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

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, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof.

Description:

Multi-unit Abutment/Xeal™/Plus 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™ and the Multi-unit Abutment Plus are made of titanium alloy.

The Multi-unit Abutment is made of pure titanium and/or titanium alloy.

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

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

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

Internal tri-channel connection for: NobelReplace®, Replace Select™, NobelSpeedy® Replace, NobelReplace® Platform Shift.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy.

Other implant systems: Astra Tech Implant System™, Aqua and Lilac. Straumann® Bone Level NC 3.3 and RC 4.1/4.8.

Multi-unit Abutment Non-Engaging, angled 30°

The Multi-unit Abutment Non-Engaging angled 30° is available for use with the All-on-4® treatment concept with guided surgery only.

Internal tri-channel connection for: NobelReplace®, Replace Select™, NobelSpeedy® Replace, NobelReplace® Platform Shift.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy.

Multi-unit Abutment, straight

Other implant systems: Straumann® Octagon soft tissue level 4.8 and 6.5.

Ankylos® Implant System 3.5, 4.5, 5.5, 7.0 mm. Astra Tech Implant System™ 4.5ST, 5.0ST mm. Camlog® Implant System 3.3, 3.8, 4.3, 5.0/6.0 mm.

Multi-unit Abutment angled 45° & 60°

External hex connection for: NobelZygoma™ 0°.

Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC

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

Intended Use:

Multi-unit Abutment/Xeal™/Plus

Multi-unit Abutment/Xeal™/Plus in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics is preferred.

Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC

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 Abutments TCC in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics is preferred.

Indications for Use:

The Multi-unit Abutment/Xeal™/Plus/TCC are premanufactured prosthetic component directly connected to the endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation.

Contraindications:

It is contraindicated to use Multi-unit Abutment/Xeal™/Plus/TCC 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 static and dynamic loads.
- Patients who are allergic or hypersensitive to commercially pure titanium or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), PP (polypropylene), sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride ($MgCl_2$).

Cautions:

General:
It is strongly recommended that Multi-unit Abutments/Xeal™/Plus/TCC are used only with compatible Nobel Biocare instruments and prosthetic components. Use of instruments and prosthetic components that are not intended to be used in combination with Multi-unit Abutments/Xeal™/Plus/TCC can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

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

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.

The colored surface of the Multi-unit Abutment Xeal™/TCC is the 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.

In general, implant placement and prosthetic design must accommodate individual patient conditions.

In the case of bruxism, other parafunctional habits, or unfavorable jaw relationships, reappraisal of the treatment option or appropriate pre- and post-treatment measures 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 procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At surgery:
Care and maintenance of 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, a dental dam, or throat shields).

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.

Never exceed the recommended maximum prosthetic tightening torque for the abutment screw (see **Table 1**). Overtightening of abutment may lead to a screw fracture.

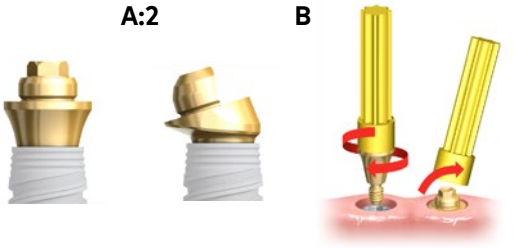
Handling Procedure:

Ensure sufficient implant stability before beginning the prosthetic procedure.

1A. Clinical procedure for placement of Straight Multi-unit Abutments:

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**



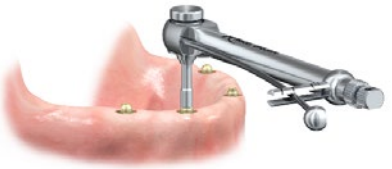
2. Tighten the clinical screw to the required torque according to **Table 1**, using a Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1085 and IFU1058 for information regarding the screwdriver. Refer to Nobel Biocare IFU1047 for information regarding the torque wrench.

Warning: Attention – Narrow platform implants are not recommended for the posterior region of the mouth due to risk of prosthetic overload. Multi-unit Abutment/Xeal™/Plus/TCC are to be used only in combination with other implants in Multi-unit restorations.

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

Caution: Each time a component is connected to the straight Multi-unit Abutment, make sure the clinical screw is not loosened and is re-tightened if necessary.

C



1B. Clinical Procedure for Placement of 17° and 30° Multi-unit Abutment:

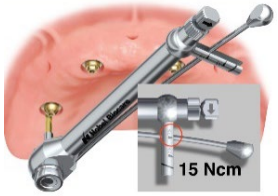
1. Select and place appropriate angulated abutment (**A:2**). Use the holder to facilitate proper position, as there are several positions possible (**D**). It is recommended to verify the final abutment selection and seating using radiographic imaging.
2. Unscrew holder (**D**).
3. Tighten the abutment to the required torque according to **Table 1**, using the appropriate screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1085 and 1058 for information regarding the screwdriver. Refer to Nobel Biocare IFU1047 for information regarding the torque wrench.

