GoldAdapt™ Engaging, GoldAdapt™ Non-Engaging
Instructions for use

Important: Please read.

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Description:

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

The GoldAdapt™ includes a plastic sleeve for wax-up support during laboratory procedure.

Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC. Internal tri-channel connection for: NobelReplace®, Replace Select™ and NobelSpeedy® Replace.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy.

Intended use:

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Indications:

GoldAdapt™ Engaging and Non-Engaging Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

GoldAdapt™ Engaging is indicated for single unit use where this component is used in the creation of a customized screw retained abutment with a cement retained crown or bridge, or a customized screw retained abutment which is directly veneered. This screw-retained solution is indicated when the screw access hole is located through the occlusal surface of posterior teeth or through the cingulum of anterior teeth without angle corrections as well as for limited interocclusal and interdental space.

GoldAdapt™ Engaging Conical Connection 3.0 is indicated for use in the treatment of missing single maxillary lateral incisors or in the mandibular central and lateral incisors.

GoldAdapt™ Non-Engaging is indicated for screw-retained multiple teeth fixed prostheses. This screw retained solution is indicated when the screw access hole are located through the occlusal surface of posterior teeth or through the cingulum of anterior teeth without angle correction as well as for limited interocclusal space. Indicated for implants with less than 40° overall divergences to allow path of insertion.

Contraindications:

It is contraindicated to use GoldAdapt™ Engaging Conical Connection 3.0 in other positions than for lateral incisors in the maxilla or central and/or lateral incisors in the mandible.

GoldAdapt™ Engaging Conical Connection 3.0 is not to be used for multiple unit restorations.

GoldAdapt™ Engaging and Non-Engaging is contraindicated for patients:

– who are medically unfit for an oral surgical procedure.

– in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

– allergic or hypersensitiv to titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium) or gold alloy (gold, platinum, palladium, iridium).

Cautions:

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

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

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).

Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Never exceed **35 Ncm** prosthetic tightening torque for the abutment screw (**15 Ncm** for NobelActive® 3.0). Overtightening of abutment may lead to a screw fracture.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

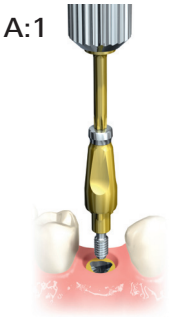
Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

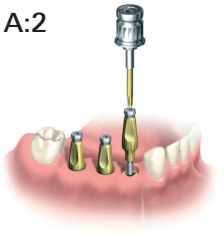
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

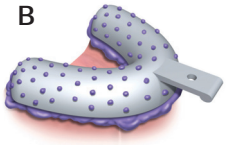
Handling instructions:

Clinical procedure:

1. Place the impression coping implant level onto the implant (**A:1** for single unit, **A:2** for multiple units) and take an implant level impression (**B**).



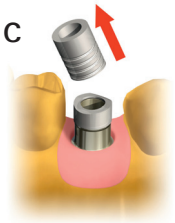




2. Connect the healing abutment or temporary restoration.

Laboratory procedure:

3. Assemble the impression coping and implant replica and position into impression.
4. Fabricate a working model with removable gingival material.
5. Attach the GoldAdapt™ into implant replica and secure with lab screw.
6. Connect abutment and reduce the plastic sleeve to appropriate height (**C**) and wax-up a framework.



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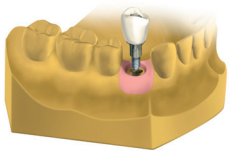
7. Fabricate the final abutment or framework using standard techniques (**D**).

D



Caution: Do not sandblast the seating surfaces.

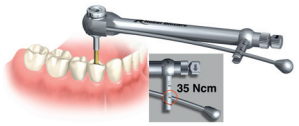
Clinical procedure:

8a. For single units: Connect the customized abutment. It is recommended to verify the final abutment seating using radiographic imaging.

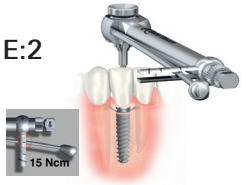
8b. For multiple units: Connect the customized abutments or implant bridge/bar. It is recommended to verify the final implant restoration seating using radiographic imaging.

9. Tighten the customized abutment(s) or implant bridge/bar, except for Conical Connection 3.0, to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**E:1**). For Conical Connection 3.0 tighten abutment to **15 Ncm** using screwdriver and wrench as described above (**E:2**).

E:1



E:2



Caution: For Conical Connection 3.0; Never exceed **15 Ncm** prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.

10. Close screw access hole.

11. Cement final restoration if applicable.

Caution: Do not use temporary cement when cementing ceramic crowns and bridges, due to increased risk of micro fractures.

GoldAdapt™ casting specifications: Melting range: 1400–1490° C/2550–2720° F. Coefficient of thermal expansion: 12 µm/m*° K.

Recommended casting alloys: Conventional gold alloys: High gold content (min 75% Au + Pt metal) alloys, standard ISO 1562 type 4.
Soldering in the range of 800–890° C/1472–1634° F.

Ceramic bonding alloys: High gold content (min 75% Au) alloys, standard ISO/DIS 9693, NIOM type A.
Soldering in the range of 800–890° C/1472–1634° F.

Materials:

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

Plastic sleeve: Polyoxymethylene (POM).

Abutment screws: Titanium alloy 90% Ti, 6% Al, 4%V.

Cleaning and sterilization instructions:

GoldAdapt™ is delivered non-sterile and for single use. Final abutment or framework should be cleaned and sterilized, if applicable, before intra oral use.

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

MR safety information:

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

Non-clinical testing has demonstrated that the product is MR conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:

– Static magnetic field of 1.5-Tesla and 3-Tesla only.

– Maximum spatial gradient magnetic field of 4000 Gauss/cm or less (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).

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

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the product when imaged with a gradient echo pulse sequence a 3 Tesla MRI system.

Should there be no MR symbol on the product label, please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

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

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

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

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Rx Only

MR
Magnetic resonance conditional

Consult instructions for use

Do not re-use

LOT
Batch code

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