Multi-unit Abutments and Healing Caps

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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 Abutment Conical Connection (CC) feature a conical connection and are available in platform sizes NP, RP, and WP. They come in a selection of different collar heights and can be straight or with an angulation of 17° or 30°. Abutment screw and handle for abutment seating included.
- Multi-unit Abutment Xeal™ Conical Connection (CC) feature a conical connection and are available in platform sizes NP, RP, and WP. They come in a selection of different collar heights and can be straight or with an angulation of 17° or 30°. Abutment screw and handle for abutment seating included.
- Multi-unit Abutments Plus Conical Connection (CC) feature a conical connection and are available in platform sizes NP, RP, and WP. They come in a selection of different collar heights and can be straight or with an angulation of 17° or 30°. Abutment screw and holder Multi-unit Abutment Plus included.
- Multi-unit Abutments Xeal™ Nobel Biocare N1™ TCC feature a tri-oval conical connection and are available in platform sizes NP and RP. They come in a selection of different collar heights and can be straight or with an angulation of 17° or 30°. Abutment screw and handle for abutment seating included.
- Multi-unit Abutments NobelReplace™ feature an internal tri-channel connection and platform sizes NP, RP, and WP. They come in a selection of different collar heights. The Multi-unit Abutments NobelReplace™ NP and RP also have a selection of different angulations of 17° and 30°. Abutment screw and handle for abutment seating included.

– Multi-unit Abutments Brånemark System® feature an external hex connection and platform sizes NP, RP, and WP. They come in a selection of different collar heights and can be straight or with an angulation of 17° or 30°. Abutment screw and handle for abutment seating included.

– Multi-unit Abutments Brånemark System® Zygoma feature an external hex connection and are available in platform size RP. They are available as straight or angled (17°) and come in different collar heights. Abutment screw and handle for abutment seating included.

– 45° and 60° Multi-unit Abutments External Hex RP feature an external hex connection, have an angulation of 45° and 60° respectively and come in different collar heights. Abutment screw included.

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 an conical connection, tri-channel connection and/or external hex connection. They are available in two heights and two diameters.

– Healing Caps Multi-unit Brånemark System® WP can be used with Multi-unit Abutments Brånemark System® featuring a WP platform.

Multi-unit Abutments are co-packed with a handle and a clinical screw. Exception: 45° and 60° Multi-unit Abutment external hex for NobelZygoma™ 0° are co-packed with an abutment screw only.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to 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.

Multi-unit Healing Caps

Same as Intended Use/Intended Purpose.

Multi-Unit Abutment Zygoma

Multi-unit abutments are indicated to support the placement of multiple unit, screw-retained prosthetic restoration in the maxilla including full arch dentures.

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 Polybutyleneterephtalate (PBT) Pocan, Grade B1501, stainless steel 1.4305/AISI 303 austenitic steel according to EN 10088-3 and ASTM F899, unalloyed titanium grade 1 and 4 according to ASTM F67 and ISO 5832-2, titanium alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating, sodium dihydrogen phosphate (NaH_2PO_4), or magnesium chloride ($MgCl_2$), or PP (polypropylene).

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

Materials

Healing Cap Wide Multi-unit Brånemark System® WP

Healing Cap: Polybutylene terephthalate (PBT) polymer.

Screw: Stainless Steel UNS S30300 (type 303). Detailed chemical composition is Iron balanced with 17.0-19.0 wt.% Chromium (Cr), 8.0-10.0 wt.% Nickel (Ni), 0.15-0.35 wt.% Sulfur (S), max. 2.0 wt.% Manganese (Mn), max. 1.0 wt.% Silicium (Si), max. 0.06 wt.% Phosphorus (P), max. 0.12 wt.% Carbon (C), max. 0.70 wt.% Molybdenum (Mo), (max.-maximum value).

Multi-unit Abutment Bmk Syst NP/RP/WP, Multi-Unit Abutment NobRpl NP/RP/WP, Brånemark System® Zygoma Multi-unit Abutment

Abutment: Commercially pure Titanium grade 4 or Commercially pure Titanium grade 1. Detailed chemical composition of Titanium grade 1 is Titanium balanced with max. 0.20 wt.% Iron, max. 0.18 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.03 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max.-maximum value). Detailed chemical composition of Titanium grade 4 is Titanium balanced with max. 0.50 wt.% Iron, max. 0.40 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max.-maximum value).

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing Carbon coating, containing Tungsten Carbide and Carbon with Chromium interlayer between substrate and Diamond like Carbon coating.

Handle: Polypropylene (PP) polymer.

Zygoma Abutment Multi-unit RP

Abutment: Commercially pure Titanium grade 4 or Commercially pure Titanium grade 1. Detailed chemical composition of Titanium grade 1 is Titanium balanced with max. 0.20 wt.% Iron, max. 0.18 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.03 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max.-maximum value). Detailed chemical composition of Titanium grade 4 is Titanium balanced with max. 0.50 wt.% Iron, max. 0.40 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max.-maximum value).