Caution: Never exceed recommended maximum 15 Ncm 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

E



1C. 45° and 60° Multi-unit Abutment:

1. Select and place appropriate angulated abutment (**A:2**). It is recommended to verify the final abutment selection and seating using radiographic imaging.

Note: The 45° and 60° Multi-Unit Abutments do not have a holder.

Caution: The screw is not locked by a holder. Ensure that the screw is engaged to the Unigrip™ Screwdriver when placing the abutment.

2. Tighten the abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**C**).

Caution: Never exceed recommended maximum 35 Ncm tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Installation of the Fixed Prosthesis on Multi-unit Abutments:

1. Remove temporary prosthesis if applicable.
2. Verify that the desired tightening torque for the Multi-unit Abutment has been applied according to **Table 1**, 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.

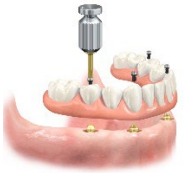
Table 1: Multi-unit Abutment Screw Tightening Torques and compatible screwdrivers

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
Tri-channel	35 Ncm	15 Ncm	--	15 Ncm
External Hex	35 Ncm	15 Ncm	35 Ncm	15 Ncm
Driver	Screwdriver Machine Multi-unit	Unigrip/ *Omnigrip mini Screwdriver	Unigrip Screwdriver	Unigrip Screwdriver

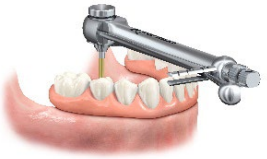
Note: Always refer to the original implant manufacturer's instructions for use, with regards to the implant indications and contraindications, as well as tooling and tightening torque.

3. Insert fixed prosthesis and tighten the prosthetic screws by alternating left and right side (**I**). Finally tighten the prosthetic screws according to **Table 1** using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**G**).

F



G



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

If the abutment cannot be removed, use the Abutment Retrieval Tool. Refer to Nobel Biocare Instructions for Use (IFU) IFU1041 for information regarding Abutment Retrieval Tool.

For additional information on restorative and dental laboratory procedures please consult the Instructions for Use available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

Straight and angulated Multi-unit Abutment Xeal™/TCC: Titanium alloy 90% Ti, 6% Al, 4%V, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Straight Multi-unit Abutment/Plus for implants with external hex connection and Internal tri-channel connection: commerically pure titanium.

All other Multi-unit Abutment/Plus and Abutment/Prosthetic screws: Titanium alloy 90% Ti, 6% Al, 4%V.

Holder for Multi-unit Abutment Xeal™ straight: PP (polypropylene).

Holder for Multi-unit Abutment Xeal™ angled: Titanium alloy 90% Ti, 6% Al, 4% V.

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 Abutment/Xeal™/Plus/TCC has been sterilized using irradiation and is 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™/Plus/TCC is 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:

The Multi-unit Abutment/Xeal™/Plus/TCC have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration and image artifact in the MR environment. The safety of the Multi-unit Abutment/Xeal™/Plus/TCC in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 compromise the integrity of the sterile barrier or the legibility of the labelling.

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

Distributed in USA by:
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887
USA

Caution: Federal law restricts this device to sale by or on the order of a dentist or a physician.

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.

LOT
Batch code

REF
Catalogue number

31
Date

Date of manufacture

Manufacturer

SN
Serial number

UDI
Unique Device Identifier

Health care centre or doctor

Patient identification

Patient number

Tooth number

Consult instructions for use

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com
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

BIO
Contains biological material of animal origin

Contains hazardous substances

PHT DEHP
Contains or presence of DEHP phthalate

LATEX
Contains or presence of natural rubber latex

PHT
Contains or presence of phthalate

Non-pyrogenic

MR
Magnetic resonance conditional

MR
Magnetic resonance safe

NON STERILE
Non-sterile

STERILE EO
Sterilized using Ethylene Oxide

STERILE R
Sterilized using irradiation

STERILE
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

CH REP
Authorised Representative in Switzerland

EC REP
Authorized representative in the European Community / European Union

UK RP
UK Responsible Person

CE
CE mark

CE 2797
CE mark with Notified Body number

EU
EU Importer

CH
Swiss Importer

UKCA
UKCA mark

UKCA 0086
UKCA mark with Approved Body number

MD
Medical device

Rx only
For prescription use only