Multi-unit Abutment Xeal™

Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC

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

Multi-unit Abutment Xeal™ and Multi-unit Abutment and Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC are premanufactured dental implant abutments to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

The Multi-unit Abutment Xeal™ are made of titanium alloy.

Multi-unit Abutment Xeal™, straight and angled 17° & 30°

Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC implant family systems.

Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC

Multi-unit Abutments Xeal™ Nobel Biocare N1™ TCC are available in NP/RP platforms, feature a tri-oval conical connection and can be used with Nobel Biocare's Nobel Biocare N1™ implant system.

Table 1 – Multi-unit Abutments with Compatible Implant Systems and Healing Caps

Multi-unit Abutment/Platforms	Implant system	Healing Cap
Internal Conical Connection (CC)		
Multi-unit Abutment Xeal™ CC NP/RP/WP	NobelActive™ NobelParallel™ CC NobelReplace CC	Healing Cap Multi-unit Titanium
17° Multi-unit Abutment Xeal™ CC NP/RP/WP	NobelActive™ NobelParallel™ CC NobelReplace CC	
30° Multi-unit Abutment Xeal™ CC NP/RP	NobelActive™ NobelParallel™ CC NobelReplace CC	
Tri-oval Conical Connection (TCC)		
Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP	Nobel Biocare N1™	Healing Cap Multi-unit Titanium
17° Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP		
30° Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC RP		

Multi-unit Abutments are co-packed with a handle and a clinical screw. Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

Intended Use/Intended Purpose

Multi-unit Abutment Xeal™

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Multi-unit Abutment Xeal™ in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics is preferred.

Multi-unit Abutment Nobel Biocare N1™ TCC

Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Indications

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

Multi-unit Abutments Nobel Biocare N1™ TCC: Multi-unit abutments are indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla or mandible, including full arch dentures.

Contraindications

It is contraindicated to use Multi-unit Abutment Xeal™ in:

- Patients who are medically unfit for an oral surgical procedure.
- 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 or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride ($MgCl_2$) or DLC (Diamond Like Carbon) coating.

Materials

- Straight Multi-unit Abutment for implants with internal conical connection and tri-oval conical connection: Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).
- Angulated Multi-unit Abutments for implants with internal conical connection and tri-oval conical connection: Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).
- Holder for straight Multi-unit Abutment: PP (polypropylene).
- Holder for angled Multi-unit Abutment: Titanium Alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3.
- Clinical screw: Titanium Alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Cautions

Multi-unit Abutments 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 Multi-unit Abutments can lead to product failure, damage to tissue, or unsatisfactory.

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

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

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.

General Caution

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.

The colored surface of the Multi-unit Abutment Xeal™, is a result of the Xeal™ surface and does not indicate the platform size.

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 and infections in the neighbouring bone). Special caution is advised in patients who receive bisphosphonate therapy.

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.

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.

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

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

At 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 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).

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.

Never exceed the recommended maximum prosthetic tightening torque for the abutment screw (see Table 2 Multi-unit Abutment Screw Tightening Torques and compatible screwdrivers). Overtightening of abutment may lead to a screw fracture.

Intended Users and Patient Groups

Multi-unit abutments are to be used by dental health care professionals.

Multi-unit abutments are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Multi-unit Abutments and Healing Caps

Multi-unit Abutments 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 Multi-unit Abutments

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

Implant abutments are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

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

Handling Procedure

Ensure sufficient implant stability before beginning the prosthetic procedure.

Clinical procedure

1A. Straight Multi-unit Abutment Xeal™/N1™ TCC

1. Select and place appropriate abutment (Figure A). Use plastic holder to facilitate the insertion (Figure C). It is recommended to verify the final abutment selection and seating using radiographic imaging.