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Handle: Polypropylene (PP) polymer.

17° Multi-unit Abutment Bmk Syst NP/RP, 30° Multi-unit Abutment Bmk Syst RP, 17° Multi-Unit Abutment NobRpl NP/RP, 30° Multi-Unit Abutment NobRpl RP, 17° Multi-unit Abutment Plus CC NP/RP/WP, 30° Multi-unit Abutment Plus CC NP/RP

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing Carbon coating, containing Tungsten Carbide and Carbon with Chromium interlayer between substrate and Diamond like Carbon coating.

Handle: Titanium alloy ELI (Extra Low Interstitial) containing 6wt.% Aluminium and 4wt.% Vanadium.

Zygoma 17° Abutment Multi-unit RP, Brånemark System® Zygoma 17° Multi-unit Abutment

Abutment and screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Handle: Titanium alloy ELI (Extra Low Interstitial) containing 6wt.% Aluminium and 4wt.% Vanadium.

45° Multi-unit Abutment External Hex RP, 60° Multi-unit Abutment External Hex RP

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing Carbon coating, containing Tungsten Carbide and Carbon with Chromium interlayer between substrate and Diamond like Carbon coating.

Healing Cap M-u Ti,, Healing Cap Wide M-u Ti

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Multi-unit Abutment Plus CC NP/RP/WP

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Handle: Polypropylene (PP) polymer.

Multi-unit Abutment Xeal™ Conical Connection NP/RP/WP

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Abutment is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

Handle: Polypropylene (PP) polymer.

17° Multi-unit Abutment Xeal™ Conical Connection NP/RP/WP. 30° Multi-unit Abutment Xeal™ Conical Connection NP/RP, 17° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC NP/RP, 30° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC RP

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Abutment is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing Carbon coating, containing Tungsten Carbide and Carbon with Chromium interlayer between substrate and Diamond like Carbon coating.

Handle: Titanium alloy ELI (Extra Low Interstitial) containing 6wt.% Aluminium and 4wt.% Vanadium.

Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP/RP

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Abutment is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing Carbon coating, containing Tungsten Carbide and Carbon with Chromium interlayer between substrate and Diamond like Carbon coating.

Handle: Polypropylene (PP) polymer.

Cautions

General

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

Multi-unit Abutments and Healing Caps Multi-unit 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 and Healing Caps Multi-unit 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 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, 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 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

Small diameter implants and angled abutments are not recommended for the posterior region.

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. 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 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, 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

Ensure sufficient implant stability before beginning the prosthetic procedure.

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

1. Select the appropriate abutment.
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 1, 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 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 (Zygoma Implant System)	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.

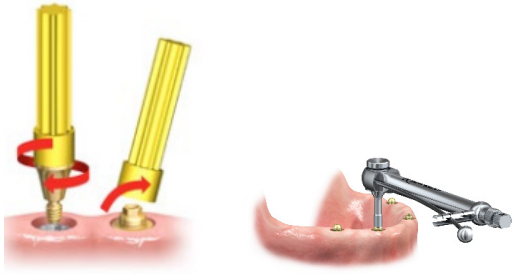

Figure 1 – Handling of Straight Multi-unit Abutment

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.
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 1.
3. Unscrew the holder.
4. 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 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.
2. Place the abutment. Hand-tighten the clinical screw using the appropriate screwdriver according to Table 1.

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 1 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 and check occlusal clearance.

2. Hand-tighten using Unigrip™ Screwdriver. Refer to Nobel Biocare IFU1085 for information regarding the screwdriver.

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

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 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.

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 1 using a Unigrip Screwdriver and Manual Torque Wrench Prosthetic.

4. Close screw access channel using suitable material.

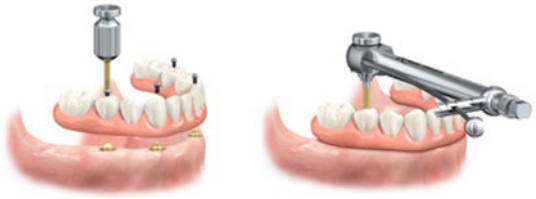

Figure 3 – Installation of the Fixed Prosthesis

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.

Sterility and Reusability Information

Multi-unit Abutments and Healing Caps Multi-unit Titanium 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.

Caution Multi-unit Abutments and Healing Caps Multi-unit Titanium 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.

Healing Cap Multi-unit Brånemark System® is delivered non-sterile and is intended for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution Healing Cap Multi-unit Brånemark System® 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.

Warning Do not use device if the packaging has been damaged or previously opened.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 the devices, 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
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
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
CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Multi-unit Abutment Plus CC NP/RP/WP	07332747000001687H
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	
Healing Cap Multi-unit Titanium	07332747000001236T
Healing Cap Multi-unit Brånemark System® WP	

Legal Statements

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Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.