Multi-unit Abutment Xeal™, Multi-unit Abutment Plus and Multi-unit Abutment

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°.

Intended Use:

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

Contraindications:

It is contraindicated to use Multi-unit Abutment/Xeal™/Plus 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), 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 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 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™ 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, 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 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 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. a throat shield).

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.

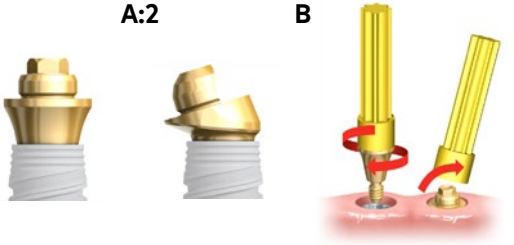
Handling Procedure:

Ensure sufficient implant stability before beginning the prosthetic procedure.

1A. Placement of Healing Abutment Nobel Biocare N1™ Base for Healing Phase:

1. 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 1**, using Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic (**C**).

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 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.

C

1B. Impression Taking using Impression Copings Open Tray Nobel Biocare N1™ Base:

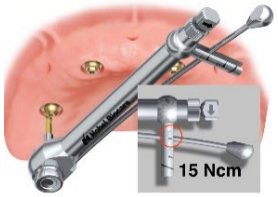
1. Place appropriate angulated abutment (**A:2**). Use the holder to facilitate proper position, as there are several positions possible (**D**). It is recommended to verify the final abutment selection and seating using radiographic imaging.
2. Unscrew holder (**D**).
3. Tighten the abutment to 15 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**E**).

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. 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.

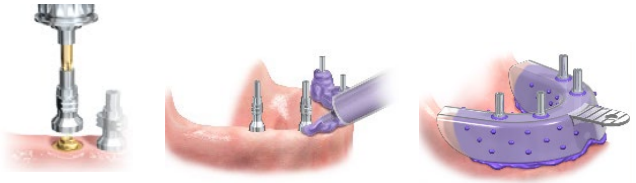
2. Tighten the abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**C**).

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

2. Take impression of abutments using open or closed impression tray technique (**F**).
Note: Hand tighten only and close impression coping recess prior to impression taking.

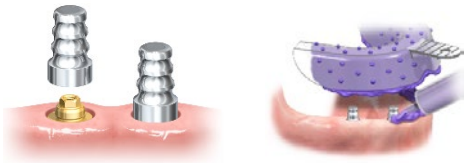
Open tray

F:1



Closed tray

F:2



3. Provisionalize or attach healing caps.

Laboratory procedure:

4. Attach abutment replicas to impression copings.

5. Fabricate a working model with removable gingival material (**G**).

G

H

6. NobelProcera® Implant Bridge Wax-up:

1. Create implant bridge framework using non-engaging temporary cylinders as a foundation and add pattern resin to fabricate desired framework design (**H**).
2. Scan the acrylic framework using the NobelProcera® Scanner according to the tutorial found within the software.
3. Once precision milled framework is delivered back to lab, veneering material is added for completion.

Clinical Procedure:

7. Remove temporary restoration if applicable.

8. Use the Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic to verify the tightening of the straight Multi-unit Abutment/Xeal™/Plus according to **table 1**. Use the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to verify tightening of the angulated Multi-unit Abutment Xeal™ to 15 Ncm.

1

Abutment (clinical) Screw Tightening Torque	Straight	Angulated (17°, 30°)	Angulated (45°, 60°)
Nobel Biocare implant systems	35 Ncm	15 Ncm	35 Ncm
*Astra Tech Implant System™ Aqua	20 Ncm	15 Ncm	–
*Astra Tech Implant System™ Lilac	25 Ncm	15 Ncm	–
*Astra Tech Implant System™ 4.5ST, 5.0ST	25 Ncm	15 Ncm	–
*Straumann® Bone Level, Straumann® Octagon soft tissue level	35 Ncm	15 Ncm	–
*Ankylos® Implant System	25 Ncm	15 Ncm	–
*Camlog®	20 Ncm	15 Ncm	–

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.

9. 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 (**J**).

I

J

10. Close screw access channel.

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™: 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.

Sterility and reusability information:

Multi-unit Abutment/Xeal™/Plus 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.

Caution: Multi-unit Abutment/Xeal™/Plus 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™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration and image artifact in the MR environment. The safety of the Multi-unit Abutment Xeal™ 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:
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411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in USA by:
Nobel Biocare USA, LLC
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Yorba Linda, CA, 92887 USA

Caution: Federal (United States) 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.

Authorized representative in the European Union

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate


Date


Date of manufacture


Do not re-sterilize


Do not re-use


Do not use if package is damaged


Double sterile barrier system

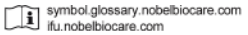
Rx Only

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation


Temperature limit


Tooth number


Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier


Use-by date

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