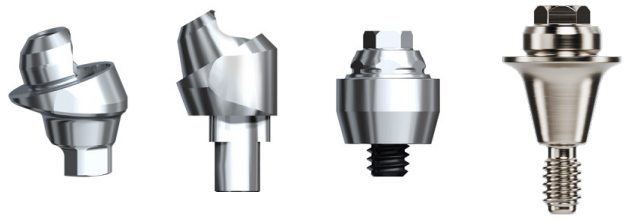
Multi-unit Abutment Plus and Multi-unit Abutment



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

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

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

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

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/Intended Purpose

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

Indications

Multi-unit Abutment/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/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) polypropylene or PBT (Polybuthylene terephtalate).
- The 45° and 60° Multi-unit Abutment external hex connection are contra-indicated for all other implants other than NobelZygoma™ 0°.

Materials

- 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/Plus straight:
  PBT (Polybuthylene terephtalate).
- Holder for Multi-unit Abutment/Plus angled:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- Gold coping:
  Gold alloy 60% Au, 19% Pt, 20% Pd, 1% Ir.

Cautions

General

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

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 esthetic results.

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.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery

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 neighboring 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 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 the clinical and/or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery

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.

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

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, swelling. During abutment placement or removal, the pharyngeal reflect (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, ulcers, 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

Clinical procedure

1A. Straight Multi-unit Abutment/Plus

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

Figure A

Figure B

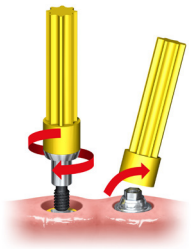


Figure C

2. Tighten the abutment according to table 1, using Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic (Figure D).

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

Figure D

1B. 17° and 30° Multi-unit Abutment/Plus

1. Place appropriate angulated abutment (Figure B). Use the holder to facilitate proper position, as there are several positions available (Figure E). It is recommended to verify the final abutment seating using radiographic imaging.

2. Unscrew holder (Figure E).

3. Tighten the abutment to 15 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (Figure F).

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

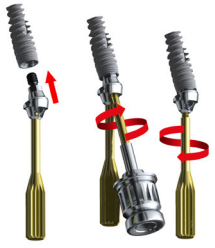


Figure E

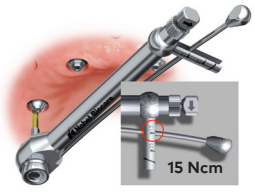


Figure F

1C. 45° and 60° Multi-unit Abutment

1. Place appropriate angulated abutment (Figure B). It is recommended to verify the final abutment 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 (Figure D).

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

3. Take impression of abutments using open or closed impression tray technique (Figure G, Figure H).

Note Hand tighten only and close impression coping recess prior to impression taking.

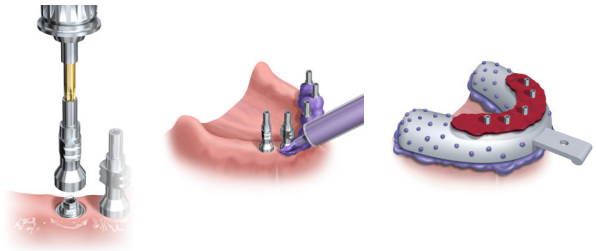


Figure G – Open tray

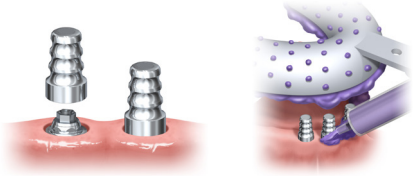


Figure H – Closed tray

4. Provisionalize or attach healing caps.

Laboratory procedure

5. Attach abutment replicas to impression copings.

6. Fabricate a working model with removable gingival material (Figure I).

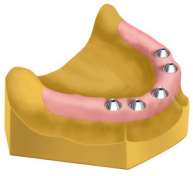


Figure I

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 (Figure J).

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 (Figure K) and reduce the height of the plastic chimney.

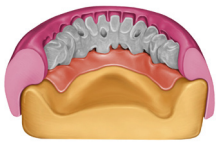


Figure J

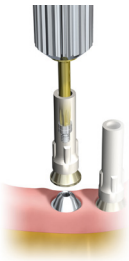


Figure K

2. Wax up framework around gold copings (Figure L)

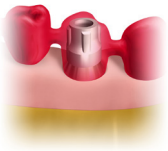


Figure L

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

5. Remove temporary restoration if applicable.

6. Use the Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic to verify the tightening of the straight Multi-unit Abutment/Plus according to Table 1. Use the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to verify tightening of the angulated Multi-unit Abutment/Plus to 15 Ncm and for 45° and 60° Multi-Unit Abutment to 35 Ncm.

Table 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™ 4.5 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.

7. Insert fixed prosthesis and tighten the prosthetic screws by alternating left and right side (Figure M, Figure N). Finally tighten the prosthetic screws according to Table 1 using Screwdriver Machine Multi-unit or Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (Figure O).

Figure M

Figure N

Figure O

8. 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.

Sterility and Reusability Information

Multi-unit Abutment/Plus 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/Plus are single use product(s) 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 Plus and Multi-unit Abutment 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 3T 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 Abutment Plus and Multi-unit Abutment 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 Abutment Plus and Multi-unit Abutment, 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
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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 Plus CC NP/RP/WP 17° Multi-unit Abutment Plus CC NP/RP/WP 30° Multi-unit Abutment Plus CC NP/RP Multi-Unit Abutment NobelReplace® NP/RP/WP 17° Multi-Unit Abutment NobelReplace® NP/RP 30° Multi-Unit Abutment NobelReplace® RP Multi-unit Abutments Brånemark System® NP/RP/WP 17° Multi-Unit Abutments Brånemark System® NP/RP 30° Multi-Unit Abutments Brånemark System® RP Multi-unit Abutments Brånemark System® Zygoma 17° Multi-unit Abutments Brånemark System® Zygoma 45° Multi-unit Abutments External Hex RP 60° Multi-unit Abutments External Hex RP	7332747000001687H

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.

						
Authorized Representative in the European Community / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat	
						
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	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
					Rx only	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	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	