

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

Instructions for use



Important: Please read.

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™, Multi-unit Abutment Plus and Multi-unit Abutment 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 Multi-unit Abutment Plus are made of titanium alloy.

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

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

Gold Coping Multi-unit may be used if a casted framework is preferred.

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:

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

Indications:

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.

45° and 60° Multi-unit Abutment for External Hex are indicated for multi-unit screw retained restorations with NobelZygoma™ 0° implants only.

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), gold alloy (gold, platinum, palladium, iridium), PP (polypropylene), sodium dihydrogen phosphate (NaH₂PO₄) or magnesium chloride (MgCl₂).
- The 45° and 60° Multi-unit Abutment external hex connection are contra-indicated for all other implants other than NobelZygoma™ 0°.

Cautions:

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory aesthetic results.

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.

Before surgery:

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

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.

With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented.

It is especially important to achieve proper stress distribution through adaptation and fitting of the prosthesis or bridge by adjusting occlusion to the opposing jaw. In addition avoid excessive transverse loading forces, particularly in immediate loading cases.

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. 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 recommended to use a rubber dam in order to prevent inhalation of loose parts.

After surgery:

To secure the long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform 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.

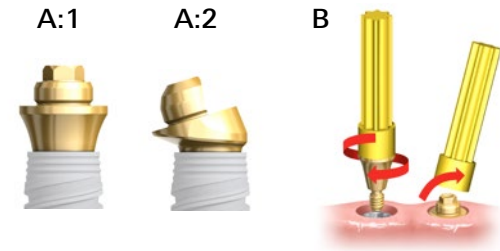
Handling instructions:

Ensure sufficient implant stability before beginning the prosthetic procedure.

Clinical procedure:

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

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.



2. Tighten the abutment according to table 1, 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™/Plus:

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).

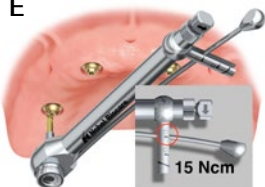
Caution: Never exceed recommended maximum **15 Ncm** tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

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).

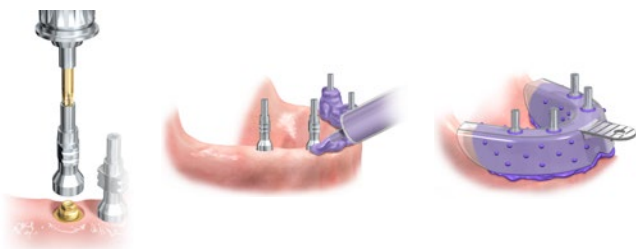
Caution: Never exceed recommended maximum **35 Ncm** tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

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.

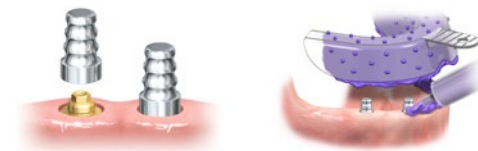
Open tray

F:1



Closed tray

F:2

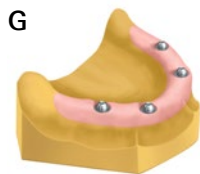


3. Provisionalize or attach healing caps.

Laboratory procedure:

4. Attach abutment replicas to impression copings.
5. Fabricate a working model with removable gingival material (G).

G



6A. 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.

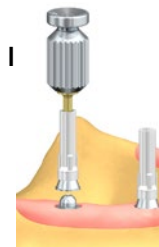
6B. Laboratory – Casted Framework:

1. Attach Gold Coping Multi-unit to the abutment replicas (I) and reduce the height of the plastic chimney.

H



I



2. Wax up framework around gold copings (J).

J



Note: The Gold Coping Multi-unit is made from a non-oxidizing alloy. Cracking of porcelain may occur if it is applied directly to the gold coping. Make sure the wax covers the Gold Coping Multi-unit with a minimum wax thickness of 0.5 mm. A reduction to 0.3 mm can be made after casting.

