Multi-unit Abutments and Healing Caps Multi-unit

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, 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:

Multi-unit Abutments:
Multi-unit abutments are premanufactured dental implant abutments which can be directly connected to an endosseous dental implant to support the placement of a dental prosthesis.

An assortment of Multi-unit abutments are available for use with various Nobel Biocare implant systems.

- Multi-unit Abutments Conical Connection (CC) are available in NP/RP/WP platforms, feature a conical connection and can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC and/or NobelReplace CC implant systems.
- Multi-unit Abutments 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.
- Multi-unit Abutments NobelReplace™ are available in NP/RP/WP and 6.0 platform, feature an internal tri-channel connection and can be used with Nobel Biocare's NobelReplace, Replace Select and/or NobelSpeedy Replace implant systems.
- Multi-unit Abutments Brånemark System® are available in NP/RP/WP platforms, feature an external hex connection and can be used with Nobel Biocare's Brånemark System and/or NobelSpeedy Groovy implant systems.
- Multi-unit Abutments Brånemark System® Zygoma feature an External Hex Connection and can be used with Nobel Biocare's Brånemark System® Zygoma implant system.
- 45° Multi-unit Abutments External Hex and 60° Multi-unit Abutments External Hex feature an External Hex Connection and can be used with Nobel Biocare's NobelZygoma™ 0° implant system.

Multi-unit Healing Caps:
Multi-unit healing caps are premanufactured dental implant healing abutments which can be directly connected to a multi-unit abutment to support healing of the surrounding soft tissues.

An assortment of multi-unit healing caps is available:

- Healing Caps Multi-unit Titanium can be used with Multi-unit Abutments featuring a Conical connection, Tri-oval conical connection, Tri-channel connection and External Hex connection NP & RP.
- Healing Caps Multi-unit Branemark System® WP can be used with Multi-unit Abutments Brånemark System® featuring a WP platform.

Table 1 summarizes the implant platforms which are compatible with the various multi-unit abutments and the corresponding healing caps.

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 Plus CC NP/RP/WP Multi-unit Abutment Xeal™ CC NP/RP/WP 17° Multi-unit Abutment Plus CC NP/RP/WP 17° Multi-unit Abutment Xeal™ CC NP/RP/WP 30° Multi-unit Abutment Plus CC NP/RP 30° Multi-unit Abutment Xeal™ CC NP/RP	NobelActive™ NobelParallel™ CC NobelReplace CC	Healing Cap Multi-unit Titanium
Tri-oval Conical Connection (TCC)		
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	Nobel Biocare N1™	Healing Cap Multi-unit Titanium
Internal Tri-channel Connection		
Multi-Unit Abutment NobelReplace NP/RP/WP 17° Multi-Unit Abutment NobelReplace NP/RP 30° Multi-Unit Abutment NobelReplace RP	NobelReplace Replace Select NobelSpeedy Replace	Healing Cap Multi-unit Titanium
External Hex		
Multi-unit Abutments Brånemark System NP/RP 17° Multi-Unit Abutments Brånemark System NP/RP 30° Multi-Unit Abutments Brånemark System RP	Brånemark System NobelSpeedy Groovy	Healing Cap Multi-unit Titanium
Multi-unit Abutments Brånemark System WP	Brånemark System NobelSpeedy Groovy	Healing Cap Multi-unit Branemark System® WP
Multi-unit Abutments Brånemark System® Zygoma 17° Multi-unit Abutments Brånemark System® Zygoma	Brånemark System® Zygoma	Healing Cap Multi-unit Titanium
45° Multi-unit Abutments External Hex RP 60° Multi-unit Abutments External Hex RP	NobelZygoma™ 0°	

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 Abutments:
Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Multi-unit Healing Caps:
Intended to be temporarily connected to an endosseous dental implant or implant abutment, to support healing of the surrounding soft tissue.

Indications:

Multi-unit Abutments:
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.

For compatibility with specific implant systems, refer to Table 1.

Multi-unit Healing Caps:
Same as Intended Use/Intended Purpose.

Contraindications:

It is contraindicated to use Multi-unit abutments and/or healing caps 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 titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), PP (polypropylene), sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride ($MgCl_2$) or DLC (Diamond Like Carbon) coating.

The 45° Multi-unit Abutments External Hex and 60° Multi-unit Abutments External Hex are contraindicated for all implants other than NobelZygoma™ 0°.

Cautions:

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

It is strongly recommended that Multi-unit Abutments and Healing caps 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 and Healing Caps 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.

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 must 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, 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 the clinical 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:
Care and maintenance of sterile 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).

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 and healing caps are to be used by dental health care professionals.

Multi-unit abutments and healing caps 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 and Healing Caps 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 and Healing Caps:
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 Procedure:

Ensure sufficient implant stability before beginning the prosthetic procedure.