Figure A

Figure B

Figure C

2. Tighten the abutment according to table 2, using Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic (Figure D).

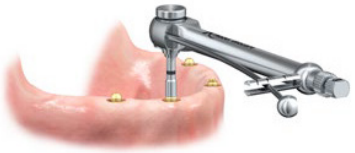

Figure D

1B. 17° and 30° Multi-unit Abutment Xeal™/N1™ TCC

1. Select and place appropriate angulated abutment (Figure B). Use the holder to facilitate proper position, as there are several positions possible (Figure E). Hand-tighten the clinical screw using appropriate screwdriver according to Table 2. It is recommended to verify the final abutment selection and seating using radiographic imaging.

2. Unscrew holder (Figure E).

3. Tighten the abutment according to Table 2, using Unigrip™ Screwdriver or Omnigrip™ Mini Screwdriver if using Multi-unit Abutment Nobel Biocare N1™ and Manual Torque Wrench prosthetic.

Caution Never exceed recommended tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Caution To place the abutment, the implant should be able to withstand the recommended tightening torque for the abutment screw. For immediate function, the implant should be able to withstand a torque of at least 35 Ncm.

Figure E

Clinical procedure

1. Remove temporary prosthesis if applicable.

2. Verify that the desired tightening torque for the Multi-unit Abutment has been applied according to Table 2, using the appropriate screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1085 for information regarding the screwdriver. Refer to Nobel Biocare IFU1098 for information regarding the torque wrench.

Table 2 – Multi-unit Abutment Screw Tightening Torques and compatible screwdrivers

Connection	Straight Multi-unit Abutment	17°/30° Multi-unit Abutment	45°/60° Multi-unit Abutment	Prosthetic screw
Conical connection (CC)	35 Ncm	15 Ncm	--	15 Ncm
Tri-oval conical connection (TCC)	20 Ncm	20 Ncm	--	15 Ncm
Driver	Multi-unit Screwdriver	Unigrip™/ Omnigrip™ mini Screwdriver	Unigrip™ Screwdriver	Unigrip™ Screwdriver

3. Insert fixed prosthesis and tighten the prosthetic screws by alternating left and right side (Figure F). Finally tighten the prosthetic screws to 15 Ncm using Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (Figure G).

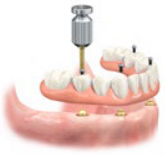

Figure F

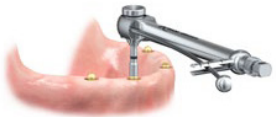

Figure G

4. Close screw access channel using suitable material.

5. If removal of the restoration is needed, open the screw access and untighten the screw using the appropriate screwdriver.

6. If the abutment cannot be removed, use the Abutment Retrieval Tool. Refer to Nobel Biocare Instructions for Use (IFU) IFU1096 for information regarding Abutment Retrieval Tool.

Sterility and Reusability Information

Multi-unit Abutment Xeal™/ N1™ TCC 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 Multi-unit Abutment Xeal™/ N1™ TCC 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

MRI Safety Information	MR	
Non-clinical testing has demonstrated the Multi-unit Abutment Xeal™ and Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC 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 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.

Performance Requirements and Limitations

To achieve the desired performance, multi-unit abutments 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 multi-unit abutments, 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
Multi-unit Abutment Xeal™ CC NP/RP/WP	7332747000001687H
17° Multi-unit Abutment Xeal™ CC NP/RP/WP	
30° Multi-unit Abutment Xeal™ CC NP/RP	
Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP	
17° Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP	
30° Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC RP	

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.

EC REP Authorized Representative in the European Community / European Union	UK RP UK Responsible Person	CH REP Authorised Representative in Switzerland	STERILE EO Sterilized using Ethylene Oxide	STERILE R Sterilized using irradiation	STERILE Sterilized using steam or dry heat	
LOT Batch code	REF Catalogue number	UDI Unique Device Identifier	SN Serial number	MD Medical device	MR 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
CE CE mark	CE 2797 CE mark with Notified Body number	UKCA UKCA mark	UKCA 0086 UKCA mark with Approved Body number	 Consult instructions for use	Rx only For prescription use only	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com 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	