments NobRpl RP Esthetic Abutment NobRpl RP 15° Esthetic Abutment NobRpl RP Universal Base Tri-Channel RP GoldAdapt Engaging NobRpl RP GoldAdapt Non-Engaging NobRpl RP Multi-unit Abutment NobRpl RP 30° Multi-unit Abutment NobRpl RP 30° Multi-u Abutm Non-Eng NobRpl RP 17° Multi-unit Abutment NobRpl RP Ball Abutment Titanium NobRpl NP NobelProcera Ab Ti NobelReplace RP w-u NobelProcera Ab Ti NobelReplace RP Procera® Abutm Zr NobRpl RP	Impr Coping Closed Tray NobRpl RP Impr Cop Cl Tray Low Prof NRpl RP Impr Coping Open Tray NobRpl RP	PIB IBO Impl Retr Instr Hex & Tri-Ch NP/RP 31 mm Bone Mill with Guide NobRpl RP Ø5.3 Implant Rescue Collar Tri-Channel Ø4.3

For contraindications specific to the Screwdrivers, refer to the Nobel Biocare Instructions for Use for the component (IFU1085).

For contraindications specific to the Nobel Biocare Reusable Instruments and Components, refer to the Nobel Biocare Instructions for Use for the component (IFU1090).

For contraindications specific to the PureSet™ Trays, refer to the Nobel Biocare Instructions for Use for the component (IFU1067).

Materials

- Replace Select™ TC implant: Commercially pure titanium grade 4 according to ASTM F67 and ISO 5832-2
- Cover screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3

Warnings

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures.

Besides the mandatory precautions for any surgery such as of 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.

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

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

Before Surgery

Careful 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 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, 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 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 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., dental dam, gauze, 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 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.

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 about appropriate oral hygiene.

Intended Users and Patient Groups

Replace Select™ TC implants are to be used by dental health care professionals.

Replace Select™ TC implants are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Replace Select™ TC

Replace Select™ TC 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 Replace Select™ TC

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 Replace Select™ TC 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

During drilling procedures bone quality should be considered. Please see Table 2 for recommended drill sequences based on bone quality to ensure optimal primary stability when applying immediate function.

Table 2 – Recommended drill sequence based on bone quality. Drills listed within brackets denote widening of cortex only.

Platform	Implant diameter	Drill Sequence (according to bone quality)		
		Soft bone	Medium bone	Dense bone
NP	Ø 3.5 mm	Ø 2.0 mm	Ø 2.0 mm Ø 2.4/2.8 mm	Ø 2.0 mm Ø 2.4/2.8 mm Ø 3.0 mm
RP	Ø 4.0 mm	Ø 2.0 mm (Ø 2.4/2.8 mm)	Ø 2.0 mm Ø 2.4/2.8 mm Ø 3.2 mm	Ø 2.0 mm Ø 2.4/2.8 mm Ø 3.4 mm

Drilling must proceed at high speed (max. 2000 rpm) for Twist/Step 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 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 drill extends up to 1 mm longer than the implant when seated.

Allow for this additional drill length when drilling near vital anatomical structures (please see Figure A for drill reference lines).

Figure A shows product reference line for Twist and Twist/Step Drills 7–15 mm, Depth probe and Replace Select™ TC RP implants in lengths (15+3) mm; (13+3) mm; (10+3) mm; (7+3) mm.

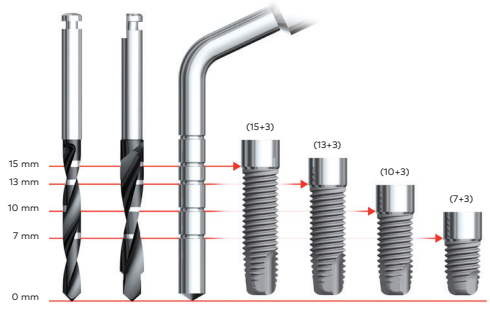

Figure A – Product reference lines

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 parameters, including esthetics, tissue thickness and available vertical space.

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

1. Prepare implant site Figure B. When using a flapless approach add-on soft tissue height to drill depth.

2. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist/Step drill.

3. Open the implant package and pick up the implant from inner casing with implant driver. The implants are ideally installed with low speed, max. 25 rpm, using drilling device Figure C or by use of Manual Torque Wrench Surgical.

Figure B – Preparation of implant site

Figure C – Implant driver picking up implant

4. Place and tighten the implant using max 45 Ncm installation torque Figure D. To ensure ideal prosthetic abutment orientation position one of the tri-channel lobes in buccal/facial position.

Caution Never exceed insertion torque of 45 Ncm for the implants. Overtightening of 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 is achieved before fully seated rotate the implant counter clockwise using drilling machine (reverse mode) or Manual Torque Wrench Surgical in reverse mode and remove implant from site.

Replace the implant back into inner case before proceeding further.

Use a wider Drill, Screw Tap or counterbore to widen the site. If Screw Tap is used place the Screw Tap into prepared implant site using low speed 25 rpm and drill to appropriate length. Switch the handpiece to reverse mode and back the Screw Tap out. Continue with implant installation until desired position is achieved.

Figure D – max 45 Ncm

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

6. Depending on surgical protocol of choice, place a Cover Screw, Healing Screw Replace Select™ TC or abutment and suture Figure E.

See Table 3 for implant specifications.

Figure E – Healing Screw Replace Select™ TC placed on implant

Table 3 – Implant specifications

Platform	Abutment interface	Platform diameter	Implant diameter	Lengths
NP	Ø 3.5 mm	Ø 3.5 mm	Ø 3.5 mm	(7+3) mm, (10+3) mm, (13+3) mm, (15+3) mm
RP	Ø 4.3 mm	Ø 4.3 mm	Ø 4.0 mm	(7+3) mm, (10+3) mm, (13+3) mm, (15+3) mm

For information specific to the Cover Screws and Healing Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016 and IFU1094).

Sterility and Reusability Information

Caution Replace Select™ TC implants are delivered sterile 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.

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

Caution Replace Select™ TC implants are a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Magnetic Resonance (MR) Safety Information

MR Safety Information for Single Tooth Configurations

MRI Safety Information	MR	
Non-clinical testing has demonstrated the NobelReplace™ TC 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 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 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.	

MR Safety Information for Multiple Teeth Configurations

MRI Safety Information	MR	
Non-clinical testing has demonstrated the NobelReplace™ TC 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 shoulder: 2.0 W/kg Superior to the shoulder: 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 2.7 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, Replace Select™ TC 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 Replace Select™ TC 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
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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 Refer to the product label to determine the applicable conformity marking 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
Replace Select™ TC	73327470000001266Z

Implant Card

Replace Select™ TC implants are 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.

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	