A. Clinical Procedure for Placement of Straight Multi-unit Abutment:

1. Select the appropriate abutment according to Table 1.
2. Place the abutment, using plastic holder to facilitate the insertion.
3. Remove the plastic holder.
4. Tighten the clinical screw to the required torque according to Table 2, using a Screwdriver Machine Multi-unit 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
Tri-channel	35 Ncm	15 Ncm	--	15 Ncm
External Hex	35 Ncm	15 Ncm	35 Ncm	15 Ncm
Driver	Multi-unit Screwdriver	Unigrip/ *Omnigrip mini Screwdriver	Unigrip Screwdriver	Unigrip Screwdriver

5. It is recommended to verify the final abutment selection and seating using radiographic imaging.
6. If required, a bone mill can be used to remove excess bone from around the seating area. Refer to Nobel Biocare IFU1089 for information regarding bone mills.

Figure 1: Handling of Straight Multi-unit Abutment

Caution: Never exceed recommended maximum tightening torque for the clinical screw. Overtightening of the 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.

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

1. Select the appropriate angulated abutment according to Table 1.
2. Place the abutment. Use the holder to facilitate proper position, as there are several positions possible. Hand-tighten the clinical screw using appropriate screwdriver according to Table 2.
3. Unscrew the holder.
4. Tighten the abutment to the required torque 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.
5. It is recommended to verify the final abutment selection and seating using radiographic imaging.
6. If required, a bone mill can be used to remove excess bone from around the seating area. Refer to Nobel Biocare IFU1089 for information regarding bone mills.

Figure 2: Handling of Angled Multi-unit Abutment

Caution: Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of the 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.

C. Clinical Procedure for Placement of 45° Multi-unit Abutments and 60° Multi-unit Abutments:

1. Select the appropriate angulated abutment according to Table 1.
2. Place the abutment. Hand-tighten the clinical screw using the appropriate screwdriver according to Table 2.

Note: The 45° Multi-unit Abutments 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.

3. Tighten the abutment to the required torque according to Table 2 using Unigrip™ 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.

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

D. Clinical Procedure for Healing Cap Multi-unit:

1. Select the appropriate Healing Cap according to Table 1 and check occlusal clearance.
2. Hand-tighten using Unigrip™ Screwdriver. Refer to Nobel Biocare IFU1085 for information regarding the screwdriver.

Caution: Blood coagulation between Healing Cap and Multi-unit Abutment may lead to difficult disassembly.

E. 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 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.
3. Insert the fixed prosthesis and tighten the prosthetic screws by alternating left and right side. Finally, tighten the prosthetic screws to the desired torque according to Table 2 using a Unigrip Screwdriver and Manual Torque Wrench Prosthetic.
4. Close screw access channel using suitable material.

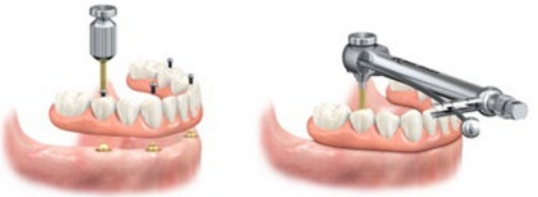

Figure 3: Installation of the Fixed Prosthesis

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 ($MgCl_2$).
- Straight Multi-unit Abutment for implants with external hex connection and internal tri-channel connection: Unalloyed Titanium Grade 1 and 4 according to ASTM F67 and ISO 5832-2.
- Angulated Multi-unit Abutments for implants with external hex connection and internal tri-channel connection: Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3.
- 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.
- Healing Caps Multi-unit Abutment Titanium: Titanium Alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3.
- Healing Caps Multi-unit Branemark System WP: Polybutylene terephthalate or 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 and healing caps 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 abutments and healing caps are single use products 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:

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 and healing caps 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 and healing caps, 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:

Manufacturer:
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
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Phone: +61 1800 804 597

Distributed in New Zealand by:
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33 Spartan Road
Takanini, Auckland, 2105 New Zealand
Phone: +64 0800 441 657

CE 2797

CE Mark for Class IIb Devices

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 Plus CC NP/RP/WP Multi-unit Abutment Xeal™ CC NP/RP/WP 17° Multi-unit Abutment Plus CC NP/RP/WP 17° Multi-unit Abutment Xeal™ CC NP/RP/WP 30° Multi-unit Abutment Plus CC NP/RP 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 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	73327470000001687H
Healing Cap Multi-unit Titanium Healing Cap Multi-unit Branemark System® WP	73327470000001236T

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.

EC REP — Authorized representative in the European Community

LOT — Batch code

REF — Catalogue number

Caution

CE marking

Consult instructions for use

Contains hazardous substances

PHT DEHP — Contains or presence of phthalate

Date

Date of manufacture

Do not resterilize

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

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com
Link to Online Symbols Glossary and IFU Portal

MR — Magnetic resonance conditional

Manufacturer

MD — Medical device

Non-pyrogenic

NON STERILE — Non-sterile

Patient identification

Patient information website

Patient number

SN — 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