3. Fabricate the restoration framework using standard techniques.

4. Complete framework with ceramic (if applicable).

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™/Plus to **15 Ncm** and for 45° and 60° Multi-Unit Abutment to **35 Ncm**.

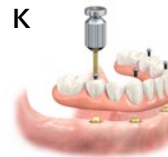
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Abutment (clinical)	Screw Tightening Torque	Straight	Angulated (17°, 30°)	Angulated (45°, 60°)
Nobel Biocare implant systems		35 Ncm	15 Ncm	35 Ncm
*Astra Tech Implant System™ Aqua		20 Ncm	15 Ncm	-
*Astra Tech Implant System™ Lilac		25 Ncm	15 Ncm	-
*Astra Tech Implant System™ 4.5 ST, 5.0 ST		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 (K). Finally tighten the prosthetic screws according to table 1 using Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (L).

K



L



10. Close screw access channel.

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

Gold Coping Multi-unit casting specifications: Melting range: 1400–1490° C/ 2550–2720° F. Coefficient of thermal expansion: 12 µm/m**° K.

Recommended casting alloys: Conventional gold alloys: High gold content (min 75% Au + Pt metal) alloys, standard ISO 1562 type 4.

Ceramic bonding alloys: High gold content (min 75% Au) alloys, standard ISO/DIS 9693, NIOM type A.

Soldering in the range of 800–890° C/1472–1634° F.

Gold Coping Bar: Soldering in the range of 800–890° C/1472–1634° F.

Materials:

Straight Multi-unit Abutment for implants with external hex connection and Internal Tri-channel connection: commercially pure titanium.

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

Straight and angulated Multi-unit Abutment Xeal™ for implants with conical connection: Titanium alloy 90% Ti, 6% Al, 4%V, sodium dihydrogen phosphate (NaH₂PO₄) and magnesium chloride (MgCl₂).

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

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

Gold coping: Gold alloy 60% Au, 19% Pt, 20% Pd, 1% Ir.

Sterility and Reusability Information:

Multi-unit Abutment/Xeal™/Plus is delivered sterile for single use only. Do not use after the labelled 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. Re-use could cause cross contamination.

Cleaning and sterilization instructions:

Gold Coping Multi-unit Abutment and Multi-unit Abutment Non-Engaging 30° are delivered non-sterile for single use only.

Final framework with the Gold Coping Multi-unit Abutment and the jig with the Multi-unit Abutment Non-Engaging 30° should be cleaned and disinfected, as applicable per manufacturer's instructions, before intraoral use.

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

Caution: Gold Coping Multi-unit Abutment and Multi-unit Abutment Non-Engaging 30° are single use products 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:

Note: Only the Conical Connection Wide Platform abutments have been assessed as MR Conditional. The other platforms and sizes have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment.

Should there be no MR symbol on the product label, please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this devices may result in patient injury.

Conical Connection Wide Platform abutments.

Non-clinical testing has demonstrated that the product is MR conditional. A patient with this device can be safely scanned in a MR system meeting the following 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 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the product is expected to produce a maximum temperature rise of 4.1° C after 15 minutes of continuous scanning.

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

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

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

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:



Manufacturer: Nobel Biocare AB, Box 5190, 402 26
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Canada license exemption: Please note that not all products may have been licenced in accordance with Canadian law.

For Prescription Use Only.

Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

Straumann® is a trademark of Straumann Group.

Camlog® is a trademark of Camlog Biotechnologies Group.

Astra Tech Implant System™ is a trademark of Dentsply Group.

Ankylos® is a trademark of Dentsply Group.

Symbol Glossary:

These symbols may be present on one or more device labels covered by this IFU.

0086



Non-sterile

Rx Only

Prescription use only



Sterilized using irradiation



Caution



Consult instructions for use



Manufacturer



Date of manufacture



Use-by date



Do not re-use



Do not use if package is damaged



Do not re-sterilize



Catalogue number



Batch code



Medical device



Keep dry



Keep away from sunlight

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