Multi-unit Abutments

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 Abutment Conical Connection (CC) feature an internal 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°. They can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC, and/or NobelReplace™ CC implant systems. Abutment screw and handle for abutment seating included.
- Multi-unit Abutment Xeal™ Conical Connection (CC) feature an internal 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°. They can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC, and/or NobelReplace™ CC implant systems. Abutment screw and handle for abutment seating included.
- Multi-unit Abutments Plus Conical Connection (CC) feature an internal 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°. They can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC and/or NobelReplace™ CC implant systems. Abutment screw and holder Multi-unit Abutment Plus included.
- Muti-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°. They can be used with Nobel Biocare's Nobel Biocare N1™ implant system. 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 and can be used with Nobel Biocare's NobelReplace™, Replace Select™, and NobelSpeedy® Replace implant systems. 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°. They can be used with Nobel Biocare's Brånemark System® and/or NobelSpeedy® Groovy implant systems. 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. They can be used with Nobel Biocare's Brånemark System® Zygoma implant system. 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. They can be used with Nobel Biocare's NobelZygoma™ 0° implant system. Abutment screw included.

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	Screwdriver
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	Healing Cap: Unigrip Straight MUAs: MUA Driver Angled MUAs: Unigrip
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	Healing Cap: Unigrip Straight MUAs: MUA Driver Angled MUAs: Omnigrip Mini
Internal Tri-channel Connection			
Multi-Unit Abutment NobRpl NP/RP/WP 17° Multi-Unit Abutment NobelReplace NP/RP 30° Multi-Unit Abutment NobelReplace RP	Replace Select™ NobelSpeedy Replace™ NobelSpeedy® Replace	Healing Cap Multi-unit Titanium	Healing Cap: Unigrip Angled MUAs: Unigrip
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	Healing Cap: Unigrip Straight MUAs: MUA Driver Angled MUAs: Unigrip
Multi-unit Abutments Brånemark System WP	Brånemark System® NobelSpeedy® Groovy	Healing Cap Multi-unit Brånemark System® WP	Healing Cap: Unigrip Straight MUAs: MUA Driver
Multi-unit Abutments Brånemark System® Zygoma 17° Multi-unit Abutments Brånemark System® Zygoma	Brånemark System® Zygoma	Healing Cap Multi-unit Titanium	Healing Cap: Unigrip Straight MUAs: MUA Driver Angled MUAs: Unigrip
45° Multi-unit Abutments External Hex RP 60° Multi-unit Abutments External Hex RP	NobelZygoma™ 0°		Healing Cap: Unigrip Angled MUAs: Unigrip

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 and IFU 1026 for Healing caps. 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.

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 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 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 unalloyed titanium grade 1 and 4 according to ASTM F67 and ISO 5832-2, pure titanium, 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 ($MgCl_2$).

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

For contraindications specific to the Implants, refer to the Nobel Biocare Instructions for Use for the component available on ifu.nobelbiocare.com

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.

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

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 are to be used by dental health care professionals.

Multi-unit Abutments are to be used in patients subject to dental implant treatment.

Handling Procedure

Ensure sufficient implant stability before beginning the prosthetic procedure.

Warning Attention – Narrow platform implants are not recommended for the posterior region of the mouth due to risk of prosthetic overload. Multi-unit Abutments are to be used only in combination with other implants in Multi-unit restorations.

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 (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.

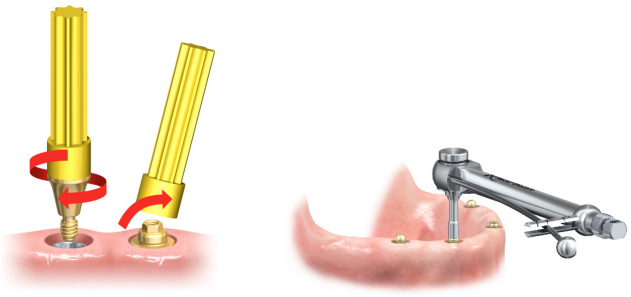


Figure A – Handling of Straight Multi-unit Abutment

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.

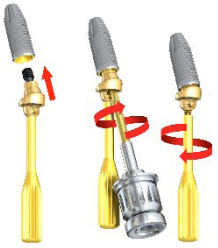


Figure B – Handling of Angled Multi-unit Abutment

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. 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.

