Multi-unit Abutment Xeal™, Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC

Instructions for use

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, it is 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™	Healing Cap
17° Multi-unit Abutment Xeal™ CC NP/RP/WP	NobelParallel™ CC	Multi-unit Titanium
30° Multi-unit Abutment Xeal™ CC NP/RP	NobelReplace CC	
Tri-oval Conical Connection (TCC)		
Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP	Nobel Biocare N1™	Healing Cap
17° Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP		Multi-unit Titanium
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.

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

Handling instructions:

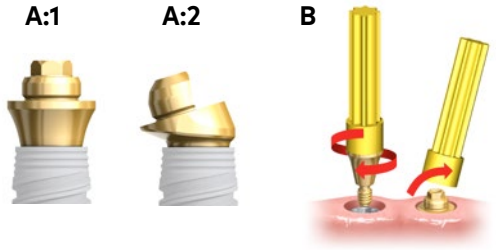
Ensure sufficient implant stability before beginning the prosthetic procedure.

Clinical procedure:

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

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

A:1 A:2 B

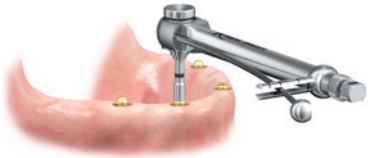


2. Tighten the abutment according to table **2**, using Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic (**C**).

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

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

C



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

1. Select and place appropriate angulated abutment (**A:2**). Use the holder to facilitate proper position, as there are several positions possible (**D**). 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 (**D**).
3. Tighten the abutment according to table **1**, 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**.

D

Clinical procedure:

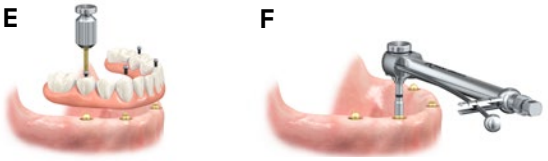
1. Remove temporary prosthesis if applicable.
2. Verify that the desired tightening torque for the Multi-unit Abutment has been applied according to Table **2**, using the appropriate screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1085 for information regarding the screwdriver. 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 (**E**). Finally tighten the prosthetic screws to **15 Ncm** using Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (**F**).

E F



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.

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.

Sterility and Reusability Information:

Multi-unit abutments have been sterilized using irradiation and are intended for single use. Do not use after the labeled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened.

Caution: Multi-unit Abutment Xeal™/N1™ TCC is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

Magnetic Resonance (MR) Safety Information:

Multi-unit abutments and healing caps which contain metallic materials can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that the metallic multi-unit abutments and healing caps are unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that multi-unit abutments and healing caps are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for these devices.

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 product must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage 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
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

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
Multi-unit Abutment Xeal™ CC NP/RP/WP	73327470000001687H
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	

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

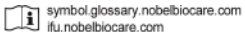

Health care centre or doctor


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