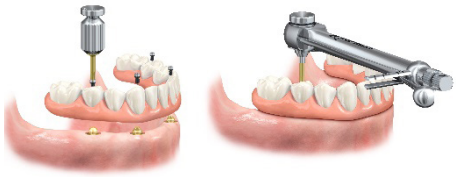


Figure C – Installation of the Fixed Prosthesis

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

Multi-Unit Abutment Brånemark System

– 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, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating, and PP (polypropylene).

– Angulated Multi-unit Abutments for implants with external hex connection and internal tri-channel connection: titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Multi-Unit Abutment NobelReplace

– Straight Multi-unit Abutment for implants with internal conical connection and tri-oval conical connection: unalloyed titanium grade 1 and 4 according to ASTM F67 and ISO 5832-2, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating, and PP (polypropylene).

– Angulated Multi-unit Abutments for implants with internal conical connection and tri-oval conical connection: titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum,

4% vanadium) according to ASTM F136 and ISO 5832-3, and DLC (Diamond Like Carbon) coating.

Multi-Unit Abutment Zygoma

- Straight Multi-unit Abutment for zygoma implants with external hex connection:
  unalloyed titanium grade 1 and 4 according to ASTM F67 and ISO 5832-2, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, and PP (polypropylene).

- Angulated Multi-unit Abutments for zygoma implants with external hex connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Brånemark System® Zygoma

- Straight Multi-unit Abutment for zygoma implants with external hex connection:
  unalloyed titanium grade 1 and 4 according to ASTM F67 and ISO 5832-2, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, and PP (polypropylene).

- Angulated Multi-unit Abutments for zygoma implants with external hex connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Multi-Unit Abutment Brånemark System

- Angulated Multi-unit Abutments for implants with external hex connection and internal tri-channel connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Multi-Unit Abutment Plus Conical Connection

- Straight Multi-unit Abutment for implants with internal conical connection and tri-oval conical connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 and PP (polypropylene).

- Angulated Multi-unit Abutments for implants with internal conical connection and tri-oval conical connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Multi-Unit Abutment Xeal Conical Connection

- Straight Multi-unit Abutment for implants with internal conical connection and tri-oval conical connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH_2PO_4), magnesium chloride ($MgCl_2$), and PP (polypropylene).

- Angulated Multi-unit Abutments for implants with internal conical connection and tri-oval conical connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating, sodium dihydrogen phosphate (NaH_2PO_4), and magnesium chloride ($MgCl_2$).

Multi-Unit Abutment Trioval Conical Connection

- Straight Multi-unit Abutment for implants with internal conical connection and tri-oval conical connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating, sodium dihydrogen phosphate (NaH_2PO_4), magnesium chloride ($MgCl_2$), and PP (polypropylene).

- Angulated Multi-unit Abutments for implants with internal conical connection and tri-oval conical connection:
  titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, DLC (Diamond Like Carbon) coating, sodium dihydrogen phosphate (NaH_2PO_4), and magnesium chloride ($MgCl_2$).

Sterility and Reusability Information

Multi-unit Abutments 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 Abutments 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 as the device sterility and/or integrity may be compromised.

Cleaning and Sterilization Instructions

Healing Cap Multi-unit Brånemark System® is delivered non-sterile by Nobel Biocare and is intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12

- Sterilization: AAMI ST79 and ISO 17665 -1

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The Healing Cap Multi-unit Brånemark System® has been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following processing instructions.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe. Repeat this step until the lumens are free of any visually datable soil.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 20 seconds until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 20 seconds.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining
4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Note FDA-cleared washer- disinfectors are to be used for the recommended cleaning parameters.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 2 presents examples of suitable sterilization pouches.

Table 2 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).

3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters Table 3:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying for a minimum of 30 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying for a minimum of 20 minutes in chamber.

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information

MR Safety Information for Multiple Teeth Configurations

MRI Safety Information		
Non-clinical testing has demonstrated the Multi-unit Abutments is 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 2.7 cm from the devices or device assemblies when imaged in a 3T MRI system.	

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
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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

CE mark

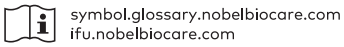
CE mark with Notified Body number

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